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Attorney for Plaintiff

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF CALIFORNIA**

DONALD FLETCHER and JANIS  
FLETCHER,

Plaintiffs,

vs.

ZIMMER BIOMET INC. f/k/a ZIMMER  
INC. and ZIMMER BIOMET HOLDINGS,  
INC. f/k/a ZIMMER HOLDINGS INC.,

Defendants.

Case No.: \_\_\_\_\_

**COMPLAINT FOR DAMAGES**

**DEMAND FOR JURY TRIAL**

Plaintiffs, DONALD FLETCHER and JANIS FLETCHER (hereinafter “Plaintiff”), individually and through their attorneys, sue ZIMMER BIOMET INC. f/k/a ZIMMER, INC., an Delaware Corporation, and ZIMMER BIOMET HOLDINGS, INC. f/k/a ZIMMER HOLDINGS INC, an Delaware Corporation, (collectively, referred to as “Zimmer”) allege and state as follows:

**NATURE OF THE ACTION**

1. This is an action for strict products liability, failure to warn, defective design, negligence, breach of express and implied warranties, negligent misrepresentation and punitive damages brought by Plaintiff DONALD FLETCHER for injuries arising out of the Zimmer M/L Taper® Hip System.





1 18. Zimmer warranted the Zimmer M/L Taper® Hip System and placed the device into  
2 the United States stream of commerce.

3 19. Before it set out to design the Zimmer M/L Taper® Hip System, Zimmer knew of  
4 the danger to human beings if cobalt-chromium metal debris from its products were released into  
5 the body through corrosion, micromotion, and/or fretting.

6 20. Before placing the Zimmer M/L Taper® Hip System on the market, Zimmer was  
7 required to mitigate risks of the product, including any element of the design that created toxic  
8 levels of corrosion and debris that could cause pain, swelling, pseudotumor formation, osteolysis,  
9 instability, dislocation, metallosis, trunnionosis, adverse tissue reaction and/or the need for early  
10 surgical revision in patients-consumers.

11 21. The Zimmer M/L Taper® Hip System taper is a 12/14 size with threading on the  
12 taper. This threading can be described as shallow grooves on the portion of the taper that articulates  
13 with the head. This threading on the taper is used to comply with the requirements of the  
14 manufacturer of ceramic head option, CeramTec.

15 22. The significance of the Zimmer M/L Taper® Hip System taper threading is (1) it  
16 protects ceramic heads and (2) provides an interface at the junction with a metal head which is  
17 much more likely to produce wear and debris under fretting conditions. The threads were not  
18 designed to enhance the performance of metal heads.

19 23. The decision to allow the use of metals and CoCr heads (rather than ceramic heads)  
20 in the Zimmer M/L Taper® Hip System created an unreasonable risk and made it defective.

21 24. The concept that that corrosion might occur at the head-neck taper junction of a total  
22 hip prosthesis was first described in the early 1980s. When Zimmer was designing the Zimmer M/L  
23 Taper® Hip System this concept had to be a consideration.

24 **ZIMMER M/L TAPER® HIP SYSTEM**

25 25. The Zimmer M/L Taper® Hip System implanted into Plaintiff DONALD  
26 FLETCHER's right hip primarily consisted of four components: a) the M/L Taper® Press-Fit  
27 Standard Neck Offset Femoral Stem made of titanium alloy, b) the Metasul® LDH Head, c) the  
28 Metasul® Duram® Acetabular Component, and d) the Metasul® LDH Head Adapter. Plaintiff's

1 Zimmer M/L Taper® Hip System implanted right hip is referred to as a “metal-on-polyethylene”  
2 bearing system.

3 26. In designing the Zimmer M/L Taper® Hip System, Zimmer knew that the use of  
4 dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and flexural  
5 rigidity contribute to causing fretting and corrosion at the femoral head-neck/stem taper interface.

6 27. Mechanically assisted crevice corrosion (“MACC”) has been identified as a cause  
7 for symptomatic implant failure in metal-on-polyethylene hip devices. MACC produces cobalt and  
8 chromium ions, fretting byproducts and corrosive debris that can lead to adverse local tissue  
9 reaction.

10 28. Adverse local tissue reaction, also referred to as aseptic lymphocyte dominated  
11 vasculitis-associated lesions (“ALVAL”), represents a distinctive periprosthetic inflammatory  
12 reaction accompanied by extensive necrosis in the soft tissue-envelope of the hip. Early detection  
13 of adverse local tissue reaction is important because as time from onset of MACC to revision  
14 surgery increases, tissue damage may worsen.

15 **FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH**  
16 **THE ZIMMER M/L TAPER® HIP SYSTEM**

17 29. Zimmer marketed its hip implants, including the Zimmer M/L Taper® Hip System,  
18 to orthopedic surgeons and hospitals rather than end-user patients.

19 30. Zimmer had the ability to inform surgeons or hospitals of developing problems or  
20 defects in its devices through e-mail, letter, recalls, warnings in product inserts and/or through its  
21 product representative(s), who works directly with the surgeon.

22 31. The mechanical environment of the junction place the Zimmer M/L Taper® Hip  
23 System at increased risk for failure from pain, swelling, pseudotumor formation, metallosis, adverse  
24 local tissue reaction, synovitis, osteolysis, and/or dislocation, resulting from excessive wear debris,  
25 fretting corrosion and recurrent repassivation.

26 32. The fretting process (mechanical micromotion) is strongly influenced by  
27 distribution of pressure and force at the junctions, rendering these junctions vulnerable to  
28 accelerated generation of metal wear debris and corrosion.

1           33. Each interface introduces a contributing source for metal wear particular and debris  
2 generation. These junctions exponentially compound and accelerate the wear debris generation  
3 process.

4           34. Corrosion is time-sensitive and accelerated with mechanical stresses. This  
5 phenomenon was known to Zimmer, or should have been known by Zimmer, at all times relevant  
6 to the design, manufacture, marketing and sale of the Zimmer M/L Taper® Hip System.

7           35. At the time of design, manufacture, testing and marketing, Zimmer knew or should  
8 have known, combinations of metal alloys at a junction, such as the metal CoCr heads and cobalt-  
9 chromium and/or titanium neck/stem junctions of the Zimmer M/L Taper® Hip System, generate  
10 excessive fretting, corrosion and metal wear debris.

11           36. Zimmer did not inform or warn and is still not informing or warning physicians or  
12 consumers either through its sales representatives, correspondence, advertising or package inserts  
13 that:

- 14                   a. Selection of a metal CoCr head rather than a ceramic head to pair  
15 with the cobalt-chromium and/or titanium neck/stem significantly  
16 increases the risk of toxic amounts of corrosion and metal debris  
17 which might cause pain; swelling; metallosis; trunnionosis; tissue  
18 necrosis; adverse local tissue reaction; osteolysis; dislocation; and/or  
19 the need for early revision;
- 20                   b. Upon information and belief, Zimmer's pre-market corrosion testing,  
21 if any, was inadequate as it pertains to the Zimmer M/L Taper® Hip  
22 System; and/or,
- 23                   c. Upon information and belief, Zimmer's Spectrum Accelerated  
24 Corrosion Fatigue ("SACF") Testing, if any, was inadequate as it  
25 pertains to the Zimmer M/L Taper® Hip System.

26           37. Zimmer never performed any clinical trials and/or studies prior to marketing the  
27 Zimmer M/L Taper® Hip System.

28           38. Zimmer did not fully and/or adequately test the configuration utilizing CoCr femoral  
heads and titanium neck/stem junctions.

          39. Zimmer continues to market the CoCr heads for use with the cobalt-chromium  
and/or titanium neck/stems in the Zimmer M/L Taper® Hip System.

1           40. Reassurances of device safety were made through direct promotional contact by  
2 Defendants' sales representatives and distributors, through word-of-mouth from Zimmer's  
3 physician/technical consultants, and/or through industry targeted promotional materials.

4           41. Despite these reassurances, the defective design and manufacture of the Zimmer  
5 M/L Taper® Hip System, with a CoCr femoral head, generates excessive fretting and corrosion  
6 occurring at the head-neck/stem taper junctions. The fretting and corrosion generates toxic metal  
7 debris, metal ions and other chemical byproducts which are released into the surrounding tissues.  
8 These metal debris, metal ions and byproducts destroy the surrounding tissue and bone, often  
9 causing pseudotumors and other metal related conditions. The release of metal debris and metal  
10 ions also causes systemic exposure to the toxic metallic elements, often reflected in elevated blood  
11 serum and/or urine testing levels.

12           42. Defendants were aware of the problems when they designed, manufactured,  
13 marketed, distributed, and/or sold the Zimmer M/L Taper® Hip System. Nonetheless, Defendants  
14 employed the design in its Zimmer M/L Taper® Hip System in reckless disregard for the safety of  
15 patients, including Plaintiff.

16           43. Despite direct knowledge of significant adverse events reported by patients and  
17 physicians, as well as awareness of failures reported in the literature and published in national  
18 registries, Defendants have continued to market the Zimmer M/L Taper® Hip System as being safe  
19 and effective with the CoCr femoral head.

20           44. From the time that Defendants first began selling the Zimmer M/L Taper® Hip  
21 System in the United States through today, its product labeling and product information failed to  
22 contain adequate information, instructions, and warnings concerning implantation of the product,  
23 specifically with a CoCr femoral head, and its increased risks of fretting and corrosion.

24           45. The problems with the Zimmer M/L Taper® Hip System are similar to the issues  
25 that caused Stryker Orthopedics' recent recall of the LFIT® Anatomic CoCr V40™ Femoral Heads  
26 on August 29, 2016. Both the LFIT® Anatomic CoCr V40™ Femoral Heads and the Metasul®  
27 Femoral Heads are made of cobalt-chromium and both are mated with metal alloy stems. Stryker's  
28 Urgent Medical Device Recall Notification states that the company initiated the worldwide recall

1 after receiving higher than expected complaints of “taper lock failure” which could cause numerous  
2 potential hazards including but not limited to excessive metal debris, excessive wear debris,  
3 disassociation of the femoral head from the hip stem and fractured hip stem trunnion leading to  
4 adverse local tissue reaction, implant loosening, loss of mobility, and pain requiring revision  
5 surgery.

6 **PLAINTIFF’S USE OF THE PRODUCT**

7 46. On or around December 20, 2007, a defectively designed, manufactured and  
8 marketed Zimmer M/L Taper® Hip System left the hands of Defendants in its defective condition,  
9 delivered into the stream of commerce, and was implanted in Plaintiff DONALD FLETCHER’s  
10 right hip at Bakersfield Memorial Hospital, 420 34<sup>th</sup> St., Bakersfield, California by Brian Brenner,  
11 M.D. Plaintiff was implanted on the right hip with the following components:

- 12 a. Metasul® Duram® Acetabular Component;  
13 b. Zimmer M/L Taper® Press-Fit Standard Neck Offset femoral  
14 stem,  
15 c. Metasul® LDH Head; and,  
16 d. Metasul® LDH Head Adapter.

17 47. As a direct and proximate result of Defendants defective design, manufacture,  
18 marketing, distribution, and/or sale of the Zimmer M/L Taper® Hip System and placing the  
19 defective Device into the stream of commerce, Plaintiff underwent revision surgery at Bakersfield  
20 Memorial Hospital performed by Fadi Saied, M.D. on September 20, 2018.

21 48. The mechanism of failure in Plaintiff’s device was exactly the same mechanism of  
22 failure that Defendants had marketed and warranted would not occur because of the Zimmer M/L  
23 Taper® Hip System design and composition. It was also the same failure mechanism that the  
24 medical and scientific community had been studying and documenting in modular device designs  
25 since the 1990s,

26 49. Moreover, the symptoms and findings associated with modular device failures  
27 reported in the literature are identical to those suffered by Plaintiff.  
28

1           50.     Prior to the Plaintiff's revision, Plaintiff had neither knowledge nor notice there was  
2 any defect in the design, manufacture or labeling of his Zimmer M/L Taper® Hip System.

3           51.     Moreover, Plaintiff had neither knowledge nor notice that there was any defect in  
4 the implantation of his Zimmer M/L Taper® Hip System.

5           52.     Neither Plaintiff nor his physicians acted negligently in any way which might have  
6 brought about the failure of the device.

7           53.     It was not until sometime on or after the date of Plaintiff's revision surgeries, when  
8 the Plaintiff was made aware of the intraoperative findings from his revision surgeries, that Plaintiff  
9 suffered an injury as a result of his implantation on right hip with the Zimmer M/L Taper® Hip  
10 System.

11           54.     It was not until sometime on or after the date of Plaintiff's revision surgeries when  
12 the Plaintiff was made aware of the intraoperative findings from his revision surgeries, that Plaintiff  
13 had any notice or knowledge that his injuries and/or that the failure of his Zimmer M/L Taper®  
14 Hip System on the right hip was the result of any defects in the design, manufacture or labeling of  
15 the Zimmer M/L Taper® Hip System.

16           55.     Prior to Plaintiff's revision surgeries, Plaintiff did not know and could not have  
17 known by the exercise of reasonable diligence that his right hip had been injured.

18           56.     Prior to Plaintiff's revision surgeries, Plaintiff did not know and could not have  
19 known by the exercise of reasonable diligence, of any cause of any injury to his right hip.

20           57.     Plaintiff's cause of action, as alleged in this complaint against Defendants, did not  
21 accrue until sometime on or after the date of Plaintiff's revision surgeries.

22           58.     As a direct and proximate result of Defendants' defective design, manufacturing,  
23 marketing, distribution, sale and warnings, of the defective Zimmer M/L Taper® Hip System,  
24 Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited  
25 to: past, present and future physical and mental pain and suffering; physical disability, and past,  
26 present and future, medical, hospital, rehabilitative and pharmaceutical expenses, and other related  
27 damages.

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**THE FDA’S 510(k) CLEARANCE PROCESS**

1  
2 59. The 510(k) clearance process refers to Section 510(k) of the Medical Device  
3 Amendments of 1976 (hereafter “MDA”) of the Federal Food, Drug and Cosmetic Act. Under this  
4 process, device manufacturers are only required to notify the FDA at least 90 days before they  
5 market a device claimed to be “substantially equivalent” to a device the FDA approved for sale  
6 prior to 1976, when the MDA was enacted.

7 60. No clinical testing is required under this process.

8 61. Subsequent amendments to the MDA allowed for 510(k) clearance for products  
9 deemed “substantially equivalent” to post-MDA, 510(k) cleared devices.

10 62. Through this domino effect, devices deemed “substantially equivalent” to devices  
11 previously deemed “substantially equivalent” to devices approved for sale by the FDA prior to  
12 1976 could be sold to patients in a matter of 90 days without any clinical testing.

13 63. Clearance for sale under the 510(k) process does not equate to FDA approval of the  
14 cleared device.

15 64. In 2012, at the request of the FDA, the National Institute of Health (hereafter “NIH”)  
16 thoroughly reviewed the 510(k) process, coming to these major conclusions:

17 **The 510(k) clearance process is not intended to evaluate the**  
18 **safety and effectiveness of medical devices with some exceptions.**  
19 **The 510(k) process cannot be transformed into a pre-market**  
20 **evaluation of safety and effectiveness so long as the standard for**  
21 **clearance is substantial equivalence to any previously cleared**  
22 **device.**

23 65. The NIH explained, “The assessment of substantial equivalence does not require an  
24 independent demonstration that the new device provides a ‘reasonable assurance of safety and  
25 effectiveness.’” Further, the NIH even pointed out that the classification of predicate devices  
26 approved for sale prior to the 1976 MDA “did not include any evaluation of the safety and  
27 effectiveness of individual medical devices . . . Thus is common for devices to be cleared through  
28 the 510(k) program by being found substantially equivalent to devices that were never individually  
evaluated for safety and effectiveness, either through the original device classification program or  
through the 510(k) process.”



1           73. Plaintiff is in the class of persons that Defendants should reasonably foresee as being  
2 subject to the harm caused by the defectively designed the Zimmer M/L Taper® Hip System,  
3 insofar as Plaintiff was the type of person for whom the hip implants were intended to be used.

4           74. At the time the Zimmer M/L Taper® Hip System left the Defendants' possession  
5 and at the time the Zimmer M/L Taper® Hip System entered the stream of commerce in the County  
6 of Kern, State of California, it was in an unreasonably dangerous or defective condition. These  
7 defects include, but are not limited to, the following:

8           a. the Zimmer M/L Taper® Hip System was not reasonably safe  
9 as intended to be used;

10           b. the Zimmer M/L Taper® Hip System had an inadequate  
11 design for the purpose of hip replacement;

12           c. the Zimmer M/L Taper® Hip System contained unreasonably  
13 dangerous design defects, including an inherently unstable and  
14 defective design paired with a Cobalt-Chromium femoral head,  
which resulted in an unreasonably high metal wear debris, corrosion,  
fretting and probability of early failure;

15           d. the Zimmer M/L Taper® Hip System's unstable and  
16 defective design resulted in a hip prosthesis which had risks which  
exceeded the benefits of the medical device;

17           e. the Zimmer M/L Taper® Hip System was not appropriately  
18 or adequately tested before its distribution; and

19           f. the Zimmer M/L Taper® Hip System had an unreasonably  
20 high propensity for corrosion, fretting and fatigue under normal and  
expected use of the Zimmer M/L Taper® Hip System.

21           75. At the time of the Zimmer Defendants' initial design and manufacture, and of all  
22 Defendants' marketing and sale of the Zimmer M/L Taper® Hip System, a feasible, alternative  
23 safer design for the Zimmer M/L Taper® Hip System was known and available, including, but not  
24 limited to, a design that utilized a ceramic femoral head and monoblock design. A ceramic head  
25 would reduce and/or eliminate metal debris and particles.

26           76. At the time of and subsequent to the Zimmer Defendants' initial design and  
27 manufacture and all Defendants' marketing and sale of the Zimmer M/L Taper® Hip System,  
28 including prior to the time of Plaintiff DONALD FLETCHER's hip implant surgery, Defendants

1 had the ability to eliminate the unsafe character of the Zimmer M/L Taper® Hip System without  
2 impairing its usefulness.

3 77. Had the Zimmer Defendants properly and adequately tested the Zimmer M/L  
4 Taper® Hip System, they would have discovered that the components, paired with a cobalt-  
5 chromium femoral head, generated excessive metal wear caused by the surface contact of the metal  
6 articulating components resulting in pain, swelling, metallosis, tissue necrosis, bone necrosis, and  
7 a host of other maladies.

8 78. The Zimmer M/L Taper® Hip System, manufactured and supplied by the Zimmer  
9 Defendants and distributed, marketed, promoted and sold by all Defendants, were, therefore,  
10 defective in design or formulation in that, when they left the hands of Defendants, the foreseeable  
11 risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would  
12 expect, and/or it failed to comply with federal requirements for these medical devices.

13 79. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the  
14 Zimmer M/L Taper® Hip System for its intended or reasonably foreseeable purpose, and pursuant  
15 to instruction, guidance, education and training specifically provided by Defendant and/or its  
16 representatives.

17 80. At all times relevant hereto, the Zimmer M/L Taper® Hip System was dangerous,  
18 unsafe and defective in design including but not limited to its tendency to: (a) create dangerous  
19 and harmful metal debris in the patient's body; (b) cause pain; (c) inhibit mobility; and (d) require  
20 revision surgery with predictable cascading complications.

21 81. Defendants knew or should have known of the unreasonably dangerous and serious  
22 risks associated with the design of the Zimmer M/L Taper® Hip System.

23 82. Such risks were scientifically knowable to Defendants.

24 83. Defendants knew or should have known of the dangers.

25 84. Defendants either performed inadequate evaluation and testing; kept themselves  
26 willfully blind to the dangers; hid the dangers from physicians and patients, or some combination  
27 of the three.  
28

1 85. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff  
2 sustained injuries as set forth above.

3 86. Defendants' dangerous design and failure to adequately test contributed to cause the  
4 injuries suffered by Plaintiff.

5 87. As a direct and proximate result of Defendants' wrongful conduct, including the  
6 defective and dangerous design and inadequate warnings of the Zimmer M/L Taper® Hip System,  
7 Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss,  
8 and other damages including, but not limited to, cost of medical care, rehabilitation, lost income,  
9 permanent instability and loss of balance, immobility, and pain and suffering, for which he is  
10 entitled to compensatory and equitable damages and declaratory relief in an amount to be proven  
11 at trial.

12 **SECOND CAUSE OF ACTION**  
13 **(AGAINST ALL DEFENDANTS)**

14 **Strict Products Liability – Failure to Warn**

15 88. Plaintiffs incorporate by reference paragraphs 1 through 87 of this Complaint, as if  
16 fully set forth herein and further allege as follows:

17 89. Defendants researched, developed, designed, tested, manufactured, inspected,  
18 labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce  
19 the Zimmer M/L Taper® Hip System, in the course of same, directly advertised or marketed the  
20 product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons  
21 responsible for consumers, and therefore had a duty to warn of the risks associated with the use of  
22 the Zimmer M/L Taper® Hip System.

23 90. Defendants distributed and sold the Zimmer M/L Taper® Hip System in their  
24 original form of manufacture, which included the defects described herein.

25 91. The Zimmer M/L Taper® Hip System was defective and unreasonably dangerous  
26 when it left the possession of Defendants because it contained an absence of warnings or limitations  
27 on when such device should be selected over safer alternatives.

28 92. The Zimmer M/L Taper® Hip System was defective and unreasonably dangerous  
when it left the possession of Defendants because it contained an absence of warnings alerting the

1 medical community and patients on the dangerous risks associated with the Zimmer M/L Taper®  
2 Hip System when used for its intended and reasonably foreseeable purpose.

3 93. The risks associated with the Zimmer M/L Taper® Hip System when used for its  
4 intended and reasonably foreseeable purpose, include but are not limited to: (a) the creation of  
5 dangerous and harmful metal debris in the patient's body; (b) pain; (c) mobility inhibition; and (d)  
6 likelihood of revision surgery with predictable cascading complications.

7 94. The Zimmer M/L Taper® Hip System was expected to and did reach Plaintiff  
8 DONALD FLETCHER and his implanting physician, in the County of Kern, State of California  
9 without substantial change or adjustment in its condition as manufactured and sold by Defendants.

10 95. The Zimmer M/L Taper® Hip System designed, developed, tested, manufactured,  
11 distributed, promoted, marketed and/or sold or otherwise placed into the stream of commerce by  
12 Defendants was in a dangerous and defective condition and posed a threat to any user or consumer  
13 of the Zimmer M/L Taper® Hip System.

14 96. At all times relevant hereto, Plaintiff DONALD FLETCHER was a person the  
15 Defendants should have considered to be subject to the harm caused by the defective nature of the  
16 Zimmer M/L Taper® Hip System.

17 97. Defendants' Zimmer M/L Taper® Hip System was implanted into Plaintiff  
18 DONALD FLETCHER and used in the manner for which it was intended.

19 98. This use has resulted in severe physical, financial, emotional and other injuries to  
20 Plaintiff DONALD FLETCHER.

21 99. Defendants failed to adequately warn health care professionals and the public,  
22 including Plaintiff and his prescribing physician, of the true risks of the Zimmer M/L Taper® Hip  
23 System, including that the Zimmer M/L Taper® Hip System was susceptible to micromotion,  
24 fretting and corrosion at the junction, generating significant and toxic amounts of metal wear debris  
25 and corrosive byproducts in patients, causing severe pain and injury, and requiring further  
26 treatment, including revision surgeries and/or hip replacements.

27 100. Defendants failed to timely and reasonably warn of material facts regarding the  
28 safety and efficacy of the Zimmer M/L Taper® Hip System. Had they done so, proper warnings

1 would have been heeded and no health care professional, including Plaintiff's physician, would  
2 have used the Zimmer M/L Taper® Hip System, or no consumer, including Plaintiff, would have  
3 purchased and/or used the Zimmer M/L Taper® Hip System.

4 101. Defendants failed to timely and reasonably provide adequate instructions and  
5 training concerning safe and effective use of the Zimmer M/L Taper® Hip System.

6 102. The Zimmer M/L Taper® Hip System, which was researched, developed, designed,  
7 tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise  
8 released into the stream of commerce by Defendants, was defective due to inadequate post-  
9 marketing warnings and/or instruction because, after Defendants knew or should have known there  
10 was reasonable evidence of an association between the Zimmer M/L Taper® Hip System  
11 components and the development of corrosion, metal fatigue, failure, micromotion and/or release  
12 of significant amounts of metal debris and/or ions, causing serious injury and pain, Defendants  
13 failed to provide adequate warnings to health care professionals and the consuming public,  
14 including Plaintiff, and continued to aggressively promote the Zimmer M/L Taper® Hip System.

15 103. The Zimmer M/L Taper® Hip System, which was researched, developed, designed,  
16 tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise  
17 released into the stream of commerce by Defendants, was defective due to inadequate post-  
18 marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer M/L  
19 Taper® Hip System resulting in revision surgery while knowing that a safer alternative design  
20 including, the use of a ceramic femoral head and monoblock stem components existed.

21 104. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal  
22 and/or concealed testing and research data; and selectively and misleadingly revealed and/or  
23 analyzed testing and research data.

24 105. Plaintiff DONALD FLETCHER and his physician used the Zimmer M/L Taper®  
25 Hip System for its intended purpose, i.e., hip replacement.

26 106. Plaintiff DONALD FLETCHER could not have discovered any defect in the  
27 Zimmer M/L Taper® Hip System through the exercise of due care.

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1 107. Defendants, as designers, manufacturers, distributors, promoters, marketers and/ or  
2 sellers of medical devices are held to the level of knowledge of experts in their field.

3 108. Neither Plaintiff DONALD FLETCHER nor his implanting physician had  
4 substantially the same knowledge about the Zimmer M/L Taper® Hip System as Defendants.

5 109. Defendants reasonably should have known the Zimmer M/L Taper® Hip System  
6 was unsuited for active individuals such as Plaintiff DONALD FLETCHER.

7 110. The warnings and instructions provided with the Zimmer M/L Taper® Hip System  
8 and through Defendants and/or its representatives did not adequately educate and train medical  
9 providers on the risk of side effects, or the cost-benefit analysis necessary for justified use of this  
10 product versus safer alternative designs.

11 111. Defendants had a continuing duty to warn the medical community and public,  
12 including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure  
13 rates or propensity for failure associated with the Zimmer M/L Taper® Hip System.

14 112. As a direct and proximate result of Defendants' failure to adequately communicate  
15 a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth  
16 herein, Plaintiff DONALD FLETCHER has sustained and will continue to sustain severe physical  
17 injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth  
18 herein.

19 113. As a direct result of Defendants' failure to warn and/or inadequate warning and their  
20 other tortious conduct, Plaintiff DONALD FLETCHER has suffered serious physical injury, harm,  
21 damages and economic loss and will continue to suffer such harm, damages and economic loss in  
22 the future.

23 114. As a direct and proximate result of Defendants' failure to warn and/or inadequate  
24 warning and their other tortious conduct, as set forth herein, Plaintiff DONALD FLETCHER has  
25 suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory  
26 damages in an amount to be determined by the trier of fact.

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**THIRD CAUSE OF ACTION**  
**(AGAINST ALL DEFENDANTS)**

**Strict Products Liability – Manufacturing Defect**

115. Plaintiffs incorporate by reference paragraphs 1 through 114 of this Complaint, as if fully set forth herein and further allege as follows:

116. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer M/L Taper® Hip System, in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

117. The Zimmer M/L Taper® Hip System manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer M/L Taper® Hip System could fail early in patients therefore causing pain and suffering, debilitation and the need for revision surgeries to replace the device with the attendant risks of complications and death from such further surgeries, Defendants continued to market the Zimmer M/L Taper® Hip System as a safe and effective hip replacement system.

118. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

**FOURTH CAUSE OF ACTION**  
**(AGAINST ALL DEFENDANTS)**

**Negligence**

119. Plaintiffs incorporate by reference paragraphs 1 through 118 of this Complaint, as if fully set forth herein and further allege as follows:

120. While the focus of Plaintiff's strict liability claims (Counts I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct.

1           121. Zimmer Defendants had a duty to exercise reasonable care in the design,  
2 formulation, manufacture, testing, quality assurance, quality control, labeling, and/or warning of  
3 the Zimmer M/L Taper® Hip System, including a duty to assure that their products did not pose a  
4 significantly increased risk of bodily harm and adverse events.

5           122. The Zimmer Defendants failed to exercise ordinary care in the design, formulation,  
6 manufacture, testing, quality assurance, quality control, labeling, and warning of the Zimmer M/L  
7 Taper® Hip System devices because they knew or should have known these products caused  
8 significant bodily harm and were not safe for use by consumers.

9           123. All Defendants failed to exercise ordinary care in the sale marketing, promotions  
10 and distribution of the Zimmer M/L Taper® Hip System devices because they knew or should have  
11 known these products caused significant bodily harm and were not safe for use by consumers.

12           124. The Zimmer Defendants failed to exercise ordinary care in testing the Zimmer M/L  
13 Taper® Hip System prior to marketing, sale and distribution of the Zimmer M/L Taper® Hip  
14 System.

15           125. At all relevant times, Defendants had a duty to exercise reasonable care in the  
16 design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer M/L  
17 Taper® Hip System, including a duty to ensure that the Zimmer M/L Taper® Hip System did not  
18 pose a significantly increased risk of bodily injury to its users.

19           126. Defendants had a duty to exercise reasonable care in the advertising and sale of the  
20 Zimmer M/L Taper® Hip System, including a duty to warn Plaintiff and other consumers, of the  
21 dangers associated with the Zimmer M/L Taper® Hip System that were known or should have been  
22 known to Defendants at the time of the sale of the Zimmer M/L Taper® Hip System to the Plaintiff.

23           127. Defendants failed to exercise reasonable care in the design, testing, manufacture,  
24 marketing, sale and distribution of the Zimmer M/L Taper® Hip System because Defendants knew  
25 or should have known that the Zimmer M/L Taper® Hip System had a propensity to cause serious  
26 injury, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion,  
27 metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the  
28 implants, bone loss, decreased range of motion, diminished mobility, and revision surgeries.

1           128. Defendants failed to exercise ordinary care in the labeling of the Zimmer M/L  
2 Taper® Hip System and failed to issue adequate pre-marketing or post-marketing warnings to  
3 doctors and the general public, including Plaintiff, regarding the risk of serious injury, including,  
4 including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions,  
5 excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implants, bone  
6 loss, decreased range of motion, diminished mobility, and revision surgeries.

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

9           130. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise  
10 due care under the circumstances as follows:

11           a. Failing to use due care in the development, design,  
12 formulation, manufacturing, labeling, testing, assembly, marketing,  
13 advertising, promotion, inspection, sale and/or distribution of the  
14 Zimmer M/L Taper® Hip System, and/or to utilize and/or implement  
reasonably safe designs for them;

15           b. At all times relevant hereto, Defendants knew or should have  
16 known that the design of the Zimmer M/L Taper® Hip System was  
generating the potential for metal on metal problems, vulnerabilities,  
and injuries;

17           c. Defendants failed to perform sufficient clinical trials and  
18 other pre-marketing evaluations to determine risk and efficacy of the  
19 Zimmer M/L Taper® Hip System;

20           d. Such testing would have revealed the increased risk of failure  
21 and tendency to cause significant corrosion, metal wear debris, metal  
byproduct release, resulting in necrosis, pain, swelling, adverse local  
22 tissue reaction, trunnionosis, and/or metallosis;

23           e. A reasonable manufacturer under the same or similar  
24 circumstances would have conducted additional testing and  
evaluation of the Zimmer M/L Taper® Hip System before placing it  
into the stream of commerce;

25           f. A reasonable manufacturer under the same or similar  
26 circumstances would have conducted adequate testing of all  
27 junctions coupled with the cobalt-chromium femoral head and  
evaluation of the Zimmer M/L Taper® Hip System before placing it  
28 into the stream of commerce;

1 g. A reasonable manufacturer under the same or similar  
2 circumstances would have required that significant information be  
3 provided to physicians regarding the risks associated with  
4 foreseeable metal on metal problems stemming from the design;

5 h. At all times relevant hereto, Defendants knew or should have  
6 known of the serious complications and high failure rate associated  
7 with the Zimmer M/L Taper® Hip System;

8 i. Failing to provide adequate and proper warnings to the public  
9 and to Plaintiff of the dangerous propensities of the Zimmer M/L  
10 Taper® Hip System when used in a reasonably foreseeable manner;

11 j. Failed to conduct adequate post marketing surveillance;

12 k. Failing to design, formulate, manufacture and incorporate or  
13 to reformulate the Zimmer M/L Taper® Hip System with reasonable  
14 safeguards and protections against the type of injury and damage  
15 suffered by Plaintiff when used in a reasonably foreseeable manner;

16 l. Failing to adequately prevent, identify, mitigate, and fix  
17 defective designs and hazards associated with the Zimmer M/L  
18 Taper® Hip System in accordance with good design practices;

19 m. Failing to notify and warn the public including Plaintiff of  
20 reported incidents involving injury, etc., and the negative health  
21 effects attendant to the use of the Zimmer M/L Taper® Hip System,  
22 thus misrepresenting the safety of the product;

23 n. Failing to make timely and adequate corrections to the  
24 manufacture, design and formulation of the Zimmer M/L Taper®  
25 Hip System so as to prevent and/or minimize the problems suffered  
26 by the Zimmer M/L Taper® Hip System use;

27 o. Despite its knowledge of these risks, Defendants continued  
28 to promote and market the device; and,

p. Being otherwise being careless, reckless and negligent.

131. Despite knowing or having reason to know of the risks, Defendants did not (1)  
perform additional testing, (2) investigate the risks, (3) suspend sales or distribution, (4) warn  
physicians or patients of the propensity for the Zimmer M/L Taper® Hip System to cause or create  
significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain,  
swelling, dislocation, osteolysis, pseudotumor formation, adverse local tissue reaction,  
trunnionosis, metallosis, and/or need for early surgical revisions.



1 138. Defendants knew or should have known, based on prior experience, adverse event  
2 reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer M/L  
3 Taper® Hip System, that their representations regarding the Zimmer M/L Taper® Hip System were  
4 false, and that they had a duty to disclose the dangers associated with the devices.

5 139. Plaintiff and his physician reasonably relied to Plaintiff's detriment upon  
6 Defendants' misrepresentations and material omissions in their marketing, advertisements, and  
7 promotions concerning the quality and safety of the Zimmer M/L Taper® Hip System. Plaintiff and  
8 his physicians reasonably relied upon Defendants' representations that the Zimmer M/L Taper®  
9 Hip System were of high quality and safe for implantation into his body.

10 140. Defendants made the representations and failed to disclose the material facts with  
11 the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance  
12 by purchasing the Zimmer M/L Taper® Hip System with a CoCr femoral head.

13 141. Defendants' representations and nondisclosures regarding the safety and efficacy of  
14 the Zimmer M/L Taper® Hip System was the direct and proximate cause of Plaintiff's injuries.

15 142. Defendants' conduct, as described above, was reckless. Defendants risked the lives  
16 of consumers and users of their products, including Plaintiff, with knowledge of the safety and  
17 efficacy problems and suppressed this knowledge from the general public. Defendants made  
18 conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.  
19 Defendants' reckless conduct warrants an award of punitive damages.

20 143. Plaintiff DONALD FLETCHER and/or his physician justifiably relied to their  
21 detriment upon Defendants' misrepresentations and omissions in their marketing, advertisements,  
22 promotions and labeling concerning these products.

23 144. Plaintiff DONALD FLETCHER and/or his physician justifiably relied upon  
24 Defendants' representations that the Zimmer M/L Taper® Hip System was safe for use in persons  
25 such as Plaintiff DONALD FLETCHER.

26 145. As a direct and proximate result of Defendants' negligent misrepresentations and/or  
27 omissions regarding the Zimmer M/L Taper® Hip System, Plaintiff DONALD FLETCHER used  
28 the Zimmer M/L Taper® Hip System and has suffered serious physical injury, harm, damages and

1 economic loss and will continue to suffer such harm, damages and economic loss in the future.

2 146. As a direct and proximate result of Defendants' negligent misrepresentations,  
3 Plaintiff DONALD FLETCHER has suffered and will continue to suffer injuries, damages and  
4 losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

5 **SIXTH CAUSE OF ACTION**  
6 **(AGAINST ALL DEFENDANTS)**

7 **Breach of Express Warranty**

8 147. Plaintiffs incorporate by reference paragraphs 1 through 146 of this Complaint, as  
9 if fully set forth herein and further allege as follows:

10 148. Defendants advertised, labeled, marketed and promoted the Zimmer M/L Taper®  
11 Hip System, representing the quality to health care professionals, the FDA, Plaintiff, and the public  
12 in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer  
13 M/L Taper® Hip System would conform to the representations. More specifically, Defendants  
14 represented that the Zimmer M/L Taper® Hip System was safe and effective, that it was safe and  
15 effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat  
16 Plaintiff's condition.

17 149. The representations, as set forth above, contained or constituted affirmations of fact  
18 or promises made by the seller to the buyer which related to the goods and became part of the basis  
19 of the bargain creating an express warranty that the goods shall conform to the affirmations of fact  
20 or promises.

21 150. The Zimmer M/L Taper® Hip System did not conform to the representations made  
22 by Defendants in that the Zimmer M/L Taper® Hip System was not safe and effective, was not safe  
23 and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in  
24 individuals, such as Plaintiff.

25 151. At all relevant times, Plaintiff used the Zimmer M/L Taper® Hip System for the  
26 purpose and in the manner intended by Defendants.

27 152. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have  
28 discovered the breached warranty and realized its danger.

1 153. The breach of the warranty was a substantial factor in bringing about Plaintiff's  
2 injuries.

3 154. Within a reasonable time after Plaintiff knew or should have known of the failure of  
4 his Zimmer M/L Taper® Hip System components, Plaintiff gave notice to Zimmer of such failure.

5 155. Zimmer breached the express warranty it provided with the devices.

6 156. As a direct and proximate result of Defendants' acts and omissions, including their  
7 failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and  
8 distribution of the Zimmer M/L Taper® Hip System and Plaintiff was implanted with the Zimmer  
9 M/L Taper® Hip System and suffered severe and debilitating injuries, economic loss, and other  
10 damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent  
11 instability and loss of balance, immobility, and pain and suffering, for which they are entitled to  
12 compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

13 **SEVENTH CAUSE OF ACTION**  
14 **(AGAINST ALL DEFENDANTS)**

15 **Breach of Implied Warranty**

16 157. Plaintiffs incorporate by reference paragraphs 1 through 156 of this Complaint, as  
17 if fully set forth herein and further allege as follows:

18 158. The Zimmer M/L Taper® Hip System was not reasonably fit for the ordinary  
19 purposes for which such goods are used and did not meet the expectations for the performance of  
20 the product when used in the customary, usual and reasonably foreseeable manner. Nor was the  
21 Zimmer M/L Taper® Hip System minimally safe for its expected purpose.

22 159. At all relevant times, Plaintiff used the Zimmer M/L Taper® Hip System for the  
23 purpose and in the manner intended by Defendants.

24 160. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have  
25 discovered the breached warranty and realized its danger.

26 161. The breach of the warranty was a substantial factor in bringing about Plaintiff's  
27 injuries.

28 162. Zimmer impliedly warranted that the Zimmer M/L Taper® Hip System and its

1 components were merchantable and fit for the ordinary and intended purposes for which hip  
2 systems are used.

3 163. Plaintiff was a foreseeable user of the Zimmer M/L Taper® Hip System.

4 164. Plaintiff's surgeon, as purchasing agent, purchased the Zimmer M/L Taper® Hip  
5 System for Plaintiff from Zimmer.

6 165. At all times relevant to this Complaint, Plaintiff was and is in privity with Zimmer.

7 166. Plaintiff used the products for its ordinary and intended purpose.

8 167. The Zimmer M/L Taper® Hip System failed while being used for its ordinary and  
9 intended purpose.

10 168. As a direct and proximate result of Zimmer's breach of implied warranty of  
11 merchantability, Plaintiff suffered injuries as described specifically above.

12 **EIGHTH CAUSE OF ACTION**  
13 **(AGAINST ALL DEFENDANTS)**

14 **Loss of Consortium**

15 169. Plaintiff JANIS FLETCHER hereby repeats, realleges and incorporates by  
16 reference all of the allegations and statements contained in Paragraphs 1 through 168, inclusive, as  
17 though fully set forth herein.

18 170. Plaintiff JANIS FLETCHER was and is the lawful spouse of Plaintiff DONALD  
19 FLETCHER and in such capacity, was and is entitled to the comfort, enjoyment, society and  
20 services of her spouse.

21 171. As a direct and proximate result of the foregoing allegations, Plaintiff JANIS  
22 FLETCHER was deprived of the comfort, enjoyment, society and services of her spouse, has  
23 suffered and will continue to suffer economic loss, and otherwise has been emotionally and  
24 economically injured. Plaintiff JANIS FLETCHER's injuries and damages are permanent and will  
25 continue into the future.

26 **PRAYER FOR RELIEF**

27 WHEREFORE, Plaintiffs pray for judgment and an award of damages against Defendants,  
28 as follows:



CIVIL COVER SHEET

Case 1:18-cv-01529-DAD-JLT Document 1-1 Filed 11/05/18 Page 1 of 1

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

DONALD FLETCHER and JANIS FLETCHER

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

(c) Attorneys (Firm Name, Address, and Telephone Number) Stuart C. Talley, KERSHAW, COOK & TALLEY PC 401 Watt Avenue, Sacramento, CA 95864 Telephone: 916-779-7000

DEFENDANTS

ZIMMER BIOMET INC. f/k/a ZIMMER INC. and ZIMMER BIOMET HOLDINGS, INC. f/k/a ZIMMER HOLDINGS INC.

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

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

Attorneys (If Known)

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

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

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

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Click here for: Nature of Suit Code Descriptions.

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Estate, etc.

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

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

VI. CAUSE OF ACTION

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

Brief description of cause: Products liability case for injuries arising out of the Zimmer M/L Taper® Hip System

VII. REQUESTED IN COMPLAINT:

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 11/01/2018 SIGNATURE OF ATTORNEY OF RECORD /s/ Stuart C. Talley

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE