	Case 1:18-cv-01529-DAD-JLT Document 1	L Filed 11/05/18 Page 1 of 27
1	Stuart C. Talley (SBN: 180374)	
2	KERSHAW, COOK & TALLEY PC	
3	401 Watt Avenue Sacramento, California 95864	
4	Tel: (916) 779-7000 Fax: (916) 721-2501	
5	Email: <u>stuart@kctlegal.com</u>	
6	Attorney for Plaintiff	
7		
8	UNITED STATES	DISTRICT COURT
9	EASTERN DISTRIC	CT OF CALIFORNIA
10		
11	DONALD FLETCHER and JANIS	Case No.:
12	FLETCHER,	
13	Plaintiffs,	COMPLAINT FOR DAMAGES
14	VS.	
15	ZIMMER BIOMET INC. f/k/a ZIMMER	
16	INC. and ZIMMER BIOMET HOLDINGS, INC. f/k/a ZIMMER HOLDINGS INC.,	
17		DEMAND FOR JURY TRIAL
18	Defendants.	
19		
20	Plaintiffs, DONALD FLETCHER and	JANIS FLETCHER (hereinafter "Plaintiff"),
21	individually and through their attorneys, sue ZII	MMER BIOMET INC. f/k/a ZIMMER, INC., an
22	Delaware Corporation, and ZIMMER BIOMET	HOLDINGS, INC. f/k/a ZIMMER HOLDINGS
23	INC, an Delaware Corporation, (collectively, ref	erred to as "Zimmer") allege and state as follows:
24	NATURE OF	THE ACTION
25	1. This is an action for strict prod	ucts liability, failure to warn, defective design,
26	negligence, breach of express and implied warr	ranties, negligent misrepresentation and punitive
27	damages brought by Plaintiff DONALD FLETC	CHER for injuries arising out of the Zimmer M/L
28	Taper [®] Hip System.	
		-1-
	COMPLAINT F	FOR DAMAGES

#

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 2 of 27

1 2. Defendant Zimmer manufactured and supplied to doctors total hip arthroplasty 2 systems known as the Zimmer M/L Taper[®] Hip System, which was designed to be implanted with 3 either (1) a cobalt-chromium femoral head or (2) a ceramic femoral head. 4 3. The Zimmer M/L Taper[®] Hip System utilized with cobalt-chromium femoral heads 5 created unreasonable risks of harm to Plaintiff DONALD FLETCHER. 6 4. The unreasonable risks of pain, swelling, metallosis, trunnionosis, adverse local 7 tissue reaction, and/or the need for early revision surgical intervention, whether from corrosion, 8 micromotion, fretting or some other mechanism, renders both the Zimmer M/L Taper® Hip System 9 with a metal cobalt-chromium femoral head defective products. 10 5. The selection and implantation of the Zimmer M/L Taper[®] Hip System by 11 Plaintiff's surgeon, Dr. Brian Brenner, was a result of the misinformation, marketing, sales, 12 promotion and direction by Zimmer. 13 PARTIES, JURISDICTION & VENUE 14 6. Plaintiffs DONALD FLETCHER and JANIS FLETCHER, his wife, are and were 15 at all times relevant, residents of California. 16 7. Defendant ZIMMER BIOMET, INC., formerly known as ZIMMER INC. is, and at 17 all times material hereto was, a corporation organized under the laws of the State of Delaware, with 18 its principal place of business in Indiana. 19 8. Defendant ZIMMER BIOMET HOLDINGS, INC., formerly known as ZIMMER 20 HOLDINGS, INC. is a corporation organized under the laws of the State of Delaware, with its 21 principal place of business in Indiana. ZIMMER, INC. is a subsidiary of ZIMMER HOLDINGS, 22 INC. ZIMMER distributes their products throughout the United States and internationally. 23 9. Defendants ZIMMER BIOMET, INC. and ZIMMER BIOMET HOLDINGS, INC., 24 are hereinafter collectively referred to as "Zimmer". "Zimmer" includes and included any and all 25 parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational 26 units of any kind, their predecessors, successors and assigns and their officers, directors, employees, 27 agents and representatives and any and all other persons acting on behalf of Defendants ZIMMER 28 BIOMET, INC. and ZIMMER BIOMET HOLDINGS, INC. -2-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 3 of 27

1 10. ZIMMER designed, manufactured, fabricated, marketed, packaged, advertised,
 2 distributed and sold the Zimmer M/L Taper® Hip System throughout the world, including in the
 3 County of Kern, State of California.

4 11. ZIMMER knowingly markets to and derives income from patients in Kern County,
5 in the State of California, from the sale of the Zimmer M/L Taper® Hip System.

6

12. The Defendants acted jointly and severally.

The defective Zimmer M/L Taper® Hip System was implanted into Plaintiff's right
hip in December 2007 at Bakersfield Memorial Hospital in Kern County, California by Brian
Brenner, M.D. At that time, the Zimmer M/L Taper® Hip System manufactured, designed,
distributed, and warranted by Defendants were implanted into Plaintiff. Plaintiff's surgeon,
medical staff, and other healthcare providers met or exceeded the standard of care applicable to the
hip replacement surgeries.

13 14. As a result of his condition, Plaintiff underwent painful, expensive, and physically
risky surgeries to remove and replace the defective Zimmer M/L Taper® Hip System on September
20, 2018 at Bakersfield Memorial Hospital, in Kern County, California by Fadi Saied, M.D.

16 15. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. §
17 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and
18 because the amount in controversy between Plaintiff and Defendants exceeds \$75,000, exclusive
19 of interest and cost, and because, among other reasons, Defendants have significant contacts with
20 this district by virtue of doing business within this judicial district.

21 16. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because a
22 substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

23

GENERAL FACTUAL ALLEGATIONS

24 17. Zimmer were the designers, manufacturers, and suppliers of the Zimmer M/L
25 Taper® Hip System and related components in the business of putting medical devices on the
26 market. Zimmer were engaged in the business of marketing, distributing, and/or selling the Zimmer
27 M/L Taper® Hip System at all times relevant hereto.

28

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 -4-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 5 of 27

Zimmer M/L Taper® Hip System implanted right hip is referred to as a "metal-on-polyethylene"
 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.

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

15

16

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH <u>THE ZIMMER M/L TAPER® HIP SYSTEM</u>

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.

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

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

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

-5-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 6 of 27

1	33.	Each interface introduces a contributing source for metal wear particular and debris
2	generation. T	hese 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	d/or titanium neck/stem junctions of the Zimmer M/L Taper® Hip System, generate
10	excessive fret	ting, corrosion and metal wear debris.
11	36.	Zimmer did not inform or warn and is still not informing or warning physicians or
12	consumers eit	ther 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 increases the risk of toxic amounts of corrosion and metal debris
16		which might cause pain; swelling; metallosis; trunnionosis; tissue
17		necrosis; adverse local tissue reaction; osteolysis; dislocation; and/or the need for early revision;
18	b.	Upon information and belief, Zimmer's pre-market corrosion testing,
19		if any, was inadequate as it pertains to the Zimmer M/L Taper [®] Hip System; and/or,
20	c.	Upon information and belief, Zimmer's Spectrum Accelerated
21		Corrosion Fatigue ("SACF") Testing, if any, was inadequate as it
22		pertains to the Zimmer M/L Taper® Hip System.
23	37.	Zimmer never performed any clinical trials and/or studies prior to marketing the
24	Zimmer M/L	Taper® Hip System.
25	38.	Zimmer did not fully and/or adequately test the configuration utilizing CoCr femoral
26	heads and tita	nium neck/stem junctions.
27	39.	Zimmer continues to market the CoCr heads for use with the cobalt-chromium
28	and/or titaniu	m neck/stems in the Zimmer M/L Taper® Hip System.
		-6-
		COMPLAINT FOR DAMAGES

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 7 of 27

2 3

1

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

4

5

6

7

8

9

11

41. Despite these reassurances, the defective design and manufacture of the Zimmer M/L Taper® Hip System, with a CoCr femoral head, generates excessive fretting and corrosion occurring at the head-neck/stem taper junctions. The fretting and corrosion generates toxic metal debris, metal ions and other chemical byproducts which are released into the surrounding tissues. These metal debris, metal ions and byproducts destroy the surrounding tissue and bone, often 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 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 V40TM Femoral Heads 26 on August 29, 2016. Both the LFIT® Anatomic CoCr V40TM 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 -7-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 8 of 27

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

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 34th St., Bakersfield, California by Brian Brenner,
11 M.D. Plaintiff was implanted on the right hip with the following components:

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

12

13

14

15

6

d. Metasul® LDH Head Adapter.

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

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

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

28

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 9 of 27

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.
28	
	-9-

1		THE FDA'S 510(k) CLEARANCE PROCESS
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, devi	ce manufacturers are only required to notify the FDA at least 90 days before they
5	market a dev	ice 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 "sub	stantially equivalent" to post-MDA, 510(k) cleared devices.
10	62.	Through this domino effect, devices deemed "substantially equivalent" to devices
11	previously de	eemed "substantially equivalent" to devices approved for sale by the FDA prior to
12	1976 could b	e 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 devic	e.
15	64.	In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH")
16	thoroughly re	eviewed 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. The 510(k) process cannot be transformed into a pre-market
19		evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared
20		device.
21	65.	The NIH explained, "The assessment of substantial equivalence does not require an
22	independent	demonstration that the new device provides a 'reasonable assurance of safety and
23	effectiveness	." Further, the NIH even pointed out that the classification of predicate devices
24	approved for	sale prior to the 1976 MDA "did not include any evaluation of the safety and
25	effectiveness	of individual medical devices Thus is common for devices to be cleared through
26	the 510(k) pr	ogram by being found substantially equivalent to devices that were never individually
27	evaluated for	safety and effectiveness, either through the original device classification program or
28	through the 5	10(k) process."
		-10-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 11 of 27

1	66. Zimmer cleared the M/L Taper® Hip System, and its related components, under a
2	process used by the United States Food and Drug Administration known as the 510(k) Premarket
3	Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device
4	does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the
5	device is supposed to demonstrate substantial equivalence to a predicate medical device.
6	67. The first components of the Zimmer M/L Taper® Hip System were cleared for sale
7	in the United States according to Section 510(k) in October 2003.
8	CAUSES OF ACTION
9	<u>FIRST CAUSE OF ACTION</u> (AGAINST ALL DEFENDANTS)
10	(AGAINST ALL DEFENDANTS)
11	Strict Products Liability – Unreasonably Dangerous Design
12	68. Plaintiffs incorporate by reference paragraphs 1 through 69 of this Complaint, as if
13	fully set forth herein and further allege as follows:
14	69. The ZIMMER Defendants had a duty to design and manufacture, and all Defendants
15	had a duty to place into the stream of commerce, distribute, market, promote and sell, the specific
16	Zimmer M/L Taper® Hip System so that it was neither defective nor unreasonably dangerous when
17	put to the use for which it was designed, manufactured, distributed, marketed and sold.
18	70. On and prior to December 2007, the Zimmer Defendants were engaged in the
19	business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants
20	and did design, manufacture, distribute, market and sell the Zimmer M/L Taper® Hip System.
21	71. The Zimmer Defendants did in fact design and manufacture, while all Defendants
22	were engaged in selling, distributing, supplying and/or promoting the Zimmer M/L Taper® Hip
23	System to Plaintiff DONALD FLETCHER and his implanting physician.
24	72. Defendants expected the Zimmer M/L Taper® Hip System they were selling,
25	distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach,
26	implanting physicians and consumers in the County of Kern, State of California, including Plaintiff
27	DONALD FLETCHER and his implanting physician, without substantial change in the condition.
28	
	-11-
	COMPLAINT FOR DAMAGES

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 12 of 27

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 9	a. the Zimmer M/L Taper® Hip System was not reasonably safe as intended to be used;
10	b. the Zimmer M/L Taper [®] Hip System had an inadequate design for the purpose of hip replacement;
11	c. the Zimmer M/L Taper® Hip System contained unreasonably
12	dangerous design defects, including an inherently unstable and
13 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 16	d. the Zimmer M/L Taper [®] Hip System's unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;
17 18	e. the Zimmer M/L Taper® Hip System was not appropriately or adequately tested before its distribution; and
19 20	f. the Zimmer M/L Taper [®] Hip System had an unreasonably 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
	-12-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 13 of 27

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

77. Had the Zimmer Defendants properly and adequately tested the Zimmer M/L Taper® Hip System, they would have discovered that the components, paired with a cobaltchromium femoral head, generated excessive metal wear caused by the surface contact of the metal articulating components resulting in pain, swelling, metallosis, tissue necrosis, bone necrosis, and 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

24

1

2

3

4

5

6

7

82. Such risks were scientifically knowable to Defendants.

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

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

28

85. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff
 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.

<u>SECOND CAUSE OF ACTION</u> (AGAINST ALL DEFENDANTS)

12

13

Strict Products Liability – Failure to Warn

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

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

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

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

27 92. The Zimmer M/L Taper® Hip System was defective and unreasonably dangerous
 28 when it left the possession of Defendants because it contained an absence of warnings alerting the -14-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 15 of 27

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

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

At all times relevant hereto, Plaintiff DONALD FLETCHER was a person the
Defendants should have considered to be subject to the harm caused by the defective nature of the
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.

99. Defendants failed to adequately warn health care professionals and the public,
including Plaintiff and his prescribing physician, of the true risks of the Zimmer M/L Taper® Hip
System, including that the Zimmer M/L Taper® Hip System was susceptible to micromotion,
fretting and corrosion at the junction, generating significant and toxic amounts of metal wear debris
and corrosive byproducts in patients, causing severe pain and injury, and requiring further
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
 -15-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 16 of 27

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

5

101. Defendants failed to timely and reasonably provide adequate instructions and 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.

28

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 17 of 27

2 3

4

1

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

108. Neither Plaintiff DONALD FLETCHER nor his implanting physician had 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.

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

27 ///

28 ///

1	THIRD CAUSE OF ACTION (AGAINST ALL DEFENDANTS)
1	(AGAINST ALL DEFENDANTS)
2	Strict Products Liability – Manufacturing Defect
3	115. Plaintiffs incorporate by reference paragraphs 1 through 114 of this Complaint, as
4	if fully set forth herein and further allege as follows:
5	116. Defendants designed, developed, manufactured, tested, packaged, advertised,
6	promoted, marketed, distributed, labeled and/or sold the Zimmer M/L Taper® Hip System, in a
7	condition which rendered it unreasonably dangerous due to its propensity to result in early failure
8	of the device. The subject product was unreasonably dangerous in construction or composition.
9	117. The Zimmer M/L Taper® Hip System manufactured and/or supplied by Defendants
10	was defective in manufacture, construction or composition in that, when it left the hands of
11 12	Defendants, it deviated in a material way from Defendants' manufacturing performance standards
12	and/or it differed from otherwise identical products manufactured to the same design formula.
13	Defendants knew or should have known that the Zimmer M/L Taper® Hip System could fail early
14	in patients therefore causing pain and suffering, debilitation and the need for revision surgeries to
15	replace the device with the attendant risks of complications and death from such further surgeries,
10	Defendants continued to market the Zimmer M/L Taper® Hip System as a safe and effective hip
18	replacement system.
19	118. As a direct and proximate result of the use of the subject product as manufactured,
20	designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff
20	suffered harm, damages and economic loss as previously described and will continue to suffer such
22	harm, damages and economic loss in the future.
23	FOURTH CAUSE OF ACTION (AGAINST ALL DEFENDANTS)
24	Negligence
25	119. Plaintiffs incorporate by reference paragraphs 1 through 118 of this Complaint, as
26	if fully set forth herein and further allege as follows:
27	120. While the focus of Plaintiff's strict liability claims (Counts I-III) is on the condition
28	of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct.
	-18-
	COMPLAINT FOR DAMAGES

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 18 of 27

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 19 of 27

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.

The Zimmer Defendants failed to exercise ordinary care in the design, formulation,
manufacture, testing, quality assurance, quality control, labeling, and warning of the Zimmer M/L
Taper® Hip System devices because they knew or should have known these products caused
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.

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

-19-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 20 of 27

1	
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, advertising, promotion, inspection, sale and/or distribution of the
13	Zimmer M/L Taper [®] Hip System, and/or to utilize and/or implement reasonably safe designs for them;
14	
15	b. At all times relevant hereto, Defendants knew or should have known that the design of the Zimmer M/L Taper® Hip System was
16	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;
22	e. A reasonable manufacturer under the same or similar
	circumstances would have conducted additional testing and evaluation of the Zimmer M/L Taper® Hip System before placing it
24 25	into the stream of commerce;
25 26	f. A reasonable manufacturer under the same or similar circumstances would have conducted adequate testing of all
26	junctions coupled with the cobalt-chromium femoral head and
27	evaluation of the Zimmer M/L Taper [®] Hip System before placing it into the stream of commerce;
28	
	-20-
	COMPLAINT FOR DAMAGES

	Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 21 of 27
1	g. A reasonable manufacturer under the same or similar circumstances would have required that significant information be
2	provided to physicians regarding the risks associated with
3	foreseeable metal on metal problems stemming from the design;
4	h. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated
5	with the Zimmer M/L Taper® Hip System;
6	i. Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of the Zimmer M/L
7	Taper® Hip System when used in a reasonably foreseeable manner;
8	j. Failed to conduct adequate post marketing surveillance;
9	k. Failing to design, formulate, manufacture and incorporate or
10	to reformulate the Zimmer M/L Taper® Hip System with reasonable safeguards and protections against the type of injury and damage
11	suffered by Plaintiff when used in a reasonably foreseeable manner;
12	1. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer M/L
13	Taper® Hip System in accordance with good design practices;
14	m. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, etc., and the negative health
15	effects attendant to the use of the Zimmer M/L Taper® Hip System, thus misrepresenting the safety of the product;
16	
17	n. Failing to make timely and adequate corrections to the manufacture, design and formulation of the Zimmer M/L Taper®
18	Hip System so as to prevent and/or minimize the problems suffered by the Zimmer M/L Taper® Hip System use;
19 20	o. Despite its knowledge of these risks, Defendants continued
20	to promote and market the device; and,
21 22	p. Being otherwise being careless, reckless and negligent.
22	131. Despite knowing or having reason to know of the risks, Defendants did not (1)
23 24	perform additional testing, (2) investigate the risks, (3) suspend sales or distribution, (4) warn
25	physicians or patients of the propensity for the Zimmer M/L Taper® Hip System to cause or create
26	significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain,
27	swelling, dislocation, osteolysis, pseudotumor formation, adverse local tissue reaction,
28	trunnionosis, metallosis, and/or need for early surgical revisions.
	-21-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 22 of 27

1	132. As a direct and proximate result of Defendants' acts and omissions, including their
2	failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling,
3	warnings and distribution of the Zimmer M/L Taper® Hip System and Plaintiff was implanted with
4	the Zimmer M/L Taper® Hip System and suffered severe and debilitating injuries, economic loss,
5	and other damages, including but not limited to, cost of medical care, rehabilitation, lost income,
6	permanent instability and loss of balance, immobility, and pain and suffering, for which he is
7	entitled to compensatory and equitable damages and declaratory relief in an amount to be proven
8	at trial.
9	<u>FIFTH CAUSE OF ACTION</u> (AGAINST ALL DEFENDANTS)
10	
11	Negligent Misrepresentation
12	133. Plaintiffs incorporate by reference paragraphs 1 through 132 of this Complaint, as
13	if fully set forth herein and further allege as follows:
14	134. Prior to the Plaintiff receiving the Zimmer M/L Taper® Hip System on his right hip,
15	Defendants misrepresented that the Zimmer M/L Taper® Hip System was a safe and effective total
16	hip replacement system.
17	135. In the exercise of reasonable care, Defendants should have known that the Zimmer
18	M/L Taper® Hip System failed to comply with federal requirements for safe design and
19	manufacture and/or was in other ways out of specification, yet they negligently misrepresented to
20	Plaintiff DONALD FLETCHER and/or his physician that their device was safe and met all
21	applicable design and manufacturing requirements.
22	136. Defendants failed to disclose material facts regarding the safety and efficacy of the
23	Zimmer M/L Taper® Hip System utilizing a CoCr femoral head, including information regarding
24	increased risk of failure, harmful side-effects, increased risk of revision surgeries and lack of
25	adequate testing.
26	137. Defendants had a duty to provide Plaintiff, physicians and other consumers with true
27	and accurate information and warnings of any known risks and harmful side effects of the medical
28	devices they marketed, distributed and sold.
	-22-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 23 of 27

1

2

3

4

5

6

7

8

9

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

139. Plaintiff and his physician reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and material omissions in their marketing, advertisements, and promotions concerning the quality and safety of the Zimmer M/L Taper® Hip System. Plaintiff and his physicians reasonably relied upon Defendants' representations that the Zimmer M/L Taper® 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
of consumers and users of their products, including Plaintiff, with knowledge of the safety and
efficacy problems and suppressed this knowledge from the general public. Defendants made
conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.
19 Defendants' reckless conduct warrants an award of punitive damages.

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

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

As a direct and proximate result of Defendants' negligent misrepresentations and/or
 omissions regarding the Zimmer M/L Taper® Hip System, Plaintiff DONALD FLETCHER used
 the Zimmer M/L Taper® Hip System and has suffered serious physical injury, harm, damages and
 -23-

Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 24 of 27

economic loss ad will continue to suffer such harm, damages and economic loss in the future.
146. As a direct and proximate result of Defendants' negligent misrepresentations,
Plaintiff DONALD FLETCHER has suffered and will continue to suffer injuries, damages and
losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.
SIXTH CAUSE OF ACTION (AGAINST ALL DEFENDANTS)
Breach of Express Warranty
147 Distriction in a material beautifum as a manual to 1 (based by 146 of this Convolution)
147. Plaintiffs incorporate by reference paragraphs 1 through 146 of this Complaint, as
if fully set forth herein and further allege as follows:
148. Defendants advertised, labeled, marketed and promoted the Zimmer M/L Taper®
Hip System, representing the quality to health care professionals, the FDA, Plaintiff, and the public
in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer
M/L Taper® Hip System would conform to the representations. More specifically, Defendants
represented that the Zimmer M/L Taper® Hip System was safe and effective, that it was safe and
effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat
Plaintiff's condition.
149. The representations, as set forth above, contained or constituted affirmations of fact
or promises made by the seller to the buyer which related to the goods and became part of the basis
of the bargain creating an express warranty that the goods shall conform to the affirmations of fact
or promises.
150. The Zimmer M/L Taper [®] Hip System did not conform to the representations made
by Defendants in that the Zimmer M/L Taper® Hip System was not safe and effective, was not safe
and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in
individuals, such as Plaintiff.
151. At all relevant times, Plaintiff used the Zimmer M/L Taper® Hip System for the
purpose and in the manner intended by Defendants.
152. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have
discovered the breached warranty and realized its danger. -24-
COMPLAINT FOR DAMAGES

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

Within a reasonable time after Plaintiff knew or should have known of the failure of
his Zimmer M/L Taper® Hip System components, Plaintiff gave notice to Zimmer of such failure.
I55. 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.

SEVENTH CAUSE OF ACTION (AGAINST ALL DEFENDANTS)

13

14

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

At all relevant times, Plaintiff used the Zimmer M/L Taper® Hip System for the
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 -25-

	Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 26 of 27
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 13	EIGHTH CAUSE OF ACTION (AGAINST ALL DEFENDANTS)
13	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:
	-26-
	COMPLAINT FOR DAMAGES

	Case 1:18-cv-01529-DAD-JLT Document 1 Filed 11/05/18 Page 27 of 27							
1	(a) For special damages, to include past and future medical and incidental expenses, according to proof;							
2	(b) For past and future loss of earnings and/or earning capacity, according to proof;							
3	(c) For past and future general damages, to include pain and							
4 5	suffering, emotional distress and mental anguish, according to proof;							
6	(d) For punitive damages;							
7	(e) For Plaintiff JANIS FLETCHER damages for loss of consortium;							
8	(f) For pre-judgment and post-judgment interest;							
9	(g) For the costs of this action; and							
10	(h) Granting any and all such other and further legal and							
11	equitable relief as the Court deems necessary, just and proper.							
12	DEMAND FOR JURY TRIAL							
13	Plaintiffs hereby demand a jury trial to the full extent permitted by law.							
14	Dated: November 1, 2018. Respectfully submitted,							
15								
16	By: <u>/s/ Stuart C. Talley</u>							
17	Stuart C. Talley							
18	KERSHAW, COOK & TALLEY PC							
19	401 Watt Avenue Sacramento, California 95864							
20	Telephone: (916) 779-7000 Facsimile: (916) 721-2501							
21	Email: stuart@kcrtegal.com							
22	Attorneys for Plaintiffs							
23								
24								
25								
26								
27								
28	-27-							
	COMPLAINT FOR DAMAGES							
II.								

CIVIL COVED SHEET

Ca	se 1.18-cv-0152			ent 1-1 Filed 1	11/05/18 Pa	de 1 d	of 1		
The JS 44 civil cover sheet and provided by local rules of cour purpose of initiating the civil d	the information contained it. This form, approved by the ocket sheet. (SEE INSTRUC	herein neither replace n he Judicial Conference of TIONS ON NEXT PAGE O	or suppler of the Uni OF THIS FC	nent the filing and service ited States in September 1 DRM.)	e of pleadings or othe 1974, is required for t	r papers a he use of	is required by l the Clerk of Co	aw, exce ourt for th	ept as he
I. (a) PLAINTIFFS			DEFENDANTS						
DONALD FLETCHER and JANIS FLETCHER				ZIMMER BIOMET INC. f/k/a ZIMMER INC. and ZIMMER BIOMET HOLDINGS, INC. f/k/a ZIMMER HOLDINGS INC.					
(b) County of Residence of	of First Listed Plaintiff			County of Residence of First Listed Defendant					
(EXCEPT IN U.S. PLAINTIFF CASES)				<i>(IN U.S. PLAINTIFF CASES ONLY)</i> NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.					
(c) Attorneys (Firm Name, Stuart C. Talley, KERSH 401 Watt Avenue, Sacra Telephone: 916-779-700	AW, COOK & TALLE1 mento, CA 95864	PC		Attorneys (If Known)					
II. BASIS OF JURISD	ICTION (Place an "X" in G	ne Box Only)	III. CI	TIZENSHIP OF P	RINCIPAL PA	RTIES (Place an "X" in	One Box j	for Plainti <u>f</u>
□ 1 U.S. Government	□ 3 Federal Question			(For Diversity Cases Only)	rf def		and One Box f	or Defenda PTF	ant) DEF
Plaintiff	(U.S. Government)	Not a Party)	Citiz		1 🗆 1 Incorpor	rated <i>or</i> Pri siness In Tl	ncipal Place his State	04	□ 4
2 U.S. Government Defendant	4 Diversity (Indicate Citizensh	ip of Parties in Item III)	Citiz	en of Another State	2 🗖 2 Incorpor of Bu		rincipal Place	05	* 5
				en or Subject of a reign Country	3 🗖 3 Foreign			06	
IV. NATURE OF SUIT		ly) RTS	F	ORFEITURE/PENALTY	Click here for: Nat BANKRUPT		-	otions. STATUT	ES
□ 110 Insurance	PERSONAL INJURY	PERSONAL INJUR	Y 🗆 62	25 Drug Related Seizure	□ 422 Appeal 28 USC	2 158	375 False C		
 120 Marine 130 Miller Act 	 310 Airplane 315 Airplane Product 	365 Personal Injury - Product Liability	0.69	of Property 21 USC 881 90 Other	□ 423 Withdrawal 28 USC 157		□ 376 Qui Ta 3729(a		3
140 Negotiable Instrument	Liability	367 Health Care/	_				🛛 400 State R	eapportion	ıment
150 Recovery of Overpayment & Enforcement of Judgment	☐ 320 Assault, Libel & Slander	Pharmaceutical Personal Injury			PROPERTY RIG ■ 820 Copyrights	<u>H18</u>	410 Antitru 430 Banks :		ng
□ 151 Medicare Act	□ 330 Federal Employers'	Product Liability	.		830 Patent		□ 450 Comm		•
152 Recovery of Defaulted Student Loans	Liability 340 Marine	368 Asbestos Personal Injury Product			840 Trademark		 460 Deport 470 Racket 		iced and
(Excludes Veterans) □ 153 Recovery of Overpayment	345 Marine Product Liability	Liability PERSONAL PROPER		LABOR	SOCIAL SECURI	TY	Corrup 480 Consur	t Organizat	
of Veteran's Benefits	350 Motor Vehicle	□ 370 Other Fraud		Act	□ 862 Black Lung (92		□ 480 Collsul □ 490 Cable/S		
 160 Stockholders' Suits 190 Other Contract 	355 Motor Vehicle Product Liability	 371 Truth in Lending 380 Other Personal 	0 72	20 Labor/Management Relations	□ 863 DIWC/DIWW □ 864 SSID Title XV		□ 850 Securit Exchar		odities/
195 Contract Product Liability	360 Other Personal	Property Damage		40 Railway Labor Act	□ 865 RSI (405(g))	-	□ 890 Other \$	statutory A	
196 Franchise	Injury 362 Personal Injury -	385 Property Damage Product Liability	0 75	51 Family and Medical Leave Act			 891 Agricul 893 Enviror 		
	Medical Malpractice	-		00 Other Labor Litigation			895 Freedo		
REAL PROPERTY 210 Land Condemnation	CIVIL RIGHTS	PRISONER PETITIO Habeas Corpus:	<u>NS</u> D 79	91 Employee Retirement Income Security Act	FEDERAL TAX S		Act	tion	
220 Foreclosure	□ 441 Voting	□ 463 Alien Detainee		income becamy rece	or Defendant)		🗖 899 Admin	istrative Pr	
 230 Rent Lease & Ejectment 240 Torts to Land 	 442 Employment 443 Housing/ 	510 Motions to Vacate Sentence			871 IRS—Third Pa 26 USC 7609	rty		view or Ap Decision	
245 Tort Product Liability	Accommodations	530 General					950 Constit	utionality	
290 All Other Real Property	□ 445 Amer. w/Disabilities - Employment	535 Death Penalty Other:	□ 46	IMMIGRATION 52 Naturalization Application	1		State St	atutes	
	446 Amer. w/Disabilities - Other	 540 Mandamus & Oth 550 Civil Rights 	er 🗆 46	55 Other Immigration Actions					
	□ 448 Education	□ 555 Prison Condition		Actions					
		560 Civil Detainee - Conditions of							
		Confinement							
V. ORIGIN (Place an "X" i	n One Box Only)								
		Remanded from [Appellate Court		stated or D 5 Transfe pened Anothe (specify)	er District	Multidistri Litigation Fransfer		Multidis Litigatic Direct F	on -
	1 28 U S C 8 1332	tute under which you a	re filing (I	Do not cite jurisdictional sta	tutes unless diversity):				
VI. CAUSE OF ACTIO	JN Brief description of ca	use:	sing out	t of the Zimmer M/L	Taper® Hip Syste	m			
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER RULE 2	IS A CLASS ACTION 3, F.R.Cv.P.	N D	EMAND \$	CHECK YES only if demanded in complaint: JURY DEMAND: X Yes D No				
VIII. RELATED CASI IF ANY	E(S) (See instructions):	JUDGE			DOCKET NUM	BER			
DATE		SIGNATURE OF AT		OF RECORD					
11/01/2018		/s/ Stuart C. Ta	allev						

FOR OFFICE	USE	ONLY

RECEIPT # AMOUNT APPLYING IFP

JUDGE

MAG. JUDGE