JS 44 (Rev. 08/16)

CIVIL COVER SHEET

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 Marilyn Adams			DEFENDANTS Zimmer US, Inc. , 2 Surgical, Inc.	Zimmer US, Inc., Zimmer Holdings, Inc., Zimmer, Inc, and Zimmer		
(b) County of Residence of First Listed Plaintiff Lehigh County (EXCEPT IN U.S. PLAINTIFF CASES)			County of Residence	County of Residence of First Listed Defendant Indiana (IN U.S. PLAINTIFF CASES ONLY)		
(c) Attorneys (Firm Name, Address, and Telephone Number) Peter M. Villari, Esquire/Nicole Matteo, Esquire VILLARI, BRANDES & GIANNONE, P.C., 161 Washington, Street, Ste.400, Conshohocken, PA 19428 (610)729-2900			Attomeys (If Known)			
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)				RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff	
1 U.S. Government Plaintiff			(For Diversity Cases Only) P1 Citizen of This State			
☐ 2 U.S. Government Defendant	Diversity (Indicate Citizenship of Parties in Item III)			2	Another State	
			Citizen or Subject of a 3 5 Foreign Nation 6 6			
IV. NATURE OF SUIT			PORPHINI DE ANNUIT EN	Click here for: Nature of Sui		
CONTRACT 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury Medical Malpractice CIVIL RIGHTS 441 Voting 442 Employment 443 Housing/ Accommodations 445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other 448 Education	PERSONAL INJURY 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 1855 Property Damage Product Liability PERSONER PETITIONS Habeas Corpus: 463 Alien Detainee 1510 Motions to Vacate Sentence 1530 General 1535 Death Penalty Other:	FORFEITURE/PENALTY □ 625 Drug Related Seizure of Property 21 USC 881 □ 690 Other LABOR □ 710 Fair Labor Standards Act □ 720 Labor/Management Relations □ 740 Railway Labor Act □ 751 Family and Medical Leave Act □ 790 Other Labor Litigation □ 791 Employee Retirement Income Security Act IMMIGRATION □ 462 Naturalization Application □ 465 Other Immigration Actions	422 Appeal 28 USC 158 423 Withdrawal 28 USC 157 PROPERTY RIGHTS 820 Copyrights 830 Patent 840 Trademark 861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 RSI (405(g)) FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff or Defendant) 871 IRS—Third Party 26 USC 7609	375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commodities/ Exchange 890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information Act 896 Arbitration 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes	
	moved from	opellate Court	(specify	Properties District Litigation Transfer		
VI. CAUSE OF ACTION Cite the U.S. Civil Statute under which you are filing (Do not cite Jurisdictional statutes unless diversity): 28 USC 1332 Brief description of cause: Failed Zimmer hip implant						
VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.			DEMAND \$	DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes □ No		
VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NO						
DATE SIGNATURE OF ATTORNEY OF RECORD 02/10/2017						
FOR OFFICE USE ONLY RECEIPT # A	MOUNT	APPLYING IFP	JUDGE	MAG. JU	DGE	

JS 44 Reverse (Rev. 08/16)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

- Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" II. in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below. United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box. Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked. Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)
- Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this III. section for each principal party.
- Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code IV. that is most applicable. Click here for: Nature of Suit Code Descriptions.
- Origin. Place an "X" in one of the seven boxes. V.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation - Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C.

Multidistrict Litigation - Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

- Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction. Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No.
Judge:
<u>JURY TRIAL DEMANDED</u>

COMPLAINT AND JURY DEMAND

Plaintiff, Marilyn Adams, by and through her attorneys, respectfully submits the following Complaint and Jury Demand against Defendants Zimmer US, Inc., Zimmer Holdings, Inc., Zimmer, Inc. and Zimmer Surgical, Inc., and alleges the following:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the Zimmer M/L Taper Hip Prosthesis (hereinafter referred to as "Zimmer Device" or "ML Taper Kinectiv").

PARTIES, JURISDICTION AND VENUE

- 2. Plaintiff, MARILYN ADAMS, is a resident of Lehigh County, Pennsylvania.
- 3. Defendant Zimmer US, Inc. was registered as a Delaware Corporation and was duly registered and/or licensed to do business in the State of Pennsylvania. Zimmer US, Inc.'s registered agent in Indiana is Corporation Service Company located at 251 E. Ohio Street, Suite 500, Indianapolis, Indiana 46204.

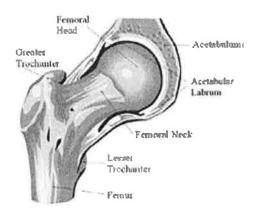
- 4. At all relevant times, Zimmer Holdings, Inc. was registered as a Delaware Corporation and is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana. Zimmer Holdings, Inc.'s registered agent in Indiana is Corporation Service Company located at 251 E. Ohio Street, Suite 500, Indianapolis, Indiana 46204.
- 5. Zimmer Holdings, Inc. is a publicly traded for-profit parent corporation that, through its subsidiaries, engages in the design, development, manufacture, and marketing of orthopedic reconstructive implants, spinal and trauma devices, dental implants, and related surgical products. Zimmer Holdings, Inc. was founded in 1927.
- 6. At all relevant times, Zimmer, Inc. was registered as a Delaware Corporation and is a wholly owned subsidiary of Zimmer Holdings, Inc., and is organized and existing under the laws of Delaware, with its principal place of business located in Warsaw, Indiana. Zimmer, Inc.'s registered agent in Indiana is Corporation Service Company located at 251 E. Ohio Street, Suite 500, Indianapolis, Indiana 46204.
- 7. Zimmer, Inc. engages in the design, research, development, manufacture, and marketing of orthopedic reconstructive implants and related surgical products, including the Zimmer Device that is the subject of this lawsuit.
- 8. At all relevant times, Zimmer Surgical, Inc. was registered as a Delaware Corporation and conducted business in the State of Indiana. Zimmer Surgical, Inc.'s registered agent in Indiana is Corporation Service Company located at 251 E. Ohio Street, Suite 500, Indianapolis, Indiana 46204.
- 9. Zimmer US, Inc., Zimmer Holdings, Inc., Zimmer, Inc. and Zimmer Surgical, Inc. will herein be collectively referred to as "ZIMMER".

- 10. This Court has jurisdiction over Plaintiff's claims under 28 U.S.C. §1332 since the amount in controversy exceeds the jurisdictional threshold and diversity of citizenship exists.
- 11. A substantial part of the events or acts giving rise to the claims herein occurred within this District and, as such, venue is appropriate in this District pursuant to 28 U.S.C. § 1391(a)(2).

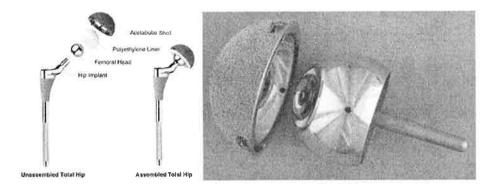
FACTUAL ALLEGATIONS

- 12. Plaintiff was implanted with a Zimmer M/L Taper Hip Prosthesis (hereinafter referred to as "Zimmer Device" or "ML Taper Kinectiv") on January 18, 2011 in the State of Pennsylvania.
- 13. On February 12, 2015, Plaintiff underwent revision surgery on her right hip in Lehigh County, Pennsylvania.
- 14. This products liability lawsuit seeks compensatory damages on behalf of Plaintiff, who was implanted with an artificial hip replacement system known as the ML Taper Kinectiv that ZIMMER designed, manufactured, marketed, sold and distributed.
- 15. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (ball like structure at the top of the femur), which rotates within the acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur and the acetabulum are strong, and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids. Over time, age and wear break down the cartilage. This forces the bone of the femur to rub directly against the bone of the acetabulum, and it can cause severe pain and immobility.

ANTERIOR HIP JOINT



16. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a liner and (4) an acetabular shell. The surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.



- 17. The ML Taper Kinectiv hip implant design is more prone to component corrosion when implanted into a human being than hip devices manufactured by other companies.
- 18. The ML Taper Kinectiv and related components were approved under a process by the Food and Drug Administration (hereinafter referred to as the "FDA") known as a 510(k).

A 510(k) medical device does not have to go through the rigors of a clinical study to gain approval by the FDA.

- 19. Before January 18, 2011, Plaintiff began medical treatment for her right hip with Dr. Prody Ververeli.
- 20. Before January 18, 2011, Dr. Prody Ververeli an orthopedic surgeon licensed to practice medicine in the Commonwealth of Pennsylvania, through his experience and training in the practice of medicine, indicated Plaintiff met the criteria to have the ML Taper Kinectiv implanted in her right hip.
- 21. At all relevant times and before the implantation of the ML Taper Kinectiv in the Plaintiff, ZIMMER knew that the ML Taper Kinectiv was defective and harmful to consumers.
- 22. At all relevant times and before the implantation of the ML Taper Kinectiv in the Plaintiff, ZIMMER had regular and frequent communications from surgeons who had implanted the ML Taper Kinectiv, including Plaintiff's surgeon, regarding failures and complications of the ML Taper Kinectiv.
- 23. On or about February 12, 2015, Dr. Prody Ververeli, an orthopedic surgeon licensed to practice medicine in the Commonwealth of Pennsylvania, performed revision surgery, including replacement of the implanted device with a DePuy Johnson and Johnson size 10.5 AML femoral component with a modified medial aspect and 6 inch leg and used a 32mm ceramic femoral head with a +5 neck length and 3 proximal cerclage cables in the State of Pennsylvania.
- 24. During the revision procedure on February 12, 2015, Dr. Ververeli noted evidence of adverse local tissue reaction and local host sensitivity to the wear debris.

COUNT I – STRICT PRODUCT LIABILITY AGAINST ZIMMER

- 25. Plaintiff incorporates by reference paragraphs 1 through 24 of the Factual Allegations as if fully set forth herein.
- 26. ZIMMER had a duty to place into the stream of commerce, manufacture, distribute, market, promote, and sell the ML Taper Kinectiv that was not defective and unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.
- 27. ZIMMER did in fact sell, distribute, supply, and/or promote the ML Taper Kinectiv to Plaintiff and her implanting physician.
- 28. ZIMMER expected the ML Taper Kinectiv it was selling, distributing, supplying, manufacturing, and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the Commonwealth of Pennsylvania, including Plaintiff and her implanting physicians, without substantial change in the condition.
- 29. At the time the ML Taper Kinectiv left the possession of ZIMMER and the time ML Taper Kinectiv entered the stream of commerce, the ML Taper Kinectiv was in an unreasonably dangerous and defective condition. These defects include but are not limited to the following:
 - (a) The ML Taper Kinectiv was not reasonably safe as intended to be used;
 - (b) The ML Taper Kinectiv had an inadequate design for the purposes of hip replacement;
 - (c) The ML Taper Kinectiv contained unreasonably dangerous design defects, including an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure;

- (d) The ML Taper Kinectiv's unstable and defective design resulted in a hip prosthesis, which had risks which exceeded the benefits of the medical device;
- (e) The ML Taper Kinectiv's unstable and defective design resulted in a hip prosthesis which was more dangerous than the ordinary consumer would expect;
- (f) The ML Taper Kinectiv failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected the Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person;
- (g) The ML Taper Kinectiv was insufficiently tested;
- (h) The warning to Plaintiff and Plaintiff's implanting physicians about the dangers the ML Taper Kinectiv posed to consumers including Plaintiff were inadequate. The inadequacy of ZIMMER's warnings include, but are not limited to, the following:
 - i. Insufficient to alert Plaintiff and Plaintiff's physicians as to the risk of adverse events and/or reactions associated with the ML Taper Kinectiv, subjecting Plaintiff to risks which exceeded the benefits of the ML Taper Kinectiv;
 - ii. Contained misleading warnings emphasizing the efficacy of the ML Taper Kinectiv while downplaying the risks associated with it, thereby making use of the ML Taper Kinectiv more dangerous than the ordinary consumer would expect;
 - iii. Contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the ML Taper Kinectiv;

- iv. Did not disclose that it was inadequately tested;
- v. Failed to convey adequate post-marketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the ML Taper Kinectiv;
- vi. Failed to contain instructions sufficient to alert consumers to the dangers they posed, and to give them the information necessary to avoid or mitigate those dangers.
- 30. Plaintiff used the ML Taper Kinectiv for its intended purpose, i.e. hip replacement.
- 31. Plaintiff could not have discovered any defect in the ML TAPER KINECTIV through the exercise of due care.
- 32. ZIMMER as designer, manufacturer, marketer, and distributor of medical devices are held to the level of knowledge of an expert in their field.
- 33. Plaintiff and the implanting physician did not have substantially the same knowledge as the designer, manufacturer, or distributor: ZIMMER.
- 34. At all times material hereto, Plaintiff was a user or consumer, defined as a purchaser, or any individual who uses or consumes the product, or any other person who, while acting for or on behalf of the injured party, was in possession and control of the product in question, or any bystander injured by the product who would reasonably be expected to be in the vicinity of the product during its reasonably expected use.
- 35. At all times material hereto, ZIMMER was a manufacturer, defined as a person or an entity that designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer.

The definition of a manufacturer includes a seller who (1) has actual knowledge of a defect in the product; (2) creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process; (3) alters or modifies the product in any significant manner after the product comes into the sellers possession and before it is sold to the ultimate user or consumer; (4) is owned in whole or significant part by the manufacturer; or, owns in whole or significant part the manufacturer.

- 36. At all times material hereto, ZIMMER was a seller, defined as a person engaged in the business of selling or leasing a product for resale, use, or consumption.
- 37. As a direct and proximate result of one or more of the foregoing wrongful acts or omissions by ZIMMER, Plaintiff was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.
- 38. Plaintiff suffered physical harm meaning bodily injury, loss of services, and rights arising from any such injuries.
- 39. ZIMMERS' defective ML Taper Kinectiv was a product, as it was an item or good that is personally at the time it is conveyed by the seller to another party.
- 40. At the time of implant, ZIMMERS' defective ML Taper Kinectiv was in a condition not contemplated by reasonable persons among those considered expected users or consumers of the product and such condition rendered the product to be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.

- 41. Unreasonably dangerous refers to any situation in which the use of a product exposes the user or consumer to a risk of physical harm to an extent beyond that contemplated by the ordinary consumer who purchases the product with the ordinary knowledge about the product's characteristics common to the community of consumers. At the time of implant, ZIMMERS' defective ML Taper Kinectiv was defective and unreasonably dangerous.
- 42. The defective condition existed at the time the product left the ZIMMERS' control.
 - 43. The defective condition was a proximate cause of Plaintiff's injuries.
- 44. ZIMMERS' ML Taper Kinectiv was defective design and/or the failure to warn of the dangers in the product's use.
- 45. ZIMMER failed to properly label the ML Taper Kinectiv to give reasonable warnings of danger about the product.
- 46. ZIMMER were sellers or otherwise put the defective ML Taper Kinectiv implanted in Plaintiff into the stream of commerce and at the time of such act said ML Taper Kinectiv was in a defective condition unreasonably dangerous to any user or consumer. ZIMMER is subject to liability for physical harm caused by the ML Taper Kinectiv because MARILYN ADAMS is in the class of persons that the ZIMMER should reasonably foresee as being subject to the harm caused by the ML Taper Kinectiv's defective condition; and ZIMMER was engaged in the business of selling such product; and the defective device or product was expected to and did reach the Plaintiffs without substantial alteration in the condition in which the product is sold by the person sought to be held liable.
- 47. As a direct and proximate result of one or more of the forgoing wrongful act or omissions by ZIMMER, Plaintiff was caused to suffer and sustain injuries of a permanent nature;

to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

COUNT II - NEGLIGENCE AGAINST ZIMMER

- 48. Plaintiffs incorporate by reference paragraphs 1 through 24 of the Factual Allegations as if fully set forth herein.
- 49. At all times relevant, it was the duty of ZIMMER to exercise due care in designing, testing, manufacturing, distributing, marketing, promoting, and selling of the ML Taper Kinectiv such that it would be reasonably safe for its intended use.
- 50. ZIMMER's negligence in the designing, testing, manufacturing, distributing, marketing, promoting, and selling of the ML Taper Kinectiv.
 - (a) ML Taper Kinectiv was negligently designed and manufactured, creating increased metal corrosion;
 - (b) surgical protocol which, among other things, creates a requisite degree of surgical skill for proper use of the device that is not possessed by a significant number of U.S. surgeons, even after a proper review of all of the ML Taper Kinectiv surgical technique literature, other ZIMMER literature, and proper training in residency programs;
 - (c) ZIMMER committed manufacturing errors, including but not limited to size tolerances out of specification and not within industry acceptable standards.
 - (d) ZIMMER, in advertising, marketing, promoting, packaging, and selling the ML Taper Kinectiv, negligently misrepresented material facts regarding the ML Taper

- Kinectiv's safety, efficacy, and fitness for human use by claiming the ML Taper Kinectiv was fit for its intended purpose when, in fact, it was not;
- (e) ZIMMER, in advertising, marketing, promoting, packaging, and selling the ML Taper Kinectiv, negligently misrepresented material facts regarding the ML Taper Kinectiv's safety, efficacy, and fitness for human use by claiming the ML Taper Kinectiv had been adequately and reliably tested when, in fact, it was not;
- (f) ZIMMER, in advertising, marketing, promoting, packaging, and selling the ML Taper Kinectiv, negligently misrepresented material facts regarding the ML Taper Kinectiv's safety, efficacy, and fitness for human use by claiming the ML Taper Kinectiv was safe and effective and was appropriate for use by human beings when, in fact, it was not;
- (g) ZIMMER, in advertising, marketing, promoting, packaging, and selling the ML Taper Kinectiv, negligently misrepresented material facts regarding the ML Taper Kinectiv's safety, efficacy, and fitness for human use by claiming the risk of serious adverse events and/or effects from the ML Taper Kinectiv's was comparable to that of other hip replacement systems, when in fact it was not;
- (h) ZIMMER, in advertising, marketing, promoting, packaging, and selling the ML Taper Kinectiv, negligently misrepresented material facts regarding the ML Taper Kinectiv's safety, efficacy, and fitness for human use by claiming the ML Taper Kinectiv had not caused or contributed to serious adverse events and/or effects requiring the premature explants of the device when, in fact, it had.

- 51. ZIMMER knew or had reason to know that Plaintiff, as a member of the general public for whose use the ML Taper Kinectiv was placed into interstate commerce, would be likely to use the ML Taper Kinectiv in a manner described in this Complaint.
- 52. ZIMMER knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the ML Taper Kinectiv, which danger would not be obvious to the general public.
- 53. As a direct and proximate result of one or more of the forgoing wrongful act or omissions by ZIMMER, Plaintiff was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

COUNT III - BREACH OF EXPRESS WARRANTY AGAINST ZIMMER

- 54. Plaintiffs incorporate by reference paragraphs 1 through 24 of the Factual Allegations as if fully set forth herein.
- 55. Plaintiff currently is not in possession of any document relating to representations, warnings, and/or communications made by ZIMMER in this action. Plaintiff reserves the right to present evidence in support of the claim which is not presently in her possession, but which will be discovered in the ordinary course of litigation. Such evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all written material or information provided on and/or within any and all packaging associated with Plaintiff's device; manufacturer's labels, package inserts; Adverse Event Reports; clinical trial data; medical literature; medical research findings and opinions; medical publications; advertisements; sales and promotional materials; internal memoranda, emails, communications and databases; sales, prescription and adverse

event report databases; and communications from ZIMMER in this action, including ZIMMER's employees, officers, directors, agents, representatives, contractors and business associates, to the public, medical community, Plaintiff's implanting surgeon and Plaintiff. Upon information, knowledge and belief, Plaintiff alleges the documents, instruments and/or evidence stated above are in the possession of ZIMMER.

- 56. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, it knew that the hip device was intended for human use.
- 57. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, Plaintiff was a foreseeable user of the device.
- 58. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, it expressly warranted that the ML Taper Kinectiv, including all of its component parts, was safe and merchantable for its intended use.
- 59. Plaintiff and her implanting surgeon reasonably relied upon the representations that the ML TAPER KINECTIV was of merchantable quality and safe for their intended uses.
 - 60. Plaintiff used the ML Taper Kinectiv for its intended purpose.
- 61. Contrary to the express, at the time ZIMMER marketed, sold and/or distributed the ML Taper Kinectiv, it was not of merchantable quality or safe for their intended use as described above.
- 62. As a direct and proximate result of one or more of the forgoing wrongful act or omissions by ZIMMER, Plaintiff was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

COUNT IV – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AGAINST ZIMMER

- 63. Plaintiff incorporates by reference paragraphs 1 through 24 of the Factual Allegations as if fully set forth herein.
- Plaintiff currently is not in possession of any document relating to representations, warnings, and/or communications made by ZIMMER in this action. Plaintiff reserves the right to present evidence in support of the claim which is not presently in her possession, but which will be discovered in the ordinary course of litigation. Such evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all written material or information provided on and/or within any and all packaging associated with Plaintiff's device; manufacturer's labels, package inserts; Adverse Event Reports; clinical trial data; medical literature; medical research findings and opinions; medical publications; advertisements; sales and promotional materials; internal memoranda, emails, communications and databases; sales, prescription and adverse event report databases; and communications from ZIMMER in this action, including ZIMMER's employees, officers, directors, agents, representatives, contractors and business associates, to the public, medical community, Plaintiff's implanting surgeon and Plaintiff. Upon information, knowledge and belief, Plaintiff alleges the documents, instruments and/or evidence stated above are in the possession of ZIMMER.
- 65. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, it knew that the hip device was intended for human use.
- 66. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, Plaintiff was a foreseeable user of the device.
- 67. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, it impliedly warranted that the ML Taper Kinectiv, including all of its component parts, was safe

and merchantable for its intended use. ZIMMER warranted that the implanted ML Taper Kinectiv was a good that at a minimum:

- (a) Would pass without objection in the trade under the contract description;
- (b) Was fit for the ordinary purposes for which such goods are used;
- (c) Would run, within the variations permitted by the agreement, of even kind, quality, and quantity within each unit and among all units involved; and/or,
- (d) Conformed to the promises or affirmations of fact made on the container or label if any.
- 68. ZIMMER, when they sold the implanted ML Taper Kinectiv, breached the foregoing implied warranty of merchantability.
- 69. Plaintiff and her implanting surgeon reasonably relied upon the representations that the ML TAPER KINECTIV was of merchantable quality and safe for their intended uses.
 - 70. Plaintiff used the ML Taper Kinectiv for its intended purpose.
- 71. Contrary to the implied warranties, at the time ZIMMER marketed, sold and/or distributed the ML Taper Kinectiv, it was not of merchantable quality or safe for their intended use as described above.
- 72. As a direct and proximate result of one or more of the forgoing wrongful act or omissions by ZIMMER, Plaintiff was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to her normal affairs and duties for an indefinite period of time.

COUNT V – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

- 73. Plaintiff incorporates by reference paragraphs 1 through 24 of the Factual Allegations as if fully set forth herein.
- Plaintiff currently is not in possession of any document relating to representations, warnings, and/or communications made by ZIMMER in this action. Plaintiff reserves the right to present evidence in support of the claim which is not presently in her possession, but which will be discovered in the ordinary course of litigation. Such evidence may include, but is not necessarily limited to: Instruction for Use Manuals; all written material or information provided on and/or within any and all packaging associated with Plaintiff's device; manufacturer's labels, package inserts; Adverse Event Reports; clinical trial data; medical literature; medical research findings and opinions; medical publications; advertisements; sales and promotional materials; internal memoranda, emails, communications and databases; sales, prescription and adverse event report databases; and communications from ZIMMER in this action, including ZIMMER's employees, officers, directors, agents, representatives, contractors and business associates, to the public, medical community, Plaintiff's implanting surgeon and Plaintiff. Upon information, knowledge and belief, Plaintiff alleges the documents, instruments and/or evidence stated above are in the possession of ZIMMER.
- 75. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, it knew that the hip device was intended for human use.
- 76. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, Plaintiff was a foreseeable user of the device.
- 77. At the time ZIMMER marketed, sold, and/or distributed the ML Taper Kinectiv, it impliedly warranted that the ML Taper Kinectiv, including all of its component parts, was fit for the particular purpose for which the implanted ML Taper Kinectiv was intended.

78. Plaintiff, the hospital and implanting surgeon relied upon ZIMMERS' skill and/or

judgment in its ability to furnish a device for the particular purpose for which the implanted ML

Taper Kinectiv was intended.

79. The implanted ML Taper Kinectivs that ZIMMER sold to hospitals, doctors and

Plaintiff were not fit for their particular purpose and ZIMMER breached their implied warranty

of fitness for particular purpose to the hospitals, doctors and Plaintiff.

80. As a direct and proximate result of one or more of the forgoing wrongful act or

omissions by ZIMMER, Plaintiff was caused to suffer and sustain injuries of a permanent nature;

to endure pain and suffering in body and mind; to expend money for medical care in the past and

in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to her

normal affairs and duties for an indefinite period of time.

WHEREFORE, Plaintiff, prays for judgment against Defendants, Zimmer US, Inc.,

Zimmer, Inc., Zimmer Holdings, Inc., and Zimmer Surgical, Inc., in a sum in excess of

jurisdictional limits of this Court, together with interests and costs of this action.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted this 10th day of February, 2017.

Respectfully submitted,

Nisole T. Matteo

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nicole Matter

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[Motion for Pro Pac Vice forthcoming]

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