### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

VICTOR BARAKAT,	§	
Plaintiff,	§	
	§	
VS.	§	CA No
	§	
ZIMMER, INC., and	§	JURY TRIAL DEMANDED
ZIMMER HOLDINGS, INC.,	§	
Defendants.	§	

#### PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW the Plaintiff, by and through his undersigned attorney, and, for his Complaint against the Defendants, alleges as follows:

#### **PARTIES**

- Plaintiff, Victor Barakat, is a citizen of the State of Texas, and resides in Plano,
   Collin County, Texas.
- 2. Defendant Zimmer, Inc., is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business in the State of Indiana.
- 3. Defendant Zimmer Holdings, Inc., is a foreign corporation incorporated under the laws of the State of Delaware and has its principal place of business in Indiana.

#### **JURISDICTION AND VENUE**

- 4. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). No Defendant is a citizen of the same state as Plaintiff and the amount in controversy exceeds \$75,000 exclusive of interest and costs.
  - 5. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a).

#### **BACKGROUND**

- 6. The Defendants designed, manufactured, distributed, and sold an implantable orthopedic reconstructive device for use in total hip arthroplasty (THA), or total hip replacement procedures, under the name of "Durom Acetabular Component," hereinafter "Durom Cup" or "Product".
- 7. On June 21, 2006, Dr. Jay Mabrey performed a left total hip arthroplasty on the person of Plaintiff Victor Barakat, including surgically implanting the Durom Cup into the body of the Plaintiff.
- 8. The Durom Cup is a cup made of cobalt chromium (CoCr). The permanent fixation of the cup is intended to occur by bone ingrowth into the porous shell of the cup. Circumferential equatorial fins around the rim of the Durom Cup are intended to hold the implant in place until new bone forms.
- 9. After the implant of the Durom Cup, Plaintiff experienced pain and discomfort and exhibited symptoms of a loose implant.
- 10. On April 10, 2009, Dr. Jay Mabrey performed a revision surgery to remove and replace the Durom Cup due to the failure of the cup to properly bond.
- 11. As a direct and proximate result of defects in the Durom Cup, the Plaintiff has suffered and will continue to suffer damages, including, but not limited to, past, present, and future pain and suffering, disability, disfigurement, expenses for medical, hospital, monitoring, rehabilitative and pharmaceutical costs, and lost wages or earnings.
- 12. Defendants designed, researched, manufactured, tested, sought approval by the U.S. Food and Drug Administration ("FDA") and advertised, promoted, marketed, sold and/or distributed the Durom Cup as an appropriate instrumentation for use in a Total Hip Arthroplasty.

- 13. Upon information and belief, the bearing surfaces of the Durom Cup (metal head and metal shell) are made of a forged cobalt chrome alloy with a high carbide content as opposed to other similar implants made from a cast metal alloy.
- 14. Upon information and belief, the back side of the cup that is expected to adhere to the pelvic bone is covered with a titanium coating to ensure adhesion of the prosthesis to the pelvis.
- 15. Upon information and belief, the Durom Cup has two equatorial fins protruding by 0.5 mm that are polished and do not have the titanium coating.
- 16. Upon information and belief, the design of the Durom Cup causes the cup to separate from the bone rather than adhere to the bone, causing pain.
- 17. Upon information and belief, in addition to a defective design of the Durom Cup, the instructions for installation and/or the form and content for proper installation provided by the Defendants did not meet FDA specifications and/or guidelines.
- 18. At all times relevant hereto, Defendants failed to properly train, instruct and/or inform the FDA and prescribing physicians of the proper technique for installation of the Durom Cup.
- 19. At all times relevant hereto, Defendants negligently designed, manufactured, marketed, advertised, promoted, sold and/or distributed the Durom Cup as a safe and effective implant for use in Total Hip Arthroplasty.
- 20. At all times relevant hereto, Defendants failed to warn of the dangers of the Durom Cup, including, but not limited to, the fact that the Durom Cup can separate from the bone rather than adhere to the bone.

- 21. Upon information and belief, Defendants concealed their knowledge of the defects in the Durom Cup from the Plaintiff and/or the physicians, hospitals, and/or the FDA.
- 22. Consequently, because of Defendants' acts and omissions, Plaintiff seeks damages including, but not limited to:
  - a) Pain and suffering (past and future);
  - b) Wage loss (past and future);
  - c) Earning impairment;
  - d) Medical expenses (past and future)
  - e) Loss of enjoyment of life;
  - f) Mental anguish and distress;
  - g) Permanent injuries and impairment; and
  - h) Attorney fees.

### COUNT 1 STRICT LIABILITY – FAILURE TO WARN

- 23. Plaintiff hereby restate and allege each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.
- 24. Defendants developed, manufactured, marketed, and distributed the Durom Cup implanted in Plaintiff Victor Barakat and sold it in the course of their business, even after acquiring knowledge that the Durom Cup was defective and dangerous and could cause injury to the plaintiff, without any warning to physicians or patients, including Plaintiff Victor Barakat and his physicians.
- 25. As a direct and proximate result of Defendants' failure to warn of this serious risk, the Plaintiff Victor Barakat has suffered substantial damages.

- 26. The Durom Cup was expected to, and did, reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition with which it was produced, manufactured, sold, distributed, and marketed by the Defendants.
- 27. At all times, the Durom Cup was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff Victor Barakat.
- 28. The Durom Cup was so defective in design or formulation or manufacture that when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design, formulation or manufacture of the Durom Cup.
- 29. At all relevant times, the Durom Cup was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.
- 30. Defendants had a duty to create and sell a product that was not unreasonably dangerous for its normal, intended use.
- 31. Defendants' Durom Cup product was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed in a defective or inadequate condition by Defendants and was unreasonably dangerous and created an unreasonable risk to its intended users, including Plaintiff Victor Barakat.
- 32. Plaintiff Victor Barakat, acting as a prudent person, could not discover that the Durom Cup was defective as herein mentioned or perceived its danger prior to February 6, 2009.
- 33. The Durom Cup as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the Defendants is defective due to inadequate warnings, inadequate instructions, and/or inadequate testing.

- 34. The Durom Cup as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the Defendants is defective due to inadequate post-marketing surveillance and/or warnings because, upon information and belief, sales continued after Defendants knew, or should have known, of the manufacturing defect and risks, including severe and permanent health consequences.
- 35. Defendants' defective design, manufacturing defect, inadequate instructions, and inadequate warnings of the dangers associated with the Durom Cup were acts that amount to willful, wanton, and/or reckless conduct by Defendants.
- 36. As a direct and proximate result of the defective condition of the Durom Cup as manufactured, promoted, distributed and sold by Defendants, Plaintiff Victor Barakat suffered and continues to suffer damages.

# COUNT 2 PRODUCTS LIABILITY – DESIGN DEFECT, MARKETING DEFECT & MANUFACTURING DEFECT

- 37. Plaintiff hereby restates and alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.
- 38. Defendants' product was defective and unsafe for its intended purposes at the time it left the control of Defendants and at the time it was sold by the retailer. The Durom Cup is defective because it did not conform to product design of other Defendants' products.
- 39. Defendants' defective product was unreasonably dangerous in construction and composition because, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product, or from otherwise identical products manufactured by the same manufacturer.

- 40. In addition, Defendants' product was defectively designed so as to render it unreasonably dangerous to Plaintiff. A safer alternative would have prevented or significantly reduced the risk of Plaintiff's injuries, without substantially impairing the product's utility. Furthermore, the safer alternative design was economically and technologically feasible at the time the product left the control of the Defendants by the application of existing or reasonably achievable scientific knowledge.
- 41. Defendants' product was unreasonably dangerous because the gravity and likelihood of injury from the Durom Cup outweighed its utility to Plaintiff and the public as a whole.
- 42. These defects were the producing cause of damage to Plaintiff which said damage was caused by a characteristic of the product that rendered it unreasonably dangerous arising from a reasonably anticipated use of the product by the Plaintiff, thus rendering Defendants liable to the Plaintiff pursuant to Tex. Civ. Prac. & Rem. Code § 82.005.
- 43. For all the reasons alleged herein, Defendants' defective product was unreasonably dangerous because an inadequate warning about the product, including inadequate warning on instruction for installation of the product, had not been provided and at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the Defendants failed to use reasonable care to provide adequate warning of such characteristic and its danger to users and handlers of the product.
- 44. Further, the Defendants, after the product left their control, acquired knowledge of a characteristic of the product that may cause damage and the danger of such characteristic (or alternatively, Defendants would have acquired such knowledge if they had acted as a reasonably prudent manufacturer), and thus are liable for damages suffered by Plaintiff, which arose as a

consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users when such knowledge was acquired.

# COUNT 3 NEGLIGENCE

- 45. Plaintiff hereby restates and alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth.
- 46. Defendants are the designer, manufacturer, seller, and/or supplier of the devices implanted in Plaintiff.
- 47. When placed in the stream of commerce, Defendants' device was not accompanied by any meaningful warnings regarding the risk associated with it. The warnings given by Defendants were silent as to the particular risks for which the device has been recalled and/or suspended.
- 48. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of its implant.
- 49. Defendants were negligent in the design, manufacture, testing, advertising, marketing, promotion, and labeling of the product, as well as in their failure to warn, and failure to properly instruct and/or train physicians in the use of its implants, including the implant received by Plaintiff. Defendants knew or should have known that patients, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
  - 50. The Durom Cup was unreasonably dangerous and defective because:
    - a) The manufacturing processes for the prosthesis and certain of its components did not satisfy the Food and Drug Administration's standards for the devices; and/or

- b) The failure of the manufacturing processes for the implants and certain of its components to satisfy the Food and Drug Administration's standards for the implants resulted in unreasonably dangerous manufacturing defects;
- c) The Defendants failed to warn of the unreasonable risks which created by these manufacturing defects; and
- d) The Defendants failed to properly instruct and/or train implanting physicians, thereby creating an unreasonably dangerous and defective device.
- 51. Defendants' actions as described herein constitute knowing omissions, suppression or concealment of material facts, made with the intent that others would rely upon such concealment, suppression or omissions in connection with the marketing of the devices.
- 52. The behavior or the Defendants demonstrates that they acted unlawfully and negligently, used or employed unconscionable commercial business practices, engaged in deception, fraud, false pretenses, false promises or misrepresentations, and/or perpetrated the knowing concealment, suppression or omission of material facts with the intent that consumers, including Plaintiff, would rely upon such concealment, suppression, or omission, in connection with the sale or advertisement of its implants.
- 53. As the direct and proximate cause and legal result of the Defendants' failure to provide appropriate warnings, instructions and/or training for Plaintiff's implant, and as a direct and legal result of the negligence, other wrongdoing and actions or omissions of Defendants described herein, the devices were implanted into Plaintiff and Plaintiff has suffered consequential damages.
- 54. Defendants' negligence was the direct and proximate cause of Plaintiff's injuries and damages set forth herein.

## COUNT 4 NEGLIGENT MISREPRESENTATION

- 55. Plaintiff hereby restates and alleges each and every allegation set forth above with the same force and effect as set forth herein and repeated at length.
- 56. Defendants made misrepresentations and/or omissions of material facts, including, but not limited to:
  - a) That Plaintiff's implant was fit for its intended use;
  - b) That Plaintiff's implant was of merchantable quality;
  - c) That Plaintiff's implant was safe and efficacious in the treatment of Plaintiff's medical condition;
  - d) That Plaintiff's implant would function as intended when necessary;
  - e) That Plaintiff's implant was defective, such that it would fail to function as intended; and
  - f) That Plaintiff's implant was inherently dangerous.
- 57. These representations and/or omissions were false and misleading at the time they were made.
- 58. Defendants negligently and carelessly made the foregoing misrepresentations without a basis.
- 59. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiff that there was no reasonable basis for making said representations herein.
- 60. When Defendants made the foregoing representations, they knew or should have known them to be false.

- 61. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiff was induced to and did subject himself to the use of the Durom Cup. If Plaintiff had known of the true facts, he would not have taken such action and risk. Plaintiff's reliance on Defendants' misrepresentations and omissions was reasonable because said representations were made by individuals and entities in a position to know the true facts.
- 62. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff will continue to suffer injury, expense and economic loss as previously described.

## COUNT 5 BREACH OF IMPLIED WARRANTY

- 63. Plaintiff restates each and every allegation set forth above with the same force and effects as it set forth herein and repeated at length.
- 64. Defendants are in the business of designing, manufacturing, and/or supplying and/or placing into the stream of commerce the Durom Cup for consumers.
- 65. By placing the Durom Cup into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.
- 66. The Durom Cup placed into the stream of commerce by Defendants was defective and accordingly, was neither fit, safe, nor merchantable for its intended use.
- 67. The defects in the Durom Cup designed, manufactured and/or supplied and/or placed into the stream of commerce by Defendants, were present at the time the product left Defendant's control.
- 68. Defendants breached the implied warranty for the Durom Cup because said product was defective, unmerchantable, and not fit for its intended purpose.

- 69. Plaintiff was a foreseeable user of the Durom Cup designed, manufactured and/or supplied and placed into the stream of commerce by Defendants.
- 70. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff will continue to suffer injury, expense and economic loss as previously described, rendering Defendants liable for said damages.

## COUNT 6 GROSS NEGLIGENCE

- 71. Plaintiff restates each and every allegation set forth above with the same force and effects as it set forth herein and repeated at length.
- 72. Plaintiff's injuries resulted from Defendants' gross negligence, malice, or actual fraud, which entitles Plaintiff to exemplary damages under Texas Civil Practice & Remedies Code § 41.003. Defendants had actual awareness of the extreme degree of risk caused by the defects in the Durom Cup, but preceded with conscious indifference to the rights, safety, and welfare of others, namely Plaintiff.

#### **DAMAGES**

- 73. By reason of all the above and as a direct and proximate result of Defendants' conduct, Plaintiff suffered the following injuries and damages:
  - a) Physical pain and suffering in the past and future;
  - b) Physical impairment in the past and future;
  - c) Mental anguish in the past and future;
  - d) Medical expenses in the past and future;
  - e) Lost earnings;
  - f) Lost earning capacity; and

g) Attorney fees.

### **PRAYER**

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be duly cited to appear and answer this Complaint and that after due proceedings are had, that there be judgment in favor of Plaintiff for the following:

- a) Actual damages and Exemplary damages;
- b) Prejudgment and postjudgment interest as provided by law;
- c) Costs of Court; and
- d) For all such other relief to which the Plaintiff may be justly entitled.

Dated: 3/10/2010 Respectfully submitted,

THE MONSOUR LAW FIRM

/s/D. Douglas Grubbs
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ATTORNEYS FOR PLAINTIFF

# Case 2:10-cv-00083-TJW-CE Document 1-1 Filed 03/10/10 Page 1 of 1 CIVIL COVER SHEET

SJS 44 (Rev. 12/07)

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 THE PROPERS OF THE FORM.)

I. (a) PLAINTIFFS	(a) PLAINTIFFS					DEFENDANTS						
(b) County of Residence of First Listed Plaintiff  (EXCEPT IN U.S. PLAINTIFF CASES)  (c) Attorney's (Firm Name, Address, and Telephone Number)  Rouglas C. Monsour, Monsour Law Firm  04 N Green Street, Longview, TX 75601				County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)  NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.  Attorneys (If Known)						ΗE		
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