UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

WALTER and BRENDA THOMAS,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	Case No. _____
ZIMMER HOLDINGS, INC and ZIMMER, INC.,	)	
	)	JURY TRIAL DEMANDED
	)	
Defendants.	)	

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiffs Walter and Brenda Thomas ("Plaintiffs"), by their undersigned counsel, bring this Complaint against Defendants Zimmer Holdings, Inc. and Zimmer, Inc., (hereinafter collectively "Zimmer" and/or "Defendants"), and allege:

INTRODUCTION

1. This product liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of Zimmer's defective hip implant component known as the Durom Acetabular Component (the "Durom Cup").

2. The Durom Cup was surgically implanted in Plaintiff Walter Thomas on May 14, 2007, and required surgical revision on October 7, 2009, because the Durom Cup was defective and failed. These multiple surgeries caused Plaintiff Walter Thomas to suffer significant injuries, including great pain and agony that restricted his ability to engage in the physical activities he enjoys, and has affected his ability to perform his basic household chores. Plaintiff Brenda Thomas asserts a derivative claim for loss of society, love, comfort and support.

3. Zimmer, founded in 1927, is one of the leading competitors in the U.S. hip and knee replacement market and accounted for seventy percent of the market in 2008.

4. In 2008, the U.S. hip and knee replacement market was valued at $6.7 billion dollars, with the hip replacement market contributing thirty-eight percent of the market at roughly $2.5 billion dollars. According to Zimmer's 2008 Annual 10-K Report, Zimmer was number one in global market share for reconstructive hip components. In the period ending December 2008, Zimmer reported $1,279.5 million in hip component sales. Zimmer's total 2008 sales exceeded $4 billion.

5. Zimmer designs, develops, manufactures, markets, tests, distributes and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures.

6. Zimmer's Durom Cup is an orthopedic device used in total hip replacement surgeries. Hip replacement surgery, also known as hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant. It is typically used to repair joint/bone damage or to treat arthritis pain in the hip joint area. The hip joint is in essence a large ball-and-socket joint composed of two parts: the head of the thighbone, or femur; and the acetabulum, a cup-shaped bone in the pelvis. Therefore, hip replacement surgery traditionally consists of two tasks: (1) replacing the end of the femur, or thighbone, with an artificial "ball," typically made of metal or stainless steel; and (2) resurfacing the hip socket using a metal shell and plastic liner, into which the ball attached to the femur will fit.

7. During hip replacement surgery, damaged portions of the hip are replaced with smooth, durable artificial surfaces to allow the joint to function properly. The Durom Cup is not cemented or screwed in place during implantation. Instead, it was designed to bond to the patient's hip bone.

8. The outside of the Durom Cup is porous, and has been sprayed with a highly engineered substance (a titanium plasma-sprayed coating) that is intended to facilitate the cup's acceptance by the human body. It is intended that the patient's own bone will grow into the exterior shell of the cup to hold the cup in place.

9. Rather than functioning in the intended manner, the Durom Cup implant resists bone growth and, as a result, instead of adhering to the bone, it comes loose and/or pops free from the hip, which can cause damage to the pelvic bone. This unintended result also causes extreme and devastating pain to the patient and necessitates revision surgery to remove the failed Durom Cup and replace it with a product that functions properly.

10. The Durom Cup is part of a metal-on-metal hip implant system, which was widely marketed by Zimmer as being more durable.

11. According to an article published in the *New York Times* on Thursday March 4, 2010, entitled "Concern Over Metal-on-Metal Implants," "studies in recent years indicate that in some cases the devices can quickly begin to wear, generating high volumes of metallic debris that is absorbed into a patient's body. That situation can touch off inflammatory reactions that cause pain in the groin, death of tissue in the hip joint and loss of surrounding bone." Plaintiff Walter Thomas, like other patients in the studies, likely suffered from metal debris causing death to the soft tissue and bone surrounding his hip, and further decreasing his chances for a successful second hip replacement.

12. The suspension of sales of Zimmer's Durom Cup was announced by Zimmer on July 22, 2008. The defects in the Durom Cup have affected and will continue to affect in the future, thousands of patients who had Durom Cups implanted in their hips. The Durom Cup has been implanted in over 12,000 patients in the United States since it was first sold on the U.S. market in 2006.

13. When introducing the Durom Cup, Zimmer represented to consumers and their physicians that the Durom Cup would provide greater range of motion and less wear on the bearing than traditional hip replacement implant components, thus making it an ideal product for younger, active patients. Contrary to Zimmer's representations, the Durom Cup is prone to an unprecedented failure rate for hip replacement implant components.

14. Since Defendants first began selling the Durom Cup in the United States in 2006 through on or about July 22, 2008, the product labeling and product information for the Durom Cup failed to contain adequate information, instructions, and warnings concerning implantation of the product and the risks that the Durom Cup can loosen and separate from the acetabulum (hip socket) in patients.

15. Despite their knowledge of the defects and serious injuries associated with use of the Durom Cup, Defendants engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Durom Cup was safe and effective.

16. At all relevant times, Zimmer knew or should have known that the Durom Cup was not safe for the patients in whom it was implanted, including Plaintiff Walter

Thomas, because of the unacceptable failure rate, which is approximately 24%, according to one leading hip surgeon.

17. On information and belief, the failure rate, to date, of Durom Cups implanted in the United States is between 20% and 30%. Since the Durom Cups often fail many months or even sometimes a year or more after the initial surgery, and are continuing to fail in patients, the true failure rate will likely be much higher, as more and more of these devices are failing in patients over time.

18. Notwithstanding the knowledge of predicted failures with the defective Durom Cup, Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced a suspension of the sale and distribution of the Durom Cup.

19. Plaintiff Walter Thomas, and other patients in whom the Durom Cups were implanted, have suffered not only physical injuries, but they also bear an unacceptable increase in the risk of severe pain and disability, with or without a costly and painful revision surgery. The revision surgery is invasive and painful and is often needed to replace the defective Durom Cup implant, as it was here.

PARTIES

20. At all times referenced herein, Plaintiffs Walter and Brenda Thomas were and are citizens of Franklin, Williamson County, Tennessee.

21. Defendant Zimmer Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all relevant times, Zimmer Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries, that it controlled, which designed, manufactured, marketed, supplied and sold to distributors, physicians, hospitals, patients and medical practitioners certain hip socket

devices known as the Durom Cup to be surgically implanted in patients throughout the United States, including in the State of Tennessee.

22. Defendant Zimmer, Inc. is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana, 46581-0708. At all times relevant, Zimmer, Inc was a wholly owned subsidiary of Defendant Zimmer Holdings, Inc. At all times relevant, Defendant, Zimmer, Inc. was duly organized and existing under the laws of the State of Delaware with its principal place of business for manufacturing the Durom Cup in Warsaw, Indiana. Defendant, Zimmer, Inc. designed, manufactured, marketed, supplied and sold the Durom Cup to physicians, hospitals, and clinics to be surgically implanted in patients in the State of Tennessee.

23. Defendant Zimmer, Inc. is a direct subsidiary of the parent company, Defendant Zimmer Holdings, Inc.

24. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority of each Defendant and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and Zimmer exercised control over its subsidiaries and affiliates. As such, each Defendants are each individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' injuries, losses and damages.

JURISDICTION AND VENUE

25. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants are citizens of different States and the amount in controversy exceeds $150,000.00 exclusive of interest and costs.

26. Venue in this action properly lies in the Middle District of Tennessee pursuant to 28 U.S.C. §§ 1391 (a) and (c), as a substantial number of the events, actions or

omissions giving rise to Plaintiffs' claims occurred in this District. At all times material hereto, Defendants conducted substantial business in the State of Tennessee and in Davidson County.

27. Upon information and belief, at all relevant times, Defendants were present and transacted, solicited and conducted business in Davidson County, Tennessee, through their employees, agents and/or sales representatives, and derived substantial revenue from such business.

28. At all relevant times, Defendants placed the defective device into the stream of interstate commerce that was implanted in Plaintiff Walter Thomas.

29. Defendants are conclusively presumed to have been doing business in this state and are subject to Tennessee's long arm jurisdiction.

30. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the State of Tennessee, including Davidson County.

31. Plaintiffs' damages in this matter accrued in the Middle District of Tennessee.

FACTUAL ALLEGATIONS

I. BACKGROUND ON ARTIFICIAL HIPS AND HIP REPLACEMENT DEVICES

32. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy — that is, the relatively simple ball and socket

structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

33. The artificial hip implantation process requires a surgeon to insert an artificial cup with a smooth lining into the patient's diseased pelvic socket. The lining serves the same purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fitted into the thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

34. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only once other therapies, such as pain medications, have failed.

35. Total hip arthroplasty ("THA") , or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As

the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear. The Durom Cup promised to offer an alternative surface that would resist wear and tear.

36. The Durom Cup is a monoblock (constructed of a single piece of material) cup made of cobalt chromium (CoCr) alloy and is designed for use in combination with Zimmer's Metasul Metal-on-Metal Tribological Solution LDH (Large Diameter Heads) for THA. The design and material of the Durom Cup are key elements to its intended stability, wear resistance, and intended bone sparing characteristics. The Durom Cup has a pure titanium plasma-sprayed coating for fixation. The coating on the Durom Cup sold in the United States has a different structure and is slightly thicker (0.1mm) compared to the same products which were sold for use in patients outside of the United States.

II. HISTORY OF THE DUROM CUP

37. The Durom Cup was launched in Europe in 2003 for hip resurfacing procedures. Hip resurfacing requires less bone removal than conventional THA, but necessitates a different surgical technique. The Durom Cup was made available in Canada and Australia in 2003, India and Korea in 2005, and Argentina in 2006.

38. On or about December 19, 2005, Zimmer submitted a section 510(k) Premarket Notification of Intent (K053536) to the FDA to manufacture and market the Durom Acetabular Component and the Metasul LDH (Large Diameter Heads) devices to the public. Three months later, on March 19, 2006, the FDA cleared the device for marketing and distribution in the United States.

39. The 510(k) approval process by the FDA is regarded as a simplified "me too" application process, which does not require extensive review and approval by the

FDA. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval. Submitters simply must compare their device to one or more legally marketed devices (devices marketed prior to May 28, 1976) and make and support their substantial equivalency claims. The FDA does not perform 510(k) pre-clearance facility inspections and submitters may market the device immediately after 510(k) clearance is granted.

40. In this instance, Zimmer submitted a simplified 510(k) application that compared the Durom Cup to earlier products called "predicate devices" manufactured by competitors. In its application, Zimmer described: "The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices."

41. No clinical studies were conducted in connection with the submission of the application for the Durom Cup. As part of the application process, Defendants stated that the "results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device (as implants)." Further in their submission to the FDA the Defendants repeat throughout that the Durom Cup is intended to be a device that is simply similar to previously approved predicate devices. Therefore, the FDA was persuaded by Defendants that any additional review and investigation was unnecessary.

III. DESIGN & MANUFACTURE OF THE DUROM CUP

42. Zimmer's Durom Cup is a flattened hemisphere, which is meant to offer a greater range and freedom of movement. With a constant wall thickness of 4 mm throughout all sizes, the cup maintains an inner diameter as large as possible, while intended to maintain maximum implant strength and minimum bone resection of acetabular bone mass.

A coating of pure titanium using a plasma spray under vacuum and static load is applied to the outer surface, called Porolock (tm) Ti VPS. The high carbon cobalt chromium (CoCr) alloy is produced by a forging rather than casting process. This means that the size of block carbides is up to eight-times smaller compared to cast cobalt chromium (CoCr) prostheses. The resulting lower surface roughness was intended to lead to a lower wear rate when compared with cast cobalt chromium (CoCr) alloys.

43. Zimmer failed to recognize the deficiencies of the Durom Cup due to poor and inadequate quality assurance procedures, including failure of Zimmer to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Durom Cup. Zimmer failed to implement or utilize adequate safeguards, tests, inspections, monitoring and quality assessments to ensure safety of the defective device. At the time the devices were manufactured and sold to patients, the devices were defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to risks of injury.

44. During the time Zimmer manufactured the Durom Cup, inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities.

45. During the course of manufacturing the Durom Cup, Zimmer failed in several ways, including, without limitation, by:

(a) failing to conduct adequate mechanical testing on components, subassemblies and/or finished Durom Cup;

(b) failing to test an adequate number of sample devices on an ongoing basis;

(c) failing to take adequate steps to specifically identify failure modes with clarity and suggest methods to monitor, avoid, and/or prevent further failures;

(d) failing to identify and/or note the significance of any testing that resulted in failure of the Durom Cup;

(e) failing to take corrective actions to eliminate or minimize further failures of the Durom Cup;

(f) failing to adequately explain performance specifications for the components, subassemblies, and finished Durom Cup;

(g) failing to adequately explain or justify all test conditions and acceptance criteria for the Durom Cup;

(h) failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and, by

(i) failing to perform adequate quality assurance testing before and after sterilization.

46. Zimmer failed to perform adequate testing of the Durom Cup, including its components and subassemblies, to ensure that the Durom Cup functioned properly during and after implantation.

47. As a result of these manufacturing and quality control problems associated with the manufacture of the Durom Cup, the component was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly approved by the FDA.

IV. DUROM CUP DEFECTS ARE EXPOSED BY LEADING PHYSICIANS

48. After the FDA initially approved the 510(k) application, Zimmer began to aggressively market the Durom Cup to physicians and their patients.

49. Relying upon Zimmer's representations, physicians began using broadly the Durom Cup instead of other models. Reports of Durom Cup failures soon followed. It is now apparent that a significant percentage of the Durom Cups have failed, and that the failure rate is unacceptably high.

50. The failure rate is estimated at upwards of 24% (twenty-four percent) when analyzing patients over a four-year period (2006-2010). This failure rate is much higher than similar products made by Zimmer, and is also much higher than the failure rate of competitor's devices. Furthermore, this rate is four times Zimmer's predicted failure rate of 5.7%

51. Lawrence Dorr, M.D., a world-renowned orthopedic surgeon and Zimmer consultant, and a team of doctors at The Arthritis Institute at Good Samaritan Hospital in Los Angeles, California, have recently published the results of their study comparing one hundred and eighty patients who had the large-diameter (44- to 50-mm) Durom Cup and fifty-four patients who had a small-diameter (28-mm Metasul®) articulation implanted between May 2006 and November 2007. The total number of clinical failures was forty-one of one hundred and eighty patients (23%). Twenty-eight of one hundred and fifty-one patients had radiographic impending failure at final follow-up (18.5%). All post-revision surgery retrieved cups were examined in detail and had no evidence of bone on the fixation surface.

52. Since at least 2007, surgeons implanting the Durom Cup complained to Zimmer that the device was failing in their patients, many of whom had to undergo painful, invasive and expensive revision surgeries.

53. One of these surgeons was Dr. Dorr, who warned Zimmer in 2007 of the high rate of Durom Cup failures. At the time Dr. Dorr warned Zimmer of the high rate of failures, he was a paid Zimmer consultant and a veteran of thousands of hip replacement surgeries.

54. In particular, Dr. Dorr informed Zimmer that x-rays showed that the Durom Cup was failing because it was separating or loosening from the bone, rather than fusing to it, causing patients crippling pain while the metal cup moved around the hip socket and rubbed against the bone.

55. Zimmer ignored Dr. Dorr's warnings and continued to sell the Durom Cup.

56. In April 2008, Dr. Dorr publicly warned other orthopedists about the cup failures his patients were experiencing and urged Zimmer to stop selling the Durom Cup.

57. On April 22, 2008, Dr. Dorr wrote the following memorandum to his colleagues at the American Association of Hip and Knee Surgeons:

> *MEMO*
> *DATE: 4/22/08*
> *TO: American Association of Hip and Knee Surgeons*
> *FROM: Larry Dorr, M.D.*
> *RE: This NOTICE is to inform you that we have had ten revisions in 165 hips and have four more that need to be revised using the Durom cup (Zimmer, Inc).*
>
> *This **failure rate** has occurred within the first two years. In the first year the x-rays looked perfect. We have revised four that did not have any radiolucent lines or migration (and John Moreland revised one). These early cups fooled us, but the **symptoms were so***

> ***classic for a loose implant*** *that we operated the patients. When we hit on the edge of the cup* ***it would just pop free****. As time goes by the cups begin developing radiolucent lines. We now have one cup at two years that has actually migrated a short distance. It has tilted into varus.* ***We do not believe the fixation surface is good on these cups****. Also there is a circular cutting surface on the periphery of the cup that we believe* ***prevents the cup from fully seating****.* ***We stopped using the cup after the first revisions****.*
>
> *We have notified Zimmer.* ***The FDA has been notified*** *and we will notify them of our continued revisions. The company does not believe it should pull the cup from the market so I am notifying all of my colleagues of our failure rate with this cup. I went through a similar scenario with the Sulzer cup failures where I was the only one experiencing revisions at the beginning and basically it was assumed that it was our technique.* ***I can assure you that this goes beyond technique****. I learned my lesson in not informing everyone about* ***this magnitude of failures*** *with the Sulzer cup problem, so it is my obligation to do so with this cup.*

(emphasis in original).

58. After informing colleagues about his experience with the Durom Cup, Dr. Dorr heard from several other doctors who reported similar problems. According to Dr. Dorr and other physicians, x-rays of patients who received defective Durom Cups showed that the socket was separating from bone, rather than fusing with it.

59. For patients (including Plaintiff), the slippage of the implant itself, as a result of its failure to adhere to the bone meant agony as the metal cup moved around in the hip socket and rubbed against bone. As a result, Plaintiff Walter Thomas could not walk without assistance. Such crippling injuries are devastating to patients as they were to Mr. Thomas.

60. Despite this memorandum, Zimmer again ignored the warnings and continued to sell the Durom Cup.

61. In late May 2008, Zimmer finally informed surgeons that it was investigating Dr. Dorr's complaint but that it was not suspending sales as Dr. Dorr had

recommended. While Zimmer investigated complaints, roughly 1300 more patients were implanted with the Durom Cup in the United States.

62. Zimmer responded by defending the Durom Cup and blaming the doctors' implantation techniques. Zimmer later attributed failures of the Durom Cup to a discrepancy in doctors' techniques in performing THA surgeries. Zimmer contended (and still apparently contends) that the technology and design parameters of the Durom Cup demand a surgical technique with "high precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the U.S." Therefore, according to Zimmer, the Durom Cup requires additional training in implantation technique and cup placement for many surgeons who use the device and who may otherwise be experts in THA.

63. Around this time, although Zimmer still maintained that there were no issues with the Durom Cup, other doctors began to stop implanting them. Even still, Zimmer continued to market the Durom Cup to unsuspecting physicians and patients, selling hundreds of units between May 2008 and July 22, 2008.

64. Throughout 2008, while the Durom Cup was being implanted in patients across the United States and around the world, Zimmer was accumulating mounting and overwhelming reports that the Durom Cups were failing at an alarming rate. Zimmer failed to disclose to physicians and patients the true failure rate.

V. TEMPORARY SUSPENSION OF THE DUROM CUP

65. Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced it was temporarily suspending Durom Cup marketing and distribution in the United States. In its announcement, Zimmer stated that the suspension was necessary "while the Company updated labeling to provide more detailed

surgical technique instructions to surgeons and implements its surgical training program in the U.S."

66. Zimmer announced that the company was taking this "voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component used in total hip replacement procedures" but that Zimmer "has found no evidence of a defect in the materials, manufacture, or design of the implant."

VI. ZIMMER'S IMPROPER FAILURE TO RECALL THE DUROM CUP

67. Under federal regulations, a recall is "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the FDA.

68. These sections also recognize that recall is an alternative to an FDA-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the FDA to monitor recalls and assess the adequacy of a firm's efforts in recall. A company's voluntary recall of a medical device and the FDA's classification of that action as a Class I recall establish that the device violates FDA regulations.

69. To date, Zimmer has not issued a public recall of the Durom Cup and instead has described its action as only a "temporary suspension" of the device. In reality, Zimmer has made the device "unavailable for purchase in the United States," (see screen shot from Zimmer e-catalog as published on Zimmer's website on February 23, 2010, attached as **Exhibit A** to this Complaint), but has not voluntarily recalled the device.

VII. PLAINTIFFS' INJURIES DUE TO THE DEFECTIVE DUROM CUP

70. Plaintiff Walter Thomas, a 63-year-old retired manufacturing plant supervisor from Franklin, Tennessee, and his wife, Brenda Thomas, have been significantly injured as a result of the implantation of the Durom Cup in Plaintiff Walter Thomas's left hip. As a result of the Durom Cup's failure, the Thomas family has had to adjust their lives to accommodate Walter's ongoing injuries.

71. Prior to Plaintiff Walter Thomas's May 14, 2007 implantation surgery, Walter was an energetic husband and father whose active lifestyle included long walks with his dog and working on major remodeling projects in the Thomas's home.

72. The defective Durom Cup limited Plaintiff Walter Thomas's activities because he struggled with bending and turning toward his left side. Walter also struggled in sitting for even short periods of time. As a result, driving became painful and he often squirmed in the vehicle while trying to find a position to minimize the pain. In addition, Walter limped during this time, especially after bending or sitting.

73. Plaintiff Walter Thomas initially did well following his 2007 implantation surgery until it became clear that the Durom Cup was slipping out of place.

74. In August 2009, Plaintiff Walter Thomas visited his orthopedic specialist, who noted that x-rays showed lucency behind the medial acetabular component. Walter's physician was concerned about lack of ingrowth to the acetabular cup and ordered a several confirmatory tests that demonstrated the defect. A revision surgery was thus recommended by his physician at that time.

75. The excruciating pain persisted until Plaintiff Walter Thomas underwent a revision surgery on October 7, 2009, just over two years after the original implantation. The acetabular cup was found to be completely loose, with very little bony in-

growth on the surface. This is exactly the type of Durom Cup failure described by Dr. Dorr that occurred in Dr. Dorr's patients.

76. Plaintiff Walter Thomas never fully recovered from the harm of the defective Durom Cup. Following the revision surgery in October 2009, he suffered complications, necessitating ongoing medical care and several additional hospitalizations.

77. Plaintiff Walter Thomas required a second hip revision, which was performed on February 1, 2010.

78. Mr. Thomas now suffers from a limited range of motion due to the modifications that had to be made to the device and a potentially permanent limp. The dislocations and multiple surgical procedures caused him extreme pain, worry, terrible fear and anxiety, and additional medical expenses.

79. In addition to his medical expenses, Plaintiff Walter Thomas has incurred out-of-pocket expenses for medical aids such as a walker, a cane, two orthotic braces, and items purchased to aid in his ability to function at home, such as a commode riser.

80. In reliance on Zimmer's marketing of the Durom Cup, Plaintiff Walter Thomas and his physician expected that this device would provide him with better stability and range of motion than other hip replacement devices on the market, and that the device would be resistant to wear, making it ideal for very active individuals such as Walter. In addition, Walter and his physician believed that the Durom Cup should last Walter at least twenty years. Walter expected a significant improvement in his quality of life after the initial hip replacement surgery, which did not occur and continues to impact him emotionally and physically.

81. Plaintiff Brenda Thomas has also suffered from the loss of Walter's companionship, services, love, society and affection. The family's well-being has suffered, and Walter and Brenda Thomas in turn have experienced physical manifestations of emotional distress.

CLAIMS FOR RELIEF

COUNT I
(Strict Liability – Failure To Warn And Instruct)

82. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

83. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Durom Cup. Defendants designed, manufactured, assembled and sold the Durom Cup to medical professionals and patients knowing that they would then be implanted in patients in need of hip prosthesis.

84. Defendants distributed and sold the Durom Cup in the condition in which it left its place of manufacture, in its original form of manufacture, which included the defects described herein. The Durom Cup was expected to and did reach Plaintiff Walter Thomas without substantial change or adjustment in its condition as manufactured and sold by Defendants.

85. The Durom Cup designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the Durom Cup. Plaintiff Walter Thomas was and is in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Durom Cup.

86. The Durom Cup was implanted and used in the manner for which it was intended. This use has resulted in severe physical and emotional and other injuries to Plaintiffs.

87. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the Durom Cup created a high risk of bodily injury and serious harm.

88. Defendants failed to provide adequate and timely warnings or instructions regarding the Durom Cup and its known or knowable defects. Defendants failed to advise patients like Walter Thomas that monitoring of the cup was necessary to avoid long and painful periods during which the device failure would go undetected – as it did here.

89. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Walter Thomas has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory damages in an amount to be proven at trial.

COUNT II
(Strict Liability – Design Defect)

90. Plaintiffs incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

91. Zimmer is the manufacturer and/or supplier of the Durom Cup and placed this device into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the Durom Cup.

92. The Durom Cup manufactured, marketed, distributed and/or supplied by Zimmer was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

93. The Durom Cup was expected to and did reach Plaintiff Walter Thomas without substantial change in condition. Alternatively, the Durom Cup manufactured and/or supplied by Defendants was defective in design or formulation, because when the Durom Cup device left the hands of Defendants, the manufacturers and/or suppliers, the Durom Cup was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

94. The Durom Cup was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Durom Cup were not in conformity with applicable requirements of the FDCA.

95. The Durom Cup manufactured and/or supplied by Zimmer was defective due to inadequate warnings and/or inadequate trials, testing and study, inadequate exposure of the real risks inherent with the device as determined by the clinical trials, and inadequate reporting of the results of the clinical trials and post-marketing clinical experiences with the device.

96. The Durom Cup manufactured and/or supplied by Zimmer was defective due to inadequate post-marketing warnings or instructions because, after Zimmer knew or had reason to know of the risk of injury from the Durom Cup, it failed to provide

adequate warnings to the medical community, patients, and the public, including Plaintiffs, and continued to promote and advertise the Durom Cup as safe and effective.

97. The Durom Cup was designed, manufactured, distributed, tested, sold, marketed, and advertised defectively by Zimmer. As a direct and proximate cause of Zimmer's defective design of the Durom Cup, Plaintiff Walter Thomas and other patients had the device implanted in their bodies, and suffered and will continue to suffer increased risk of long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery, and pain and suffering.

98. Zimmer was or should have been in possession of evidence demonstrating that the Durom Cup caused serious injuries and would fail. Nevertheless, Zimmer continued to market the device by providing false and misleading information with regard to the safety and efficacy of the Durom Cup.

99. Zimmer's actions, as described above, were performed willfully, intentionally and with reckless disregard for the rights of Plaintiffs, other patients and the public.

100. As a result of Zimmer's conduct, Plaintiffs suffered the losses, injuries and damages specified herein.

COUNT III
(Strict Liability –Manufacturing Defect and Failure to Adhere to Quality Controls)

101. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

102. The Durom Cup is defectively manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the Durom Cup.

103. The Durom Cup was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Durom Cup were not in conformity with applicable requirements of the FDCA.

104. The Durom Cup was expected to and did reach the Plaintiff Walter Thomas without substantial change or adjustment to its mechanical function.

105. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Durom Cup.

106. Furthermore, the Durom Cup and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

107. The Durom Cup was defective due to inadequate warnings or instruction because Defendants knew or should have known that the Durom Cup created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers of this risk.

108. The Durom Cup is inherently dangerous for its intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to Plaintiffs for their breach of duty to Plaintiffs.

109. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Walter Thomas has sustained and will continue to sustain severe physical injuries, and Plaintiffs have suffered and will continue to suffer severe emotional distress, mental

anguish, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT IV
(Negligence)

110. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

111. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiffs to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and Plaintiffs of the defective nature of the Durom Cup.

112. Defendants breached their duty of reasonable care to Plaintiffs by defectively designing, manufacturing, and/or negligently failing to warn of these defects in the Durom Cup, thereby causing Plaintiffs' injuries and damages.

113. Defendants breached their duty of reasonable care to Plaintiffs by manufacturing and assembling the Durom Cup in such a manner that it was prone to failures and malfunction and thus exposed Plaintiff Walter Thomas to severe and lasting physical trauma and injuries.

114. Defendants breached their duty of reasonable care to Plaintiffs by failing to promptly and adequately notify the FDA and warn and instruct Plaintiff, the medical community, and the public at the earliest possible date of known defects in the Durom Cup. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

115. Defendants' conduct, as described above, was reckless in that Defendants were aware of, yet consciously disregarded, a substantial and unjustifiable risk that Durom cup users, including Plaintiff Walter Thomas, would suffer serious injury or death

as a result of Defendants' defective design and manufacture of the Durom cup, as well as Defendants' failure to warn of these defects. This disregard constituted a gross deviation from the standard of care that an ordinary person would have exercised under the circumstances, warranting the imposition of punitive damages against Defendants.

116. As a direct and proximate result of Defendants' wrongful misconduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT V
(Negligence *Per Se*)

117. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

118. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Durom Cup, and otherwise distributing the Durom Cup.

119. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se*.

120. Plaintiffs, as a purchaser of the Durom Cup, are within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

121. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VI
(Breach Of Implied Warranty)

122. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

123. Defendants impliedly warranted that the Durom Cup, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs and their physicians, was merchantable and fit and safe for ordinary use.

124. Defendants further impliedly warranted that the Durom Cup, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs and their physicians, was fit for the particular purposes for which it was intended and was sold.

125. Contrary to these implied warranties, the Durom Cup was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

126. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VII
(Breach Of Express Warranty)

127. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

128. Defendants expressly warranted to Plaintiffs by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiffs, and the general public, that the Durom Cup was safe, effective, fit and proper for its intended use.

129. In allowing the implantation of the Durom Cup, Plaintiffs and their physician relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Durom Cup was not safe and was unfit for the uses for which it was intended.

130. Through sale of the Durom Cup, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

131. Defendants breached their warranty of the mechanical soundness of the Durom Cup by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew or should have known of the defects and risk of product failure and resulting patient injuries.

132. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT VIII
(Negligent Misrepresentation)

133. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

134. At the time Defendants manufactured, designed, marketed, sold and distributed the Durom Cup for use by Plaintiffs, Defendants knew or should have known of the use for which the Durom Cup was intended and the serious risks and dangers associated with such use of the Durom Cups.

135. Defendants owed a duty to physicians and patients using the Durom Cup, including Plaintiffs, to accurately and truthfully disclose the risks of the Durom Cup. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff Walter Thomas's physicians, the medical community, Plaintiffs, and the public about the risks of the Durom Cup, which Defendants knew or in the exercise of diligence should have known.

136. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs sustained and will continue to sustain severe physical injuries. severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT IX
(Intentional Misrepresentation)

137. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

138. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the Durom Cup, owed a duty to provide accurate and complete information to Plaintiff, his physicians, and the public regarding the Durom Cup.

139. However, Defendants misled Plaintiff Walter Thomas, his physicians, and the public into believing that the Durom Cup was safe and effective for use in hip replacement surgery; engaged in deceptive, misleading and unconscionable promotional or

sales methods to convince physicians and patients to use the Durom Cup, even though Defendants knew or should have known that the Durom Cup was unreasonably unsafe. Defendants also failed to warn physicians and the public about the safety risks of the Durom Cup and the Metasul implant system they designed, marketed and sold.

140. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Durom Cup was safe for human use, had no unacceptable side effects, and would not interfere with daily life.

141. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Durom Cup. Defendants, through promotional practices as well as the publication of medical literature, deceived potential treating physicians, Plaintiff Walter Thomas, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff Walter Thomas, regarding the safety of the Durom Cup.

142. Defendants expressly denied that the Durom Cup created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Durom Cup.

143. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, physicians, Plaintiff Walter Thomas, and the public, the truth regarding Durom Cup failures for months, if not years, all the while undertaking a major advertising campaign to sell the Durom Cup. Defendants received reports of the Durom Cup defects from various sources, including Dr. Dorr, and

intentionally withheld this information from physicians and patients, while continuing to sell the Durom Cup for implantation in individuals such as Plaintiff Walter Thomas.

144. Further, even as Defendants eventually may have disclosed some information regarding the Durom Cup defects, any such disclosures were incomplete and misleading.

145. Defendants effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the Durom Cup. The truth did not begin to emerge until, at the earliest, May 2008 when Zimmer issued a "Dear Doctor" letter to physicians that suggested that Durom Cup defects were arising because of doctors' surgical techniques. This letter was inadequate and failed to fully inform physicians, patients, including Plaintiff Walter Thomas, and the public of the true defects in the Durom Cup, defects that were known to Defendants. Even after the letter, Defendants' sales representatives continued to assure physicians and patients that the Durom Cup was adequate and reliable for the purpose intended and they continued to sell the Durom Cup.

146. Through the materials they disseminated, Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the Durom Cup.

147. Defendants possessed evidence demonstrating the Durom Cup was defective and likely to fail and injure patients. Nevertheless, Defendants continued to market the Durom Cup by providing false and misleading information with regard to its safety to Plaintiff Walter Thomas and Plaintiff Walter Thomas's physicians.

148. Defendants engaged in all the acts and omissions described above with the intent that Plaintiff Walter Thomas's physicians and Plaintiff Walter Thomas would rely

on these misrepresentations, deception and concealment in deciding to use Defendants' Durom Cup rather than another Zimmer product or a competitors' similar product.

149. Plaintiff Walter Thomas and Plaintiff Walter Thomas's physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above. This reliance proximately caused the injuries and damages described in this Complaint.

150. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Walter Thomas sustained and will continue to sustain severe physical injuries. Plaintiffs suffered and will continue to suffer severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory damages and in an amount to be proven at trial.

COUNT X
(Constructive Fraud)

151. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

152. At the time Defendants sold the Durom Cup to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the Durom Cup, which knowledge was not possessed by Plaintiff Walter Thomas or his physicians, and Defendants thereby held a position of superiority over Plaintiffs.

153. Through their unique knowledge and expertise regarding the defective nature of the Durom Cup, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiff Walter Thomas that they had knowledge of the truth of the representation that the Durom Cup was safe and effective for its intended use and was not defective.

154. Defendants' representations to Plaintiffs, the medical community, and the public were unqualified statements made to induce Plaintiffs and their physicians to purchase and use the Durom Cup; and Plaintiff Walter Thomas and his physicians relied upon the statements prior to purchasing the device and having it implanted in Plaintiff Walter Thomas's body.

155. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff Walter Thomas and his physician and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiff Walter Thomas and his physicians reasonably relied on Defendants' representations.

156. As a foreseeable, direct and proximate result of Defendants' willful and wrongful conduct and reckless disregard for Mr. Thomas' well-being, Plaintiffs sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory, punitive and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT XI
(Negligent Infliction Of Emotional Distress)

157. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

158. Defendants carelessly and negligently manufactured, marketed and sold the Durom Cup to Plaintiff Walter Thomas, carelessly and negligently concealed the Durom Cup defects from Plaintiff, and carelessly and negligently misrepresented the quality, safety and usefulness of the Durom Cup.

159. Plaintiff Walter Thomas was directly involved in and directly impacted by Defendants' carelessness and negligence, in that Plaintiff Walter Thomas has sustained and

will continue to sustain severe physical injuries, economic losses, and other damages as a direct result of his (and his physicians') decision to purchase, use and have implanted in his hip a defective and dangerous product manufactured, sold and distributed by Defendants.

160. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs suffered injuries, damages and harm detailed herein, for which they are entitled to compensatory damages in an amount to be proven at trial.

COUNT XII
(Loss Of Consortium)

161. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

162. At all relevant times hereto, Plaintiff Walter Thomas was married to his spouse, Brenda Thomas, who has suffered injuries and losses as a result of Defendants' wrongful conduct.

163. For the reasons set forth herein, Plaintiff Brenda Thomas has necessarily paid and has become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

164. For the reasons set forth herein, Plaintiff Brenda Thomas has suffered and will continue to suffer the loss of her beloved husband's support, companionship, services, society, love and affection.

165. Plaintiff Brenda Thomas alleges her marital relationship with Walter Thomas has been impaired and depreciated, and the marital association between husband and wife has been damaged and altered.

166. Plaintiff Brenda Thomas has suffered great emotional pain and mental anguish as a direct and proximate result of the injuries to her husband Walter Thomas. Plaintiff Brenda Thomas has experienced physical manifestations of emotional distress, including backaches, an upset digestive system, and difficulty sleeping or leaving Walter at home alone.

167. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Brenda Thomas has sustained and will continue to sustain severe emotional distress, economic losses and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff Brenda Thomas and severally for all general, special and equitable relief to which she is entitled by law.

COUNT XIII
(Unjust Enrichment)

168. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

169. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' Durom Cup by Plaintiffs Walter and Brenda Thomas.

170. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiffs, as reasonable consumers, expected.

171. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT XIV
(Punitive Damages)

172. All preceding allegations are incorporated by references as if fully set forth herein.

173. The acts of Zimmer were willful and wanton, malicious, and showed a total disregard for human life and human suffering. Based upon the acts alleged herein, Zimmer knew or should have known, in light of the surrounding circumstances, that their conduct would naturally and probably result in injury and damage. Zimmer continued such conduct with malice and/or in reckless disregard of the consequences, from which malice may be inferred. The Thomases should be awarded punitive damages against Zimmer, based upon the acts herein so as to punish Zimmer and deter similar conduct.

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for judgment against Defendants and in their favor and award additional relief as follows:

1. Economic and non-economic damages in an amount in excess of $150,000 as provided by law and to be supported by the evidence at trial;

2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;

3. Loss of consortium damages for the acts complained of herein in an amount to be determined by a jury;

4. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

5. Punitive damages for the acts complained of herein in an amount to be determined by a jury

6. For an award of attorneys' fees and costs;

7. For prejudgment interest and the costs of suit; and,

8. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all claims so triable in this civil action, as provided by Rule 34(b) of the Federal Rules of Civil Procedure.

DATED: May 20, 2010

BY: Elizabeth A. Alexander

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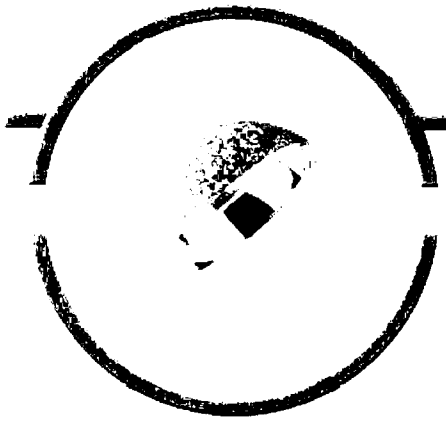
Attorneys for Plaintiffs Walter and Brenda Thomas

Exhibit A



Durom® Acetabular Components

Sterile: Yes
Material: CoCrMo (BIOLOX®DELTA SUL®-21WF), Titanium (Porolock® Ti-VPS)
Packaging: 1/Box
Note: Sterilization by Radiation

Enlarge Image

ENTER PRODUCT # EXCLUDING DASHES
EX: 00123412312

01.00214.044	0100214044	44	38	D	Not in US
01.00214.046	0100214046	46	44	F	Not in US
01.00214.048	0100214048	48	42	H	Not in US
01.00214.050	0100214050	50	44	J	Not in US
01.00214.052	0100214052	52	46	L	Not in US
01.00214.054	0100214054	54	48	N	Not in US
01.00214.056	0100214056	56	50	P	Not in US
01.00214.058	0100214058	58	52	R	Not in US
01.00214.060	0100214060	60	54	T	Not in US
01.00214.062	0100214062	62	56	V	Not in US
01.00214.064	0100214064	64	58	X	Not in US
01.00214.066	0100214066	66	60	Z	Not in US

JS 44 (Rev. 12/07)

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 THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Walter Thomas and Brenda Thomas

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

(c) Attorney's (Firm Name, Address, and Telephone Number)

Elizabeth A. Alexander, Lieff, Cabraser, Heimann & Bernstein, LLP, 150 4th Ave N, Ste 1650, Nashville, TN 37219, 615-313-9000

DEFENDANTS

Zimmer Holdings, Inc. and Zimmer, Inc.

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)

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

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

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

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

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 (Excl. 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

TORTS

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
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 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

OTHER STATUTES
- ☐ 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
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

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

Brief description of cause:
product liability and negligence

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $**

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
05/20/2010

SIGNATURE OF ATTORNEY OF RECORD
Elizabeth A. Alexander

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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:

I. (a) 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.

(b) 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.)

(c) 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)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" 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; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

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 date.

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. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. 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

VII. 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 dollar amount (in thousands of dollars) 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.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

COPY

WALTER THOMAS and BRENDA THOMAS

Plaintiff

v.

ZIMMER HOLDINGS, INC. and ZIMMER, INC.

Defendant

Civil Action No. 3 10 0492

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Zimmer, Inc.
through its Registered Agent, Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, Delaware 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Elizabeth A. Alexander
Lieff, Cabraser, Heimann & Bernstein, LLP
150 Fourth Avenue North, Suite 1650
Nashville, Tennessee 37219

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON

CLERK OF COURT

Date: MAY 20 2010

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

COPY

WALTER THOMAS and BRENDA THOMAS

Plaintiff

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Lieff, Cabraser, Heimann & Bernstein, LLP
150 Fourth Avenue North, Suite 1650
Nashville, Tennessee 37219

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON

CLERK OF COURT

Date: MAY 20 2010

RD

Signature of Clerk or Deputy Clerk