

1 Kent L. Klaudt, Esq. (SBN 183903)
kklaudt@lchb.com
2 Barbra L. Williams, Esq. (SBN 249967)
bwilliams@lchb.com
3 LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
275 Battery St., 29th Floor
4 San Francisco, CA 94111
Phone: (415) 956-1000
5 Fax: (415) 956-1008

6 *Local Counsel for Plaintiffs*

7 Jake G. Pipinich, Esq., OBA #22687
(*Pro Hac Vice* application pending)
8 Jimmie A. Franklin, Esq., OBA #12295
Lynn R. Anderson, Esq., OBA #16473
9 GARRETT LAW OFFICE, P.C.
111 West Fifth Street, Suite 800
10 Tulsa, OK 74103
Phone: (918) 622-9292
11 Fax: (918) 549-6794

12 *Counsel for Plaintiffs*

13 UNITED STATES DISTRICT COURT
14 EASTERN DISTRICT OF CALIFORNIA
15

16 JOHN P. HERNANDEZ and
17 ESTELLA M. HERNANDEZ,

18 Plaintiffs,

19 v.

20 ZIMMER HOLDINGS, INC., a Delaware
21 Corporation, and ZIMMER, INC., a
Delaware Corporation,

22 Defendants.
23

Case No.

COMPLAINT FOR DAMAGES

JURY TRIAL DEMANDED

1 COME NOW Plaintiffs JOHN HERNANDEZ and ESTELLA HERNANDEZ
2 (collectively “Plaintiffs”), by their attorneys, Lief, Cabraser, Heimann & Bernstein, LLP and the
3 Garrett Law Office, P.C., and for their Complaint against Defendants, allege as follows:

4 **PARTIES**

5 1. Plaintiffs JOHN HERNANDEZ and ESTELLA HERNANDEZ are adult
6 individuals and they are residents of Bakersfield, Kern County, California.

7 2. Defendant Zimmer Holdings, Inc., is a corporation incorporated under the
8 laws of the State of Delaware and has its principal place of business in the State of Indiana.

9 3. Defendant Zimmer, Inc., is a corporation incorporated under the laws of
10 the State of Delaware, and has its principal place of business in the State of Indiana.

11 4. Defendants Zimmer Holdings, Inc. and Zimmer, Inc. (collectively
12 “Zimmer” or “Defendants”) manufactured, marketed and distributed and continue to
13 manufacture, market and distribute orthopedic products, including reconstructive implants used in
14 hip replacement surgery.

15 5. Zimmer is the nation’s largest producer of orthopedic devices, and it does a
16 substantial amount of business in Kern County, California, including marketing and sales of the
17 Durom Cup, the orthopedic device at issue in this case.

18 **JURISDICTION AND VENUE**

19 6. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C.
20 § 1332(a). No Defendant is a citizen of the same state as the Plaintiffs and the amount in
21 controversy exceeds \$75,000.00 for both Plaintiffs, exclusive of interest and costs.

22 7. Venue in this jurisdiction is proper pursuant to 28 U.S.C. § 1391(a).

23 **FACTUAL ALLEGATIONS**

24 8. Zimmer was founded in 1927, and purports to be a worldwide leader in the
25 design and manufacture of orthopedic reconstructive, spinal and trauma devices, dental implants,
26 and related orthopedic surgical products. Zimmer’s 2008 sales exceeded \$4 billion.

27 9. Total hip arthroplasty (THA), also called total hip replacement, is a
28 common medical procedure performed on more than 442,000 patients in the U.S. each year,

1 according to a Millennium Research Group report issued March 2008. The surgery is designed to
2 help relieve pain and improve joint function in people with severe hip degeneration due to
3 arthritis or trauma.

4 10. The Zimmer Metasul® Durom® Acetabular Component (hereinafter
5 “Durom Cup”) is a metal monoblock cup made of cobalt chromium (CoCr) alloy cup with a
6 coating of titanium plasma spray. It is intended for press-fit fixation in the acetabulum (hip
7 socket), which is the cup-shaped cavity at the base of the hipbone into which the ball-shaped head
8 of the femur fits. The Durom Cup is not cemented or screwed in place during implantation;
9 rather, the patient’s bone is supposed to bond to the implant. Unlike traditional hip replacement
10 parts, the Zimmer Durom Cup is made from a single piece of material and is designed to address
11 some of the more common problems with hip replacement components, such as wear of the
12 bearing, limited range of motion, and instability.

13 11. The Durom Cup was launched in Europe in 2003 for hip resurfacing, a
14 procedure that requires less bone removal than conventional THA, but also uses a different
15 surgical technique. In the United States, the Durom Cup was approved for use in THA by the
16 FDA on or around March of 2006.

17 12. The Durom Cup model distributed in the United States differs from the
18 model distributed in Europe in that the coating on the Durom Cup sold in the United States has a
19 different structure and is thicker compared to the coating on the model sold outside the United
20 States. Additionally, with respect to the implantation of the Durom Cup, orthopedic surgeons
21 implanting the Durom Cup model distributed outside the United States received different training
22 and instructions than those surgeons implanting the Durom Cup model marketed within the
23 United States.

24 13. In April of 2008, Lawrence Dorr, M.D., a former consultant for Zimmer
25 and veteran of more than 5,000 hip replacement surgeries, notified the Defendant that
26 approximately 23 percent of his patients who had the Durom Cup implanted required a revision
27 surgery and that he was discontinuing use of the product.
28

1 14. On July 22, 2008, Defendants sent a letter to surgeons notifying them that
2 they were temporarily suspending the marketing and distribution of the Durom Cup in the United
3 States to allow Zimmer time to update labeling to provide more detailed surgical technique
4 instructions and implement a surgical training program for U.S. surgeons. Although Defendants
5 denied that the product was defective in its manufacturing or design, they admitted that
6 “additional surgical technique instructions and training are necessary in the United States, and we
7 strongly recommend that U.S. surgeons stop implanting the Durom Cup until receiving such
8 training.”

9 15. In a press release dated July 22, 2008, Zimmer stated that it had reviewed
10 data on more than 1,300 patients that had the Durom Cup implanted in the United States
11 (approximately 10 percent of all Durom Cup procedures in the United States as of that date).
12 Defendants further claimed that where “appropriate and necessary surgical techniques” had been
13 used, the revision rate was 1.5 percent. By contrast, the revision rate for remaining patients was
14 claimed by Zimmer to be 5.7 percent. In fact, the revision rate is far higher than claimed by
15 Zimmer, and is actually at least 20 to 30 percent, if not higher.

16 16. In a letter dated August 16, 2008 to hip surgeons in the United States,
17 Defendants provided those surgeons with updated product labeling on the Durom Cup, more
18 detailed surgical technique instructions, and specific information regarding a comprehensive
19 surgical training program, which Defendants stated they developed in collaboration with several
20 experts.

21 17. In addition to the updated documents, Defendant also announced that they
22 were launching a comprehensive surgical skills training curriculum.

23 18. Defendant noted that surgeons must complete at least an online training
24 course, which reviewed the critical aspects of the Durom Cup design, preoperative planning
25 considerations, and comprehensive information regarding the critical technique steps to implant
26 the device. This was the minimum required training to resume product use.

27 19. Zimmer also established webcasts as follow-up to the online training; a
28 surgical skills course that offered experience with cadavers to practice implantation of the Durom

1 Cup in a controlled environment, and a surgeon-to-surgeon training course with one-on-one
2 learning with an expert in the operating room.

3 20. From 2006 through the date of this Complaint, Defendants generally
4 manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise
5 engaged in all activities that are part and parcel of the sale and distribution of a medical device,
6 and by said activities, caused the Durom Cup to be placed into the stream of commerce
7 throughout the United States, including in the State of California.

8 21. Defendants made, participated in, and/or contributed to filings with the
9 FDA in conjunction with the 510(k) approval process for the Durom Cup.

10 22. Upon information and belief Defendants were in control of the design,
11 assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying,
12 promotion, sales, and the issuance of product warnings and related information with respect to the
13 Durom Cup.

14 23. Defendants were at all times material hereto subject to the laws of the
15 United States of America, including provisions relating to the FDA, and the rules and regulations
16 thereof, in conjunction with the approval process, labeling, and other after-market activities that
17 pertain to the Durom Cup.

18 24. The Durom Cup has been widely advertised, marketed, and represented by
19 the Defendants as a safe and effective treatment.

20 25. From the time the Defendants first began selling the Durom Cup in the
21 United States through at least on or about August 16, 2008, the product labeling and product
22 information for the Durom Cup failed to contain adequate information, instructions, and warnings
23 concerning implantation of the product and the risks that the Durom Cup can loosen and separate
24 from acetabulum (hip socket) in patients.

25 26. Despite its knowledge of the serious injuries associated with use of the
26 Durom Cup, Defendants engaged in a marketing and advertising program which, as a whole, by
27 affirmative and material misrepresentation and omissions, falsely and deceptively sought to create
28

1 the image and impression that the Durom Cup was safe and effective for use in hip replacement
2 surgery.

3 27. Defendants downplayed and understated the health hazards and risks
4 associated with the use of the Durom Cup and through promotional literature as well as sales
5 visits to orthopaedic surgeons, deceived doctors and potential users of the Durom Cup by relaying
6 positive information, while concealing the nature and extent of known adverse and serious health
7 effects.

8 **Plaintiffs' Experience with the Durom Cup and Resulting Injuries**

9 28. Prior to July 15, 2008, the orthopedic surgeon for Plaintiff, as well as
10 Plaintiff John Hernandez, were exposed to the aforementioned advertising and marketing
11 campaign directly by the Defendant.

12 29. Plaintiff and Plaintiff's orthopedic surgeon, either through direct
13 promotional contact with Defendants, through word-of-mouth from other health care providers,
14 and/or through promotional materials, received the information the Defendants intended that they
15 receive, to wit: that the Durom Cup was safe and effective for use in total hip replacement
16 ("THA") procedures.

17 30. Sometime prior to July 15, 2008, Defendants manufactured the Zimmer
18 Metasul® Durom® Acetabular Component, Reference No. 01.00214.152, Lot No. 2357515, with
19 additional components, which were subsequently implanted into the body of Plaintiff John
20 Hernandez.

21 31. Sometime prior to July 15, 2008, Defendants provided this Zimmer
22 Metasul® Durom® Acetabular Component and additional components to Plaintiff's orthopedic
23 surgeon for implantation, and all of these components were subsequently implanted into the body
24 of Plaintiff John Hernandez.

25 32. Using the training and instruction provided by Defendants, on July 15,
26 2008 Plaintiff's orthopedic surgeon implanted this Zimmer Metasul® Durom® Acetabular
27 Component and other Zimmer components into the body of Plaintiff John Hernandez at
28 Bakersfield Memorial Hospital in Bakersfield, California.

1 replacement surgery. On information and belief, Defendants' fraudulent misrepresentation
2 described herein was intentional and was made to maintain the sales volume of the Durom Cup.

3 41. Defendants fraudulently concealed safety issues with the Durom Cup in
4 order to induce orthopedic surgeons to implant the Durom Cup into patients, including Plaintiff
5 John Hernandez.

6 42. At the time Defendants concealed the fact that the Durom Cup was not
7 safe, Defendants were under a duty to communicate this information to orthopedic surgeons, the
8 FDA, the medical community, and the general public in such a manner that they could appreciate
9 the risks associated with the Durom Cup.

10 43. Plaintiff and Plaintiff's physician relied upon the Defendants' untruths
11 regarding the safety of the Durom Cup.

12 44. As a direct and proximate result of Defendants' malicious and/or
13 intentional concealment of material life-altering information from Plaintiff and Plaintiff's
14 orthopedic surgeon, Defendants caused or contributed to Plaintiff's injuries.

15 45. It is unconscionable and outrageous that Defendants would risk the safety
16 of consumers. Despite their knowledge of defects and the high failure rate likely in the Durom
17 Cup, the Defendants made conscious decisions not to redesign, label, warn or inform the
18 unsuspecting consuming public and the medical community. Defendants' outrageous conduct
19 rises to the level necessary that Plaintiffs should be awarded punitive damages to deter
20 Defendants from this type of outrageous conduct in the future and to discourage Defendants from
21 placing profits above the safety of patients.

22 46. Defendants' fraudulent concealment tolled the statute of limitations
23 because only Defendants knew the true dangers associated with the Durom Cup as described
24 herein. Defendants did not disclose this information to the Plaintiff, Plaintiff's physician, the
25 medical community, or the general public. Without full knowledge of the dangers of the Durom
26 Cup, Plaintiffs were unable to promptly evaluate whether or not Plaintiff John Hernandez had
27 been injured by his implanted Durom Cup.
28

1 warnings, and distribution of the device to insure that it was fit for its intended use and safe for
2 use by consumers.

3 67. Defendants failed to exercise ordinary care in the design, testing,
4 manufacturing, quality assurance, quality control, labeling, advertising, marketing and sale,
5 warnings, and distribution of the Durom Cup, in that the Defendants knew or should have known
6 that the implant created a high risk of unreasonable harm and injury to consumers.

7 68. Defendants were negligent in the design, testing, manufacturing, quality
8 assurance, quality control, labeling, advertising, marketing and sale, warnings, and distribution of
9 the Durom Cup, in that, among other things, they:

10 a. Failed to use due care in designing and manufacturing the Durom
11 Cup, so as to avoid the aforementioned risks to individuals;

12 b. Failed to accompany the implant and its components with proper
13 warnings of the true risks of the true risks and dangerous conditions of the Durom Cup;

14 c. Failed to provide adequate training and instruction to medical care
15 providers for appropriate use of the Durom Cup (inter-alia, that Defendants failed to instruct
16 implanting surgeons of proper surgical techniques and methods);

17 d. Placed an unsafe product into the stream of commerce;

18 e. Were otherwise careless or negligent.

19 69. As a direct and proximate cause of the Defendants' misconduct as set forth
20 herein, Plaintiff John Hernandez has suffered and continues to suffer serious and permanent non-
21 economic and economic injuries.

22 **COUNT V**
23 **(Negligent Misrepresentation)**

24 70. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
25 forth here and further allege on information and belief as follows:

26 71. Prior to and after the Plaintiff was implanted with the Durom Cup,
27 Defendants misrepresented that the Durom Cup was a safe and effective hip joint replacement
28 system component.

1 representations regarding the safety and risks of the Durom Cup to consumers, including
2 Plaintiffs and the medical community.

3 105. Defendants' representations were made with the intent of defrauding and
4 deceiving consumers, including Plaintiffs and the medical community, with the intent of
5 encouraging and inducing sales of the Durom Cup.

6 106. Defendant knowingly, consciously, and deliberately placed its financial
7 gain above the rights and safety of Plaintiffs and other consumers.

8 107. Defendants' fraudulent representations evinced its callous, reckless,
9 willful, and depraved indifference to the health, safety, and welfare of consumers, including
10 Plaintiffs.

11 108. Plaintiffs were unaware of the falsity of Defendants' representations and
12 reasonably relied upon Defendants' representations.

13 109. As a direct and proximate result of Defendants' fraudulent
14 misrepresentation pertaining to the Durom Cup, Plaintiffs have sustained serious and permanent
15 injuries, and will continue to suffer injury, harm, and economic losses.

16 **COUNT X**
17 **(Violation of Cal. Rev. Stat. Bus. & Prof. Code § 17500, et seq.)**

18 110. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
19 forth here and further allege on information and belief as follows:

20 111. Defendants violated the deceptive trade practices and/or false advertising
21 laws of the State of California by use of false and misleading advertisements and representations
22 and omissions of material fact in connection with the marketing, promotion, and sale of the
23 Durom Cup.

24 112. Defendants communicated the purported benefits of the Durom Cup, while
25 failing to disclose the true risks and dangerous conditions of the Durom Cup with the intent that
26 consumers, like Plaintiffs, and the medical community rely on the omissions and
27 misrepresentations and purchase and implant the Durom Cup.

28

1 c. Physical Impairment (including but not limited to the loss of
2 enjoyment of life), past and future;

3 d. Reasonable expenses of necessary medical care, past and future;

4 e. Lost wages in the past, and

5 f. Loss of earning capacity in the future.

6 **PRAYER FOR RELIEF**

7 **WHEREFORE**, Plaintiffs pray for relief as follows:

8 1. Awarding compensatory damages to Plaintiff John Hernandez for past and
9 future damages, including, but not limited to, pain and suffering for severe and permanent
10 personal injuries sustained by the Plaintiff, health care costs, medical monitoring, (all as pled
11 herein) together with interest and costs provided by law;

12 2. Awarding compensatory damages to Plaintiff Estella Hernandez for past
13 and future damages, including, but not limited to, all of her loss of consortium related damages
14 together with interest and costs provided by law;

15 3. Punitive and/or exemplary damages for the wanton, willful, fraudulent,
16 reckless acts of the Defendants, who demonstrated a complete disregard and reckless indifference
17 for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to
18 punish Defendants and deter future similar conduct;

19 4. Awarding all applicable statutory damages of the state whose law will
20 govern this action;

21 5. Awarding Plaintiffs pre and post-judgment interest (as allowed by law);

22 6. Awarding Plaintiffs reasonable attorneys' fees;

23 7. Awarding Plaintiffs the costs of these proceedings; and

24 8. Such other and further relief as this Court deems just and proper.

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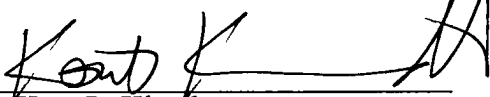
DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all issues triable

Respectfully,

DATED: July 19, 2010

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

By: 
Kent L. Klaudt

Kent L. Klaudt, Esq. (SBN 183903)
kklaudt@lchb.com
Barbra L. Williams, Esq. (SBN 249967)
bwilliams@lchb.com
275 Battery St., 29th Floor
San Francisco, CA 94111
Phone: (415) 956-1000
Fax: (415) 956-1008

Local Counsel for Plaintiffs

GARRETT LAW OFFICE, P.C.
Jake G. Pipinich, OBA #22687
(Pro Hac Vice application pending)
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Lynn R. Anderson, OBA #16473
(Pro Hac Vice application pending)
111 West Fifth Street, Suite 800
Tulsa, OK 74103
Phone: (918) 622-9292
Fax: (918) 549-6794

Counsel for Plaintiffs John P. Hernandez and Estella M. Hernandez