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Attorneys for Plaintiff

PLAINTIFF (singular); PLAINTIFF and SPOUSE (consortium); PLAINTIFF, Individually and on behalf of the ESTATE of DECEASED, Plaintiff, vs. HOWMEDICA OSTEONICS CORPORATION, a New Jersey corporation, d/b/a STRYKER ORTHOPAEDICS, Defendant.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO.:

COMPLAINT

COMES NOW, Plaintiff(s), by and through the undersigned counsel, and bring this complaint against Defendant, Howmedica Osteonics Corporation, and alleges as follows:

1. This is an action for damages relating to Defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "The Trident ® Acetabular System" (hereinafter "Trident System" or "Defective Device).

PARTIES, JURISDICTION AND VENUE

2. Plaintiff(s) is/are [a] citizens and residents of the jurisdiction set forth in the short form complaint.

3. Venue in this action properly lies in Atlantic County as the Defendant conducts substantial business in this county and the case has been coordinated in Atlantic County by the Administrative Office of the Courts.

4. Defendant, Howmedica Osteonics Corporation (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, NJ 07430 and conducts business throughout the United States including in the States of New Jersey and Plaintiff's resident State.

THE PRODUCT

5. At all times material hereto, Defendant Stryker/Howmedica (hereinafter referred to collectively as "Defendant") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name "The Trident ® Acetabular System" (hereinafter "Trident System" or "Defective Device"), either directly or indirectly, to members of the general public including within both the State of New Jersey and Plaintiff's resident State.

6. On February 3, 2003, Defendant received FDA approval to sell its Trident System in the United States.

7. The Trident System containing a ceramic-on-ceramic acetabular bearing couple is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis.

8. The Trident System is an artificial hip replacement device consisting of four basic components: an alumina ceramic insert (socket liner), an alumina ceramic femoral head (ball), a metal acetabular shell (socket), and a metal femoral stem (hip stem). The metal acetabular shell

that is the subject of the recall referenced herein below was and is also available for use with the polyethylene insert (socket liner) and whether coupled with a ceramic or polyethylene liner, is included within the meaning of the "Trident System" that is the subject of this complaint.

9. The alumina ceramic insert contains a pre-assembled titanium alloy sleeve on the back of the insert which mates with the metal acetabular shell component via a taper locking mechanism; and the bearing couple consists of a "Howmedica Osteonics Alumina C-Taper Head" and a "Howmedica Osteonics Alumina Insert". The Trident System implant has bearing surfaces (the ball and socket) made of alumina ceramic.

10. Since its initial approval, the Trident System has been modified through 510(k) submissions made by Defendant including but not limited to: May 25, 2004 – increasing wall thickness in the Trident "T" Acetabular Shells; March 14, 2006 – manufacturing process changes for the ceramic femoral heads and inserts; and July 7, 2006 – two geometrical modifications to the Trident Constrained Acetabular Insert.

11. Defendant's Defective Device(s) was/were placed into the stream of interstate commerce and was/were implanted in Plaintiff..

12. At all times material hereto, the acetabular hip implant device used in Plaintiff's surgery was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendant.

[ALLEGATIONS PERTAINING TO SQUEAKING – Paragraphs 13 - 39]

13. After the implantation of the Defective Device, Plaintiff began experiencing [and continues to experience – if yet to be revised] audible sounds during motion emanating from the location of the Defective Device.

14. As a result of the implantation of the Defective Device, Plaintiff is at an increased risk to suffer past, present and future joint aspirations of the synovial fluid surrounding the hip to detect titanium and/or ceramic debris from the hard on hard bearing surface contact and/or impingement of the stem on the elevated lip surrounding the ceramic liner and/or having to undergo a pre-mature revision surgery.

15. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering as described herein below; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE EXISTENCE OF RISK FOR, AND UNDERREPORTED PREVELANCE RATE OF AUDIBLE SOUND DURING MOTION

16. Upon introducing the Stryker Trident system into the marketplace between February and March of 2003, Defendant failed to include any warning in its package insert and label regarding the existence of, much less prevalence rate for, the risk of patients experiencing audible sounds emanating from their ceramic hips. *See* Defendant's Package Insert and Label submitted to the FDA at:

http://www.accessdata.fda.gov/cdrh_docs/pdf/P000013c.pdf

17. However, on March 28-29, 2003, Defendant presented at a symposium of experts in the field of ceramic acetabular components in Berlin, Germany and was aware of both the existence of risk for, and increasing prevalence of, audible noise emanating from ceramic on ceramic acetabular devices, including the newly approved Stryker Trident system, during motion. Specifically, Defendant's own consultants, J. Wesley Mesko and Benjamin E. Bierbaum, gave presentations on behalf of Stryker regarding the Trident system within

minutes of a presentation detailing the very issue of growing concern among the scientific community regarding squeaking from ceramic on ceramic devices such as Defendant's Trident System. *See* Eichman TH, Clarke IC, Gustafson GA, *Squeaking in a ceramic-on-ceramic total hip*, Proceedings of the 8th Biolox Symposium (Presentation 5.8), March 2003. Berlin

18. However, Defendant did nothing to update its label and package inserts to properly and adequately warn of this risk.

19. Thereafter, as early as September 15, 2003, Defendant began receiving notice of squeaking problems with its particular Stryker Trident system from clinical physicians in the field who reported adverse events to Defendant and/or the FDA, thereafter identified within the FDA's MAUDE database.

20. The MAUDE database is replete with reported adverse events which would have provided any reasonable manufacturer of the clear and apparent risk of squeaking including the following exemplar audible sound related adverse events with date of incident and associated description:

a. 1/15/03 – squeaking no pain, scratched head visible on explants;
b. 3/6/03 – noise when hip flexed resulted in revision;
c. 6/16/03 – squeaking but issue with patient following MD post op orders;
d. 12/10/03 – squeaking, liner fracture found at revision;
e. 3/01/04 – clicking noise and pain, patient revised;
f. 3/25/04 – loud squeak;
g. 8/27/04 – squeaking, chirping worse during activity, less during cold weather, without pain;
h. 12/1/04 – squeaking both hips with pain but fell in bathtub;
i. 1/17/05 – grinding and pop, x-rays showed constrained and worn liner with failure;
j. 2/9/05 – squeaking and scraping;
k. 3/15/05 – clicks with intermittent pain, revised;
l. 3/21/05 – chronic squeak, revised;
m. 4/21/05 – squeaking and chirping, revision;
n. 6/1/05 – felt slipping, unstable, pop, jarring, grind then screech/chirp, revised;

o. 7/5/05 – squeaking one year post op with femur/buttock pain;
p. 7/20/05 – bearing squeak with impingement of trunion on shell and liner with flexion;
q. 8/1/05 – squeaking and popping with severe pain;
r. 9/12/05 – squeaking and knocking, posterior impingement with liner wear/contact with liner;
s. 9/15/05 – click or clunk with pain with revision;
t. 10/1/05 – dislocation time of implant, remedial surgery then chronic squeaking;
u. 10/19/05 – ceramic on ceramic squeaking;
v. 11/28/05 – squeaky ceramic insert;
w. 11/30/05 – ceramic squeak, revision, surgeon saw loose cup;
x. 12/8/05 – noise during each step, x-ray showed loose liner in metal insert, revision; and
y. 1/13/06 – clicking/squeaking, revision. Femoral neck/stem impinging on liner of cup.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

21. However, again, Defendant failed to take any appropriate action to update its package insert and/or label in furtherance of warning consumers of the risk for audible sounds upon motion until sometime on or before February of 2006 when it generically referenced the possibility of audible sound in its label.

22. In or about October of 2006, Defendant finally appeared to provide some quantification which would provide an adequate warning regarding the prevalence of squeaking. Specifically, Defendant purported to have undertaken a review of data from a post marketing study allegedly substantiating prevalence rate of squeak of 0.5%.

23. However, by December of 2006, Defendant became aware that such prevalence rate of 0.5% was grossly low to the actual rate experienced and reported at the December 2006 American Association of Orthopaedic Surgeons national symposium.

24. Moreover, Defendant was likewise aware that the data used from the Defendant's "clinical study" that Defendant's paid consultants re-reviewed to arrive at the labeled 0.5% rate

of audible sound was inherently unreliable for many reasons including: that the study was a product of coupling two different systems, the Defective Device and its predecessor ABC components, into one study (http://www.aboutstryker.com/labeling/) while ignoring the fact that the ABC system did not contain a raised outer titanium sleeve or rim which has been found to be, in part, one of the very causes of the heightened prevalence of audible sound within Defendant's Trident system; that the study was limited to a 3 to 5 year follow up of Tridents implanted as part of a pre-approval clinical study starting in September of 1999 thereby only containing data relating to implants from 1999 through 2002 – 2004 and was therefore of limited temporal relevance; that the study was not originally powered to detect the prevalence of audible sound as this was not a part of the protocol nor patient follow up questionnaire; and that over half of the authors of the study set forth in bold below (and in particular the authors believed to have allegedly lead the effort to re-analyzed said data for the purpose in coming up with a prevalence rate reference by an asterisk) were paid consultants of Defendant who have since been identified by the Department of Justice as receiving l kick-backs from Defendant:

a. Benjamin Bierbaum, M.D., Boston, MA;
b. Joseph McCarthy, M.D., Boston, MA
c. Arnold Scheller, M.D., Boston, MA
d. Donald Reilly, M.D., Boston, MA
e. William Capello, M.D., Indianapolis, IN *
f. James D'Antonio, M.D., Sewickley, PA *
g. Jonathan Hottenstein, M.D., Sewickley, PA
h. James Robertson, M.D., Atlanta, GA
i. Scott Siverhus, M.D., Toledo, OH
j. Robert Zann, M.D., Boca Raton, FL
k. William Hozak, M.D., Philadelphia, PA
l. William Jaffe, M.D., New York City, NY
m. Patrick Meere, M.D., New York City, NY
n. Ormond Mahoney, M.D., Athens, GA
o. Clifford Colwell, M.D., La Jolla, CA
p. Richard Walker, M.D., La Jolla, CA
q. Stephen Copp, M.D., La Jolla, CA
r. J. Wesley Mesko, M.D., Lansing, MI

http://www.stryker.com/meetourconsultants/consultants/

25. The follow brief overview of literature highlights the known concern regarding the prevalence rate of audible sounds among the Trident System well in excess of Defendant's stated rate of 0.5%. As time has passed and more studies have revealed clinical data, the rates of audible noise are extraordinarily alarming, to wit:

a. Jarrett CA, Ranawat A, Bruzzone M, Rodriguez J, Ranawat C, *The squeaking hip: an underreported phenomenon of ceramic-on-ceramic total hip arthroplasty.* J Arthroplasty. 2007; 22(2):302. (prospective study involving 143 patients (159 COC THAs), 31 patients (20 percent) reported noise including squeaking in their new hips). Since his podium presentation that Defendant attended through representatives in December of 2006, Dr. Jarrett has updated these numbers to 15 of 149 in a follow up study, which translates to 11.4% of patients squeaking);

b. *What's making the noise in squeaky hips?* Mary Ann Porucznik, Jan/Feb 2007 AAOS Now http://www.aaos.org/news/bulletin/janfeb07/clinical6.asp. (review of Dr. Richard Rothman's podium speech and data reporting a total incidence of squeaking hips at their institution of 2.7 percent (30 of 1,056 COC THAs) from 2003 to 2005.

c. Restrepo C, Parvizi J, Kurtz SM, Sharkey PF, Hozack WJ, Rothman RH, *The noisy ceramic hip: Is component malpositioning the cause?* J Arthroplasty. 2008; 23:643-649. (February 15, 2007 podium presentation from Stryker consultants Richard Rothman, Peter Sharkey and William Hozack reflecting 29 of 1056 (2.6%) patients with squeaking);

d. Wright, T. et al., *Joint Replacement: Implant Bearing Surface Materials*, 11/26/07 (prevalence rate reported between 1-10%).

e. Rodriquez Jose A., DelaValle A, *Squeaking in Total Hip Replacement: A Cause for Concern.* Orthopedics Today. 2008 September; 31:874

(documenting squeak among a matching of Stryker Trident with one of two often used stems at between 2.7% to 11% prevalence);

f. Murphy S., *Proper implant selection can quiet ceramic hips*. Orthopedics Today. 2008 April; 28:98 (study comparing Stryker Trident with two different stems to other non-Stryker Trident systems concluding increased incidence of squeaking among Stryker Trident System of 9 of 118 [7.6%]; 10 of 321 [3.1%] in relation to incidence of squeaking in 4 of 700 or [0.6%] for non-Stryker product);

g. Keurentjes, et al., *High incidence of squeaking in THA's with alumina ceramic-on-ceramic bearings*. Clin Orthop Relat Res. 466:1438-1443, 2008. (study reflecting prevalence of squeak with Stryker Trident System with ABG II stem of 9 of 42 [21%] rate;

h. Swanson Todd V., et al., *Influence of Prosthetic Design on Squeaking After Ceramic-on-Ceramic Total Hip Arthroplasty*, poster presented at the American Academy of Orthopaedic Surgeon's (AAOS) Annual Meeting in Las Vegas, Nevada in February of 2009. (study reflecting prevalence of Stryker Trident to be many multiples of other product components and as a system reflects squeak in 16 of 45 [35.6%] of which 5 of 45 [11.1%] as to sounds which were always audible to others.

i. Masonis et al. evaluated 81 total hip arthroplasties with the Trident design (Stryker, Mahwah, New Jersey), with mean duration of follow-up of four years resulting in finding of prevalence rate of acoustic noise of 28%.

26. It is known that audible sound will become appreciable after a lapse of time from the initial implant, with an average lapse of time between 8.3 to 37.9 months.

27. However, irrespective of the reported actual rate of audible sounds from the Trident System between 5 to 70 times the reported rate, Defendant's label continues to reflect the mean incidence rate of audible sound from its Stryker Trident System of 0.5%.

28. Unfortunately, for patients with squeaking hips, many in the medical community, including Dr. Aldo Toni and his colleagues, who first established a reported protocol for performing a differential diagnosis and provided clinical recommendations for squeaking among orthopedic physicians, believe that squeaking is a precursor to failure. By any account, the numbers of squeaking implants is not only exponentially greater than Stryker will admit but is reaching alarming proportions.

Duty to Update Stryker Trident Label

29. During the time Defendant has marketed, labeled, and sold its Trident System, it knew or should have known of both the likelihood of patients developing audible sounds and the fact that its quantitative representation on prevalence was significantly lower than reported. Moreover, Defendant had a duty to update its label appropriately.

30. Specifically, Defendant's Premarket Approval Application for the Trident System was first filed on March 2, 2000, and then amended several times. As part of the PMA process, Defendant was required, and did, submit a label for the FDA's review. Under the FDA regulatory scheme, once a device has received premarket approval, a manufacturer generally must obtain FDA approval before making any changes in the labeling, or any other attribute that would affect the device's safety or effectiveness. The important exception to that regulatory scheme is that the MDA allows a "Special PMA Supplement–Changes Being Effected" ("CBE Supplement") under 21 C.F.R. § 814.39(d) (2008).

31. At least until August 22, 2008, when the FDA published a final rule in the Federal Register entitled "Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices", modifying 21 CFR Parts 314, 601 and 814, concerning when a change to the labeling of an approved drug, biologic, or medical

device may be made in advance of the agency's review and approval of such change, the CBE supplement procedure allowed Defendant to change the Stryker Trident labeling in advance of FDA review and approval. In fact, state law imposes a duty on a manufacturer to change its product's label without FDA approval, which Defendant could have accomplished through the CBE supplement method but failed to properly and adequately do so.

32. A CBE Supplement permits a manufacturer to make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" prior to FDA approval. 21 C.F.R. 814.39(d)(2)(i). A manufacturer is also allowed to make "[l]abeling changes that delete misleading, false, or unsupported indications." 21 C.F.R. § 814.39(d)(2)(iii). If these changes are not objected to by the FDA, they become accepted as part of the label.

33. This CBE system is nearly identical to the CBE system applicable to pharmaceutical products. In Wyeth, 129 S. Ct. at 1196, the United States Supreme Court, conducted a detailed review of that system and found that state law claims premised on the same are not preempted:

> There is ... an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C).

34. Under both the MDA and the regulations applicable to pharmaceutical products, the manufacturer has a duty to update the label about adverse effects once there is a "reasonable evidence of a causal association." 21 C.F.R. 814.39(d)(2)(i).

35. That obligation was made explicit in the FDA's Conditions of Approval to the Trident System. Those conditions state: "A PMA supplement *must* be submitted when unanticipated adverse effects, *increases in the incidence of anticipated adverse effects*, or device failures necessitate a labeling, manufacturing, or device modification" (emphasis added).

36. Moreover, the PMA Approval Letter explicitly allowed Defendant to make such changes prior to FDA approval under the "Special PMA Supplement–Changes Being Effected" provision in the federal regulations: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA *unless the change is of a type for which a 'Special PMA Supplement Changes Being Effected' is permitted under 21 C.F.R. 814.39(d)...*"

37. On February 3, 2003, the Center for Devices and Radiological Health ("CDRH") completed its review of Howmedica's Osteonics System and Trident System and granted PMA approval. The PMA Approval Letter also explained that: "Failure to comply with the conditions of [PMA] approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

38. The initial label drafted and submitted by Defendant as part of the PMA process failed to state anything regarding audible noise. At some point it appears that Defendant made changes to is label including a warning about the risk for audible sounds. However, it does not

appear that Defendant ever provided the FDA with notice (timely and/or otherwise) that it updated its label to state that an "audible noise during motion such as a 'squeak' had been reported for patients receiving a ceramic-on-ceramic bearing couple" or that the prevalence rate for audible sound was 0.5%. Accordingly, Defendant was in violation of the federal regulations relating the CBE changes and the vary Conditions for Approval of the subject PMA thereby, according to the express admonitions in the application, voided PMA approval.

39. Plaintiff's Defective Device was thereby misbranded as the label was false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. §352.

[ALLEGATIONS PERTAINING TO LOOSENING OR OTHER NON-SQUEAKING COMPLICATIONS – Paragraphs 40 - 56]

40. After the implantation of the Defective Device, Plaintiff began experiencing and continues to experience if not revised significant pain and discomfort in the area of Plaintiff's implanted Defective Device(s). Certain Plaintiffs continue to have pain or discomfort even following due to revision due to complications secondary to the original defective implant.

41. As a result of the implantation of the Defective Device, Plaintiff has or may suffered additional and resultant bone loss and has or is at risk of undergoing premature revision surgery to remove the Defective Device.

42. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering as described herein below; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE EXISTENCE OF RISK FOR ASCEPTIC LOOSENING OF THE TRIDENT CUP DUE TO LACK OF BONE INGROWTH

43. In advertising the benefits of the Stryker Trident System to orthopedic surgeons, Defendant placed a document on its website which appeared to be a medical study regarding the benefits of the Trident System authored by several of its long-standing paid consultants, Drs. William Capello, M.D.; James D'Antonio, M.D.; and Michael Manley, Ph.D., to re-draft and publish an article entitled New Experience with Alumina: Alumina Ceramic Bearings for Total Hip Arthroplasty.

http://www.stryker.com/stellent/groups/public/documents/web_prod/025313.pdf

44. In it, Defendant states the following benefits of the Trident System in relation to the risk of loosening and the protections against loosening afforded patients by selecting the Trident System. Specifically, Defendant states:

> The most common mode of long-term failure for total hip arthroplasty is aseptic loosening. It has been recognized that particulate debris, in particular polyethylene particulate debris, is responsible in many cases for the inflammatory response that leads to bone resorption and loosening of the implants over time. The actual biologic event is caused by macrophage induced resorption of bone at the prosthetic bone interface secondary to the presence of particulate polyethylene and other debris. If the life expectancy of implants is to be improved, then better bearing surface materials will be necessary for the future. An alumina-on-alumina ceramic bearing couple has many theoretical advantages. It not only eliminates polyethylene from the device system but its extremely low coefficient of friction and potential for superior wear resistance is very attractive. Clinical experiences and retrievals of ceramic implants have indicated that ceramic debris is less reactive than metal or polyethylene debris.

45. Defendant's label represents that Defendant's "clinical study" of the Stryker Trident at two years, between 1999 and 2001, revealed no incidence of loose cups among 209 Trident implants.

46. Defendant's label further supported the notion that the Stryker Trident was a more safe system with less risk of loosening, stating:

> "Alumina ceramic is extremely hard--in fact, its hardness is second only to diamond--and provides excellent lubrication between the ball and socket"; and ". . .it is anticipated that these improved wear characteristics will extend the life of the implants."

47. Moreover, Defendant's paid consultant, J. Wesley Mesko reported in 2003 that, at 3 to 5 years, following up on 188 of the original 209 hips, the Trident System was revised due to loosening only one time equaling a rate of 0.5% revision rate. *See* Mesko JW, All Alumina Articulation in the Stryker Howmedica-Osteonics THA. *A United States Experience 36-60 Months Follow-up*, Proceedings of the 8th Biolox Symposium (Presentation 5.3), March 2003. Berlin.

48. The FDA MAUDE Data base is replete with evidence of adverse events in the form of loose cups associated with the Stryker Trident System and the events and issues of underreporting merely had to catch up with the growing problematic clinical experience in the field in which many more patients were forced to endure a loosened cup post implant and the attendant pain and revision surgery than is typical for cementless cup implants.

49. As revealed by the FDA's November 28, 2007 483 Warning Letter issued to Defendant, Defendant reported to the FDA on August 1, 2007, that it had received increased product complaints/product experience reports (PER's) for acetabular shell loosening; however, the FDA found that Defendant initiated no effective corrective or preventive actions in order to prevent the recurrence of nonconforming product and other quality problems in violation of federal regulations as detailed below.

50. On January 21, 2008, Defendant finally commenced a recall of the Defective Devices, the reason for which, as stated on the FDA website was due to "Foreign material: Some

of the parts tested exceeded Stryker Orthopaedics internal acceptance criteria for manufacturing residuals."

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=68363

51. A review of medical literature regarding the mechanism for and duration of time relating to asceptic loosening due to osteolysis reveals that Plaintiff's product did not become loose due to any cause other than having had an adulterated device with foreign or other body material on the cup which caused a lack of boney in-growth and resultant loosening.

52. Specifically, modern non-cemented cups typically have a 5 year or greater survivorship of approximately 97% (+/- 2%), most failing with aseptic loosening, with a failure rate of about 3-5% beginning at about 5 years.

53. Absent some other cause, aseptic loosening during the first 3 years post implant is extremely rare. *See* The results of titanium - coated RM acetabular component at 20 years. Ihle M et al., *J Bone Joint Surg*-BR 2008; 90-B: 1284-90; Increased risk for revision of acetabular cups coated with hydroxyapatite: A register study on 8,043 hips. Hailer N, Kärrholm J, Lazarinis S., 10th Congress of EFORT, June 5, 2009; Factors affecting aseptic loosening of 4750 total hip arthroplasties: multivariate survival analysis Bordini B, Stea S, De Clerico M, Strazzari S, Sasdelli A, Toni A BMC Musculoskeletal Disorders 2007, 8:69 (24 July 2007); and Third-Generation Alumina-on-Alumina Ceramic Bearings in Cementless Total Hip Arthroplasty. *J Bone Joint Surg* (American). 2007;89-A:2676-2683 (though a shorter time observation of 7 years, ceramics should become loose seldom because of low wear rate).

54. Defendant made errors in its manufacture of Defendant's Trident Acetabular System and, as a result, the Plaintiff's Defective Device was adulterated within the meaning of section 21 U.S.C. § 351(h) in that the methods used in, or the facilities or controls used for, its

manufacture was not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Relations (C.F.R.), Part 820.]

55. Defendant had a duty to update its label through the CBE process to adequately and properly warn consumers including Plaintiff of the risk of suffering from a loose cup beyond vague reference to the potentiality for such complication based on information Defendant had in its possession and/or was obligated to investigate which revealed or would have revealed an increased risk and prevalence rate for loosening associated with its cups.

56. Plaintiff's Defective Device was thereby misbranded as the label was false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. §352.

[ALLEGATIONS PERTAINING TO MALSEATED LINERS; AND FRACTURED OR CHIPPING OF COMPONENTS – Paragraphs 57 – 70]

57. After the implantation of the Defective Device, Plaintiff began experiencing, and continues to experience if not revised, significant pain and discomfort in the area of Plaintiff's implanted Defective Device(s).

58. As a result of the implantation of the Defective Device, Plaintiff has suffered or may suffer additional and resultant bone loss and has or is at risk of undergoing premature revision surgery to remove the Defective Device.

59. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering as described herein below; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE EXISTENCE OF RISK FOR MALSEATED LINERS; AND FRACTURED OR CHIPPING OF COMPONENTS

60. In advertising the benefits of the Stryker Trident System to orthopedic surgeons, Defendant placed a document on its website which appeared to be a medical study regarding the benefits of the Trident System authored by several of its long-standing paid consultants, Drs. William Capello, M.D.; James D'Antonio, M.D.; and Michael Manley, to re-draft and publish an article entitled New Experience with Alumina: Alumina Ceramic Bearings for Total Hip Arthroplasty.

http://www.stryker.com/stellent/groups/public/documents/web_prod/025313.pdf

61. In it, Defendant states the following benefits of the Trident System in relation to the risk of chipping and liner fracture and the protections against loosening afforded patients by selecting the Trident System. Specifically, Defendant states:

> Another important design feature of the new system is the protection of the ceramic acetabular liner from impingement on the femoral neck. The components used in this study are recessed within the metal shell reducing the potential for impingement on the periphery of the ceramic which can lead to chipping and fracture. In the current study involving 349 ABC alumina ceramic implants and 185 Trident™ implants, no fractures of component have occurred. With regards to the nine peripheral chips that occurred on the ABC system, these again were technical problems related to the placement of the ceramic insert within the titanium acetabular component. If the ABC shell is canted and is wedged in the shell, and then an impaction force is delivered to seat the insert, a peripheral chip can occur. Evaluation of these components studied in the laboratory indicate that if

a chipped component is replaced and fully seated the small peripheral chips do not create a stress riser or weaken the basic strength of the acetabular component. It is recommended that when a peripheral chip occurs, the insert and shell should be removed and replaced. One of the peripheral chips was left in place without any known clinical or radiographic adverse consequence. The development of Trident®, which contains the titanium sleeve around the alumina, helps to avoid the risk of peripheral chips.

62. Defendant's label represents that Defendant's "clinical study" of the Stryker Trident at two years, between 1999 and 2001, revealed no incidence of chipping or fractures of component among 209 Trident implants.

63. Moreover, Defendant's paid consultant, J. Wesley Mesko reported in 2003 that, at 3 to 5 years, following up on 188 of the original 209 hips, that, though the Trident System's predecessor ABC design resulted in "[a] 2.6% intraoperative insertional crack rate of the alumina liner" and that this "resulted in an acetabular redesign with a second, non-randomized study of 209 additional hips. With a minimum of 24-month observation of this group, there have been no ceramic failures, and the clinical and radiographic results are not statistically different from the original control patients." *See* Mesko JW, All Alumina Articulation in the Stryker Howmedica-Osteonics THA. *A United States Experience 36-60 Months Follow-up*, Proceedings of the 8th Biolox Symposium (Presentation 5.3), March 2003. Berlin.

64. The FDA MAUDE Data base contains evidence of adverse events in the form of fractured liners and/or balls and liner chipping associated with the Stryker Trident System and clearly the events and issues of underreporting merely had to catch up with the growing

problematic clinical experience in the field in which many more patients were forced to endure a fractured and/or chipped post implant; pain; and revision surgery than is typical for cementless cup implants.

65. As revealed by the FDA's November 28, 2007 483 Warning Letter issued to Defendant, Defendant reported to the FDA on August 1, 2007, that it had received increased product complaints/product experience reports (PER's) for acetabular fractures and chipping; however, the FDA found that Defendant initiated no effective corrective or preventive actions in order to prevent the recurrence of nonconforming product and other quality problems in violation of federal regulations as detailed below. Moreover, the FDA stated the following about the Defendant's own investigation, called CAPA 4293 (Plaintiff does not have a copy of the unredacted version) as to the Trident System:

> Your March 1, 2006 technical assessment and medical assessment states that if the taper on the ceramic sleeve does not lock with the taper on the shell, then the ceramic liner is free to move with the shell (hazard is moderate). This motion between the two metal surfaces will create metal wear debris particles. Over time, these particles may lead to metalosis and require revision surgery. In addition, if the compressive forces are removed from the hip, the liner may be able to slide out of the shell and dislocate the patient's hip. In this scenario, no closed reduction would be possible, necessitating a revision surgery. Furthermore, your medical assessment states that the greatest medical risk to the patient is a non-solidly locked insert which will potentially lead to immediate removal and change of the shell or premature failure (due to debris). In addition your technical and medical assessment states that increased medical risk to patient will occur when the locking bead on the poly liner is only partially captured and the locking strength is compromised. The surgeon would not notice that locking strength was compromised and the increased forces applied by a constrained liner could cause disassociation which would force revision surgery.
>
> However, CAPA 4293 does not evaluate the causes of breakage, stresses in parts, and loss of function requiring revision surgery. For example, your potential failure mode (d-FMEA) states that the potential engineering cause of the failure for breakage is due to the quality of the **[redacted]** (chip off due to quality of **[redacted]** and misfit of component **[redacted]**. These potential failures of your devices include local insert fractures (**[redacted]** chip migrates within joint causing **[redacted]** fracture) breakage and migration within the joint which causes

pain and loss of function requiring revision surgery, and a mismatch of the **[redacted]** and **[redacted]** which results in excessive stresses in parts **[redacted]** breaks apart and migrates within the joint).

See Stryker Orthopaedics Corp., Warning Letter Pages 7 and 8 of 9 http://www.fda.gov/foi/warning_letters/s6627c.htm 1/16/2008

66. A review of medical literature regarding this mechanism reveals the following partial reporting and conclusions in pertinent part reached in 2007 regarding the mal-seating liner issues related to the Trident System:

> We reviewed the initial post-operative radiographs of the Trident acetabulum and identified a problem with seating of the metal-backed ceramic liner. We identified 117 hips in 113 patients who had undergone primary total hip replacement using the Trident shell with a metal-backed alumina liner. Of these, 19 (16.4%) were noted to have incomplete seating of the liner, as judged by plain anteroposterior and lateral radiographs. One case of complete liner dissociation necessitating early revision was not included in the prevalence figures. One mis-seated liner was revised in the early post-operative period and two that were initially incompletely seated were found on follow-up radiographs to have become correctly seated. There may be technical issues with regard to the implanting of this prosthesis of which surgeons should be aware. However, there is the distinct possibility that the Trident shell deforms upon implantation, thereby preventing complete seating of the liner.

See Langdown AJ. Incomplete seating of the liner with the Trident acetabular system: A CAUSE FOR CONCERN? J Bone Joint Surg Br. 2007 Mar;89(3):291-5 (abstract).

67. More recently, in a 2010 published study, it has been revealed in pertinent part that:

> In the study of 61 Tridents showed radiographically post implant that the metal-backed ceramic liner was malseated in 7 hips (11.5%), completely seated in 50 hips (82%), and suspicious in 4 hips (6.5%) with a potential for an 18% mal-seating rate.

> Further, the Miller et al reported an incidence of 7.2% liner malseating in a series of 694 patients who underwent ceramic-on-ceramic THA and that Langdown et al reported 19 malseated liners (16.8%) among 117 THAs using the Trident.
>
> The clinical significance of liner malseating appears to be related to the poorly distributed forces applied over the liner during impaction. Various reports have shown that a forced impaction of a malpositioned ceramic liner could result in chipping or fracture of the material.3,21,22 Disengagement of a malseated liner requiring revision surgery has been also reported. Malseating may cause suboptimal function of the taper-locking mechanism.

See Alba J, et al Incomplete Seating of a Metal-backed Alumina Liner in Ceramicon-Ceramic Total Hip Arthroplasty *ORTHOPEDICS* 2010; 33:15

68. Defendant made errors in its manufacture of Defendant's Trident Acetabular System and, as a result, the Plaintiff's Defective Device was adulterated within the meaning of section 21 U.S.C. § 351(h) in that the methods used in, or the facilities or controls used for, its manufacture was not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Relations (C.F.R.), Part 820.]

69. Moreover, Plaintiff's Defective Device was misbranded as the label was false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. §352.

70. Defendant had a duty to update its label through the CBE process to adequately and properly warn consumers including Plaintiff of the risk of suffering from a mal-seated liner beyond vague reference to the potentiality for such complication based on information Defendant

had in its possession and/or was obligated to investigate which revealed or would have revealed an increased risk and prevalence rate for liner mal-seating associated with its system.

THE RECALLS

71. On March 13, 2006, Defendant initiated a recall of a batch of Trident PSL HA Solid Back Acetabular Shells, formally known under the U.S. Food and Drug Administration Recall #: Z-1261-2007. The stated reason for this recall was that Defendant had identified dimensional anomalies in the recalled components. Specifically, their anomalies were due to an alleged discovery of a machine operator's failure to inspect product dimensional features prior to release wherein shells were found to be out of tolerance. However, this recall was initiated only after the FDA performed an inspection; it was not simply initiated as a preventative unilateral act by Defendant.

72. On August 30, 2007, Defendant initiated a recall of a batch of Trident PSL HA Solid Back Acetabular Shells, which recall is formally known under the U.S. Food and Drug Administration Recall #: Z-0073-2008. The stated reason for such recall was that Defendant had identified that "specific lots of Trident PSL Acetabular shells may have a dimensional discrepancy. The deviation regarding the difference in wall thickness will increase the gap between the shell and liner on one side and will decrease the gap between shell and liner on the opposing side, resulting in interference."

73. On January 21, 2008, Defendant initiated a recall of a batch of Trident PSL and Hemispherical Cups manufactured in their Cork, Ireland facilities, Recall notification letters were sent to Stryker Branches/agencies, OR Supervisors and Chief of Orthopaedics were went on this date, however, a Patient information sheet was not sent out until February 4, 2008 to surgeons and hospitals. The scope of the recall includes Trident PSL and Hemispherical Shells

manufactured by Defendant at the Cork, Ireland facility from January 2000 through the end of December 2007. The recall came after an investigation into an identified deviation between specifications and processes for manufacturing required by the FDA, including the existence of "manufacturing residuals" within Defendant defective Trident devices.

74. On February 28, 2008, Defendant broadened the previous recalls to include all Trident PSL and Hemispherical Cups and expanded the manufacturing dates from 1998 through the end of December 2007.

75. As to each of the devices within the scope of the underlying recalls, it was determined by the FDA that the removal of the products from the market and the corrective action taken by Defendant should be classified as Class II Recalls under federal regulation.

76. However, upon information and belief, Defendant has failed to properly initiate a recall including Defendant's Defective Devices beyond the limited scope of the above referenced recalls.

THE FEDERAL REQUIREMENTS

77. Federal regulation states "Recall means 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." See 21 CFR §7.3(g).

78. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3 (m).

79. Federal regulation states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3 (m).

80. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

81. "Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall." 21 CFR §7.40(a).

82. A company's voluntary recall of a medical device and the FDA's classification of that action as a recall establishes that the device violates FDA regulations: "A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in §5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure." 21 CFR §7.46.

83. As to all components recalled by Defendant, Defendant acknowledged that said Stryker Trident implants were manufactured in a manner violative of the FDA regulations.

84. The violation of the federal regulations including making an adulterated device specifically led to Plaintiff's injuries and damages.

85. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

86. The definition of adulterated for devices like the Trident System includes: manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions. If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements

87. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. §352.

88. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or

serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

89. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

90. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.

91. Pursuant to federal regulation, manufacturers must report to FDA in 5 business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53.

92. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals.

FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

93. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

94. Pursuant to federal regulation, a manufacturer must report to the FDA (through a Post-Market Approval (PMA) Supplement) any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. A manufacturer may

implement changes to a device that enhance the safety of the device prior to obtaining FDA approval, if the manufacturer submits a special report entitled: "Special PMA Supplement-Changes Being Effected" and provides a full explanation of any labeling changes or changes in quality control or manufacturing process that add a new specification of test method, or otherwise provide additional assurance of purity, strength, or reliability of the device.

95. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

96. As evidence of Defendant's violations of federal regulations relating to the Trident System, on March 15, 2007 (well before Defendant initiated a recall on January 21, 2008 and later sent a Patient information sheet was not sent out until February 4, 2008 to surgeons and hospitals), the United States Food and Drug Administration (FDA) issued a Warning letter to Defendant arising from its inspections of Defendant's Cork, Ireland facilities between October 31, 2006 and November 3, 2006. The FDA investigation revealed that Defendant Trident Acetabular System hip replacement systems were adulterated within the meaning of section 21 U.S.C. § 351(h) in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Relations (C.F.R.), Part 820.]

97. A Form FDA 483, List of Inspectional Observations, was issued to Defendant after these inspections, and the following violations were determined to have occurred:

> A.Failure to establish and maintain adequate procedures for implementing a corrective and preventative action, as required by 21 CFR 820.100(a);
> B.Failure to timely implement a specification to define the requirements for trending including nonconforming data on an ongoing basis;

C.Failure to timely make changes to procedures to lessen confusion and better assure that root causes of non-conforming product are identified;
D.Failure to document risk analysis and verification that was required;
E.Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, including the evaluation of nonconforming product, as required by 21 CFR 820.90(a);
F.Failure to perform root cause investigations and initiate corrective/preventative actions;
G.Failure to timely conduct a full review of processes to ensure changed control requirements;
H.Failure to ensure that all product non-conformities are identified and addressed in accordance with the Corrective and Preventative Action Procedure;
I.Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5);
J.Failure to perform an adequate "Investigation/Analysis" to establish "root cause"; that a thorough "corrective/preventative action" (CAPA) be undertaken; and a full "Validations/Qualifications" be completed; and
K.Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2).

98. As evidence of Defendant's violations of federal regulations relating to the Trident System, on November 28, 2007 (well before Defendant initiated a recall on January 21, 2008 and later sent a Patient information sheet was not sent out until February 4, 2008 to surgeons and hospitals), the FDA issued another Warning Letter to Defendant arising from inspections of Defendant's Mahwah, NJ facilities between June 1, 2007 through July 12, 2007. The FDA investigation revealed that Defendant hip implants with ceramic bearing components including the Trident Acetabular System were adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Relations (C.F.R.), Part 820.

99. A Form FDA 483, List of Inspectional Observations was issued to Defendant after these inspections, and the following continued violations were determined to have occurred:

A. Failure to establish and maintain procedures for identifying all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems, and verifying or validating the corrective and preventive action to ensure that such action is effective as required by 21 CFR § 820.1 00(a)(3) & (a)(4);
B. Failure to take proper action relating to "continual complaints from January of 2005 through May of 2007 concerning your Trident Hemispherical and Trident PSL cups that have failed to function and concerning hip implant components that have poor fixation. In some instances, these problems have required revision surgeries. In addition, complaints were also received between January of 2005 through April of 2007 for squeaking noises of hip implants with ceramic bearing components; some of those problems resulted in revision surgeries due to implant failures (fractures, pain, wear particles, and fragments). Furthermore, complaints were received between January of 2005 through June of 2007 concerning improper seating of hip implants in broached bones resulting in bone fractures";
C. Failure to implement adequate corrective and preventive actions (which would include verifying or validating the corrective and preventive action to ensure that such action is effective) in order to prevent the recurrence of nonconforming product and other quality problems;
D. Failure to prevent the recurrence of poor fixation of the hip implant component or prevent the failure to function which has resulted in revision surgeries;
E. Failure in properly correcting imprecise manufacturing processes relating to the acetabular reamers causing manufactured implants and reamers to have dimensional mismatches due to manufacturing problems (deviations);
F. Failure to evaluate the causes of breakage, stresses in parts, and loss of function requiring revision surgery relating to customer complaints regarding squeaking/noisy ceramic on ceramic hip joints;
G. Failure to implement effective corrective or preventive actions in order to prevent the recurrence of nonconforming product and other quality problems such as Complaint 64304, dated December 13, 2006, involving a patient who felt grinding crunching and screeching in the right leg and Complaint 71000, dated March 20, 2007, reporting a patient who went to the hospital because they felt that something was wrong and x-rays showed a broken cera (fractured or fragmented or cracked);
H. Failure to have a proper design validation in support of changes to show that shell fixation issues are not the result of a dimensional or tolerance mismatch;
I. Failure to prevent the recurrence of nonconforming product and other quality issues such as continued complaints concerning the Trident Hemispherical and Trident PSL cups that failed to function and hip implant components with poor fixation which have required revision surgeries;

J. Failure to control and take action on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities;

K. Failure to prevent the recurrence of squeaking noises of hip implants with ceramic bearing components which have resulted in revision surgeries due to implant failures (fractures, pain, wear particles, and fragments);

L. Failure to take effective action regarding trend analysis, which shows an increase in product complaints/product experience reports (PERs);

M. Failure to provide validation of any corrective and preventive action in order to ensure that any such action is effective and does not adversely affect the finished device;

N. Failure to properly test the performance of the devices under actual conditions of use in the actual environment in which the device is expected to be used;

O. Failure to verify and validate corrective and preventive action relating to continued complaints that have resulted in revision surgeries;

P. Failure to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR § 820.70(c). Specifically, procedure 90S1512 (version 35) Microbial and Environmental monitoring, states that when mold and bacteria action limits are exceeded, an investigation and corrective actions will be performed. No corrective actions were performed by your firm in order to prevent the recurrence of out-of-specification microbiological results received from your purified water and air monitoring samples for the implant final cleaning and packaging areas that are used for your sterile implantable devices;

Q. Failure in misbranding the Trident PSL Acetabular Shell devices under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 C.F.R Part 806 - Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to, the following: Failure to report product correction or removal actions to FDA within 10 days of initiating the correction or removal is a violation of 21 C.F.R. § 806.10(b);

R. Failure to have an adequate system in place to identify when a correction or removal needs to be reported to the FDA as required under 21 C.F.R. § 806; and

S. Failure to control and take action on devices distributed that are suspected of having potential nonconformities such as those referenced in Regulatory Summary (RA # 2006-007).

100. Defendant has failed to develop practices and procedures to assure their compliance with federal law, including compliance with the Medical Device Reporting

procedures set forth in 21 C.F.R. §803, the failure analysis and quality assurance procedures set forth in 21 C.F.R. §820, and the recall and notification procedures set forth in 21 C.F.R. §806.

101. Upon information and belief, and based on the FDA 483 Warning Letter along with the Defendant's recall which encompass Plaintiff's Defective Device, Plaintiff believes that Defendant violated these specific federal regulations which, if not violated, would have resulted in the Defective Device not being implanted in Plaintiff's body.

102. Defendant failed to develop practices and procedures to assure compliance with 21 C.F.R. §814 concerning device modifications, instructions for use and pre-market approval condition. Defendant has also failed to comply with 21 C.F.R. §§803, 806 and 820, concerning maintaining MDRs, implementing device Removals and Corrections, and establishing Quality Systems.

103. Defendant failed to develop practices and procedures to assure compliance with the federal requirements for reporting adverse events, or MDRs, in accordance with 21 U.S.C. §360.

104. Defendant failed to update its label to adequately warn consumers of risks associated with its device and could have, through a Special PMA Supplement, made such changes without prior FDA approval. Such labeling changes would have deleted false, misleading, or unsupported indications as allowed under 21 Code Feds. Regs. § 814.39(d)(2).

105. Despite the obligations described above, and the obligations of every medical device manufacturer to comply with federal law, Defendant failed to meet numerous federal requirements in its manufacture and sale of the Trident System.

106. Specifically, it is believed further that with respect to the Trident System, Defendant failed to timely report adverse events, failed to timely conduct failure investigations

and analysis, failed to timely report any and all information concerning product failures and corrections, failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing, or device modification, failed to conduct necessary design validation, and sold a misbranded and adulterated product.

107. Defendant was negligent and is liable to Plaintiff for the acetabular hip implant device implanted into Plaintiff because the manufacturing processes for the subject defective Trident hip devices and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards and applicable federal regulations for the device; the failure of the manufacturing processes for the acetabular hip implant device and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards and applicable federal regulations for the device resulted in unreasonably dangerous defects, and the Defendant failed to warn of the unreasonable risks created by these manufacturing defects as required by the federal regulations.

108. As a direct and proximate cause of the Defendant's violations of the Medical Device Act, the Premarketing Approval Application and applicable federal requirements, Plaintiff suffered injuries and damages.

109. Plaintiff brings this cause, premised solely upon Defendant's violations of federal regulations and law, under the common law and statutory laws of New Jersey and Plaintiff's resident State, as applicable, which provide damage remedies for such claims and, wherein such state laws do not impose any requirements upon Defendant which are different from, or in addition to the requirements imposed upon by federal law, the same are parallel to such federal requirements and accordingly this action is not subject to preemption under § 360k. The causes

of action set forth in this complaint are not preempted by § 360k, because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement which is different from, or in addition to, any requirement applicable under" the Food, Drug and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the Food, Drug and Cosmetic Act and regulations promulgated thereunder.

CAUSES OF ACTION

COUNT I - NEW JERSEY PRODUCTS LIABILITY ACT – STRICT LIABILITY (N.J.S.A. 2A:58C-1 *et seq.* or RESIDENT STATE STRICT LIABILITY LAW)

110. Plaintiff realleges and incorporates by reference the allegations set forth above.

111. Defendant is a manufacturer and/or seller of the Trident System within the meaning of N.J.S.A. 2A:58C- and the law of the Plaintiff's resident State's laws, if deemed applicable.

112. Defendant failed to act as required by law as evidenced by its violations of federal requirements as set forth herein above and otherwise failed to undertake necessary and reasonable steps including a failure to perform adequate testing in that adequate testing would have shown that the Trident System possessed serious potential side effects that rendered the product unfit for its intended use and unreasonably dangerous.

113. The Trident System manufactured, supplied and/or sold by Defendant was defective in design, manufacture, formulation, and/or labeling in that when it left the hands of the manufacturer and/or sellers, the foreseeable risks exceeded the benefits.

114. Alternatively, the Trident System manufactured, supplied and/or sold by Defendant was defective in design, manufacture, formulation and/or labeling in that when it left the hands of the manufacturer and/or supplier/seller, it was in a defective condition and

unreasonably dangerous, and was more dangerous that an ordinary consumer would expect and more dangerous than other alternative products.

115. The Trident System manufactured, supplied and/or sold by Defendant was defective in design and manufacturing in that there exists a safer alternative design and its failure to comply with federal regulations.

116. Defendant is liable due to the manufacturing defects of the Trident system in that the product deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.

117. The Trident system was not merchantable and reasonably suited to the use intended and its condition when sold is the proximate cause of the injury sustained by the plaintiff.

118. The Trident system manufactured and supplied by defendant was defective due to inadequate warnings, inadequate testing, and inadequate post-marketing warnings, inadequate post-marketing instructions, because after Defendant knew or should have known of the risk of injury from the Trident system yet failed to provide adequate warnings to implanting physicians and users of the Trident system.

119. As a result of the defective condition of the Trident System as manufactured and/or supplied by Defendant, Plaintiff suffered compensable damages.

WHEREFORE, Plaintiff respectfully requests that they be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT II – BREACH OF EXPRESS WARRANTY
(N.J.S.A. 12A:2-313 or RESIDENT STATE EXPRESS WARRANTY LAW)

120. Plaintiff realleges and incorporates by reference the allegations set forth above.

121. On February 3, 2003, the Center for Devices and Radiological Health ("CDRH") completed its review of Howmedica's Osteonics System and Trident System and granted PMA approval. Related to warranties, the PMA Approval Letter specifically provided: "The CDRH *does not evaluate information related to contractual liability warranties*, however you should be aware that any such warranty statements *must be truthful, accurate, and not misleading*, and must be *consistent with applicable Federal and State laws*" (emphasis added).

122. Through their public statements, their descriptions of the Trident System and their promises relating to the Trident System, Defendant expressly warranted among other things that the Trident System was efficacious and safe for its intended use; had an audible sound prevalence rate of 0.5%; would last longer that competing acetabular devices; and was more suitable for younger adults that other devices given its purported longevity.

123. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Trident System, but which contained material misrepresentations and utterly failed to warn of the risks of the Trident System; (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the Trident System and the downplaying of the risks associated with the Trident System; (iv) false and misleading written information supplied by Defendant.

124. Plaintiff further alleges that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendant and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

125. When Defendant made these express warranties, Defendant knew the purpose for which Trident System was to be used and warranted it to be in all respects safe and proper for such purpose.

126. Defendant drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

127. The Trident System does not conform to Defendant's representations in that it is not safe and produces serious side effects.

128. As such, the Trident System did not conform to Defendant's promises, descriptions or affirmations of fact and was not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such devices are used.

129. Defendant therefore breached its warranties to Plaintiff in violation of N.J.S.A. 12A:2-313, or the resident State law on Express Warranty codifying the Uniform Commercial Code, by manufacturing, marketing and selling the Trident System to Plaintiff causing damages as well be established at trial.

WHEREFORE, Plaintiff respectfully requests that they be granted relief against Defendant, as contained in the Prayer For Relief.

COUNT III
NEGLIGENCE: VIOLATION OF RESIDENT STATE DUTIES OF CARE

130. Plaintiffs incorporate by reference each preceding and succeeding paragraphs as though set forth fully at length herein

131. Defendants, directly or indirectly marketed, designed, developed, manufactured, tested, produced, labeled, inspected, packaged, distributed, promoted, advertised, released, or sold the Trident System in the stream of commerce when they knew or in the exercise of ordinary care, should have known that the device posed a significant risk to the health, well-

being and safety of the Plaintiff which risk was not known to Plaintiff, or Plaintiff's implanting surgeons.

132. The Trident System implanted in Plaintiff was manufactured in violation of the Federal Food, Drug and Cosmetic Act and regulations promulgated pursuant to it.

133. As a result of Defendant's violations of a purely federal statutory and regulatory standard of care, the Trident System implanted in Plaintiff suffered catastrophic failure.

134. It was the duty of the defendant to comply with the Federal Food, Drug and Cosmetic Act, and the regulations promulgated pursuant to it, yet notwithstanding this duty, Defendant violated the Act and regulations in one or more of the following ways:

a. By introducing or delivering for introduction into interstate commerce a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;
b. By adulterating a device in interstate commerce in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;
c. By receiving in interstate commerce a device that was adulterated and delivering the device for pay or otherwise in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;
d. By manufacturing a device that was adulterated in violation of 21 U.S.C. §§ 331, 351(h); 21 C.F.R. Part 820;
e. By providing a misbranded product by, among other things, having a false or misleading label in violation of 21 U.S.C. §352;
f. By failing to establish and maintain adequate procedures to control product that does not conform to specified requirements, including the evaluation of nonconforming product, after such nonconforming product in violation of 21 CFR 820.90(a);
g. By failing to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications in violation of 21 CFR 820.90(b)(2);
h. By manufacturing Plaintiff's Stryker Trident in deviation of the manufacturing specifications approved by the FDA in the Defendant's premarket approval application in violation of the Federal Food, Drug and Cosmetic Act; and/or
i. By violating the federal regulations as outlined above in Paragraphs 23 through 53.

135. Defendant owed such duty to Plaintiff and breach said duty.

136. As a direct and legal result of the Defendant's negligence, Plaintiff has sustained serious and permanent injuries including, but not limited to the following: physical pain and suffering; mental anguish, past medical expenses, loss of future and past earnings, and any other relief available under the law.

137. The defective design existed before the product left the control of Defendants. The product did not undergo any substantial alteration before reaching Plaintiff.

138. Plaintiff and Plaintiff's implanting surgeon(s) were foreseeable users, who were not expected to know of the dangers and defects of the Trident System and who did not know of those dangers.

139. Defendants are strictly liable for the design defect, manufacturing defect, and failure to warn.

140. As a direct and proximate result, Plaintiff has suffered implantation with an adulterated and/or misbranded medical device.

141. The above described egregious misconduct constitutes the wanton and willful disregard for health and safety for which the common law mandates exemplary damages to punish Defendants and to deter Defendants from such conduct in the future.

COUNT IV
PUNITIVE DAMAGES UNDER THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *et seq.*) and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq and* PLAINTIFFS' RESPECTIVE RESIDENT STATE PUNITIVE DAMAGE LAW

142. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

143. At all times material hereto, the Defendant knew or should have known that The Trident System product was inherently more dangerous with respect to the risk of loosening and

a shorter life span and need for additional surgeries than the alternative hip replacement systems on the market.

144. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

145. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

146. At all times material hereto, the Defendant knew and recklessly disregarded the fact that the Trident System was subject to loosening in persons implanted with the device with far greater frequency than safer alternative hip replacement systems.

147. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

148. The Defendant knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

149. The Defendant's intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and Plaintiff's surgeon(s) of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

150. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

151. The aforesaid conduct of Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

152. Defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that the entire want of care raises the presumption of conscious indifference to the consequences.

153. Defendant knowingly withheld or misrepresented information required to be submitted under the FDAs regulations, which information was material and relative to the injuries suffered by the Plaintiffs, as set forth in N.J.S. 2A:58c-5C.

154. Plaintiff alleges this cause of action for punitive damages, despite the holding of *McDarby v. Merck* given the pendency of an appeal before the Appellate Division on the propriety of punitive damages in the Diet Drug Litigation, or in the event a choice of law analysis is conducted and the plaintiff's resident State law is determined to govern.

155. Defendant is also responsible for punitive damages due to its willful and wanton and reckless disregard for the safety of others by virtue of violation of the Punitive Damage laws of the Plaintiffs' resident State jurisprudence.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V

LOSS OF CONSORTIUM ON BEHALF OF SPOUSE

156. Plaintiff(s) hereby restate and allege each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

157. Plaintiff Spouse is and at all times relevant hereto has been the lawful spouse of Plaintiff and as such Plaintiff Spouse is entitled to the comfort and enjoyment of Plaintiff's society and services.

158. As a direct and proximate result of the foregoing misconduct of the Defendants, Spouse has been deprived of Plaintiff's companionship, services, solace, consortium, affection and attention to which Spouse is entitled.

159. As a result of all of the foregoing, Plaintiff Spouse has been and will continue to be injured and damaged.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff pray for judgment against the Defendant as follows:

a. Awarding compensatory damages resulting from Defendant's violation of the PLA and associated New Jersey common law and/or resident State product liability and negligence law.

b. Awarding compensatory damages resulting from Defendant's breach of warranty.

c. Awarding loss of consortium damages.

d. Awarding actual damages to the Plaintiff incidental to Plaintiff's purchase and use of The Trident System in an amount to be determined at trial;

e Awarding punitive damages to the Plaintiff;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g Awarding the costs and the expenses of this litigation to the Plaintiff;

h Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

f. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

WEITZ & LUXENBERG
A New York Professional Corporation
Attorneys for Plaintiff

Ellen Relkin

Dated: Jan. 25, 2010

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CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned attorney for Plaintiff certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;

2. No other action or arbitration proceeding is contemplated; and

3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of this action that should be joined pursuant to R. 4:28.

I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, _____ is hereby designated as trial counsel in this matter.