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Attorneys for Plaintiff Linda Kay Benton

LINDA KAY BENTON; **Plaintiff,** **vs.** **HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS,** JILL DOE MANUFACTURERS (1-10), JACK DOE WHOLESALERS (1-10), JAKE DOE SELLERS (1-10), JANE DOE DISTRIBUTORS and MARKETERS (1-10), **Defendants.**	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY CIVIL ACTION** **DOCKET NO:**

COMPLAINT AND JURY DEMAND

COMES NOW, Plaintiff, **Linda Kay Benton,** by and through the undersigned counsel, and bring this complaint against Defendant, Howmedica Osteonics Corporation and Jane and John Doe defendants, and allege 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 Tritanium Acetabular Cup under the name "Trident® Tritanium™ Acetabular System" (hereinafter "Tritanium Acetabular Cup" or "Device").

PARTIES, JURISDICTION AND VENUE

2. Plaintiff **Linda Kay Benton** is a citizen and resident of Benbrook, Texas.

3. Venue in this action properly lies in Bergen County as the Defendant conducts substantial business and is headquartered in this county.

4. Defendant, Howmedica Osteonics Corporation, (hereinafter "Howmedica," "Stryker" or "Defendant"), 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 Texas.

5. Jill Doe Manufacturers (1-10), Jack Doe Wholesalers (1-10), Jake Doe Sellers (1-10), Jane Doe Distributors and Marketers (1-10), are corporations, partnerships, companies, persons or other entities involved in the marketing, design, development, manufacture, testing, selling, labeling, packaging, advertising, promoting, supplying, distribution, implantation or release of the Tritanium Acetabular Cup, whose identities are not presently known by Plaintiff. The Doe Defendants are sued individually in their official capacity.

THE PRODUCT

6. At all times material hereto, Defendant Howmedica developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Device under the name "Tritanium Acetabular Cup," either directly or indirectly, to members of the general public within the State of New Jersey and outside the State of New Jersey, including Plaintiff herein.

7. Defendant's Device was placed into the stream of interstate commerce and was implanted in Plaintiff.

8. As a direct and proximate result of Defendant placing the Device into the stream of commerce, Plaintiff has suffered and continue to suffer both injuries and damages, including, but not limited to: physical and mental pain and suffering; medical, hospital, rehabilitative and pharmaceutical expenses; lost wages; and other related damages.

9. The Tritanium Acetabular Cup is a hip replacement prosthesis. It 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.

10. On July 22, 2008, Defendant first received FDA clearance to sell its Tritanium Acetabular Cup in the United States.

11. The Tritanium Acetabular Cup is one of several component parts that are intended to be implanted as part of an artificial hip replacement system and is designed to be used with any number of components comprised of a ceramic or polyethylene liner or insert (which fits within the cup), a femoral head or ball, and a stem (which is impacted into the femoral bone).

12. The Tritanium Acetabular Cup is manufactured utilizing a different coating process and material than that utilized by the Defendant and other orthopedic companies.

13. At all times material hereto, Defendant developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Tritanium Acetabular Cup under the name Trident® Tritanium™ Acetabular System", either directly or indirectly, to members of the general public within the State of Virginia, including Plaintiff Terese Panecaldo through Plaintiff's medical providers.

14. According to Stryker's materials, the Tritanium Acetabular Cup was developed to increase "rotational stability" and provide surgeons with a "highly porous ingrowth surface" to resist loosening of the component.

THE STRYKER TRITANIUM HISTORY

15. Defendant first received FDA clearance to sell the Tritanium Acetabular Cup on July 22, 2008, via the FDA's 510(k) approval process. Under the 510(k) approval process, manufacturers like Defendant need not submit any clinical safety data whatsoever. Instead, the 510(k) application relies primarily on bench testing data to show the applicant's product is "substantially equivalent" to other devices already commercially available on the market.

16. On October 23, 2009, Defendant received additional 510(k) clearance from the FDA for a "non-modular" iteration of the Tritanium Acetabular Shell. The Non-Modular Tritanium Acetabular Shell is a "one-time" device used with a "one-time" polyethylene liner, which is permanently cemented in the shell.

17. On April 11, 2011, Defendant received 510(k) clearance for a Tritanium Acetabular Shell with "Peri-Apatite" coating on the bone-implant interface. This iteration added a Particle Sintered Foam (PFS) Tritanium coating overlaid with Peri-Apatite coating (precipitated calcium phosphate coating). The Peri-Apatite coating used has a "greater thickness range of 35-75 microns" as compared to the predicate device.

18. On January 26, 2015, Defendant received 510(k) clearance for the Tritanium PST Acetabular Shell. This modification essentially kept the inner bearing surface the same, but completely replaced the outer shell surface with a "porous structured surface" that was previously used on the predicate PST Acetabular Shell.

19. On October 14, 2016, Defendant received 510(k) clearance for the Trident II Tritanium Acetabular Shell. This device is described as an "extension" of the Tritanium line, consisting of "a unique configuration of both solid and porous structures that are simultaneously

built using a Laser Rapid Manufacturing (LRM) method of additive manufacturing, applying Stryker's proprietary Tritanium® In-Growth Technology."

20. Upon information and belief, Defendant changed the outer coating of the shell in 2015, and then further changed the fundamental design of the cup including the porous coating in 2016, to address loosening and migration issues that plagued the performance of the cup's earlier versions.

EVIDENCE OF SAFETY ISSUES

21. As of June 2018, the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database contains over 200 complaints relating to Defendant's Tritanium Acetabular Cup, including over 130 incidences specifically relating to loosening or migration.

22. Peer-reviewed reports of loosening and safety issues with the Tritanium Acetabular Cup have appeared at orthopaedic conferences and in print.

23. Sales Representatives of Defendant Stryker have attended numerous revision surgeries where the Tritanium Device was removed by surgeons due to loosening, and Defendant has taken the failed hip for analysis to assess why it was prematurely failing.

24. Defendants have been aware of the Tritanium Device's dangerous propensity for early failure due to acetabular aseptic loosening for a significant period of time. Defendants first posted clinical study results of the Trident® Tritanium™ Acetabular Shell Revision Study on clinicaltrials.gov on November 20, 2017, and thus possessed the data prior thereto.

25. The Trident® Tritanium™ Acetabular Shell Revision Study's Primary Outcome Measure was the number of Tritanium acetabular shells requiring revision or pending revision of the acetabular shell (as defined by radiographic parameters) due to instability or lack of fixation at 5 years post-operative.

26. This study was presumably performed due to recognition of reports and complaints of acetabular loosening with the device.

27. While 190 participants began the Trident® Tritanium™ Acetabular Shell Revision Study, well over half (105) failed to complete the study, including 15 deaths, 20 withdrawals, 31 subjects terminated, and 8 instances of removal/revision of the Tritanium component that were excluded from the study without explanation.

28. The Trident® Tritanium™ Acetabular Shell Revision Study results claim "[n]o cases were pending revision" at the time the study concluded, and that a Kaplan-Meier analysis indicated a revision rate of 2.43%.

29. In November 2017, *Arthroplasty Today* published an article on behalf of the American Association of Hip and Knee Surgeons by Long *et al.* presenting a case series from the Department of Orthopaedic Surgery at NYU Langone Orthopedic Hospital. The article, entitled "Early Aseptic Loosening of the Tritanium Primary Acetabular Component with Screw Fixation," describes five (5) patients at the institution who underwent revision THA for early aseptic acetabular cup loosening of the Tritanium cup after having presented with groin and hip pain and undergoing radiographic examination consistent with acetabular component loosening. The report describes the risk of early acetabular cup loosening and its associated clinical presentation, workup, and surgical management in patients with the Tritanium primary cup augmented with screws.

30. In February 2018, Orthopaedic Proceedings, in conjunction with the British Editorial Society of Bone & Joint Surgery, published an article abstract by Carli *et al.* entitled "Primary Tritanium Acetabular Components are Associated with a High Prevalence of Radiolucencies Which Compromise Clinical Function at Short Term Follow-up." The study

evaluated 121 THAs using the Tritanium primary acetabular cup to assess the clinical and radiographic performance of the Tritanium cup's novel porous surface with respect to osseointegration. Although the study determined there was "adequate implant survivorship" at the study's endpoint of roughly 4 years, "over one third of hips implanted with a Tritanium coated primary shell exhibit radiographic signs of fibrous ingrowth that appear to increase in prevalence over time and lead to poorer clinical function. We advocate that patients that have received this implant be followed closely for evidence of clinical deterioration and component loosening."

31. Despite the above, to date, Defendant has still not issued a safety notice of any kind, label or surgical manual change, let alone initiated any voluntary product recall.

STRYKER TRITANIUM FAILURE

32. Defendant's Tritanium Acetabular Cup was implanted in Plaintiff **Linda Kay Benton**'s left hip on October 31st, 2014.

33. A period of time after the implantation of the Tritanium Acetabular Cup, Plaintiff began experiencing discomfort.

34. In light of the Plaintiff's worsening symptoms she was taken back for revision surgery to Plaintiff's left hip on January 24th, 2018. During that surgery, it was discovered that, "the acetabular liner and 2 screws within the cup were noted to be loose. They were removed without complication…The cup was noted to have no evidence of ingrowth or spot welding."

35. As a direct and proximate result of Defendant placing the Tritanium Acetabular Cup into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and

damages, including but not limited to physical and mental pain and suffering; and medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

36. Despite Stryker's claims to the contrary, Defendant's Stryker's Tritanium Acetabular Cup has been shown, to lack adequate and proper bone ingrowth leading to clinical deterioration, loosening and the need for premature revision surgery.

37. At all times material hereto, the Tritanium Acetabular Cup implanted in the Plaintiff was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY- DEFECTIVE DESIGN

38. Plaintiff realleges and incorporates by reference the allegations set above as if set forth herein.

39. This is an action for strict liability based upon design defect against Defendant.

40. Defendant Stryker's Tritanium Acetabular Cup is designed in such a way that, when used as intended, the Device causes serious and permanent damage to patients in whom the devices are implanted necessitating another surgery to remove and replace the Device. The damage and mechanism of injury have been previously described herein. Defendant acted unreasonably in its design of the Device in that Defendant failed to adopt a safer design for the Device that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

41. Defendant Stryker's Tritanium Acetabular Cup does not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant.

42. The risks of using Defendant Stryker's Tritanium Acetabular Cup outweigh the benefits.

43. There were numerous safer alternative designs to the Device which in reasonable probability would have prevented or significantly reduced the risk of the loosening and personal injuries suffered by Plaintiff without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the Tritanium Acetabular Cup left the control of Defendant by the application of existing or reasonably-achievable scientific knowledge.

44. The design defects in Defendant's Tritanium Acetabular Cup caused serious damage to Plaintiff, including but not limited to the following: bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

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

COUNT II – STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT

45. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

46. This is an action for strict liability based on a manufacturing defect.

47. The Tritanium Acetabular Cup is designed for implantation into the human body and to last for fifteen or more years. The Tritanium Acetabular Cup was also designed to be compatible with human tissue and bone.

48. The Tritanium Acetabular Cup implanted in Plaintiff failed and was removed within a short period of time after the original dates of implantation.

49. The Tritanium Acetabular Cup installed in the hips of Plaintiffs herein were not compatible with human tissue and bone. The Device loosened causing the need for early painful revision surgery. Defendant failed to manufacture the Tritanium Acetabular Cup in a manner that prevented loosening, and, in fact, manufactured the product such that it caused loosening.

50. The Tritanium Acetabular Cup implanted in the hip of Plaintiff contained manufacturing defects, upon information and belief.

51. The manufacturing defects in the Tritanium Acetabular Cup implanted in the hip of Plaintiff caused serious damage to Plaintiff including but not limited to the following: bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings, all of which damages and losses.

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

COUNT III – STRICT PRODUCTS LIABILITY- FAILURE TO WARN

52. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

53. The Tritanium Acetabular Cup implanted into Plaintiff contained no warnings or, in the alternative, inadequate warnings as to the risks that the product could cause loosening necessitating early revision and its greater propensity to cause loosening as compared with alternative acetabular cups.

54. The material, warnings and instructions that accompanied the Tritanium Acetabular Cup failed to provide that level of information that an ordinary consumer, including Plaintiff and her surgeon, would expect when using the implants in a manner reasonably foreseeable to the Defendant. Moreover, the Device left the Defendant's control without an adequate warnings and instructions, and created an unreasonably dangerous condition in that Defendants, as the seller and manufacturer, knew or in the exercise of ordinary care should have known that the Device posed a substantial risk of harm. Alternatively, after the Device left the Defendants' control, Defendants became aware of, or in the exercise of ordinary care should have known, that the Device posed a substantial risk of harm to patients, including Plaintiff, yet Defendants failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

55. Had Plaintiff received proper or adequate warnings as to the risks associated with using the Device, Plaintiff would not have used the product.

56. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Tritanium Acetabular Cup, Plaintiff's surgeon would not have recommended the device; would have used an alternate device; or, at a minimum, would have provided Plaintiff with adequate warnings and obtained informed consent.

57. Defendants' conduct as alleged herein constitutes deliberate concealment or nondisclosure of after-acquired knowledge of the Device's harmful effects, thus rendering the Device's warnings, labelling and surgical instructions inadequate.

58. Defendants' conduct as alleged herein constitutes manipulation of the post-clearance and thus post-market regulatory process, thus rendering the Device's warnings, labelling and surgical instructions inadequate.

59. Defendants knew or should have known in the post-clearance and thus marketing phase that the Device's warnings and instructions were inadequate based on requirements to update warnings and surgical instructions to address newly discovered risks and guidance on how to minimize or mitigate the risks.

60. Defendant's failure to warn of the Tritanium Acetabular Cup's risks caused serious damage to Plaintiff, including one or more of the following: bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings, all of which damages and losses will continue in the future.

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

COUNT IV –NEGLIGENCE UNDER TEXAS LAW

61. Defendant Stryker designed, manufactured, marketed, detailed, advertised both to physicians and consumers the Tritanium Acetabular Cup.

62. As a result, Defendant Stryker had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted.

63. Defendant Stryker failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted and is therefore negligent in the following respects:

a. Defendant failed to adequately design and manufacture the device to insure that it would not loosen in the patient. The flaws include but are not limited to;

   i. The incompatibility of the specific porous coating with patients acetabulum preventing proper and adequate ingrowth;

   ii. Poor design of the porous coating such that ingrowth is not adequately achieved resulting in micro motion and early loosening;

   iii. Poor design of the cup which can deform on impaction during implantation making the connection with the acetabular bone surface irregular;

   iv. A combination of the above factors that leads to rapid, premature loosening of the cup resulting in fibrosis formation, soft tissue and bony necrosis or disruption and pain and premature failure of the device.

b. Defendant Stryker failed to adequately test the device to ensure that it would not loosen in the patient;

c. Defendant Stryker failed to conduct anything other than bench testing so that when manufactured and marketed, patients became in essence Defendant's first clinical trial.

d. Defendant made affirmative representations that the device would be adequate in design to prevent the condition that in fact occurred: loosening of the cup.

These representations were false and misleading to both physicians and the consumer;

e. Defendants trained its sales force to detail the device utilizing representations that the Defendants knew or should have known were false, creating in the minds of both surgeons and consumers that the device would be subject to loosening in a reduced manner or not at all;

f. Defendants specifically marketed the device as a safe alternative to other cup surfaces;

g. Defendant Stryker failed to manufacture the product to Defendant's own internal specifications such that the acetabular cup prematurely failed;

h. Defendant Stryker failed to adequately test the coating's efficacy and bio-mechanical compatibility;

i. Defendants failed to promptly act upon reports of failure or warn surgeons such that the device continued to be implanted.

64. The above conduct exhibits Defendants' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, debilitating injury that was permanent to patients, including Plaintiff.

65. As a direct and proximate result of the Defendants' negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

COUNT V – BREACH OF EXPRESS WARRANTY

66. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

67. Through their public statements, their descriptions of the Tritanium Acetabular Cup and their promises relating to the Tritanium Acetabular Cup, Defendant expressly warranted among other things that the Tritanium Acetabular Cup was efficacious and safe for its intended use and was designed and constructed of materials that would prevent or minimize loosening and would provide superior component longevity that competing products.

68. 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 Tritanium Acetabular Cup, but which contained material misrepresentations and utterly failed to warn of the risks of the Tritanium Acetabular Cup; (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the Tritanium Acetabular Cup and the downplaying of the risks associated with the Tritanium Acetabular Cup; (iv) false and misleading written information supplied by Defendant.

69. 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.

70. When Defendant made these express warranties, Defendant knew the purpose for which Tritanium Acetabular Cup was to be used and warranted it to be in all respects safe and proper for such purpose.

71. 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.

72. The Tritanium Acetabular Cup does not conform to Defendant's representations in that it is not safe.

73. As such, the Tritanium Acetabular Cup 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.

74. Defendant therefore breached its express warranties by manufacturing, marketing and selling the Tritanium Acetabular Cup to Plaintiff causing damages as will be established at trial.

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

COUNT VI - BREACH OF IMPLIED WARRANTIES UNDER TEXAS LAW

75. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

76. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Hip Stems.

77. At all relevant times, Defendant intended that the Tritanium Acetabular Cup be used in the manner that Plaintiff in fact used the Device and Defendant impliedly warranted the Device to be of merchantable quality; safe and fit for such use; and warranted that the Device was adequately tested.

78. Defendant was aware that consumers, including Plaintiff, would use the Tritanium cup as a hip implant; which is to say that Plaintiff was a foreseeable user.

79. Plaintiff was at all relevant times in privity with Defendants.

80. The Tritanium cup was expected to reach and did in fact reach consumers, including Plaintiff, without substantial changes in the condition in which the Devices were manufactured and sold by Defendant.

81. Defendant breached various implied warranties with respect to the Device in the following manner:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Devices were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Device;

b. Defendant represented that the Device was safe, and/or safer than other alternative hip implants and fraudulently concealed information which demonstrated that the Device was not safer than alternatives available on the market; and

c. Defendant represented that the Device was more efficacious than other alternative devices and fraudulently concealed information, regarding the true efficacy of the Device.

82. In reliance upon Defendant's implied warranties, Plaintiff used the Device as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

83. Defendant breached their implied warranty to Plaintiff in that the Tritanium cup was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of N.J. Stat. Ann. §§ 12A:2-314, *et seq.*

84. As a result of Defendants' foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects.

85. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

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

COUNT VII – PUNITIVE DAMAGES UNDER COMMON LAW, 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.)

86. Plaintiff realleges and incorporates by reference the paragraphs above, as though fully set forth herein.

87. At all times material hereto, Defendant knew or should have known that the Tritanium Acetabular Cup was inherently more dangerous than alternative hip replacement systems on the market, including having a greater risk of failure, shorter life span, and an increased need for additional surgeries due to premature failure of the Device.

88. At all times material hereto, Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the Tritanium Acetabular Cup.

89. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Device.

90. At all times material hereto, Defendant knew and recklessly disregarded the fact that the Tritanium Acetabular Cup was subject to loosening and failure in patients implanted

with the device, including Plaintiff, with far greater frequency than safer alternative hip replacement systems.

91. Notwithstanding the foregoing, Defendant continued to aggressively market the Device without disclosing the aforesaid side effects and risks to Plaintiff when there were safer alternative methods and products available.

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

93. Defendant's intentional and/or reckless, fraudulent, and malicious failure to disclose information deprived Plaintiff and Plaintiff's surgeons of necessary information to enable Plaintiff to weigh the true risks of using the Device against its benefits.

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

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

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

97. Plaintiff alleges the cause of action for punitive damages, despite the holding of *McDarby v. Merck*, in that the Tritanium Acetabular Cup was never "approved" as safe and effective, and the holding in that case is otherwise inapplicable herein.

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

PRAYER FOR RELIEF

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

a. Awarding compensatory damages.

b. Awarding actual damages to the Plaintiff **Linda Kay Benton** incidental to Plaintiff **Linda Kay Benton**'s purchase and use of the Tritanium Acetabular Cup in an amount to be determined at trial;

c. Awarding punitive damages to the Plaintiff;

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

e. Awarding the costs and the expenses of their litigation to the Plaintiff;

g. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

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

WILENTZ, GOLDMAN, & SPITZER, P.A.
Attorneys for Plaintiff

Dated: August 14, 2019

/s/ Joshua S. Kincannon
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DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

WILENTZ, GOLDMAN, & SPITZER, P.A.
Attorneys for Plaintiff

Dated: August 14, 2019

/s/ Joshua S. Kincannon
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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. Pursuant to R. 4:5-1, I hereby certify that there are related civil proceedings: Penecaldo v. Howmedica Osteonics Corporation, et al.; Knudsen v. Howmedica Osteonics Corporation, et al.; Clark v. Howmedica Osteonics Corporation, et al.

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 their 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.

WILENTZ, GOLDMAN, & SPITZER, P.A.
Attorney for Plaintiff

Dated: August 14, 2019

/s/ Joshua S. Kincannon
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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Joshua S. Kincannon is hereby designated as trial counsel in their matter.

WILENTZ, GOLDMAN, & SPITZER, P.A.
Attorneys for Plaintiff

Dated: August 14, 2019

/s/ Joshua S. Kincannon
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Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-005898-19

Case Caption: BENTON LINDA VS HOWMEDICA OSTEONICS CORP.
Case Initiation Date: 08/14/2019
Attorney Name: JOSHUA S KINCANNON
Firm Name: WILENTZ GOLDMAN & SPITZER
Address: 90 WOODBRIDGE CENTER DR STE 900 PO BOX 10
WOODBRIDGE NJ 070950958
Phone: 7326368000
Name of Party: PLAINTIFF : Benton, Linda, K
Name of Defendant's Primary Insurance Company (if known): None

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

08/14/2019
Dated

/s/ JOSHUA S KINCANNON
Signed