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Filed and Attested by
PROTHONOTARY
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R. WEISS

IN RE ARTELON® SPACER IMPLANT LITIGATION	:	APRIL TERM, 2011
	:	CIVIL ACTION NO. 01932

NOTICE TO PLEAD
Code 2090

You have been sued in Court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written appearance, personally, or by an attorney, and filing in writing with the Court your defense objections to the claims set forth against you.

You are warned that if you fail to do so, the case may proceed without you, and a judgment may be entered against you by the Court without further notice for any money claims in the Complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO A LAWYER AT ONCE. IF YOU DO NOT KNOW A LAWYER, CALL THE LAWYER REFERENCE SERVICE, 566-6625.

Le han demandado a usted en la corte. Si desea defenderse contra las quejas presentadas es absolutamente necesario que usted responda dentro de 20 dias despues de ser servideo con esta demanda y aviso. Para defenderse, es necesario que usted, o su abogado, registre con la corte en forma escrita, cualquier objeccion contra las quejas en esta demanda.

Recuerde: Si usted no responde a esta demanda, se puede proseguir con el proceso sin su participacion. Entonces, la corte puede, sin notificarlo, decidir a favor del demandente y requerira que usted cumpla con todas las provisiones de esta demanda. Por razon de esa decision, es posible que usted pueda perder dinero, propiedad o estros derechos importantes.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO CONOCE A UN ABOGAGO LLAME AL “LAWYER REFERENCE SERVICE” SERVIDIO DE REFERENCIA DE ABOGADOS 238-6333.

Case ID: 110401932

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PLAINTIFFS' GENERAL MASTER LONG-FORM COMPLAINT AND JURY DEMAND

Pursuant to the June 8, 2011 Order of the Honorable Sandra Mazer Moss, the undersigned attorneys for plaintiffs in all actions in the Artelon® Spacer Implant Litigation bring the Master General Long-Form Complaint against the defendants set forth below. This document relates to all actions.

SMALL BONE INNOVATIONS, INC.
1380 S. Pennsylvania Avenue
Morrisville, PA 19067

ARTIMPLANT USA, INC.
2007 Hillside Circle
Lansdale, PA 19446

ARTIMPLANT AB
Hulda Mellgrens gata 5
SE-421 32 Västra Frölunda
SWEDEN

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1. This Complaint is a Master Complaint filed for all plaintiffs represented by plaintiffs' counsel who has signed agreement to the Master Long Form Complaint.

2. All allegations pleaded herein are deemed pleaded in any "Short-Form" Complaint hereafter filed. Notwithstanding that the law of another State might apply under a conflict of laws analysis, the Master Long Form Complaint is filed under Pennsylvania law and may he adopted by a resident of any state or commonwealth.

3. All plaintiffs who use this Master Long Form Complaint and any Short Form Complaint based hereon agree that Pennsylvania substantive law applies.

DEFENDANTS

4. Defendant Small Bone Innovations, Inc. ("SBI") is the distributor of the Artelon® CMC Spacer implant in the United States, which is manufactured by the Swedish company, Defendant, Artimplant AB. SBI is a Delaware corporation with its principal place of business at 1380 S. Pennsylvania Avenue, Morrisville, PA. At all times relevant hereto, SBI was engaged in Pennsylvania in labeling, marketing, distributing, promoting and selling the Artelon® CMC Spacer implant.

5. Defendant Artimplant USA, Inc. is the United States subsidiary of Defendant, Artimplant AB, the manufacturer of the Artelon® CMC Spacer implant. Artimplant USA, Inc. is a Delaware corporation with its principal place of business located at 2007 Hillside Circle, Lansdale, Pennsylvania.

6. Defendant Artimplant AB is a company incorporated in the country of Sweden. It is the parent and sole owner of its United States subsidiary of Artimplant USA and is also the manufacturer of the Artelon® CMC Spacer implant.

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JURISDICTION/VENUE

7. This Court has personal jurisdiction over Defendants pursuant to Pa.C.S. § 5301 and 5322, because each Defendant transacts and carries on a continuous and systematic part of their general business in this Commonwealth.

8. Venue is proper in Philadelphia County, pursuant to Pa. R. Civ. P. 2179(a)(2), by virtue of the fact that Defendants regularly conduct business here. Furthermore, Defendants now, and at all relevant times, conducted business and solicited business in the Commonwealth of Pennsylvania through the sale of the Artelon® CMC Spacer.

GENERAL ALLEGATIONS

9. The Defendants manufacture, promote, and/or distribute the medical device implant known as the Artelon® CMC Spacer (the "Spacer"). The Spacer is designed for patients suffering from early to mid-stage osteoarthritis of the carpometacarpal joint, also known as the basal thumb joint. The Spacer is shaped like the letter "T" and is surgically implanted into the basal thumb joint in between the trapezium bone and the first metacarpal bone.

10. The implantation of the Spacer is commonly known as the "Artelon® Procedure." It is an alternative to the Ligament Reconstruction-Tendon Interposition procedure ("LRTI procedure") in which a tendon from the patient's wrist is harvested and implanted into the joint space between the trapezium and thumb metacarpal bone.

11. The LRTI procedure has been successfully utilized for decades.

12. The Spacer material was patented in 2000, and the Spacer itself was approved for marketing by the United States Food and Drug Administration ("FDA") in September of 2004 through the FDA's 510(k) approval process.

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13. The Spacer is a multifilament comprised of two materials: a non-biodegradable component known as polyurethaneurea and a biodegradable component known as e-polycaprolactone. The biodegradable e-polycaprolactone dissolves over a period of six years after implantation. According to the Defendants' literature, during that time period, the Spacer is supposed to act as a "tissue scaffold" that supports regeneration of the patient's tissues. After a patient undergoes the Artelon® Procedure and receives an implanted Spacer, the patient is placed in a spica cast for 5-6 weeks. Thereafter, patients undergo approximately two (2) months of physical therapy. The goal of a successful Artelon® Procedure is to relieve pain, to recapture and re-establish the patient's grip strength and to re-establish the patient's capacity to use the thumb.

14. However, in many patients, the Spacer triggers, among other responses, an autoimmune response as the biodegradable material (e-polycaprolactone) degrades over time.

15. As the Spacer's e-polycaprolactone breaks down, small particles of the material known as particulate debris break free of the Spacer and spread throughout the joint space.

16. The patient's immune system responds to the particulate debris as if it is an infection. The white blood cells attack the patient's healthy bone and cause a process known as osteolysis, which is a degeneration or dissolution of bone tissue. The patient suffers increased and unanticipated pain, swelling, limitation on range of motion, and failure of the Spacer. This condition requires additional surgery to remove the Spacer.

17. Through the 510(k) approval process, FDA approved the Spacer for sale in the United States on September 21, 2004.

18. During the 510(k) approval process, one or more of the Defendants claimed that the Spacer was "substantially equivalent" to the Avanta Orthopedics TRL Trapezium Soft Skeletal Implant, because both devices are T-shaped basal thumb joint implants.

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19. However, the Avanta Implant is made of silicone and is not designed to break down and be absorbed in the joint space.

20. During the 510(k) approval process, one or more of the Defendants advocated the Spacer to the FDA by citing to a predicate device that is not an orthopedic implant but is made from the same bio-absorbable material as the Spacer. The Defendants cited to bio-absorbable sutures made of polycarprolactone. Thus, the Defendants represented to the FDA that a finding of substantial equivalence under the 510(k) approval process was warranted because the Spacer was (a) shaped like the Avanta product and (b) composed of the same material as bio-absorbable sutures.

21. No previous implant device, however, was (a) ever made from e-polycaprolactone and also (b) used in a joint bearing application such as the basal thumb joint, where the implant is subjected to intense compressive and shearing loads.

22. Because of the e-polycaprolactone material from which the Spacer is made, and because of the joint bearing stress to which the Spacer is subjected, the Spacer can break down prematurely, cause a foreign body reaction, and/or fail. One or more of these events requires revision or replacement surgery and removal of the Spacer.

23. The foreign body reaction and/or requirement of revision surgery regarding the Spacer have been reported in multiple peer-reviewed medical journal articles, which are attached as Exhibits A through C.

24. A recent study sponsored by the Swedish manufacturer Defendant Artimplant AB reported at page 245 a revision surgery rate of nearly 17% on or around one year after implantation. *See* Exhibit D attached.

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25. Anecdotal evidence from surgeons shows that the actual failure rate may be higher. *See* Exhibit E.

26. In September 2004, at the time of the FDA application for 510(k) approval, there was very little clinical evidence that the device was safe and effective for its intended use. The very limited study Artimplant AB relied upon when it sought FDA 510(k) approval showed that 20% of the patients who received the Spacer suffered an adverse inflammatory reaction. See Excerpt from 510(k) approval process, attached as Exhibit F.

27. Despite these facts, Defendants have marketed, sold, and continue to sell the Spacer throughout the United States.

28. Despite these facts, Defendants have failed to disclose in their labeling or advertising that the Sapcer may break down prematurely, cause a foreign body reaction, and/or fail.

29. As a result of having the Spacer implanted, Plaintiffs have been exposed to a hazardous and dangerous medical device that is unsafe for its intended use and has caused injuries to Plaintiffs and some or all of the following damages:

a. increased and unnecessary pain in and around the location of the CMC joint where the Spacer was implanted;

b. substantial loss of hand function;

c. permanent loss of hand function;

d. pain and mental anguish;

e. wage loss;

f. substantial medical costs and debts;

g. the costs, pain, and mental anguish of extensive corrective surgery;

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h. continued substantial pain, weakness and swelling in and around the CMC thumb joint; and

i. loss of consortium.

30. Defendants SBI, Artimplant USA, and Artimplant AB manufactured, promoted, marketed, sold, and/or distributed the Spacer in Pennsylvania and throughout the country.

31. Upon information and belief, Defendants SBI and/or Artimplant USA also packaged and labeled the Spacer sold in the United States.

32. During this time period, Defendants knew or should have known about the Spacer's defective propensities, but still manufactured, promoted, marketed, sold, and distributed the Spacer.

33. During this time period, Defendants failed to warn Plaintiffs or their physicians of the risk that the Spacer would prematurely degrade, ultimately fail, and require additional surgery, removal, and therapy.

34. Neither Plaintiffs nor their physicians knew of the Defendants' misrepresentations or omissions at the time they purchased and accepted the Spacer as an implant.

35. In reliance upon Defendants' misrepresentations and/or omissions, Plaintiffs' physicians reasonably believed that the Spacer was a safe treatment for Plaintiffs' condition.

36. Plaintiffs and their physicians reasonably relied upon the Defendants' misrepresentations and/or omissions.

37. Based on such reliance, Plaintiffs were induced to permit and in fact did permit the implantation of the Spacer manufactured and/or distributed by the Defendants.

38. Had Plaintiffs or their physicians been informed of the true facts concerning the causal nexus between the Spacer and, among other things, the failure of the Spacer and/or the

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inflammatory response and/or osteolysis suffered by users, neither Plaintiffs nor their physicians would have consented to the implantation of the Spacer.

39. Plaintiffs and their physicians justifiably and reasonably relied upon the Defendants' misrepresentations and/or omissions, because the Defendants were in a special relationship to Plaintiffs in that Defendants held themselves out as experts in the field of medical devices.

COUNT I
NEGLIGENCE

40. Plaintiffs incorporate by reference paragraphs 1 through 39 of this Complaint, as if fully set forth herein.

41. At all times relevant to this action, Defendants had a duty to each and every user of the Spacer to exercise reasonable care and to comply with the existing standards of care in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the Spacer, which Defendants introduced into the stream of commerce. Defendants' duty included a duty to ensure that users, such as Plaintiffs, would not suffer unreasonable, dangerous, or untoward adverse side effects.

42. At all relevant times, Defendants knew or reasonably should have known that the Spacer was unreasonably dangerous and defective when used as directed and as designed.

43. Defendants knew or reasonably should have known the following:

a. The material used in the Spacer had never been previously used in a joint bearing application where the material would be subjected to significant compressive and shearing loads;

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b. There was very little clinical evidence that the device was safe and effective for its intended use;

c. The study Swedish manufacturer and Defendant Artimplant AB relied upon when seeking FDA approval showed that 20% of the patients in the study suffered an adverse inflammatory reaction to the material from which the Spacer is made;

d. The risk of an inflammatory response, including but not limited to osteolysis and other serious post-operative problems, outweighed the Spacer's possible benefits.

44. Based on what they knew or reasonably should have known, the Defendants deviated from standards of due care, deviated from the standard of care, and were negligent in one or more of the following ways:

a. The Defendants failed to conduct necessary tests and studies to determine whether or not the Spacer was unreasonably dangerous;

b. The Defendants failed to instruct or warn the medical community that the Defendants had not yet adequately established that the Spacer was safe for its designed and intended use;

c. The Defendants failed to disclose to the medical community that implantation of the Spacer could result in an adverse inflammatory reaction with associated osteolysis and could cause serious and permanent injury to the basal thumb joint that would require, among other things, a revision surgery to remove the defective Spacer;

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d. The Defendants failed to disclose to the medical community that there were no studies or tests that showed that the Artelon® Procedure and the Spacer were safe and effective alternatives to the LRTI procedure.

47. At all relevant times, Defendants knew or reasonably should have known that the Spacer was unreasonably dangerous and defective when used as directed and designed, including but not limited to the following particulars:

a. The only human study regarding the safety of the Spacer that Defendant Artimplant AB upon when seeking FDA 510(k) approval showed a 20% incidence of an inflammatory response in patients in whom the Spacer was implanted;

b. The e-polycaprolactone used in the Spacer had never before been used in an implant for joint bearing applications; and

c. The Defendants were aware of problems with the Spacer, but failed to warn patients or doctors of the potential for adverse surgical outcomes for patients in whom the Spacer was (or is) implanted.

48. The defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiffs that would not have occurred but for the use and implantation of the Spacer.

49. The injuries and damages suffered by Plaintiffs were the reasonably foreseeable results of the Defendants' negligence.

50. Had Defendants performed tests and studies necessary to determine that the Spacer could cause an adverse inflammatory response in the patient, including but not limited to osteolysis, and/or had Defendants properly warned Plaintiffs' physicians and Plaintiffs of this fact, Plaintiffs would not have accepted the Spacer as an implant, would not have suffered,

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among other things, an inflammatory response, the premature failure of the Spacer, loss of wages, loss of consortium, additional corrective surgery, and pain and suffering.

51. As a direct and proximate cause of Defendants' negligence, Plaintiffs suffered a prolonged recovery, including increased pain, swelling, and limitation on range of motion, and the loss of use and function of the thumb and hand. Also as a result of Defendants' negligence, Plaintiffs were required to undergo an additional surgery to address the damaged and compromised basal thumb joint. Plaintiffs will also require future medical care, including physical therapy, pain management, and/or additional basal thumb joint surgery. In addition, Plaintiffs have suffered mental distress and anguish and possible permanent impairment of the use and function of her basal thumb joint.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for compensatory damages and damages for pain and suffering in an amount in excess of $50,000.00, together with interest and costs of suit, attorney's fees, lost wages, and all other relief the Court deems just and proper that will compensate the Plaintiffs for their injuries and deter the Defendants and others from the conduct set forth above.

COUNT II
NEGLIGENT FAILURE TO WARN

52. Plaintiffs incorporate by reference paragraphs 1 through 51 of this Complaint, as if fully set forth herein.

53. Defendants distributed, marketed, advertised, represented, sold, and continue to sell the Spacer despite the fact that the Spacer is negligently designed and manufactured and created a foreseeable risk that exceeded the benefits associated with the Spacer's design and/or formulation.

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54. The Defendants negligently failed to warn about clinical trials, *in vivo* and *in vitro* testing and study, and inadequately reported the results of such trials.

55. The Defendants negligently failed to warn both before and after the Spacer was sold and implanted, even though the Defendants knew or should have known of the risk of injury from the Spacer. Defendants also failed to provide adequate warnings to the medical community and patients and continued to promote the Spacer as safe and effective.

56. The Defendants' negligent failure to warn was a substantial factor in bringing about the injuries to Plaintiffs because those injuries would not have occurred but for the use of the Spacer and the Defendants' failure to warn the Plaintiffs and/or their treating physicians, both before and after the Defendants knew or should have known of the Spacer's negligent manufacture and design.

57. As a direct and proximate cause of the Defendants' negligent failure to warn of the Spacer's defective design and manufacture and other wrongdoing and actions described herein, Plaintiffs suffered the injuries and damages as described in paragraphs 29 and 51 above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for compensatory damages and damages for pain and suffering in an amount in excess of $50,000.00, together with interest and costs of suit, attorney's fees, lost wages, and all other relief the Court deems just and proper that will compensate the Plaintiffs for their injuries and deter the Defendants and others from the conduct set forth above.

COUNT III
NEGLIGENT MISREPRESENTATIONS

58. Plaintiffs incorporate by reference paragraphs 1 through 57 as if fully set forth herein.

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59. Defendants herein represented and marketed the Spacer as being safe and effective.

60. After Defendants became aware of the risks of the Spacer, they failed to communicate to the Plaintiffs, Plaintiffs' physician, and/or Plaintiffs' other healthcare providers that the Spacer was negligently designed and could, as a result of its implantation in Plaintiffs and other patients, have adverse consequences, including but not limited to failure and the necessity of revision surgery.

61. Plaintiffs, therefore, bring this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

a. Plaintiffs incorporate all facts and allegations previously stated in this Amended Complaint;

b. the Defendants failed to warn Plaintiffs, other consumers, and the medical community of the negligently design and manufacture of the Spacer, as supplied by the Defendants;

c. the Defendants, individually, and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about the Spacer in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, the Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

d. the above misrepresentations were made to Plaintiffs, the general public, Plaintiffs' physicians, and/or Plaintiffs' other healthcare providers;

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e. Plaintiffs, her physicians, and/or her healthcare providers justifiably relied upon the Defendants' misrepresentations; and

f. consequently, Plaintiffs' use of the Spacer was to her detriment, and the Defendants' negligent misrepresentations proximately caused Plaintiffs' injuries and monetary losses.

WHEREFORE, Plaintiffs prays for judgment against Defendants, jointly and severally, in compensatory damages and damages for pain and suffering in an amount in excess of $50,000.00, together with interest, costs of suit, attorney's fees, lost wages, and all other relief the Court deems just and proper, that will compensate Plaintiffs for her injuries and deter the Defendants and others from the conduct set forth above.

COUNT IV
STRICT PRODUCT LIABILITY

62. Plaintiffs incorporate by reference paragraphs 1 through 61 as if fully set forth herein.

63. Defendants placed the Spacer into the stream of commerce.

64. Plaintiffs received the Spacer as an implant in her hand as prescribed by her surgeon in a manner that Defendants intended the Spacer to be used.

65. Defendants placed the Spacer into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the Spacer.

66. The Spacer was defective in design and/or formulation because, when it was distributed by Defendants, the foreseeable risks of use following basal joint surgery exceeded the benefits associated with the design and/or formulation.

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67. The Spacer was expected to and did reach Plaintiffs without substantial change in condition. Alternatively, the Spacer distributed by Defendants was defective in design or formulation because, when it left the hands of Defendants, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

68. The Spacer was defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of such studies.

69. The Spacer was defective due to inadequate pre- and post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from the Spacer, it failed to provide adequate warnings to the medical community and patients, and continued to market and promote the Spacer as safe and effective.

70. The Spacer that was distributed, marketed, advertised, represented and sold by Defendants was a substantial factor in bringing about the Plaintiffs' injuries that would not have occurred but for the use of the Spacer.

71. As a direct and proximate result of the defective condition of Defendants' product, Plaintiffs suffered and will continue to suffer injury, damages, and losses as alleged herein.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in compensatory damages and pain and suffering in an amount in excess of $50,000.00, together with interest, costs of suit, attorney's fees, and all other relief the Court deems just and proper, that will compensate Plaintiffs for her injuries, expenses, and pain and suffering.

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COUNT V
LOSS OF CONSORTIUM

72. Plaintiffs incorporate by reference paragraphs 1 through 71 as if fully set forth herein.

73. Some of the Plaintiffs (hereinafter "Plaintiffs/Spouses") were and are at all relevant times herein the spouses of Plaintiffs who were damaged by the Artelon® Procedure and Spacer.

74. By reason of the foregoing facts, the Plaintiffs/Spouses have been caused presently and in the future the loss of companionship, society and services of their spouses who have been damaged by the Artelon® Procedure and Spacer and, for that reason, the Plaintiffs/Spouses have also suffered great mental anguish.

75. By reason of the foregoing facts, the Plaintiffs/Spouses have paid and have become liable to pay for medical aid, treatment, medications, and expenses and will necessarily incur future similar costs in connection with the injuries and pain and suffering sustained by their spouses who sustained damages from the Spacer.

WHEREFORE, the Plaintiffs/Spouses demand judgment against the Defendants, jointly and severally, for damages for loss of consortium in excess of $50,000, together with interest, cost of suit, attorney's fees, and all such other relief as the Court deems proper that will

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compensate the Plaintiffs/Spouses for the loss of companionship, services, and society, as well as his expenses and mental anguish.

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CERTIFICATE OF SERVICE

I, David D. Langfitt, Esquire, hereby certify that a copy of the foregoing Master Long-Form Complaint and Jury Demand was served on this date via electronic mail and in the designated manner on the following persons:

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