

**IN RE: ALLODERM® LITIGATION**

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: MIDDLESEX COUNTY**

**CASE NO. 295**

**CIVIL ACTION**

**PLAINTIFFS,**

*Plaintiff,*

**v.**

**LIFECELL CORPORATION**

*Defendant.*

**MASTER LONG FORM COMPLAINT  
FOR HERNIA REPAIR AND  
ABDOMINAL RECONSTRUCTION**

**JURY TRIAL DEMANDED**

**PLAINTIFFS' MASTER LONG FORM COMPLAINT**

1. This Master Long Form Complaint for In re: AlloDerm® Litigation (“Master Long Form Complaint”) is intended to serve the administrative functions of efficiency and economy by presenting certain common claims and common questions of fact and law for consideration by this Court in the context of centralized management. The Master Long Form Complaint does not necessarily include all claims asserted in all of the actions that have been transferred to this Court, nor is it intended to consolidate for any purposes the separate claims of the plaintiffs herein. Those matters are set forth in the individual actions filed by each of the respective plaintiffs. This Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any Plaintiff relinquish the right to add or assert or seek leave to add or assert any additional claims or predicates for claims depending upon further information that they may uncover.

2. By operation of the Order of this Court, all allegations pled herein are deemed pled in any Short-Form Complaint hereafter filed.

3. Plaintiffs (“Plaintiff”)<sup>1</sup>, by and through the undersigned counsel, hereby submit this Plaintiffs’ Master Long Form Complaint for In re: AlloDerm® Litigation against Defendant LifeCell Corporation (“LifeCell”). Plaintiff makes the following allegations based upon his personal knowledge, and upon information and belief, as well as upon his attorneys’ investigative efforts, regarding the use of AlloDerm ® Regenerative Tissue Matrix (“AlloDerm”) in his hernia repair surgery.

4. As more specifically pleaded below, each Plaintiff maintains that the AlloDerm is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacks proper warnings and instructions as to the dangers associated with its use.

**I. PARTIES, VENUE AND JURISDICTION**

5. Plaintiff is a competent adult, or the duly authorized representative of an individual and/or estate of a deceased individual, who suffered damages as a result of the use of AlloDerm in his hernia repair and/or abdominal reconstruction surgery.

6. Plaintiff’s spouse is a competent adult who is legally married by statute or common law to Plaintiff and who suffered damages as a result of the use of AlloDerm in Plaintiff’s hernia repair and/or abdominal reconstruction surgery. Plaintiff’s spouse asserts derivative claims including, but not limited to, loss of consortium.

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<sup>1</sup> Through this Master Long Form Complaint for Hernia Repair and Abdominal Reconstruction, the singular party designation of “plaintiff is used with the understanding that the allegations herein are made by – and apply to – multiple Plaintiffs as specifically identified in the Short Form Complaints filed with this Court. Similarly, use of the masculine pronoun is used through the Master Long Form Complaint for Hernia Repair and Abdominal Reconstruction with the understanding that the allegations herein are made by – and apply to – Plaintiffs of both genders.

7. Not all claims asserted in this Master Long Form Complaint will necessarily be asserted by all Plaintiffs.

8. At all times relevant to the allegations in the complaint, Plaintiff resided in the United States of America or its territories.

9. “Plaintiff” or “Plaintiffs” as used herein may refer to the Plaintiff and Plaintiff’s spouse collectively.

10. Defendant LifeCell is a New Jersey resident with its principal place of business located at One Millennium Way, Branchburg, New Jersey 08876.

11. LifeCell is incorporated under the laws of Delaware.

12. At all relevant times, LifeCell designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold AlloDerm from its principle place of business in New Jersey.

13. At all relevant times, LifeCell designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold AlloDerm to be used in patients throughout the United States, including the State of New Jersey and this County.

14. LifeCell regularly transacts business in the State of New Jersey.

15. Venue is proper in Middlesex County pursuant to the Supreme Court of New Jersey’s Order dated July 12, 2011 assigning all AlloDerm® Regenerative Tissue Matrix cases to be filed and/or transferred to Middlesex County for centralized management.

16. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et. seq.* to recover damages and other relief, including the costs of suit, reasonable attorneys’ fees and expert fees, for the injuries Plaintiff has sustained as a result of the

Defendant's negligence and wrong conduct in connection with the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distribution, labeling, and/or sale of AlloDerm.

17. This is an action for damages that exceeds the jurisdictional minimum of this Court.

## **II. GENERAL ALLEGATIONS**

18. This case involves AlloDerm, a biologic product processed from donated human tissue, which was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and sold by LifeCell starting in or around 1992.

19. AlloDerm is comprised of allograft human tissue. LifeCell aseptically processes human tissue to remove the epidermis and cells and then freeze-dries the processed tissue to remove moisture. The end product, AlloDerm, is a white colored, uniform allograft.

20. A component of human skin is elastin. Elastin is a protein that coils and recoils within the elastic fibers of the connective tissue and provides the elasticity present in the human skin.

21. LifeCell's aseptic processing of human tissue to form AlloDerm does not remove the elastin from the human tissue.

22. The elasticity present in human skin is present in AlloDerm.

23. AlloDerm was LifeCell's first commercial product.

24. AlloDerm was first used for burn patients in or around 1992.

25. In or around 1994, AlloDerm started being used for periodontal surgery and plastic and reconstructive surgeries.

26. LifeCell advertised, promoted, marketed, distributed and sold AlloDerm for use in hernia repair or abdominal reconstruction surgeries starting in or around 1994, however, LifeCell did not specifically include hernia repair surgery as one of the surgical uses for AlloDerm on LifeCell's website nor did LifeCell specifically include hernia repair surgery or abdominal reconstruction surgery as one of the surgical uses for AlloDerm in its labels, package inserts, and instructions for use.

27. In approximately 2000, LifeCell began actively advertising, promoting, marketing, and selling AlloDerm for use in hernia repair and abdominal reconstruction surgeries.

28. LifeCell advertised, promoted, marketed, and sold AlloDerm for use in hernia repair and abdominal reconstruction surgeries without conducting sufficient testing to determine the extent and effect of AlloDerm's propensity to stretch, expand, thin out, pull, sag, loosen, spread, and/or dissolve when used for hernia or abdominal repair surgeries.

29. Since approximately 2000, LifeCell's sales representatives and/or other agents hired to advertise, promote, market, distribute and/or sell AlloDerm have actively contacted surgeons across the United States promoting the use of AlloDerm for hernia repair and abdominal reconstruction surgeries.

30. LifeCell knew, or should have known, that AlloDerm could stretch, expand, thin out, pull, sag, loosen, spread and/or dissolve as early as 1994, when it began advertising, promoting, marketing, distributing and selling AlloDerm for reconstructive surgeries.

31. LifeCell knew, or should have known, that an AlloDerm graft must be pre-stretched before it can be used in a hernia repair or abdominal reconstruction surgery.

32. Before March 2000, LifeCell did not provide any references and/or instructions to pre-stretch AlloDerm before using the product in hernia repair or abdominal reconstruction

surgeries. On or around March 3, 2000, LifeCell started instructing physicians to suture AlloDerm intra-operatively “under significant tension” and “after proper re-hydration,” however, LifeCell provided no specific reference, instruction, and/or warning in AlloDerm’s label, pamphlet or instructions for use to pre-stretch AlloDerm before implanting for hernia repair surgeries.

33. In or around 2008, LifeCell advised surgeons that AlloDerm could stretch up to fifty-percent (50%).

34. In or around 2008, LifeCell advertised, promoted and marketed AlloDerm stating that surgeons could buy smaller pieces of AlloDerm because it stretched out increasing the size of the graft.

35. AlloDerm’s current instructions for use in May 2011 instruct physicians to suture “AlloDerm under significant tension to ensure the laxity is removed as much as possible. Removing the laxity will increase the surface area of each graft by 30–50%. For example, a 16 x 20 cm graft will expand up to 19 x 25 cm when sutured under significant tension.”

36. AlloDerm was, and is, advertised, promoted, marketed and represented by LifeCell in its label, brochure, package insert, instructions for use, website, through its sales representatives and otherwise, as a safe and effective product for hernia repair product.<sup>2</sup> In fact, LifeCell marketed AlloDerm as a more effective alternative when compared to other hernia repair products.

37. LifeCell has and continues to advertise, promote, and market AlloDerm as a “strong intact repair for challenging hernia repair.”<sup>3</sup>

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<sup>2</sup> “AlloDerm® Tissue Matrix provides a strong and safe hernia repair and may minimize the risk of short- and long term complications.” <http://www.lifecell.com/alloderm-regenerative-tissue-matrix/33/> (last visited September 22, 2011)

<sup>3</sup> <http://www.lifecell.com/alloderm-regenerative-tissue-matrix/95/> (last visited September 22, 2011)

38. Upon information and belief, LifeCell advertises, promotes, and markets the natural elasticity of the human skin as a benefit to using AlloDerm over other products, in particular synthetic hernia repair products.

39. LifeCell advertises, promotes, and markets that AlloDerm when used for hernia repair may keep "patients from undergoing additional surgical interventions;"<sup>4</sup> and that the use of AlloDerm for hernia repair surgery minimizes the potential for recurrence, scarring and erosion.<sup>5</sup>

40. AlloDerm is not cleared or approved by the FDA.<sup>6</sup>

41. AlloDerm has been classified as banked human tissue by the FDA since 1996.

42. In 2007, AlloDerm sales generated \$167 million in revenue for LifeCell.<sup>7</sup>

43. To date, AlloDerm has been implanted in more than one million grafts and implants.<sup>8</sup>

44. Despite representations made by LifeCell, the natural properties and/or elasticity of AlloDerm cannot properly sustain tissue growth and/or support herniated, compromised, or weakened tissue, especially in the abdominal region.

45. Once implanted, AlloDerm stretches, expands, thins out, pulls, sags, loosens, spreads, dissolves, and otherwise fails, resulting in serious injury to the user's abdominal area and/or requiring additional surgery. These injuries include, but are not limited to, hernia recurrence, abdominal deformity, pain, overall sickness, and disability.

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<sup>4</sup> <http://www.lifecell.com/alloderm-regenerative-tissue-matrix/33/> (last visited November 22, 2010, the AlloDerm website as of September 22, 2011 no longer contains this quote).

<sup>5</sup> "The flexibility of the matrix provides a tension-free repair that could minimize the potential for recurrence, scarring and erosion." <http://www.lifecell.com/downloads/casestudies/Scott.Hiatal%20Hernia.2004.Final.pdf> (last visited September 22, 2011)

<sup>6</sup> Kinetic Concepts, Inc. Form 10-K, 2009, page 26.

<sup>7</sup> <http://www.reuters.com/article/idUSN0745955020080407>

<sup>8</sup> <http://www.lifecell.com/health-care-professionals/> (last visited September 22, 2011)

46. Upon information and belief, LifeCell has initiated a silent recall of AlloDerm for use in hernia repair surgeries and has stopped advertising, promoting, and marketing AlloDerm for general use in hernia and abdominal repair surgeries. As a replacement for AlloDerm, LifeCell advertises, promotes, and markets Strattice™ Reconstructive Tissue Matrix, a surgical mesh derived from porcine dermis.

47. To date, scientific and medical studies regarding AlloDerm use in hernia repair surgeries acknowledge the lack of long-term studies testing the safety, efficacy, and failure rate of AlloDerm.

48. At all times relevant herein, Defendant knew or should have reasonably known that AlloDerm was not properly designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold, did not have proper warnings and instructions, was not suitable for the purpose it was intended, including but not limited to hernia repair and abdominal reconstruction surgery, and that it was unreasonably likely to fail and injure the product's users.

49. The AlloDerm implanted in Plaintiff was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold by Defendants to be used by surgeons for hernia repair and abdominal reconstruction surgery and was further represented by Defendants to be appropriate, effective, suitable and/or superior for such purpose.

50. The AlloDerm product used in Plaintiff completely failed resulting in harm to Plaintiff.

51. As a direct and proximate result of LifeCell's defective and negligent design, development, processing, manufacturing, testing, packaging, advertising, promotion, marketing,



distribution and/or sale of AlloDerm, Plaintiff suffered multiple injuries, incurred medical bills, will need future medical care to treat resultant injuries, sustained a loss of earnings in the past and will suffer a loss of earning capacity in the future.

52. As a direct and proximate result of LifeCell's defective and negligent labeling, inadequate warnings and/or instructions for use regarding AlloDerm, Plaintiff suffered multiple injuries, incurred medical bills, will need future medical care to treat resultant injuries, sustained a loss of earnings in the past and will suffer a loss of earning capacity in the future.

### **III. DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT**

53. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

54. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, fraudulent concealment, and/or minority tolling.

55. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

56. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultation with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to AlloDerm was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations

for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

57. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant is estopped from asserting a statute of limitations defense due to Defendant's fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiff's physicians of the true risks associated with AlloDerm. As a result of Defendant's fraudulent concealment, Plaintiffs and Plaintiff's treating physicians and surgeons were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant.

58. Defendant is estopped from asserting a statute of limitations defense because Defendant fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and Defendant's tortious conduct.

#### **IV. CLAIMS FOR RELIEF**

59. The Plaintiffs set forth the following statements and claims as a whole and in the alternative such that the sufficiency of this Complaint shall not be defeated by an inconsistency or insufficiency (if any) among any one or more of the alternative statements of claims.

#### **COUNT I - Products Liability Failure to Warn (N.J.S.A. 2A:58C-1 et seq.)**

60. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege in the alternative as follows.

61. Defendant, as the manufacturer and seller of AlloDerm, had the duty to make a product that is reasonably fit, safe, and suitable for reasonably foreseeable uses.

62. Defendant owed that duty to reasonably foreseeable users of the product, including Plaintiff and Plaintiff's physicians,

63. AlloDerm was not reasonably safe for its intended purpose of hernia repair and/or abdominal reconstruction surgeries because it contained warnings insufficient to alert users, including Plaintiff and Plaintiff's physicians, to the risks of using the biologic product in reasonably foreseeable procedures. Plaintiff had AlloDerm surgically implanted for an intended purpose.

64. Defendant, as manufacturer and/or distributor of the biologic product, is held to the level of knowledge of an expert in the field.

65. The warnings and/or instructions that were given by Defendant failed to properly warn and instruct users, including Plaintiff and Plaintiff's physicians, of the increased risks associated with AlloDerm including but not limited to stretching, expanding, thinning out, pulling, sagging, loosening, spreading, and/or dissolving causing serious injury and/or additional surgery.

66. AlloDerm was, and is, unaccompanied by proper warnings regarding the high failure rate of the product and high likelihood of re-herniation, other possible adverse effects, and the comparative severity of such adverse effects. The warnings given did not, and do not, accurately reflect the severity of the adverse effects or the true potential and/or likelihood or rate of these affects.

67. Defendant failed to perform adequate testing to show that the nature and quality of AlloDerm resulted in an extremely high failure rate and other serious potential adverse effects.

68. Had adequate testing been performed on AlloDerm, the biologic would have been allowed to enter the stream of commerce, if at all, only with instructions for use that would have

clearly and completely instructed surgeons how to properly implant AlloDerm in hernia repair and abdominal reconstruction surgeries and with warnings that would have clearly and completely identified the risks and dangers of AlloDerm.

69. Defendant failed to provide full and accurate warnings and/or instructions to the public, including Plaintiff and/or Plaintiff's physicians that AlloDerm would stretched if not pre-stretched before it was implanted or implanted under the appropriate tension.

70. Defendant failed to disclose, suppressed and/or mischaracterized the known risks of AlloDerm and continued to promote, market, sell, and distribute this product as an effective and superior method of hernia repair and/or abdominal reconstruction.

71. Defendant knew, or should have known, that AlloDerm was defective and ineffective when used for hernia repair and abdominal reconstruction, and would result in an extremely high rate of failure and pose unreasonably dangerous risks to patients implanted with this product. Defendant failed to exercise reasonable care to inform users, including Plaintiff and Plaintiff's physicians, of the true risks and dangers of using AlloDerm for hernia repair and abdominal reconstruction and instead heavily promoted, marketed, and sold AlloDerm for use in hernia repair and abdominal reconstruction surgeries despite the fact this was an improper use and/or application of the biologic product.

72. AlloDerm was further defective due to inadequate post-marketing warning, labeling, or instruction because, after Defendant knew or should have known of the high risk of implant failure, serious bodily harm, and additional surgery, Defendant failed to provide an adequate warning to persons such as Plaintiff and Plaintiff's physicians of the biologic product knowing it would fail, cause serious injury and result in additional surgery.

73. Defendant had no reason to believe that those for whose use their product was supplied would realize its extremely high rate of failure and associated risks and dangers.

74. Defendant, as a manufacturer and/or distributor of the biologic product, is held to the level of knowledge of an expert in the field.

75. Plaintiff and Plaintiff's physicians reasonably relied upon the skill, superior knowledge and judgment of the Defendant.

76. As the manufacturer of AlloDerm, Defendant had a duty to warn of risks, failures, and dangers potentially resulting from Plaintiff and Plaintiff's medical providers' use of the Defendant's hernia repair and abdominal reconstruction product.

77. Defendant's duty to warn is part of their general duty to design, manufacture, and sell products that are reasonably safe for their foreseeable uses.

78. Defendant breached its duty to warn as stated herein.

79. Defendant is strictly liable for all harm resulting from its failure to warn Plaintiff and Plaintiff's physicians of all the risks and unreasonable dangerous defects resulting from Plaintiff and Plaintiff's physician's foreseeable use of AlloDerm for hernia repair.

80. Defendant's conduct is outrageous because of intentional or reckless indifference to the health and safety of the public in general, including Plaintiff, so as to justify an award of punitive damages.

81. As a direct and proximate result of the Defendant's failure to warn, Plaintiff sustained and will continue to sustain damages in the future, including, but not limited to past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and loss of income and loss of, or diminution of, the ability to earn income in the future.

WHEREFORE, Plaintiff prays for judgment in Count I against Defendant LifeCell for damages for pain and suffering, loss of enjoyment of life, past and future medical expense, past and future lost wages, and punitive damages to punish and deter any such conduct in the future, together with interest from the date of injury and costs, along with any other relief this Court deems just and proper under the circumstances.

**COUNT II - Products Liability Defective Manufacturing**  
**(N.J.S.A. 2A:58C-1, et seq.)**

82. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege in the alternative as follows.

83. At all times material to this action, Defendant was responsible for designing, developing, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling, and/or selling AlloDerm.

84. At all times material to this action, AlloDerm was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including Plaintiff and Plaintiff's physicians, without substantial change in the condition in which it was sold.

85. Defendant, as the manufacturer and seller of AlloDerm, had a duty to Plaintiff and Plaintiff's physicians to design, develop, process, manufacture, test, package, advertise, promote, market, distribute, label, and/or sell a product that is reasonably safe, suitable, and fit for its intended or reasonably foreseeable uses.

86. At all times material to this action. AlloDerm was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, Defendant's AlloDerm contained manufacturing defects, which rendered the product unreasonably dangerous for its intended use;
- b. AlloDerm's manufacturing defects occurred while the product was in the possession and control of Defendant;
- c. AlloDerm's manufacturing defects existed before it left the control of the Defendants.

87. As a direct and proximate result of AlloDerm's manufacturing defects, Plaintiff sustained and will continue to sustain damages in the future, including, but not limited to past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and loss of income and loss of, or diminution of, the ability to earn income in the future.

WHEREFORE, Plaintiff prays for judgment in Count II against Defendant LifeCell for damages for past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and loss of income and loss of, or diminution of, the ability to earn income in the future and punitive damages to punish and deter any such conduct in the future, together with interest from the date of injury and costs, along with any other relief this Court deems just and proper under the circumstances.

**COUNT III - Products Liability Design Defect**  
**(N.J.S.A. 2A:58C-1, et seq.)**

88. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege in the alternative as follows.

89. At all times material to this action, Defendant was responsible for designing, developing, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling, and/or selling AlloDerm.

90. Defendant, as the manufacturer and seller of AlloDerm, had a duty to Plaintiff and Plaintiff's physicians to design, develop, process, manufacture, test, package, advertise, promote, market, distribute, label, and/or sell a product that is reasonably safe, suitable, and fit for its intended or reasonably foreseeable uses.

91. At all times material hereto, AlloDerm was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold by the Defendants, in a defective and unreasonably dangerous condition because it was not safe for its reasonably foreseeable and intended use in hernia repair and abdominal reconstruction surgeries.

92. AlloDerm is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

93. At all times material to this action, AlloDerm was expected to reach, and did reach, consumers throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

94. At all times material to this action, AlloDerm was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, AlloDerm contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiffs, to risks that exceeded the benefits of its use, including but not limited to, the risks of hernia recurrence, abdominal deformity, pain, overall sickness, and disability;



- b. When placed in the stream of commerce, AlloDerm was defective in design and/or formulation, making the use of the product more dangerous than an ordinary consumer would expect, and more dangerous than the risks associated with the other allografts or biologic products on the market;
- c. AlloDerm's design defects existed before it left the control of the Defendant;
- d. AlloDerm was insufficiently tested;
- e. AlloDerm caused harmful side effects that outweighed any potential utility; and
- f. Defendant's product was not accompanied by adequate instructions and/or warnings to fully apprise Plaintiff and Plaintiff's physicians of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendant liable to Plaintiff.

95. In addition, at the time the biologic product left the control of Defendant, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

96. As a direct and proximate result of the biologic product's design, Plaintiff sustained and will continue to sustain damages in the future, including, but not limited to past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and loss of income and loss of, or diminution of, the ability to earn income in the future.

WHEREFORE, Plaintiff prays for judgment in Count III against Defendant LifeCell for damages for past, present and future pain and suffering, serious and permanent physical injuries, loss of enjoyment of life, past and future medical expenses, and loss of income and loss of, or diminution of, the ability to earn income in the future and punitive damages to punish and deter

any such conduct in the future, together with interest from the date of injury and costs, along with any other relief this Court deems just and proper under the circumstances.

**COUNT IV - Per Quod**

97. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges in the alternative as follows.

98. Plaintiff's spouse was, at all times relevant herein, the legal partner of Plaintiff and, lives and cohabits with Plaintiff.

99. By reason of the foregoing, Plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment, attendance, and for medications, and will necessarily incur further expenses of a similar nature for Plaintiff in the future.

100. By reason of the foregoing, the Plaintiff's spouse has been caused, presently and in the future the loss of his spouse's companionship, services, society, and the abilities of his spouse have been impaired and depreciated, and the marital association between legal partners has been altered, and as such the Plaintiff has been caused great mental anguish.

WHEREFORE, Plaintiffs pray for judgment in Count IV against Defendant LifeCell for damages for pain and suffering, loss of enjoyment of life, past and future medical expense, past and future lost wages, and punitive damages to punish and deter any such conduct in the future, together with interest from the date of injury and costs, along with any other relief this Court deems just and proper under the circumstances.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against Defendant for:

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
2. Restitution and disgorgement of profits;
3. Reasonable attorneys' fees;
4. The costs of these proceedings;
5. All ascertainable economic damages;
6. Punitive damages;
7. Such other and further relief as this Court deems just and proper.

**Respectfully submitted,**

**ANAPOL, SCHWARTZ, WEISS, COHAN,  
FELDMAN & SMALLEY, P.C.**

  
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**LAWRENCE R. COHAN, ESQUIRE**  
**ADRIANNE E. WALVOORD, ESQUIRE**

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**SOL H. WEISS, ESQUIRE**  
**sweiss@anapolschwartz.com**

*Of Counsel*

*Attorneys for Plaintiffs*

Dated: \_\_\_\_\_

**JURY DEMAND**

Plaintiffs hereby demand a trial by jury.

**DESIGNATION OF TRIAL COUNSEL**


Pursuant to R. 4:25-4, Lawrence R. Cohan, Esquire and Adrienne E. Walvoord, Esquire are hereby designated as trial counsel for Plaintiffs in the within matter.

**RULE 4:5-1 CERTIFICATION**

I hereby certify that to the best of my knowledge that matter in controversy is the subject of numerous other actions all of which are assigned to the Honorable Jessica R. Mayer in the Superior Court of New Jersey Middlesex County under the Master Case Number 295, and that no other parties are necessary to join at this time.

I hereby certify that the foregoing statements made by me are true. I am aware if any of the foregoing statements made by me are willfully false, I am subject to punishment.

**ANAPOL, SCHWARTZ, WEISS, COHAN,  
FELDMAN & SMALLEY, P.C.**

  
\_\_\_\_\_  
**LAWRENCE R. COHAN, ESQUIRE  
ADRIANNE E. WALVOORD, ESQUIRE**  
*Attorneys for Plaintiffs*

**SOL H. WEISS, ESQUIRE**  
*Of Counsel*

Dated: \_\_\_\_\_

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing Plaintiffs' Master Long Form Complaint *In Re: AlloDerm® Litigation* has been served this same day by electronic mail to the following counsel for Defendant at the following address:

David W. Field, Esquire  
Lowenstein Sandler PC  
65 Livingston Ave.  
Roseland, NJ 07068  
[dfield@lowenstein.com](mailto:dfield@lowenstein.com)  
*Liaison Counsel for Defendant LifeCell Corporation*

The foregoing statement made by me is true. I am aware that if the statement is willfully false, I am subject to punishment.

**ANAPOL, SCHWARTZ, WEISS, COHAN,  
FELDMAN & SMALLEY, P.C.**

  
\_\_\_\_\_  
**LAWRENCE R. COHAN, ESQUIRE**  
*Attorneys for Plaintiffs*