LOWENSTEIN SANDLER PC

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IN RE: ALLODERM® LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY CASE NO. 295 CIVIL ACTION
PLAINTIFFS, Plaintiff, v. LIFECELL CORPORATION Defendant.	ANSWER AND DEFENSES TO MASTER LONG FORM COMPLAINT JURY TRIAL DEMANDED

Defendant LifeCell Corporation ("LifeCell" or "defendant"), by and through its attorneys, hereby responds to the Master Long Form Complaint filed by Plaintiffs as follows:

- 1. The statements set forth in paragraph 1 of the Master Long Form Complaint are not factual allegations to which a denial or admission would be appropriate. To the extent the Court Rules require a response to the statements set forth in paragraph 1, Defendant is without knowledge and information sufficient so as to form a response to those statements.
- 2. Defendant objects to the allegations set forth in paragraph 2 of the Master Long Form Complaint on the ground that they purport to state a legal conclusion.

- 3. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 3 of the Master Long Form Complaint.
- 4. Defendant denies the allegations set forth in paragraph 4 of the Master Long Form Complaint.

I. Parties, Venue And Jurisdiction

- 5. Defendant denies that Plaintiff suffered damages as a result of the use of AlloDerm, and otherwise is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 5 of the Master Long Form Complaint.
- 6. Defendant denies that Plaintiff suffered damages as a result of the use of AlloDerm, and otherwise is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 6 of the Master Long Form Complaint.
- 7. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 7 of the Master Long Form Complaint.
- 8. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 8 of the Master Long Form Complaint.
- 9. The statements set forth in paragraph 9 of the Master Long Form Complaint are not factual allegations to which a denial or admission would be appropriate. To the extent the Court Rules require a response to the statements set forth in paragraph 9, Defendant is without knowledge and information sufficient so as to form a response to those statements
- 10. Defendant admits the allegations set forth in paragraph 10 of the Master Long Form Complaint.
- 11. Defendant admits the allegations set forth in paragraph 11 of the Master Long Form Complaint.
- 12. Defendant admits the allegations set forth in paragraph 12 of the Master Long Form Complaint.

- 13. Defendant admits the allegations set forth in paragraph 13 of the Master Long Form Complaint.
- 14. Defendant admits the allegations set forth in paragraph 14 of the Master Long Form Complaint.
- 15. Defendant admits the allegations set forth in paragraph 15 of the Master Long Form Complaint.
- 16. Defendant denies that Plaintiff suffered injuries as a result of the use of AlloDerm, and denies that Defendant was negligent or engaged in wrongful conduct, and otherwise is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 16 of the Master Long Form Complaint.
- 17. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 17 of the Master Long Form Complaint.

II. General Allegations

- 18. Defendant admits the allegations set forth in paragraph 18 of the Master Long Form Complaint.
- 19. Defendant admits that the allegations set forth in paragraph 19 of the Master Long Form Complaint describes in simple terms some of the process steps which human tissue is processed to create AlloDerm.
- 20. Defendant admits the allegations set forth in paragraph 20 of the Master Long Form Complaint.
- 21. Defendant admits the allegations set forth in paragraph 21 of the Master Long Form Complaint.
- 22. Defendant admits the allegations set forth in paragraph 22 of the Master Long Form Complaint.
 - 23. Defendant denies the allegations set forth in paragraph 23 of the Complaint.

- 24. Defendant admits the allegations set forth in paragraph 24 of the Master Long Form Complaint.
- 25. Defendant admits the allegations set forth in paragraph 25 of the Master Long Form Complaint.
- 26. Defendant denies that it advertised, promoted, marketed, distributed and sold AlloDerm for use in hernia repair surgeries starting in or around 1994, but otherwise admits the allegations set forth in paragraph 26 of the Master Long Form Complaint regarding LifeCell's activities in or around 1994.
- 27. Defendant denies the allegations set forth in paragraph 27 of the Master Long Form Complaint.
- 28. Defendant denies the allegations set forth in paragraph 28 of the Master Long Form Complaint.
- 29. Defendant denies the allegations set forth in paragraph 29 of the Master Long Form Complaint.
- 30. Defendant denies the allegations set forth in paragraph 30 of the Master Long Form Complaint.
- 31. Defendant is unable to admit or deny the allegations set forth in paragraph 31 of the Master Long Form Complaint because no time period is alleged, but to the extent the Court Rules require a response to the allegations set forth in paragraph 31, Defendant denies those allegations.
- 32. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 32 of the Master Long Form Complaint.
- 33. Defendant admits the allegations set forth in paragraph 33 of the Master Long Form Complaint, except that it denies that such advice began in 2008.
- 34. Defendant admits the allegations set forth in paragraph 34 of the Master Long Form Complaint, except that it denies that such advice began in 2008.

- 35. Defendant admits the allegations set forth in paragraph 35 of the Master Long Form Complaint.
- 36. Defendant admits that it advertises AlloDerm as a safe and effective product for hernia repair for certain indicated conditions and otherwise denies the allegations set forth in paragraph 36 of the Master Long Form Complaint.
- 37. Defendant admits the allegations set forth in paragraph 37 of the Master Long Form Complaint.
- 38. Defendant denies the allegations set forth in paragraph 38 of the Master Long Form Complaint.
- 39. Defendant admits the allegations set forth in paragraph 39 of the Master Long Form Complaint.
- 40. Defendant admits the allegations set forth in paragraph 40 of the Master Long Form Complaint, but denies that AlloDerm is subject to FDA clearance and approval regulations.
- 41. Defendant admits the allegations set forth in paragraph 41 of the Master Long Form Complaint.
- 42. Defendant admits the allegations set forth in paragraph 42 of the Master Long Form Complaint.
- 43. Defendant denies the allegations set forth in paragraph 43 of the Master Long Form Complaint.
- 44. Defendant denies the allegations set forth in paragraph 44 of the Master Long Form Complaint.
- 45. Defendant denies the allegations set forth in paragraph 45 of the Master Long Form Complaint.
- 46. Defendant denies the allegations set forth in paragraph 46 of the Master Long Form Complaint.
- 47. Defendant denies the allegations set forth in paragraph 47 of the Master Long Form Complaint.

- 48. Defendant denies the allegations set forth in paragraph 48 of the Master Long Form Complaint.
- 49. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 49 of the Master Long Form Complaint.
- 50. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 50 of the Master Long Form Complaint.
- 51. Defendant denies the allegations set forth in paragraph 51 of the Master Long Form Complaint.
- 52. Defendant denies the allegations set forth in paragraph 52 of the Master Long Form Complaint.

III. Discovery Rule, Tolling and Fraudulent Concealment

- 53. Defendant repeats and realleges each and every response set forth in preceding paragraphs as if set forth at length herein.
- 54. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 54 of the Master Long Form Complaint.
- 55. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 55 of the Master Long Form Complaint.
- 56. Defendant denies the allegations set forth in paragraph 52 of the Master Long Form Complaint.
- 57. Defendant denies the allegations set forth in paragraph 53 of the Master Long Form Complaint.
- 58. Defendant denies the allegations set forth in paragraph 54 of the Master Long Form Complaint.

III. Claims for Relief

59. Defendant objects to the allegations set forth in paragraph 59 of the Master Long Form Complaint on the ground that they purport to state a legal conclusion.

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

- 60. Defendant repeats and realleges each and every response set forth in preceding paragraphs as if set forth at length herein.
- 61. Defendant objects to the allegations set forth in paragraph 61 in the First Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 62. Defendant objects to the allegations set forth in paragraph 62 in the First Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 63. Defendant denies the allegations set forth in paragraph 63 in the First Count of the Master Long Form Complaint.
- 64. Defendant objects to the allegations set forth in paragraph 64 in the First Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 65. Defendant denies the allegations set forth in paragraph 65 in the First Count of the Master Long Form Complaint.
- 66. Defendant denies the allegations set forth in paragraph 66 in the First Count of the Master Long Form Complaint.
- 67. Defendant denies the allegations set forth in paragraph 67 in the First Count of the Master Long Form Complaint.
- 68. Defendant denies the allegations set forth in paragraph 68 in the First Count of the Master Long Form Complaint.
- 69. Defendant denies the allegations set forth in paragraph 69 in the First Count of the Master Long Form Complaint.
- 70. Defendant denies the allegations set forth in paragraph 70 in the First Count of the Master Long Form Complaint.
- 71. Defendant denies the allegations set forth in paragraph 71 in the First Count of the Master Long Form Complaint.

- 72. Defendant denies the allegations set forth in paragraph 72 in the First Count of the Master Long Form Complaint.
- 73. Defendant denies the allegations set forth in paragraph 73 in the First Count of the Master Long Form Complaint.
- 74. Defendant objects to the allegations set forth in paragraph 74 in the First Count of the Master Long Form Complaint on the ground that they are duplicative of paragraph 64 and on the ground that they state a legal conclusion.
- 75. Defendant denies the allegations set forth in paragraph 75 in the First Count of the Master Long Form Complaint.
- 76. Defendant objects to the allegations set forth in paragraph 76 in the First Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 77. Defendant objects to the allegations set forth in paragraph 77 in the First Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 78. Defendant denies the allegations set forth in paragraph 78 in the First Count of the Master Long Form Complaint.
- 79. Defendant denies the allegations set forth in paragraph 79 in the First Count of the Master Long Form Complaint.
- 80. Defendant denies the allegations set forth in paragraph 80 in the First Count of the Master Long Form Complaint.
- 81. Defendant denies the allegations set forth in paragraph 81 in the First Count of the Master Long Form Complaint.

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

- 82. Defendant repeats and realleges each and every response set forth in preceding paragraphs as if set forth at length herein.
- 83. Defendant admits the allegations set forth in paragraph 83 in the Second Count of the Master Long Form Complaint.

- 84. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 84 in the Second Count of the Master Long Form Complaint.
- 85. Defendant objects to the allegations set forth in paragraph 85 in the Second Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 86. Defendant denies the allegations set forth in paragraph 86 in the Second Count of the Master Long Form Complaint.
- 87. Defendant denies the allegations set forth in paragraph 87 in the Second Count of the Master Long Form Complaint.

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

- 88. Defendant repeats and realleges each and every response set forth in the preceding paragraphs as if set forth at length herein.
- 89. Defendant admits the allegations set forth in paragraph 89 in the Third Count of the Master Long Form Complaint.
- 90. Defendant objects to the allegations set forth in paragraph 90 in the Third Count of the Master Long Form Complaint on the ground that they state a legal conclusion.
- 91. Defendant denies the allegations set forth in paragraph 91 in the Third Count of the Master Long Form Complaint.
- 92. Defendant denies the allegations set forth in paragraph 92 in the Third Count of the Master Long Form Complaint.
- 93. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 93 in the Third Count of the Master Long Form Complaint.
- 94. Defendant denies the allegations set forth in paragraph 94 in the Third Count of the Master Long Form Complaint.

- 95. Defendant denies the allegations set forth in paragraph 95 in the Third Count of the Master Long Form Complaint.
- 96. Defendant denies the allegations set forth in paragraph 96 in the Third Count of the Master Long Form Complaint.

COUNT IV - Per Quod

- 97. Defendant repeats and realleges each and every response set forth in the preceding paragraphs as if set forth at length herein.
- 98. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 98 in the Fifth Count of the Master Long Form Complaint.
- 99. Defendant is without knowledge and information sufficient so as to form a response to the allegations set forth in paragraph 99 in the Fifth Count of the Master Long Form Complaint.
- 100. Defendant denies the allegations set forth in paragraph 100 in the Fifth Count of the Master Long Form Complaint.

DEFENSES.

FIRST DEFENSE

The Master Long Form Complaint fails to state a claim upon which relief may be granted against defendant.

SECOND DEFENSE

Plaintiffs' claims against defendant are barred by the applicable statute of limitations or statute of repose.

THIRD DEFENSE

Plaintiffs' claims against defendant are barred by the equitable doctrines of laches, estoppel, and waiver.

FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, and accord and satisfaction.

FIFTH DEFENSE

Plaintiffs' losses, if any, are the result of conduct by parties over which defendant had no control, or intervening or superceding causes over which defendant had no control.

SIXTH DEFENSE

Plaintiffs' claims against defendant are barred to the extent that plaintiffs failed to mitigate their damages, if any.

SEVENTH DEFENSE

Defendant did not breach any duty owed to plaintiffs or any other party to this litigation.

EIGHTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the matters alleged in the Master Long Form Complaint. Pursuant to the doctrines of assumption of risk or informed consent, this conduct bars in whole or in part the damages plaintiff seeks to recover.

NINTH DEFENSE

Any injuries incurred by plaintiffs were not proximately caused by defendant.

TENTH DEFENSE

Defendant is free from any negligence.

ELEVENTH DEFENSE

Plaintiffs' claims are barred or reduced by the contributory or comparative negligence of the plaintiffs.

TWELFTH DEFENSE

Any injury or expenses incurred by plaintiffs may have been caused, in whole or in part, by operation of nature or act of God.

THIRTEENTH DEFENSE

Defendant did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Master Long Form Complaint.

FOURTEENTH DEFENSE

Plaintiffs have failed to join and/or keep in this litigation indispensable parties needed to adjudicate this matter.

FIFTEENTH DEFENSE

Plaintiffs lack standing to assert any claims against defendant.

SIXTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

SEVENTEENTH DEFENSE

The Master Long Form Complaint's prayer for damages is barred because plaintiffs' damages, if any, are speculative, uncertain, and incapable of being ascertained.

EIGHTEENTH DEFENSE

To the extent plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate defendant's rights under the United States Constitution.

NINETEENTH DEFENSE

Should defendant be held liable to plaintiffs, defendant is entitled to a credit or set off for the total of all amounts paid to plaintiffs from all other sources.

TWENTIETH DEFENSE

Defendant's liability, if any, will not result from its own conduct, but instead, will derive solely from an obligation imposed by law. As such, defendant is entitled to express and/or implied indemnity from other defendants and/or third parties not yet parties to this suit.

TWENTY-FIRST DEFENSE

At all relevant times Defendant's packaging, marketing and educational materials for AlloDerm contained warnings that were adequate to advise intended users of AlloDerm of the appropriate use and risks of AlloDerm

TWENTY-SECOND DEFENSE

Plaintiffs fail to state a claim for punitive damages for which relief may be granted, and fail to state a claim for punitive damages with the requisite degree of particularity.

TWENTY-THIRD DEFENSE

Any duty to warn on the part of defendant was satisfied by defendant's instructions to the prescribing physician, under the "learned intermediary" doctrine.

TWENTY-FOURTH DEFENSE

At all relevant times, no feasible and safer alternative existed to AlloDerm for use in complex hernia repair.

TWENTY-FIFTH DEFENSE

AlloDerm was at all times relevant to this litigation the state of the art in complex hernia repair.

TWENTY-SIXTHDEFENSE

Defendant reserves the right to supplement its Answer with additional defenses that become available or apparent during the course of investigation, preparation, or discovery, and/or to amend its Answer accordingly.

WHEREFORE, defendant LifeCell Corporation demands judgment against plaintiffs Anne Marie Remington and Melvin Remington to include the following:

- (1) dismissal with prejudice of the Master Long Form Complaint;
- (2) costs and reasonable attorneys' fees; and
- (3) all other relief that the Court deems appropriate and proper.

LOWENSTEIN SANDLER PC

Attorneys At Law 65 Livingston Avenue Roseland, New Jersey 07068 973.597.2500 Attorneys for Defendant LifeCell Corporation

Dated: November 16, 2011

Stephen R. Buckingham

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, defendants designate David W. Field and Stephen R. Buckingham as trial counsel.

JURY DEMAND

Defendant demands trial by jury as to all issues so triable.

LOWENSTEIN SANDLER PC

Attorneys At Law 65 Livingston Avenue Roseland, New Jersey 07068 973.597.2500 Attorneys for Defendant

LifeCell Corporation

Dated: November 16, 2011

Stepher R. Buckingham

CERTIFICATIONS

I hereby certify that pursuant to <u>R.</u> 4:5-1, the matters in controversy assigned to the Honorable Jessica R. Mayer under Master Case No. 295 are not the subject of any other action pending in any other Court or arbitration proceeding, nor is any other action or arbitration proceeding contemplated. I further certify that I am not aware of other parties who should be joined in this action at the present time. I further certify that this pleading was filed and served in accordance with the applicable Rule.

Dated: November 16, 2011

btephen R. Buckingham

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Defendant's Answer and Defenses to Master Long Form Complaint has been served this same day by electronic mail to the following counsel for Plaintiffs at the following addresses:

Adrianne E. Walvoord, Esq. awalvoord@anapolschwartz.com

Lawrence R. Cohan, Esq. <u>lcohan@anapolschwartz.com</u>

Dated: November 16, 2011

Stephen R Buckingham