

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**In re: Cook Medical, Inc. Pelvic Repair  
System Products Liability Litigation**                    )     **MDL No. 2440**

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**THIS DOCUMENT RELATES TO: ALL CASES**

**ANSWER TO FIRST AMENDED MASTER LONG FORM COMPLAINT  
AND JURY DEMAND**

Defendants Cook Medical Incorporated (hereinafter “Cook Medical”), Cook Biotech Incorporated (hereinafter “Cook Biotech”), and Cook Incorporated (sometimes hereafter collectively referred to as “Cook” or the “Cook Defendants”) hereby submit their answer to the First Amended Master Long Form Complaint and Jury Demand (“Master Complaint”).

**I.     PARTIES**

**A.     Plaintiffs**

1.     The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by the United States Food and Drug Administration (“FDA”) in 21 C.F.R. § 878.3300(a). The Cook Defendants are without information as to the remaining allegations in paragraph 1.

2.     The Cook Defendants are without information as to the allegations in paragraph 2.

**B.     Defendants**

3.     The Cook Defendants admit only that Cook Incorporated is an Indiana corporation with its principal place of business at 750 N. Daniels Way, Bloomington, Indiana 47404-9120, and that, per its website, it “is also on the forefront of developing next generation technologies that advance combination drug/device and biologic/device design concepts.” The

Cook Defendants further admit only that Cook Incorporated does business in all states of the United States of America. The Cook Defendants deny all other allegations in paragraph 3.

4. The Cook Defendants admit only that Cook Biotech is an Indiana corporation with its principal place of business at 1425 Innovation Place, West Lafayette, Indiana 47906, and that Cook Biotech was created to develop and manufacture biomaterials from natural tissue sources for use in medical products. The Cook Defendants further admit only that Cook Biotech conducts research, development and manufacturing operations in a state-of-the-art facility; that Cook Biotech operates its own processing and production line where natural tissues are transformed into acellular biomaterials; that, in cooperation with Purdue University researchers, Cook Biotech developed the Surgisis® Biodesign® system and line of products that can remodel native tissues using a biomaterial made from non-dermis, non-crosslinked porcine small intestinal submucosa (the “Biodesign Products” or “Biodesign Product”); that several FDA-cleared products using this technology are currently available from Cook Biotech and Cook Medical, as Cook Biotech’s distributor; and that numerous potential medical applications for products made from porcine small intestinal submucosa and other natural tissues are under development. The Cook Defendants deny all other allegations in paragraph 4.

5. The Cook Defendants admit only that Cook Medical is an Indiana corporation with its principal place of business at 1025 W. Acuff Road, Bloomington, Indiana 47402-4195, that Cook Medical was established to offer a synchronized service for the efficient purchase and distribution in the United States of medical devices manufactured by subsidiaries of Cook Group Incorporated (“Cook Group”), including Cook Biotech, that Cook Medical has a particular focus on lowering supply chain costs, and that Cook Medical coordinates price file access, purchase orders, ship points and accounts payable. The Cook Defendants further admit only that Cook

Medical does business in all states of the United States of America. The Cook Defendants deny all other allegations in paragraph 5.

6. The Cook Defendants admit only that Cook Biotech has designed, patented, manufactured and labeled the Biodesign Products, that Vance Products Incorporated d/b/a Cook Urological Incorporated (“Cook Urological”) (now merged into Cook Incorporated), marketed, sold and distributed some Biodesign Products until October 17, 2005, and that Cook Medical has marketed, sold, and distributed the Biodesign Products since October 17, 2005. The Cook Defendants deny all other allegations in paragraph 6.

7. The Cook Defendants deny any and all allegations in paragraph 7.

8. The Cook Defendants admit only that some of the officers of some of the Cook Defendants are also officers of some of the other Cook Defendants. The Cook Defendants deny any and all other allegations in paragraph 8.

9. The Cook Defendants deny that they have “were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling” any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants admit only that Cook Biotech has designed, patented, manufactured and labeled the Biodesign Products, that Cook Urological (now merged into Cook Incorporated), marketed, sold and distributed some Biodesign Products until October 17, 2005, and that Cook Medical has marketed, sold, and distributed the Biodesign Products since October 17, 2005. The Cook Defendants deny any and all remaining allegations in paragraph 9.

10. The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 10.

## **II. JURISDICTION AND VENUE**

11. The Cook Defendants admit only that, if Plaintiffs include individuals who are residents of any state other than Indiana, then those Plaintiffs and the Cook Defendants are residents of different States for purposes of diversity subject matter jurisdiction. The Cook Defendants are without information as to the remaining allegations in paragraph 11.

12. The Cook Defendants admit only that Cook Incorporated and Cook Medical conduct business in all states of the United States of America. The Cook Defendants deny any and all remaining allegations in paragraph 12.

13. The Cook Defendants admit only that Cook Incorporated and Cook Medical conduct business in all states of the United States of America. The Cook Defendants deny any and all remaining allegations in paragraph 13.

## **III. “DEFENDANTS’ PELVIC MESH PRODUCTS”<sup>1</sup>**

14. The Cook Defendants admit only that Cook Biotech has designed and manufactured the Biodesign Products. The Cook Defendants further admit only that Cook Urological, which merged into Cook Incorporated effective January 1, 2012, marketed and sold, Biodesign Products for the treatment of pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”) beginning in approximately 1999 until October 17, 2005. The Cook Defendants further admit only that Cook Medical began marketing and selling Biodesign

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<sup>1</sup> The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by FDA in 21 C.F.R. § 878.3300(a).

Products for the treatment of POP and SUI beginning on October 17, 2005. The Cook Defendants deny any and all remaining allegations in paragraph 14.

15. The Cook Defendants admit only that Cook Biotech sought and obtained clearance from FDA under Section 510(k) of the Food, Drug & Cosmetic Act (“FDCA”) to market a device then known as the “Surgisis™ Sling” on September 23, 1999, and to market a device then known as the “Stratasis Sling Kit” on April 9, 2002. The Cook Defendants deny all other allegations in paragraph 15.

16. The Cook Defendants admit only that Cook Biotech has designed and manufactured the Biodesign Products. The Cook Defendants further admit only that Cook Urological, which merged into Cook Incorporated effective January 1, 2012, marketed and sold, Biodesign Products for the treatment of POP and SUI beginning in approximately 1999 until October 17, 2005. The Cook Defendants further admit only that Cook Medical began marketing and selling Biodesign Products for the treatment of POP and SUI beginning on October 17, 2005. The Cook Defendants deny any and all remaining allegations in paragraph 16.

17. The Cook Defendants admit only that Cook Biotech has designed and manufactured the Biodesign Products. The Cook Defendants further admit only that Cook Urological, which merged into Cook Incorporated effective January 1, 2012, marketed and sold, Biodesign Products for the treatment of POP and SUI beginning in approximately 1999 until October 17, 2005. The Cook Defendants further admit only that Cook Medical began marketing and selling Biodesign Products for the treatment of POP and SUI beginning on October 17, 2005. The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 17.

18. The Cook Defendants admit only that Cook Medical previously stated on its website at [http://www.cookmedical.com/bioNew/bio\\_overview.html](http://www.cookmedical.com/bioNew/bio_overview.html) about the Biodesign Products what Plaintiffs quote in paragraph 18 (aside from typographical difference(s) in Plaintiffs' transcription of the web site text and that the language to which Plaintiffs have added emphasis in their quotation was not given special emphasis on the website). The Cook Defendants deny any and all other allegations in paragraph 18.

19. The Cook Defendants admit only that Cook Biotech previously stated on its website about its Biodesign Products what Plaintiffs quote in paragraph 19, except that the language to which Plaintiffs have added emphasis in their quotation was not given special emphasis on the website, and they deny any and all other allegations in paragraph 19.

20. The Cook Defendants admit only that on August 30, 2011, MED Institute, Incorporated, a Cook Group subsidiary, submitted to FDA on behalf of Cook Biotech a letter dated August 30, 2011, with which it forwarded a document entitled "Literature Review: The Safety and Effectiveness of Pelvic Organ Prolapse Repair Depends on the Type of Biomaterial Used," and that such document stated, among other things, that "any inflammation is localized in regions where small remnants of the synthetic suture used to affix the graft remain," but the Cook Defendants deny that the excerpt from that literature review which Plaintiffs quote was given special emphasis in the document submitted to FDA. The Cook Defendants deny all other allegations in paragraph 20.

21. The Cook Defendants admit only that the articles listed in paragraph 21 exist and that those articles state only what they state (which is not the same thing as what Plaintiffs allege they state), and the Cook Defendants deny all other allegations in paragraph 21.

#### **IV. FACTUAL BACKGROUND**

22. The Cook Defendants admit only that Cook Biotech has designed and manufactured the Biodesign Products. The Cook Defendants further admit only that Cook Urological, which merged into Cook Incorporated effective January 1, 2012, marketed and sold, Biodesign Products for the treatment of POP and SUI beginning in approximately 1999 until October 17, 2005. The Cook Defendants further admit only that Cook Medical began marketing and selling Biodesign Products for the treatment of POP and SUI beginning on October 17, 2005. The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 22 that relate to them, and are without information as to the remaining allegations in paragraph 22.

23. The Cook Defendants admit only that Cook Medical markets the Biodesign Products consistent with applicable provisions of the FDCA and applicable FDA regulations. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 23.

24. The Cook Defendants deny that they manufacture, market, sell, or distribute any products that are pelvic “surgical mesh” products as that term is defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 24.

25. The Cook Defendants admit only that Cook Biotech sought and obtained clearance from FDA under Section 510(k) of the FDCA to market the Biodesign Products. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic

“surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 25.

26. The Cook Defendants admit only that Cook Medical markets the Biodesign Products consistent with applicable provisions of the FDCA and applicable FDA regulations. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 26.

27. The Cook Defendants admit only that Cook Medical markets the Biodesign Products consistent with applicable provisions of the FDCA and applicable FDA regulations. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 27.

28. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 28.

29. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 29.

30. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 30, including subparagraphs a-k.

31. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 31.

32. The Cook Defendants deny any and all allegations in paragraph 32.

33. The Cook Defendants deny that they manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 33 that are related to them, and are without information as to the remaining allegations in paragraph 33.

34. The Cook Defendants admit only that the FDA Public Health Notification referenced in paragraph 34 states only what it states. The Cook Defendants deny the allegations to the extent that they attempt to characterize or interpret the FDA Public Health Notification referenced. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 34.

35. The Cook Defendants admit only that the FDA Safety Communication referenced in paragraph 35 states only what it states. The Cook Defendants deny the allegations to the extent that they attempt to characterize or interpret the FDA Safety Communication referenced. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 35.

36. The Cook Defendants admit only that the FDA Safety Communication referenced in paragraph 36 states only what it states, which is misquoted in part by Plaintiffs. The Cook Defendants deny the allegations to the extent that they attempt to characterize or interpret the

FDA Safety Communication referenced. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 36.

37. The Cook Defendants deny any and all allegations in paragraph 37.

38. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 38.

39. The Cook Defendants admit only that the publication referenced in paragraph 39 states only what it states. The Cook Defendants deny the allegations to the extent that they attempt to characterize or interpret that publication. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 39.

40. The Cook Defendants deny any and all allegations in paragraph 40.

41. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 41, including subparts (1) through (4).

42. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 42.

43. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 43, including subparagraphs a-w.

44. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 44.

45. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 45.

46. The Cook Defendants admit only that other treatments and devices for SUI and POP exist besides the Biodesign Products. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 46.

47. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 47.

48. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 48.

49. The Cook Defendants are without information regarding whether Plaintiffs had implanted in them any Biodesign Products, and, if so, the condition of any such Biodesign

Products. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 49.

50. The Cook Defendants are without information regarding whether Plaintiffs had implanted in them any Biodesign Products, and, if so, in what manner. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 50.

51. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 51.

52. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 52.

53. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 53.

54. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 54.

55. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21

C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 55, including subparagraphs a-l.

56. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 56.

57. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 57.

58. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 58.

59. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 59.

60. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 60.

61. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 61.

62. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 62.

63. The Cook Defendants deny any and all allegations in paragraph 63.

64. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 64.

65. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 65.

66. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 66.

67. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 67.

68. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 68.

69. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 69.

70. The Cook Defendants deny any and all allegations in paragraph 70.

71. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 71.

72. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 72.

73. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 73.

74. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 74.

75. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 75.

76. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 76.

77. The Cook Defendants deny any and all allegations in paragraph 77.

78. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 78.

79. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 79.

80. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 80.

81. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 81.

82. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 82.

#### V. **FRAUDULENT CONCEALMENT**<sup>2</sup>

83. The Cook Defendants deny any and all allegations in paragraph 83.

84. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 84.

85. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 85.

86. The Cook Defendants deny any and all allegations in paragraph 86.

87. The Cook Defendants deny any and all allegations in paragraph 87.

88. The Cook Defendants deny any and all allegations in paragraph 88.

89. The Cook Defendants deny any and all allegations in paragraph 89.

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<sup>2</sup> The Cook Defendants deny any and all allegations in this heading to Section V.

**VI. CAUSES OF ACTION**

**COUNT I**

**NEGLIGENCE<sup>3</sup>**

90. The Cook Defendants incorporate by reference their responses to paragraphs 1-89 (identified in paragraph 90 as paragraphs 1-96) as if fully stated herein.

91. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 91.

92. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 92, including subparagraphs a-j.

93. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 93, including subparagraphs a-b.

94. The Cook Defendants deny any and all allegations in paragraph 94, including subparagraphs a-b.

95. The Cook Defendants deny any and all allegations in paragraph 95.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count I, and for all other proper relief.

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<sup>3</sup> The Cook Defendants deny any and all allegations in this heading to Count I.

**COUNT II**

**STRICT LIABILITY—MANUFACTURING DEFECT**<sup>4</sup>

96. The Cook Defendants incorporate by reference their responses to paragraphs 1-95 (identified in paragraph 96 as paragraphs 1-102) as if fully stated herein.

97. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 97.

98. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 98.

99. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 99.

100. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 100.

101. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 101.

102. The Cook Defendants deny any and all allegations in paragraph 102.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count II, and for all other proper relief.

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<sup>4</sup> The Cook Defendants deny any and all allegations in this heading to Count II.

**COUNT III**

**STRICT LIABILITY—FAILURE TO WARN<sup>5</sup>**

103. The Cook Defendants incorporate by reference their responses to paragraphs 1-102 (identified in paragraph 103 as paragraphs 1-109) as if fully stated herein.

104. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 104.

105. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 105.

106. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 106.

107. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 107, including subparagraphs a-k.

108. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 108.

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<sup>5</sup> The Cook Defendants deny any and all allegations in this heading to Count III.

109. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 109.

110. The Cook Defendants deny any and all allegations in paragraph 110.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count III, and for all other proper relief.

#### **COUNT IV**

#### **STRICT LIABILITY—DEFECTIVE PRODUCT<sup>6</sup>**

111. The Cook Defendants incorporate by reference their responses to paragraphs 1-110 (identified in paragraph 111 as paragraphs 1-117) as if fully stated herein. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 111.

112. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 112.

113. To the extent that paragraph 113 contains allegations requiring a response, the Cook Defendants deny any and all such allegations.

114. To the extent that paragraph 114 contains allegations requiring a response, the Cook Defendants deny any and all such allegations.

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<sup>6</sup> The Cook Defendants deny any and all allegations in this heading to Count IV.

115. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 115.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count IV, and for all other proper relief.

## **COUNT V**

### **STRICT LIABILITY—DESIGN DEFECT<sup>7</sup>**

116. The Cook Defendants incorporate by reference their responses to paragraphs 1-115 (identified in paragraph 116 as paragraphs 1-122) as if fully stated herein.

117. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 117, including subparagraphs a-k.

118. The Cook Defendants deny any and all allegations in paragraph 118.

119. The Cook Defendants deny any and all allegations in paragraph 119.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count V, and for all other proper relief.

## **COUNT VI**

### **COMMON LAW FRAUD<sup>8</sup>**

120. The Cook Defendants incorporate by reference their responses to paragraphs 1-119 (identified in paragraph 120 as paragraphs 1-126) as if fully stated herein.

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<sup>7</sup> The Cook Defendants deny any and all allegations in this heading to Count V.

<sup>8</sup> The Cook Defendants deny any and all allegations in this heading to Count VI.

121. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 121.

122. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 122.

123. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 123.

124. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 124, including subparagraphs a-m.

125. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 125.

126. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 126.

127. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 127.

128. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 128.

129. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 129.

130. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 130.

131. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 131.

132. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 132.

133. The Cook Defendants deny any and all allegations in paragraph 133.

134. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 134.

135. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 135.

136. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 136.

137. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 137.

138. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 138.

139. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 139.

140. The Cook Defendants deny any and all allegations in paragraph 140.

141. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 141.

142. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 142.

143. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 143.

144. The Cook Defendants admit only that Cook Medical markets the Biodesign Products consistent with applicable provisions of the FDCA and applicable FDA regulations. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 144.

145. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 145.

146. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 146.

147. The Cook Defendants deny any and all allegations in paragraph 147.

148. The Cook Defendants deny any and all allegations in paragraph 148.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count VI, and for all other proper relief.

## **COUNT VII**

### **FRAUDULENT CONCEALMENT**<sup>9</sup>

149. The Cook Defendants incorporate by reference their responses to paragraphs 1-148 (identified in paragraph 149 as paragraphs 1-155) as if fully stated herein.

150. To the extent that paragraph 150 contains allegations requiring a response, the Cook Defendants deny any and all such allegations.

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<sup>9</sup> The Cook Defendants deny any and all allegations in this heading to Count VII.

151. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 151.

152. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 152.

153. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 153, including subparagraphs a-c.

154. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 154.

155. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 155.

156. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 156.

157. The Cook Defendants deny any and all allegations in paragraph 157.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count VII, and for all other proper relief.

**COUNT VIII**  
**CONSTRUCTIVE FRAUD<sup>10</sup>**

158. The Cook Defendants incorporate by reference their responses to paragraphs 1-157 (identified in paragraph 158 as paragraphs 1-164) as if fully stated herein.

159. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 159.

160. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 160.

161. The Cook Defendants are without information regarding the article referred to in paragraph 161 as “the recent study published in *Obstetrics & Gynecology*, August, 2010[.]” The Cook Defendants deny any and all allegations that are related to them in paragraph 161, and are without information as to any remaining allegations in paragraph 161.

162. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 162.

163. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 163.

164. The Cook Defendants deny any and all allegations in paragraph 164.

165. The Cook Defendants deny any and all allegations in paragraph 165.

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<sup>10</sup> The Cook Defendants deny any and all allegations in this heading to Count VIII.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count VIII, and for all other proper relief.

**COUNT IX**

**NEGLIGENT MISREPRESENTATION<sup>11</sup>**

166. The Cook Defendants incorporate by reference their responses to paragraphs 1-165 (identified in paragraph 166 as paragraphs 1-172) as if fully stated herein.

167. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 167.

168. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 168.

169. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 169.

170. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 170.

171. The Cook Defendants deny any and all allegations in paragraph 171.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count IX, and for all other proper relief.

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<sup>11</sup> The Cook Defendants deny any and all allegations in this heading to Count IX.

**COUNT X**

**BREACH OF EXPRESS WARRANTY<sup>12</sup>**

172. The Cook Defendants incorporate by reference their responses to paragraphs 1-171 (identified in paragraph 172 as paragraphs 1-182) as if fully stated herein.

173. The Cook Defendants admit only that Cook Biotech has designed, patented, manufactured and labeled the Biodesign Products, that Cook Urological (now merged into Cook Incorporated), marketed, sold and distributed some Biodesign Products until October 17, 2005, and that Cook Medical has marketed, sold, and distributed the Biodesign Products since October 17, 2005. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 173.

174. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 174.

175. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 175.

176. The Cook Defendants deny any and all allegations in paragraph 176.

177. The Cook Defendants are without information regarding whether any Biodesign Products reached Plaintiffs’ or Plaintiffs’ physicians, and, if so, the condition of any such Biodesign Products. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21

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<sup>12</sup> The Cook Defendants deny any and all allegations in this heading to Count X.

C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 177.

178. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 178, including subparagraphs a-c.

179. The Cook Defendants are without information regarding whether Plaintiffs had implanted in them any Biodesign Products, and, if so, in what manner. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 179.

180. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 180.

181. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 181 that are related to them, and are without information as to the remaining allegations in paragraph 181.

182. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 182.

183. The Cook Defendants deny any and all allegations in paragraph 183.

184. The Cook Defendants deny any and all allegations in paragraph 184.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count X, and for all other proper relief.

**COUNT XI**

**BREACH OF IMPLIED WARRANTY<sup>13</sup>**

185. The Cook Defendants incorporate by reference their responses to paragraphs 1-184 (identified in paragraph 185 as paragraphs 1-195) as if fully stated herein.

186. The Cook Defendants admit only that Cook Biotech has designed, patented, manufactured and labeled the Biodesign Products, that Cook Urological (now merged into Cook Incorporated), marketed, sold and distributed some Biodesign Products until October 17, 2005, and that Cook Medical has marketed, sold, and distributed the Biodesign Products since October 17, 2005. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 186.

187. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 187.

188. The Cook Defendants are without information regarding whether Plaintiffs had implanted in them any Biodesign Products, and, if so, in what manner. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 188.

189. The Cook Defendants deny any and all allegations in paragraph 189.

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<sup>13</sup> The Cook Defendants deny any and all allegations in this heading to Count XI.

190. The Cook Defendants are without information regarding whether any Biodesign Products reached Plaintiffs or Plaintiffs' physicians, and, if so, the condition of any such Biodesign Products. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic "surgical mesh" product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 190.

191. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic "surgical mesh" product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 191, including subparagraphs a-c.

192. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic "surgical mesh" product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 192.

193. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic "surgical mesh" product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 193.

194. The Cook Defendants deny any and all allegations in paragraph 194.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XI, and for all other proper relief.

## **COUNT XII**

### **VIOLATION OF CONSUMER PROTECTION LAWS<sup>14</sup>**

195. The Cook Defendants incorporate by reference their responses to paragraphs 1-194 (identified in paragraph 195 as paragraphs 1-205) as if fully stated herein.

196. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 196.

197. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 197.

198. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 198.

199. To the extent there are allegations in paragraph 199 requiring a response, the Cook Defendants deny any and all allegations in paragraph 199.

200. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 200.

201. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 201.

202. The Cook Defendants deny any and all allegations in paragraph 202.

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<sup>14</sup> The Cook Defendants deny any and all allegations in this heading to Count XII.

203. The Cook Defendants deny any and all allegations in paragraph 203.

204. The Cook Defendants deny any and all allegations in paragraph 204.

205. The Cook Defendants deny any and all allegations in paragraph 205.

206. The Cook Defendants deny any and all allegations in paragraph 206.

207. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 207.

208. The Cook Defendants deny any and all allegations in paragraph 208.

209. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 209.

210. The Cook Defendants deny any and all allegations in paragraph 210.

211. The Cook Defendants deny any and all allegations in paragraph 211.

212. The Cook Defendants deny any and all allegations in paragraph 212.

213. The Cook Defendants deny any and all allegations in paragraph 213.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XII, and for all other proper relief.

### **COUNT XIII**

#### **GROSS NEGLIGENCE<sup>15</sup>**

214. The Cook Defendants incorporate by reference their responses to paragraphs 1-213 (identified in paragraph 214 as paragraphs 1-224) as if fully stated herein.

215. The Cook Defendants deny any and all allegations in paragraph 215.

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<sup>15</sup> The Cook Defendants deny any and all allegations in this heading to Count XIII.

216. The Cook Defendants deny any and all allegations in paragraph 216.

217. The Cook Defendants deny any and all allegations in paragraph 217.

218. The Cook Defendants deny any and all allegations in paragraph 218.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XIII, and for all other proper relief.

#### **COUNT XIV**

#### **UNJUST ENRICHMENT<sup>16</sup>**

219. The Cook Defendants incorporate by reference their responses to paragraphs 1-218 (identified in paragraph 219 as paragraphs 1-229) as if fully stated herein.

220. The Cook Defendants admit only that Cook Biotech has designed, patented, manufactured and labeled the Biodesign Products, that Cook Urological (now merged into Cook Incorporated), marketed, sold and distributed some Biodesign Products until October 17, 2005, and that Cook Medical has marketed, sold, and distributed the Biodesign Products since October 17, 2005. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 220.

221. The Cook Defendants are without information regarding whether Plaintiffs purchased any Biodesign Products and, if so, for what purpose. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 221.

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<sup>16</sup> The Cook Defendants deny any and all allegations in this heading to Count XIV.

222. The Cook Defendants are without information regarding whether Plaintiffs purchased any Biodesign Products. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all remaining allegations in paragraph 222.

223. The Cook Defendants deny any and all allegations in paragraph 223.

224. The Cook Defendants deny any and all allegations in paragraph 224.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XIV, and for all other proper relief.

#### **COUNT XV**

#### **LOSS OF CONSORTIUM<sup>17</sup>**

225. The Cook Defendants incorporate by reference their responses to paragraphs 1-224 (identified in paragraph 225 as paragraphs 1-235) as if fully stated herein.

226. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 226.

227. The Cook Defendants deny any and all allegations in paragraph 227.

228. The Cook Defendants deny any and all allegations in paragraph 228.

229. The Cook Defendants deny any and all allegations in paragraph 229.

230. The Cook Defendants deny any and all allegations in paragraph 230.

231. The Cook Defendants deny any and all allegations in paragraph 231.

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<sup>17</sup> The Cook Defendants deny any and all allegations in this heading to Count XV.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XV, and for all other proper relief.

**COUNT XVI**

**PUNITIVE DAMAGES<sup>18</sup>**

232. The Cook Defendants incorporate by reference their responses to paragraphs 1-231 (identified in paragraph 232 as paragraphs 1-242) as if fully stated herein.

233. The Cook Defendants deny any and all allegations in paragraph 233.

234. The Cook Defendants deny any and all allegations in paragraph 234.

235. The Cook Defendants deny any and all allegations in paragraph 235.

236. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 236.

237. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 237.

238. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 238.

239. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 239.

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<sup>18</sup> The Cook Defendants deny any and all allegations in this heading to Count XVI.

240. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 240.

241. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 241.

242. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 242.

243. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 243.

244. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 244.

245. The Cook Defendants deny that they or any related company manufacture, market, or sell any product that is a pelvic “surgical mesh” product as defined by FDA in 21 C.F.R. § 878.3300(a). The Cook Defendants deny any and all allegations in paragraph 245.

246. The Cook Defendants deny any and all allegations in paragraph 246.

247. The Cook Defendants deny any and all allegations in paragraph 247.

248. The Cook Defendants deny any and all allegations in paragraph 248.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XVI, and for all other proper relief.

**COUNT XVII**

**DISCOVERY RULE AND TOLLING<sup>19</sup>**

249. The Cook Defendants incorporate by reference their responses to paragraphs 1-248 (identified in paragraph 249 as paragraphs 1-259) as if fully stated herein.

250. To the extent that paragraph 250 contains allegations requiring a response, the Cook Defendants deny any and all allegations in paragraph 250.

251. The Cook Defendants deny any and all allegations in paragraph 251.

252. The Cook Defendants deny any and all allegations in paragraph 252.

253. The Cook Defendants deny any and all allegations in paragraph 253.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing by their allegations in Count XVII, and for all other proper relief.

**FURTHER ANSWERS AND AFFIRMATIVE DEFENSES**

1. Plaintiffs assumed the risk associated with the use of any medical device or product made by Cook Biotech or sold by Cook Medical or Cook Urological (now merged into Cook Incorporated) in connection with medical treatment provided to them by providing their informed consent prior to undergoing medical treatment.

2. One or more of Plaintiffs' claims fails to state a claim upon which relief may be granted.

3. Any medical device or product made by Cook Biotech or sold by Cook Medical or Cook Urological (now merged into Cook Incorporated) was supplied to a knowledgeable and sophisticated user of such product, who was a learned intermediary, with adequate warnings or instructions for use, or the learned intermediary otherwise had knowledge of such information.

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<sup>19</sup> The Cook Defendants deny any and all allegations in this heading to Count XVII.

4. Plaintiffs' fault caused or contributed to the conditions alleged in the Master Complaint such that their fault diminishes proportionately any amount awarded as compensatory damages.

5. The Cook Defendants reserve the right to assert that Plaintiffs' damages, if any, are the result of the acts or omissions of one of its co-defendants and any entities related to its co-defendants, where applicable; one or more of the physicians, surgeons, or other healthcare providers who treated Plaintiffs, hospitals where they were treated, or such entities' employees, agents, contractors or other persons or entities, who will be identified to the parties within a reasonable time after learning of their identities and the basis for such a claim. Any such fault diminishes proportionally any amount awarded as compensatory damages to Plaintiffs.

6. Any medical device or product that was made by Cook Biotech or sold by Cook Medical or Cook Urological (now merged into Cook Incorporated) that is involved in this case conformed to the recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, and distributed.

7. Any medical device or product that was made by Cook Biotech or sold by Cook Medical or Cook Urological (now merged into Cook Incorporated) that is involved in this case conformed to any and all applicable codes, standards, regulations or specification established, adopted, promulgated, or approved by the United States or the several states.

8. All or some of Plaintiffs' claims against the Cook Defendants are preempted by the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*

9. Venue is not proper in this forum.

10. All or some of Plaintiffs' claims against the Cook Defendants are barred by operation of the Indiana Products Liability Act, Ind. Code § 34-20-1-1 *et seq.*

11. All or some of Plaintiffs' claims against the Cook Defendants are barred by applicable state statutes, statutes of limitations, applicable statutes of repose, or the doctrine of laches.

12. The Cook Defendants reserve the right to assert additional further answers and defenses as they become known through its continuing investigation, discovery and trial preparations.

WHEREFORE, the Cook Defendants pray that Plaintiffs take nothing against them by the Master Complaint, and for all other proper relief.

**DEMAND FOR JURY TRIAL**

The Cook Defendants demand a jury trial on all issues so triable.

Respectfully submitted,

/s/ Douglas B. King

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 27, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

*/s/Douglas B. King* \_\_\_\_\_