

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: COLOPLAST CORP. PELVIC SUPPORT
SYSTEMS PRODUCTS LIABILITY LITIGATION

MDL NO. 2387

THIS DOCUMENT RELATES TO ALL CASES

**COLOPLAST CORP. AND COLOPLAST MANUFACTURING US, LLC'S JOINT
MASTER LONG FORM ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS'
FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND**

Defendant Coloplast Corp. and Defendant Coloplast Manufacturing US, LLC, by and through undersigned counsel, hereby file their Joint Master Answer and Affirmative Defenses (“Master Responsive Pleading”) to Plaintiffs’ First Amended Master Long Form Complaint and Jury Demand (“Master Complaint”). Unless otherwise specified in an individual response, Defendant Coloplast Corp. and Defendant Coloplast Manufacturing US, LLC will hereinafter be referred to collectively as “Coloplast.” By operation of the Order of this Court, all responses and defenses pled herein are deemed pled in any previously filed Answer or Entry of Appearance and in any Entry of Appearance hereafter filed. Coloplast expressly reserves any and all defenses now available or that may become available in the future, and reserves the right to assert case-specific defenses at a later time.

Coloplast denies each and every thing, fact, matter, and allegation set forth therein except as herein qualified, admitted, or otherwise explained. Coloplast presumes that all captions, titles, and headings in the Master Complaint are intended to be non-substantive and do not require specific responses; to the extent that they are intended to be substantive allegations, Coloplast hereby denies all such assertions. In further response to the numbered allegations

contained in the Master Complaint, Coloplast states as follows:

I. PARTIES

A. Plaintiffs

1. Coloplast lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 1 of Master Complaint and, therefore, denies the same.

2. The allegations in Paragraph 2 are insufficiently precise to allow an admission or denial, and further purport to assert legal conclusions to which no response is needed. To the extent a response is called for, Coloplast lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 2 of the Master Complaint and, therefore, denies the same.

B. Defendants

3. Coloplast admits that Coloplast Corp. is a corporation organized and existing under the laws of the state of Delaware with its principal place of business at 1601 West River Road, Minneapolis, Minnesota, and that it is a wholly-owned subsidiary of Coloplast A/S. Coloplast denies any remaining allegations in Paragraph 3 of the Master Complaint.

4. The allegations in Paragraph 4 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast states that some of these allegations purport to assert a legal conclusion to which no response is required, and further states that Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore denies the allegations contained therein.

5. Coloplast admits that Coloplast A/S is a foreign corporation with its principal

place of business in Denmark. Coloplast denies the remaining allegations in Paragraph 5 of the Master Complaint.

6. Coloplast admits Coloplast Manufacturing US, LLC is a limited liability corporation with Coloplast Corp. as its principal member. Coloplast denies the remaining allegations in Paragraph 6 of the Master Complaint.

7. Coloplast admits that Porges S.A. is a French corporation with its principal place of business at Centre d'affaires La Boursidière 92350 Le Plessis-Robinson cdx., France. Coloplast further admits that Porges S.A. is a wholly owned subsidiary of Coloplast A/S. Coloplast denies any remaining allegations in Paragraph 7 of the Master Complaint.

8. Paragraph 8 of the Master Complaint contains no factual allegations and therefore no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied. Coloplast further states that no part of this Answer is submitted on behalf of Defendant Coloplast A/S or Defendant Porges S.A.

9. The allegations in Paragraph 9 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

10. The allegations in Paragraph 10 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as

to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

11. The allegations in Paragraph 11 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

12. The allegations in Paragraph 12 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

13. The allegations in Paragraph 13 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

14. The allegations in Paragraph 14 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent

a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

15. The allegations in Paragraph 15 of the Master Complaint purport to list the name of a third party entity without raising any allegations concerning said third party entity. These allegations are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

16. The allegations in Paragraph 16 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

17. The allegations in Paragraph 17 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein. To the extent that this Paragraph intends to incorporate by reference any other allegations in the Master Complaint, Coloplast incorporates by reference its admissions, denials, and responses to such incorporated allegations as if fully set forth herein.

18. Coloplast denies the allegations in Paragraph 18 of the Master Complaint.

II. JURISDICTION AND VENUE

19. The allegations in Paragraph 19 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the

extent a response is necessary, Coloplast denies the allegations in Paragraph 19 of the Master Complaint.

20. The allegations in Paragraph 20 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast denies the allegations in Paragraph 20 of the Master Complaint.

21. The allegations in Paragraph 21 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast denies the allegations in Paragraph 21 of the Master Complaint.

III. Defendants' Pelvic Mesh Products

22. The allegations in Paragraph 22 of the Master Complaint are insufficiently precise to allow a specific admission or denial, and further purport to set forth legal conclusions regarding regulatory actions by the Food & Drug Administration ("FDA"), to which no response is required. To the extent a response is required, Coloplast Manufacturing US, LLC denies the allegations as stated. By way of further statement, Coloplast Corp. states it generally packaged, labeled, marketed, sold and distributed certain medical devices, some of which are used to treat pelvic organ prolapse and/or stress urinary incontinence. However, after a reasonable investigation, Coloplast Corp. lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Coloplast device was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies the same. Coloplast Corp. denies any remaining allegations in Paragraph 22 of the Master Complaint.

23. The allegations in Paragraph 23 of the Master Complaint are insufficiently precise

to allow a specific admission or denial. To the extent a response is required, Coloplast Manufacturing US, LLC denies the allegations as stated. By way of further statement, Coloplast Corp. states that it packaged, labeled, marketed, sold and distributed certain medical devices to treat pelvic organ prolapse and/or stress urinary incontinence, including T-Sling-Universal Polypropylene Sling, Aris-Transobturator Sling System, Supris-Suprapubic Sling System, Novasilk-Synthetic Flat Mesh, Exair-Prolapse Repair System, Restorelle, Omnisure, and Minitape. Coloplast Corp. further states that it sold and distributed devices made of biologic materials known as Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis. To the extent they are intended to allege any wrongdoing by or liability on the part of Coloplast Corp., Coloplast Corp. denies any remaining allegations in Paragraph 23 of the Master Complaint.

24. The allegations in Paragraph 24 of the Master Complaint are not directed to Coloplast and therefore require no response from it. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

IV. Factual Background

25. The allegations in Paragraph 25 of the Master Complaint are insufficiently precise to allow a specific admission or denial. To the extent a response is required, Coloplast Manufacturing US, LLC denies the allegations as stated. By way of further statement, Coloplast Corp. states it generally packaged, labeled, marketed, sold and distributed certain medical devices to treat pelvic organ prolapse and/or stress urinary incontinence. Coloplast Corp. denies any remaining allegations in Paragraph 25 of the Master Complaint.

26. The allegations in Paragraph 26 of the Master Complaint are insufficiently precise to allow a specific admission or denial. To the extent a response is required, Coloplast

Manufacturing US, LLC denies the allegations as stated. By way of further statement, Coloplast Corp. states that it generally packaged, labeled, marketed, sold and distributed certain medical devices to treat pelvic organ prolapse and/or stress urinary incontinence. To the extent those allegations purport to cast liability either directly or indirectly upon or allege misconduct on the part of Coloplast Corp., Coloplast Corp. denies any remaining allegations on Paragraph 26 of the Master Complaint.

27. The allegations in Paragraph 27 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is required, Coloplast states the allegations in Paragraph 27 may not be correct or accurate with respect to any particular individual. Moreover, to the extent those allegations purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

28. The allegations in Paragraph 28 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is required, Coloplast states the allegations in Paragraph 28 may not be correct or accurate with respect to any particular individual. Moreover, to the extent those allegations purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

29. Coloplast denies the vague, undefined, and generalized allegations in Paragraph 29 of the Master Complaint.

30. Coloplast denies the allegations in Paragraph 30 of the Master Complaint.

31. Coloplast denies the allegations in Paragraph 31 of the Master Complaint.

32. Coloplast denies the allegations in Paragraph 32 of the Master Complaint.

33. Coloplast denies the allegations in Paragraph 33 of the Master Complaint as stated. By way of further answer, Coloplast states that the first sentence of Paragraph 33 of the

Master Complaint purports to characterize regulatory actions by the FDA, which actions speak for themselves, and Coloplast denies all allegations which are inconsistent with or contradicted by the FDA's actions. The remaining allegations purport to characterize the FDA's regulatory process for approving certain products, a legal conclusion to which no response is required. Coloplast further states that the allegations in Paragraph 33 do not fully or accurately describe the FDA's regulatory process, and accordingly denies the allegations in Paragraph 33 of the Master Complaint.

34. The allegations in Paragraph 34 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

35. The allegations in Paragraph 35 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast states that the allegations purport to quote and characterize written documents, which documents speak for themselves, and Coloplast denies all allegations inconsistent with or unsupported by these documents. Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations, and therefore, denies the allegations contained therein.

36. The allegations contained in the first sentence of Paragraph 36 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Paragraph 36 of the Master Complaint is vague, and purports to refer to documents that speak for themselves and should be read in their entirety. Coloplast denies all remaining allegations that are inconsistent with or unsupported by the referenced documents.

37. Coloplast admits, upon information and belief, that the Mentor Aris Trans-Obturator Tape and Surgical Kit was manufactured by ABISS. Coloplast denies the remaining allegations in Paragraph 37 of the Master Complaint as stated.

38. The allegations in Paragraph 38 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, denies the allegations contained therein.

39. The allegations in Paragraph 39 of the Master Complaint are not directed to Coloplast and therefore require no response from it. To the extent a response is necessary, Coloplast lacks knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted in the first sentence of Paragraph 39, and therefore, denies the allegations contained therein. The allegations in the third sentence of Paragraph 39 purport to characterize the regulatory process and decision making of the FDA, and Coloplast denies all allegations inconsistent with or unsupported by the FDA's actions. Coloplast lacks knowledge and information sufficient to form a belief as to the truthfulness or accuracy of the purported quotation, and accordingly denies the same.

40. With respect to the allegations in Paragraph 40 of the Master Complaint, Coloplast states that Paragraph 40 refers to documents that speak for themselves and should be read in their entirety. To the extent the allegations in Paragraph 40 are inconsistent with or unsupported by the referenced documents, Coloplast denies the allegations.

41. With respect to the allegations in the first sentence of Paragraph 41 of the Master Complaint, Coloplast admits it began marketing the Exair Prolapse Repair System in May 2009 for use by physicians and other qualified medical professionals to treat conditions, including

pelvic organ prolapse, in patients for whom its use was deemed appropriate by their physicians. The allegations in the second sentence of Paragraph 41 purport to characterize the construction and use of the Exair Prolapse Repair System, which descriptions are incomplete and are therefore denied to the extent they purport to be a complete description. The allegations in the third sentence purport to describe the regulatory approval by FDA of this device, which proceedings speak for themselves, and Coloplast denies all allegations inconsistent with or unsupported by those proceedings.

42. With respect to the allegations in Paragraph 42 of the Master Complaint, Coloplast admits it received regulatory approval to market the Supris Retropubic Sling System in June 2011, for use by physicians and other qualified medical professionals to treat conditions, including stress urinary incontinence, in patients for whom its use was deemed appropriate by their physicians. The remaining allegations in Paragraph 42 purport to characterize the FDA's basis for its regulatory action, which actions speak for themselves, and Coloplast denies all allegations inconsistent with or unsupported by those proceedings.

43. Coloplast admits it acquired Mpathy Medical Devices ("Mpathy") on October 29, 2010. Coloplast further states, upon information and belief, the remaining allegations in Paragraph 43 of the Master Complaint refer to a website that speaks for itself and should be read in its entirety. To the extent the remaining allegations in Paragraph 43 are inconsistent with or unsupported by the referenced website, Coloplast denies the allegations.

44. The allegations in Paragraph 44 of the Master Complaint purport to characterize a website and press release that speak for themselves and should be read in their entirety. Coloplast further denies the allegations in Paragraph 44 because the purported quotation has been altered, is incomplete, and has been taken out of context.

45. The allegations in the first two sentences of Paragraph 45 of the Master Complaint purport to characterize an FDA statement, which statement is in writing and speaks for itself and should be read in its entirety, and Coloplast denies all allegations inconsistent with or unsupported by the FDA's statement. Coloplast is without information sufficient to admit or deny the allegations in the third sentence of Paragraph 45, and accordingly denies the same.

46. The allegations in Paragraph 46 of the Master Complaint purport to characterize an FDA statement, which statement is in writing, speaks for itself, and should be read in its entirety. The purported quotation of this statement has been altered, is incomplete, and has been taken out of context, and accordingly is denied. Coloplast further denies all allegations in Paragraph 46 to the extent they are inconsistent with or unsupported by the characterized writing.

47. Coloplast denies the allegations in the first sentence of Paragraph 47 of the Master Complaint. The allegations of the second sentence purports to characterize and quote an FDA statement, which statement is in writing and speaks for itself. Coloplast denies all allegations inconsistent with or unsupported by the written document.

48. The allegations in Paragraph 48 of the Master Complaint purport to characterize a document released by the FDA, which document is in writing and speaks for itself. Coloplast denies all allegations in Paragraph 48 which are inconsistent with or unsupported by the referenced documents.

49. The allegations in Paragraph 49 of the Master Complaint purport to characterize a document released by the FDA, which document is in writing and speaks for itself. Coloplast denies all allegations in Paragraph 49 which are inconsistent with or unsupported by the referenced documents.

50. The allegations in Paragraph 50 of the Master Complaint purport to characterize a

document released by the FDA, which document is in writing, speaks for itself, and should be read in its entirety. The purported quotations of this statement have been altered, are incomplete, and have been taken out of context, and accordingly these allegations are denied. Coloplast further denies all allegations in Paragraph 50 to the extent they are inconsistent with or unsupported by the characterized writing.

51. The allegations in the first two sentences of Paragraph 51 of the Master Complaint purport to characterize an advocacy document from a lobbying group, which document is in writing and speaks for itself and should be read in its entirety. To the extent the allegations in the first two sentences of Paragraph 51 are inconsistent with or unsupported by the referenced document, Coloplast denies the allegations. Coloplast is without information sufficient to admit or deny the allegations in the third sentence of Paragraph 51, and accordingly denies the same.

52. The allegations in Paragraph 52 of the Master Complaint purport to characterize a written document which speaks for itself and should be read in its entirety. The purported quotation of this statement has been altered, is incomplete, and has been taken out of context, and accordingly is denied. Coloplast further denies all allegations in Paragraph 52 to the extent they are inconsistent with or unsupported by the characterized writing.

53. The allegations in Paragraph 53 of the Master Complaint purport to characterize a written document which speaks for itself and should be read in its entirety. The purported quotation of this statement has been altered, is incomplete, and has been taken out of context, and accordingly is denied. Coloplast further denies all allegations in Paragraph 53 to the extent they are inconsistent with or unsupported by the characterized writing.

54. Coloplast denies the allegations in Paragraph 54 of the Master Complaint. By way of further answer, Coloplast states that that the FDA's written positions speak for themselves and should be read in their entirety.

55. Coloplast denies the allegations in Paragraph 55 of the Master Complaint. By way of further statement, these allegations purport to characterize and then quote a written statement from the FDA. This written document speaks for itself and should be read in its entirety. The purported quotation of this statement has been altered, is incomplete, and has been taken out of context, and accordingly is inaccurate.

56. Coloplast denies the allegations in Paragraph 56 of the Master Complaint.

57. Coloplast denies the allegations in Paragraph 57 of the Master Complaint.

58. The allegations in Paragraph 58 of the Master Complaint purport to characterize written statements by the FDA which speak for themselves and should be read in their entirety. The purported quotations of these statement have been altered, are incomplete, and have been taken out of context, and accordingly these allegations are denied. Coloplast further denies all allegations in Paragraph 58 to the extent they are inconsistent with or unsupported by the characterized writings.

59. Coloplast states that, upon information and belief, Paragraph 59 of the Master Complaint refers to a website that speaks for itself and should be read in its entirety. The purported quotation of this website has been altered, is incomplete, and has been taken out of context, and accordingly these allegations are denied. Coloplast further denies all allegations in Paragraph 59 to the extent they are inconsistent with or unsupported by the characterized writing.

60. Coloplast denies the allegations in the first sentence of Paragraph 60 of the Master Complaint. The remaining allegations in Paragraph 60 purport to characterize various

publications that speak for themselves and should be read in their entirety. Coloplast denies the remaining allegations in Paragraph 60 to the extent they are inconsistent with or unsupported by the characterized writing.

61. The allegations in the first sentence in Paragraph 61 are vague, and Coloplast can neither admit nor deny these allegations as stated. Coloplast states that, upon information and belief, the remaining allegations in Paragraph 61 of the Master Complaint refer to a website maintained by Coloplast which speaks for itself and should be read in its entirety. To the extent the allegations in Paragraph 61 are inconsistent with or unsupported by the referenced website, Coloplast denies the allegations.

62. Coloplast denies the allegations in the first sentence of Paragraph 62 of the Master Complaint. The remaining allegations in Paragraph 62 purport to characterize various publications that speak for themselves and should be read in their entirety. Coloplast denies the remaining allegations in Paragraph 62 to the extent they are inconsistent with or unsupported by the characterized writing.

63. Coloplast denies the allegations in Paragraph 63 of the Master Complaint.

64. Coloplast denies the allegations in Paragraph 64 of the Master Complaint.

65. Coloplast denies the allegations in Paragraph 65 of the Master Complaint.

66. Coloplast denies the allegations in Paragraph 66 of the Master Complaint.

67. Coloplast denies the allegations in Paragraph 67 of the Master Complaint, including all separate sub-parts.

68. Coloplast denies the allegations in Paragraph 68 of the Master Complaint, including all separate sub-parts.

69. Coloplast denies the allegations in Paragraph 69 of the Master Complaint.

70. Coloplast denies the allegations in Paragraph 70 of the Master Complaint.

71. Coloplast denies the allegations in Paragraph 71 of the Master Complaint.

72. Coloplast denies the allegations in Paragraph 72 of the Master Complaint.

73. Coloplast denies the allegations in Paragraph 73 of the Master Complaint.

74. Coloplast denies the allegations in Paragraph 74 of the Master Complaint.

75. Coloplast denies the allegations in Paragraph 75 of the Master Complaint.

76. Coloplast denies the allegations in Paragraph 76 of the Master Complaint.

77. Coloplast lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence of Paragraph 77 of the Master Complaint and therefore denies the same. Coloplast denies the remaining allegations in Paragraph 77.

78. Coloplast lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 78 of the Master Complaint and therefore denies the same. To the extent the allegations in Paragraph 78 are intended to imply that Coloplast either caused or is in any way responsible for the purported injuries referenced therein, Coloplast denies all such allegations.

79. Coloplast denies the allegations in Paragraph 79 of the Master Complaint.

80. The allegations in Paragraph 80 of the Master Complaint are vague and hypothetical, and accordingly Coloplast denies the allegations. To the extent the allegations in Paragraph 80 are intended to imply that Coloplast either caused or is in any way responsible for the purported injuries referenced therein, Coloplast denies all such allegations.

81. Coloplast denies the allegations in Paragraph 81 of the Master Complaint.

82. Coloplast denies the allegations in Paragraph 82 of the Master Complaint.

83. Coloplast denies the allegations in Paragraph 83 of the Master Complaint.

84. Coloplast denies the allegations in Paragraph 84 of the Master Complaint.

85. Coloplast denies the allegations in Paragraph 85 of the Master Complaint.

86. Coloplast denies the allegations in Paragraph 86 of the Master Complaint.

87. The allegations in Paragraph 87 of the Master Complaint are vague and accordingly Coloplast denies the allegations. To the extent the allegations in Paragraph 87 are intended to imply that Coloplast either caused or is in any way responsible for the purported injuries referenced therein, Coloplast denies all such allegations.

88. Coloplast denies the allegations in Paragraph 88 of the Master Complaint.

89. The allegations in Paragraph 89 of the Master Complaint are vague and hypothetical, and accordingly Coloplast denies these allegations. To the extent the allegations in Paragraph 89 are intended to imply that Coloplast either caused or is in any way responsible for the purported injuries referenced therein, Coloplast denies all such allegations.

90. Coloplast denies the allegations in Paragraph 90 of the Master Complaint.

91. Coloplast denies the allegations in Paragraph 91 of the Master Complaint.

92. Coloplast denies the allegations in Paragraph 92 of the Master Complaint.

93. Coloplast denies the allegations in Paragraph 93 of the Master Complaint.

94. Coloplast denies the allegations in Paragraph 94 of the Master Complaint.

V. Causes of Action

COUNT I: NEGLIGENCE

95. In response to Paragraph 95 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 94 of the Master Complaint as set forth above.

96. The allegations in Paragraph 96 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast admits to the duties imposed by law but otherwise denies the allegations in Paragraph 96 of the Master Complaint.

97. Coloplast denies the allegations in Paragraph 97 of the Master Complaint, including subparts (a)-(e).

98. Coloplast denies the allegations in Paragraph 98 of the Master Complaint, including subparts (a)-(i).

99. Coloplast denies the allegations in Paragraph 99 of the Master Complaint, including subparts (a)-(u).

100. Coloplast denies the allegations in Paragraph 100 of the Master Complaint, including subparts (a)-(c).

101. Coloplast denies the allegations in Paragraph 101 of the Master Complaint.

102. Paragraph 102 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT II: STRICT LIABILITY-DESIGN DEFECT

103. In response to Paragraph 103 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 102 of the Master Complaint as set forth above.

104. Coloplast denies the allegations in Paragraph 104 of the Master Complaint, including subparts (a)-(l).

105. Coloplast denies the allegations in Paragraph 105 of the Master Complaint.

106. Coloplast denies the allegations in Paragraph 106 of the Master Complaint.

107. Paragraph 107 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

108. In response to Paragraph 108 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 107 of the Master Complaint as set forth above.

109. Coloplast denies the allegations in Paragraph 109 of the Master Complaint.

110. Coloplast denies the allegations in Paragraph 110 of the Master Complaint.

111. Coloplast denies the allegations in Paragraph 111 of the Master Complaint.

112. Paragraph 112 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

113. In response to Paragraph 113 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 112 of the Master Complaint as set forth above.

114. Coloplast denies the allegations in Paragraph 114 of the Master Complaint.

115. Coloplast denies the allegations in Paragraph 115 of the Master Complaint.

116. Coloplast denies the allegations in Paragraph 116 of the Master Complaint.

117. Paragraph 117 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

118. In response to Paragraph 118 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 117 of the Master Complaint as set forth above.

119. Coloplast denies the allegations in Paragraph 119 of the Master Complaint.

120. Coloplast denies the allegations in Paragraph 120 of the Master Complaint.

121. Paragraph 121 of the Master Complaint contains no factual allegations and therefore no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

122. Paragraph 122 of the Master Complaint contains no factual allegations and therefore no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

123. Coloplast denies the allegations in Paragraph 123 of the Master Complaint.

124. Paragraph 124 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT VI: BREACH OF EXPRESS WARRANTY

125. In response to Paragraph 125 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 124 of the Master Complaint as set forth above.

126. Coloplast denies the allegations in Paragraph 126 of the Master Complaint.

127. Coloplast lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 127 of the Master Complaint and therefore denies the same.

128. Coloplast denies the allegations in Paragraph 128 of the Master Complaint.

129. Coloplast denies the allegations in Paragraph 129 of the Master Complaint.

130. Coloplast denies the allegations in Paragraph 130 of the Master Complaint.

131. Coloplast denies the allegations in Paragraph 131 of the Master Complaint.

132. Paragraph 132 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT VII: BREACH OF IMPLIED WARRANTY

133. In response to Paragraph 133 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 132 of the Master Complaint as set forth above.

134. Coloplast denies the allegations in Paragraph 134 of the Master Complaint.

135. Coloplast lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 135 of the Master Complaint and therefore denies the same.

136. Coloplast denies the allegations in Paragraph 136 of the Master Complaint.

137. Coloplast denies the allegations in Paragraph 137 of the Master Complaint.

138. Coloplast denies the allegations in Paragraph 138 of the Master Complaint.

139. Coloplast denies the allegations in Paragraph 139 of the Master Complaint.

140. Paragraph 140 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT VIII: FRAUDULENT CONCEALMENT

141. In response to Paragraph 141 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 140 of the Master Complaint as set forth above.

142. Coloplast denies the allegations in Paragraph 142 of the Master Complaint.

143. Coloplast denies the allegations in Paragraph 143 of the Master Complaint.

144. Coloplast denies the allegations in Paragraph 144 of the Master Complaint.

145. The allegations in the first sentence of Paragraph 145 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast admits to the duties imposed by law, but otherwise denies the allegations in the first sentence of Paragraph 145 of the Master Complaint. Coloplast denies the allegations in the second sentence of Paragraph 145.

146. Coloplast denies the allegations in Paragraph 146 of the Master Complaint.

147. Coloplast denies the allegations in Paragraph 147 of the Master Complaint.

148. Coloplast denies the allegations in Paragraph 148 of the Master Complaint.

149. Coloplast denies the allegations in Paragraph 149 of the Master Complaint.

150. Coloplast denies the allegations in Paragraph 150 of the Master Complaint.

151. Coloplast denies the allegations in Paragraph 151 of the Master Complaint.

152. Paragraph 152 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT IX: CONSTRUCTIVE FRAUD

153. In response to Paragraph 153 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 152 of the Master Complaint as set forth above.

154. Coloplast denies the allegations in Paragraph 154 of the Master Complaint.

155. Coloplast denies the allegations in Paragraph 155 of the Master Complaint.

156. The allegations in Paragraph 156 of the Master Complaint are vague, and purport to refer to and characterize a publication that speaks for itself and should be read in its entirety. To the extent the allegations in Paragraph 156 are inconsistent with or unsupported by the referenced document, Coloplast denies the allegations.

157. Coloplast denies the allegations in Paragraph 157 of the Master Complaint.

158. Coloplast denies the allegations in Paragraph 158 of the Master Complaint.

159. Coloplast denies the allegations in Paragraph 159 of the Master Complaint.

160. Coloplast denies the allegations in Paragraph 160 of the Master Complaint.

161. Paragraph 161 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs

are entitled to any of the relief requested.

COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

162. In response to Paragraph 162 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 161 of the Master Complaint as set forth above.

163. The allegations in paragraph 163 of the Master Complaint are not directed to Coloplast and therefore require no response from it. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

164. The allegations in paragraph 164 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied.

165. The allegations in paragraph 165 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast denies the allegations in Paragraph 165 of the Master Complaint.

166. Coloplast denies the allegations in Paragraph 166 of the Master Complaint.

COUNT XI: NEGLIGENT MISREPRESENTATION

167. In response to Paragraph 167 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 166 of the Master Complaint as set forth above.

168. The allegations in the first sentence of Paragraph 168 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from

Coloplast. To the extent a response is necessary, Coloplast admits to the duties imposed by law, but otherwise denies the allegations in the first sentence of Paragraph 168 of the Master Complaint. Coloplast denies the allegations in the second sentence of Paragraph 168.

169. Coloplast denies the allegations in Paragraph 169 of the Master Complaint.

170. Coloplast denies the allegations in Paragraph 170 of the Master Complaint.

171. Coloplast denies the allegations in Paragraph 171 of the Master Complaint.

172. Coloplast denies the allegations in Paragraph 172 of the Master Complaint.

173. Paragraph 173 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT XII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

174. In response to Paragraph 174 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 173 of the Master Complaint as set forth above.

175. Coloplast denies the allegations in Paragraph 175 of the Master Complaint.

176. Coloplast denies the allegations in Paragraph 176 of the Master Complaint.

177. Coloplast denies the allegations in Paragraph 177 of the Master Complaint.

178. Paragraph 178 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

179. In response to Paragraph 179 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 178 of the Master Complaint as set forth above.

180. Coloplast denies the allegations in Paragraph 180 of the Master Complaint.

181. Coloplast denies the allegations in Paragraph 181 of the Master Complaint.

182. Coloplast denies the allegations in Paragraph 182 of the Master Complaint.

183. The allegations in paragraph 183 of the Master Complaint are vague, and appear to set forth legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, and also to the extent these allegations purport to assert Coloplast engaged in any wrongful conduct, Coloplast denies the allegations in Paragraph 183 of the Master Complaint.

184. The allegations in paragraph 184 of the Master Complaint are vague, and appear to set forth legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, and also to the extent these allegations purport to assert Coloplast engaged in any wrongful conduct, Coloplast denies the allegations in Paragraph 184 of the Master Complaint.

185. The allegations in paragraph 185 of the Master Complaint are vague, and appear to set forth legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, and also to the extent these allegations purport to assert Coloplast engaged in any wrongful conduct, Coloplast denies the allegations in Paragraph 185 of the Master Complaint.

186. The allegations in paragraph 186 of the Master Complaint are vague, and appear

to set forth legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, and also to the extent these allegations purport to assert Coloplast engaged in any wrongful conduct, Coloplast denies the allegations in Paragraph 186 of the Master Complaint.

187. Coloplast denies the allegations in Paragraph 187 of the Master Complaint.

188. The allegations in Paragraph 188 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast admits to the duties imposed by law, but otherwise denies the allegations in Paragraph 188 of the Master Complaint.

189. Coloplast denies the allegations in Paragraph 189 of the Master Complaint.

190. Coloplast denies the allegations in Paragraph 190 of the Master Complaint.

191. Coloplast denies the allegations in Paragraph 191 of the Master Complaint.

192. Coloplast denies the allegations in Paragraph 192 of the Master Complaint.

193. Coloplast denies the allegations in Paragraph 193 of the Master Complaint.

194. Coloplast denies the allegations in Paragraph 194 of the Master Complaint.

195. Coloplast denies the allegations in Paragraph 195 of the Master Complaint.

196. Coloplast denies the allegations in Paragraph 196 of the Master Complaint.

197. Coloplast denies the allegations in Paragraph 197 of the Master Complaint.

198. Coloplast denies the allegations in Paragraph 198 of the Master Complaint.

199. Coloplast denies the allegations in Paragraph 199 of the Master Complaint.

200. Coloplast denies the allegations in Paragraph 200 of the Master Complaint.

201. Paragraph 201 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast

denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT XIV: GROSS NEGLIGENCE

202. In response to Paragraph 202 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 201 of the Master Complaint as set forth above.

203. Coloplast denies the allegations in Paragraph 203 of the Master Complaint.

204. Coloplast denies the allegations in Paragraph 204 of the Master Complaint.

205. The allegations in paragraph 205 of the Master Complaint set forth the legal conclusions of the pleading party for which no response is required from Coloplast. However, to the extent they purport to cast liability either directly or indirectly upon Coloplast, those allegations are denied. Coloplast further asserts the Master Complaint has failed to allege any basis for any damages as against Coloplast, including but not limited to exemplary damages.

206. The allegations in the second sentence of Paragraph 206 of the Master Complaint purport to set forth the legal conclusions of the pleading party for which no response is required from Coloplast. To the extent a response is necessary, Coloplast denies the allegations in Paragraph 206 of the Master Complaint. Coloplast further asserts the Master Complaint has failed to allege any basis for any damages as against Coloplast, including but not limited to exemplary damages.

207. Paragraph 207 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT XV: UNJUST ENRICHMENT

208. In response to Paragraph 208 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 207 of the Master Complaint as set forth above. By way of further response, Coloplast states that the remaining allegations in Paragraph 208 are vague and insufficiently precise to allow an admission or denial, and accordingly denies the same.

209. Coloplast lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 209 of the Master Complaint and therefore denies the same.

210. Coloplast denies the allegations in Paragraph 210 of the Master Complaint.

211. Coloplast denies the allegations in Paragraph 211 of the Master Complaint.

212. Coloplast denies the allegations in Paragraph 212 of the Master Complaint.

213. Paragraph 213 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs are entitled to any of the relief requested.

COUNT XVI: LOSS OF CONSORTIUM

214. In response to Paragraph 214 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 213 of the Master Complaint as set forth above.

215. Coloplast denies the allegations in Paragraph 215 of the Master Complaint.

216. Paragraph 216 of the Master Complaint does not contain allegations of fact and therefore no response is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed in this paragraph and denies that Plaintiffs

are entitled to any of the relief requested.

COUNT XVII: PUNITIVE DAMAGES

217. In response to Paragraph 217 of the Master Complaint, Coloplast adopts and incorporates by reference its responses to Paragraph 1 through 216 of the Master Complaint as set forth above.

218. Coloplast denies the allegations in Paragraph 218 of the Master Complaint.

219. Coloplast denies the allegations in Paragraph 219 of the Master Complaint.

220. Coloplast denies the allegations in Paragraph 220 of the Master Complaint.

221. Coloplast denies the allegations in Paragraph 221 of the Master Complaint.

222. Coloplast denies the allegations in Paragraph 222 of the Master Complaint.

223. Coloplast denies the allegations in Paragraph 223 of the Master Complaint.

224. Coloplast denies the allegations in Paragraph 224 of the Master Complaint.

225. Coloplast denies the allegations in Paragraph 225 of the Master Complaint.

226. Coloplast denies the allegations in Paragraph 226 of the Master Complaint.

227. Coloplast denies the allegations in Paragraph 227 of the Master Complaint.

228. Coloplast denies the allegations in Paragraph 228 of the Master Complaint.

PRAYER FOR RELIEF AND PURPORTED DEMAND FOR JURY TRIAL

Plaintiffs' "Prayer for Relief" section of the Master Complaint does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, Coloplast denies each and every allegation and assertion listed under the "Prayer for Relief" section of the Master Complaint and denies that Plaintiffs are entitled to any of the relief requested.

Plaintiffs' purported demand for jury trial as to all issues does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, Coloplast denies that Plaintiffs' purported demands for equitable relief are triable by jury.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to Coloplast in this matter. Coloplast accordingly preserves the right to assert these separate and additional defenses in response to the allegations in the Master Complaint. Upon completion of discovery Coloplast may withdraw any of these additional defenses as may be appropriate. Coloplast further reserves the right to amend its answer and defenses, and to assert additional defenses and other claims, as discovery proceeds.

FIRST DEFENSE

Plaintiffs' Master Complaint fails to state a claim, or claims, upon which relief may be granted against Coloplast.

SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitation, repose, or other periods of limitation applicable to the Plaintiffs' claims.

THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because the device(s) was not in a defective condition when it left the possession, custody and control of Coloplast and it was fit and proper for the use for which it was designed and intended.

FOURTH DEFENSE

Plaintiffs' Master Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

FIFTH DEFENSE

The device(s), including the methods and techniques of manufacturing, inspection, and testing, that is the subject of this Master Complaint conformed with the state of the art at the time the device(s) was first sold.

SIXTH DEFENSE

The proximate cause of the alleged injuries described in the Master Complaint may have been the use of the device(s) for a purpose, in a manner, or in an activity other than that which was reasonably foreseeable or was contrary to an express or adequate warning appearing on, attached to, and delivered with the device(s).

SEVENTH DEFENSE

Plaintiffs cannot show that any reasonable alternative design would have rendered the device(s) safer overall.

EIGHTH DEFENSE

The alleged injuries and damages described in the Master Complaint were the result of Plaintiffs' negligence, carelessness, assumption of risk, or otherwise wrongful or unsafe conduct and the damages, if any, should thereby be reduced or eliminated by Plaintiffs' percentage of negligence and fault.

NINTH DEFENSE

The alleged injuries and damages described in the Master Complaint were the result of, and were caused solely and proximately by, the acts, fault, conduct, or negligence of persons or

entities other than Coloplast; such negligence, fault, act, or conduct was of a character that is not reasonably expected to happen in the natural sequence of events; and such negligence, fault, act, or conduct was the independent, intervening, and superseding cause and therefore the sole proximate cause of any such damages, thus relieving Coloplast of any liability.

TENTH DEFENSE

The alleged injuries and damages described in the Master Complaint were the result of, and were caused by preexisting physical, medical, or physiological conditions, for which Coloplast has no legal responsibility.

ELEVENTH DEFENSE

Plaintiffs, in consenting to the treatment prescribed by a physician or other medical or healthcare provider, expressly and voluntarily assumed the risk of any injury or adverse effects associated with the device(s).

TWELFTH DEFENSE

The learned intermediary doctrine bars the Plaintiffs' claims because Coloplast properly warned the physicians of the risks associated with the device(s).

THIRTEENTH DEFENSE

Plaintiffs' physicians and other medical and healthcare providers and their agents, servants and employees were sophisticated users of the subject device(s) and possessed adequate information concerning warnings, precautions and potential complications for those physicians and other medical and healthcare providers to assess the risks versus the benefits of the subject device(s) before they prescribed and used it. Therefore, Plaintiffs' claims against Coloplast are barred.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred because the benefits of the subject device(s) outweigh the risks, if any, that might be associated with the device(s).

FIFTEENTH DEFENSE

If the injuries claimed by Plaintiffs were related to the use of the device(s), which is expressly denied, any such injuries were the result of an idiosyncratic or allergic reaction to the device(s).

SIXTEENTH DEFENSE

Plaintiffs' claims are barred because the device(s) was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for its intended uses, thereby barring Plaintiffs' recovery.

SEVENTEENTH DEFENSE

Plaintiffs' claimed damages proximately resulted from alterations or modifications of the device(s), which were not reasonably foreseeable or were made by a person other than Coloplast and were subsequent to the time of the original sale. Consequently, the alterations or modifications were the proximate cause of any alleged injuries or damages precluding liability of Coloplast.

EIGHTEENTH DEFENSE

Plaintiffs' damages are subject to set-off, reduction, and related legal principles where such damages are attributable to the fault of others or non-parties.

NINETEENTH DEFENSE

Plaintiffs' claims are barred in whole or in part by the warranties and exclusions of warranties provided and offered when the device(s) was purchased.

TWENTIETH DEFENSE

Plaintiffs' claims for breach of warranty are barred by the applicable state's Uniform Commercial Code or other applicable law.

TWENTY-FIRST DEFENSE

Plaintiffs' claims are barred by the relevant provisions of the Restatement (Third) of Torts, including, but not limited to, the doctrines described in section 6(c) and 6(d) of the Restatement (Third) of Torts: Product Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with the product would have prescribed, and did prescribe, the alleged device(s) for the classes of patients to which the Plaintiffs belonged. In addition, Coloplast provided prescribing physicians with the reasonable instructions or warnings regarding foreseeable risks of harm.

TWENTY-SECOND DEFENSE

Plaintiffs' claims are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited to, § 402A, comment k.

TWENTY-THIRD DEFENSE

Coloplast gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Coloplast intends to rely upon same in defense of this action.

TWENTY-FOURTH DEFENSE

All or some of Plaintiffs' claims may be barred by federal preemption, including Title 21, U.S.C. and the 1976 medical device amendments.

TWENTY-FIFTH DEFENSE

Plaintiffs' claims are barred in whole or in part because Coloplast did not have a duty to provide any warnings for the device(s) in addition to, or other than, the warnings provided in conformity with federal law and regulations of the federal Food and Drug Administration.

TWENTY-SIXTH DEFENSE

Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

TWENTY-SEVENTH DEFENSE

Plaintiffs' claims are barred in whole or in part because the commercial speech relating to the device(s) is protected under the First Amendment of the United States Constitution and the applicable state constitution(s).

TWENTY-EIGHTH DEFENSE

Plaintiffs' claims fail because Plaintiffs did not detrimentally rely on any labeling, warnings, or information concerning the subject device(s).

TWENTY-NINTH DEFENSE

The warnings and instructions accompanying the device(s) at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions.

THIRTIETH DEFENSE

Plaintiffs cannot state a claim upon which relief may be granted with regard to warnings and labeling for medical devices because the remedy sought by Plaintiffs is subject to the exclusive jurisdiction of the FDA.

THIRTY-FIRST DEFENSE

This Court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to medical device labeling by the FDA.

THIRTY-SECOND DEFENSE

Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Master Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

THIRTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because the Plaintiffs failed to exercise reasonable care and diligence to mitigate, minimize, or avoid the alleged injuries and damages, and any recovery which may be awarded to them in this action should be reduced accordingly.

THIRTY-FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the Plaintiffs, their physicians or their medical care providers did not receive, directly or indirectly, or rely upon any express or implied warranty from Coloplast or, if so, any breach thereof by Coloplast was not a proximate cause of the Plaintiffs' damages.

THIRTY-FIFTH DEFENSE

Plaintiffs failed to provide Coloplast with timely notice of any alleged breach of warranty or any alleged defect as required by the applicable laws and statutes.

THIRTY-SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of estoppel, laches, and waiver.

THIRTY-SEVENTH DEFENSE

Venue may be improper.

THIRTY-EIGHTH DEFENSE

To the extent that Plaintiffs' claims have been settled or Plaintiffs will in the future settle with any person or entity with respect to the injuries asserted in the Master Complaint, the liability of Coloplast, if any, should be reduced accordingly.

THIRTY-NINTH DEFENSE

Collateral sources, managed care discounts, and charitable and/or governmental benefits received, available, or to be received in the future reduce the Plaintiffs' alleged damages.

FORTIETH DEFENSE

This case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

FORTY-FIRST DEFENSE

Upon information and belief, each item of economic loss alleged in the Master Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

FORTY-SECOND DEFENSE

To the extent that Plaintiffs' Master Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Master Complaint, such benefits are not recoverable in this action under applicable law.

FORTY-THIRD DEFENSE

Plaintiffs' claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or by release of claims.

FORTY-FOURTH DEFENSE

Coloplast is entitled to and claims the benefits of all defenses and presumptions set forth in or arising from any rule of law or statute in this State or any other state whose law is deemed to apply in this litigation.

FORTY-FIFTH DEFENSE

Coloplast denies any conduct for which punitive or exemplary damages could or should be awarded and denies that sufficient evidence has been produced to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.

FORTY-SIXTH DEFENSE

Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad and would violate Coloplast's constitutional rights as secured by the Fifth and Seventh Amendments to the United States Constitution, would violate its rights to due process and equal protection under the Fourteenth Amendment of the United States Constitution and the prohibition against excessive fines in the United States Constitution, and would contravene other provisions of the United States Constitution and any applicable state constitution.

FORTY-SEVENTH DEFENSE

Plaintiffs cannot recover punitive or exemplary damages against Coloplast because such an award, which is penal in nature, would violate Coloplast's constitutional rights under the United States Constitution and any applicable state constitution, unless Coloplast is afforded the same procedural safeguards as are criminal defendants, including but not limited to the right to avoid self-incrimination, the right to forego production and disclosure of incriminating documents and the right to the requirement of a level of proof beyond a reasonable doubt.

FORTY-EIGHTH DEFENSE

Any imposition of punitive or exemplary damages in this case would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute, if imposed, an undue and unreasonable burden on interstate commerce.

FORTY-NINTH DEFENSE

With respect to Plaintiffs' demand for punitive or exemplary damages, Coloplast specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under applicable state law or other applicable law.

FIFTIETH DEFENSE

Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of No. America v. Gore*, 116 U.S. 1589 (1996) (as extended by *Cooper Indus. v. Leatherman Tool Group*, 2001 W.L. 501732 (U.S. May 14, 2001), *State Farm Mut. Auto. Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008)).

FIFTY-FIRST DEFENSE

No act or omission of Coloplast caused or contributed to Plaintiffs' alleged injuries. Further no act or omission of Coloplast was fraudulent, willful and malicious and done with a conscious disregard for the rights of Plaintiff and others, as alleged in the Complaint. No act or omission of Coloplast was fraudulent, malicious or grossly negligent. Accordingly, Plaintiffs' Master Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

FIFTY-SECOND DEFENSE

Plaintiffs' claims for injunctive or other equitable relief are barred because there is an adequate remedy at law.

FIFTY-THIRD DEFENSE

Coloplast is unaware at this time of any settlements by any alleged joint tortfeasor. In the event any settlement has been or will be made by any alleged joint tortfeasor, then Coloplast is entitled to a full credit, offset, pro rata reduction, or percentage reduction, based on the percentage of fault attributable to each settling party, person, or other entity herein, and Coloplast makes known to the other parties and to the Court that it will avail itself of its rights.

FIFTY-FOURTH DEFENSE

To the extent that Plaintiffs' pleas for punitive damages expose Coloplast to double jeopardy or call for Coloplast to be punished more than once for the same conduct, Plaintiffs' pleas violate Coloplast's rights under the Fifth and Fourteenth Amendments of the United States Constitution.

FIFTY-FIFTH DEFENSE

To the extent that Plaintiffs seek punitive damages, either unlimited or limited, the Complaint seeks excessive fines in violation of Coloplast's rights provided in the Eighth and Fourteenth Amendments of the United States Constitution. Any award of punitive damages is also excessive under those constitutional provisions to the extent that it does not bear a reasonable relation to the injury, harm, and damages actually suffered by the Plaintiffs.

FIFTY-SIXTH DEFENSE

To the extent that Plaintiffs' Master Complaint seeks recovery of punitive damages, it violates Coloplast's rights to equal protection as provided the Fourteenth Amendment to the United States Constitution.

FIFTY-SEVENTH DEFENSE

To the extent that Plaintiffs' Master Complaint seeks recovery of punitive damages, it also violates Coloplast's rights to contract, as provided in Article I, Section 10 of the United States Constitution.

FIFTY-EIGHTH DEFENSE

An award of punitive damages based on conduct or acts committed by those who are not Coloplast's vice-principals would violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution and the common law and public policies of the Florida and would be erroneous.

FIFTY-NINTH DEFENSE

Any award of punitive damages based on anything other than Coloplast's conduct as alleged in Plaintiffs' Complaint would violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution and the common law and public policies of the applicable state constitution. Any other basis for awarding punitive damages in this case would not protect Coloplast against impermissible multiple punishment for the same wrong.

SIXTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, for a lack of personal or subject matter jurisdiction.

SIXTY-FIRST DEFENSE

This injuries or damages sustained by the Plaintiffs, if any, can be attributed to several causes, and accordingly, should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

SIXTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by any applicable state statutes barring recovery for such claims in product liability and/or personal injury actions.

SIXTY-THIRD DEFENSE

Coloplast reserves the right to raise any additional defenses as may be revealed by discovery in this matter.

SIXTY-FOURTH DEFENSE

Coloplast hereby gives notice that it intends to rely upon and incorporates by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

JURY DEMAND

Coloplast requests a trial by jury composed of the maximum number of jurors allowed by law, on all issues so triable.

WHEREFORE, Defendant Coloplast prays that:

- (1) Plaintiffs take nothing by reason of the Master Complaint;
- (2) that a Judgment against Plaintiffs and in favor of Coloplast be entered;
- (3) Coloplast be awarded its costs and expenses; and
- (4) this Court award Coloplast any other and general or specific relief as this Court may deem just and proper.

Respectfully submitted,

s/ Lana K. Varney

Lana K. Varney
Fulbright & Jaworski L.L.P.
98 San Jacinto Boulevard, Suite 1100
Austin, TX 78746
Telephone: (512) 536-4594
Facsimile: (512) 536-4598
lvarney@fulbright.com

Ronn B. Kreps
Fulbright & Jaworski L.L.P.
2100 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
Telephone: (612) 321-2810
Facsimile: (612) 321-2288
rkreps@fulbright.com

*Counsel for Defendant Coloplast Corp. and
Defendant Coloplast Manufacturing US, LLC*

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 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/ Lana K. Varney
