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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

MDL NO. 15-02641-PHX-DGC

DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER TO PLAINTIFFS' MASTER COMPLAINT; JURY TRIAL DEMAND

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (Bard and BPV are collectively "Defendants") hereby answer the Plaintiffs' Master Complaint for Damages for Individual Claims ("Complaint" or "Plaintiffs' Complaint"). Defendants hereby deny any and all Causes of Action or factual allegations added by any individual plaintiff through use of the Short Form Complaint for Damages. Defendants reserve the right to seek dismissal of any case adopting the Complaint that is inconsistent

with the terms of any pretrial or case management order entered by the Court in this matter, or for any other reason.

Defendants deny all allegations set forth in the Master Complaint except to the extent such allegations are specifically admitted below.

RESPONSE TO SPECIFIC ALLEGATIONS

1. Defendants admit that Plaintiffs purport to bring this action as stated in the Complaint, but Defendants deny that there is any legal or factual basis for such relief. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiffs' Complaint.

2. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. No response is required with respect to the statement contained in Paragraph 2 of Plaintiffs' Complaint pertaining to the Recovery® Cone. To the extent a response is required, Defendants deny the propriety of Plaintiffs' reference to the Recovery® Cone Removal System as a "Bard IVC Filter," as suggested in Paragraph 2 of Plaintiffs' Complaint.[1]

[1] Defendants further deny the propriety of the use, reference, or incorporation, express or implied, of the term "Bard IVC Filter" to include the Recovery® Cone Removal System throughout Plaintiffs' Complaint. Defendants expressly deny that the Recovery® Cone Removal System is an inferior vena cava filter and deny that any plaintiff alleges injury indirectly or directly related to the Recovery® Cone Removal System. Defendants expressly incorporate their denial to the allegation that the Recovery® Cone Removal System may be properly designated as an inferior vena cava filter in response to every allegation in Plaintiffs' Complaint wherein the term "Bard IVC Filters" is included. To aid in clarity, Defendants will utilize the term "Bard Inferior Vena Cava Filters"

3. Defendants admit that Plaintiffs purport to bring their actions for damages related to Bard's manufacture or BPV's design, sale, marketing, and/or distribution of Recovery®, G2®, G2®X, Eclipse®, Meridian®, or Denali® filters. Defendants deny the remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of Plaintiffs' Complaint regarding the condition of Bard Inferior Vena Cava Filters upon receipt by any physician and, on that basis, deny the allegations. Defendants deny the remaining allegations contained in Paragraph 4 of Plaintiffs' Complaint.

5. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of Plaintiffs' Complaint regarding the manner in which plaintiffs' physicians used Bard Inferior Vena Cava Filters and, on that basis, deny the allegations. Defendants deny the remaining allegations contained in Paragraph 5 of Plaintiffs' Complaint.

6. The allegations contained in Paragraph 6 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny that there is any defect in any Bard Inferior Vena Cava Filter. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 6 of Plaintiffs' Complaint.

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throughout this Answer, as defined in response to Paragraph 2 of Plaintiffs' Complaint, *supra.*

7. The allegations contained in Paragraph 7 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny that there is any defect in any Bard Inferior Vena Cava Filter. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 7 of Plaintiffs' Complaint.

PARTIES

8. The allegations of Paragraph 8 of Plaintiffs' Complaint are not directed to Bard or BPV and, as a result, require no response by Defendants. However, to the extent Paragraph 8 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

9. The allegations of Paragraph 9 of Plaintiffs' Complaint are not directed to Bard or BPV and, as a result, require no response by Defendants. However, to the extent Paragraph 9 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

10. Defendants deny the allegations contained in Paragraph 10 of Plaintiffs' Complaint.

11. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of Arizona. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®,

and Denali®. Defendants deny the remaining allegations contained in Paragraph 11 of Plaintiffs' Complaint.

12. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of Arizona. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint.

13. The allegations contained in Paragraph 13 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

14. The allegations contained in Paragraph 14 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

15. The allegations contained in Paragraph 15 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

16. The allegations contained in Paragraph 16 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

17. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names

Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 17 of Plaintiffs' Complaint.

18. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 18 of Plaintiffs' Complaint.

19. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 19 of Plaintiffs' Complaint.

JURISDICTION AND VENUE

20. The allegations contained in Paragraph 20 of Plaintiffs' Complaint are legal conclusions, which do not require a response. Defendants further state that the allegations in Plaintiffs' Complaint are insufficient on their own to establish jurisdiction under 28 U.S.C. § 1332. Plaintiffs can only establish jurisdiction under 28 U.S.C. § 1332 by pleading facts in a Short Form Complaint that show diversity of citizenship.

21. Defendants admit that BPV is an Arizona Corporation that is authorized to do business, and does business, in Arizona and in various states and jurisdictions throughout the United States. Defendants further admit that Bard is authorized to do business, and does business, in Arizona and in various states and jurisdiction throughout the United States.

22. The allegations contained in Paragraph 22 of Plaintiffs' Complaint purport to quote an order of the Judicial Panel on Multidistrict Litigation. Defendants do not deny that the order exists but further state that the order speaks for itself, and any characterization inconsistent with the order is denied.

23. The allegations contained in Paragraph 23 of Plaintiffs' Complaint purport to quote an order of the Judicial Panel on Multidistrict Litigation. Defendants do not deny that the order exists but further state that the order speaks for itself, and any characterization inconsistent with the order is denied.

24. The allegations contained in Paragraph 24 of Plaintiffs' Complaint purport to quote this Court's Case Management Order No. 2. Defendants do not deny that the order exists but further state that the order speaks for itself, and any characterization inconsistent with the order is denied.

GENERAL FACTUAL ALLEGATIONS

25. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 25 of Plaintiffs' Complaint.

26. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 26 of Plaintiffs' Complaint.

27. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 27 of Plaintiffs' Complaint.

28. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 28 of Plaintiffs' Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 28 of Plaintiffs' Complaint and, on that basis, deny them.

29. Defendants lack knowledge or information or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market. Defendants also lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when optional or retrievable filters came to be marketed or the other allegations regarding optional or retrievable filters marketed by other manufacturers. Defendants deny any remaining allegations contained in Paragraph 29 of Plaintiffs' Complaint.

30. Defendants deny the allegations contained in Paragraph 30 of Plaintiffs' Complaint.

31. Defendants deny the allegations contained in Paragraph 31 of Plaintiffs' Complaint.

32. Defendants deny the allegations contained in Paragraph 32 of Plaintiffs' Complaint, except Defendants admit that physician input and feedback was valuable in the development of Defendants' Inferior Vena Cava Filters. Defendants deny any remaining allegations contained in Paragraph 32 of Plaintiffs' Complaint.

33. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding other manufacturers' belief or motivations and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 33 of Plaintiffs' Complaint.

34. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable use on July 25, 2003. Defendants deny any remaining allegations contained in Paragraph 34 of Plaintiffs' Complaint.

35. Defendants deny the allegations contained in Paragraph 35 of Plaintiffs' Complaint.

36. Defendants deny the allegations contained in Paragraph 36 of Plaintiffs' Complaint.

37. To the extent the allegations contained in Paragraph 37 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants specifically deny that the known risks associated with inferior vena cava filters generally outweigh the benefits of inferior vena cava filters, which can be life-saving. Defendants deny any remaining allegations contained in Paragraph 37 of Plaintiffs' Complaint.

38. To the extent the allegations contained in Paragraph 38 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants specifically deny that the known risks associated with inferior vena cava filters generally outweigh the benefits of inferior vena cava filters, which can be life-saving. Defendants deny any remaining allegations contained in Paragraph 38 of Plaintiffs' Complaint, including all sub-parts thereof.

39. To the extent the allegations contained in Paragraph 39 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants specifically deny that the known risks associated with inferior vena cava filters generally outweigh the benefits of inferior vena cava filters, which can be life-saving. Defendants deny any remaining allegations contained in Paragraph 39 of Plaintiffs' Complaint.

40. Defendants admit that Defendants have previously and continue currently to market the Simon Nitinol Filter, which was cleared by FDA for permanent use. Defendants deny any remaining allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Defendants admit that the Simon Nitinol Filter was initially manufactured by Nitinol Medical Technologies. Defendants further admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Recovery® Filter was developed in furtherance of those efforts. Defendants further admit that Bard acquired Nitinol Medical Technologies' inferior vena cava filter product line in 2001. Defendants deny any remaining allegations contained in Paragraph 41 of Plaintiffs' Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of Plaintiffs' Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of Plaintiffs' Complaint.

44. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations of the FDA approval and clearance processes. Defendants deny any remaining allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. The allegations pertaining to the requirements and purpose of Section 510(k) of the Food, Drug and Cosmetic Act are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations of the FDA approval and clearance processes. To the extent the allegations contained in Paragraph 45 of Plaintiffs' Complaint purport to quote or paraphrase the case

Horn v. Thoratec Corp., the document speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 45 of Plaintiffs' Complaint.

46. The allegations pertaining to the requirements and purpose of Section 510(k) of the Food, Drug and Cosmetic Act are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations of the FDA approval and clearance processes. To the extent the allegations contained in Paragraph 46 of Plaintiffs' Complaint purport to quote or paraphrase the case *Medtronic v. Lohr*, the case speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. The allegations pertaining to the post-market obligations of Defendants are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations accurately and completely reflect Defendants' post-market obligations. To the extent the allegations contained in Paragraph 47 of Plaintiffs' Complaint purport to quote or paraphrase the case *Wyeth v. Levine*, the document speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 47 of Plaintiffs' Complaint.

48. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2013, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act.

49. Defendants deny the allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. Defendants deny the allegations contained in Paragraph 50 of Plaintiffs' Complaint.

51. Defendants admit that a nickel-titanium alloy named Nitinol is used in the manufacture of the Recovery Filter. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 52 of Plaintiffs' Complaint.

53. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. To the extent the allegations contained in Paragraph 53 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 53 of Plaintiffs' Complaint.

54. Defendants admit that Nitinol possesses shape-memory. Defendants deny any remaining allegations contained in Paragraph 54 of Plaintiffs' Complaint.

55. Defendants admit that Nitinol possesses shape-memory and that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants deny any remaining allegations of Paragraph 55 of Plaintiffs' Complaint.

56. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly via an introducer sheath, which is included in the delivery system for the device. Defendants admit that the Recovery® Filter was designed to be retrieved

endovascularly as well. Defendants deny any remaining allegations of Paragraph 56 of Plaintiffs' Complaint.

57. Defendants admit that the Recovery® Filter is intended for the uses described in the Instructions for Use which accompany each device. To the extent the allegations contained in Paragraph 57 of Plaintiffs' Complaint purport to quote or paraphrase the Recovery® Filter Instructions for Use, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 57 of Plaintiffs' Complaint.

58. The allegations pertaining to FDA requirements related to the Recovery® Cone Removal System are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations contained in Paragraph 58 of Plaintiffs' Complaint.

59. Defendants admit that the Recovery® Cone Removal System has been marketed previously as a Class I medical device and a cleared accessory of Bard's Inferior Vena Cava Filters. Defendants deny any remaining allegations contained in Paragraph 59 of Plaintiffs' Complaint.

60. Defendants deny the allegations contained in Paragraph 60 of Plaintiffs' Complaint.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiffs' Complaint.

62. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every

manufacturer of inferior vena cava filters. Defendants deny the remaining allegations contained in Paragraph 62 of Plaintiffs' Complaint.

63. Defendants deny the allegations contained in Paragraph 63 of Plaintiffs' Complaint.

64. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations contained in Paragraph 64 of Plaintiffs' Complaint.

65. The allegations pertaining to FDA's MAUDE database contain legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations contained in Paragraph 65 of Plaintiffs' Complaint.

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiffs' Complaint.

67. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 67 of Plaintiffs' Complaint.

68. Defendants admit that they BPV marketed and sold the Recovery® Filter until September 2005. Defendants further admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants further

admit that the G2® Filter was cleared by the FDA in August 2005 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 68 of Plaintiffs' Complaint.

69. Defendants admit that the G2® Filter was cleared by the FDA in August 2005 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 69 of Plaintiffs' Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. To the extent the allegations contained in Paragraph 71 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 71 of Plaintiffs' Complaint.

72. To the extent the allegations contained in Paragraph 72 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 72 of Plaintiffs' Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of Plaintiffs' Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiffs' Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiffs' Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiffs' Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Defendants admit that fracture is a well-document complication that may occur with any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of filter fracture associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 80 of Plaintiffs' Complaint.

81. Defendants admit that perforation and tilt are well-document complications that may occur with any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter perforation or tilt result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of filter perforation or tilt associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 81 of Plaintiffs' Complaint.

82. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 82 of Plaintiffs' Complaint, including all sub-parts thereof.

83. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 83 of Plaintiffs' Complaint, including all sub-parts thereof.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiffs' Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiffs' Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiffs' Complaint.

87. The allegations contained in Paragraph 87 of Plaintiffs' Complaint purport to quote from documents, which speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 87 of Plaintiffs' Complaint, including all sub-parts thereof.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiffs' Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of Plaintiffs' Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiffs' Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs' Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiffs' Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiffs' Complaint.

95. The allegations contained in Paragraph 95 of Plaintiffs' Complaint purport to quote from documents, which speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 95 of Plaintiffs' Complaint, including all sub-parts thereof.

96. The allegations contained in Paragraph 96 of Plaintiffs' Complaint purport to quote from documents, which speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 96 of Plaintiffs' Complaint, including all sub-parts thereof.

97. Defendants deny the allegations contained in Paragraph 97 of Plaintiffs' Complaint.

98. Defendants admit that the Eclipse® filter, cleared by FDA in 2010, was electropolished. Defendants deny the remaining allegations contained in Paragraph 98 of Plaintiffs' Complaint.

99. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian® Filter, which has caudal anchors on the six filter "arms," was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 99 of Plaintiffs' Complaint.

100. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are

continually striving to improve the life-saving performance of those devices. The Denali® Filter, which has penetration limiters on the six filter "legs," was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 100 of Plaintiffs' Complaint.

101. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Denali® Filter, which has penetration limiters on the six filter "legs," was developed in furtherance of those efforts. Defendants deny that there exists any analysis or study that definitively demonstrates that filter tilt results in a clinically significant occurrence of filter perforation. Defendants deny any remaining allegations contained in Paragraph 101 of Plaintiffs' Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiffs' Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiffs' Complaint.

104. The allegations contained in Paragraph 104 of Plaintiffs' Complaint purport to quote from the Recovery® Filter Instructions for Use, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 104.

105. The allegations contained in Paragraph 105 of Plaintiffs' Complaint purport to quote from the Recovery® Filter Instructions for Use, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 105.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiffs' Complaint.

107. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, they are continually evaluating the performance of such devices. To that end, a multifunctional team evaluated occurrences of adverse events related to the Recovery® Filter in 2004. Defendants deny any remaining allegations contained in Paragraph 107 of Plaintiffs' Complaint.

108. The allegations contained in Paragraph 108 of Plaintiffs' Complaint purport to quote from a document, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 108.

109. The allegations contained in Paragraph 109 of Plaintiffs' Complaint purport to quote from a document, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 109.

110. Defendants deny the allegations contained in Paragraph 110 of Plaintiffs' Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiffs' Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiffs' Complaint.

113. Defendants admit that the G2® Filter was cleared by the FDA in August 2005 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. To the extent the allegations contained in Paragraph 113 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 113 of Plaintiffs' Complaint.

114. To the extent the allegations contained in Paragraph 114 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 114 of Plaintiffs' Complaint.

115. To the extent the allegations contained in Paragraph 115 of Plaintiffs' Complaint purport to quo te or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 115 of Plaintiffs' Complaint.

116. To the extent the allegations contained in Paragraph 116 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 116 of Plaintiffs' Complaint.

117. To the extent the allegations contained in Paragraph 117 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 117 of Plaintiffs' Complaint.

118. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter. To the extent the allegations contained in Paragraph 118 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 118 of Plaintiffs' Complaint.

119. Defendants admit that the G2® Filter System was marketed after clearance was obtained by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny the remaining allegations contained in Paragraph 119 of Plaintiffs' Complaint.

120. Defendants admit that the G2® Filter System and Simon Nitinol Filter were both available for purchase beginning in 2005. Defendants deny the remaining allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs' Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs' Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiffs' Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of Plaintiffs' Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiffs' Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of

inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 130 of Plaintiffs' Complaint, including all sub-parts thereof.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiffs' Complaint. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiffs' Complaint. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications.

134. To the extent the allegations contained in Paragraph 134 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter. Defendants further admit that the G2® Express filter and G2® Filter are similarly designed, except that the G2® Express Filter was equipped with a snarable "hook" to facilitate retrieval via a snare device. Defendants deny any remaining allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Eclipse® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 138 of Plaintiffs' Complaint.

139. Defendants admit that the Eclipse® filter, cleared by FDA in 2010, was electropolished. Defendants deny the remaining allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. To the extent the allegations contained in Paragraph 140 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speaks for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of Plaintiffs' Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Defendants admit that the Meridian® Filter was cleared by the United States Food and Drug Administration in 2011 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 144 of Plaintiffs' Complaint.

145. To the extent the allegations contained in Paragraph 145 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speak for themselves, and any characterization inconsistent with the documents is denied. The

allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to which no answer is required. Defendants deny any remaining allegations contained in Paragraph 145 of Plaintiffs' Complaint.

146. Defendants deny the allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian® Filter was developed in furtherance of those efforts. Defendants admit that the Meridian® Filter is made of nitinol. Defendants deny any remaining allegations contained in Paragraph 147 of Plaintiffs' Complaint.

148. Defendants admit that the Meridian® Filter is electropolished and that the Meridian® Filter has caudal anchors on the six filter "arms". Defendants deny any remaining allegations contained in Paragraph 148 of Plaintiffs' Complaint.

149. Defendants deny the allegations contained in Paragraph 149 of Plaintiffs' Complaint.

150. Defendants deny the allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants admit that the Denali® Filter was cleared by the United States Food and Drug Administration in 2013 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 151 of Plaintiffs' Complaint.

152. To the extent the allegations contained in Paragraph 152 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speak for themselves, and any characterization inconsistent with the documents is denied. The allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to

which no answer is required. Defendants deny any remaining allegations contained in Paragraph 152 of Plaintiffs' Complaint.

153. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian® Filter was developed in furtherance of those efforts. Defendants admit that the Meridian® Filter is made of nitinol. Defendants admit that the Meridian® Filter is electropolished and that the Meridian® Filter has caudal anchors, cranial anchors, and penetration limiters. Defendants deny any remaining allegations contained in Paragraph 153 of Plaintiffs' Complaint.

154. Defendants deny the allegations contained in Paragraph 154 of Plaintiffs' Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of Plaintiffs' Complaint.

156. Defendants deny the allegations contained in Paragraph 156 of Plaintiffs' Complaint.

157. Defendants deny the allegations contained in Paragraph 157 of Plaintiffs' Complaint.

158. Defendants deny the allegations contained in Paragraph 158 of Plaintiffs' Complaint.

159. Defendants deny the allegations contained in Paragraph 159 of Plaintiffs' Complaint.

160. Defendants incorporate by reference their responses to Paragraphs 1-159 of Plaintiffs' Complaint as if fully set forth herein.

161. Defendants deny the allegations contained in Paragraph 161 of Plaintiffs' Complaint.

162. Defendants deny the allegations contained in Paragraph 162 of Plaintiffs' Complaint.

163. Defendants deny the allegations contained in Paragraph 163 of Plaintiffs' Complaint.

164. Defendants deny the allegations contained in Paragraph 164 of Plaintiffs' Complaint.

165. The allegations contained in Paragraph 165 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 165 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

COUNT I: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

166. Defendants incorporate by reference their responses to Paragraphs 1-165 of Plaintiffs' Complaint as if fully set forth herein.

167. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the brand of any inferior vena cava filter implanted in any plaintiff and, on that basis, denies the allegations.

168. Defendants deny the allegations contained in Paragraph 168 of Plaintiffs' Complaint.

169. Defendants deny the allegations contained in Paragraph 169 of Plaintiffs' Complaint.

170. Defendants deny the allegations contained in Paragraph 170 of Plaintiffs' Complaint.

COUNT II: STRICT PRODUCTS LIABILITY – INFORMATION DEFECT

171. Defendants incorporate by reference their responses to Paragraphs 1-170 of Plaintiffs' Complaint as if fully set forth herein.

172. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the brand of any inferior vena cava filter implanted in any

plaintiff and, on that basis, deny the allegations. Defendants deny any remaining allegations contained in Paragraph 172 of Plaintiffs' Complaint.

173. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 173 of Plaintiffs' Complaint.

174. Defendants deny the allegations contained in Paragraph 174 of Plaintiffs' Complaint.

175. Defendants deny the allegations contained in Paragraph 175 of Plaintiffs' Complaint, including all sub-parts thereof.

176. Defendants deny the allegations contained in Paragraph 176 of Plaintiffs' Complaint.

177. Defendants deny the allegations contained in Paragraph 177 of Plaintiffs' Complaint.

178. Defendants deny the allegations contained in Paragraph 178 of Plaintiffs' Complaint.

179. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 179 of Plaintiffs' Complaint and, on that basis, deny the allegations.

180. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 180 of Plaintiffs' Complaint and, on that basis, deny the allegations.

181. Defendants deny the allegations contained in Paragraph 181 of Plaintiffs' Complaint.

COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

182. Defendants incorporate by reference their responses to Paragraphs 1-181 of Plaintiffs' Complaint as if fully set forth herein.

183. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 183 of Plaintiffs' Complaint.

184. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 184 of Plaintiffs' Complaint and, on that basis, deny the allegations.

185. Defendants deny the allegations contained in Paragraph 185 of Plaintiffs' Complaint.

186. Defendants deny the allegations contained in Paragraph 186 of Plaintiffs' Complaint.

187. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 187 of Plaintiffs' Complaint and, on that basis, deny the allegations.

188. Defendants deny the allegations contained in Paragraph 188 of Plaintiffs' Complaint.

189. Defendants deny the allegations contained in Paragraph 189 of Plaintiffs' Complaint.

190. Defendants deny the allegations contained in Paragraph 190 of Plaintiffs' Complaint.

191. Defendants deny the allegations contained in Paragraph 191 of Plaintiffs' Complaint.

COUNT IV: NEGLIGENCE – DESIGN

192. Defendants incorporate by reference their responses to Paragraphs 1-191 of Plaintiffs' Complaint as if fully set forth herein.

193. Defendants deny the allegations contained in Paragraph 193 of Plaintiffs' Complaint, including all sub-parts thereof.

194. Defendants deny the allegations contained in Paragraph 194 of Plaintiffs' Complaint, including all sub-parts thereof.

195. The allegations contained in Paragraph 195 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 195 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

196. Defendants deny the allegations contained in Paragraph 196 of Plaintiffs' Complaint, including all sub-parts thereof.

197. Defendants deny the allegations contained in Paragraph 197 of Plaintiffs' Complaint.

COUNT V: NEGLIGENCE – MANUFACTURE

198. Defendants incorporate by reference their responses to Paragraphs 1-197 of Plaintiffs' Complaint as if fully set forth herein.

199. The allegations contained in Paragraph 199 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 199 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

200. Defendants deny the allegations contained in Paragraph 200 of Plaintiffs' Complaint, including all sub-parts thereof.

201. Defendants deny the allegations contained in Paragraph 201 of Plaintiffs' Complaint.

COUNT VI: NEGLIGENCE – FAILURE TO RECALL/RETROFIT

202. Defendants incorporate by reference their responses to Paragraphs 1-201 of Plaintiffs' Complaint as if fully set forth herein.

203. Defendants deny the allegations contained in Paragraph 203 of Plaintiffs' Complaint.

204. Defendants deny the allegations contained in Paragraph 204 of Plaintiffs' Complaint.

205. Defendants deny the allegations contained in Paragraph 205 of Plaintiffs' Complaint.

206. Defendants deny the allegations contained in Paragraph 206 of Plaintiffs' Complaint.

207. Defendants deny the allegations contained in Paragraph 207 of Plaintiffs' Complaint.

208. Defendants deny the allegations contained in Paragraph 208 of Plaintiffs' Complaint.

209. Defendants deny the allegations contained in Paragraph 209 of Plaintiffs' Complaint.

COUNT VII: NEGLIGENCE – FAILURE TO WARN

210. Defendants incorporate by reference their responses to Paragraphs 1-209 of Plaintiffs' Complaint as if fully set forth herein.

211. Defendants deny the allegations contained in Paragraph 211 of Plaintiffs' Complaint.

212. Defendants deny the allegations contained in Paragraph 212 of Plaintiffs' Complaint.

213. Defendants deny the allegations contained in Paragraph 213 of Plaintiffs' Complaint.

214. Defendants deny the allegations contained in Paragraph 214 of Plaintiffs' Complaint.

215. The allegations contained in Paragraph 215 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 215 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

216. Defendants deny the allegations contained in Paragraph 216 of Plaintiffs' Complaint.

217. Defendants deny the allegations contained in Paragraph 217 of Plaintiffs' Complaint.

COUNT VIII: NEGLIGENT MISREPRESENTATION

218. Defendants incorporate by reference their responses to Paragraphs 1-217 of Plaintiffs' Complaint as if fully set forth herein.

219. Defendants deny the allegations contained in Paragraph 219 of Plaintiffs' Complaint.

220. Defendants deny the allegations contained in Paragraph 220 of Plaintiffs' Complaint.

221. The allegations contained in Paragraph 221 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 221 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

222. Defendants deny the allegations contained in Paragraph 222 of Plaintiffs' Complaint.

223. Defendants deny the allegations contained in Paragraph 223 of Plaintiffs' Complaint.

224. Defendants deny the allegations contained in Paragraph 224 of Plaintiffs' Complaint.

225. Defendants deny the allegations contained in Paragraph 225 of Plaintiffs' Complaint.

226. The allegations contained in Paragraph 226 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 226 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

227. Defendants deny the allegations contained in Paragraph 227 of Plaintiffs' Complaint.

228. Defendants deny the allegations contained in Paragraph 228 of Plaintiffs' Complaint.

COUNT IX: NEGLIGENCE PER SE

229. Defendants incorporate by reference their responses to Paragraphs 1-228 of Plaintiffs' Complaint as if fully set forth herein.

230. The allegations contained in Paragraph 230 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 230 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

231. Defendants deny the allegations contained in Paragraph 231 of Plaintiffs' Complaint, including all sub-parts thereof.

232. The allegations contained in Paragraph 232 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 232 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

233. Defendants deny the allegations contained in Paragraph 233 of Plaintiffs' Complaint.

234. Defendants deny the allegations contained in Paragraph 234 of Plaintiffs' Complaint.

COUNT X: BREACH OF EXPRESS WARRANTY

235. Defendants incorporate by reference their responses to Paragraphs 1-234 of Plaintiffs' Complaint as if fully set forth herein.

236. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 236 of Plaintiffs' Complaint and, on that basis, deny the allegations.

237. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 237 of Plaintiffs' Complaint.

238. Defendants deny the allegations contained in Paragraph 238 of Plaintiffs' Complaint.

239. Defendants deny the allegations contained in Paragraph 239 of Plaintiffs' Complaint, including all sub-parts thereof.

240. Defendants deny the allegations contained in Paragraph 240 of Plaintiffs' Complaint.

COUNT XI: BREACH OF IMPLIED WARRANTY

241. Defendants incorporate by reference their responses to Paragraphs 1-240 of Plaintiffs' Complaint as if fully set forth herein.

242. Defendants deny the allegations contained in Paragraph 242 of Plaintiffs' Complaint.

243. Defendants deny the allegations contained in Paragraph 243 of Plaintiffs' Complaint, including all sub-parts thereof.

244. Defendants deny the allegations contained in Paragraph 244 of Plaintiffs' Complaint.

COUNT XII: FRAUDULENT MISREPRESENTATION

245. Defendants incorporate by reference their responses to Paragraphs 1-244 of Plaintiffs' Complaint as if fully set forth herein.

246. Defendants deny the allegations contained in Paragraph 246 of Plaintiffs' Complaint, including all sub-parts thereof.

247. Defendants deny the allegations contained in Paragraph 247 of Plaintiffs' Complaint.

248. Defendants deny the allegations contained in Paragraph 248 of Plaintiffs' Complaint.

249. Defendants deny the allegations contained in Paragraph 249 of Plaintiffs' Complaint.

250. Defendants deny the allegations contained in Paragraph 250 of Plaintiffs' Complaint.

251. Defendants deny the allegations contained in Paragraph 251 of Plaintiffs' Complaint.

252. Defendants deny the allegations contained in Paragraph 252 of Plaintiffs' Complaint.

253. Defendants deny the allegations contained in Paragraph 253 of Plaintiffs' Complaint.

254. Defendants deny the allegations contained in Paragraph 254 of Plaintiffs' Complaint.

255. Defendants deny the allegations contained in Paragraph 255 of Plaintiffs' Complaint.

256. Defendants deny the allegations contained in Paragraph 256 of Plaintiffs' Complaint.

257. Defendants deny the allegations contained in Paragraph 257 of Plaintiffs' Complaint.

258. Defendants deny the allegations contained in Paragraph 258 of Plaintiffs' Complaint.

259. Defendants deny the allegations contained in Paragraph 259 of Plaintiffs' Complaint.

COUNT XIII: FRAUDULENT CONCEALMENT

260. Defendants incorporate by reference their responses to Paragraphs 1-259 of Plaintiffs' Complaint as if fully set forth herein.

261. Defendants deny the allegations contained in Paragraph 261 of Plaintiffs' Complaint.

262. Defendants deny the allegations contained in Paragraph 262 of Plaintiffs' Complaint, including all sub-parts thereof.

263. Defendants deny the allegations contained in Paragraph 263 of Plaintiffs' Complaint.

264. Defendants deny the allegations contained in Paragraph 264 of Plaintiffs' Complaint.

265. Defendants deny the allegations contained in Paragraph 265 of Plaintiffs' Complaint.

266. Defendants deny the allegations contained in Paragraph 266 of Plaintiffs' Complaint.

COUNT XIV: VIOLATIONS OF APPLICABLE STATE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR DECEPTIVE TRADE PRACTICES

267. Defendants incorporate by reference their responses to Paragraphs 1-266 of Plaintiffs' Complaint as if fully set forth herein.

268. The allegations contained in Paragraph 268 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 268 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

269. Defendants deny the allegations contained in Paragraph 269 of Plaintiffs' Complaint.

270. Defendants deny the allegations contained in Paragraph 270 of Plaintiffs' Complaint.

271. Defendants deny the allegations contained in Paragraph 271 of Plaintiffs' Complaint.

272. Defendants deny the allegations contained in Paragraph 272 of Plaintiffs' Complaint.

273. Defendants deny the allegations contained in Paragraph 273 of Plaintiffs' Complaint.

274. Defendants deny the allegations contained in Paragraph 274 of Plaintiffs' Complaint.

275. Defendants deny the allegations contained in Paragraph 275 of Plaintiffs' Complaint.

276. Defendants deny the allegations contained in Paragraph 276 of Plaintiffs' Complaint.

277. Defendants deny the allegations contained in Paragraph 277 of Plaintiffs' Complaint.

278. Defendants deny the allegations contained in Paragraph 278 of Plaintiffs' Complaint.

279. Defendants deny the allegations contained in Paragraph 279 of Plaintiffs' Complaint.

280. Defendants deny the allegations contained in Paragraph 280 of Plaintiffs' Complaint.

281. Defendants deny the allegations contained in Paragraph 281 of Plaintiffs' Complaint.

282. Defendants deny the allegations contained in Paragraph 282 of Plaintiffs' Complaint.

283. Defendants deny the allegations contained in Paragraph 283 of Plaintiffs' Complaint.

284. Defendants deny the allegations contained in Paragraph 284 of Plaintiffs' Complaint.

285. Defendants deny the allegations contained in Paragraph 285 of Plaintiffs' Complaint.

286. Defendants deny the allegations contained in Paragraph 286 of Plaintiffs' Complaint.

287. Defendants deny the allegations contained in Paragraph 287 of Plaintiffs' Complaint.

288. Defendants deny the allegations contained in Paragraph 288 of Plaintiffs' Complaint.

289. Defendants deny the allegations contained in Paragraph 289 of Plaintiffs' Complaint.

290. Defendants deny the allegations contained in Paragraph 290 of Plaintiffs' Complaint.

291. Defendants deny the allegations contained in Paragraph 291 of Plaintiffs' Complaint.

292. Defendants deny the allegations contained in Paragraph 292 of Plaintiffs' Complaint.

293. Defendants deny the allegations contained in Paragraph 293 of Plaintiffs' Complaint.

294. Defendants deny the allegations contained in Paragraph 294 of Plaintiffs' Complaint.

295. Defendants deny the allegations contained in Paragraph 295 of Plaintiffs' Complaint.

296. Defendants deny the allegations contained in Paragraph 296 of Plaintiffs' Complaint.

297. Defendants deny the allegations contained in Paragraph 297 of Plaintiffs' Complaint.

298. Defendants deny the allegations contained in Paragraph 298 of Plaintiffs' Complaint.

299. Defendants deny the allegations contained in Paragraph 299 of Plaintiffs' Complaint.

300. Defendants deny the allegations contained in Paragraph 300 of Plaintiffs' Complaint.

301. Defendants deny the allegations contained in Paragraph 301 of Plaintiffs' Complaint.

302. Defendants deny the allegations contained in Paragraph 302 of Plaintiffs' Complaint.

303. Defendants deny the allegations contained in Paragraph 303 of Plaintiffs' Complaint.

304. Defendants deny the allegations contained in Paragraph 304 of Plaintiffs' Complaint.

305. Defendants deny the allegations contained in Paragraph 305 of Plaintiffs' Complaint.

306. Defendants deny the allegations contained in Paragraph 306 of Plaintiffs' Complaint.

307. Defendants deny the allegations contained in Paragraph 307 of Plaintiffs' Complaint.

308. Defendants deny the allegations contained in Paragraph 308 of Plaintiffs' Complaint.

309. Defendants deny the allegations contained in Paragraph 309 of Plaintiffs' Complaint.

310. Defendants deny the allegations contained in Paragraph 310 of Plaintiffs' Complaint.

311. Defendants deny the allegations contained in Paragraph 311 of Plaintiffs' Complaint.

312. Defendants deny the allegations contained in Paragraph 312 of Plaintiffs' Complaint.

313. Defendants deny the allegations contained in Paragraph 313 of Plaintiffs' Complaint.

314. Defendants deny the allegations contained in Paragraph 314 of Plaintiffs' Complaint.

315. Defendants deny the allegations contained in Paragraph 315 of Plaintiffs' Complaint.

316. Defendants deny the allegations contained in Paragraph 316 of Plaintiffs' Complaint.

317. Defendants deny the allegations contained in Paragraph 317 of Plaintiffs' Complaint.

318. Defendants deny the allegations contained in Paragraph 318 of Plaintiffs' Complaint.

319. Defendants deny the allegations contained in Paragraph 319 of Plaintiffs' Complaint.

320. Defendants deny the allegations contained in Paragraph 320 of Plaintiffs' Complaint.

321. Defendants deny the allegations contained in Paragraph 321 of Plaintiffs' Complaint.

322. Defendants deny the allegations contained in Paragraph 322 of Plaintiffs' Complaint.

323. Defendants deny the allegations contained in Paragraph 323 of Plaintiffs' Complaint.

COUNT XV: LOSS OF CONSORTIUM

324. Defendants incorporate by reference their responses to Paragraphs 1-323 of Plaintiffs' Complaint as if fully set forth herein.

325. Defendants deny the allegations contained in Paragraph 325 of Plaintiffs' Complaint.

326. Defendants deny the allegations contained in Paragraph 326 of Plaintiffs' Complaint.

327. Defendants deny the allegations contained in Paragraph 327 of Plaintiffs' Complaint.

328. Defendants deny the allegations contained in Paragraph 328 of Plaintiffs' Complaint.

329. Defendants deny the allegations contained in Paragraph 329 of Plaintiffs' Complaint.

330. Defendants deny the allegations contained in Paragraph 330 of Plaintiffs' Complaint.

COUNT XVI: WRONGFUL DEATH

331. Defendants incorporate by reference their responses to Paragraphs 1-330 of Plaintiffs' Complaint as if fully set forth herein.

332. Defendants deny the allegations contained in Paragraph 332 of Plaintiffs' Complaint.

333. Defendants deny the allegations contained in Paragraph 333 of Plaintiffs' Complaint.

334. Defendants deny the allegations contained in Paragraph 334 of Plaintiffs' Complaint.

335. Defendants deny the allegations contained in Paragraph 335 of Plaintiffs' Complaint.

COUNT XVII: SURVIVAL

336. Defendants incorporate by reference their responses to Paragraphs 1-335 of Plaintiffs' Complaint as if fully set forth herein.

337. Defendants deny the allegations contained in Paragraph 337 of Plaintiffs' Complaint.

338. Defendants deny the allegations contained in Paragraph 338 of Plaintiffs' Complaint.

PUNITIVE DAMAGES ALLEGATIONS

339. Defendants incorporate by reference their responses to Paragraphs 1-338 of Plaintiffs' Complaint as if fully set forth herein.

340. Defendants deny the allegations contained in Paragraph 340 of Plaintiffs' Complaint.

341. Defendants deny the allegations contained in Paragraph 341 of Plaintiffs' Complaint.

342. Defendants deny the allegations contained in Paragraph 342 of Plaintiffs' Complaint.

343. Defendants deny the allegations contained in Paragraph 343 of Plaintiffs' Complaint.

344. Defendants deny the allegations contained in Paragraph 344 of Plaintiffs' Complaint.

345. Defendants deny the allegations contained in Paragraph 345 of Plaintiffs' Complaint.

346. Defendants deny the allegations contained in Paragraph 346 of Plaintiffs' Complaint.

347. Defendants deny the allegations contained in Paragraph 347 of Plaintiffs' Complaint.

348. Defendants deny the allegations contained in Paragraph 348 of Plaintiffs' Complaint.

349. Defendants deny the allegations contained in Paragraph 349 of Plaintiffs' Complaint.

PRAYER FOR RELIEF

Furthermore, responding to the unnumbered Paragraph, including sub-parts numbered Paragraphs A-K, following the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and sub-parts.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs is barred to the extent Plaintiffs voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiffs.

6. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

8. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

9. There was no defect in the products at issue with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

10. If there were any defect in the products – and Defendants deny that there were any defects – nevertheless, there was no causal connection between any alleged defect and the products on the one hand and any damage to Plaintiffs on the other with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to by other persons or entities that are severally liable for all or part of Plaintiffs' alleged injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiffs' alleged damages.

12. Plaintiffs' claims are barred to the extent that the injuries alleged in the Plaintiffs' Complaint were caused by the abuse, misuse, abnormal use, or use of the products at issue in a manner not intended by Defendants and over which Defendants had no control.

13. Plaintiffs' claims are barred to the extent that the injuries alleged in the Plaintiffs' Complaint were caused by a substantial change in the products after leaving the possession, custody, and control of Defendants.

14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or Defendants.

15. Plaintiffs' claims for breach of implied warranty must fail because the products were not used for its ordinary purpose.

16. Defendants neither had nor breached any alleged duty to warn with respect to the products, with the result that Plaintiffs are not entitled to recover in this cause.

17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate warnings and instructions to learned intermediaries.

18. At all relevant times herein, Plaintiffs' physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the subject products.

19. If Plaintiffs have been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged damages.

20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were unknown, unknowable, or not reasonably foreseeable to Defendants.

21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

22. At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

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

25. If Plaintiffs suffered any damages or injuries, which are denied, Defendants state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the doctrines of contributory and/or comparative negligence.

26. In the further alternative, and only in the event that it is determined that Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiffs, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the future.

27. Should Defendants be held liable to Plaintiffs, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs from all collateral sources.

28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of claims, and the prohibition on double recovery for the same injury.

29. The injuries and damages allegedly sustained by Plaintiffs may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs over which Defendants had no control.

30. The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

31. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

32. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiffs' defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and comments thereto.

33. Plaintiffs cannot show that any reasonable alternative design would have rendered Bard's Inferior Vena Cava Filters as alleged in Plaintiffs' Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be identified by Plaintiffs.

34. The devices at issue were not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).

35. At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

37. Plaintiffs' alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.

38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiffs' Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate

Defendants' rights under the Constitution of the United States and analogous provisions of the various states' constitutions.

40. To the extent Plaintiffs' claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

41. Defendants are entitled to, and claim the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute that may be applicable.

42. Regarding Plaintiffs' demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

43. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the various states' constitutions, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and

Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

44. Plaintiffs have failed to plead their fraud claims with the particularity required under applicable state's statutory and/or common law.

45. Plaintiffs' cases may be subject to dismissal or transfer under the doctrine of forum non conveniens.

46. Plaintiffs' product liability claims are barred because the benefits of the products outweighed their risks.

47. Venue may be improper in any individual case where the plaintiff does not reside in the forum wherein his or her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

48. The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' laws.

49. Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs seek damages in excess of applicable state-law caps and limits on recovery of damages or of specific categories of damages.

50. Plaintiffs' claims are barred, in whole or in part, by insufficiency of service and/or insufficiency of service of process.

51. Defendants are entitled to and claim 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 case.

52. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

53. Defendants assert that choice of law rules should determine which jurisdiction's laws govern this case and expressly reserve the right to supplement this answer with any defenses that may be available to it under the law of the jurisdictions determined to apply to it in accordance with choice of law rules.

54. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiffs are not entitled to the relief demanded in the Plaintiffs' Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This _____ day of _____, 20__.

s/Richard B. North, Jr.
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on [DATE], I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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