

Edward J. Fanning
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 622-4444
efanning@mccarter.com

IN RE: Bard Implanted Port Catheter
Products Liability Litigation

Superior Court of New Jersey, Law Division –
Bergen County
Master Docket No. BER-L-2403-25-MCL.
MCL No. 640

**DEFENDANTS' ANSWER TO
PLAINTIFFS' MASTER COMPLAINT
AND AFFIRMATIVE DEFENSES**

Defendants Becton, Dickinson and Company; C. R. Bard, Inc.; Bard Access Systems, Inc.; and Bard Peripheral Vascular, Inc. (collectively, “Defendants”) hereby answer the Plaintiffs’ Master Long-Form Complaint (“Complaint” or “Plaintiffs’ Complaint”). Defendants hereby deny any and all Causes of Action or factual allegations added by any individual plaintiffs through use of the Short-Form Complaint for Damages. Defendants further deny Plaintiffs’ alleged injuries are the result of any wrongful conduct or defective product attributable to Defendants and deny that Plaintiffs are entitled to any relief from Defendants for the claims set forth in Plaintiffs’ Complaint. 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 Long-Form Complaint except to the extent such allegations are specifically admitted below.

Responding to the second unnumbered paragraph beginning “Plaintiffs intend...” of Plaintiffs’ Complaint, the allegations contained in said paragraph are not directed to Defendants and, as a result, require no response from Defendants. Furthermore, the allegations contained in the second unnumbered paragraph beginning “Plaintiffs intend...” include legal conclusions,

which do not require a response. Further answering, Defendants deny Plaintiffs' alleged injuries are the result of any wrongful conduct or defective product attributed to Defendants and deny that Plaintiffs are entitled to any relief from Defendants for the claims set forth in Plaintiffs' Complaint. Defendants deny all remaining allegations set forth in the second unnumbered paragraph beginning "Plaintiffs' intend..." of Plaintiffs' Complaint, including any allegations contained in Footnote 1.

Responding to the third unnumbered paragraph beginning "This Master Complaint..." of Plaintiffs' Complaint, the allegations contained in said paragraph are not directed to Defendants and, as a result, require no response from Defendants. Furthermore, the allegations contained in the second unnumbered paragraph beginning "This Master Complaint..." include legal conclusions, which do not require a response. Further answering, Defendants deny Plaintiffs' alleged injuries are the result of any wrongful conduct or defective product attributed to Defendants and deny that Plaintiffs are entitled to any relief from Defendants for the claims set forth in Plaintiffs' Complaint. Defendants deny all remaining allegations set forth in the third unnumbered paragraph beginning "This Master Complaint" of Plaintiffs' Complaint.

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 deny the remaining allegations contained in Paragraph 1 of Plaintiffs' Complaint.

2. The allegations contained in Paragraph 2 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent a response is required, Defendants admit that the products listed in Paragraph 2 of Plaintiffs' Complaint are an incomplete, inaccurate, and imprecise list of certain implantable port catheter products designed,

manufactured, or marketed by certain Defendants. Except as specifically admitted, the allegations of Paragraph 2 are denied.

3. Defendants admit that Plaintiffs purport to bring their actions for damages related to Defendants' design, research, development, licensing, testing, assembling, manufacturing, labeling, packaging, promoting, marketing, advertising, distributing, supplying, and/or selling certain implantable port catheter products. However, Defendants deny that there is any legal or factual basis for such relief. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Defendants admit that there are various well-known and warned about complications associated with any implanted port or catheter product. 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 and, on that basis, deny the allegations.

6. The allegations contained in Paragraph 6 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. The allegations contained in Paragraph 6 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent Paragraph 6 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

7. The allegations contained in Paragraph 7 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent Paragraph 7 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

8. Defendants deny the allegations contained in Paragraph 8 of Plaintiffs' Complaint.

9. To the extent the allegations contained in Paragraph 9 of Plaintiffs' Complaint, including Footnote 2, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 9 of Plaintiffs' Complaint.

10. The allegations contained in Paragraph 10 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response by Defendants. However, to the extent Paragraph 10 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is denied.

11. The allegations contained in Paragraph 11 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response by Defendants. Moreover, the allegations contained in Paragraph 11 include legal conclusions, which do not require any response. However, to the extent Paragraph 11 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is denied.

12. Defendants admit that Becton, Dickinson and Company ("BD") is a corporation organized under the laws of the State of New Jersey with its principal place of business in Franklin Lakes, New Jersey.

13. Defendants admit that BD is a corporation organized under the laws of the State of New Jersey.

14. Defendants admit the allegations contained in Paragraph 14 of Plaintiffs' Complaint.

15. Defendants admit that BD is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of Arizona.

16. Defendants deny the allegations contained in paragraph 16, except to admit that BD is a corporation organized under the laws of the State of New Jersey with its principal place of business in Franklin Lakes, New Jersey. Defendants further admit that, in accord with Food and Drug Administration regulations, BD is involved with the design, manufacture, and distribution of certain prescription medical devices, among other products. Defendants further admit that BD is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of New Jersey. Defendants deny the remaining allegations contained in Paragraph 16 of Plaintiffs' Complaint.

17. Defendants admit that C. R. Bard, Inc. ("C. R. Bard") is a corporation organized under the laws of the State of New Jersey with its principal place of business in Franklin Lakes, New Jersey.

18. Defendants admit that C. R. Bard is a corporation organized under the laws of the State of New Jersey.

19. Defendants admit the allegations contained in Paragraph 19 of Plaintiffs' Complaint.

20. Defendants admit that C. R. Bard is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of New Jersey.

21. Defendants deny the allegations contained in Paragraph 21, except to admit that C. R. Bard is a corporation organized under the laws of the State of New Jersey with its principal place of business in Franklin Lakes, New Jersey. Defendants further admit that, in accord with Food and Drug Administration regulations, C. R. Bard is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter products. Defendants further admit that C. R. Bard is authorized to do business, and does business,

in various states and jurisdictions throughout the United States, including the State of New Jersey. Defendants deny the remaining allegations contained in Paragraph 21 of Plaintiffs' Complaint.

22. Defendants admit that Bard Access Systems, Inc. ("BAS") is a corporation organized under the laws of the State of Utah with its principal place of business in Salt Lake City, Utah.

23. Defendants admit that BAS is a corporation organized under the laws of the State of Utah.

24. Defendants admit the allegations contained in Paragraph 24 of Plaintiffs' Complaint.

25. Defendants admit the allegations contained in Paragraph 25 of Plaintiffs' Complaint.

26. Defendants deny the allegations contained in Paragraph 26 of Plaintiffs' Complaint.

27. To the extent the allegations contained in Paragraph 27 of Plaintiffs' Complaint, including Footnote 3, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 27 of Plaintiffs' Complaint.

28. Defendants admit that BAS is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of New Jersey.

29. Defendants admit that, in accord with Food and Drug Administration regulations, BAS is involved with the design, manufacture, and distribution of certain prescription medical devices, including implantable port catheter devices. Defendants further admit that BAS is authorized to do business, and does business, in various states and jurisdictions throughout the

United States, including the State of New Jersey. Defendants deny the remaining allegations contained in Paragraph 29 of Plaintiffs' Complaint.

30. Defendants admit that Bard Peripheral Vascular, Inc. ("BPV") is a corporation organized under the laws of the State of Arizona with its principal place of business in Tempe, Arizona.

31. Defendants admit that BPV is a corporation organized under the laws of the State of Arizona.

32. Defendants admit the allegations contained in Paragraph 32 of Plaintiffs' Complaint.

33. Defendants admit the allegations contained in Paragraph 33 of Plaintiffs' Complaint.

34. Defendants deny the allegations contained in Paragraph 34 of Plaintiffs' Complaint.

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

36. To the extent the allegations contained in Paragraph 36 of Plaintiffs' Complaint, including Footnote 4, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 36 of Plaintiffs' Complaint, including Footnote 4.

37. Defendants deny the allegations contained in Paragraph 37, except to admit that BPV is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of New Jersey.

38. Defendants admit that, in accord with Food and Drug Administration regulations, BPV is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices. Defendants further admit 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 deny the remaining allegations contained in Paragraph 38 of Plaintiffs' Complaint.

Allegations Regarding BD Acquisition of C. R. Bard, BAS, and BPV

39. Defendants admit the allegations contained in Paragraph 39 of Plaintiffs' Complaint.

40. Defendants admit the allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Defendants deny the 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 deny the allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. Defendants admit the allegations contained in Paragraph 45 of Plaintiffs' Complaint.

46. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 46 of Plaintiffs' Complaint as said allegations are too overbroad and vague and, on that basis, deny the allegations.

47. The allegations contained in Paragraph 47 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. The allegations contained in Paragraph 47 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 47 of Plaintiffs' Complaint and, on that basis, deny the allegations.

48. The allegations contained in Paragraph 48 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. The allegations contained in Paragraph 48 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 48 of Plaintiffs' Complaint and, on that basis, deny the allegations.

Allegations Regarding Jurisdiction and Venue

49. The allegations contained in Paragraph 49 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants admit the allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. The allegations contained in Paragraph 50 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants admit that BD and C. R. Bard are corporations organized under the laws of the State of New Jersey with their principal place of business in Franklin Lakes, New Jersey. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 50 of Plaintiffs' Complaint as to BPV and BAS and, on that basis, deny the allegations.

51. Defendants admit that BD and C. R. Bard are corporations organized under the laws of the State of New Jersey with their principal place of business in Franklin Lakes, New Jersey.

52. The allegations contained in Paragraph 52 of Plaintiffs' Complaint all sub-parts thereof are conclusions of law, which do not require a response. To the extent a response is required, Defendants deny the allegations.

53. To the extent the allegations contained in Paragraph 53 of Plaintiffs' Complaint, including Footnote 5, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

54. The allegations contained in Paragraph 54 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants admit that they conduct business in New Jersey and Bergen County.

Factual Allegations

Allegations Regarding Implanted Port Catheters

55. To the extent the allegations contained in Paragraph 55 of Plaintiffs' Complaint, including Footnote 6, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Insofar as any of these allegations may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 55 are denied, including Footnote 6.

56. Defendants admit that the products listed as "Bard IPCs" in Plaintiffs' Complaint are an incomplete, inaccurate, and imprecise list of certain implantable port catheter products designed, manufactured, or marketed by certain Defendants. Insofar as any of these allegations may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 56 are denied.

57. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 57 of Plaintiffs' Complaint, including Footnote 7, and therefore leave Plaintiffs to their proofs.

58. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 58 of Plaintiffs' Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegations are denied. Except as specifically admitted, the allegations of Paragraph 58 are denied.

59. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 59 of Plaintiffs' Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 59 are denied.

60. To the extent the allegations contained in Paragraph 60 of Plaintiffs' Complaint, including Footnote 8, 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 60 of Plaintiffs' Complaint.

61. Defendants admit that implantable port catheter devices may be used to deliver medications, I.V. fluids, parenteral nutrition solutions, or blood products and may be used for the

withdrawal of blood samples directly as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Except as specifically admitted, the allegations of Paragraph 61 of Plaintiffs' Complaint are denied.

62. To the extent the allegations contained in Paragraph 62 of Plaintiffs' Complaint, including Footnote 9, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants admit that two of the components of implantable port catheter devices are the port and catheter. Insofar as any of the allegations of Paragraph 62 may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 62 are denied.

63. Defendants admit that two of the components of implantable port catheter devices are the port and catheter. Insofar as any of the allegations of Paragraph 63 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 63 are denied.

64. Defendants admit that implantable port catheter devices may have a variety of different design aspects and features. Insofar as any of the allegations of Paragraph 64 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

65. Defendants admit that implantable port catheter devices are accessed via the septum and can be used to deliver medication directly into a patient's bloodstream as prescribed by

licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 65 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 65 are denied.

66. To the extent the allegations contained in Paragraph 66 of Plaintiff's Complaint, including Footnote 10, 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 66 of Plaintiffs' Complaint.

67. Defendants admit that implantable port catheter devices may be described in terms of "single lumen" or "dual lumen." Insofar as any of the allegations of Paragraph 67 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

68. Defendants admit that port bodies may be made of a variety of materials, including but not limited to plastic, silicone, or titanium. Insofar as any of the allegations of Paragraph 68 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

69. Defendants admit that two of the components of implantable port catheter devices are the port and catheter. Insofar as any of the allegations of Paragraph 69 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 69 are denied.

70. To the extent the allegations contained in Paragraph 70 of Plaintiff's Complaint, including Footnote 11, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. Defendants admit that part of the procedure to connect a catheter to a port involves advancing a catheter lock, or "cathlock." Defendants further admit that its implantable port catheter devices are intended to be used consistent with their applicable Instructions for Use. Insofar as any of the allegations of Paragraph 71 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

72. Defendants admit that certain products may consist of a catheter that is "pre-attached" to a port, or a catheter that is an "attachable" catheter. Defendants further admit that its implantable port catheter devices are intended to be used consistent with their applicable Instructions for Use. Insofar as any of the allegations of Paragraph 72 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

73. Defendants admit that various catheters from various manufacturers exist, including but not limited to ChronoFlex and Groshong catheters. Except as specifically admitted, the allegations of Paragraph 73 of Plaintiff's Complaint are denied.

74. Defendants admit that catheters may be comprised of a variety of materials, including but not limited to silicone or polyurethane. Insofar as any of the allegations of Paragraph 74 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

75. Defendants admit that catheters may vary in width for a variety of reasons, including but not limited to differences in a patient's anatomy. Defendants further admit that its

implantable port catheter devices are intended to be used consistent with their applicable Instructions for Use. Insofar as any of the allegations of Paragraph 75 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

76. Defendants make no response to the allegations of this Paragraph insofar as the allegations contained therein are not directed against these Defendants. Defendants generally agree that catheters are typically measured in the French Scale based on a catheter's diameter. Insofar as any of the allegations of Paragraph 76 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

77. Defendants make no response to the allegations of this Paragraph insofar as the allegations contained therein are not directed against these Defendants. Insofar as any of the allegations of Paragraph 77 of Plaintiff's Complaint purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

78. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 78 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 78 are denied.

79. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 79 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product

was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 79 are denied.

80. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 80 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 80 are denied.

81. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 81 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 81 are denied.

82. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 82 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such

product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 82 are denied.

83. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 83 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 83 are denied.

Defendants' Development of IPC Devices and Technologies

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's Complaint, except to admit that certain Defendants were involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices, among other products, sometime during the 1980s.

85. To the extent the allegations contained in Paragraph 85 of Plaintiff's Complaint, including all sub-parts thereof, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 85 of Plaintiffs' Complaint.

86. To the extent the allegations contained in Paragraph 86 of Plaintiff's Complaint, including all sub-parts thereof, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 86 of Plaintiffs' Complaint.

87. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 87 of Plaintiff's Complaint, including all sub-parts thereof, may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 87 are denied.

88. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 88 of Plaintiff's Complaint, including all sub-parts thereof, may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 88 are denied.

89. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 89 of Plaintiff's Complaint, including all sub-parts thereof, may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 89 are denied.

90. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals

in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 90 of Plaintiff's Complaint, including all sub-parts thereof, may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 90 are denied.

91. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants further admit that certain implantable port catheter devices contain palpation bumps. Insofar as any of the allegations in Paragraph 91 of Plaintiff's Complaint, may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 91 are denied, including Footnote 12.

92. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants further admit that certain implantable port catheter devices are radiopaque. Insofar as any of the allegations in Paragraph 92 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 92 are denied.

93. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals

in accordance with accompanying Instructions for Use. Defendants further admit that certain port bodies are radiopaque. Insofar as any of the allegations in Paragraph 93 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 93 are denied, including Footnote 13.

94. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants further admit that certain implantable port catheter devices are radiopaque. Insofar as any of the allegations in Paragraph 94 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 94 are denied.

Allegations Regarding Defendants' Development of Power-Injectable IPCs

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint, except to admit that certain Defendants were involved with the design, manufacture, and distribution of certain prescription medical devices, including implantable port catheter devices, among other products, sometime during the mid-2000s. Insofar as any of the allegations in Paragraph 95 may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 95 are denied.

96. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 96 of Plaintiff's Complaint regarding Factual Allegations may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 96 are denied.

97. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 97 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 97 are denied.

98. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals in accordance with accompanying Instructions for Use. Insofar as any of the allegations in Paragraph 98 of Plaintiff's Complaint may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 98 are denied.

99. Defendants admit that implantable port catheter devices can be used to deliver medication directly into a patient's bloodstream as prescribed by licensed medical professionals

in accordance with accompanying Instructions for Use. Defendants further admit that some of the listed devices correspond to power-injectable ports and that the products listed are an incomplete, inaccurate, and imprecise list of power-injectable ports. Insofar as any of the allegations in Paragraph 99 of Plaintiff's Complaint, including all sub-parts thereof, may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 99 are denied.

Allegations Regarding Regulatory Clearance

100. The allegations contained in Paragraph 100 of Plaintiffs' Complaint include legal conclusions, which do not require a response.

101. The allegations contained in Paragraph 101 of Plaintiffs' Complaint include legal conclusions, which do not require a response.

102. The allegations contained in Paragraph 102 of Plaintiffs' Complaint include legal conclusions, which do not require a response.

103. The allegations contained in Paragraph 103 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations contained in Paragraph 103 of Plaintiffs' Complaint.

104. The allegations contained in Paragraph 104 of Plaintiffs' Complaint include legal conclusions, which do not require a response.

105. The allegations contained in Paragraph 105 of Plaintiffs' Complaint, including Footnote 14, include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 105 of Plaintiffs' Complaint purport to quote or paraphrase the

case *Horn v. Thoratec Corp.*, the case speaks for itself, and any characterization inconsistent with the case law is denied.

106. The allegations contained in Paragraph 106 of Plaintiffs' Complaint, including Footnote 15, include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 106 of Plaintiffs' Complaint purport to quote or paraphrase the case *Medtronic, Inc. v. Lohr*, the case speaks for itself, and any characterization inconsistent with the case law is denied.

107. The allegations contained in Paragraph 107, including Footnote 16, of Plaintiffs' Complaint include legal conclusions, which do not require a response.

108. The allegations contained in Paragraph 108 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 108 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

109. The allegations contained in Paragraph 109 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 109 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

110. The allegations contained in Paragraph 110 of Plaintiffs' Complaint, including Footnote 17, include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 110 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

111. The allegations contained in Paragraph 111 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 111 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

112. The allegations contained in Paragraph 112 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 112 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

113. The allegations contained in Paragraph 113 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent the allegations contained in Paragraph 113 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

114. To the extent the allegations contained in Paragraph 114 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 18, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 114 of Plaintiffs' Complaint.

115. To the extent the allegations contained in Paragraph 115 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 19, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 115 of Plaintiffs' Complaint.

116. To the extent the allegations contained in Paragraph 116 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 20, purport to quote or paraphrase a document, the

document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 116 of Plaintiffs' Complaint.

117. To the extent the allegations contained in Paragraph 117 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 21, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 117 of Plaintiffs' Complaint.

118. To the extent the allegations contained in Paragraph 118 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 22, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 118 of Plaintiffs' Complaint.

119. To the extent the allegations contained in Paragraph 119 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 23 purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 119 of Plaintiffs' Complaint

120. To the extent the allegations contained in Paragraph 120 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 24, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. To the extent the allegations contained in Paragraph 121 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 25, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 121 of Plaintiffs' Complaint.

122. To the extent the allegations contained in Paragraph 122 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 26, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 122 of Plaintiffs' Complaint.

123. To the extent the allegations contained in Paragraph 123 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 27, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 123 of Plaintiffs' Complaint.

124. To the extent the allegations contained in Paragraph 124 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 28, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 124 of Plaintiffs' Complaint.

125. To the extent the allegations contained in Paragraph 125 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 29, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 125 of Plaintiffs' Complaint.

126. To the extent the allegations contained in Paragraph 126 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 30, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. To the extent the allegations contained in Paragraph 127 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 31, purport to quote or paraphrase a document, the

document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. To the extent the allegations contained in Paragraph 128 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 32, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. To the extent the allegations contained in Paragraph 129 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 33, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. To the extent the allegations contained in Paragraph 130 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 34, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 130 of Plaintiffs' Complaint.

131. To the extent the allegations contained in Paragraph 131 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 35, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 131 of Plaintiffs' Complaint.

132. To the extent the allegations contained in Paragraph 132 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 36, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. To the extent the allegations contained in Paragraph 133 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 37, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 133 of Plaintiffs' Complaint.

134. To the extent the allegations contained in Paragraph 134 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 38, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. To the extent the allegations contained in Paragraph 135 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 39, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. To the extent the allegations contained in Paragraph 136 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 40, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. To the extent the allegations contained in Paragraph 137 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 41, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. To the extent the allegations contained in Paragraph 138 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 42 purport to quote or paraphrase a document, the

document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 138 of Plaintiffs' Complaint.

Allegations Regarding Development of Barium-Sulfate Catheters

139. Defendants admit that barium sulfate is a radiopaque substance used in various implantable medical devices made by various manufacturers. Insofar as any of the allegations of Paragraph 139 purport to cast liability either directly or indirectly upon Defendants, such allegations are denied.

140. Defendants admit that certain Bard implantable port catheters are comprised of a mixture of barium sulfate with polyurethane or silicone. Defendants deny the remaining allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. To the extent the allegations contained in Paragraph 141 of Plaintiffs' Complaint, including all sub-parts thereof, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. To the extent the allegations contained in Paragraph 142 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 43 through 55, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 142 of Plaintiffs' Complaint.

143. Defendants admit that certain Bard ChronoFlex catheters contain certain amounts of barium sulfate. Defendants deny the remaining allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Defendants admit that certain Bard catheters may contain a mixture of barium sulfate and silicone. Defendants deny the remaining allegations contained in Paragraph 144 of Plaintiffs' Complaint.

145. Defendants admit that certain Groshong catheters may contain a mixture of barium sulfate and silicone. Defendants deny the remaining allegations contained in Paragraph 145 of Plaintiffs' Complaint.

146. Defendants admit that their Groshong catheters contain certain amounts of barium sulfate. Defendants deny the remaining allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants admit that certain Bard catheters may contain a mixture of barium sulfate and silicone while others may contain a mixture of barium sulfate and polyurethane. Defendants deny the remaining allegations contained in Paragraph 147 of Plaintiffs' Complaint.

148. Defendants admit that certain Bard catheters may contain a mixture that includes barium sulfate. Defendants deny the remaining allegations contained in Paragraph 148 of Plaintiffs' Complaint.

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

150. To the extent the allegations contained in Paragraph 150 of Plaintiffs' Complaint, including Footnote 56, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants deny the allegations contained in Paragraph 151 of Plaintiffs' Complaint.

152. Defendants deny the allegations contained in Paragraph 152 of Plaintiffs' Complaint.

153. To the extent the allegations contained in Paragraph 153 of Plaintiffs' Complaint, including Footnote 57, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 153 of Plaintiffs' Complaint.

154. To the extent the allegations contained in Paragraph 154 Plaintiffs' Complaint, including Footnote 58, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining 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 deny the allegations contained in Paragraph 160 of Plaintiffs' Complaint.

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

162. To the extent the allegations contained in Paragraph 162 of Plaintiffs' Complaint, including Footnote 59, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 162 of Plaintiffs' Complaint.

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

164. To the extent the allegations contained in Paragraph 164 of Plaintiffs' Complaint, including Footnote 60, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 164 of Plaintiffs' Complaint.

165. Defendants deny the allegations contained in Paragraph 165 of Plaintiffs' Complaint.

166. The allegations of Paragraph 166 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response by Defendants. However, to the extent Paragraph 166 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is denied.

167. To the extent the allegations contained in Paragraph 167 of Plaintiffs' Complaint, including Footnote 61, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 167 of Plaintiffs' Complaint.

168. To the extent the allegations contained in Paragraph 168 of Plaintiffs' Complaint, including Footnote 62, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 168 of Plaintiffs' Complaint.

169. To the extent the allegations contained in Paragraph 169 of Plaintiffs' Complaint, including Footnote 63, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 169 of Plaintiffs' Complaint.

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

171. To the extent the allegations contained in Paragraph 171 of Plaintiffs' Complaint, including Footnote 64, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 171 of Plaintiffs' Complaint.

172. Defendants deny the allegations contained in Paragraph 172 of Plaintiffs' Complaint.

173. To the extent the allegations contained in Paragraph 173 of Plaintiffs' Complaint, including Footnote 65, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 173 of Plaintiffs' Complaint.

174. To the extent the allegations contained in Paragraph 174 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 66, purport to quote or paraphrase a document, the

document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 174 of Plaintiffs' Complaint.

175. To the extent the allegations contained in Paragraph 175 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 67, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 175 of Plaintiffs' Complaint.

176. To the extent the allegations contained in Paragraph 176 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 68, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 176 of Plaintiffs' Complaint.

177. To the extent the allegations contained in Paragraph 177 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 69, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 177 of Plaintiffs' Complaint.

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

179. Defendants deny the allegations contained in Paragraph 179 of Plaintiffs' Complaint.

180. Defendants deny the allegations contained in Paragraph 180 of Plaintiffs' Complaint.

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

182. Defendants deny the allegations contained in Paragraph 182 of Plaintiffs' Complaint.

183. Defendants deny the allegations contained in Paragraph 183 of Plaintiffs' Complaint.

184. Defendants deny the allegations contained in Paragraph 184 of Plaintiffs' Complaint.

Allegations Regarding Defendants' Development of Port Reservoirs

185. Defendants admit that port reservoirs on some Bard implantable port catheter devices contain polyoxymethylene. Defendants deny the remaining allegations contained in Paragraph 185 of Plaintiffs' Complaint, including all sub-parts thereof.

186. The allegations contained in Paragraph 186 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 186 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

187. The allegations contained in Paragraph 187 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 187 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

188. The allegations contained in Paragraph 188 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 188 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

189. The allegations contained in Paragraph 189 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 189 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

190. The allegations contained in Paragraph 190 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 190 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

191. The allegations contained in Paragraph 191 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 191 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

192. The allegations contained in Paragraph 192 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 192 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

193. The allegations contained in Paragraph 193 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 193 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

194. The allegations contained in Paragraph 194 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 194

purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

195. Defendants admit that certain Bard implantable port catheters are manufactured utilizing Delrin 500 NC010. Defendants deny the remaining allegations contained in Paragraph 195 of Plaintiffs' Complaint, including all sub-parts thereof.

196. The allegations contained in Paragraph 196 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 196 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

197. The allegations contained in Paragraph 197 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 197 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied, including the allegations contained in Footnote 70 of Plaintiffs' Complaint.

198. The allegations contained in Paragraph 198 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 198 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied, including the allegations contained in Footnote 71 of Plaintiffs' Complaint.

199. Defendants deny the allegations contained in Paragraph 199 of Plaintiffs' Complaint.

200. Defendants deny the allegations contained in Paragraph 200 of Plaintiffs' Complaint.

201. The allegations contained in Paragraph 201 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 201

purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

202. The allegations contained in Paragraph 202 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 202 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

203. The allegations contained in Paragraph 203 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 203 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

204. Defendants deny the allegations contained in Paragraph 204 of Plaintiffs' Complaint, including all sub-parts thereof.

205. Defendants admit that certain implantable port catheter devices contain palpation bumps. Insofar as any of the allegations in Paragraph 205 may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 205 are denied.

206. Defendants admit that a purpose of the inclusion of palpation bumps on certain implantable port catheter devices is to aid in proper identification of the device. Insofar as any of the allegations in Paragraph 206 may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the proximate cause of any injury to Plaintiff, such allegation is denied. Except as specifically admitted, the allegations of Paragraph 206 are denied.

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.

210. Defendants deny the allegations contained in Paragraph 210 of Plaintiffs' Complaint, including the allegations contained in Footnote 72.

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

Allegations Regarding Post-Market Performance

212. Defendants admit that there are various well-known and warned about complications associated with any implanted port or catheter product, including infection. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of implantable ports and catheters. Defendants deny the remaining allegations contained in Paragraph 212 of Plaintiffs' Complaint.

213. Defendants admit that there are various well-known and warned about complications associated with any implanted port or catheter product, including fracture, migration, or perforation. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of implantable ports and catheters. Defendants deny the remaining allegations contained in Paragraph 213 of Plaintiffs' Complaint.

214. Defendants admit that there are various well-known and warned about complications associated with any implanted port or catheter product, including thromboembolism. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of implantable ports and catheters. Defendants deny the remaining allegations contained in Paragraph 214 of Plaintiffs' Complaint.

215. Defendants admit that there are various well-known and warned about complications associated with any implanted port or catheter product. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of implantable ports and catheters. Defendants deny the remaining allegations contained in Paragraph 215 of Plaintiffs' Complaint.

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

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

218. Defendants deny the allegations contained in Paragraph 218 of Plaintiffs' Complaint.

219. To the extent the allegations contained in Paragraph 219 of Plaintiffs' Complaint, including Footnote 73, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Insofar as any of the allegations in Paragraph 219 may be read to assert a claim that any Defendant's product was defectively designed, or contained an inadequate warning, or that the condition of such product was the

proximate cause of any injury to Plaintiff, such allegation is denied. Any remaining allegations contained in Paragraph 219 of Plaintiffs' Complaint are denied.

Allegations Regarding Alleged Defects

220. To the extent the allegations contained in Paragraph 220 of Plaintiffs' Complaint, including Footnote 74, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

221. To the extent the allegations contained in Paragraph 221 of Plaintiffs' Complaint, including Footnote 75, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

222. Defendants deny the allegations contained in Paragraph 222 of Plaintiffs' Complaint, including Footnote 76.

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. Defendants deny the allegations contained in Paragraph 226 of Plaintiffs' Complaint.

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

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

229. Defendants deny the allegations contained in Paragraph 229 of Plaintiffs' Complaint.

230. Defendants deny the allegations contained in Paragraph 230 of Plaintiffs' Complaint.

231. Defendants deny the allegations contained in Paragraph 231 of Plaintiffs' Complaint.

232. Defendants deny the allegations contained in Paragraph 232 of Plaintiffs' Complaint.

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

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

235. Defendants deny the allegations contained in Paragraph 235 of Plaintiffs' Complaint.

236. Defendants deny the allegations contained in Paragraph 236 of Plaintiffs' Complaint.

237. Defendants deny the 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.

240. Defendants deny the allegations contained in Paragraph 240 of Plaintiffs' Complaint, including all sub-parts thereof.

Allegations Regarding Alleged Misrepresentations

241. To the extent the allegations contained in Paragraph 241 of Plaintiffs' Complaint, including Footnote 77, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied.

242. Defendants admit that there are various well-known and warned about complications associated with any implanted port or catheter product. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of implantable ports and catheters. Defendants deny the remaining allegations contained in Paragraph 242 of Plaintiffs' Complaint.

243. Defendants deny the allegations contained in Paragraph 243 of Plaintiffs' Complaint, including Footnote 78.

244. To the extent the allegations contained in Paragraph 244 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 79, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 244 of Plaintiffs' Complaint, including all sub-parts thereof.

245. To the extent the allegations contained in Paragraph 245 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 80 and 81, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 245 of Plaintiffs' Complaint, including all sub-parts thereof.

246. To the extent the allegations contained in Paragraph 246 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 82, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 246 of Plaintiffs' Complaint, including all sub-parts thereof.

247. To the extent the allegations contained in Paragraph 247 of Plaintiffs' Complaint, including all sub-parts thereof and Footnote 83, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 247 of Plaintiffs' Complaint, including all sub-parts thereof.

248. To the extent the allegations contained in Paragraph 248 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 84 through 87, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 248 of Plaintiffs' Complaint.

249. To the extent the allegations contained in Paragraph 249 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 88 through 90, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 249 of Plaintiffs' Complaint.

250. To the extent the allegations contained in Paragraph 250 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 91 through 94, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document

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

251. To the extent the allegations contained in Paragraph 251 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 95 through 97, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 251 of Plaintiffs' Complaint.

252. To the extent the allegations contained in Paragraph 252 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 98 through 101, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining allegations contained in Paragraph 252 of Plaintiffs' Complaint.

253. To the extent the allegations contained in Paragraph 253 of Plaintiffs' Complaint, including all sub-parts thereof and Footnotes 101 through 102, purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny the remaining 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.

Allegations Regarding Plaintiffs' Alleged Injuries

257. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 257 of Plaintiffs' Complaint and, on that basis, deny the allegations.

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

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

260. Defendants deny the allegations contained in Paragraph 260 of Plaintiffs' Complaint, including all sub-parts thereof.

261. Defendants deny the allegations contained in Paragraph 261 of Plaintiffs' Complaint, including all sub-parts thereof.

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. The allegations contained in Paragraph 264 are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations.

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

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

Allegations Regarding Count I: Design Defect – Strict Liability

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

268. The allegations contained in Paragraph 268 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent Paragraph 268 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

269. Defendants admit that, in accordance with applicable Food and Drug Administration regulations, BD is involved with the design, manufacture, and distribution of certain prescription medical devices, among other products; C. R. Bard is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; BAS is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; and, BPV is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices which are intended for implant by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants deny the remaining allegations contained in Paragraph 269 of Plaintiffs' Complaint.

270. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 270 of Plaintiffs' Complaint and, on that basis, deny the allegations.

271. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 271 of Plaintiffs' Complaint and, on that basis, deny the allegations.

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 lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 281 of Plaintiffs' Complaint and, on that basis, deny the allegations.

282. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 282 of Plaintiffs' Complaint and, on that basis, deny the allegations.

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. The allegations contained in Paragraph 288 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 288 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 288 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port*

Catheter Products Liability Litigation (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count II: Failure to Warn/Instruct – Strict Liability

289. Defendants incorporate by reference their Responses to Paragraphs 1-288 of Plaintiffs' Complaint as if set forth fully herein.

290. The allegations contained in Paragraph 290 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent Paragraph 290 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

291. Defendants admit that, in accordance with applicable Food and Drug Administration regulations, BD is involved with the design, manufacture, and distribution of certain prescription medical devices, among other products; C. R. Bard is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; BAS is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; and, BPV is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices which are intended for implant by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants deny the remaining allegations contained in Paragraph 291 of Plaintiffs' Complaint.

292. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 292 of Plaintiffs' Complaint and, on that basis, deny the allegations.

293. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 293 of Plaintiffs' Complaint and, on that basis, deny the allegations.

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

295. Defendants deny the allegations contained in Paragraph 295 of Plaintiffs' Complaint, including all sub-parts thereof.

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. The allegations contained in Paragraph 311 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 311 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 311 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port*

Catheter Products Liability Litigation (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count III: Manufacturing Defect – Strict Liability

312. Defendants incorporate by reference their Responses to Paragraphs 1-311 of Plaintiffs' Complaint as if set forth fully herein.

313. The allegations contained in Paragraph 313 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent Paragraph 313 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

314. Defendants admit that, in accordance with applicable Food and Drug Administration regulations, BD is involved with the design, manufacture, and distribution of certain prescription medical devices, among other products; C. R. Bard is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; BAS is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; and, BPV is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices which are intended for implant by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants deny the remaining allegations contained in Paragraph 314 of Plaintiffs' Complaint.

315. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 315 of Plaintiffs' Complaint and, on that basis, deny the allegations.

316. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 316 of Plaintiffs' Complaint and, on that basis, deny the allegations.

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

318. Defendants deny the allegations contained in Paragraph 318 of Plaintiffs' Complaint, including all sub-parts thereof.

319. The allegations contained in Paragraph 319 of Plaintiffs' Complaint 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 319 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law. Defendants deny the remaining allegations contained in Paragraph 319 of Plaintiffs' Complaint, including all sub-parts thereof.

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.

324. Defendants deny the allegations contained in Paragraph 324 of Plaintiffs' Complaint.

325. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 325 of Plaintiffs' Complaint and, on that basis, deny the allegations.

326. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 326 of Plaintiffs' Complaint and, on that basis, deny the allegations.

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.

331. Defendants deny the allegations contained in Paragraph 331 of Plaintiffs' Complaint.

332. The allegations contained in Paragraph 332 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 332 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 332 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the

allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count IV: Breach of Express Warranty

333. Defendants incorporate by reference their Responses to Paragraphs 1-332 of Plaintiffs' Complaint as if set forth fully herein.

334. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 334 of Plaintiffs' Complaint and, on that basis, deny the allegations.

335. To the extent the allegations contained in Paragraph 335 of Plaintiffs' Complaint are conclusions of law, no answer is required. To the extent a response is required, Defendants admit that, in accordance with applicable Food and Drug Administration regulations, BD is involved with the design, manufacture, and distribution of certain prescription medical devices, among other products; C. R. Bard is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; BAS is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices; and, BPV is involved with the design, manufacture, and distribution of certain prescription medical devices, including certain implantable port catheter devices which are intended for implant by licensed medical professionals in accordance with accompanying Instructions for Use. Defendants deny any remaining allegations contained in Paragraph 335 of Plaintiffs' Complaint.

336. Defendants deny the allegations contained in Paragraph 336 of Plaintiffs' Complaint, including all sub-parts thereof.

337. To the extent the allegations contained in Paragraph 337 of Plaintiffs' Complaint, and all sub-parts thereof, purport to quote or paraphrase from one or more documents, the documents speak for themselves, and any characterizations inconsistent with the documents are denied. Defendants deny the remaining allegations contained in Paragraph 337 of Plaintiffs' Complaint, including all sub-parts thereof.

338. To the extent the allegations contained in Paragraph 338 of Plaintiffs' Complaint, and all sub-parts thereof, purport to quote or paraphrase from one or more documents, the documents speak for themselves, and any characterizations inconsistent with the documents are denied. Defendants deny the remaining allegations contained in Paragraph 338 of Plaintiffs' Complaint, including all sub-parts thereof.

339. Defendants deny the allegations contained in Paragraph 339 of Plaintiffs' Complaint.

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, including all sub-parts thereof.

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. The allegations contained in Paragraph 346 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 346 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 346 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count V: Violation of the New Jersey Consumer Fraud Act

347. Defendants incorporate by reference their Responses to Paragraphs 1-346 of Plaintiffs' Complaint as if set forth fully herein.

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

349. Defendants deny the allegations contained in Paragraph 349 of Plaintiffs' Complaint, including all sub-parts thereof.

350. The allegations contained in Paragraph 350 of Plaintiffs' Complaint contain conclusions of law, to which no response is required.

351. Defendants deny the allegations contained in Paragraph 351 of Plaintiffs' Complaint.

352. To the extent the allegations contained in Paragraph 352 of Plaintiffs' Complaint contain conclusions of law, no response is required. To the extent a response is required, the allegations contained in Paragraph 352 of Plaintiffs' Complaint are denied.

353. To the extent the allegations contained in Paragraph 353 of Plaintiffs' Complaint contain conclusions of law, no response is required. To the extent a response is required, the allegations contained in Paragraph 353 of Plaintiffs' Complaint are denied.

354. To the extent the allegations contained in Paragraph 354 of Plaintiffs' Complaint contain conclusions of law, no response is required. To the extent a response is required, the allegations contained in Paragraph 354 of Plaintiffs' Complaint are denied.

355. Defendants deny the allegations contained in Paragraph 355 of Plaintiffs' Complaint.

356. Defendants deny the allegations contained in Paragraph 356 of Plaintiffs' Complaint.

357. Defendants deny the allegations contained in Paragraph 357 of Plaintiffs' Complaint.

358. Defendants deny the allegations contained in Paragraph 358 of Plaintiffs' Complaint.

359. Defendants deny the allegations contained in Paragraph 359 of Plaintiffs' Complaint.

360. Defendants deny the allegations contained in Paragraph 360 of Plaintiffs' Complaint.

361. Defendants deny the allegations contained in Paragraph 361 of Plaintiffs' Complaint.

362. Defendants deny the allegations contained in Paragraph 362 of Plaintiffs' Complaint.

363. Defendants deny the allegations contained in Paragraph 363 of Plaintiffs' Complaint.

364. Defendants deny the allegations contained in Paragraph 364 of Plaintiffs' Complaint.

365. Defendants deny the allegations contained in Paragraph 365 of Plaintiffs' Complaint.

366. Defendants deny the allegations contained in Paragraph 366 of Plaintiffs' Complaint.

367. The allegations contained in Paragraph 367 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 367 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 367 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port*

Catheter Products Liability Litigation (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count VI: Loss of Consortium

368. Defendants incorporate by reference their Responses to Paragraphs 1-367 of Plaintiffs' Complaint as if set forth fully herein.

369. Defendants deny the allegations contained in Paragraph 369 of Plaintiffs' Complaint.

370. Defendants deny the allegations contained in Paragraph 370 of Plaintiffs' Complaint.

371. Defendants deny the allegations contained in Paragraph 371 of Plaintiffs' Complaint.

372. Defendants deny the allegations contained in Paragraph 372 of Plaintiffs' Complaint.

373. Defendants deny the allegations contained in Paragraph 373 of Plaintiffs' Complaint.

374. Defendants deny the allegations contained in Paragraph 374 of Plaintiffs' Complaint.

375. Defendants deny the allegations contained in Paragraph 375 of Plaintiffs' Complaint.

376. The allegations contained in Paragraph 376 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 376 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 376 of Plaintiffs' Complaint purport

to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count VII: Wrongful Death

377. Defendants incorporate by reference their Responses to Paragraphs 1-376 of Plaintiffs' Complaint as if set forth fully herein.

378. Defendants deny the allegations contained in Paragraph 378 of Plaintiffs' Complaint.

379. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 379 of Plaintiffs' Complaint and, on that basis, deny the allegations.

380. Defendants deny the allegations contained in Paragraph 380 of Plaintiffs' Complaint.

381. Defendants deny the allegations contained in Paragraph 381 of Plaintiffs' Complaint.

382. 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 deny the remaining allegations contained in Paragraph 382 of Plaintiffs' Complaint.

383. The allegations contained in Paragraph 383 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 383 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 383 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Count VIII: Survival

384. Defendants incorporate by reference their Responses to Paragraphs 1-383 of Plaintiffs' Complaint as if set forth fully herein.

385. Defendants deny the allegations contained in Paragraph 385 of Plaintiffs' Complaint.

386. 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 deny the remaining allegations contained in Paragraph 386 of Plaintiffs' Complaint.

387. The allegations contained in Paragraph 387 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 387 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 387 of Plaintiffs' Complaint purport

to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Punitive Damages

388. Defendants incorporate by reference their Responses to Paragraphs 1-387 of Plaintiffs' Complaint as if set forth fully herein.

389. Defendants deny the allegations contained in Paragraph 389 of Plaintiffs' Complaint, including all sub-parts thereof.

390. Defendants deny the allegations contained in Paragraph 390 of Plaintiffs' Complaint.

391. Defendants deny the allegations contained in Paragraph 391 of Plaintiffs' Complaint.

392. The allegations contained in Paragraph 392 of Plaintiffs' Complaint are not directed to Defendants and, as a result, require no response from Defendants. To the extent Paragraph 392 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. To the extent the allegations contained in Paragraph 392 of Plaintiffs' Complaint purport to incorporate by reference the general (non-bellwether specific) reports from Plaintiffs' experts in the multidistrict litigation captioned *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), Defendants deny the

allegations set forth in those reports. Defendants correspondingly incorporate by reference the general (non-bellwether specific) reports from Defendants' experts in *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona), as if set forth herein.

Allegations Regarding Timeliness and Tolling of Statutes of Limitation and Repose

393. Defendants incorporate by reference their Responses to Paragraphs 1-392 of Plaintiffs' Complaint as if set forth fully herein.

394. Defendants deny the allegations contained in Paragraph 394 of Plaintiffs' Complaint.

395. Defendants deny the allegations contained in Paragraph 395 of Plaintiffs' Complaint.

396. Defendants deny the allegations contained in Paragraph 396 of Plaintiffs' Complaint.

397. Defendants deny the allegations contained in Paragraph 397 of Plaintiffs' Complaint.

398. To the extent the allegations contained in Paragraph 398 of Plaintiffs' Complaint, including Footnote 103, purport to quote or paraphrase from one or more documents, the documents speak for themselves, and any characterizations inconsistent with the documents are denied. Defendants deny the remaining allegations contained in Paragraph 398 of Plaintiffs' Complaint, including Footnote 103.

399. Defendants deny the allegations contained in Paragraph 399 of Plaintiffs' Complaint.

400. Defendants deny the allegations contained in Paragraph 400 of Plaintiffs' Complaint.

401. Defendants deny the allegations contained in Paragraph 401 of Plaintiffs' Complaint.

402. Defendants deny the allegations contained in Paragraph 402 of Plaintiffs' Complaint.

403. Defendants deny the allegations contained in Paragraph 403 of Plaintiffs' Complaint.

404. To the extent the allegations contained in Paragraph 404 of Plaintiffs' Complaint contain conclusions of law, no response is required. To the extent a response is required, the allegations contained in Paragraph 404 of Plaintiffs' Complaint are denied.

405. To the extent the allegations contained in Paragraph 405 of Plaintiffs' Complaint, including Footnote 104, contain conclusions of law, no response is required. Defendants deny the remaining allegations contained in Paragraph 405 of Plaintiffs' Complaint.

406. The allegations contained in Paragraph 406 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent Paragraph 406 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of certain plaintiffs are barred because the Court lacks subject matter jurisdiction over the claims of such plaintiffs.

THIRD AFFIRMATIVE DEFENSE

The Complaint is barred because the Court lacks personal jurisdiction over Defendants.

FOURTH AFFIRMATIVE DEFENSE

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

FIFTH AFFIRMATIVE DEFENSE

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

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because plaintiffs are not the real parties in interest.

SEVENTH AFFIRMATIVE DEFENSE

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.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of repose.

TENTH AFFIRMATIVE DEFENSE

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 failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs failed to exercise ordinary care for their respective safety such that each Plaintiff is not entitled to recover.

TWELFTH AFFIRMATIVE DEFENSE

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

THIRTEENTH AFFIRMATIVE DEFENSE

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.

FOURTEENTH AFFIRMATIVE DEFENSE

Defendants' conduct 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.

FIFTEENTH AFFIRMATIVE DEFENSE

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.

SIXTEENTH AFFIRMATIVE DEFENSE

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

SEVENTEENTH AFFIRMATIVE DEFENSE

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.

EIGHTEENTH AFFIRMATIVE DEFENSE

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, setoff, 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.

NINETEENTH AFFIRMATIVE DEFENSE

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.

TWENTIETH AFFIRMATIVE DEFENSE

The products at issue in the Complaint were modified, altered, or changed from the condition in which they were sold, which modification, alteration, or change caused or contributed to cause Plaintiffs' alleged damages.

TWENTY-FIRST AFFIRMATIVE DEFENSE

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. Plaintiffs also did not plead that timely notice of the alleged breach was given.

TWENTY-SECOND AFFIRMATIVE DEFENSE

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

TWENTY-THIRD AFFIRMATIVE DEFENSE

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

TWENTY-FOURTH AFFIRMATIVE DEFENSE

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

TWENTY-FIFTH AFFIRMATIVE DEFENSE

There should be no recovery against Defendants for any failure to warn or inadequacy of warning because, at all pertinent times, Plaintiffs possessed or should have possessed good and adequate knowledge which negated any need for said warning.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

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

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

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.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

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.

TWENTY-NINTH AFFIRMATIVE DEFENSE

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.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs lack standing, capacity, and/or competency to maintain claims for damages or other relief.

THIRTY-FIRST AFFIRMATIVE DEFENSE

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

THIRTY-SECOND AFFIRMATIVE DEFENSE

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.

THIRTY-THIRD AFFIRMATIVE DEFENSE

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.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

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.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

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.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

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.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

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.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint is barred because the products at issue, and all conduct of these answering Defendants, complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States and by all applicable States.

THIRTY-NINTH AFFIRMATIVE DEFENSE

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.

FORTIETH AFFIRMATIVE DEFENSE

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.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs cannot show that any reasonable alternative design would have rendered Defendants' implantable port catheter products as alleged in Plaintiffs' Complaint to be safer, nor could Defendants have known of any alternative design that may be identified by Plaintiffs.

FORTY-SECOND AFFIRMATIVE DEFENSE

The devices at issue were not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiffs' claims are barred.

FORTY-THIRD AFFIRMATIVE DEFENSE

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.

FORTY-FOURTH AFFIRMATIVE DEFENSE

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

FORTY-FIFTH AFFIRMATIVE DEFENSE

Defendants specifically plead all affirmative defenses under New Jersey's version of 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.

FORTY-SIXTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law and by the lack of privity between Plaintiffs and Defendants. Defendants further specifically plead as to any breach of warranty claim all defenses available to Defendants under the UCC, as enacted in any state(s) whose law is deemed to apply in any plaintiff's case, and under the common law principle of any state(s) whose law is deemed to apply in any plaintiff's case.

FORTH-SEVENTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs assert alleged violation of consumer protection laws, Defendants specifically plead all affirmative defenses available to Defendants under the rules and statutes of any state(s) whose law is deemed to apply to any plaintiff's case, and under the common law principles of any state(s) whose law is deemed to apply to any plaintiff's case.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to plead their claims based on fraud, deceit, or other misrepresentations or omissions with sufficient particularity.

FORTY-NINTH AFFIRMATIVE DEFENSE

Defendants specifically plead, to the extent Plaintiffs plead claims based on allegations of fraud, deceit, fraud by concealment and negligent misrepresentation claims, all affirmative defenses available to Defendants under the rules and statutes of any state(s) whose law is deemed to apply in any plaintiff's case, and under any common law principles of any state(s) whose law is deemed to apply in any plaintiff's case.

FIFTIETH AFFIRMATIVE DEFENSE

Plaintiffs' alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Joint Tortfeasors Contribution Law and Comparative Negligence Act.

FIFTY-FIRST AFFIRMATIVE DEFENSE

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).

FIFTY-SECOND AFFIRMATIVE DEFENSE

Defendants are entitled to the protections afforded under the New Jersey Punitive Damages Act, or any other applicable law, and any award of punitive damages to Plaintiffs in this case would be in violation of the limitations set forth in the New Jersey Punitive Damages Act or any applicable law.

FIFTY-THIRD AFFIRMATIVE DEFENSE

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

FIFTY-FOURTH AFFIRMATIVE DEFENSE

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 N. America v. Gore, 517 U.S. 559 (1996); Cooper Indus., 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.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

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, including analogous provisions of the New Jersey Constitution, 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 plaintiffs 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.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' substantive law, statute of limitations, and/or statute of repose.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

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.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

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.

FIFTY-NINTH AFFIRMATIVE DEFENSE

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.

SIXTIETH AFFIRMATIVE DEFENSE

Defendants are entitled to, and claim the benefit of, all limitations of awards, caps on recovery, setoffs, defenses, and presumptions set forth in or arising from any rule of law or statute in any state(s) whose law is deemed to apply in any plaintiff's case.

SIXTY-FIRST AFFIRMATIVE DEFENSE

Defendants specifically plead all affirmative defenses available to Defendants under the rules and statutes of any state(s) whose law is deemed to apply in any plaintiff's case, and under any common law principles of any state(s) whose law is deemed to apply in any plaintiff's case.

SIXTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs cannot rely on principles of successor liability, veil-piercing, agency, or any other similar theory to hold one or more Defendants liable for the conduct of other Defendants.

SIXTY-THIRD AFFIRMATIVE DEFENSE

Defendants incorporate by reference, and hereby give notice of their intent to rely upon, the defenses of all others who may become parties to this action as though fully set forth herein.

SIXTY-FOURTH AFFIRMATIVE DEFENSE

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 and/or the New Jersey Court Rules.

SIXTY-FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff alleges the existence of a defect in a product designed, manufactured, sold, or distributed by Defendants, which Defendants deny, Defendants did not have notice of any alleged defect.

SIXTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are or may be barred, in whole or in part, to the extent that Plaintiffs released, settled with, entered into an accord and satisfaction, or otherwise comprised their respective claims. Defendants are entitled to a setoff for the entire amount of proceeds Plaintiffs have or may recover from all other sources.

SIXTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with industry custom/usage standards and/or legislative, administrative, and/or regulatory standards.

SIXTY-EIGHTH AFFIRMATIVE DEFENSE

The design complained of in Plaintiffs' Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiffs, were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

SIXTY-NINTH AFFIRMATIVE DEFENSE

Defendants intend to rely upon any additional defenses under New Jersey law that become available during the course of investigation and/or discovery and reserve the right to amend their Answer to assert these defenses.

SEVENTIETH AFFIRMATIVE DEFENSE

There should be no recovery against Defendants for any failure to warn or inadequacy of warning because, at all pertinent times, Plaintiffs possessed or should have possessed good and adequate knowledge which negated any need for said warning.

SEVENTY-FIRST AFFIRMATIVE DEFENSE

Defendants are entitled to, and hereby assert, all defenses and protections provided by the New Jersey Products Liability Act.

SEVENTY-SECOND AFFIRMATIVE DEFENSE

Defendants invoke each and every statutory and common law defense available to them under New Jersey state law applicable to any claim alleged in the Complaint.

SEVENTY-THIRD AFFIRMATIVE DEFENSE

Defendants are entitled to, and hereby assert, all defenses and protections provided by the New Jersey Products Liability Act.

SEVENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' may not recover under the New Jersey Consumer Fraud Act because that claim(s) is subsumed by the New Jersey Products Liability Act, and is therefore improperly pled.

SEVENTY-FIFTH AFFIRMATIVE DEFENSE

Defendants reserve the right to assert and rely upon additional separate defenses that become available or apparent through discovery, development of the case, or otherwise. Defendants expressly reserve the right to amend their Answer and Separate Defenses to assert any and all such separate defenses.

REQUEST FOR ALLOCATION OF FAULT

The liability of any joint tortfeasor who does not appear at trial, whether due to settlement, dismissal, or any other applicable cause, shall remain in issue and Defendants shall request an allocation of fault by the finder of fact to said tortfeasor and/or a credit in favor of Defendants, consistent with such allocation. See R. 4:7-5; *Young v. Latta*, 123 N.J. 584 (1991).

DEMAND FOR TRIAL BY JURY

Defendants respectfully request a trial by jury as to all issues involved herein.

DESIGNATION OF TRIAL COUNSEL PURSUANT TO RULE 4:25-4

Pursuant to Rule 4:25-4, Edward J. Fanning, Jr. is hereby designated as trial counsel for Defendants.

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.

MCCARTER & ENGLISH, LLP

By: s/ Edward J. Fanning, Jr.
Edward J. Fanning, Jr.
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Phone: (973) 639-7927
Fax: (973) 297-3868
Email: efanning@mccarter.com