IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

RENA HUNTER, in her capacity as Heir at Law and Personal Representative of the Estate of DONNA WOOD,	)	
Plaintiff,	)	**Case No.**
v.	)	
BECTON, DICKINSON AND CO., et al.	)	
Defendants.	)	

COMPLAINT

COMES NOW Plaintiff Rena Hunter, through counsel and for her Complaint against Becton, Dickinson & Company, C.R. Bard, Inc.; Bard Access Systems, Inc.; and Bard Peripheral Vascular, Inc.; and DOES 1 through 10 (collectively, the "Defendants"), and states as follows:

1. This is an action for damages relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective device sold under the trade name of Bard PowerPort M.R.I. Implantable Port (hereinafter "PowerPort" or "Defective Device").

2. Plaintiff Rena Hunter is an adult resident and citizen of Colorado and is the surviving sister of Decedent Donna Wood (hereinafter Decedent).

3. Plaintiff brings this action for the wrongful death of Donna Wood as an heir at law on behalf of all heirs at law of Donna Wood and as the appointed Personal Representative of the Estate of Donna Wood.

4. Defendant Becton, Dickinson and Company ("BD") is a New Jersey corporation with a principal place of business at 1 Becton Drive in Franklin Lakes, New Jersey. BD is one of the largest global medical technology companies in the world with diverse business units offering

products in various healthcare subfields. BD is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort. BD is the parent company of Defendants C.R. Bard, Inc. and Bard Access Systems, Inc.

5. Defendant C.R. Bard, Inc. ("Bard") is a New Jersey corporation with its principal place of business located at 1 Becton Drive in Franklin Lakes, New Jersey. Bard conducts business throughout the United States, including the State of Colorado, and is a wholly owned subsidiary of BD. Bard, as an agent of BD, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort. Bard, along with its subsidiaries and business units, was acquired by BD in 2017 in a transaction which integrated and subsumed Bard's business units into BD's business units. In said transaction, Bard's product offerings, including the PowerPort were taken over by and integrated into BD's Interventional segment, one of three of BD's principal business segments. Following the acquisition, Bard's Board of Directors dissolved, with some former Bard directors joining BD's Board of Directors.

6. Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located in Salt Lake City, Utah. BAS conducts business throughout the United States, including the State of Colorado, and is a wholly owned subsidiary of BD. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort.

7. Defendant Bard Peripheral Vascular, Inc. ("BPV") is an Arizona corporation with its principal place of business located in Tempe, Arizona. BPV conducts business throughout the United States including the State of Colorado and is a wholly owned subsidiary of BD and C.R. Bard, Inc. BVP is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort.

8. BD is the nominal corporate parent of Bard, BAS, and BVP, but the latter three are alter egos of BD in that BD exercises complete domination and control over Bard, BAS, and BVP, having completely integrated the latter's assets, liabilities, and operations into its own such that Bard, BAS, and BVP have ceased to function as separate corporate entities.

9. BD's control over Bard, BAS, and BVP has been purposefully used to perpetrate the violation of various legal duties in contravention of Plaintiff's legal rights. The breaches by BD of various legal duties as described herein are the proximate cause of the injuries described herein.

10. In addition to BD's liability for Plaintiff's damages as a result of its abuse of the corporate form, BD is directly liable as a result of its own wrongful conduct as set forth herein.

11. Plaintiff is ignorant of the true names and capacities of defendants sued herein as DOES 1 through 10, inclusive, and therefore sues these defendants by such fictitious names. Plaintiff will amend this complaint to allege their true names and capacities when ascertained.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

13. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are produced, sold to and consumed by individuals in the State of Colorado, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

14. Defendants have and continue to conduct substantial business in the State of Colorado and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this district, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

15. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Colorado, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

16. The Bard PowerPort M.R.I. Implantable Port ("PowerPort") is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

17. According to Defendants, the PowerPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

18. The intended purpose of the PowerPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

19. The PowerPort is a system consisting of two primary components: an injection port and a polyurethane catheter.

20. The PowerPort includes a port reservoir which is comprised of Polyoxymethylene ("POM"). POM is an acetal thermoplastic polymer material commonly marketed under the trade name Delrin.

21. POM is a lower-cost material in comparison to titanium, and Defendants manufacture the PowerPort utilizing POM in the construction of the port reservoir, including but not limited to the PowerPort M.R.I Implantable Port and the X-Port isp M.R.I. Implantable Port.

22. POM is known to undergo oxidative degradation during processing, in vivo, and when exposed to radiography; leading to the reduction of the mechanical properties of the polymer and the release of toxic formaldehyde as a degradation product.

23. The formulation of POM which Defendants utilize in the manufacture of their plastic port devices is Delrin 500 NC010 provided by DuPont.

24. DuPont Delrin 500 NC010 comes with a Medical Caution Statement which prohibits use of Delrin 500 NC010 for applications involving permanent implantation in the human body as well as "brief or temporary" implantation absent explicit permission from DuPont.[1]

25. Delrin 500 NC010 is not compliant with applicable specification standards adopted by the FDA for POM used in medical devices, including ASTM F1855-00.

26. The process for the POM-containing ports lacks adequate measures to stabilize the material to prevent oxidative degradation.

27. Reduction of the mechanical properties of POM precipitate physical degradation of the surface of the polymer, including formation of cracks, fissures, and other physical defects.

[1] DuPont Medical Caution Statement H-51459 (H-50102)

28. Formation of such surface defects on an in vivo biomaterial increases the risk of thrombosis and infection by creating a physical nidus for fibrinous blood products and microscopic pathogens.

29. Colonization of the POM surface defects by bacteria often leads to formation of biofilm in the port reservoir and the catheter.

30. At all times relevant to this action, Defendants could have designed the PowerPort with more stable plastic materials, including:

a. Manufacturing the plastic port reservoir using POM stabilized with an effective ensemble of antioxidant additives, including hindered phenolic antioxidant and a secondary thermostabilizer such as a phosphite ester;

b. Manufacturing the plastic port reservoir using ultra-high molecular weight polyethylene (UHMWP); or

c. Manufacturing the plastic port with a formulation of POM which renders it suitable for medical applications.

31. The PowerPort is manufactured to include a reservoir with three raised bumps on the anterior surface of the septum.

32. The stated purpose of the palpation bumps is to aid in identification of the port as a power-injectable device.

33. After implantation, the raised bumps cause undue compression stress on the tissue of the subcutaneous pocket into which the port is placed. Such compression stress leads to ulceration and tissue necrosis which potentiates port and catheter infection as well as possible erosion of the port through the skin of the patient.

34. The incidence of tissue erosion associated with Defendants' products featuring

palpation bumps is unreasonably high, such that multiple medical institutions, including Massachusetts General Hospital have implemented policies prohibiting placement of ports featuring palpation bumps due to the high rate of erosion.[2]

35. At all times relevant to this action, Defendants could have designed the PowerPort in a manner that reduced the unreasonable risk of port and catheter infection as well as erosion by omitting the palpation bumps from the design.

36. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

37. The PowerPort is "indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples."

38. According to Defendants' marketing materials, the polyurethane catheter "has less propensity for surface biodegradation, making it more resistant to environmental stress cracking."

39. The polyurethane comprising the catheter in the PowerPort is a formulation called Chronoflex AL, which Defendants obtain from a biomaterials supplier called AdvanSource Biomaterials Corporation (AdvanSource), which is a division of Mitsubishi Chemical America, Inc.

40. Chronoflex AL is one of a large number of biomaterials manufactured by AdvanSource, many of which have mechanical properties superior to Chronoflex AL.

41. The Chronoflex catheter included in Defendants' PowerPort is comprised of a polymeric mixture of polyurethane and barium sulfate, a compound which is visible in certain

[2] Common Port Problems, Massachusetts General Hospital Department of Interventional Radiology, https://www.mghpcs.org/EED/CL/Assets/documents/modules/central-line-portal-infusion-lecture-2018.pdf

radiologic studies.

42. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the catheter.

43. The mechanical integrity of a barium sulfate-impregnated polyurethane is affected by the concentration of barium sulfate as well as the homogeneity of the modified polymer.

44. Defendants' manufacturing process in constructing the Chronoflex Catheter implanted in Decedent involved too high a concentration of barium sulfate particles, leading to improperly high viscosity of the raw polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

45. This improper mixing led to pockets of barium sulfate and entrapped air being distributed through the catheter body and on the inner and outer surfaces of same.

46. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissures, pits and cracks.

47. The roughened catheter surface leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

48. Although the surface degradation and resulting risk of infection can be reduced or avoided with design modifications to encapsulate the radiopaque compound or by using a different polymer formulation, Defendants elected not to incorporate those design elements into the PowerPort.

49. At all times relevant, Defendants misrepresented the safety of the PowerPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled,

marketed, distributed, and sold the PowerPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

50. At all times relevant to this action, Defendants knew and had reason to know, that the PowerPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to surface degradation and resulting thromboembolism, infection, mechanical failure, and a variety of other complications.

51. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with PowerPorts had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; thromboembolism; infection; sepsis; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

52. Soon after the PowerPort was introduced to market, which was years before Decedent was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the PowerPort was precipitating infection post-implantation. Defendants also received large numbers of AERs reporting that PowerPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage;

b. cardiac/pericardial tamponade;

c. cardiac arrhythmia and other symptoms similar to myocardial infarction;

d. severe and persistent pain;

e. and perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

53. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are thousands of recorded device failures and/or injuries related to the Defendants' implantable port products – including the product implanted in Decedent – which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

54. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[3]

55. Prior to the discontinuation of the ASR program, Defendants reported thousands of episodes of failures of their implanted port/catheter products, thereby concealing them from physicians and patients.

56. Defendants were aware or should have been aware that the PowerPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

57. Defendants also intentionally concealed the severity of complications caused by the PowerPort and the likelihood of these events occurring.

58. Rather than alter the design of the PowerPort to make it safer or adequately warn physicians of the dangers associated with the PowerPort, Defendants continued to actively and aggressively market the PowerPort as safe, despite their knowledge of numerous reports of infection and other serious injuries.

59. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton,

[3] Christina Jewett, Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices, Kaiser Health News (Mar. 2019)

gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Decedent. Defendants had actual knowledge of the dangers presented by the PowerPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Decedent, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the PowerPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO DECEDENT

60. On or about November 15, 2021, Decedent Donna Wood was implanted with a PowerPort M.R.I. Implantable Port via left subclavian vein for administration of chemotherapy for breast cancer. This procedure took place at San Luis Valley Health Regional Medical Center in Alamosa, Colorado, and was performed by Dr. Carla Christ, M.D.

61. Defendant, BAS directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the PowerPort product that was implanted in Decedent.

62. On or about February 24, 2022, Decedent was seen in the oncology department when her medical team noticed that Decedent looked ill. Decedent's medical team drew blood cultures and told Decedent to make her way to the emergency room. Blood cultures drawn directly from Decedent's PowerPort were positive.

63. On or about February 25, 2022, Decedent was admitted to San Luis Valley Health Regional Medical Center for neutropenic sepsis and fever. Blood cultures were repeated, which were drawn peripherally, and the results were again positive. An electrocardiogram (EKG) was also conducted that same day, which indicated that Decedent had sinus tachycardia with frequent

ventricular contractions. Decedent was moved from the ER to the Intensive Care Unit.

64. On the night of February 25, 2022, Decedent went into septic shock and was placed on vasopressors. Decedent was also becoming unresponsive.

65. On or about February 26, 2022, Decedent had several episodes of vomiting blood. Decedent's medical team decided that she needed a higher level of care and transferred her to the Intensive Care Unit at Centura Penrose Hospital.

66. On or about February 27, 2022, Decedent was transferred via Flight for Life Colorado to Centura Penrose Hospital in Colorado Springs, Colorado.

67. On March 1, 2022, Decedent passed away. Her death certificate listed severe sepsis with septic shock and infected left subclavian port as causes of her death.

68. As a direct and proximate result of the defective PowerPort and the wrongful acts and omissions of Defendants as alleged herein, Decedent sustained serious injuries and complications, which ultimately led to her death.

69. As a direct and proximate result of the defective PowerPort and the wrongful acts and omissions of Defendants as alleged herein, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses due to the death of Decedent.

70. The Defendants concealed their knowledge of the PowerPort's unreasonably dangerous risks from Decedent and her physicians.

71. Numerous reports of PowerPort catheter-related infection in the absence of medical provider error were recorded and reported to Defendants prior to the implantation of the PowerPort in Decedent

72. However, Defendants continued to actively and aggressively market the PowerPort as safe, despite knowledge of numerous reports of such injuries. Defendants utilized marketing

communications, including the Instruction for Use, and direct communications from sales representatives to Decedent's health care providers to intentionally mislead her health care providers into believing these failures were caused by factors other than catheter design and composition.

73. Defendants did not adequately warn Decedent or decedent's physicians of the true quantitative or qualitative risk of infection associated with the PowerPort.

74. Defendants did not adequately warn Decedent or Decedent's physicians that the risk of catheter infection increases the longer the device is implanted.

75. Defendants did not adequately communicate the extent or seriousness of the danger of catheter infection to Decedent or her physicians.

76. Rather than alter the design of their product to make it safer or warn physicians of the dangers associated with the PowerPort, the Defendants chose to continue their efforts to promote their defective product.

77. Decedent's physicians relied upon the representations, including the instructions for use distributed with the product implanted in Decedent, and advertisements to Decedent's detriment.

78. The Defendants knowingly concealed the dangerous propensity of this device to precipitate infection. Defendants further concealed their knowledge that these failures were caused by the catheter design and that the failures were known to be causing serious injuries.

79. As a result of the failure of the Defendants' PowerPort and the Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Decedent and Decedent's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Decedent had been exposed to the risks identified in this Complaint, and

that those risks were the direct and proximate result of the Defendants' acts, omissions and misrepresentations.

80. The Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing and selling the PowerPort.

81. As a direct and proximate result of the defective PowerPort and the wrongful acts and omissions of Defendants as alleged herein, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief, loss of companionship, pain and suffering, and emotional stress. Accordingly, Plaintiff seeks compensatory damages.

COUNT I – NEGLIGENCE – ALL DEFENDANTS

82. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

83. Plaintiff brings this count against Defendants BD, Bard, BAS, BPV, and Does 1 through 10, inclusive.

84. The Defendants owed Decedent and Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the PowerPort.

85. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the PowerPort before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the PowerPort;

c. Failing to conduct sufficient post-market testing and surveillance of the

PowerPort;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the PowerPort to consumers, including Decedent, without an adequate warning of the significant and dangerous risks of the PowerPort and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the PowerPort; and

f. Negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of its adverse effects.

86. As a direct and proximate result of the defective PowerPort and the wrongful acts and omissions of Defendants as alleged herein, Decedent sustained serious injuries and complications, including infection and sepsis, that ultimately led to her death.

87. As a direct and proximate result of the defective PowerPort and the wrongful acts and omissions of Defendants as alleged herein, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief, loss of companionship, pain and suffering, and emotional stress. Accordingly, Plaintiff seeks compensatory damages.

88. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligently, fraudulently, and with malice.

COUNT II – STRICT PRODUCTS LIABILITY – FAILURE TO WARN – ALL DEFENDANTS

89. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

90. Plaintiff brings this count against Defendants BD, Bard, BAS, BPV, and Does 1 through 10, inclusive.

91. Defendants designed, set specifications, manufactured, prepared, compounded,

assembled, processed, marketed, labeled, distributed, and sold the PowerPort, including the one implanted into Decedent, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

92. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

93. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the PowerPort that was implanted into Decedent that the PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

94. Defendants further knew that these devices raised the risk of infection by virtue of the catheter design and composition.

95. As a result, the device was unreasonably dangerous when put to its reasonably anticipated use in that the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it.

96. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the PowerPort in that Defendants:

a. Failed to provide any warning of the true quantitative or qualitative risk and the

true extent of infection associated with the PowerPort product to Decedent or her physicians;

b. Failed to provide any warning as to the true extent or seriousness of the danger of infection that the device could cause.

97. No reasonable health care provider, including Decedent's health care providers, and no reasonable patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

98. Had the Defendants provided an adequate warning of the risks attendant to the PowerPort enumerated herein, Decedent would not have consented to be implanted with the product.

99. The warnings, labels, and instructions provided by the Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

100. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

101. The device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

102. When Decedent was implanted with the device, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

103. Defendants intentionally underreported the number and nature of adverse events to

Decedent's health care providers, as well as the FDA.

104. Neither Decedent nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

105. Decedent and her health care providers used PowerPort in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream. Moreover, Decedent's health care providers did not place or maintain the device incorrectly such that it increased the risk of malfunction.

106. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Decedent, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Decedent was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

107. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Decedent's serious injuries and complications sustained, which ultimately led to her death.

108. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief, loss of companionship, pain and suffering, and emotional stress. Accordingly, Plaintiff seeks compensatory damages.

109. In other words, had Defendants provided adequate warnings, Decedent and her

physicians would not have used the device.

COUNT III – STRICT PRODUCTS LIABILITY – DESIGN DEFECT – ALL DEFENDANTS

110. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

111. Plaintiff brings this count against Defendants BD, Bard, BAS, BPV, and Does 1 through 10, inclusive.

112. The PowerPort implanted in the Decedent was not reasonably safe for its intended use and was defective with respect to its design.

113. The PowerPort was in a defective condition at the time that it left the possession or control of Defendants.

114. The PowerPort was unreasonably dangerous to the user or consumer.

115. The PowerPort was expected to and did reach the consumer without substantial change in its condition.

116. Defendants are strictly liable to the Plaintiff and the heirs of Decedent for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

117. As a direct and proximate result of the PowerPort's aforementioned defects, Decedent sustained serious injuries and complications, including infection and sepsis, that ultimately led to her death.

118. As a direct and proximate result of the PowerPort's aforementioned defects, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief, loss of companionship, pain and suffering, and emotional stress.

COUNT IV – BREACH OF IMPLIED WARRANTY – ALL DEFENDANTS

119. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

120. Plaintiff brings this count against Defendants BD, Bard, BAS, BPV, and Does 1 through 10, inclusive.

121. Defendants impliedly warranted that the PowerPort was merchantable and fit for the ordinary purposes for which it was intended.

122. When the PowerPort was implanted in Decedent, it was being used for the ordinary purposes for which it was intended.

123. The Decedent, individually and/or by and through her physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the PowerPort implanted in her.

124. Privity exists between Decedent because Decedent's physicians acted as Decedent's purchasing agents in the subject transaction and/or because Decedent was a third-party beneficiary of the subject contract.

125. Defendants breached these implied warranties of merchantability because the PowerPort implanted in the Decedent was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but is not limited to, the following:

a. Defendants' manufacturing process in constructing the Chronoflex Catheter implanted in Decedent involved too high a concentration of barium sulfate particles, leading to improperly high viscosity of the raw polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. This improper mixing leads to pockets of barium sulfate and entrapped air being distributed throughout the catheter body and on the surface of the catheter; and

c. The roughened catheter surface leads to the collection and proliferation of microbes and/or fungi, thereby drastically increasing the risk of infection and sepsis.

126. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective PowerPort in the Decedent's body, which caused serious injuries and complications and ultimately led to her death.

127. The PowerPort was sold to Decedent's health care providers for implantation in patients, such as the Decedent.

128. As a direct and proximate result of Defendants' breaches of their implied warranties, Decedent suffered injuries and complications, including infection and sepsis, that resulted in her death.

129. As a direct and proximate result of Defendants' breaches of their implied warranties, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief, loss of companionship, pain and suffering, and emotional stress.

130. Upon information and belief, Decedent's health care providers sent notice to Defendants of the adverse event and thus, the nonconformity of the device at issue, within a reasonable time following discovery of the breach of warranty and before suit was filed.

COUNT V – BREACH OF EXPRESS WARRANTY – ALL DEFENDANTS

131. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

132. Plaintiff brings this count against Defendants BD, Bard, BAS, BPV, and Does 1 through 10, inclusive.

133. Defendants through their officers, directors, agents, representatives, and written

literature and packaging, and written and media advertisement, expressly warranted to Decedent and/or to decedent's healthcare providers that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

134. The PowerPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

135. At all relevant times, the PowerPort did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

136. Decedent, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the PowerPort.

137. Privity exists between Decedent because Decedent's physicians acted as Decedent's purchasing agents in the subject transaction and/or because Decedent was a third-party beneficiary of the subject contract.

138. At all relevant times, the PowerPort was used on Decedent by Decedent's physicians for the purpose and in the manner intended by Defendants.

139. Decedent and Decedent's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

140. As a direct and proximate result of the breach of Defendants' express warranties, Decedent sustained severe physical injuries and complications, resulting in her death.

141. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief,

loss of companionship, pain and suffering, and emotional stress.

142. Upon information and belief, Decedent's healthcare providers sent notice to Defendants of the adverse event and thus, the nonconformity of the device at issue, within a reasonable time following discovery of the breach of warranty and before suit was filed.

COUNT VI – FRAUDULENT CONCEALMENT – ALL DEFENDANTS

143. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

144. Plaintiff brings this count against Defendants BD, Bard, BAS, BPV, and Does 1 through 10, inclusive.

145. Beginning from the time that Defendants introduced the device at issue to the marketplace and continuing to the present, Defendants fraudulently concealed information with respect to the PowerPort in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the PowerPort was safe and fraudulently withheld and concealed information about the substantial risks of using the PowerPort;

b. Defendants represented that the PowerPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the PowerPort was not safer than alternatives available on the market;

c. Defendants concealed the dangerous propensity of this device to precipitate infection;

d. Defendants concealed their knowledge that these failures were caused by the catheter design and that the failures were known to be causing serious injuries;

e. That frequency of these failures and the severity of injuries were substantially worse than had been reported.

146. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the PowerPort.

147. The concealment of information by the Defendants about the risks of the PowerPort was intentional, and the representations made by Defendants were known by Defendants to be false.

148. The concealment of information and the misrepresentations about the PowerPort was made by the Defendants with the intent that Decedent's health care providers and Decedent rely upon them.

149. Decedent and her physicians relied upon the representations and were unaware of the substantial risks of the PowerPort which the Defendants concealed from the public, including Decedent and her physicians.

150. As a direct and proximate result of Defendants' actions, omissions and misrepresentations, Decedent suffered severe physical injuries, including infection and sepsis, resulting in her death.

151. As a direct and proximate result of Defendants' actions, omissions and misrepresentations, Plaintiff and the heirs of Decedent have sustained damages and non-economic losses under C.R.S. § 13-21-203 and Colorado law due to the wrongful death of Decedent, including damages for grief, loss of companionship, pain and suffering, and emotional stress.

152. The Defendants acted with oppression, fraud, and malice towards Decedent, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

153. Had Defendants not concealed this information, neither Decedent nor her health care providers would have consented to using the device in Decedent.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, and special, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

SURVIVAL ACTION

154. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

155. As Personal Representative of the Estate of Donna Wood, Plaintiff is entitled to bring and does hereby bring a claim on behalf of the Estate of Donna Wood.

156. As a direct and proximate result of Defendants' negligence, willful conduct, and/or omissions, Donna Wood personally suffered damages, including costs for medical treatment.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, for all allowable damages in an amount that is fair and reasonable as determined by a jury, prejudgment interest, post-judgment interest, costs, and all other proper relief.

WRONGFUL DEATH

157. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

158. Plaintiff is Decedent's sister and is one of Decedent's heirs at law who has sustained a loss by reason of the death of Decedent.

159. Plaintiff is entitled to bring and does hereby bring a wrongful death claim on behalf of, and for the benefit of, Decedent's heirs at law.

160. As a direct and proximate result of Defendants' wrongful acts, omissions and tortious conduct alleged herein, the death of Decedent caused substantial damages and non-

economic losses to Plaintiff and the heirs of Decedent, including:

a. Funeral and burial expenses;

b. The loss of Decedent's support, services, care, and relationship;

c. The loss of Decedent's companionship, comfort, consortium, and society;

d. Grief and mental anguish;

e. Pain and suffering and emotional distress; and

f. Further damages as set forth in C.R.S. § 13-21-203 and as allowed under Colorado law.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, for all allowable damages in an amount that is fair and reasonable as determined by a jury, prejudgment interest, post-judgment interest, costs, and all other proper relief.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgment be entered against all Defendants on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including medical and funeral expenses, according to proof at the time of trial;

e. Awarding pre-judgment and post-judgment interest to the Plaintiff;

f. Awarding the costs and the expenses of this litigation to the Plaintiff;

g. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: November 17, 2023

Respectfully submitted,

/s/ Roman Balaban
Roman Balaban, CO# 39148
Balaban Law
8055 E. Tufts Ave., #325
Denver, CO 80237
Phone: 303-377-3474
Fax: 303-377-3576
Email: balaban@denverfirm.com

ATTORNEYS FOR PLAINTIFF