

EXHIBIT 1

VIRGINIA:

IN THE CIRCUIT COURT OF LOUDOUN COUNTY

WILLIAM WILCOX
5 Mystic Lane
Round Hill, VA 20141

Plaintiff,

v.

CIVIL ACTION NO. CL23-1569

AZIYO BIOLOGICS, INC.
Serve Registered Agent:
Corporation Service Company
251 Little Falls Drive
Wilmington, Delaware 19808

DEMAND FOR JURY TRIAL

MEDTRONIC SOFAMOR DANEK USA, INC.
Serve Registered Agent
Corporation Service Company, 251 100
Shockoe Slip, Floor 2, Richmond, VA
232191

SPINALGRAFT TECHNOLOGIES, LLC
Serve Registered Agent:
Corporation Service Company
100 Shockoe Slip, Floor 2
Richmond, VA 232191

DCI DONOR SERVICES, INC.
Serve Registered Agent:
Corporation Service Company
2908 Poston Ave.
Nashville, TN 19808

NEW MEXICO DONOR SERVICES
Serve Registered Agent:
Corporation Service Company
MC-CSC1726 E. Michigan Drive, Ste. 101
Hobbes, NM 88240

Defendants.

CIRCUIT COURT
CLERKS OFFICE
LOUDOUN COUNTY, VA
FESTE: YDB D.C.

2023 MAR - 7 A 11: 23

FILED

PLAINTIFF'S COMPLAINT

COMES NOW Plaintiff, William Wilcox, by and through his attorneys, as and for their complaint against Defendants, Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., Spinalgraft Technologies, LLC, DCI Donor Services, Inc., and New Mexico Donor Services (collectively, "Defendants"), alleges as follows:

I. INTRODUCTION

1. This action seeks to recover damages for the personal injuries suffered by WILLIAM WILCOX, which were the direct and proximate result of the wrongful conduct of AZIYO BIOLOGICS, INC., MEDTRONIC SOFAMOR DANEK USA, INC., SPINALGRAFT TECHNOLOGIES, LLC, DCI DONOR SERVICES, INC., and NEW MEXICO DONOR SERVICES in connection with the procurement, research, testing, design, development, manufacture, production, inspection, labeling, advertisement, marketing, promotion, sale, and distribution of FiberCel Fiber Viable Bone Matrix ("FiberCel") and its components.

II. PARTIES

2. Plaintiff, William Wilcox ("Plaintiff"), is, and at all relevant times was, a resident of the Commonwealth of Virginia, residing in Loudoun County.

3. Defendant AZIYO BIOLOGICS, INC. ("Aziyo") is a Delaware corporation, whose registered agent for service of process is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Aziyo's principal place of business is located at 12510 Prosperity Drive, Suite 370, Silver Springs, Maryland 20904. Aziyo does business throughout the United States, including conducting regular business in Virginia.

4. Aziyo sells a variety of medical products, including implantable electronic devices, orthopedic and spinal repair products, and soft tissue reconstruction products.

5. Upon information and belief, Aziyo developed, manufactured, marketed, promoted, distributed, supplied and/or sold FiberCel which was implanted into Plaintiff, and which is the subject of this complaint.

6. Defendant MEDTRONIC SOFAMOR DANEK, INC., is incorporated in Tennessee, having its principal place of business at 2600 Sofamor Danek Drive, Memphis, TN 38132 USA with a registered agent for service located at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. MEDTRONIC SOFAMOR DANEK, INC., does business throughout the United States, including conducting regular business in Virginia.

7. Defendant SPINALGRAFT TECHNOLOGIES, LLC is a Tennessee limited liability company having its principal place of business at 4340 Swinnea Road, Memphis, TN 38118 USA with a registered agent for service located at Corporation Service Company, 100 Shockoe Slip, Floor 2, Richmond, VA 232191. SPINALGRAFT TECHNOLOGIES, LLC does business throughout the United States, including conducting regular business in Virginia.

8. Defendant SPINALGRAFT TECHNOLOGIES, LLC has three (3) members: Jason M. Bristow, Martha Ha, and Philip J. Albert. Upon information and belief, all members are citizens of the State of Minnesota.

9. MEDTRONIC SOFAMOR DANEK USA, INC. and SPINALGRAFT TECHNOLOGIES, LLC (collectively, "Medtronic") develop therapeutic and diagnostic medical products, and are among the world's largest medical technology, services, and solutions companies.

10. Upon information and belief, Medtronic was designated as the exclusive U.S. distributor of the FiberCel manufactured by Defendant Aziyo.

11. At all times relevant, Medtronic distributed, supplied and/or sold FiberCel, which was implanted into Plaintiff, and which is the subject of this Complaint.

12. Defendant DCI DONOR SERVICES, INC. is incorporated in Tennessee, having its principal place of business at 566 Mainstream Drive, Suite 300, Nashville, TN 37228 USA with a registered agent for service located at Corporation Service Company, 2908 Poston Ave, Nashville, TN 19808. DCI DONOR SERVICES, INC. is the parent company of NEW MEXICO DONOR SERVICES. DCI DONOR SERVICES does business throughout the United States, including conducting regular business in Virginia.

13. Defendant NEW MEXICO DONOR SERVICES is incorporated in New Mexico, having its principal place of business at 1609 University Boulevard NE, Albuquerque, NM 87102 USA with a registered agent for service located at Corporation Service Company, MC-CSC1726 E. Michigan Drive, Ste. 101, Hobbes, NM 88240. NEW MEXICO DONOR SERVICES does business throughout the United States, including conducting regular business in Virginia.

14. DCI DONOR SERVICES, INC. and NEW MEXICO DONOR SERVICES (collectively, "Donor Defendants" or "Donor Services") are engaged in the business of, inter alia, locating, properly identifying and qualifying parts of human cadavers that should at all times qualify for processing, distribution and ultimately for use in a wide variety of surgical procedures where human bone tissue, etcetera, can be appropriately and safely utilized.

15. Upon information and belief, the Donor Defendants harvested, processed, supplied and/or sold human tissue for use in FiberCel which was implanted into Plaintiff, and which is the subject of this complaint.

16. Defendants, at all times relevant to this lawsuit, manufactured, developed, designed, tested, marketed, distributed, promoted, supplied and/or otherwise sold (directly or

indirectly) FiberCel and/or the human tissue used in FiberCel to various locations for use in surgeries requiring bone grafting, including to Inova Loudoun Hospital, where contaminated FiberCel was surgically implanted into Plaintiff William Wilcox, causing him to suffer harm as described herein.

III. JURISDICTION AND VENUE

17. At all times relevant to this action, the Defendants have been engaged, either directly or indirectly, in the business of manufacturing, testing, marketing, selling, and/or distributing FiberCel and/or the human tissue used in FiberCel within the Commonwealth of Virginia, with a reasonable expectation that the product would be used in this state, and thus regularly solicited or transacted business in this state.

18. This Court has jurisdiction over this civil action pursuant to Va. Code § 8.01-328.1 (1950, as amended).

19. Venue in this district is proper under Va. Code § 8.01-262 (1950, as amended) because there exists a practical nexus to Loudoun County including, but not limited to, the location of fact witnesses, the Plaintiff, and other evidence to the action, a substantial part of the events giving rise to Plaintiff's claims occurred in Loudoun County, the Plaintiff's injury occurred in Loudoun County, and the Defendants regularly conduct business in Loudoun County.

IV. FACTUAL ALLEGATIONS

A. FiberCel Fiber Viable Bone Matrix

20. FiberCel Fiber Viable Bone Matrix ("FiberCel") is made from human tissue consisting of cancellous bone particles with preserved cells, combined with demineralized cortical fiber. The human tissue donor product involved in this case was harvested by Defendants DCI Donor Services, Inc and New Mexico Donor Services (the "Donor Defendants"). It is engineered

to be like natural tissue and is used as a bone void filler in various orthopedic and spinal procedures. The allografts contain the scaffold, growth factors and cells required for regeneration critical for successful bone formation.

21. FiberCel is marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft. FiberCel is made with donor tissue and growth factor cells.

22. On June 20, 2019, Aziyo announced it had signed an exclusive, multi-year distribution agreement with Defendant Medtronic in the U.S. orthopedic market. According to the agreement, Aziyo agreed to manufacture and supply FiberCel to Medtronic for distribution through the company's sales and marketing organization.

B. FiberCel Recall

23. On June 2, 2021, the United States Food & Drug Administration (FDA) issued an urgent voluntary recall of FiberCel, specifically three products from Donor Lot Number NMDS210011: VMB9901, VBM9905, and VBM9910.

24. Aziyo and Medtronic initiated the voluntary recall in response to reports of patients testing positive for Tuberculosis and post-surgical infections following the surgical implantation of FiberCel as part of an orthopedic or spinal procedure.

25. Tuberculosis ("TB") is an infectious disease caused by bacteria known as *Mycobacterium tuberculosis*. TB is highly contagious, and mostly impacts the lungs, but can also spread through the lymph nodes to other parts of the body, including the kidneys, brain, and spine.

26. Once *mycobacterium tuberculosis* is introduced to the body, the bacteria must then proliferate within the new host for the host to develop disease. When this bacterium is introduced

in a surgical wound, the patient is already in an immunocompromised position, causing them to have an increased likelihood of developing TB, which can be fatal.

27. The recalled contaminated FiberCel lot contained 154 units delivered to 20 states.

28. Defendant Aziyo has acknowledged many post-surgical infections. Many patients that have received FiberCel from this Donor Lot have tested positive for Tuberculosis, including Plaintiff.

29. This recall acknowledged that viruses and bacteria, including Tuberculosis, can be transplanted into patients along with the FiberCel product.

30. The Centers for Disease Control released a report confirming the dissemination of tuberculosis via FiberCel to 113 patients.

C. Plaintiff Received the Contaminated FiberCel and as a Result, Suffered Severe Injury

31. Plaintiff William Wilcox underwent spinal surgery on March 8, 2021, at Inova Loudoun Hospital, 44045 Riverside Parkway, Leesburg, Loudoun County, Virginia.

32. Plaintiff William Wilcox's surgery included bone grafting, utilizing FiberCel from Donor Lot Number NMDS210011.

33. Unbeknownst to Plaintiff or his physicians at the time of his surgery, the FiberCel implanted into Plaintiff was contaminated with tuberculosis.

34. On June 8, 2021, Plaintiff's physicians notified Plaintiff he may have been exposed to TB. Plaintiff subsequently tested positive for TB.

35. Plaintiff's tuberculosis was caused by the contaminated and recalled FiberCel used in his operation.

36. As a direct and proximate result of the implantation of contaminated FiberCel, Plaintiff was forced to undergo two revision surgeries in an attempt to mitigate the damage done by the contaminated FiberCel.

37. As a direct and proximate result of the implantation of contaminated FiberCel, Plaintiff was forced to undergo a grueling medical protocol to manage his TB diagnosis.

38. Plaintiff will require continued medical monitoring now and into the future in order to monitor Plaintiff's health related to the ongoing and serious nature of his tuberculosis diagnosis.

39. Plaintiff would not have suffered from tuberculosis had Defendants sold and distributed a product that was free from tuberculosis contamination.

40. Plaintiff further has experienced significant side effects from the extensive treatments causing a cascade of sequential complications caused by the contaminated FiberCel product.

41. As a direct and proximate result of Plaintiff's exposure to Defendants' contaminated FiberCel product used in his spinal surgery, Plaintiff has suffered and continues to suffer from severe pain and discomfort, emotional distress, the loss of daily functions, and economic loss, including, but not limited to, present and future medical expenses, lost earnings, and future lost earning capacity, all of which are a direct result of Defendants' liability producing conduct.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

Failure to Warn

(Against Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies LLC)

42. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

43. Defendants owed a duty of reasonable care to adequately warn of the risks associated with the use of FiberCel to foreseeable users, including Plaintiff.

44. Defendants knew or reasonably should have known that the warnings provided to users of FiberCel regarding the risks associated with its use were incorrect or inadequate in at least the following material respects:

- a. FiberCel was unaccompanied by proper warnings regarding all possible risks associated with its use and the comparative severity, incidence, and duration of adverse effects;
- b. Defendants failed to include adequate warnings that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of FiberCel, including, among other things, development of TB;
- c. Defendants failed to immediately warn patients and physicians after they learned that their product was contaminated with TB; and
- d. Otherwise failed to provide adequate warnings.

45. By failing to warn Plaintiff and Plaintiff's physicians of the adverse health risks associated with FiberCel, Defendants breached their duty to Plaintiff of reasonable care and safety.

46. Defendants, as manufacturers and distributors of human tissue products, are held to the level of knowledge of an expert in the field; and further, Defendants knew, or should have known, that the warnings they distributed regarding the risks of a contaminated product causing TB and associated injuries and complications following the implantation of FiberCel were inadequate.

47. Plaintiff did not have the same expert knowledge as Defendants, and no adequate warning of other clinically relevant information and data was communicated to Plaintiff or Plaintiff's physicians.

48. Defendants have a continued duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding

the risks and dangers associated with FiberCel, as it came or could have become available to Defendants.

49. Defendants marketed, promoted, distributed, and sold an unreasonably dangerous and defective human tissue product, FiberCel, to health care providers empowered to implant FiberCel into consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of FiberCel, which resulted in severe injury to Plaintiff.

50. Defendants knew or should have known that consumers, including Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

51. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with the implantation of FiberCel.

52. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with the implantation of FiberCel, Defendants breached their duty of reasonable care and safety.

53. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

54. Defendants' failure to provide adequate warnings was a proximate cause of Plaintiff's injuries and damages.

55. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to contaminated FiberCel and suffered the injuries and damages set forth herein above.

56. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

SECOND CAUSE OF ACTION

Failure to Warn

(Against DCI Donor Services, Inc. and New Mexico Donor Services)

57. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

58. The Donor Defendants owed a duty of reasonable care to adequately warn of the risks associated with the use of their human tissue that was used in the subject FiberCel lot to foreseeable users, including Plaintiff.

59. While harvesting, processing, and selling their human tissue product, the Donor Defendants knew of a limited slate of conditions to test for, yet they failed to adequately test for those conditions, failed to warn the other Defendants that limited testing was done, and failed to warn hospitals and end-users like Plaintiff that its human tissue used in FiberCel was contaminated with tuberculosis and could cause substantial harm.

60. The Donor Defendants knew or reasonably should have known that the warnings provided to users of FiberCel, which contained the Donor Defendants contaminated human tissue, regarding the risks associated with its use were incorrect or inadequate in at least the following material respects:

- a. FiberCel, including its human tissue component, was unaccompanied by proper warnings regarding all possible risks associated with its use and the comparative severity, incidence, and duration of adverse effects;
- b. Donor Defendants failed to provide adequate warnings that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of FiberCel and the Donor Defendants human tissue, including, among other things, development of TB;
- c. Donor Defendants failed to immediately warn patients and physicians after they learned that their human tissue product was contaminated with TB; and

d. Otherwise failed to provide adequate warnings.

61. By failing to warn Plaintiff and Plaintiff's physicians of the adverse health risks associated with FiberCel and the contaminated human tissue used to make FiberCel, Donor Defendants breached their duty to Plaintiff of reasonable care and safety.

62. Donor Defendants, as harvesters, processors, and sellers of human tissue products, are held to the level of knowledge of an expert in the field; and further, Donor Defendants knew, or should have known, that the warnings they provided regarding the risks of a contaminated human tissue product causing TB and associated injuries and complications following the implantation of FiberCel were inadequate.

63. Plaintiff did not have the same expert knowledge as Donor Defendants, and no adequate warning of other clinically relevant information and data was communicated to Plaintiff or Plaintiff's physicians.

64. Donor Defendants have a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with its human tissue product, as it came or could have become available to Defendants.

65. Donor Defendants harvested, processed, and sold unreasonably dangerous and defective human tissue for use in FiberCel, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Donor Defendants mislead the medical community about the risk and benefit balance of their human tissue to be used in FiberCel.

66. Donor Defendants knew or should have known that consumers, including Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Donor Defendants' failures.

67. Donor Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with the implantation of human tissue contaminated with TB.

68. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with the implantation of human tissue contaminated with TB, Donor Defendants breached their duty of reasonable care and safety.

69. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

70. Donor Defendants' failure to provide adequate warnings was a proximate cause of Plaintiff's injuries and damages.

71. As a direct and proximate result of the actions and inactions of the Donor Defendants as set forth above, Plaintiff was exposed to contaminated human tissue through the implantation of the FiberCel product and suffered the injuries and damages set forth herein above.

72. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

THIRD CAUSE OF ACTION

Negligence

(Against Aziyo Biologics, Inc., Medtronic Sofamor Danck USA, Inc., and Spinalgraft Technologies LLC)

73. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

74. Defendants owed a duty to Plaintiff William Wilcox to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, quality assurance, quality control, and distribution of FiberCel into the stream of commerce, including a duty to assure that the FiberCel would not cause those who used it, including William Wilcox, to suffer adverse harmful effects.

75. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of FiberCel.

76. Defendants knew or should have known that those individuals who used the defective FiberCel were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

77. Defendants were negligent in designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of FiberCel. The negligence of Defendants, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

- a. Designing manufacturing, producing, creating, and/or promoting FiberCel without adequately, sufficiently, or thoroughly testing the FiberCel units to ensure they were free from contamination of communicable diseases, including but not limited to, tuberculosis;
- b. Not conducting a sufficient quality control testing program to determine whether or not the subject FiberCel was manufactured properly and was free from contamination or other defects making it unsafe for users of the product;
- c. Failing to adequately and properly obtain and review complete donor medical history;

- d. Negligently failing to timely recall their dangerous and defective FiberCel lots at the earliest date that it became known that certain lots of FiberCel were, in fact, dangerous and defective;
- e. Negligently manufacturing FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;
- f. Negligently producing FiberCel in a manner that was dangerous to those individuals who had it transplanted into their bodies;
- g. Negligently and carelessly harvesting an unqualified and inadequately screened human donor;
- h. Failing to adequately test the human donor tissue and/or bone;
- i. Failing to warn individuals who were using the product of the risks of contracting tuberculosis; and
- j. Were otherwise careless and negligent.

78. Defendants knew or should have known that consumers, such as Plaintiff William Wilcox, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

79. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

80. Defendants' negligence was the proximate cause of Plaintiff William Wilcox's physical, mental, emotional injuries and harm, and economic loss.

81. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to contaminated FiberCel and suffered the injuries and damages set forth herein above.

82. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

FOURTH CAUSE OF ACTION

Negligence

(Against DCI Donor Services, Inc. and New Mexico Donor Services)

83. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

84. Donor Defendants owed a duty to Plaintiff William Wilcox to exercise reasonable care in harvesting, processing, supplying, promoting, selling, testing, quality assurance, quality control, and distribution of human tissue into the stream of commerce, including a duty to assure that their human tissue, which was used in the subject FiberCel lot, would not cause those who used it, including William Wilcox, to suffer adverse harmful effects.

85. Donor Defendants failed to exercise reasonable care in the harvesting, processing, supplying, testing, quality assurance, quality control, sale, and distribution of their human tissue product for use in FiberCel.

86. Donor Defendants knew or should have known that those individuals who were exposed to their contaminated human tissue used in FiberCel were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

87. Donor Defendants were negligent in the harvesting, processing, supplying, testing, quality assurance, quality control, sale, and distribution of their human tissue product for use in FiberCel. The negligence of Donor Defendants, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

- a. Harvesting, processing, and selling human tissue for use in FiberCel without adequately, sufficiently, or thoroughly testing the human tissue to ensure that it was free from contamination of communicable diseases, including but not limited to, tuberculosis;

- b. Not conducting a sufficient quality control testing program to determine whether or not the subject human tissue used in the aforementioned defective FiberCel lot was properly harvested and was free from contamination or other defects making it unsafe for users of the product;
- c. Failing to adequately and properly obtain and review complete donor medical history;
- d. Negligently failing to timely recall their dangerous and contaminated human tissue at the earliest date that it became known that its human tissue sold for use in FiberCel was in fact, dangerous and defective;
- e. Negligently harvesting, processing, and selling human tissue for use in FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;
- f. Negligently and carelessly harvesting an unqualified and inadequately screened human donor;
- g. Negligently failing to test the human donor tissue and/or bone;
- h. Failing to warn individuals who were using their human tissue of the risks of contracting tuberculosis; and
- i. Were otherwise careless and negligent.

88. Donor Defendants knew or should have known that consumers, such as Plaintiff William Wilcox, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Donor Defendants' failure to exercise ordinary care, as set forth above.

89. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

90. Donor Defendants' negligence was the proximate cause of Plaintiff William Wilcox's physical, mental, emotional injuries and harm, and economic loss.

91. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to contaminated FiberCel and suffered the injuries and damages set forth herein above.

92. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

FIFTH CAUSE OF ACTION
Breach of Implied Warranty
(Against Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft Technologies LLC)

93. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

94. Defendants are in the business of designing, manufacturing, testing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel.

95. By placing FiberCel into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

96. The FiberCel placed into the stream of commerce by Defendants and implanted into Plaintiff was contaminated, leading those persons who received FiberCel implants to develop tuberculosis, including Plaintiff, and accordingly, was not fit, safe, or merchantable for its intended use.

97. The contamination in the FiberCel, manufactured, supplied, and placed into the stream of commerce by Defendants was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff as part of his spinal operation.

98. Defendants breached the implied warranty for FiberCel because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff William Wilcox, including his development of tuberculosis.

99. Plaintiff William Wilcox was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants.

100. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

101. As a direct and proximate result of the foregoing breach of implied warranty the Defendants, Plaintiff was exposed to contaminated FiberCel and suffered the injuries and damages set forth herein above.

102. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

SIXTH CAUSE OF ACTION

**Breach of Implied Warranty of Fitness for a Particular Purpose
(Against Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and Spinalgraft
Technologies LLC)**

103. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

104. Defendants are in the business of designing, manufacturing, testing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel.

105. When Defendants placed FiberCel into the stream of commerce, they knew that the buyer was relying on its skill and judgment to select and furnish material suitable for implantation in the Plaintiff's spine.

106. By placing FiberCel into the stream of commerce, Defendants impliedly warranted that it was fit for the intended purpose of being placed in Plaintiff's spine.

107. The FiberCel placed into the stream of commerce by Defendants and implanted into Plaintiff was contaminated, leading those persons who received FiberCel implants to develop tuberculosis, including Plaintiff, and accordingly, was not fit or safe for its intended use.

108. The contamination in the FiberCel, manufactured, supplied, and placed into the stream of commerce by Defendants was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff as part of his spinal operation.

109. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

110. Defendants breached the implied warranty for FiberCel because it was contaminated and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff William Wilcox, including his development of tuberculosis.

111. Plaintiff William Wilcox was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants.

112. As a direct and proximate result of the foregoing breach of implied warranty the Defendants, Plaintiff was exposed to contaminated FiberCel and suffered the injuries and damages set forth herein above.

113. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

(Against Aziyo Biologics, Inc., Medtronic Sofamor Danck USA, Inc., and Spinalgraft Technologies LLC)

114. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

115. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that FiberCel and its

human tissue component are safe, effective, fit, and proper for their intended use. Plaintiff and Plaintiff's physicians utilized FiberCel relying upon these warranties.

116. Defendants' own promotion states that FiberCel is processed in sterile conditions and is screened for bacteria and communicable disease.

117. In utilizing FiberCel, Plaintiff relied on the skill, judgment, representation, and foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel is unsafe and unfit for its intended uses.

118. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

119. As a direct and proximate result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

120. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

EIGHTH CAUSE OF ACTION
Breach of Express Warranty
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

121. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

122. At all times mentioned, Donor Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that their human tissue product sold for use in FiberCel is safe, effective, fit, and proper for its intended use.

Plaintiff and Plaintiff's physicians utilized FiberCel and the human tissue used in FiberCel relying upon these warranties.

123. In utilizing FiberCel and the human tissue used in FiberCel, Plaintiff relied on the skill, judgment, representation, and foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel and its human tissue component are unsafe and unfit for its intended uses.

124. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

125. As a direct and proximate result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

126. Plaintiff seeks compensatory and punitive damages for all of the foregoing in an amount to be determined by the jury.

NINTH CAUSE OF ACTION

Medical Monitoring

(Against Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., Spinalgraft Technologies LLC)

127. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein

128. As a result of the Defendants' negligence, Plaintiff has been diagnosed with TB, and may in the future experience ongoing symptoms of TB, in addition to other injuries and harm that he may suffer as a result of his TB diagnosis.

129. A monitoring procedure exists to monitor Plaintiff's TB since all TB patients require continual and ongoing monitoring of their potentially deadly disease.

130. Plaintiff will be required to undergo testing and analysis to monitor the spread and progression of his TB.

131. Ongoing TB testing requires expenditures of time and money.

132. The prescribed monitoring regime is different from that normally recommended for an individual like Plaintiff in the absence of the development of TB.

133. The prescribed monitoring regime is reasonably necessary according to contemporary scientific and medical principles.

134. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

135. Defendants' acts were negligent and reckless, and they should be held accountable, and should compensate Plaintiff for the ongoing costs of monitoring his TB.

136. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

TENTH CAUSE OF ACTION

Medical Monitoring

(Against DCI Donor Services, Inc. and New Mexico Donor Services)

137. Plaintiff incorporates paragraphs 1 through 41 and 147 through 154 as though the same were set forth at length herein.

138. As a result of the Donor Defendants' negligence, Plaintiff has been diagnosed with TB, and may in the future experience ongoing symptoms of TB, in addition to other injuries and harm that he may suffer as a result of his TB diagnosis.

139. A monitoring procedure exists to monitor Plaintiff's TB since all TB patients require continual and ongoing monitoring of their potentially deadly disease.

140. Plaintiff will be required to undergo testing and analysis to monitor the spread and progression of his TB.

141. Ongoing TB testing requires expenditures of time and money.

142. The prescribed monitoring regime is different from that normally recommended for an individual like Plaintiff in the absence of the development of TB.

143. The prescribed monitoring regime is reasonably necessary according to contemporary scientific and medical principles.

144. Defendants' actions described above were performed willfully, wantonly, and with reckless disregard of the life and safety of the Plaintiff and the general public.

145. Donor Defendants' acts were negligent and reckless, and they should be held accountable, and should compensate Plaintiff for the ongoing costs of monitoring his TB

146. Plaintiff seeks compensatory and punitive damages for all of the foregoing in the amounts set forth below.

ELEVENTH CAUSE OF ACTION

**Punitive Damages
(Against All Defendants)**

147. Plaintiff incorporates paragraphs 1 through 41 as though the same were set forth at length herein.

148. Plaintiff is further informed and believes that Defendants' misconduct, as previously outlined herein, constituted a conscious disregard for the rights and safety of other persons, including Plaintiff William Wilcox, that had a great probability of causing substantial harm including, but not limited to, exposing William Wilcox and other recipients of FiberCel to tuberculosis, a potentially deadly infectious disease.

149. Plaintiff is further informed and believes that Defendants engaged in conduct with respect to the contaminated FiberCel unit alleged herein which was a legal cause of loss, damages, injuries, and harm to Plaintiff, and which exposed Plaintiff and other recipients of the contaminated

FiberCel units to serious complications, including the diagnosis of tuberculosis in Plaintiff's post-surgical wound.

150. Defendants designed, manufactured, produced, created, and/or promoted the subject FiberCel from tissue that was harvested from an unqualified and inadequately screened donor, conducted no meaningful quality control, and then placed this exceedingly dangerous material into the stream of commerce in willful, wanton, and reckless disregard of the safety of the public and this Plaintiff.

151. Defendants' actions and inactions leading to the contamination of the FiberCel product were outrageous, willful and wanton, and done with reckless disregard for the safety of the Plaintiff.

152. The Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiff was the direct proximate cause of Plaintiff's injuries and damages.

153. As a direct and proximate result of the Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiff, the Plaintiff has suffered and continues to suffer damages as set forth above.

154. Defendants thereby acted with a conscious disregard for the rights and safety of Plaintiff William Wilcox and other users of the contaminated FiberCel units, thus warranting an award of punitive damages to Plaintiff.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff William Wilcox prays for relief against Defendants, jointly and severally, as follows:

a. Judgment against Defendants, jointly and severally, in the sum of TWENTY-FIVE MILLION DOLLARS (\$25,000,000.00) in compensatory damages exclusive of interest and costs,

and in an amount to fully compensate Plaintiff William Wilcox for all past, present, and future pain and suffering, from the date of injury pursuant to Va. Code Ann. § 8.01-382 (1950, as amended);

b. Special damages, exclusive of interest and costs, and in an amount to fully compensate Plaintiff William Wilcox for all of his injuries and damages, both past and present;

c. Punitive and/or exemplary damages in the sum of THREE HUNDRED FIFTY THOUSAND DOLLARS (\$350,000.00) in punitive damages exclusive of interest and costs for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

d. An order to establish a medical monitoring protocol for Plaintiff William Wilcox to monitor his health;

e. Attorneys' fees, expenses, and costs of this action;

f. Pre-judgment and post-judgment interest in the maximum amount allowed by law;

and

g. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,
William Wilcox,
By Counsel



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To be admitted pro hac vice as counsel for Plaintiff

Dated: March 7, 2023