IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

DANNA BRACKENBURY, individually, and as Trustee for the Heirs and Next of Kin of Terrance Lee Brackenbury, Plaintiff, v. SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC., jointly and individually, Defendants.	Case No. 17-cv-4186 Jury Trial Demanded

COMPLAINT

Plaintiff Danna Brackenbury, in her own right and as Trustee for the Heirs and Next of Kin of Terrance Lee Brackenbury, through her Complaint, and pursuant to Minn. Stat. § 573.02, brings this action against Defendants Sorin Group Deutschland GmbH and Sorin Group USA, Inc. (collectively, "Sorin") hereby alleges as follows:

THE PARTIES

1. Plaintiff Danna Lynne Brackenbury is the Wife and Trustee to the Heirs and Next of Kin of Terrance Lee Brackenbury, deceased, and is a citizen of New Mexico, residing at 1674 Calle de Oriente Norte, Santa Fe, NM 87507.
2. Plaintiff, as the appointed Trustee for the Heirs and Next of Kin of Terrance Brackenbury, brings this action, in relevant part, pursuant to Minnesota's Wrongful Death statute, Minn. Stat. § 573.02 et seq. Plaintiff, as the surviving spouse of Terrance Brackenbury, brings this action, individually, for her Loss of Consortium claim.

3. Defendant Sorin Group Deutschland GbmH ("Sorin GmbH") is a foreign corporation with its headquarters in Munich, Germany. Sorin GmbH is a wholly owned subsidiary of LivaNova, PLC. Sorin GmbH designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Terrance Brackenbury's heart surgery on April 17, 2015.

4. Defendant Sorin Group, USA, Inc. ("Sorin USA") is a Delaware Corporation with its principal place of business at 14401 West 65th Way, Arvada, Colorado 80004. Sorin USA is a wholly owned subsidiary of LivaNova, PLC. Sorin USA designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Terrance Brackenbury's heart surgery on April 17, 2015. Sorin USA is a registered corporation with the Minnesota Secretary of State. Sorin USA's registered agent in Minnesota is CT Corporation System, Inc., residing at 1010 Dale St. N, St. Paul, MN 55117-5603.

JURISDICTION AND VENUE

5. Personal Jurisdiction exists over Sorin GmbH and Sorin USA (collectively, "Sorin") pursuant to Minnesota Statute § 543.19 (the "long-arm" statute) and federal due process standards because Sorin regularly conducted business in Minnesota and maintained systematic and continuous contact with Minnesota. Furthermore, Sorin designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Terrance Brackenbury's heart surgery. Upon information and belief, Sorin sold the Sorin 3T Heater-Cooler Device directly to Regions Hospital in St. Paul, Minnesota, where Mr. Brackenbury's heart surgery took place.

6. This Court has Subject Matter Jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties and the amount in controversy exceeds $75,000.

7. Venue is proper in the District of Minnesota pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the causes of action occurred in Minnesota, and pursuant to 28 U.S.C. § 1391(c) because Defendants are subject to Personal Jurisdiction in the District of Minnesota.

FACTUAL ALLEGATIONS

8. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

9. The Sorin 3T Heater-Cooler Device ("Sorin 3T") is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T is not intended to come into contact with the patient.

10. The Sorin 3T is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510(k) Premarket Notification process.

11. Prior to commercialization of the Sorin 3T in the United States, Sorin submitted a 510(k) Premarket Notification of intent to market the Sorin 3T with the Department of Health and Human Services. A letter from the FDA dated June 6, 2006, informed Sorin that the FDA

determined the Sorin 3T to be substantially equivalent to legally marketed predicate devices that do not require a premarket approval (PMA) application.[1]

12. Following the 510(k) approval in 2006, and at all relevant times, Sorin was in the business of designing, licensing, manufacturing, distributing, marketing, advertising, selling, and/or delivering the Sorin 3T into the stream of commerce in the United States and Minnesota, including marketing, selling, and/or delivering the Sorin 3T that was used in Mr. Brackenbury's heart surgery.

13. At all relevant times, Sorin was required to develop and test safe cleaning/disinfection protocols for the Sorin 3T, and to provide safe cleaning/disinfection instructions in the Sorin 3T's labeling and Instructions for Use ("IFU").

14. The development and testing of the cleaning/disinfection procedures conducted by Sorin was done without consideration for the presence of mycobacteria, and the instructions for cleaning/disinfecting the Sorin 3T in the IFU and elsewhere were insufficient to properly disinfect the Sorin 3T from the presence of mycobacteria.

15. Between April 11 and April 13, 2011, the FDA conducted an inspection of Sorin GmbH's manufacturing facility. Upon information and belief, this is the same facility that designed, manufactured, and/or assembled the Sorin 3T that was used in Mr. Brackenbury's heart surgery on April 17, 2015.

16. The FDA's 2011 Establishment Inspection Report found several issues related to the cleaning/disinfecting of the Sorin 3T. Specifically, the inspector found that (i) the design inputs do not include an input for the cleaning of the water tank to prevent bacterial growth;

[1] The 510(k) approval is attached as Ex A. All exhibits are incorporated as referenced herein.

(ii) the design output includes a cleaning procedure for the U.S., but requires the use of agents that are not available in the U.S.; (iii) the design verification was not performed in relation to the U.S. cleaning IFU; (iv) risk analysis does not include possible contamination from water held in the tank in relation to the patient, operating room, or operation; and (v) design changes were not adequately verified.

17. On November 18, 2016, The European Centre for Disease Prevention and Control ("ECDC") reported that cases of infection caused by Mycobacterium chimaera ("M. chimaera") in patients who had recently undergone open-heart surgery had been reported in seven European countries (France, Germany, Ireland, the Netherlands, Spain, the UK and Switzerland).[2] The ECDC reported that the outbreaks began in 2011.

18. Based upon these outbreaks in Europe, the FDA's inspection, and their own investigation and testing, Sorin knew or should have known in 2011 of the association between non-tuberculous mycobacterium ("NTM") infections and the use of the Sorin 3T when used in open-heart surgeries.

19. Upon information and belief, on or around January 2014, Sorin received notification from a hospital that at least one patient suffered an infection following an open-heart surgery in which the Sorin 3T was used. The hospital proceeded to test all Sorin 3T units, and found that all units were contaminated with bacteria.

20. On or around July 14, 2014, Sorin issued an "Important Information" letter to hospitals that had purchased the Sorin 3T.[3] The letter warned that "Some cardiac surgery patients have been infected with a slow growing *Mycobacterium chimaera*." The letter further stated that

[2] The ECDC report is attached as Ex. B.
[3] The Important Information Letter is attached as Ex. C.

"during the investigation work it has been identified that some hospitals' heater cooler devices are contaminated."

21. On or around August 6, 2014, Sorin USA filed a MAUDE adverse event report with the FDA.[4] The event description was reported as follows:

> "The 15 pts have tested positive +afb for an atypical mycobacterium infection. All infections have been surgical site infections. The investigation is still on-going. The common denominator for the cardiac surgeries is the profusion machine. The machine has been cultured and found to have the mycobacterium in the water."

22. Upon information and belief, on or around August 2014, Sorin GmbH performed its own investigation in its manufacturing facility. That investigation revealed the presence of mycobacteria on Sorin 3T units at the manufacturing facility. Upon information and belief, this is the facility that manufactured the Sorin 3T used in Mr. Brackenbury's April 17, 2015 surgery. However, the results of this investigation were not made public until nearly two years later, when the FDA issued a Safety Communication on June 1, 2016.[5]

23. On or around June 15, 2015, Sorin issued a Field Safety Notice[6] related to Mycobacterium risk and the Sorin 3T. The Field Safety Notice warned as follows:

> "Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which organism could potentially contact the patient and subsequently contaminate the surgical site."

[4] The MAUDE report is attached as Ex. D.
[5] The June 1, 2016 Safety Communication is attached as Ex. E.
[6] The Field Safety Notice is attached as Ex. F.

24. The June 15, 2015 Field Safety Notice also included an updated IFU, which provided updated cleaning and disinfection procedures. However, these updated cleaning/disinfecting procedures were still ineffective and failed to properly clean and disinfect the Sorin 3T.

25. On or around July 15, 2015, Sorin issued a Class 2 Recall of the Sorin 3T. Sorin reported the reason for the recall as, "Potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per Instructions for Use."[7]

26. By the time the Class 2 recall and Field Safety Notice were issued, Sorin knew, or should have known, that design and/or manufacturing defects in the Sorin 3T rendered the device prone to colonization and transmission of bacteria, including Mycobacteria, regardless of the cleaning and/or disinfection procedures used.

27. On or around August 24 to August 27, 2015, the FDA conducted a follow-up investigation at the Sorin manufacturing facility. The FDA's 2015 investigation noted that several problems continued to exist related to lack of a validated cleaning and disinfecting process for the Sorin 3T. This was the same or similar problem that the FDA identified in its 2011 inspection.

28. On or around October 15, 2015, the FDA issued a Safety Communication in regard to the Sorin 3T.[8] That Safety Communication stated that between January 2010 and August 2015, that FDA had received thirty-two (32) Medical Device Reports of patient infections associated with the Sorin 3T.

[7] The July 15, 2015 Class 2 Recall Notice is attached as Ex. G.
[8] The October 15, 2015 Safety Communication is attached as Ex. H.

29. On December 29, 2015, the FDA sent a Warning Letter to the C.E.O. of LivaNova, the parent company of Sorin GmbH and Sorin USA.[9] The Warning Letter stated that several violations of the Food, Drug, and Cosmetic Act ("FDCA") were present with respect to the Sorin 3T, including, among other things, the following:

    a. That the Sorin 3T devices are adulterated within the meaning of section 501(h) of the FDCA, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation of title 21, Code of Federal Regulations (CFR), part 820.

    b. Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

    c. Failure to adequately update the cleaning and disinfection IFU after receiving complaints of patient death due to infections caused by the Sorin 3T. The updated cleaning and disinfection test does not demonstrate an adequate verification or validation of the new cleaning IFU because the acceptance criteria do not demonstrate an adequate level reduction for bacteria. Additionally, Puristeril is not available in the U.S., and therefore Sorin recommends substituting Clorox, but the test report does not demonstrate the amounts of Clorox described in the IFU are equivalent to Puristeril.

[9] The Warning Letter is attached as Ex. I.

d. Failure to validate a process, with a high degree of assurance and approved according to established procedures, where process results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a).

e. Failure to adequately develop, implement, and maintain written MDR (Medical Device Research) procedures, as required by 21 CFR 803.17.

30. On or around April 18, 2016, EuroSurveillance published an article entitled, "Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016" (the "EuroSurveillance article").[10]

31. The EuroSurveillance article reported the following:

> "Invasive infections with *Mycobacterium chimaera* were reported in patients with previous open chest surgery and exposure to contaminated heater-cooler units (HCUs) . . . Clinical infections occurred in five male German cases over 50 years of age (range 53–80). Cases had been exposed to HCUs from one single manufacturer during open chest surgery up to five years prior to onset of symptoms. During environmental investigations, *M. chimaera* was detected in samples from used HCUs from three different countries and samples from new HCUs as well as in the environment at the manufacturing site of one manufacturer in Germany. Our investigation suggests that at least some of the *M. chimaera* infections may have been caused by contamination of HCUs at manufacturing site."

32. Upon information and belief, the "single manufacturer" referred to by the EuroSurveillance article is Sorin, and the manufacturing site is Sorin's facility in Munchen, Germany. Upon information and belief, this is the site where the Sorin 3T used in Mr. Brackenbury's April 17, 2015 surgery was manufactured.

[10] The EuroSurveillance article is attached as Ex. J.

33. On or around June 1, 2016, the FDA issued another Safety Communication in regard to the Sorin 3T. That Safety Communication stated, "Testing conducted by [Sorin] in August 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility. Units from this facility can be found worldwide."

34. On or around July 2016, Sorin issued at least one MAUDE adverse event report after a hospital continued to find mycobacteria, including mycobacteria avium complex and mycobacteria intracellular complex, on the Sorin 3T. The hospital had strictly followed the updated IFU cleaning/disinfecting procedure since August 2015.[11]

35. On or around October 13, 2016, the Center for Disease Control and Prevention ("CDC") issued a Health Advisory in regard to the Sorin 3T and the risk of infection after surgery.[12]

36. The CDC Health Advisory advised hospitals to notify patients who underwent open-heart surgey involving a Sorin 3T that the device was potentially contaminated, stating that information indicated the devices "were likely contaminated with the rare bacteria *Mycobacterium chimaera* during manufacturing."

37. The CDC Health Advisory went on to state the following:

> "[The] CDC in collaboration with National Jewish Health completed a whole-genome sequencing analysis and results demonstrate that M. chimaera isolates from patients with heater-cooler associated infections and from the 3T heater-cooler devices from several U.S. hospitals (in Pennsylvania and Iowa) are all highly related to each other. This evidence for likely point-source contamination of the 3T heater-cooler devices is consistent with recent reports from Europe [links omitted] that describe matching of M. chimaera sequences from environmental isolates at the device production site in Germany and isolates from patients and devices in Europe."

[11] The adverse event report is attached as Ex. K.
[12] The CDC Health Advisory is attached as Ex. L.

38. On or around October 13, 2016, the FDA issued an updated Safety Communication regarding M. chimaera infections association with the Sorin 3T.[13] The updated Safety Communication echoed the CDC's finding that results of testing done by the CDC and National Jewish Health "strongly suggest that the tested 3T devices had a common source of *M. chimaera* contamination."

39. The design and manufacturing defects in the Sorin 3T allowed bacteria, including NTM and M. chimaera, to colonize and multiply within the water and component parts of the device. Bacteria was then able to reach the surgical site and cause infection, as it did during Mr. Brackenbury's surgery, through aerosolization, fluid leakage, or by other means.

40. Sorin knew or should have known of this risk before 2011, and clearly knew of the risk by 2014, when its *own investigation* revealed that the Sorin 3T devices were contaminated with mycobacteria at the manufacturing facility. Despite knowledge of the risk to patients and others, Sorin continued to manufacture, assemble, distribute, advertise, and/or sell the Sorin 3T to hospitals in the United States, including Minnesota.

FACTS ABOUT NONTUBERCULOUS MYCOBACTERIA (NTM)

41. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

42. Nontuberculous mycobacteria, or NTM, are bacteria that are typically not harmful, but can be harmful, especially in persons with weakened immune systems, or persons who have recently undergone vascular grafting, prosthetic valve surgery, or other types of invasive surgery.

[13] The October 13, 2106 Updated Safety Communication is attached as Ex. M.

43. Because NTM are slow growing, it can take months or years for symptoms to materialize after exposure.

44. The symptoms of an NTM infection are very general, including fevers, chills, nausea, and weight loss, among others. These symptoms also make an NTM infection difficult to diagnose in early stages.

45. Mycobacterium chimaera, or M. chimaera, is a sub-species of NTM. Like other NTM infections, M. chimaera may cause serious illness and/or death.

FACTS SPECIFIC TO TERRANCE BRACKENBURY

46. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

47. On or around April 15, 2015, Mr. Brackenbury suffered an ST-elevated myocardial infarction (STEMI) while exercising at a gym. He was taken to Regions Hospital in St. Paul, Minnesota.

48. On or around April 17, 2015, Mr. Brackenbury underwent an open-heart procedure at Regions Hospital. The procedure included coronary artery bypass grafting, aortic valve replacement, and ascending aortic aneurysm repair.

49. The Sorin 3T was used during Mr. Brackenbury's open-heart procedure to assist in the cooling and re-warming of Mr. Brackenbury.

50. Mr. Brackenbury contracted a latent NTM infection, specifically M. chimera, from the Sorin 3T device that was used in his open-heart surgery on April 17, 2015 at Regions Hospital. Mr. Brackenbury contracted the M. chimaera infection, which ultimately led to his illness and death, because the bacteria reached the surgical site near Mr. Brackenbury's sternum.

This occurred because the bacteria from the Sorin 3T became aerosolized during his procedure, fluid leakage occurred, by other means, and/or by some combination thereof.

51. From approximately May 2015 to September 2015, Mr. Brackenbury continued to have post-operative follow-up visits. By September 2015, Mr. Brackenbury had lost about 25 lbs. from diet and exercise, was active in cycling and Tai Chi, and was generally making an excellent recovery.

52. On or around January 2016, Mr. Brackenbury began to experience fever and chills. On or about February 25, 2016, he experienced weakness in his legs and had difficulty climbing stairs.

53. On or around July 13, 2016, Mr. Brackenbury visited Fisher's Landing Family Medicine in Vancouver, Washington, with complaints of fatigue, and sudden, rapid weight loss.

54. On or around late July 2016, Mr. Brackenbury noticed a nodule (an abnormal lump) in the sternal scar area from his April 2015 open-heart surgery.

55. On or around September 1, 2016, 17ml of a thick, cloudy fluid was aspirated from Mr. Brackenbury's sternal abscess, the area near his scar from the 2015 open-heart surgery. Given the concerns for infection, he was admitted to Oregon Health and Science University (OHSU) later that day.

56. Between around September 1 and September 6, 2016, OHSU performed a series of tests, including imaging studies of the chest and abdomen, labs and cultures to identify the source and type of infection, and Mr. Brackenbury was given antibiotics to treat suspected organisms, blood product transfusions, and other treatment methods. However, nothing was able to control the infection.

57. On or around September 7, 2016, Mr. Brackenbury underwent a redo sternotomy and drainage of multiple abscesses. Cultures taken during this procedure tested positive for acid fast bacillus. It was at this point that mycobacterium, possibly M. chimaera, was suspected as the likely cause of the infection. Samples were also sent to the University of Washington for PCR studies.

58. On or around September 12, 2016, the University of Washington Medical Center Lab confirmed the presence of mycobacterium intracellulare or M. chimaera[14] in the samples from the sternal tissue.

59. Mr. Brackenbury's treating physicians at OHSU associated his M. chimaera infection with his April 17, 2015 open-heart surgery.

60. Despite a valiant effort by OHSU to halt the infection, Mr. Brackenbury's condition worsened, and on September 14, 2016, his level of care was reduced to provide for comfort alone. He died later that day at the age of 67.

61. Mr. Brackenbury's immediate cause of death was listed as multisystem organ failure, caused by septic shock as a consequence of disseminated mycobacterium infection.

62. Genetic sequencing later confirmed that Mr. Brackenbury had been suffering from an M. chimaera infection.

COUNT I

Strict Liability – Design Defect
(On Behalf of the Heirs and Next of Kin of Terrance Brackenbury)

63. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

[14] The method of testing used did not distinguish between these two organism types.

64. At all relevant times, Sorin was engaged in the design, development, testing, manufacture, assembly, promotion, marketing, and/or sale of the Sorin 3T that was used in Mr. Brackenbury's April 17, 2015 open-heart surgery.

65. The Sorin 3T was defective at the time that it was designed, manufactured, assembled, and sold. The Sorin 3T was defective in that its design prevented it from being properly and consistently cleaned and disinfected based on the accompanying IFU and other labels, instructions, or cleaning procedures, thus rendering the Sorin 3T unsafe for use by Regions Hospital, and unsafe for use in Mr. Brackenbury's open-heart surgery on April 17, 2015.

66. The Sorin 3T used by Regions Hospital in the surgery of Mr. Brackenbury on April 17, 2015, was expected to reach, and did reach, Regions Hospital and Mr. Brackenbury, the intended consumer and ultimate consumer, without substantial change to the condition in which it was sold by Sorin.

67. At the time the Sorin 3T left the possession of Sorin, the Sorin 3T was defective, and its condition made it unreasonably dangerous for Mr. Brackenbury and others who may have been exposed to the device at Regions Hospital. The Sorin 3T was defective because its design allowed bacteria, including mycobacteria, to collect and multiply and to form biofilm in the device. Said bacteria could subsequently come into contact with vulnerable patients and others in the operating room, or to infect other areas of the operating room, through aerosolization, fluid leakage, or other means.

68. Sorin intended for the Sorin 3T to be used in heart surgeries (among others) at Regions Hospital, like the one Mr. Brackenbury had on April 17, 2015. Sorin knew or should have known that the Sorin 3T would be used by patients like Mr. Brackenbury at Regions Hospital.

69. The Sorin 3T was used by Regions Hospital for Mr. Brackenbury's surgery in the manner in which it was intended, thus it was reasonably foreseeable that the Sorin 3T would be used in Mr. Brackenbury's surgery.

70. At all relevant times, Mr. Brackenbury could not have discovered the design defects associated with the Sorin 3T through the exercise of due diligence, nor could he have been expected to perceive the danger posed by the Sorin 3T. Thus, the dangerous condition of the Sorin 3T was unknowable to Mr. Brackenbury.

71. The Sorin 3T, as designed by Sorin, transmitted bacteria, including M. chimaera, directly to patients undergoing invasive surgery, including Mr. Brackenbury, through aerosolization, fluid leakage, or by other means.

72. The foreseeable risks of transmitting bacteria to patients undergoing invasive surgery, including Mr. Brackenbury, far outweighs any utility of using the Sorin 3T. The foreseeable risks also far outweigh any cost of designing, manufacturing, and producing an alternative design of the Sorin 3T that is not defective.

73. Mr. Brackenbury had a reasonable expectation that the Sorin 3T would not be unreasonably dangerous and defective, and that the device would not cause him to contract the M. chimaera bacteria that would ultimately take his life.

74. The use of the Sorin 3T during Mr. Brackenbury's open-heart surgery on April 17, 2015, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent disability and death.

75. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on April 17, 2015, specifically the defective design of the device, Mr. Brackenbury suffered catastrophic injury, disability, and death.

76. As a result of the foregoing, Plaintiff and the Heirs and Next of Kin of Terrance Brackenbury have incurred expenses for the funeral of the decedent and have sustained pecuniary loss within the meaning of Minn. Stat. § 573.02 and were otherwise damaged in an amount not yet determined but for which Minnesota law provides a remedy.

COUNT II

Strict Liability – Manufacturing Defect
(On Behalf of the Heirs and Next of Kin of Terrance Brackenbury)

77. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

78. At all relevant times, Sorin was engaged in the design, development, testing, manufacture, assembly, promotion, marketing, and/or sale of the Sorin 3T that was used in Mr. Brackenbury's April 17, 2015 open-heart surgery.

79. The Sorin 3T was defective at the time that it was designed, manufactured, assembled, and sold. The Sorin 3T was defective in that its design and manufacture prevented it from being properly and consistently cleaned and disinfected based on the accompanying IFU and other labels, instructions, or cleaning procedures, thus rendering the Sorin 3T unsafe for use by Regions Hospital, and unsafe for use in Mr. Brackenbury's open-heart surgery on April 17, 2015.

80. The Sorin 3T's was further defective in its manufacture, in that the device was exposed to the M. chimaera bacteria at the time that the device was manufactured. This occurred because M. chimaera was present at Sorin's manufacturing facility where the Sorin 3T, including the Sorin 3T used in Mr. Brackenbury's surgery, was designed, manufactured, and/or assembled.

81. The Sorin 3T used by Regions Hospital in the surgery of Mr. Brackenbury on April 17, 2015, was expected to reach, and did reach, Regions Hospital and Mr. Brackenbury, the intended consumer and ultimate consumer, without substantial change to the condition in which it was sold by Sorin.

82. At the time the Sorin 3T left the possession of Sorin, the Sorin 3T was defective, and its condition made it unreasonably dangerous for Mr. Brackenbury and others who may have been exposed to the device at Regions Hospital. The Sorin 3T was defective because its design and manufacture allowed bacteria, including mycobacteria, to collect and multiply and to form biofilm in the device. In fact, the M. chimaera bacteria was present on the Sorin 3T at the time it left Sorin's manufacturing facility. Said bacteria could subsequently come into contact with vulnerable patients and others in the operating room, or to infect other areas of the operating room, through aerosolization, fluid leakage, or other means.

83. Sorin intended for the Sorin 3T to be used in heart surgeries (among others) at Regions Hospital, like the one Mr. Brackenbury had on April 17, 2015. Sorin knew or should have known that the Sorin 3T would be used by patients like Mr. Brackenbury at Regions Hospital.

84. The Sorin 3T was used by Regions Hospital for Mr. Brackenbury's surgery in the manner in which it was intended, thus it was reasonably foreseeable that the Sorin 3T would be used in Mr. Brackenbury's surgery.

85. At all relevant times, Mr. Brackenbury could not have discovered the manufacturing defects associated with the Sorin 3T through the exercise of due diligence, nor could he have been expected to perceive the danger posed by the Sorin 3T. Thus, the dangerous condition of the Sorin 3T was unknowable to Mr. Brackenbury.

86. The Sorin 3T, as designed by Sorin, transmitted bacteria, including M. chimaera, directly to patients undergoing invasive surgery, including Mr. Brackenbury, through aerosolization, fluid leakage, or by other means.

87. The foreseeable risks of transmitting bacteria to patients undergoing invasive surgery, including Mr. Brackenbury, far outweighs any utility of using the Sorin 3T.

88. Sorin failed to prevent the Sorin 3T from being manufactured, assembled, and/or prepared to be distributed in a manner that would have prevented the device from being contaminated while on the production line or elsewhere while in Sorin's possession or control.

89. Sorin manufactured, assembled, and/or sold the Sorin 3T with NTM including M. chimaera, present in and/or on the device. The contamination occurred on the production line or elsewhere while in Sorin's possession or control.

90. Sorin's failure to ensure proper sanitation in the workplace, failure to ensure proper workmanship, failure to ensure adequate testing of component parts, and/or failure to ensure adequate labeling for the Sorin 3T caused the Sorin 3T to be manufactured in a manner that made the device defective and unreasonably dangerous.

91. Mr. Brackenbury had a reasonable expectation that the Sorin 3T would not be unreasonably dangerous and defective, and that the device would not cause him to contract the M. chimaera bacteria that would ultimately take his life.

92. The use of the Sorin 3T during Mr. Brackenbury's open-heart surgery on April 17, 2015, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent disability and death.

93. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on April 17, 2015, specifically the defective manufacture the device, Mr. Brackenbury suffered catastrophic injury, disability, and death.

94. As a result of the foregoing, Plaintiff and the Heirs and Next of Kin of Terrance Brackenbury have incurred expenses for the funeral of the decedent and have sustained pecuniary loss within the meaning of Minn. Stat. § 573.02 and were otherwise damaged in an amount not yet determined but for which Minnesota law provides a remedy.

COUNT III

Strict Liability – Failure to Warn
(On Behalf of the Heirs and Next of Kin of Terrance Brackenbury)

95. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

96. At all relevant times, Sorin was engaged in the design, development, testing, manufacture, assembly, promotion, marketing, and/or sale of the Sorin 3T that was used in Mr. Brackenbury's April 17, 2015 open-heart surgery.

97. The Sorin 3T was defective at the time that it was designed, manufactured, assembled, and sold. The Sorin 3T was defective in that its design and manufacture prevented it from being properly and consistently cleaned and disinfected based on the accompanying IFU and other labels, instructions, or cleaning procedures, thus rendering the Sorin 3T unsafe for use by Regions Hospital, and unsafe for use in Mr. Brackenbury's open-heart surgery on April 17, 2015.

98. The Sorin 3T was further defective and unreasonably dangerous in that the "IFU" and other labels and materials failed to adequately warn hospital staff, patients, and others, about the

Sorin 3T's serious risk of causing infection from aerosolization and/or fluid leakage from the device, which can lead to serious infections and death.

99. At all relevant times, Sorin was aware of the Sorin 3T's defects which caused the unreasonably dangerous condition.

100. The Sorin 3T was in a defective condition at the time it left Sorin.

101. Sorin failed to timely and adequately warn hospitals/healthcare providers and patients of the serious risks associated with the Sorin 3T, including, but not limited to:

    a. That the Sorin 3T was contaminated with NTM, specifically M. chimaera, at the time the device was manufactured;

    b. That the Sorin 3T could harbor and grow bacteria, including M. chimaera;

    c. That the bacteria, including M. chimaera, can reach the surgical site during an operation through aerosolization, fluid leakage, and/or other methods.

102. Further, Sorin failed to adequately and timely provide cleaning and disinfecting procedure that ensured that the Sorin 3T would not continue to be contaminated with bacteria, including M. chimaera.

103. Mr. Brackenbury had a reasonable expectation that the Sorin 3T would not be unreasonably dangerous and defective, that Sorin provided all proper warnings and IFU regarding the Sorin 3T, and that the device would not cause him to contract the M. chimaera bacteria that would ultimately take his life.

104. If Plaintiff or Mr. Brackenbury had been made aware of the significant risks of NTM and M. chimaera infection associated with the use of the Sorin 3T, Mr. Brackenbury would not have consented to use of the Sorin 3T during his April 17, 2015 surgery.

105. The use of the Sorin 3T during Mr. Brackenbury's open-heart surgery on April 17, 2015, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent disability and death.

106. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on April 17, 2015, and as a result of Sorin's failure to warn, Mr. Brackenbury suffered catastrophic injury, disability, and death.

107. As a direct and proximate cause of Sorin's failure to warn Regions Hospital, Plaintiff, Mr. Brackenbury, the FDA, and the public about the significant risk of NTM and M. chimaera infection from use of the Sorin 3T in surgery, Mr. Brackenbury suffered catastrophic injury, disability, and death.

108. As a result of the foregoing, Plaintiff and the Heirs and Next of Kin of Terrance Brackenbury have incurred expenses for the funeral of the decedent and have sustained pecuniary loss within the meaning of Minn. Stat. § 573.02 and were otherwise damaged in an amount not yet determined but for which Minnesota law provides a remedy.

COUNT IV

Negligence
(On Behalf of the Heirs and Next of Kin of Terrance Brackenbury)

109. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

110. Sorin owed a duty of reasonable care to the public and all foreseeable users of the Sorin 3T, including patients, when it designed, tested, assembled, manufactured, marketed, distributed, and sold the Sorin 3T into the stream of commerce. This duty of reasonable care required Sorin to assure that the product was in full compliance with FDA and other

regulations, and was not defective or unreasonably dangerous for its intended purpose and other foreseeable uses.

111. Sorin breached this duty of care by designing, testing, assembling, manufacturing, marketing, distributing, and selling the Sorin 3T in a manner that made the device defective and unreasonably dangerous for its intended and foreseeable use. This defect stems from the Sorin 3T's propensity to permit the colonization and growth of bacteria, including NTM and M. chimaera, and the ability of said bacteria to reach the surgical site through aerosolization, fluid leakage, or other means.

112. Sorin further breached this duty by allowing the Sorin 3T devices, including the device used in Mr. Brackenbury's open-heart surgery, to become contaminated with NTM and M. chimaera while still in Sorin's possession and control, and then sold to the end user without being disinfected.

113. Sorin owed Plaintiff and Mr. Brackenbury a duty of reasonable care to discover these defects and to timely warn the FDA, Regions Hospital, and Mr. Brackenbury about these defects.

114. Sorin failed to timely warn the FDA, Regions Hospital, and Mr. Brackenbury about these defects, thereby breaching its duty of care.

115. Sorin owed a duty to Plaintiff, Mr. Brackenbury, all foreseeable users, and the general public to develop, test, and produce a cleaning and disinfecting procedure to be included in the IFU that adequately eliminated the presence of NTM and M. chimaera from the Sorin 3T.

116. Sorin failed to develop, test, and produce a cleaning and disinfecting procedure that adequately eliminated the presence of NTM and M. chimaera from the Sorin 3T, thereby breaching its duty of care.

117. Sorin owed a duty to Plaintiff, Mr. Brackenbury, all foreseeable users, and the general public to issue a timely recall of all Sorin 3T units in use throughout the United States and abroad when Sorin became aware that the Sorin 3T unites had become contaminated at Sorin's manufacturing facility.

118. Sorin breached this duty by failing to timely recall all Sorin 3T devices, despite Sorin's knowledge that the devices had been exposed to the M. chimaera bacteria and were possibly contaminated.

119. As a direct and proximate cause of Sorin's breach of duty, Mr. Brackenbury became infected with M. chimaera as a result of bacteria from the Sorin 3T reaching the surgical site—at his open chest—on April 17, 2015.

120. As a direct and proximate cause of Sorin's breach of duty, Mr. Brackenbury became seriously ill with infection, and ultimately died as a result of the M. chimera infection.

121. As a result of the foregoing, Plaintiff and the Heirs and Next of Kin of Terrance Brackenbury have incurred expenses for the funeral of the decedent and have sustained pecuniary loss within the meaning of Minn. Stat. § 573.02 and were otherwise damaged in an amount not yet determined but for which Minnesota law provides a remedy.

COUNT V

Loss of Consortium
(On Behalf of Danna Brackenbury)

122. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

123. Plaintiff Danna Brackenbury was entitled to the care, comfort, companionship, services, and consortium of her husband, Terrance Brackenbury.

124. As a direct and proximate result of the negligence, carelessness, and willful and wanton conduct by Sorin as outlined herein, Mr. Brackenbury contracted an M. chimaera infection, fell severely ill, and lost his life.

125. As a result of the injuries and wrongful death of Terrance Brackenbury, Plaintiff was, and will continue to be, deprived of care, comfort, companionship, services, and consortium of her Husband.

126. As a result of the foregoing, Plaintiff incurred damages related to the loss of Terrance Brackenbury's services and companionship that she would have received in the usual course of married life, and other damages reasonable under the circumstances for which Minnesota law provides a remedy.

ACTUAL DAMAGES

127. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

128. As a direct and proximate result of the acts, omissions, and violations of Defendants as alleged herein, Plaintiff has suffered injuries and damages. Plaintiff seeks compensation from Defendants for injuries including, but not limited to:

    a. Pecuniary losses resulting from the death of Mr. Brackenbury;

    b. Loss of consortium damages incurred by Mrs. Brackenbury;

    c. Medical bills and expenses, including funeral expenses;

    d. Any and all such further relief to which Plaintiff may be entitled under the law.

PRAYER FOR RELIEF

129. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

130. Plaintiff, Danna Brackenbury, in her own right and as Trustee on Behalf of the Heirs and Kin of Terrance Brackenbury, requests the Court to enter judgment against the Defendants, jointly and individually, for a reasonable amount greater than $75,000, together with interests, costs, and disbursements incurred herein.

PLAINTIFF HEREBY DEMANDS A TRIAL BY JURY

Dated: September 8, 2017

JOHNSON BECKER PLLC

/s/ Michael K. Johnson
Michael K. Johnson (MN Bar 0258696)
Ken Pearson (MN Bar #016088X)
Leland P. Abide (MN Bar #0398269)
JOHNSON BECKER, PLLC
444 Cedar St., Suite 1800
St. Paul, Minnesota 55101
Telephone: (612) 436-1800
Facsimile: (612) 436-1801
mjohnson@johnsonbecker.com
kpearson@johnsonbecker.com
labide@johnsonbecker.com

Attorneys for Plaintiff