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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HAYES GARVER II, and MARIA GARVER, Husband and Wife, Plaintiffs, v. SORIN GROUP DEUTSCHLAND, GMBH, LIVANOVA DEUTSCHLAND, GMBH, SORIN GROUP USA, INC., and LIVANOVA HOLDING USA, INC., jointly and individually, Defendants.	Case No. 2:17-cv-7802 COMPLAINT FOR DAMAGES JURY TRIAL DEMANDED

Plaintiffs Hayes G. Garver II and Maria V. Garver, Husband and Wife, bring this action against Defendants Sorin Group Deutschland, GmbH, LivaNova Deutschland, GmbH, Sorin Group USA, Inc., and LivaNova Holding USA, Inc., and hereby allege as follows:

THE PARTIES

1. Plaintiffs Hayes and Maria Garver, Husband and Wife, are residents of California, residing in Hermosa Beach, County of Los Angeles, CA 90254.

2. Defendant Sorin Group Deutschland, GbmH is a foreign corporation with its headquarters in Munich, Germany. Sorin Group Deutschland, GmbH designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Mr. Garver's open-heart surgery on September 10, 2014. Sorin Group Deutschland, GmbH is a wholly owned subsidiary of LivaNova, PLC. Upon information and belief, Sorin Group Deutschland, GmbH, has undergone a name change and is now known as LivaNova Deutschland, GmbH. For brevity's sake, Plaintiff will refer to this entity as "Sorin GmbH," encompassing both Sorin Group Deutschland, GmbH and LivaNova Deutschland, GmbH.

3. Defendant Sorin Group USA, Inc. is a Delaware Corporation with its principal place of business at 14401 West 65th Way, Arvada, Colorado 80004. Sorin Group USA, Inc. designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Mr. Garver's open-heart surgery on September 10, 2014. Sorin Group USA, Inc. is a registered corporation with the California Secretary of State. Sorin Group USA, Inc.'s registered agent in California is CT Corporation System, residing at 818 W 7th St., Suite 930, Los Angeles, California 90017. Sorin Group USA, Inc. is a wholly owned subsidiary of LivaNova, PLC. Upon information and belief, Sorin Group USA, Inc. has undergone a name change and is now known as LivaNova Holding USA, Inc. For brevity's sake, Plaintiff will refer to this entity as "Sorin

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USA," encompassing both Sorin Group USA, Inc., and LivaNova Holding USA, Inc.

JURISDICTION AND VENUE

4. Personal Jurisdiction exists over Sorin GmbH and Sorin USA (collectively, "Sorin") pursuant to California Civil Procedure Code § 410.10 (the "long-arm" statute) and federal due process standards because Sorin regularly conducted business in California and maintained systematic and continuous contact with California. Furthermore, Sorin designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Mr. Garver's open-heart surgery on September 10, 2014. Upon information and belief, Sorin sold the Sorin 3T Heater-Cooler Device directly to Kaiser Permanente Medical Center in Los Angeles, California, where Mr. Garver's open-heart surgery took place.

5. 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.

6. Venue is proper in the Central District of California 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 within the Central District of California, and pursuant to 28 U.S.C. § 1391(c) because Defendants are subject to Personal Jurisdiction in California.

FACTUAL ALLEGATIONS

7. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

8. 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)

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hours or less. The Sorin 3T is not intended to come into contact with the patient.

9. 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.

10. 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]

11. 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 California, including marketing, selling, and/or delivering the Sorin 3T that was used in Mr. Garver's heart surgery.

12. 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").

13. 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.

14. 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

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

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used in Mr. Garver's open-heart surgery on September 10, 2014.

15. 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; (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.

16. 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.

17. 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.

18. 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.

19. On or around July 14, 2014, Sorin issued an "Important Information"

[2] The ECDC report is attached as Ex. B.

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

20. 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."

21. 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. Garver's open-heart surgery on September 10, 2014. 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]

22. 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

[3] The Important Information Letter is attached as Ex. C.
[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.

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> 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 organisms could potentially contact the patient and subsequently contaminate the surgical site."

23. 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.

24. 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]

25. 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.

26. 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.

27. 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)

[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.

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Medical Device Reports of patient infections associated with the Sorin 3T.

28. 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

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

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equivalent to Puristeril.

d. Failure to validate a process, with a high degree of assurance and approval 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.

29. 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]

30. 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."

31. Upon information and belief, the "single manufacturer" referred to by the EuroSurveillance article is Sorin, and the manufacturing site is Sorin's facility in

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

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Munich, Germany. Upon information and belief, this is the site where the Sorin 3T used in Mr. Garver's September 10, 2014 surgery was manufactured.

32. 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."

33. 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]

34. 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]

35. The CDC Health Advisory advised hospitals to notify patients who underwent open-heart surgery 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."

36. 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

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

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> 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."

37. 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."

38. 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. Garver's surgery, through aerosolization, fluid leakage, or by other means.

39. 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 California.

FACTS ABOUT NONTUBERCULOUS MYCOBACTERIA (NTM)

40. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

41. 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.

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

43. 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.

44. 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 HAYES GARVER

45. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

46. On or around September 10, 2014, Mr. Garver underwent a redo sternotomy, aortic valve replacement (an open-heart procedure) at Kaiser Permanente Medical Center in Los Angeles, California.

47. During Mr. Garver's open-heart surgery, the Sorin 3T was used to cool and re-warm Mr. Garver.

48. M. chimaera bacteria from the Sorin 3T used in Mr. Garver's procedure reached the surgical site and Mr. Garver's open-heart through aerosolization, fluid leakage, or by other means.

49. Between late 2016 and early 2017, Mr. Garver made periodic visits to Kaiser Medical Center with complaints of significant and worsening back pain.

50. On or around early February 2017, healthcare providers at Kaiser Medical Center suspected that a bacterial infection may be the cause of Mr. Garver's symptoms.

51. On or around February 4, 2017, healthcare providers at Kaiser Medical Center noted that Mr. Garver needed to be accessed for a possible M. chimaera infection due to his previous exposure to the Sorin 3T during his open-heart procedure on September 10, 2014.

52. On or around February 4, 2017, healthcare providers at Kaiser collected

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cultures to perform an Acid-Fast Bacilli (AFB) test on Mr. Garver to test for the presence of Mycobacteria.

53. On or around February 27, 2017, the AFB test confirmed the presence of Mycobacterium avium-intracellulare-scrofulaceum (MAI) complex.[14] At this time, doctors at Kaiser suspected that Mr. Garver was suffering from an M. Chimaera infection.

54. Beginning around February 2017, Mr. Garver was treated with an antibiotic regiment and other therapy designed to combat M. Chimaera.

55. Mr. Garver remains on antibiotic therapy to this day.

56. On or around April 6, 2017, partial 16s genetic sequencing confirmed that Mr. Garver was suffering from an M. chimaera infection.

COUNT I

Strict Liability – Design Defect (On Behalf of Hayes Garver)

57. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

58. 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. Garver's September 10, 2014 open-heart surgery.

59. 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 Kaiser Permanente Medical Center, and Mr. Garver in his September 10, 2014 open-heart surgery.

60. The Sorin 3T used by Kaiser Permanente Medical Center in the surgery

[14] M. Chimaera is a species of MAI. The AFB test does not distinguish between MAI and M. Chimaera.

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of Mr. Garver was expected to reach, and did reach, Kaiser Permanente Medical Center and Mr. Garver, the intended consumer and ultimate consumer, without substantial change to the condition in which it was sold by Sorin.

61. 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. Garver and others who may have been exposed to the device at Kaiser Permanente Medical Center. 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.

62. Sorin intended for the Sorin 3T to be used in heart surgeries (among others) at Kaiser Permanente Medical Center, like the one Mr. Garver had on September 10, 2014. Sorin knew or should have known that the Sorin 3T would be used by patients like Mr. Garver at Kaiser Permanente Medical Center.

63. The Sorin 3T was used by Kaiser Permanente Medical Center for Mr. Garver's surgery in the manner in which it was intended, thus it was reasonably foreseeable that the Sorin 3T would be used in Mr. Garver's surgery.

64. At all relevant times, Mr. Garver 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. Garver.

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

66. The foreseeable risks of transmitting bacteria to patients undergoing invasive surgery, including Mr. Garver, far outweigh any utility of using the Sorin 3T. The foreseeable risks also far outweigh any cost of designing, manufacturing,

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and producing an alternative design of the Sorin 3T that is not defective.

67. Mr. Garver 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.

68. The use of the Sorin 3T during Mr. Garver's open-heart surgery on September 10, 2014, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent pain and suffering and disability.

69. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on September 10, 2014, specifically the defective design of the device, Mr. Garver suffered catastrophic injury, pain and suffering, and disability.

70. As a result of the foregoing, Mr. Garver has incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT II

Strict Liability – Manufacturing Defect (On Behalf of Hayes Garver)

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

72. 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. Garver's September 10, 2014 open-heart surgery.

73. 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

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cleaning procedures, thus rendering the Sorin 3T unsafe for use by Kaiser Permanente Medical Center, and unsafe for use in Mr. Garver's open-heart surgery on September 10, 2014.

74. 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. Garver's surgery, was designed, manufactured, and/or assembled.

75. The Sorin 3T used by Kaiser Permanente Medical Center in the surgery of Mr. Garver on September 10, 2014, was expected to reach, and did reach, Kaiser Permanente Medical Center and Mr. Garver, the intended consumer and ultimate consumer, without substantial change to the condition in which it was sold by Sorin.

76. 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. Garver and others who may have been exposed to the device at Kaiser Permanente Medical Center. 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.

77. Sorin intended for the Sorin 3T to be used in heart surgeries (among others) at Kaiser Permanente Medical Center, like the one Mr. Garver had on September 10, 2014. Sorin knew or should have known that the Sorin 3T would be used by patients like Mr. Garver at Kaiser Permanente Medical Center.

78. The Sorin 3T was used by Kaiser Permanente Medical Center for Mr. Garver's surgery in the manner in which it was intended, thus it was reasonably foreseeable that the Sorin 3T would be used in Mr. Garver's surgery.

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79. At all relevant times, Mr. Garver 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. Garver.

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

81. The foreseeable risks of transmitting bacteria to patients undergoing invasive surgery, including Mr. Garver, far outweigh any utility of using the Sorin 3T.

82. 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.

83. 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.

84. 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.

85. Mr. Garver 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.

86. The use of the Sorin 3T during Mr. Garver's open-heart surgery on September 10, 2014, was the cause-in-fact of his injuries, specifically, his

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contraction of M. chimaera, and his subsequent pain and suffering and disability.

87. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on September 10, 2014, specifically the defective manufacture the device, Mr. Garver suffered catastrophic injury, pain and suffering, and disability.

88. As a result of the foregoing, Mr. Garver has incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT III

Strict Liability – Failure to Warn (On Behalf of Hayes Garver)

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

90. 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. Garver's September 10, 2014 open-heart surgery.

91. 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 Kaiser Permanente Medical Center, and unsafe for use in Mr. Garver's open-heart surgery on September 10, 2014.

92. 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

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aerosolization and/or fluid leakage from the device, which can lead to serious infections and death.

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

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

95. 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.

96. 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.

97. Mr. Garver 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.

98. If Mr. Garver had been made aware of the significant risks of NTM and M. chimaera infection associated with the use of the Sorin 3T, Mr. Garver would not have consented to use of the Sorin 3T during his September 10, 2014 surgery.

99. The use of the Sorin 3T during Mr. Garver's open-heart surgery on September 10, 2014, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent injury, pain and suffering, and

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disability.

100. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on September 10, 2014, and as a result of Sorin's failure to warn, Mr. Garver suffered catastrophic injury, pain and suffering, and disability.

101. As a direct and proximate cause of Sorin's failure to warn Kaiser Permanente Medical Center, Plaintiffs, the FDA, and the public about the significant risk of NTM and M. chimaera infection from use of the Sorin 3T in surgery, Mr. Garver suffered catastrophic injury, pain and suffering, and disability.

102. As a result of the foregoing, Mr. Garver has incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT IV

Negligence
(On Behalf of Hayes Garver)

103. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

104. Sorin owed a duty of reasonable care to Plaintiffs, 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.

105. 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

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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.

106. Sorin further breached this duty by allowing the Sorin 3T devices, including the device used in Mr. Garver'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.

107. Sorin owed Plaintiffs a duty of reasonable care to discover these defects and to timely warn the FDA, Kaiser Permanente Medical Center, and the Garvers about these defects.

108. Sorin failed to timely warn the FDA, Kaiser Permanente Medical Center, and the Garvers about these defects, thereby breaching its duty of care.

109. Sorin owed a duty to Plaintiffs, 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.

110. 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.

111. Sorin owed a duty to Plaintiffs, 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.

112. 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.

113. As a direct and proximate cause of Sorin's breach of duty, Mr. Garver

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became infected with M. chimaera as a result of bacteria from the Sorin 3T reaching the surgical site—at his open chest—on September 10, 2014.

114. As a direct and proximate cause of Sorin's breach of duty, Mr. Garver became seriously ill with an M. chimaera infection resulting in catastrophic injury, pain and suffering, and disability.

115. As a result of the foregoing, Mr. Garver has incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT V

Loss of Consortium
(On Behalf of Maria Garver)

116. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

117. Plaintiff Maria Garver is entitled to the care, comfort, companionship, services, and consortium of her husband, Hayes Garver.

118. As a direct and proximate result of the negligence, carelessness, and willful and wanton conduct by Sorin as outlined herein, Mr. Garver contracted an M. chimaera infection, fell severely ill, and will continue to suffer and be disabled as a result of his infection.

119. As a result of the injuries to Hayes Garver, Maria Garver was, and will continue to be, deprived of care, comfort, companionship, services, and consortium of her Husband.

120. As a result of the foregoing, Maria Garver incurred damages related to the loss of Hayes Garver's services, society, and companionship that she would have received in the usual course of married life, and other damages reasonable under the circumstances for which California law provides a remedy.

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ACTUAL DAMAGES

121. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

122. As a direct and proximate result of the acts, omissions, and violations of Defendants as alleged herein, Plaintiffs have suffered injuries and damages. Plaintiffs seek compensation from Defendants for injuries including, but not limited to:

a. Pain and suffering, including mental suffering and emotional distress;

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

c. Medical bills and expenses, including future expense;

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

PUNITIVE DAMAGES

123. Plaintiffs incorporate by reference each and every allegation in the Complaints, as if fully set forth herein.

124. Sorin's conduct as described above demonstrates a willful and wanton disregard for the safety of Mr. Garver and other patients exposed to the Sorin 3T.

125. Sorin's negligence, carelessness, recklessness, and maliciousness in this case warrants an award of punitive damages in favor of Plaintiffs under California Civil Code § 3294.

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PRAYER FOR RELIEF

126. Plaintiffs incorporate by reference each and every allegation in this Complaint, as if fully set forth herein.

127. Plaintiffs request 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.

Dated: October 25, 2017

WALKUP, MELODIA, KELLY & SCHOENBERGER

By: /s/ Khaldoun A. Baghdadi
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DEMAND FOR JURY TRIAL

Plaintiffs hereby request a jury trial on all issues raised in this Complaint.

Dated: October 25, 2017

WALKUP, MELODIA, KELLY & SCHOENBERGER

By: /s/ Khaldoun A. Baghdadi
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