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Case No. N17C-07-319 DCS

IN THE SUPERIOR COURT OF THE STATE OF DELWARE

MICHELE WHITE, Individually and as Personal Representative of THE ESTATE OF DENNIS L. GERACE, SR. A.K.A. DENNIS L. GERACE, FRANCES GERACE and DENNIS GERACE, JR.,	C.A. No.
Plaintiffs, v.	JURY TRIAL DEMANDED
SORIN GROUP DEUTSCHLAND, GMBH, SORIN GROUP USA, INC., and CHRISTIANA CARE HEALTH SERVICES, INC., d/b/a CHRISTIANA HOSPITAL and d/b/a CHRISTIANA CARE HEALTH SYSTEMS,	
Defendants.	

COMPLAINT

1. Plaintiff Michele White, individually and as personal representative of the Estate of Dennis L. Gerace Sr. a.k.a Dennis L. Gerace, deceased, is a citizen of the State of Pennsylvania, residing therein at 296 Goldsmith Hollow Road, Shinglehouse, PA 16748. Ms. White is the daughter of the deceased.

2. Plaintiff Dennis Gerace Jr. is a citizen of the State of Delaware residing therein at 2209 Milltown Road, Wilmington, Delaware, 19804. Mr. Gerace is the son of the deceased, Dennis Gerace Sr.

3. Plaintiff Frances Gerace is a citizen of the State of Delaware residing therein at 103 Matthew Avenue, Wilmington, Delaware, 19808. Ms. Gerace was the wife of the deceased, Dennis Gerace Sr.

4. Defendant, Sorin Group Deutschland GmbH ("Sorin Deutschland") is a foreign for-profit corporation headquartered in Munich, Germany and is a wholly owned subsidiary of LivaNova, PLC. Upon information and belief, Sorin Deutschland designed, tested, assembled, manufactured, marketed, distributed and/or sold to Christiana Care Health Services, Inc. the Sorin heating and cooling device ("HCD") that was used during Dennis Gerace's heart surgery.

5. Defendant, Sorin Group USA, Inc. ("Sorin USA") is a Delaware Corporation and wholly owned subsidiary of LivaNova, with a principal place of business at 14401 West 65th Way, Arvada, Colorado 80004. Upon information and belief, Sorin USA designed, tested, assembled, manufactured, marketed, distributed and/or sold the Sorin HCD used in the surgery of Dennis Gerace.

6. Personal jurisdiction exists over Defendant, Sorin Deutschland, due to the fact that it regularly conducted business in Delaware during all relevant times, including the marketing sale, and/or distribution of the Sorin HCD. Sorin Deutschland maintained and continues to maintain general and specific contacts in Delaware.

7. Personal jurisdiction exists over Defendant, Sorin USA, due to the fact that it is a Delaware corporation that regularly conducted business in Delaware during all relevant times, including the marketing sale, and/or distribution of the Sorin HCD. Sorin USA maintained and continues to maintain general and specific contacts in Delaware. Upon information and belief, Sorin USA sold the Sorin HCD directly to Defendants, Christiana Care Health Systems, Inc. d/b/a Christiana Hospital and/or Christiana Care Health Services, Inc. d/b/a Christiana Hospital. Sorin USA expressly consented to jurisdiction in Delaware by registering as a domestic corporation doing business in the Delaware.

8. Hereinafter, Defendants, Sorin Deutschland and Sorin USA, shall be collectively referred to as the "Sorin Defendants."

9. At all relevant times, the Sorin Defendants were acting individually, and/or by and through their duly authorized actual, apparent, and/or ostensible agents, servants, and/or employees, who were acting within the scope of their employment, service, and/or agency with the Sorin Defendants. The identities of these authorized, actual, and/or ostensible agents, servants, and/or employees, are known to the Sorin Defendants and are currently unknown to Plaintiffs, and include, but are not limited to, all those responsible for the design, development, testing, assembling, manufacturing, marketing, sale, and/or distribution of the Sorin HCD and those responsible for the collection, dissemination, and communication of

information relating to the safety of the Sorin HCD. Sorin Defendants are therefore liable to Plaintiff for the negligent and otherwise wrongful acts and omissions of the aforementioned agents.

10. During all relevant times, the Sorin Defendants designed, manufactured, assembled, marketed, sold, and/or distributed the Sorin HCD that is the subject of this lawsuit and that was used during Dennis Gerace's heart surgery at Christiana Hospital in Newark, Delaware on or about October 16, 2015.

11. At all relevant times, Sorin Defendants knew, or should have known, that the design and/or manufacturing defects in its Sorin HCD allowed bacterial colonization to which patients like Dennis Gerace would be, and were in fact, exposed to during heart surgery, thus posing a significant risk of bodily injury.

12. Defendant Christiana Care Health Services, Inc. d/b/a Christiana Care Health Systems and d/b/a Christiana Hospital is and was, at all times relevant hereto, a corporation organized and existing under the laws of the state of Delaware. Defendant Christiana Care Health Services, Inc. owns, operates, controls and/or maintains a health system and network of hospitals, medical practices, clinics and physicians, including Christiana Hospital, and employs and/or oversees physicians, nurses, and staff who practice medicine therein.

13. Hereinafter, Defendants, Christiana Care Health Services, Inc. d/b/a Christiana Hospital and Christiana Care Health Systems shall be collectively referred to as the "Christiana Hospital Defendants."

14. Venue is proper in New Castle County because the medical care that is the subject of these claims was provided by the Christiana Hospital Defendants in New Castle County, and because Sorin Defendants regularly conduct business in New Castle County.

15. At all relevant times, the Christiana Hospital Defendants were acting individually, and/or by and through their duly authorized actual, apparent, and/or ostensible agents, servants, and/or employees, who were acting within the course and scope of their employment, service, and/or agency with the Christiana Hospital Defendants. The identities of these authorized, actual, and/or ostensible agents, servants, and/or employees, are known to Christiana Hospital Defendants, and currently unknown to Plaintiff, and include, but are not limited to, any and all administrators, perfusionists, physicians, residents, fellows, interns, physician assistants, nurse practitioners, nurses, medical students, operating room technicians, medical staff personnel, and/or other agents who were responsible for: (1) the maintenance, inspection, cleaning, and/or disinfection of the Sorin HCD used during the heart surgery of Dennis Gerace on October 16, 2015; (2) the adoption, enforcement, and/or execution of policies and procedures for the maintenance,

inspection, cleaning, and/or disinfection of the Sorin HCD on or before October 16, 2015; and (3) the receipt, dissemination, and/or communication of information concerning the Sorin HCD and the risks such devices posed to patients. The Christiana Hospital Defendants are therefore liable to Plaintiff for the negligent and otherwise wrongful acts and omissions of its agents.

16. At all relevant times, Christiana Hospital Defendants, and/or their agents, were engaged in the practice of medicine and were obligated to adhere to the applicable standard of care.

17. At all relevant times, Dennis Gerace was under the medical care of Christiana Hospital Defendants directly and through its agents, ostensible agents, employees, and medical staff.

FACTS

18. At all material times, the Sorin Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, delivering, and/or introducing their Sorin HCD into the stream of commerce, including Newark, Delaware.

19. At all material times, the Sorin HCD was used during open heart surgery at Christiana Hospital, and specifically during the coronary artery revascularization, aortic valve replacement, endoscopic vein harvest (left) and

intraoperative transesophageal echocardiography procedures performed on Dennis Gerace on October 16, 2015.

20. The Sorin HCD is a free-standing unit on wheels, separate from the heart-lung machine, that consists of cold and hot reservoirs of water that are circulated to and from the heart lung machine via long plastic tubes or hoses that are connected to the heat exchanger of the heart and lung machine. At no time does the HCD or the water circulating to and from the HCD come in direct contact with the patient or the patient's blood.

21. On or about April 11, 2011 through April 13, 2011, the Federal Drug Administration ("FDA") conducted an inspection of the Sorin Group Deutschland GmbH manufacturing facility where, upon information and belief, the Sorin HCD in question was manufactured, and filed an Establishment Inspection Report that found deviations to the quality system regulations that included the following observation that the Sorin Defendants had not adequately implemented the procedure for design controls in relation to the Heater-Cooler 3T design file. Specifically, the FDA noted that:

a. The design inputs do not include the requirement for cleaning of the water tank.

b. The design output of the device includes a cleaning procedure for the US; however, the cleaning agents to be used are not available in the US.

c. The design verification was not performed in relation to the US cleaning instructions for uses.

d. Risk analysis does not include possible contamination from water held in the tank in relation to the patient, operating room, or operation.

e. Design Changes were not adequately verified.

22. The Sorin Defendants knew, or should have known, based on their own information, investigation, and/or testing, and based on an outbreak of cases in Europe reported in medical literature as early as 2011, of the association of non-tuberculous mycobacterium ("NTM") infections with the use of their Sorin HCD when used in heart surgery.

23. Upon information and belief, in January of 2014, the Sorin Defendants were specifically notified that testing had confirmed that Sorin HCD's were contaminated with mycobacterium chimaera.

24. Upon information and belief, in January 2014 the Sorin Defendants were also presented with a medical study demonstrating that Sorin HCD's were releasing water vapor during surgery that was contaminated with mycobacterium and that the airborne bacterium was being transmitted to and infecting patients.

25. Upon information and belief, the Sorin Defendants took no action to warn hospitals and/or purchasers of Sorin HCD units that the units were contaminated and causing infections until July 14, 2014.

26. Upon information and belief, on or about July 14, 2014, the Sorin Defendants sent out an "Important Information" letter to hospitals that purchased the Sorin HCD. The letter was addressed and otherwise made available to users of the Sorin HCD, including the Christiana Hospital Defendants, alerting them of the risk of infection from NTM as a result of using the Sorin HCD.

27. In August 2014, one year and two months before Dennis Gerace's heart surgery, Sorin discovered that the water supply at its Sorin Deutschland manufacturing facility was contaminated with NTM. Sorin did not tell hospitals or health care providers about this discovery and indeed, this information was not made public until the FDA issued a "Safety Communication" on June 1, 2016.

28. Subsequent genome sequencing performed by the CDC confirmed that the specific mycobacterium species found in Sorin Deutschland's manufacturing facility was a genetic match for the bacterium cultured from infected patients in Delaware.

29. On or about August 24, 2015 through August 27, 2015, the FDA performed an inspection of the Sorin Deutschland's manufacturing facility as a follow-up to its April 2011 inspection and noted several objectionable observations related to the lack of validation for an implemented disinfection process related to the Sorin Heater Cooler System 3T, the same or similar problem identified at the 2011 inspection.

30. The Sorin Defendants knew, or should have known, based on their own information, investigation and/or testing, based on reports received in January 2014, and based on an outbreak of NTM infections in Europe, that there was a risk of NTM infections when its Sorin HCD was used during heart surgery.

31. Despite knowledge of the design defect and NTM contamination during the manufacture of its Sorin HCD, and despite knowledge of the catastrophic injuries, conditions, complications, infections, and/or deaths caused by the use of its Sorin HCD during heart surgery, the Sorin Defendants continued to manufacture, market, advertise, sell, and/or deliver its Sorin HCD to hospitals throughout the United States, including Christiana Hospital in Delaware.

32. Sorin Defendants knew, or should have known, prior to Dennis Gerace's heart surgery on October 16, 2015, that using the Sorin HCD posed serious risks to the health and lives of patients undergoing surgery, particularly heart surgery. Yet it failed to take action or warn against these dangers.

33. On October 16, 2015, Dennis Gerace underwent heart surgery to repair a bicuspid aortic valve at Christiana Hospital.

34. Upon information and belief, a Sorin HCD was used during Dennis Gerace's heart surgery.

35. Initially, Mr. Gerace's surgery appeared to be a complete success and his recuperation seemed to go well.

36. In May of 2016, Mr. Gerace began experiencing intermitted cold symptoms, including fevers and chills.

37. On June 29, 2016, Mr. Gerace reported to Christiana Hospital with complaints of fever associated with chills and discomfort. These symptoms were noted to have begun 7 weeks prior.

38. Mr. Gerace was admitted to Christiana Hospital for suspicion of endocarditis and kidney failure.

39. Mr. Gerace had 2 transesophageal echocardiograms, which showed vegetation on the aortic valve and pacemaker lead, and an aortic valve abscess.

40. While at Christiana Hospital Mr. Gerace was seen by Dr. David Cohen and Dr. David Bergamo, infectious disease doctors, where upon a bone marrow biopsy was ordered and the biopsy was cultured.

41. Mr. Gerace was discharged on August 5, 2016 with, among other things, a diagnosis of a fever of unknown origins and was instructed to follow up with, among other doctors, his primary care physician and Dr. Cohen "as soon as possible."

42. Mr. Gerace continued to follow-up with his infectious disease doctors.

43. On August 8, 2016, the results of Mr. Gerace's bone marrow biopsy came back positive for mycobacterium and was identified as mycobacterium chimaera.

44. On August 17, 2016, Dr. David Cohen diagnosed Mr. Gerace with mycobacterium avium-intracellulare.

45. Mr. Gerace was immediately placed on a cocktail of powerful antibiotics known to have high toxicity and significant side-effects.

46. Despite this aggressive therapy of medication, Mr. Gerace's health continued to decline and he started developing more symptoms, including but not limited to difficulty swallowing, weight loss and extreme fatigue.

47. On November 8, 2016, Mr. Gerace returned to the emergency department at Christiana Hospital with general malaise and weakness

48. Mr. Gerace and was admitted to the ICU, but his health continued to decline with worsening respiratory failure and renal failure with oliguria and metabolic acidosis.

49. As Mr. Gerace was not responding to treatment and his health was failing, Mr. Gerace was sent to comfort care.

50. On November 16, 2016, Mr. Gerace passed away from mycobacterium avium complex (mycobacterium chimera) sepsis with endocarditis.

51. Mr. Gerace's NTM infection has resulted in significant injury, including but not limited to a painful death.

52. On June 15, 2015, Sorin Defendants issued a safety notice to hospitals that purchased a Sorin HCD again advising them of the potential for infection and instructions for cleaning and disinfecting the Sorin HCD.

53. Upon information and belief, the original Sorin HCD cleaning and disinfecting process involved six steps. The updated process, posted on Sorin's website, included fifty-six steps to "enhance" the cleaning and disinfecting process.

54. Upon information and belief, the "enhanced" cleaning process developed by Sorin Defendants was never validated and subsequent studies showed it was ineffective at removing mycobacterium biofilm.

55. On July 15, 2015, the FDA issued a Class 2 Recall of the Sorin 3T Heater-Cooler due to the "[p]otential colonization of . . . Mycobacteria, in Soren Heater-Cooler devices."

56. On or about September 18, 2015, the FDA received a MAUDE Adverse Event Report from a health care provider that found an unusual cluster of NTM in patients after cardiothoracic surgery. Additionally, the health care provider expressed concern about inconsistent cleaning and disinfecting instructions for the Sorin HCD.

57. On October 15, 2015, the FDA issued a Safety Communication explaining that the Agency received thirty-two Medical Device Reports of infections associated with heater-cooler device contamination.

58. On October 21, 2015, The Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance Communication to raise awareness about the relationship between NTM infections and heater-coolers.

59. On December 11, 2015, the Pennsylvania Department of Health ("PADOH") issued an advisory warning that the Sorin HCD had the potential for colonization and aerosolization of bacteria.

60. The Department of Health noted the inconsistencies in cleaning and disinfecting instructions from heater-cooler manufacturers, including the Sorin Defendants.

61. Additionally, the PADOH stated it "**observed engineering differences** that might predispose certain units to increased risk of biofilm and aerosolization of bacteria."

62. A public health investigation of heater-cooler devices in Switzerland found air culture samples that were positive for NTM.

63. On December 29, 2015, the FDA issued a warning letter to LivaNova's CEO identifying several "serious" violations of the Federal Food, Drug, and Cosmetic Act ("the Act") regarding the Sorin HCD, including the following:

a. The devices were "adulterated" within the meaning of section 501(h) of the Act in that "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 found at Title 21, Code of Federal Regulations (CFR), Part 280;"

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

d. Failure to adequately develop, implement, and maintain written Medical Device Reporting ("MDR") procedures, as required by 21 CFR 803.17l;

e. Failure to submit to the FDA an approved application for premarket approval (PMA) in effect pursuant to section 5159(a) of the Act or an approved application for an investigational device exemption under section 520(g) of the Act;

f. Failure to notify the FDA of the intent to introduce the device into commercial distribution as required by section 510(k) of the Act, resulting in misbranding of the Heater Cooler System 3T as defined by section 520(o) of the Act;

g. Failure to submit to the FDA a new 510(k), to assure that the appropriate testing and validation of the cleaning/disinfecting protocols had taken place, following significant labeling changes that can affect the safety or effectiveness of the device, specifically, distributing the Sorin HCD with Modified Instructions for Use (Versions 013 and 014) with respect to the operating, maintaining, cleaning, and disinfecting of the device, including adding more instruction details, changes to the cleaning/disinfecting process (e.g. chemicals used and amounts used), and expansion of the process to include the entire circuit instead of only the tanks;

h. Failure or refusal to furnish material or information, with respect to the device in question, to the FDA as required by or under section 519 of the Act and 21 CFR Part 806—Medical Devices; Reports of Corrections and Removals, resulting in **"misbranding"** of the Sorin 3T Heater Cooler System device as defined in section 502(t)(2) of the Act;

i. Failure to submit to the FDA a written report, as required by 21 CFR 806.10, of any correction or removal of advice initiated to remedy a violation of the Act caused by the device which may present a risk to health.

64. On June 1, 2016, the FDA issued a "Safety Communication" warning patients who had undergone surgery in which a Sorin HCD was used that NTM contamination was found on the production line and in the water supply at the Sorin Deutschland's manufacturing facility.

65. At all relevant times, the Sorin Defendants marketed its Sorin HCD to the medical community, including Christiana and its servants, agents and employees who were involved in the purchase and maintenance of the of the Sorin HCD used during Dennis Gerace's heart surgery in October 2015, as a safe, effective, reliable medical device to be used during heart surgery, such as the one performed on Mr. Gerace.

66. At all relevant times, the Sorin Defendants marketed and sold their Sorin HCD to the medical community, including the Christiana Hospital Defendants, hospitals, administrators, cardiothoracic surgeons, perfusionists, and/or other

consumers when it knew, or should have known, of a serious design defect that exposed heart surgery patients to NTM, a potentially life threatening infection.

67. At all relevant times, the Sorin Defendants failed to adequately test or research the risks and benefits of its Sorin HCD.

68. At all relevant times, feasible and alternative designs and products to the Sorin HCD have existed. Indeed, upon information and belief, the Sorin Defendants initiated design and manufacturing changes to the Sorin HCD beginning in 2015.

69. At all relevant times, the Sorin HCD was used during heart surgery procedures, a manner foreseeable by Sorin Defendants.

70. At all relevant times, the Sorin Defendants provided incomplete, ineffective, inadequate, and misleading instructions and training to the users of its Sorin HCD, including the Christiana Hospital defendants and their agents and employees who were involved in the purchase, maintenance and use of the of the Sorin HCD used during Dennis Gerace's heart surgery in October 2015.

71. At all relevant times, the Sorin HCD used in the heart surgery of Dennis Gerace was in the same or substantially similar condition as when it left the possession of the Sorin Defendants.

72. Dennis Gerace contracted a latent NTM infection from a contaminated Sorin HCD during his heart surgery at Christiana Hospital in October 2015.

73. The Christiana Hospital Defendants and their agents who were involved in the purchase, maintenance and use of the Sorin HCD used during Dennis Gerace's heart surgery in October 2015, undertook and/or assumed a duty to render reasonable, proper, adequate, and appropriate medical care to Dennis Gerace, and to avoid harm to him. The Christiana Hospital Defendants breached that duty.

74. Dennis Gerace relied on the knowledge, treatment, skill, and expertise, of the Christiana Hospital Defendants and their agents who were involved in the purchase, maintenance and use of the Sorin HCD used during Dennis Gerace's heart surgery in October 2015.

75. On October 14, 2016, the Delaware Division of Public Health issue a Delaware Health Alert Network No. 371, which advised hospitals to notify patients who underwent heart surgery that the Sorin HCD was potentially contaminated, putting patients at risk for a life-threatening infection.

76. The Christiana Hospital Defendants knew, or should have known, prior to October 16, 2015 that patients who underwent heart surgery at Christiana Hospital, including Dennis Gerace, were exposed to NTM. Yet, the Christiana Hospital Defendants continued to use the Sorin HCD on patients, including Dennis Gerace, and failed to formally notify patients until October 25, 2016.

77. The conduct of all Defendants increased the risk of harm for, was a substantial factor in causing, and/or was a factual and/or proximate cause of, the injuries and damages suffered by Dennis Gerace.

78. As a direct and proximate result of the wanton, reckless, outrageous, tortious, and/or negligent conduct of all Defendants, jointly and severally, Dennis Gerace experienced multiple injuries and damages, including, but not limited to: chronic mycobacterium infection requiring long-term use of toxic antibiotics, mycobacterium infection in his bone marrow, and death. These injuries have caused substantial pain, suffering, and loss of life's pleasures.

79. Plaintiffs claim all damages recoverable under the law, including compensatory and punitive damages (punitive damages against the Sorin Defendants only).

NEGLIGENCE

Plaintiff v. Sorin Defendants

80. The preceding paragraphs are incorporated by reference as though fully set forth herein.

81. The Sorin Defendants individually and by and through their actual, authorized, and/or apparent agents, servants, and/or employees, were negligent and reckless by reason of its designing, manufacturing, assembling, and distributing the Sorin HCD used by the Christiana Hospital Defendants during the heart surgery

performed on Dennis Gerace on October 16, 2015, in one or more of the following particular respects:

a. Failure to manufacture, design, and/or produce a Sorin HCD that was not "adulterated" within the meaning of section 501(h) of the Act in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 280;

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 validate a process, with a high degree of assurance and approved according to established procedures, whose results can be fully verified by subsequent inspection and test, as required by 21 CFA 820.75(a);

d. Failure to adequately develop, implement, and maintain written Medical Device Reporting ["MRD"] procedures as required by 21 CFR 803.17;

e. Failure to submit to the FDA an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g);

f. Failure to notify the FDA of the intent to introduce the device into commercial distribution as required by section 510(k) of the Act, 21 U.S.C. § 360(k), resulting in misbranding of the Heater Cooler System 3T as defined by section 520(o) of the Act, 21 U.S.C.§ 352(0);

g. Failure to submit to the FDA a new 510(k), to assure that the appropriate testing and validation of the cleaning/disinfecting

protocols had taken place, following significant labeling changes that can affect the safety or effectiveness of the device, specifically, distributing the Sorin HCD with modified Instructions for Use ["IFU"] (Versions 013 and 014) with respect to the operating, maintaining, cleaning, and disinfecting of the device, including adding more instruction details, changes to the cleaning/disinfecting process (e.g. chemicals used and amounts used), and expansion of the process to include the entire circuit instead of only the tanks;

h. Failure or refusal to furnish material or information, with respect to the device in question, to the FDA as required by or under section 519 of the Act, 21 U.S.C. § 3601, and 21 CFR Part 806—Medical Devices; Reports of Corrections and Removals, resulting in "misbranding" of the Sorin HCD device as defined in section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2);

i. Failure to submit to the FDA a written report, as required by 21 CFR 806.10, of any correction or removal of advice initiated to remedy a violation of the Act caused by the device which may present a risk to health;

j. Failure to adequately, appropriately, properly, reasonably, and timely address the problems with their Sorin HCD after learning of an unusual cluster of non-tuberculous mycobacterium seen in patients post cardiothoracic surgery;

k. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning of recent reports from Europe indicating that aerosolization of this NTM bacteria being emitted from the Sorin heater cooler device;

l. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning of concerns on the maintenance of this machine;

m. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after learning of inconsistencies between the manufacturer

instructions and the user manual, field safety notice, FAQ, "quick start" guide, and instructional video;

n. Failure to adequately, appropriately, properly, reasonably, and timely consistently distribute the method of updating disinfection requirements for the Sorin HCD;

o. Failure to adequately, appropriately, properly, reasonably, and timely train their servants, employees and/or agents regarding the method of cleaning, maintaining, and/or disinfecting the Sorin HCD such that their sales representative's verbal info is consistent with the written recommendations;

p. Failure to adequately, appropriately, properly, reasonably, and timely train their servants, employees and/or agents regarding the method of cleaning, maintaining, and/or disinfecting the Sorin HCD such that company's representative sent to place a new machine in production would follow the manufacturer's established guidelines for disinfection;

q. Failure to adequately, appropriately, properly, reasonably, and timely develop and provide to the Christiana Hospital Defendants and their servants, employees and/or agents, including the treating healthcare providers of Dennis Gerace, disinfection procedure changes that will actually mitigate any potential biofilm growth;

r. Failure to adequately, appropriately, properly, reasonably, and timely develop and provide to the Christiana Hospital Defendants and their servants, employees and/or agents, including the treating healthcare providers of Dennis Gerace, documentation or studies that disinfection procedure changes actually mitigate any potential biofilm growth;

s. Failure to adequately, appropriately, properly, reasonably, and timely develop and provide to the Christiana Hospital Defendants and their servants, employees and/or agents, including the treating healthcare providers of Dennis Gerace, steps for meeting the new recommended disinfection protocols that are not confusing and complex;

t. Failure to adequately, appropriately, properly, reasonably, and timely design their Sorin HCD so as to make it less susceptible to cause life-threatening infections with NTM;

u. Failure to adequately, appropriately, properly, reasonably and, timely design their Sorin HCD so as to prevent life-threatening infections with NTM;

v. Failure to adequately, appropriately, properly, reasonably, and timely test the Sorin HCD to determine if the distributed instructions for cleaning and disinfecting actually prevented life threatening infections with NTM;

w. Failure to adequately, appropriately, properly, reasonably, and timely test the Sorin HCD to determine if the design increased the risk, compared to alternate designs, of life-threatening infections with NTM;

x. Failure to adequately, appropriately, properly, reasonably, and timely eliminate, rectify, and/or warn of known risks and dangers of life-threatening infections with NTM associated with their Sorin HCD;

y. Failure to adequately, appropriately, properly, reasonably, and timely recall, modify, retrofit, and/or re-design their defective Sorin HCD;

z. Failure to adequately, appropriately, properly, reasonably, and timely remove their defectively designed Sorin HCD from the stream of commerce;

aa. Failure to adequately, appropriately, properly, reasonably, and timely recommend users of their defective Sorin HCD to stop using their defective Sorin HCD product;

bb. Failure to adequately, appropriately, properly, reasonably, and timely design a HCD that did not create a no-flow and/or low-flow area or areas, and/or blind spots, that made the Sorin HCD more difficult and/or impossible to adequately clean, disinfect,

and/or maintain, thus increasing the risk of contamination with NTM and increasing the risk of infecting the patient who is in the operating room undergoing open heart surgery with an NTM infection;

cc. Failure to adequately, appropriately, properly, reasonably, and timely design a HCD that was easier to maintain, clean, and/or disinfect;

dd. Failure to adequately, appropriately, properly, reasonably, and timely monitor and test the production line in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

ee. Failure to adequately, appropriately, properly, reasonably, and timely monitor and test the water supply used in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

ff. Failure to formulate, adopt, and/or enforce the appropriate rules, guidelines, policies, and/or protocols, and to properly oversee and supervise all persons in their corporation who are responsible to ensure that these protocols are followed, to prevent the failure to adequately, appropriately, properly, reasonably, and timely monitor and test the production line in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

gg. Failure to formulate, adopt, and/or enforce the appropriate rules, guidelines, policies, and/or protocols, and to properly oversee and supervise all persons in their corporation who are responsible to ensure that these protocols are followed, to prevent the failure to adequately, appropriately, properly, reasonably, and timely monitor and test the water supply used in the plants that manufacture the Sorin HCD to ensure that it was not contaminated with NTM;

hh. Failure to adequately, appropriately, properly, reasonably, and timely address the design problems with their Sorin HCD after

learning, as early as 2011 of reports from Europe indicating that aerosolization of NTM bacteria being emitted from the Sorin heater cooler device was causing serious life-threatening infections in patients undergoing cardiac surgery, and in 2011 when the FDA inspected their manufacturing facility in Germany and issued an Establishment Inspection Report noted multiple quality violations;

ii. Failure to adequately, appropriately, properly, reasonably, and timely remove from the stream of commerce, and/or recommend that hospitals stop using, their defectively designed Sorin HCD when they knew, as early as August, 2014, that the water supply for the production line in their Sorin HCD manufacturing facility in Germany was contaminated with NTM;

jj. Failure to adequately, appropriately, properly, reasonably, and timely warn hospitals who had purchased their Sorin HCD of the design problems with their Sorin HCD after learning, as early as 2011 of reports from Europe indicating that aerosolization of NTM bacteria being emitted from the Sorin heater cooler device was causing serious life-threatening infections in patients undergoing cardiac surgery, and in 2011 when the FDA inspected their manufacturing facility in Germany and issued an Establishment Inspection Report noted multiple quality violations, and when they knew, as early as August, 2014, that the water supply for the production line in their Sorin HCD manufacturing facility in Germany was contaminated with NTM; and

kk. Failure to adequately, appropriately, properly, reasonably, and timely remove from the stream of commerce, and/or recommend that hospitals stop using, their defectively designed Sorin HCD when they knew, as early as August, 2014, that the water supply for the production line in their Sorin HCD manufacturing facility in Germany was contaminated with NTM.

ll. Failure to otherwise act with ordinary care; that is, the absence of the kind of care a reasonably prudent and careful person would exercise in similar circumstances.

82. The Sorin Defendants undertook and/or assumed a duty of care to Dennis Gerace and to avoid harm to him, which duty was breached by defendants.

83. Dennis Gerace relied on the duty of care owed by the Sorin Defendants.

84. The Sorin Defendants had a continuing post-sale duty to timely warn of problems with their Sorin HCD that posed a significant risk to the patients at the time those problems are discovered, whether that be in 2011 when the Sorin Defendants knew, or should have known, of a design defect based on reports from Europe indicating that aerosolization of NTM bacteria being emitted from the Sorin heater cooler device that was causing serious life-threatening infections in patients undergoing cardiac surgery, in 2011 when the FDA inspected their manufacturing facility in Germany and issued an Establishment Inspection Report noted multiple quality violations, in January 2014 when the problem of aerosolizing NTM was confirmed, or in August, 2014, when testing confirmed that their water supply for the production line in their Sorin HCD manufacturing facility in Germany was contaminated with NTM.

85. The Sorin Defendants breached its duty of care to Dennis Gerace and his healthcare providers, including the Christiana Hospital Defendants, through its wanton, outrageous, reckless and negligent designing, manufacturing, labeling, warnings, instructions, sale, and/or distribution of its Sorin HCD that was used in the heart surgery of Dennis Gerace.

86. Despite the fact that the Sorin Defendants knew, or should have known, as early as 2011 during the FDA inspection that the defective design of the Sorin HCD prevented it from being reliably and consistently cleaned, disinfected, and/or maintained, thus rendering it unsafe for its intended use, and despite the fact that they knew or should have known as early as August of 2014 that their production line water supply and equipment at the Sorin Deutschland facility was contaminated with NTM, the Sorin Defendants continued with reckless indifference to public and consumer safety to promote, manufacture, assemble, sell, and distribute their Sorin HCD.

87. For a significant period of time before the open heart surgery of Dennis Gerace, in October 2015, the Sorin Defendants knew, or should have known, that their Sorin HCD design was defective and that their production line water supply was contaminated with NTM, and, as a result, their Sorin HCD had a significant risk of causing life-threatening infections with NTM in patients in whom the Sorin HCD was used during open heart surgery.

88. The Sorin Defendants, while actually and subjectively aware of the significant increased risk involved, nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others, and/or provided material representations that were false and known to be false and/or made as positive assertions of safety, all with reckless disregard to the truth, with the intent that these

false representations would result in consumers, like the Christiana Hospital Defendants, and ultimate consumers, like Dennis Gerace, to continue to purchase and/or use their defective Sorin HCD.

89. Despite the possession of the knowledge and information described herein, the Sorin Defendants failed to modify, amend, and/or alter their advertising, promotional literature, labeling, warning, and/or instructions to adequately disclose to treating physicians and health care providers of Dennis Gerace, including the Christiana Hospital Defendants and their agents, and the ultimate consumer, Dennis Gerace, the defective design of its Sorin HCD that significantly increased the risk of a life-threatening infection with NTM.

90. The failure of the Sorin Defendants to re-design and/or re-label and/or amend its advertising, promotional literature, instructions, and/or warnings, was wanton and willful conduct made in reckless regard to the health and well-being of consumers, such as the Christiana Hospital Defendants, as this conduct was intended to conceal the adverse information known by the Sorin Defendants from the consumer, treating physicians and healthcare providers of Dennis Gerace, including the Christiana Hospital Defendants and their agents.

91. The careless, wanton, willful, outrageous, reckless and negligence of the Sorin Defendants increased the risk of harm of, was a substantial factor in

causing, and/or was a factual cause and/or was a proximate cause of the injuries and damages suffered by Dennis Gerace, as set forth more fully above.

92. The Sorin Defendants' reckless indifference appreciably increased the risk of harm to Dennis Gerace.

93. The Sorin Defendants persistently distributed an inherently dangerous product, its Sorin HCD, with knowledge of its injury causing effect among the consuming public, like Dennis Gerace.

94. As a direct and proximate result of the wanton, outrageous, reckless, tortious, willful, and negligent conduct of the Sorin Defendants, as set forth herein, Dennis Gerace was catastrophically injured and sustained severe pain, suffering, disability, and impairment.

95. The conduct of the Sorin Defendants described herein, was aggravated by the willful, and/or wanton conduct made in reckless disregard to the health and well-being of consumers, including Dennis Gerace, for which the law allows, and entitling plaintiffs to an award of punitive damages.

BREACH OF IMPLIED WARRANTY

Plaintiff v. Sorin Defendants

96. The preceding paragraphs are incorporated by reference as though fully set forth herein.

97. At all relevant times, the Sorin Defendants manufactured, assembled, marketed, advertised, promoted, sold, distributed, and/or placed into interstate commerce their defective Sorin HCD, including the Sorin HCD used by the Christiana Hospital Defendants during the heart surgery of Dennis Gerace.

98. At all relevant times, the Sorin Defendants intended their Sorin HCD to be used during heart surgery and it was used for the heart surgery of Dennis Gerace.

99. At all material times hereto, the Sorin Defendants breached implied warranties with respect to their Sorin HCD, including implied warranties that their Sorin HCD was of merchantable quality, and that their Sorin HCD had been adequately and appropriately tested, and was fit for its intended use during heart surgery. As such the Sorin Defendants violated 6 *Del. C.* § 2-314 and/or §2-315.

100. The treating physicians and healthcare providers of Dennis Gerace including the Christiana Hospital Defendants and their servants, employees and/or agents, and the ultimate consumer Dennis Gerace, in reliance on these warranties, used the defective Sorin HCD during Dennis Gerace's heart surgery.

101. At the time of making such implied warranties, the Sorin Defendants knew, or should have known, that their Sorin HCD did not conform to these implied warranties because it was not safe due the defective design that increased the risk of

life-threatening NTM infections, thus making the Sorin HCD unreasonably dangerous for its intended use.

102. The breach of these implied warranties made by the Sorin Defendants to the treating physicians and healthcare providers of Dennis Gerace including the Christiana Hospital Defendants and their servants, employees and/or agents, and the ultimate consumer Dennis Gerace, was a substantial factor in, and/or a factual cause of, the injuries to Dennis Gerace.

103. As a direct and proximate result of the wanton, outrageous, reckless, tortious, willful, and negligent conduct of the Sorin Defendants, Dennis Gerace was catastrophically injured and sustained severe pain, suffering, disability, and impairment.

104. Plaintiff claims all damages recoverable under the law, including compensatory and punitive damages.

NEGLIGENCE

Plaintiff v. Christiana Hospital Defendants

105. The preceding paragraphs are incorporated by reference as though fully set forth herein.

106. The Christiana Hospital Defendants in breach of the applicable standard of care negligently used the Sorin HCD during Dennis Gerace's October

2015 heart surgery, despite knowing or having reason to know that it may have been contaminated with NTM.

107. The Christiana Hospital Defendants in breach of the applicable standard of care failed to take mitigating action to reduce the risk of infection, including using sterile water in the machine, removing biofilm, preventing the aerosolizing of mycobacterium and/or positioning the Sorin HCD away from the surgical field.

108. The Christiana Hospital Defendants in breach of the applicable standard of care failed to properly clean, maintain and disinfect the Sorin HCD.

109. The Christiana Hospital Defendants undertook and/or assumed a duty to render reasonable, proper, adequate, and appropriate medical care to Dennis Gerace and to avoid harm to him, which duty was breached by Defendants.

110. Dennis Gerace relied on the knowledge, treatment, and skill of the Christiana Hospital Defendants.

111. The carelessness and negligence of the Christiana Hospital Defendants increased the risk of harm to, and was a substantial factor in causing, and/or a factual cause of, and/or a proximate cause of the injuries and damages suffered by Dennis Gerace.

112. As a direct and proximate result of the negligent conduct of the Christiana Hospital Defendants, Dennis Gerace was catastrophically injured and sustained severe pain, suffering, disability, and impairment.

113. Plaintiff claims all damages recoverable under the law, including compensatory damages.

CORPORATE ADMINISTRATIVE (DIRECT) NEGLIGENCE

Plaintiff v. Christiana Hospital Defendants

114. The preceding paragraphs are incorporated by reference as though fully set forth herein.

115. In addition to the derivative and vicarious liability of the Christiana Hospital Defendants for the negligent acts and omissions of its employees, servants, and/or apparent, actual, authorized, and/or ostensible agents, who were involved in the medical care of Dennis Gerace during his heart surgery at Christiana Hospital on or about October 16, 2015, including the proper use, care, cleaning, disinfecting, and maintenance of the Sorin HCD used in the operating room, Christiana Hospital also owed direct and non-delegable duties to Mr. Gerace, including an administrative duty to:

a. use reasonable care and maintain safe and adequate facilities and equipment, including sterile equipment not contaminated by a dangerous bacterium;

b. select and retain only competent nurses, medical staff and physicians, including professional staff who adhere to and

implement appropriate policies to clean, maintain and disinfect medical devices;

c. oversee all persons who practice medicine within its walls as to patient care, including agents, servants and employees responsible for purchasing, maintaining, cleaning and sterilizing medical devices;

d. formulate, adopt, and enforce adequate rules and policies to ensure quality of care for the patients, including policies and procedures to ensure that all medical devices are properly cleaned, sterilized and safe for use; and

e. properly train employees, including training employees to clean, disinfect, sterilize and maintain medical equipment.

116. The Christiana Hospital Defendants undertook and/or assumed a duty to render reasonable, proper, adequate, and appropriate hospital administrative care to Dennis Gerace and to avoid harm to him, which duty was breached by Christiana Hospital Defendants.

117. Dennis Gerace relied on the knowledge, treatment, and skill of the Christiana Hospital Defendants.

118. The carelessness and departure from the applicable standard of care in hospital administration by the Christiana Hospital Defendants increased the risk of harm to, and was a substantial factor in causing, and/or a factual cause of, and/or a proximate cause of the injuries and damages suffered by Dennis Gerace.

119. As a direct and proximate result of the negligent conduct of the Christiana Hospital Defendants, Dennis Gerace was catastrophically injured and sustained severe pain, suffering, disability, and impairment.

120. Plaintiff claims all damages recoverable under the law, including compensatory damages.

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Plaintiff v. Christiana Hospital Defendants

121. The preceding paragraphs are incorporated by reference as though fully set forth herein.

122. The October 16, 2015 incident involving Dennis Gerace would not have ordinarily occurred and Dennis Gerace would not have been catastrophically injured if the Christiana Hospital Defendants, who had management and control over the Sorin 3T HCD, had used proper care.

123. The Sorin 3T HCD that caused the October 16, 2015 incident involving Dennis Gerace was under the management and control of the Christiana Hospital Defendants.

124. Dennis Gerace has no responsibility for the October 16, 2015 incident.

125. Invasive NTM infections do not occur in cardio-thoracic surgical patient's absence exposure from a contaminated heater-cooler machine. The NTM infection suffered by Dennis Gerace was so unique and rare that Dennis Gerace

could have only been infected by the mycobacterium chimaera from the Sorin 3T HCD.

126. As a direct and proximate result of the negligent conduct of the Christiana Hospital Defendants, Dennis Gerace was catastrophically injured and sustained severe pain, suffering, disability, impairment and death.

127. Plaintiff claims all damages recoverable under the law, including compensatory damages.

COUNT I
WRONGFUL DEATH

Plaintiff v. All Defendants

128. The preceding paragraphs are incorporated by reference as though fully set forth herein.

129. Plaintiff brings this action on behalf of all persons entitled by law to recover damages for the death of Dennis Gerace, pursuant to Delaware law, including but not limited to Delaware's Wrongful Death Act, 10 Del. C. § 3724.

130. Dennis Gerace is survived by, among others, his wife, Frances Gerace, his daughter, Michele White, and his son, Dennis Gerace, Jr. Frances Gerace, Michele Gerace, and Dennis Gerace, Jr. claim all damages permitted by 10 Del. C. §3724, including but not limited to their mental anguish due to his death.

131. Plaintiff claims damages for the pecuniary losses suffered by Mr. Gerace's survivors by reasons of his death as well as reimbursement for hospital,

nursing, medical, funeral expenses and the expenses of the administration of his Estate and all of the other proper losses under law.

132. The Defendants' carelessness, medical negligence, administrative negligence, gross negligence, misconduct and reckless disregard for Mr. Gerace's life and safety were a substantial factor in causing and increased the risk of harm that his injuries and death would occur.

133. Plaintiff claims all damages recoverable under the law, including compensatory and punitive damages.

COUNT II
WRONGFUL DEATH

Plaintiff v. All Defendants

134. The preceding paragraphs are incorporated by reference as though fully set forth herein.

135. Plaintiff brings this action on behalf of the Estate of Dennis L Gerace for all damages recoverable under Delaware law pursuant to Delaware's Survival Act, 10 Del. C. § 3701, including but not limited to pain and suffering which Mr. Gerace suffered before his death, loss of earnings and earning capacity suffered by Mr. Gerace from the date of his death until such time in the future as he probably would have lived and the total limitation and deprivation of Mr. Gerace's normal activities, pursuits and pleasures from the date of his death until such time in the future as he probably would have lived but for the conduct of Defendants.

136. The Defendants' carelessness, negligence, gross negligence, misconduct and reckless disregard for Mr. Gerace's life and safety were a substantial factor in causing and increased the risk of harm that his injuries and death would occur.

137. Plaintiffs claim all damages recoverable under the law, including compensatory and punitive damages (punitive damages against the Sorin Defendants only).

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, for such general, punitive as to the Sorin Defendants, and special damages, as the jury deems just and appropriate, plus costs, pre and post-judgment interest, and reasonable attorneys' fees.

ASHBY & GEDDES

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