UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

STEVEN FOSTER, individually and on behalf of all others similarly situated, Plaintiff, v. LIVANOVA PLC, SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC., Defendants.	)	Case No.: JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Steven Foster, individually and on behalf of all similarly situated persons, by and through his undersigned attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge.

NATURE OF THE ACTION

1. Plaintiff brings this action individually and on behalf of all persons similarly situated in the South Carolina who were unknowingly exposed to potentially fatal bacteria during open chest surgery.

2. Plaintiff and the Class Members were exposed to nontuberculous mycobacterium ("NTM") through a Sorin 3T Heater-Cooler System (the "Sorin 3T System") used to regulate their blood temperature during open chest surgeries at Greenville Health Hospital System ("Greenville Health") and Palmetto Health Richland Hospital ("Palmetto Health").

3. As further described below, Defendants LivaNova PLC, Sorin Group Deutschland GmbH, and Sorin Group USA, Inc. knew or should have known that design and/or manufacturing

defects in their Sorin 3T System cause bacterial colonization to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death. Additionally, Defendants knew or should have known of proper disinfectant and sterilization procedures to clean the Sorin 3T System to prevent the colonization and spreading of NTM bacteria.

4. Through this action, Plaintiff and the Class seek damages for their existing injuries and medical monitoring to screen for NTM infection, and pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., seek a declaration that the Sorin 3T System was and is defective and unsafe for its intended use.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 U.S.C. § 1332(a)(2). Plaintiff is a citizen and resident of the State of South Carolina. Defendant LivaNova PLC is a foreign corporation incorporated under the laws of England and Wales with a corporate headquarters in Milan, Italy. Defendant Sorin Group Deutschland GmbH is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA, Inc. is the U.S. distributor of the medical device at issue, with a principal place of business in Arvada, Colorado. The amount in controversy exceeds $75,000.

6. This Court additionally has subject matter over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). There are hundreds of putative class members who are or were citizens of South Carolina at the time of their exposure, and Defendants are each citizens of another state and/or a foreign country. The aggregate of the Class Members' claims is more than $5 million dollars, exclusive of interests and costs.

7. This Court has personal jurisdiction over this action pursuant to Fed. R. Civ. P. 4 and S.C. Code Ann. § 36-2-803. Defendants are non-domiciliaries of South Carolina, contract business

within South Carolina, and maintain general and specific contacts in South Carolina. Defendants have committed tortious acts within South Carolina causing injury to persons within South Carolina. Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in South Carolina. Defendants are in the business of researching, designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, the Sorin 3T System in South Carolina.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction, and Defendants conduct substantial business within this District.

THE PARTIES

9. Plaintiff is a resident and citizen of South Carolina residing in Columbia, SC. On March 13, 2014, Plaintiff underwent open heart surgery at Palmetto Health Richland Hospital ("Palmetto Health"). Because of the use of the Sorin 3T System during his surgery, Plaintiff was exposed to NTM.

10. Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation incorporated under the laws of England and Wales with a headquarters in Milan, Italy. LivaNova is a global medical device company specializing in, among other products, devices used in the treatment of cardiovascular diseases. LivaNova, pursuant to a merger agreement between Sorin Group S.p.A.[1] and non-party, Cybertronics, Inc., advised purchasers in the United States that it is the responsible party for Sorin 3T System. Further, LivaNova was the recipient of various communications from the FDA regarding safety concerns about the Sorin 3T System.

[1] Upon information and belief, Sorin Group S.p.A. was the original holding company of Defendants Sorin Group Deutschland GmbH and Sorin Group USA, Inc.

11. Defendant Sorin Group Deutschland GmbH ("Sorin") is a foreign for-profit corporation headquartered in Munich, Germany. Sorin designed, manufactured, and marketed the Sorin 3T System used in Plaintiff's and Class Members' surgeries. In October 2015, Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company.

12. Defendant Sorin Group USA, Inc. ("Sorin USA") is a U.S. designer, manufacturer, marketer, and distributor of the Sorin 3T System, with a principal place of business in Arvada, Colorado. As set forth in LivaNova's Form 10-Q filed with the Security and Exchange Commission, Defendants Sorin and Sorin USA are wholly owned subsidiaries of LivaNova. Each Defendant markets and sells products under the LivaNova name.

GENERAL FACTUAL ALLEGATIONS

A. The Sorin 3T System

13. Defendants market and sell thermal regulator devices to be used on patients in the operating room, including the Sorin 3T System.

14. Prior to May 5, 2014, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System.

15. The Sorin 3T System used at Greenville Health and Palmetto Health during the relevant time period was designed, manufactured, marketed, and/or sold by Defendants LivaNova, Sorin, and Sorin USA to Greenville Health and Palmetto Health in South Carolina.

16. The Sorin 3T System is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or

"510K process").[2]

17. Before commercial distribution in the United States of the Sorin 3T System, the Defendants submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary of Health and Human Services for FDA approval. The FDA determined that the Sorin 3T System was substantially equivalent to legally marketed predicate devices that do not require approval of a premarket approval ("PMA") application. This determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601.[3] Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safety of the medical device. The PMA process is required for Class III medical devices while Class I and Class II predicate medical devices can be approved through the less rigorous 510K process.

18. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with all of the Act's requirements, including but not limited to: "Registration and Listing (21 C.F.R. part 807); Labeling (21 C.F.R. part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21 C.F.R. part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21 C.F.R. 1000-1050."

[2] A 510K premarket notification is a premarket submission made to the FDA to establish that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (PMA). 21 C.F.R. 807.92(a)(3).
[3] The FDA Determination Letter of Approval is attached as Exhibit A.

B. Two South Carolina Hospitals Announce Patient Exposure to Deadly Bacteria

19. On or about June 20, 2014, Greenville Health publically announced that approximately 14 patients had tested positive for a rare nontuberculosis mycobacterium infection, known as Mycobacterium abscessus ("*M. abscessus*"). The majority of those patients were exposed to the bacterium during open chest surgeries. At that time, Greenville Health indicated that there had been three (3) deaths resulting from the same infection. On or about June 26, 2014, Greenville Health released a second statement indicating that there were 15 confirmed cases of patients with the infection. On July 21, 2014, Greenville Health confirmed that the patient death toll had increased to four (4).

20. In the July 21, 2014 announcement, Greenville Health stated that it sent out letters to "…approximately 180 patients on whom specific cardiopulmonary surgical equipment had been used" since those patients were at risk after potentially being exposed to the *M. abscessus* bacterium.[4]

21. On or about December 16, 2016, Palmetto Health announced that hundreds of its patients were exposed to rare and potentially fatal bacteria during open chest surgeries.

22. According to Palmetto Health, those at risk include patients who underwent open chest surgery at its facility during the last four years.

23. Palmetto Health sent letters to individual patients that informed them of the exposure and advised them to follow up with their physicians.[5]

C. The Fatal Bacteria

24. The bacteria at issue, known as nontuberculous mycobacterium ("NTM"), occurs naturally in the environment. Because the Sorin 3T System aerosolized NTM into the operating room during open chest surgeries, patients were exposed to a greater amount of NTM than naturally

[4] The letter sent to patients by Greenville Health is attached as Exhibit B.
[5] The letter sent to Plaintiff by Palmetto Health is attached as Exhibit C.

occurring background levels.

25. If allowed within the operative field, NTM poses a significant health risk to surgical patients and patients with compromised immune systems.

26. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to four years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease. The recommended monitoring period after exposure is at least four years.

27. Symptoms of an NTM infection are very general and may include any combination of the following: fever, pain, redness, heat or pus around a surgical incision, night sweats, joint pain, muscle pain, and fatigue.

28. Because NTM symptoms are non-specific and manifestation may take several weeks to several years, a patient will most likely fail to link the infection to his or her prior heart surgery, particularly as more time elapses between surgery and initial symptomatology.

29. The diagnosis of an NTM infection requires targeted culturing, molecular diagnostic testing, and/or other screening processes not performed unless physicians are acutely aware of NTM exposure.

30. Most NTM infections are naturally resistant to common antibiotics. To overcome drug resistance, it is often necessary to take several different antibiotics at the same time. Depending on the severity of the infection, treatment may be needed for as long as two years.

31. While an NTM infection diagnosed early may be successfully treated with a series of antibiotics, there is a significant risk of death in cases diagnosed late and in individuals with considerably weakened immune systems.

32. Upon information and belief, 15 individuals who underwent open chest surgery at

Greenville Health during the relevant time period have been diagnosed with a NTM infection. Of that infected group, four have died.

33. Investigations were undertaken by the South Carolina Department of Health and Environmental Control ("DHEC") in an effort to determine the cause(s) for the *M. abscessus* infection outbreak at Greenville Health. On July 21, 2014, prior to the recall on the Sorin 3T System, DHEC released a statement that outlined specific measures that needed to be immediately implemented at Greenville Health as it related to the "cardioplegia machine."

D. Medical Devices Identified as the Infection Source

34. Heater-cooler devices work by aerosolizing temperature controlled water. When the water used in the reservoir of the device contains even trace levels of NTM, the bacteria colonizes, and patients are exposed to the bacteria that are aerosolized through the device's exhaust vent.

35. The airborne transmission of NTM from contaminated heater-cooler units was recognized as a patient risk throughout Europe as early as 2011.

36. A Rapid Risk Assessment released by the European Centre for Disease Prevention and Control ("ECDC") in April 2015 notes that invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany, and the Netherlands since 2011.

37. A public health investigation in Switzerland included microbiological examinations of environmental samples that identified *M. Chimaera* (a strand of NTM) contamination in heater-cooler units, including water samples from the units. Air sampling cultures were positive for *M. chimaera* when the units were running, but negative when they were turned off.

38. In July 2015, an article was published in the Journal of Clinical Infectious Diseases following patients in Europe who contracted NTM. The article concluded that the epidemiological and microbiological features of the prolonged outbreak in Europe provided evidence of the airborne

transmission of *M. Chimaera* from contaminated heater-cooler units.

39. On October 15, 2015, the Food and Drug Administration ("FDA") issued a Safety Communication noting that between January 2010 and August 2015, the agency received 32 Medical Device Reports of patient infections associated with heater-cooler device contamination, eight in the U.S., and the remaining 24 predominantly from Western Europe.

40. On October 21, 2015, the Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication intended to raise awareness among health departments, healthcare facilities, and providers of the association between NTM infections and the use of heater-cooler devices.

E. Recall of the Sorin 3T System

41. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[6]

42. The recall directed customers to follow the *new* cleaning and disinfection procedures outlined in a Field Safety Notice issued by LivaNova and/or Sorin on June 15, 2015 to users in European Union English-speaking countries, followed up by a similar Notice to users in the United States on August 6, 2015.[7]

43. Sorin indicated that it was providing the Field Safety Notice Letters for the following reasons.

> [To] remind [affected users] of the importance of following [the company's] disinfection and maintenance procedures.

[6] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=138337 (last visited January 22, 2017).

[7] The June 3, 2015 Notice is attached as Exhibit D, and the August 6, 2015 Notice is attached as Exhibit E.

> [To] inform [affected users that] . . . there is a possibility that bacteria can be aerosolized when the [heater-cooler] device is operated serving as a potential source for contamination.
>
> [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[8]

44. According to this Field Safety Notice, the company's hygiene concept was "enhanced" by introducing the following modifications:

a. The use of filtered tap water when filling the device;

b. Instead of three different procedures (every five days, every two weeks, and every three months), only two different procedures (every seven days and every 14 days) to make disinfection easier;

c. The option to use peracetic acid instead of chloride solution;

d. H2O2 in low dose for preservation;

e. All external tubing, bottles, and buckets were to be included in the disinfection process;

f. The use of polyethylene tubing that meets national drinking water standards; and

g. That unused heater-coolers must be disinfected bi-weekly.

45. However, in May 2015, a month prior to the recall, LivaNova and/or Sorin determined that devices that had not been maintained according to the manufacturer's instructions for use ("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

46. Upon information and belief, LivaNova and/or Sorin knew or should have known that

[8] Exhibit E at 1.

design and/or manufacturing defects in its 3T System render it prone to bacterial colonization, *regardless of the cleaning and disinfection procedures used*.

47. The FDA recently raised significant questions about the safety and efficacy of the Sorin 3T System.

48. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning 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 820."[9]

49. In the letter, the FDA identified various design change orders dating back to December 11, 2012 that had never been submitted to the FDA for approval.

50. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, that had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

F. Patient Risk Due to Continued Use of the Sorin 3T System

51. In response to the infection outbreak, Greenville Health "instituted numerous measures focused on reducing or eliminating the levels of mycobacterium within [its] facilities."[10]

52. Palmetto Health "has created a comprehensive plan which includes changing venting of the current machines in the operating room and has ordered new machines."[11]

53. It is unknown to Plaintiff whether Greenville Health or Palmetto Health replaced their

[9] The December 29, 2015 Warning Letter is attached as Exhibit F.
[10] *See* https://www.ghs.org/upload/docs/GHSInvestigation.pdf (last visited January 17, 2017).
[11] *See* https://www.palmettohealth.org/medical-services/cardiac-services/cardiovascular-surgery/heater-cooler-faq (last visited January 22, 2017).

original 3T Systems with new 3T Systems of the same design, which are also prone to bacterial colonization and aerosolization.

54. Upon information and belief, other hospitals throughout South Carolina continue to use the Sorin 3T Heater-Cooler System, placing open chest surgery patients at significant risk of injury or death.

CLASS ACTION ALLEGATIONS

55. The Class claims all derive directly from a single course of conduct by the Defendants. The Defendants engaged in uniform and standardized conduct toward the Class. They did not differentiate, in degree of care or candor, their actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief, the same legal standards under South Carolina and/or federal law govern. Accordingly, Plaintiff brings this lawsuit as a class action on his own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rule of Civil Procedure 23. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

Class Definition

56. Plaintiff seeks to certify a class defined as follows:

> All individuals residing in the State of South Carolina who underwent open chest surgery at Greenville Health or Palmetto Health since January 1, 2011 and who are currently asymptomatic for nontuberculous mycobacterium (or "NTM") infection.

Claims for actual injury from an NTM infection are excluded from the claims brought in this class action.

57. Plaintiff seeks to certify the above defined Class for all causes of action alleged herein.

58. The prerequisites to maintaining a class action under Fed. R. Civ. P. 23(a) and (b) are met for the following reasons.

Numerosity

59. Upon information and belief, Plaintiff states that there are hundreds or thousands of individuals who underwent open chest surgery during the relevant time periods. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical.

Commonality

60. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to Plaintiff and Class Members are:

a. Whether and the degree to which they were exposed to NTM during their surgeries;

b. Whether they were exposed to NTM at rates higher than, or through a more dangerous manner than, the general population;

c. Whether the 3T System is the source of their NTM exposure;

d. Whether Defendants knew or should have known of their NTM exposure;

e. Whether their exposure to NTM was caused by the negligence of the Defendants;

f. Whether the 3T System is defectively designed;

g. Whether safer alternative designs for the 3T System existed which could have prevented the colonization and aerosolization of bacteria;

h. Whether the 3T System used in their surgeries contained manufacturing defects;

i. Whether the 3T System is unsafe for its intended use; and

j. Whether the Defendants are legally responsible for implementing and maintaining a medical monitoring fund to provide NTM screening.

Typicality

61. Plaintiff's claims are typical of the claims of Class Members because they each underwent heart surgeries at [insert hospital(s)] during the time period in which the allegedly defective medical devices were used. Plaintiff alleges that his exposure to NTM occurred in substantially the same way. As such, the claims or defenses of the representative parties are typical of the claims or defenses of the Class.

Adequacy of Representation

62. Plaintiff will fairly and adequately protect the interests of Class Members. Plaintiff has retained counsel competent and experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiff is typically situated and has no conflict of interest with the Class as a whole.

Class Action Maintainable under Rule 23(b)(2)

63. A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only individual class members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, Defendants will remain free from responsibility for exposing at least [insert] patients to a potentially deadly bacterium

and Class Members, who have limited resources, will either be forced to fund their own medical screening or forgo the necessary screening due to financial constraints.

Class Maintainable under Rule 23(b)(3)

64. By negligently exposing Plaintiff and Class Members to NTM, Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making the implementation and maintenance of a medical monitoring fund and declaratory relief the appropriate remedies for the Class.

Ascertainability

65. The Class Members are ascertainable as Greenville Health and Palmetto Health can identify every single class member from their respective contemporaneously kept medical records, as evidenced by the fact that Greenville Health and Palmetto Health have sent letters to their respective patients warning them of potential exposure to NTM. Accordingly, nothing more than a ministerial act on the part of non-parties Greenville Health and Palmetto Health will be necessary to ascertain all potential Class Members.

TOLLING OF THE STATUTE OF LIMITATIONS

Discovery Rule

66. Under South Carolina law, the discovery rule tolls the statute of limitations when a plaintiff, due to facts or circumstances not within his or her control, is unable to discover his injury and its cause within the prescribed time period.

67. Under the discovery rule, the statute of limitations begins to run when a plaintiff knows, or in the exercise of reasonable diligence should have known: (1) that he or she has been injured, and (2) that his or her injury was caused by the conduct of another.

68. Prior to Greenville Health's June 20, 2014 and Palmetto Health's December 16, 2016

announcements and correspondence advising that Plaintiff and Class Members may have been exposed to NTM, Plaintiff was wholly unaware of both his exposure to NTM and the fact that his exposures may have been caused by a defective medical device.

69. Any applicable statute of limitation has therefore been tolled by Plaintiff's and Class Members' lack of knowledge of the facts alleged herein prior to June 20, 2014 and December 16, 2016.

COUNT I - NEGLIGENCE

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

71. Defendants owed a duty of reasonable care to the general public, including Plaintiff, when it designed, labeled, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, instructed, and sold the Sorin 3T System, to assure that the product complied with FDA regulations and was not defective and/or unreasonably dangerous for its intended purposes and foreseeable uses.

72. Defendants breached this duty in the design, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling of Sorin 3T System in a defective and unreasonably unsafe condition by, *inter alia*:

a. Failing to conduct adequate safety and efficacy testing before seeking to have the Sorin 3T System put into the stream of commerce;

b. Failing to notify the FDA of design change orders to the Sorin 3T System;

c. Supplying "validation" studies to the FDA that failed to demonstrate the safety and efficacy of cleaning and disinfection procedures for the Sorin 3T System;

d. Failing to warn Plaintiff and Class Members of the potential for bacterial colonization and patient exposure to such bacteria;

e. Designing the Sorin 3T System in such a way that it is prone to bacterial colonization and aerosolization; and

f. Failing to ensure proper workmanship, materials, and labeling for the Sorin 3T System.

73. Defendants owed Plaintiff and the Class a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA, the medical community, Plaintiff, the Class, and the public of a defect once it was discovered. Defendants violated these duties when they failed to do so, which further placed Plaintiff and the Class Members at risk for harm and injury.

74. The Sorin 3T System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution, and advertising from the system that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution, and advertising of the Sorin 3T System used at Greenville Health and Palmetto Health was in violation of those requirements.

75. Defendants had the duty to comply with and not deviate from statutory requirements, which amongst other things, require that the device be manufactured, labeled, and designed according to the standards set forth in the FDA approval. Defendants violated these duties when they failed to comply with and deviated from the statutory requirements.

76. As a direct and proximate result of Defendants' negligence, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT II – STRICT PRODUCTS LIABILITY

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

78. Under South Carolina Code § 15-73-10, Defendants' sale of the Sorin 3T System in a defective condition or unreasonably dangerous condition, along with Defendants' violations of federal regulations as outlined herein, establish a prima facie case of strict liability in tort.

79. As a direct and proximate result of Defendants' violations, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT III – BREACH OF EXPRESS WARRANTY

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

81. Defendants expressly warranted through their marketing, advertising, distributors, and sales representatives that the Sorin 3T System was of merchantable quality and fit for the ordinary purposes and uses for which it was sold.

82. Defendants breached these express warranties by designing, labeling, manufacturing, and selling the defective and unreasonably dangerous Sorin 3T System that was neither of merchantable quality nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff and the Class Members, during foreseeable use.

83. As a direct and proximate result of Defendants' breach of implied warranties,

Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT IV – BREACH OF IMPLIED WARRANTY

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

85. Defendants impliedly warranted through their marketing, advertising, distributors, and sales representatives that the Sorin 3T System was of merchantable quality and fit for the ordinary purposes and uses for which it was sold.

86. When the Sorin 3T System was used during Plaintiff's and the Class Members' heart procedures, the system was being used for the original purposes for which it was approved and intended.

87. Plaintiff and the Class Members, individually and/or by and through their healthcare providers, relied upon Defendants' implied warranties of merchantability in consenting to have the heart procedures performed with assistance of the Sorin 3T System.

88. Defendants breached these implied warranties of merchantability because the Sorin 3T System was neither merchantable nor suited for the intended uses for which it was sold.

89. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT V – NEGLIGENT MISREPRESENTATION

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

91. Defendants negligently misrepresented to the FDA, the medical community, Plaintiff, the Class Members, and the public the defective nature and extent of adverse reactions and labeling errors of the Sorin 3T System.

92. Defendants failed to adhere to FDA regulations by failing to appropriately report all of the information and knowledge in their possession regarding the dangers Defendants knew their product presented, including, but not limited to, the fact that colonization of Mycobacteria inside the Sorin 3T System could occur if specific disinfection and maintenance procedures were not implemented.

93. Had Defendants accurately and truthfully represented to the FDA, the medical community, Plaintiff, the Class Members, and the public the material facts relating to the risks of the Sorin 3T System, Greenville Health and Palmetto Health would not have utilized the Sorin 3T System as they did during the procedures that caused Plaintiff's and the Class Members' injuries.

94. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT VI – MISREPRESENTATION BY OMISSION

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

96. Throughout the relevant time period, Defendants knew that the Sorin 3T System was defective and unreasonably unsafe for intended purposes, which Defendants failed to properly report to the FDA, the medical community, Plaintiff, the Class Members, and the public.

97. Defendants had a duty to disclose to the FDA, the medical community, Plaintiff, the Class Members, and the public the defective nature and extent of adverse reactions and labeling errors of the Sorin 3T System, because the Defendants were in a superior position to know the true quality, safety, and efficacy of the Sorin 3T System.

98. Defendants concealed from and/or failed to disclose to the FDA, the medical community, Plaintiff, the Class Members, and the public that the Sorin 3T System was defective, unsafe, unfit for its intended uses, and not of merchantable quality.

99. The facts concealed and/or not disclosed to the FDA, the medical community, Plaintiff, the Class Members, and the public were material facts that a reasonable person would have considered important in deciding whether to utilize the Sorin 3T System.

100. As a direct and proximate result of Defendants' concealment and misrepresentations by omission, Plaintiff and the Class Members have suffered an injury-in-fact in the form of necessary healthcare, attention, and services, and emotional distress and anxiety resulting from knowing they have been exposed to NTM that may lead to serious illness or death, for which Plaintiff and the Class is entitled to and compensatory and punitive damages in an amount to be proven at trial.

COUNT VII – MEDICAL MONITORING

101. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

102. The latency period for the manifestation of an NTM infection is estimated to be between

anywhere from two weeks to five years after exposure.

103. Plaintiff and Class Members have been exposed to NTM at rates higher than, or in a substantially more dangerous manner than, the general population. Plaintiff's exposure levels are therefore substantial in nature.

104. When NTM is transmitted in the method described above, namely airborne transmission from a contaminated medical device to an individual undergoing invasive heart surgery, it is widely acknowledged as dangerous and potentially life-threatening bacteria.

105. Plaintiff's and the Class Members' exposure to NTM was proximately caused by Defendants' negligence as described herein.

106. Monitoring procedures exist that make the detection of NTM infections possible.

107. NTM infections are capable of early detection by way of existing scientific methods including, but not limited to, targeted culturing and DNA sequencing of invasive samples (*e.g.*, blood, pus, tissue biopsy, or implanted prosthetic material).

108. Because NTM screening is not conducted in the absence of exposure to NTM, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require specialized screening not within the purview of routine medical exams.

109. The prescribed monitoring regime is reasonably necessary according to contemporary scientific principles in order to provide for early diagnosis of NTM infections leading to benefits in treatment, management, rehabilitation, and prevention or mitigation of long term health consequences, including death.

110. Due to the liability of Defendants as pleaded in the preceding causes of action, one element of Defendants' responsibility and of the damages sought in this case is the establishment

of a court-approved program funded by Defendants to pay for the costs of NTM screening to mitigate the risk of serious illness or death.

111. Without a medical monitoring program, Plaintiff and the Class Members might not receive prompt medical care that could prolong their productive lives, increase prospects for improvement of their quality of life, and minimize disability.

112. For the foregoing reasons, Plaintiff seeks declaratory and injunctive relief in the form of a medical monitoring program funded by Defendants for the benefit of Plaintiff and the Class Members to provide them with all future medical monitoring necessary to detect NTM.

113. In the alternative, Plaintiff seeks compensatory damages adequate to pay for such medical monitoring.

COUNT VIII – DECLARATORY RELIEF

114. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

115. Pursuant to 28 U.S.C. § 2201, a court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

116. Declaratory relief is intended to minimize "the danger of avoidable loss and unnecessary accrual of damages." 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 1998).

117. Plaintiff alleges that the Sorin 3T System is defective in that it is prone to bacterial colonization that may be transmitted to patients during surgery.

118. There are actual controversies between Plaintiff and Defendants, concerning: (1) whether the Sorin 3T System is defective, (2) whether Defendants knew, or should have known, of defects in their Sorin 3T System, and (3) whether Defendants failed to adequately warn of the risk of

bacterial colonization in their Sorin 3T System.

119. The declaratory relief requested herein will generate common answers that will settle the controversy related to the alleged defects in the Sorin 3T System. There is an economy to resolving this issue as it has the potential to eliminate the need for continued and repeated litigation regarding alleged defects in this medical device.

120. Plaintiff therefore seeks a declaration that the Sorin 3T System is defective and that Defendants must expeditiously notify the Class of such defects.

PUNITIVE DAMAGES

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

122. Defendants' acts, omissions, and violations as set forth herein constitute intentional, fraudulent, malicious, and/or reckless conduct. Accordingly, Plaintiff and the Class is entitled to an award of punitive damages.

PRAYER FOR RELIEF

Plaintiff, on behalf of himself and all others similarly situated, requests the Court to enter judgment against Defendants as follows:

A. An order certifying the proposed Class, designating Plaintiff as the named representative of the Class, and designating the undersigned as Class Counsel;

B. An award to Plaintiff and the Class of actual damages, punitive damage, costs, and disbursements in this action, including reasonable attorneys' fees, as permitted by law;

C. A declaration that Defendants are financially responsible for implementing and maintaining a fund for the medical monitoring of Plaintiff and Class Members;

D. A declaration that the Sorin 3T System is defective and unsafe for its intended use;

E. An award of pre-judgment and post-judgment interest, as provided by law;

F. Leave to amend this Complaint to conform to the evidence produced at trial; and

G. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

Dated: January 23, 2017

Respectfully submitted,

MCGOWAN, HOOD & FELDER, LLC

/s/ James L. Ward, Jr.

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