IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION
CIVIL ACTION NO. 8:16-cv-02688-MGL

Phillip Lamar West, Individually, and Karen Austin, Individually, and as Husband and Wife, Plaintiffs, vs. LivaNova PLC, Sorin Group Deutschland GMBH, and Sorin Group USA, Inc., Defendants.	)	**COMPLAINT**

The Plaintiffs, complaining of the acts of the Defendants above-named, would respectfully show unto the Court as follows:

PARTIES TO THIS ACTION

1. Plaintiff Phillip Lamar West is a resident and citizen of Anderson County, State of South Carolina. On May 5, 2014, Plaintiff West underwent an aortic valve replacement and a bypass procedure at the Greenville Health System Hospital ("GHS") in Greenville, South Carolina. During the procedure, the Sorin 3T Heater-Cooler System was used, exposing him to non-tuberculosis Mycobacteria. Plaintiff Karen Austin is his wife and was married to him at the time of this procedure.

2. The Defendant LivaNova PLC ("LivaNova") is a foreign for-profit corporation, incorporated in England and Wales with headquarters in Milan, Italy. LivaNova is a global medical device company specializing in medical devices used in the treatment of cardiovascular diseases. LivaNova is the party responsible to purchasers in the United States for the Sorin 3T

Heater-Cooler Systems.[1]

3. Upon information and belief, the Defendant Sorin Group Deutschland GMBH ("Sorin") is a foreign for-profit corporation, with headquarters in Munich, Germany. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in Plaintiff West's surgical procedure in Greenville, South Carolina. Plaintiffs are under the information and belief that Sorin merged with LivaNova in October, 2015, with LivaNova continuing as the named entity.

4. Upon information and belief, the Defendant Sorin Group USA, Inc. ("Sorin USA") is a United States designer, manufacturer, marketer, and distributor of the Sorin 3T Heater-Cooler System, with its principal place of business in Arvada, Colorado. Plaintiffs are under the information and belief that Defendants Sorin and Sorin USA are wholly-owned subsidiaries of LivaNova and market and sell medical devices and products under the name of LivaNova.

JURISDICTION AND VENUE

5. This Court has personal jurisdiction over this action pursuant to FRCP 4 and pursuant to SC Code Ann. § 36-2-803. The Defendants are non-domiciliaries of the State of South Carolina and contract business within the State of South Carolina. The Defendants have committed tortious acts within the State of South Carolina, causing injury to a person within the State of South Carolina, and said Defendants expect or should reasonably expect to have consequences in the State of South Carolina; the Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in the State of South Carolina. The Defendants are in the business of researching,

[1] This information was obtained from the FDA website through the various communications published online regarding the Sorin 3T System.

designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, Sorin Group Stockert Heater-Cooler 3T thermal regulator devices in the State of South Carolina.

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties and the amount in controversy exceeds $75,000.00.

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

FACTUAL ALLEGATIONS

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

9. The Defendants market and sell thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System").

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

11. 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]

12. 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.

13. 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 (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 1000-1050."

14. On or about June 20, 2014, GHS publically announced that approximately 14 patients had tested positive for a rare non-tuberculosis mycobacterium infection, known as

[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 CFR 807.92(a)(3).

[3] Please see the FDA Determination Letter of Approval attached hereto as "Exhibit A".

Mycobacterium abscessus ("*M. abscessus*"). The majority of those patients were exposed to the bacterium during open heart surgeries. At that time, GHS indicated that there had been three (3) deaths resulting from the same infection. On or about June 26, 2014, GHS released a second statement indicating that there were 15 confirmed cases of patients with the infection. On July 21, 2014, GHS confirmed that the patient death toll had increased to four (4).

15. In the July 21, 2014 announcement, GHS 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, including Plaintiff West.[4]

16. *M. abscessus* is most commonly found in water, soil, and dust. If allowed within the operative field, it poses a significant health risk to surgical patients and patients that are immunodeficient.[5]

17. *M. abscessus* can take anywhere from weeks to years before it manifests into a non-tuberculosis mycobacterium infection.

18. Tissue that has been infected with *M. abscessus* usually presents as "red, warm, tender to the touch, swollen, and/or painful" and infected areas can appear as "boils." Additional signs and symptoms of the infection include "fever, chills, muscles aches, and a general feeling of illness."[6]

19. Diagnosis of *M. abscessus* can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the bacterium can be found in the blood and isolated from a blood sample. Targeted cultures, screenings, and proper testing are usually not performed

[4] Please see "Exhibit B" attached hereto, which is a copy of the actual letter submitted to the patients by GHS.
[5] Centers for Disease control website: http://www.cdc.gov/HAI/organisms/mycobacterium.html
[6] Id.

unless the physician has been made aware of this type of mycobacterium exposure.[7]

20. While death is certainly a risk of this type of infection, there are treatments available. Those include draining collections of pus or removing the infected tissue, coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time. The type and period of treatment can vary greatly from patient to patient.[8]

21. Investigations were undertaken by the South Carolina Department of Health and Environmental Control (SC DHEC) in an effort to determine the cause(s) for the *M. abscessus* infection outbreak at GHS. On July 21, 2014, prior to the recall on the Sorin 3T System, SC DHEC released a statement that outlined specific measures that needed to be immediately implemented at GHS as it related to the "cardioplegia machine."[9]

22. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System due to the "potential colonization of organisms, including Mycobacteria, in Sorin Heater-Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[10]

23. The recall instructed all affected customers to follow *new* Instructions for Use, which were outlined in the June 15, 2015 Field Safety Notice Letter for EU English-speaking countries, followed up by a similar letter to users in the United States on August 6, 2015[11], both issued by i.V. Christian Peis, the Director of Quality Assurance for Sorin.

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

A. [To] remind [affected users] of the importance of following the company's

[7] Id.
[8] Id.
[9] Please see the SC DHEC letter, attached hereto as "Exhibit C." The "cardioplegia machine" is the Sorin 3T System.
[10] Please see the Recall Information from the FDA database, attached hereto as "Exhibit D."
[11] Please see the 6/15/15 Field Safety Notice Letter, attached hereto as "Exhibit E" and 8/6/15 letter as "Exhibit F."

disinfection and maintenance procedures;

B. [To] inform [affected users] that there is a possibility that bacteria can become aerosolized when the heater-cooler device is operated and serve as a source for contamination; and

C. [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[12]

25. Upon information and belief, the Defendants knew or should have known that design and/or manufacturing defects in its Sorin 3T System made it susceptible to bacterial colonization, specifically Mycobacteria, despite any cleaning and disinfection procedures utilized.

26. 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."[13]

27. The FDA noted several other violations by the Defendants in the Warning Letter, which include, but are not limited to, the following:

A. 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);

B. Failure to validate a process, with a high degree of assurance and approved

[12] Id.

[13] Please see the 12/29/15 Warning Letter, attached hereto as "Exhibit G."

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);

C. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act 21 USC § 360i and 21 CFR Part 803 – Medical Device Reporting;

D. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17;

E. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

F. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (e.g., distributing the device with modified instructions for use with respect to the operating, maintaining, cleaning, and disinfecting of the device, among other modifications).

28. Contrary to the Defendants' representations and marketing to the FDA, medical community, and to the patients themselves, Defendants' Sorin 3T System has high injury and complication rates, fails to perform as intended, requires patients to undergo additional operations, and has caused severe and sometimes irreversible injuries, conditions, and damages to a significant number of patients, including Plaintiff West, all of which are violations of Federal and South Carolina State rules and regulations.

29. In violation of Federal and South Carolina State requirements, the Defendants consistently under-reported and withheld information about the propensity of the Sorin 3T System to experience complications and its failure to perform as expected, has misrepresented

the efficacy and safety of Defendants' system through various means and media, actively misleading the FDA, the medical community, patients, and the public at large.

30. Defendants knew, and continue to know, that its disclosures to the FDA, the public, and Plaintiff were, and are, incomplete and misleading and that the Sorin 3T System was and is causing numerous patients severe injuries and complications, which violates Federal and State requirements. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, the medical community, health care providers, and patients. As a result, the Defendants actively and intentionally misled the FDA and the public, including the medical community, healthcare providers, and patients, into believing that the Sorin 3T System was safe and effective, leading to the use of Defendants' system during surgical procedures, such as the one undertaken by Plaintiff West, as more fully described herein.

31. In violation of Federal and State rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Sorin 3T System.

32. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use have existed at all times relevant.

33. The Defendants' 3T Sorin System was at all times relevant, utilized in a manner foreseeable to the Defendants.

34. The Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, which is in direct violation of Federal and State regulations and in violation of regulations required pursuant to the 510K Approval of the Sorin 3T System in order to increase the number of hospitals and physicians utilizing the device,

thereby increasing its sales.

35. The Sorin 3T System used during Plaintiff West's surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

36. The injuries, conditions, and complications Plaintiffs suffered due to the Sorin 3T System include, but are not limited to, excruciating pain, weakness, excessive additional and debilitating medical treatment, suffering, and permanent injury. Additional information that may be necessary to further establish Plaintiff West's claims will be gathered throughout the discovery process of this litigation since Plaintiffs are privy to limited supporting documentation at this time.

37. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the Sorin 3T System, in violation of Federal and State requirements, it continued to manufacture, market, provide inadequate instructions for use, and sell the Sorin 3T System, and also failed to adequately warn, label, instruct, and disseminate information with regard to Defendants' Sorin 3T System both prior to and after the marketing and sale of the System.

FACTS SPECIFIC TO THIS CASE

38. Defendants' Sorin 3T System was used during Plaintiff West's aortic valve replacement and Cardiac Bypass Grafting Procedure, performed at GHS, on or about May 5, 2014, wherein the Plaintiff West's surgeon, Dr. Barry Davis, used the device to assist in the cooling and re-warming of Plaintiff West's blood. Plaintiff West was subsequently discharged from the hospital.

39. Over the following days and weeks, Plaintiff West's condition began to

deteriorate. Initially, while there were no observable signs of infection initially around the incision site, Plaintiff West began running a high-grade fever, displayed signs of increasing weakness, and developed pneumonia.

40. On or about June 17, 2014, Plaintiff West began treatment at GHS for a red rash around his sternal wound and an area toward the superior aspect of his incision that appeared to be swollen and contain fluid. Plaintiff West was placed on antibiotics and scheduled to undergo sternal debridement by Dr. Davis. Plaintiff West underwent the sternal debridement, was fitted with a wound vac, and was continued on the antibiotics while the wound contents were cultured. Plaintiff West had to undergo additional debridement, as well as a pectoralis major muscle flap procedure, which has severely affected the use of his arm. The wound cultured out Mycobacteria. Plaintiff West was discharged home with the wound vac, and was scheduled for home health care, as well as regular treatment by an Infectious Disease physician in addition to his cardiologist and a thoracic surgeon.

41. On or about July 24, 2014, Plaintiff West was readmitted to GHS for delayed healing of his surgical wound. While attempting to dress his wound, nurses found pus bubbling from the tissue at the incision site.

42. Due to the severity of Plaintiff West's wound dehiscence and exposure of wires and sutures, he was again taken for a sternal debridement and wound flap procedure review. All of the sutures and wiring had to be redone.

43. Blood cultures were positive for gram-positive cocci. Plaintiff West had contracted the *M. abscessus* infection and was placed on additional antibiotics. GHS physicians were not sure of the source of his infection at that time.

44. Plaintiff West continued treatment for the *M. abscessus* sternal wound infection,

and was either hospitalized or received treatment at a physician's office in August, September, October, November and December of 2014, as well as January and February of 2015. Plaintiff West's treatment by physicians for this *M. abscessus* infection is ongoing.

COUNT I - NEGLIGENCE

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

46. The Defendants owed a duty of reasonable care to the general public, including Plaintiff West, 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 was in compliance with FDA regulations and not defective and/or unreasonably dangerous for its intended purposes and foreseeable uses.

47. The Defendants breached this duty by designing, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling the Sorin 3T System in a defective and unreasonably unsafe condition including, but not limited to, its propensity for the colonization of organisms, including Mycobacteria.

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

49. 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 GHS during Plaintiff West's heart procedure was done so in violation of those requirements.

50. The 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 laid out in the FDA approval. The Defendants violated these duties when it failed to comply therewith and deviated from the statutory requirements.

51. As a direct and proximate result of Defendants' violations, Plaintiffs have suffered severe debilitating injuries, economic loss, and other damages, including, but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering.

52. Under South Carolina law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of common law negligence.

53. Under South Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in an unreasonably dangerous product proximately causing injuries to the Plaintiff West.

COUNT II - STRICT PRODUCTS LIABILITY

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

55. Under South Carolina Code § 15-73-10, the Defendants' sale of the product 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.

56. As a direct and proximate result of Defendants' violations of Federal and State laws, Plaintiffs have suffered severe, debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, pain and suffering, and death.

57. Under South Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in an unreasonably dangerous product proximately causing injuries to Plaintiffs.

COUNT III - BREACH OF EXPRESS WARRANTY

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

59. The Defendants warranted, both expressly and impliedly, through its 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.

60. The Defendants are aware that health care providers and patients, including Plaintiff West, rely upon the representations made by the Defendants when choosing, selecting, and purchasing its products, including the Sorin 3T System.

61. Due to the defective and unreasonably dangerous design, labeling, and manufacturing of the Sorin 3T System, which was in violation of statutory requirements and regulations, the product 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 West, during foreseeable use.

62. The Defendants' violations of Federal and State statutory rules and regulations and the defective and unreasonably dangerous condition of the Sorin 3T System constituted a breach of the Defendants' express and implied warranties, and such breaches were a direct and proximate cause of the incident and injuries described herein, and for which Plaintiffs are entitled to attorney's fees, compensatory, and punitive damages in an amount to be proven at trial.

COUNT IV - BREACH OF IMPLIED WARRANTIES

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

64. Defendants warranted, both expressly and impliedly, through its 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.

65. When the Sorin 3T System was used during Plaintiff West's heart procedure, the system was being used for the original purposes for which it was approved and intended.

66. Plaintiff West, individually and/or by and through his healthcare provider, relied upon Defendants' implied warranties of merchantability in consenting to have the heart procedure performed with assistance of the Sorin 3T System.

67. Defendants breached these implied warranties of merchantability because the Sorin 3T System was neither merchantable nor suited for the intended uses as warranted.

68. Defendants' breach of its implied warranties resulted in the use of an unreasonably dangerous and defective product during Plaintiff West's heart procedure, placing Plaintiff West's health and safety in jeopardy.

69. As a direct and proximate result of the Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, the Plaintiff has suffered injury and has further experienced significant mental and physical pain and suffering, sustained permanent injury, underwent rigorous and debilitating medical treatment, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income and other damages, for which Plaintiff is entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT V - NEGLIGENT MISREPRESENTATION

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

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

72. The Defendants failed to adhere to FDA regulations by failing to appropriately report all of the information and knowledge in their possession in regards to the dangers that the 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.

73. Had the Defendants accurately and truthfully represented to the FDA, the medical community, Plaintiff West, and the public, the material facts relating to the risks of the Sorin 3T System, Plaintiff West and/or Plaintiff West's healthcare provider would not have utilized the Sorin 3T System as it did during Plaintiff West's heart procedure.

74. Under South Carolina law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of negligent misrepresentation.

75. Under South Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in the negligent misrepresentation of an unreasonably dangerous product proximately causing injuries to Plaintiff West.

76. As a direct and proximate result of the Defendants' negligent misrepresentations and violations as outlined above, Plaintiffs have suffered injuries and have further experienced

significant mental and physical pain and suffering, sustained permanent injury, underwent rigorous and debilitating medical treatment, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income and other damages, for which Plaintiffs are entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VI - MISREPRESENTATION BY OMISSION

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

78. Throughout the relevant time period, Defendants knew that the Sorin 3T System was defective and unreasonably unsafe for intended purposes, which the Defendants failed to properly report to the FDA.

79. The Defendants were under a duty to disclose to the FDA, Plaintiff West, and the medical community, the defective nature and extent of adverse reactions and labeling errors of the system because the Defendants were in a superior position to know the true quality, safety, and efficacy of the Sorin 3T System.

80. The Defendants concealed from and/or failed to disclose to the FDA, Plaintiff West, Plaintiff West's healthcare providers, and the medical community that its Sorin 3T System was defective, unsafe, and unfit for the purposes intended, and that it was not of merchantable quality.

81. The facts concealed and/or not disclosed to the FDA, Plaintiff West, or the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize the Sorin 3T System, and were facts that were required to be disclosed pursuant to Federal and State statutes and regulations.

82. Under South Carolina law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of misrepresentation by omission.

83. Under South Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant thereto, which resulted in Defendants' misrepresentation by omission of an unreasonably dangerous product that proximately caused injuries to the Plaintiff West.

84. As a direct and proximate result of the Defendants' concealment and misrepresentations by omission and violations outlined above, the Plaintiffs have suffered severe injuries and have further experienced significant mental and physical pain and suffering, sustained permanent injury, underwent rigorous and debilitating medical treatment, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income and other damages, for which Plaintiffs are entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VII - VIOLATION OF THE S.C. UNFAIR TRADE PRACTICES ACT

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

86. At all times relevant to this action, the South Carolina Unfair Trade Practices Act, codified at S.C. Code Ann. §39-5-20, was in effect. The section states:

(a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

(b) It is the intent of the legislature that in construing paragraph (a) of this section the courts will be guided by the interpretations given by the

Federal Trade Commission and the Federal Courts to § 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended.

87. The Defendants have engaged in deceptive acts or practices in violation of the South Carolina Unfair Trade Practices Act, including but not limited to, utilizing deception, fraud, misrepresentation, concealment, omission, and suppression of research from investigations, adverse events reported to the FDA, and clinical trials regarding the safety, efficacy, instructions for use, and the unreasonably dangerous nature of the Sorin 3T System.

89. The Defendants violated the South Carolina Unfair Trade Practices Act by concealing, omitting, and failing to inform the FDA, the Plaintiffs, the medical community, and other purchasers of the failures, adverse reactions, complications, and the insufficiency of the Instructions for Use as it related to the Sorin 3T System.

90. Defendants' deceptive acts and practices occurred during a course of conduct involving trade or commerce.

91. As a direct and proximate cause of the Defendants' violations of Federal requirements and the South Carolina Unfair Trade Practices Act, Plaintiffs have sustained severe physical and emotional injuries and economic loss, for which Plaintiffs are entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VIII - LOSS OF CONSORTIUM

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

93. Due to the Defendants' deviations as further outlined herein, this Loss of Consortium claim allows a remedy to Karen Austin, the wife of Plaintiff West, against the

Defendants.

94. As a direct and proximate result of the Defendants' deviations from the applicable standards of care as expressed herein, Plaintiff Austin has been, and will continue to be, deprived of the consortium, society, comfort, protection, and services of her husband, thereby causing and continuing to cause economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering and prays for judgment against the Defendants as set forth in this Complaint.

PUNITIVE DAMAGES

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

96. The acts, omissions, and violations of the Defendants as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiffs are entitled to an award of punitive damages.

ACTUAL DAMAGES

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

98. As a direct and proximate result of the acts, omissions, and violations of the Defendants alleged herein, Plaintiffs suffered injuries and damages. The injuries and damages for which Plaintiffs seek compensation from the Defendants include, but are not limited to:

a. physical pain and suffering of a past, present and future nature;

b. emotional pain and suffering of a past, present and future nature;

c. permanent impairment and scarring;

d. medical bills and expenses of a past, present and future nature;

e. loss of earnings;

f. loss of earning capacity;

g. loss of enjoyment of life;

h. pre- and post-judgment interest;

i. statutory and discretionary costs;

j. loss of consortium of spouses; and

k. any and all such further relief, both general and specific, to which they may be entitled to under the premises.

PRAYERS FOR RELIEF

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

100. **WHEREFORE, PREMISES CONSIDERED,** the Plaintiffs bring this Complaint against the Defendants for personal injuries and pray for a judgment against the Defendants for compensatory and punitive damages, in an amount considered fair and reasonable by a jury and for all such further relief, both general and specific, to which Plaintiffs may be entitled under the premises.

Respectfully submitted,

McGowan Hood & Felder, LLC

s/ J. Stephen Welch

J. Stephen Welch (Fed ID No. 5055)
P.O. Box 1788
1501 N. Fant Street
Anderson, SC 29622-1778 (29621)
T: (864) 225-6228
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ATTORNEYS FOR PLAINTIFFS

July 29, 2016

JURY REQUEST

The Plaintiff hereby respectfully requests a trial by jury.

Respectfully submitted,

McGowan Hood & Felder, LLC

s/ J. Stephen Welch

J. Stephen Welch (Fed ID No. 5055)
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ATTORNEYS FOR PLAINTIFFS

July 29, 2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Principal Consultant, Regulatory Services
49 Plain Street
North Attleboro, MA 02760

Re: K052601
Stockert Heater-Cooler System 3T
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary Bypass Temperature Controller
Regulatory Class: Class II
Product Code: DWC
Dated: May 15, 2006
Received: May 16, 2006

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K052601

Device Name: Stöckert Heater-Cooler System 3T

Indications for Use:

The Stöckert Heater-Cooler System 3T is used with a Stöckert S3 heart-lung machine and/or any other heart lung machine featuring a separate temperature control for extracorporeal perfusion of durations of up to 6 hours.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052601

JUN - 6 2006

K052601

Traditional 510(k) Premarket Notification
510(k) Summary
Sorin Group Deutschland GmbH, Stöckert Heater-Cooler System 3T

1. SUBMITTER/HOLDER

Sorin Group Deutschland GmbH
Lindberghstrasse 25
80939 Munich
Germany

Contact: Helmut Höfl, Director, Quality Assurance and Regulatory Affairs
Telephone: 011 49 89 323 010

Date Prepared: September 19, 2005

2. DEVICE NAME

Proprietary Name: Stöckert Heater-Cooler System 3T
Common/Usual Name: Heater-Cooler
Classification Name: Cardiopulmonary bypass temperature controller

3. PREDICATE DEVICE

- Cincinnati Subzero Hemotherm (CSZ Hemotherm) (K811742)
- Alpha Omega, Inc. Dual^2 Cooler-Heater (K001520)
- Jostra AB Heater-Cooler Unit 30 (K031544)

4. DEVICE DESCRIPTION

The Sorin Group Deutschland GmbH Stöckert Heater-Cooler System 3T consists of standard and optional components. The standard components comprise the heater-cooler base unit, water connectors, CAN-connecting cable for the S3 System, potential equalization cable, and Operating Instructions. Patient blankets used with the System are already legally marketed in the United States.

5. INTENDED USE

The Stöckert Heater-Cooler System 3T is intended to provide temperature-controlled water to heat exchanger devices (cardiopulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardiopulmonary bypass procedures lasting six (6) hours or less.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Sorin Group Deutschland GmbH bases the claim of substantial equivalence of the Stöckert Heater-Cooler System 3T to the cited predicate devices based on equivalence in intended use, fundamental technological and operational characteristics. Testing submitted in this premarket notification demonstrates that the Stöckert Heater-Cooler System 3T complies with specifications, meets user requirements, and the differences between the proposed device and cited predicate devices do not raise new issues of safety or effectiveness.

GREENVILLE HEALTH SYSTEM

Information Services Center

525 Grove Road
Greenville, SC 29605
ghs.org

July 18, 2014

[redacted]

CERTIFIED AND REGULAR MAIL

To the family of Ms. Elliott,

This is in follow up to previous communication with you about the ongoing investigation into the atypical mycobacterium infection outbreak at Greenville Memorial Hospital. In follow up to conversations with Ms. Elliott's physician about her diagnosis, culture results, and treatment plan, a representative of the hospital spoke with you to let you know that other patients also have developed an infection with this mycobacterium. At that time, we committed to providing further information to you about the situation as the investigation progressed.

We are now able to provide more details to you. Attached is a written update on that investigation including information such as how and when we became aware of the potential outbreak, what we know about the source of the infection, and what we have done to eliminate further risk to patients.

I hope that this information will provide the additional information you seek. I am truly sorry for your loss. I understand this must be a very difficult time for you. Please be assured that our goal is to provide quality care to every patient who allows us the privilege of caring for them. Although this is not how we would have preferred for your loved one – and we know that you would not have preferred this either, we are confident that it can result in improvements within GHS, and in other healthcare facilities across the U.S.

Just as GHS elected a transparent approach in communicating to you, other patients, and to the public that we are investigating this infection outbreak, we anticipate continuing that transparency. Should you have further questions about the infection investigation, please contact one of our Quality Management staff at (864) 455-7125.

Sincerely,

Robert L. Mobley, M.D.
Medical Director of Quality

Attachments: Update on Infection Investigation, EPA Factsheet

GREENVILLE HEALTH SYSTEM

Information Services Center

525 Grove Road
Greenville, SC 29605
ghs.org

Update on Infection Outbreak Investigation

Background

In late May 2014, an outbreak of an unusual bacterial surgical site infection was suspected at Greenville Memorial Hospital. This is the first time GHS has experienced an outbreak of surgical site infections involving mycobacterium. Mycobacterium abscessus is an environmental contaminant and can be found in water and dust. The environmental bacteria are considered widespread and part of the natural flora of potable water in the U.S. EPA regulations do not require that it be eradicated because the organism is not thought to be harmful to the general public under normal circumstances, said DHEC. There are no national standards of care regarding whether hospitals should screen for this bacterium or how they should treat incoming water.

It has been described as a cause of healthcare-associated infections. The bacterium is harmless in most circumstances but can result in infections if it comes into contact with surgical sites, especially in immuno-compromised individuals. Exposure pathways of potential concern also include ingestion, inhalation and entry of organisms through abraded skin, according to the Environmental Protection Agency.

Investigation

Because of the organism's long incubation period of an average of 79 days in the GHS patients, patients did not typically show signs of infection until as long as several months after their surgeries. The first-recognized patient tested positive in March 2014. Because of the strong surveillance system, we were able to identify the potential problem and take immediate and appropriate action. In May, when several patients developed similar infections with this same mycobacterium, our hospital epidemiologist identified this as a potential infection outbreak. GHS then began an aggressive sequential elimination of potential sources based on epidemiologic evidence. Water studies showed that some water samples inside Greenville Memorial Hospital tested positive for the bacterium.

Preliminary information focused the investigation on ice from a filtered-water ice machine used in the Operating Room during cardiac surgery. During cardiac surgery, cooling techniques are used to stop the heart without damaging the heart tissue. The equipment used for that cooling of the blood and heart uses ice. The ice never directly touches the patient. The ice machine was removed from use on May 21 as a precaution while the investigation continued. Subsequently, ice required for those surgeries was made using sterile water.

As an additional measure, equipment used for cardiopulmonary perfusion was removed from use on June 6 as part of the expanding investigation. That machine used a closed system in which cooled or heated water encased in tubes is run in close proximity to patient blood (also encased in tubes) as part of a heating/cooling procedure used in cardiac surgeries.

At that point, GHS also reached out to the S.C. Department of Health and Environmental Control (DHEC) and Centers for Disease Control and Prevention (CDC), as well as other authorities in atypical mycobacterium for additional expertise with the investigation.

Current Status

As the investigation progressed, we instituted numerous measures focused on reducing or eliminating the levels of mycobacterium within our facilities. Many of these processes were already in place but GHS is continuing or strengthening them. The control measures include:

1. Flushing scrub sinks in the OR for at least 10 minutes in the morning before first use.
2. Installing point-of-use bacteriologic filters in the operating room, including scrub sinks. The filters are able to screen the extremely small bacterium, which is only .2 microns in size and one of the smallest bacteria now known; in comparison, a single human red blood cell is about 5 microns across.
3. Shortening the disinfectant cycle on the machine which actually utilized the ice. GHS has now moved to a weekly disinfectant cycle on the machine, rather than the two week cycle recommended by the manufacturer. This cleaning schedule issue was reported to the U.S. Food and Drug Administration for investigation
4. Inspecting internal water systems to assess for unused plumbing branches and ensuring water flow is constant through the pipes, which would help discourage the organism. GHS engineers have completed this work within the operating room area.
5. Temporarily closing an operating suite associated with the cardiac cases as a precaution. That operating suite reopened July 16, after cultures of the environment were negative.
6. Instituting ultra-violet light disinfection throughout the operating rooms as part of a general disinfection schedule.
7. Ensuring that future installation of plumbing in the facility does not create unused branches in the plumbing system in order to prevent stagnation and microbial contamination of tap water.
8. Using an even stronger disinfecting process that is more effective against this specific organism. All operating rooms were previously disinfected by a standard EPA approved product; however, the product now being used is tuberculocidal.

9. Installing a point of use bacteriologic filter for the ice machine once it is returned to service. Continuing a cleaning disinfection schedule of the ice machine in accordance with manufacturer recommendations.
10. Requesting an independent analysis of the cardiopulmonary perfusion machine. The result of that analysis is that it is unlikely that the equipment allowed tap water to contact patients; nonetheless, the hospital will not return it to use.
11. Devising more stringent internal procedures for cleaning the operating room. For example, covering the OR table -- including preparation for emergency surgery - is done on the day of the surgery and assuring that no operating room bed coverings are present while cleaning is performed.
12. Eliminating use of tap water contact with medical equipment and supplies. GHS does adhere to evidence-based practice, recommendations of regulatory agencies, guidelines from professional societies, as well as manufacturer recommendations for equipment used in the operating room. Prior to this outbreak, and depending upon information from the above sources, the equipment and its purpose, non-sterile water may have come in contact with equipment in the OR when use of sterile water was not required. However, DHEC has advised GHS that exposure to *M. abscessus* may best be avoided by preventing any possible tap water contact with medical equipment and supplies.
13. Continuing to ensure that medications and flushes given during surgery are stored in areas that do not have a water source and, when utilized in the OR, preparation and handling should be done away from any source of tap water or ice.
14. Continuing to emphasize meticulous adherence to infection prevention methods by staff in the operating rooms for the prevention of surgical site infections.

GHS plans to continue working with experts including DHEC and CDC on this investigation. Clinical isolates are being submitted to CDC for molecular analysis and comparison of culture results. GHS plans to continue heightened surveillance for further cases for at least 4 months.

Patient / Family Communication

Communication with individual patients about the situation has been an ongoing process. Each time a GHS surgeon suspected a patient of developing an infection, it was communicated to the patient. The surgeon also discussed culture results and treatment. Physicians are prohibited from discussing a patient's condition with other patients due to privacy laws. However, patients were informed of the infection outbreak, once that outbreak was confirmed. We personally reached out to each of the affected patients or families in order to share information regarding the situation, either by face-to-face conversations or phone calls. Each patient / family we met with was given a card with the name and phone number for someone they could call to request additional information. Our staff continue to support and respond to patient needs.

In addition, although the investigation had not yet provided conclusions, it was decided, out of an abundance of caution, that GHS would notify patients who were believed to be at risk for developing this infection, based on the investigation at that time. A letter was written to make these patients aware of the situation and to ask them to notify their surgeon should they develop signs of infection. That letter was sent to close to 200 patients on whom specific cardiopulmonary surgical equipment had been used, via regular and certified mail.

Even though the overwhelming majority of surgical patients treated at Greenville Memorial have not been affected by this rare mycobacterial infection, because of our commitment to transparency we thought it was important to notify the community about the infection out of extreme precaution to ensure their safety and to alert them about possible symptoms.

We regret that any patient within our care could possibly be affected by this situation. Our thoughts are with those involved. Our ongoing priority is continued safe and effective care for the patients who allow us the privilege of caring for them.

United States
Environmental Protection
Agency

Office of Science and Technology
Office Of Water
Washington DC, 20460

EPA-822-F-02-002
March 2002

EPA MYCOBACTERIA: DRINKING WATER FACT SHEET

GENERAL INFORMATION

- *Mycobacteria* belong to the
  - Order Actinomycetales,
  - Family Mycobacteriaceae, and
  - Genus Mycobacterium.

- There are approximately 90 recognized species of *Mycobacteria*, over 20 of which are known to cause disease in humans.

- Non-tuberculosis mycobacteria (NTM) have been identified in numerous environmental sources, including water.

- There has been recent interest in the NTM species, due to their ability to cause disease in humans and animals after environmental exposures.

Characteristics and Classification:

- *Mycobacteria* are rod-shaped bacteria which require oxygen for growth. Each species has an acid-fast staining property during some stage of its growth cycle.

- Mycobacterium have been referred to as the 'ducks of the microbial world' due to their thick, waxy, outer coating which enables them to thrive in aquatic environments.

- The various species of Mycobacteria are classified based on their growth rates in culture into the following three categories: slow growers, rapid growers and those not yet cultivated.

ENVIRONMENTAL OCCURRENCE

- NTM have been found to be ubiquitous in the environment.

- NTM species have been isolated from numerous water sources, including waste water, surface water, recreational water, ground water and tap water.

- Piped water supplies are readily colonized by mycobacteria. Biofilms may serve as a reservoir for these opportunistic pathogens.

- Few studies are available which quantify the concentrations of NTM in water. Some reports indicate that NTM have been recovered in 11% to 38% of raw water samples at concentrations of <0.1 to 48 organisms per milliliter of water.

HEALTH EFFECTS IN HUMANS

Transmission to Humans:

- NTM are not thought to be transmitted by the human to human route, but are instead thought to be transmitted from environmental sources.

- Exposure pathways of potential concern include ingestion, inhalation and entry of organisms through abraded skin.

Symptoms:

- The clinical symptoms seen following infection with NTM depend greatly on the mycobacterial species.

- Common clinical syndromes include:
  - Pulmonary infection
  - Infection of the lymph nodes
  - Ear infection
  - Skin & soft tissue infection
  - Catheter-associated infection
  - Whole Body (e.g., blood) ifection

- In general, symptoms seen in children are similar to those reported in adults. Pulmonary disease is relatively rare in children. The most common form of clinically significant NTM infection in children is infection of the lymph nodes in the neck.

Treatment:

- Treatment of NTM infection depends on the location and extent of disease involvement, status of the host's immune system, and the mycobacterial species.
  - Treatment of pulmonary and whole body infections most often requires a multidrug regimen.
  - Treatment for cutaneous lesions may include surgical removal or drug therapy. Often, cutaneous lesions will disappear without requiring treatment.

Disease Occurrence and Outbreaks:

- NTM diseases are not reportable, therefore, information regarding the occurrence of disease outbreaks is likely to be underestimated. However, human infections due to NTM appear to be increasing at a significant rate across the United States.

- CDC estimates that NTM diseases (non-AIDS related) occur in 1.8 out of 100,000 individuals per year in the U.S., of which approximately 72% are attributable to *M. avium* complex (MAC).

- It has been estimated that in the U.S., 25% to 50% of individuals with AIDS will develop NTM diseases, primarily attributable to MAC. The recent use of highly active anti-retro viral therapy (HAART) in AIDS patients suggests a decrease in the risk and rate of NTM infections in these individuals.

- Waterborne NTM have been associated with hospital (nosocomial) outbreaks worldwide. These disease outbreaks usually involve sternal wound infections, plastic surgery wound infections or postinjection abscesses. Mycobacterial infections in patients undergoing dialysis treatment have also been reported.

- Although not reported frequently, some outbreaks of mycobacterial infection have been reported after exposures in public swimming areas.

- Some false outbreaks have been reported as a result of contaminated sampling equipment or water supplies used for diagnostic procedures. Therefore, it is important that precautions be taken when performing diagnostic tests in order to lessen the chance of false-positive test results.

HEALTH EFFECTS IN ANIMALS

- Several of the NTM species are known to cause disease in animals. These include MAC, *M. marinum*, *M. ulcerans*, *M. paratuberculosis*, *M. simiae*, *M. fortuitum* and *M. smegmatis*.
- Symptoms seen following infection depend on the host organism and the species of NTM.
- *M. paratuberculosis* is the causative agent of Johne's disease; a slow, progressive infection of the intestine which occur mainly in cattle, sheep and goats.
- *M. marinum* is an important cause of death and economic loss in fish populations.
- *M. fortuitum* and *M. smegmatis* are known to produce mastitis in sheep and cattle and skin and soft tissue disease in domestic house cats.
- Destruction or isolation of infected animals is the most common form of treatment, however, drug therapy has been successful in some cases.

RISK FACTORS

- The general population (healthy individuals) is fairly resistant to infection.
- Certain individuals are at increased risk for developing NTM associated diseases due to the presence of predisposing factors, including:
  - traumatic breaches of the skin
  - pre-existing pulmonary disease or damage
  - lung architectural defects
  - bronchiectasis
  - generalized congenital and acquired immunosuppressive disorders (e.g., HIV)

ANALYTICAL METHODS

- The most common method for the identification of mycobacterial species in water samples is through culture isolation. The bacterial culture is evaluated for morphology, growth rates and other biochemical parameters in order to determine the species.
- Several other methods have been developed for the detection of mycobacteria in samples, including:
  - Polymerase chain reaction (PCR)
  - Radiometric methods (BACTEC)
  - GC/MS
  - Nucleic acid probes
- Although promising, these methods only provide qualitative information regarding the presence of mycobacteria in water and do not provide a measure of concentration.
- When collecting samples for use in culture isolation, a decontamination step is necessary to kill the other bacteria and fungi present in the water. This is because there is a large problem of contamination of samples due to the presence of non-mycobacterial bacteria which are capable of growing at faster rates than the species of interest. Acids, alkalis and detergents are often used during the decontamination process since mycobacteria are generally more resistant to these chemicals than are other bacteria.

WATER TREATMENT

- In general, two mechanisms can be used to eliminate microbes from drinking water: removal or disinfection.
- Removal treatments such as filtration, sedimentation, coagulation, flocculation and adsorption are primarily physical operations that remove bacteria from the water.
- Disinfection treatment technologies may kill bacteria using chemicals such as chlorine, ozone, bromine, iodine or hydrogen peroxide which are added to the water, or may inactivate microbes via UV radiation.
- NTM are relatively resistant to standard water disinfection procedures and, therefore, can occur in potable water.
- Overall, there is little information available regarding the effectiveness of various disinfection treatments on mycobacterial species in water. However, EPA is actively studying methods to reduce the occurrence of *Mycobacteria* in drinking water and will update this fact sheet when better information becomes available.

REGULATORY INFORMATION

- EPA has established a Maximum Contaminant Level Goal (MCLG) of zero organisms (bacteria and viruses), including mycobacteria, for drinking water. An MCLG is a non-enforceable guideline based solely on an evaluation of possible health risks, taking into consideration a margin for public safety.

ADDITIONAL INFORMATION

- EPA has established the Safe Drinking Water Hotline, a toll-free number for further information on drinking water quality, treatment technologies, and for obtaining Health Advisories or other regulatory information.
- Safe Drinking Water Hotline:
  800-426-4791
  9:00 a.m. - 5:30 p.m. (Eastern Time)
  Monday-Friday (excluding holidays). Your state or county health officials or experts in your state's Department of Environmental Protection or Natural Resources may also be of assistance.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices: FDA Safety Communication

Date Issued: October 15, 2015

Audiences:

- Health Care Providers who use heater-cooler devices
- Hospital staff who are responsible for operating and maintaining devices
- Infection Control Practitioners
- Infectious Disease Specialists
- Surgeons
- Perfusionists
- Operating Room Managers, Directors and Staff
- Risk Managers

Medical Specialties: Cardiothoracic Surgeons, Cardiovascular Surgeons, Orthopedic Surgeons, Neurosurgeons, General Surgeons, Anesthesiologists, Infection Control, Infectious Disease Physicians, Intensive Care Physicians

Product: All heater-cooler devices. Heater-cooler devices provide heated and/or cooled water to 1) oxygenator heat exchangers, 2) cardioplegia (paralysis of the heart) heat exchangers, and/or 3) warming/cooling blankets.

Purpose:
The FDA wants to heighten awareness about infections associated with heater-cooler devices and steps health care providers and health facilities can take to mitigate risks to patients.

Summary of Problem and Scope:
Heater-cooler devices are used during cardiothoracic surgeries, as well as other medical and surgical procedures to warm or cool a patient to optimize medical care and improve patient outcomes. Heater-cooler devices include water tanks that provide temperature-controlled water to external heat exchangers or warming/cooling blankets through closed circuits. Although the water in the circuits does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device or transmit bacteria through the air (aerosolize) through the device's exhaust vent into the environment and to the patient.

Through the FDA's analysis of adverse event reports, the medical literature, and information from national and international public health agencies, we are aware that the use of heater-cooler devices has been associated with Nontuberculous Mycobacteria (NTM) infections, primarily in patients undergoing cardiothoracic surgical procedures. NTM organisms are widespread in nature and can be found in soil and water, including tap water sources. They are typically not harmful, but in rare cases may cause infections in very ill patients and/or in individuals with compromised immune systems.

Between January 2010 and August 2015, the FDA received 32 Medical Device Reports (MDRs) of patient infections associated with heater-cooler devices or bacterial heater-cooler device contamination. Twenty-five of these MDRs were reported to the FDA in 2015. Some reports describe NTM infections related to cardiothoracic surgeries, but other reports do not specify the procedure the patient was undergoing. Eight reports were related to 3 events describing patient infections occurring in U.S. health care facilities. The remaining 24 reports involved health care facilities outside the United States, most of these in Western Europe. In some cases, patients presented with infections several months to years after their surgical procedures. It is important to note that half of the 32 reports submitted to the FDA describe bacterial contamination of the heater-cooler device without known patient involvement or infection. The FDA is not aware of NTM infections acquired by hospital staff.

It is possible that some cases have not been reported to the FDA. It is challenging for a health care facility, health care provider, manufacturer, or patient to recognize that infections, particularly NTM infections, may be associated with the use of or exposure to a particular medical device. The FDA continues to evaluate reports through follow up with health care facilities and manufacturers to determine which factors may have contributed to the reported events.

Recommendations for Health Care Facilities and Staff
In addition to following standard precautions, the FDA recommends that facilities and staff using heater-cooler devices consider implementing the following measures to reduce risk to patients:

- Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer's device labeling. Ensure you have the most current version of the manufacturers' instructions for use readily available to promote adherence.
- Do not use tap water to rinse, fill, refill or top-off water tanks since this may introduce NTM organisms. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. When making ice needed for patient cooling during surgical procedures use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. Deionized water and sterile water created through reverse osmosis is not recommended because it may promote corrosion of the metal components of the system.
- Direct the heater-cooler's vent exhaust away from the surgical field to mitigate the risk of aerosolizing heater-cooler tank water into the sterile field and exposing the patient.
- Establish regular cleaning, disinfection and maintenance schedules for heater-cooler devices according to the manufacturers' instructions to minimize the risk of bacterial growth and subsequent patient infection.
- Develop and follow a comprehensive quality control program for maintenance, cleaning, and disinfection of heater-cooler devices. Your program may include written procedures for monitoring adherence to the program and documenting set up, cleaning, and disinfection processes before and after use.
- Immediately remove from service heater-cooler devices that show discoloration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth. Consult your hospital infection control officials to perform the appropriate follow up measures and report events of device contamination to the manufacturer.
- Consider performing environmental, air, and water sampling and monitoring if heater-cooler contamination is suspected. Environmental monitoring requires specialized expertise and equipment to collect and process samples, which may not be feasible in all facilities.
- Health care facilities should follow their internal procedures for notifying and culturing patients if they suspect infection associated with heater-cooler devices.
- Submit a report to the manufacturer and to the FDA **via MedWatch (/Safety/MedWatch/HowToReport/ucm2007306.htm)**, as described below, if you suspect heater-cooler devices have led to patient infections.

FDA Activities:

The FDA is actively engaged with stakeholder groups to better understand the causes and risk factors for transmission of microbial agents associated with these devices and to develop strategies to minimize patient exposure. Our ongoing activities include:

- Working with health care facilities and professional medical societies to understand their experiences with heater-cooler devices.
- Evaluating information about documented and potential infections from multiple sources, including **medical device adverse event reports (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** submitted to the FDA, the medical literature, international public health agencies and federal partners.
- Collaborating with medical device manufacturers to review their existing cleaning and disinfection protocols provided in the instructions for use for currently marketed devices.

FDA continues to actively monitor this situation and will provide updates as appropriate.

Reporting Problems to the FDA:
Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of medical devices. Health care providers should submit voluntary reports of infection transmission associated with heater-cooler devices or reports describing difficulty following the manufacturers' instructions for use to the agency via the **Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** process. If a health care provider suspects bacterial contamination of the heater-cooler device following use, we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Additional Resources:
American Thoracic Society. **An Official ATS/IDSA Statement: Diagnosis, Treatment and Prevention of Nontuberculous Mycobacterial Diseases: (https://www.thoracic.org/statements/resources/mtpi/nontuberculous-mycobacterial-diseases.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** 2007.

European Centre for Disease Prevention and Control (ECDC). **Rapid Risk Assessment: Invasive cardiovascular infection by *Mycobacterium chimaera* potentially associated with heater-cooler units used during cardiac surgery:** **(http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** April 30, 2015.

References:

Kohler, P.; Kuster, SP.; Bloemberg, G. **Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated *Mycobacterium chimaera* infections subsequent to open heart surgery.** **(http://eurheartj.oxfordjournals.org/content/ehj/early/2015/07/16/eurheartj.ehv342.full.pdf)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** Eur Heart J. 2015 Jul 17. *(Abstract)*

Sax, H.; Bloemberg, G.; Hasse, B.; et al. **Prolonged outbreak of *Mycobacterium chimaera* infection after open chest heart surgery.** **(http://cid.oxfordjournals.org/content/early/2015/03/11/cid.civ198.abstract)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** Clin Infect Dis. 2015 Mar 11. *(Abstract)*

Falkinham JO.; Pruden A.; Edwards M. **Opportunistic Premise Plumbing Pathogens: Increasingly Important Pathogens in Drinking Water. (http://www.mdpi.com/2076-0817/4/2/373/pdf)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** Pathogens 2015;4(2):373-386.

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

Preventing Tubing and Luer Misconnections

(/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)

Re: DHEC PHI: Outbreak #14-096: Final Notification of an Outbreak of Non-tuberculous Mycobacteria surgical site infections in an Upstate hospital

Crist, Matthew

[redacted]

Upstate_ORT <upstate_ort@dhec.sc.gov>; CO_ORT_LHF <co_ort_lhf@dhec.sc.gov>;

DO NOT FORWARD THIS REPORT OUTSIDE DHEC

This is an updated report of an evolving public health investigation. Information contained herein may be preliminary and is subject to change. Please direct questions regarding this investigation to the incident and area commanders.

- Incident Commander: Kate Habicht
- Area Commander: Matthew Crist
- Hospital Contact: Beth Smith, Jennifer Maculosa, William Kelly, and Connie Steed
- CDC contact: Alice Guh and Matt Arduino

Outbreak number: 14-096 Final Notification

Initial Notification: Wednesday, May 23, 2014

New information: A conference call was held between DADE, CDC, and GMH. The environmental interventions were summarized by GMH. In addition to the water filters they have installed in the ORs system wide they are also planning to install filters in high risk areas such as the bone marrow transplant unit, hematology/oncology unit, and neonatal intensive care unit. They are also purchasing a ClO2 treatement system to target biofilms in the water system at GMH.

The PFGE results were also discussed as below with CDC providing additional insight in addressing questions from GMH. As there have now been no additional cases diagnosed in over 12 weeks, this investigation is now closed.

1. Situation Summary

- Earliest Onset: May 2013
- Date of Notification: May 23, 2014
- Case Counts: 18: 18 confirmed (M abscessus positive cultures)
- Greenville Memorial Hospital has had 18 cases of surgical site infections (SSI) from Mycobacterium abscessus. 14 cases have occurred among patients undergoing [redacted] surgery. 2 underwent [redacted] 1 had multiple surgeries to treat [redacted] and 1 had [redacted] Thirteen of the fourteen [redacted] cases occurred in OR [redacted] compared to 1 in the other 2 [redacted] surgery ORs. Four patients [redacted] The dates of surgery have ranged from 02/2013 to 05/2014 and culture dates have ranged from 05/2013 to 08/2014.

2. Case Definition.

Suspect: A surgical patient at Greenville Memorial Hospital who develops a surgical site infection post-operatively with positive acid fast bacteria cultures.

Confirmed: A surgical patient at Greenville Memorial Hospital who develops a surgical site infection post-operatively with cultures positive for M. abscessus.

3. Investigative Activities

The hospital has aggressively explored any potential sources of tap water contamination in the OR. The only sources of non-sterile water in the OR identified was the ice used in the [redacted] solution cooling machine (this would only be used in the [redacted] surgeries), and water in the closed circuits of the heater/cooler machine used to regulate patient body temperature(also only used for the [redacted] cases). Environmental samples have been sent to CDC and multiple cultures grew AFB and the samples from scrub sinks have speciated M abscessus. Clinical isolates were sent to CDC for PFGE testing for molecular typing and comparison to environmental isolates. The isolates from [redacted] surgery patients were either indistinguishable or closely related the environmental isolate collected from the scrub sink outside of the [redacted] ORs. The facility has been communicating directly with CDC as they have submitted environmental cultures directly to CDC. Environmental isolates initially sent to a lab in Tyler, TX were sent back to GMH, and sent to CDC for further molecular analysis and showed similar results. The 2 clinical isolates least closely related to any of the other isolates were the 2 submitted from patients with [redacted] surgery rather than [redacted] surgery.

Engineering has reviewed plumbing in the OR and performed physical inspection in the C-core where multiple areas were identified with dead end piping where stagnant water was likely present and could provide an area for amplification of Non-Tuberculous Mycobacteria. A culture of the piping removed has now grown M. abscessus. This isolate will also be sent to CDC. They have installed point of use filters in all of the OR scrub sinks and the sinks in the decontamination areas. Flushing of scrub sinks and decontamination sinks was performed daily until the filters could be installed as this has been shown to decrease colony counts in tap water. Greenville Health System is planning to inspect for dead end piping and install filters in scrub sinks for the OR and other procedural areas throughout all the hospitals in GHS.

The facility began freezing sterile water and using it in the [redacted] machine and have begun cleaning the machine weekly rather than every other week as it was noted that the majority of cases had undergone surgery in the second week following cleaning of the machine. The heater/cooler machine used to induce hypothermia was inspected by ECRI and no defects were found. An alternate type of machine that does not require tap water is currently being used. Observations have been performed in the OR which did not reveal an obvious source of contamination. IP staff has also investigated potential exposures following surgery in their post-operative course. A new ice machine has been installed with a filter on the water line.

A site visit was conducted 6/11 by DADE staff. The visit included meeting with the hospital epidemiologist, IP staff, and OR clinical and administrative staff. A tour was taken of the OR suite with particular attention to OR[redacted] The [redacted] machine and heater/cooler machine used to regulate patient body temperature were examined. A tour was also taken of the central processing areas where high-level disinfection of the surgical instruments is performed.

Prior to the site visit IP staff identified a nearby water closet where the heater/cooler machine was filled with tap water, where PPE such as surgical hats, boufants, and shoe covers were stored. These materials were all removed and OR staff instructed that no PPE (or other clean storage materials) be stored near any water source. The IP staff also identified that the operating table was being dressed after the last case of the day but before a terminal cleaning was performed and have since eliminated that process.

The facility has disclosed the outbreak to the cases and their families. The facility made the decision to perform contact outreach to [redacted] surgery patients going back to August 2013. These approximately 150 patients were notified through a letter. A press release was also conducted and a Q and A session was held for the media with weekly follow up press releases. They also sent email communications to all hospital staff and a separate email to medical staff.

The hospital temporarily closed the operating room where the majority of the cases have had surgery, beginning 6/6 through 7/16. The OR staff discarded all disposable materials in the room. On 6/11 the facility also instituted UV

light treatment of the 2 other rooms being used for [redacted] surgery at 5:00 AM prior to the first case of the day.

5/21 Ice machine was no longer used to supply ice to [redacted] machine- heater/cooler machine was used to bypass need for ice in the [redacted] machine.
6/6 OR [redacted] was closed (Closed through 7/15/14). [redacted] surgeries shifted to OR 31 and 32.
6/6 Began using ice in [redacted] machine but began using frozen distilled water rather than frozen tap water. Stopped using heater/cooler machine used in [redacted] cases.
6/10 Water closet cleaned out and no longer used to store clean materials.
6/11 Began performing UV light treatment of ORs 31 and 32 at 5:00 AM before the first case of the day and planned to continue this practice daily.
6/16 (weeek of) began cleaning the [redacted] machine once a week
6/23 (week of) began flushing OR and decon sinks each morning
6/27 Dead space piping cut off and capped
6/27 Began requiring Avagard use after first scrub of the day with soap and water
mid-July water filters installed

4. Assessment

This Mycobacterium abscesses SSI outbreak is likely resulting from tap water contamination of the surgical field. Environmental cultures grew M abscesses in the hospital water, largely from the scrub sinks, and high colony counts likely indicate amplification within the facility. The depth of the infections would suggest that the infections are occuring intra-operatively rather than post-operatively. Thus far all case surgical dates have been prior to the initiation of the investigation and infection control measures. Due to the prolonged incubation period there is a delay in being able to assess the impact of interventions. Dead spaces in plumbing could have potentially lead to amplication of NTM within the facility. This is supported by the high colony counts of NTM in water samples at the points of use compared to the municipal water samples. PFGE results from CDC have indicated that the isolates from the scrub sink outside of OR [redacted] and the heater cooler machine which was filled in the mop closet are closely related to the clinical isolates from the [redacted] cases.

5. Recommended Actions

Incident commander will maintain and update the linelist.
Area commander will facilitate a call between DHEC, CDC, and GMH to discuss PFGE results when testing completed.
Area commander will continue to follow up with facility, consult with CDC, provide consultation and make recommendations.

Matt Crist

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Class 2 Device Recall STOCKERT HEATERCOOLER SYSTEM 3T

[22]

Date Posted	July 15, 2015
Recall Status[1]	Open
Recall Number	Z-2080-2015
Recall Event ID	71593[23]
510(K)Number	K052601[24]
Product Classification	Controller, temperature, cardiopulmonary bypass[25] - **Product Code** DWC[26]
Product	Sorin Stockert Heater-Cooler 3T, 120 V / 60 Hz Temperature control for extracorporeal perfusion of durations up to 6 hours.
Code Information	Product code 16-02-85 Serial number 16S10958-16S15634
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004-3503
For Additional Information Contact	Cheri Voorhees 303-467-6306
Manufacturer Reason for Recall	Potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per Instructions for Use.
FDA Determined Cause [2]	Error in labeling
Action	Sorin Group issued a Field Safety Notice dated June 15, 2015, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to review their inventory and identify any affected devices. For each unit customers were instructed to determine if the device has been maintained according to the Instructions for Use. If yes, customers should strictly adhere to the new Instructions for Use. Customers were also provide with a Response form to confirm they received, read and understood the Field Notice. Customers were instructed to return the completed form to assist in monitoring the effectiveness of the communication. For technical support customers should call 1-800-221-7943, ext 6355. For questions regarding this recall call 303-467-6306.
Quantity in Commerce	1755
Distribution	Worldwide Distribution - US (nationwide) and Internationally to AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SK, AE, AR, AU, AZ, BD, BH, BR, BY, CA, CL, CN, CO, CR, DZ, EC, EG, ET, GE, GY, HK, ID, IL, IN, IQ, IR, JO, JP, KR, KW, KZ, LB, LK, LY, MA, MN, MU, MX, MY, NG, NP, NZ, OM, PA, PE, PH, PK, PR, PS, QA, RE, RU, SA, SG, SV, SY, TH, TN, TR, TT, TW,

UA, VN, ZA.

Total Product Life Cycle TPLC Device Report[27]

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[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = DWC and Original Applicant = SORIN GROUP DEUTSCHLAND GMBH[29]

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Page Last Updated: 06/13/2016

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

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FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices

Affected Devices:	Sorin Group perfusion system – Heater Cooler 1T and Heater Cooler 3T devices (refer to Attachment 1 for affected catalog and serial numbers)
Date:	03. June 2015
Reference No:	9611109-06/03/15-002-C
Attention:	Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices
Reason:	Sorin has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site. Sorin Group is providing this notification to: (1) remind you of the importance of following the company's disinfection and maintenance procedures; (2) inform you that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and (3) provide you with updated Instructions for Use regarding disinfection and maintenance procedures.

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Dear Valued Customer:

The purpose of this letter is to advise you that Sorin Group Deutschland GmbH ("Sorin") is executing a voluntary field safety correction for the Heater Cooler 1T and the Heater Cooler 3T devices ("heater cooler devices"). This field safety notice describes below, immediate action to be taken by you.

- If your heater cooler device has been strictly maintained according to the Instructions for Use, please strictly adhere to the new Instructions for Use provided in **Attachment 1** of this letter.
- If your heater cooler device has **not** been strictly maintained according to the Instructions for Use, please perform the steps included in the *Immediate Customer Action* section of this letter.

Description of Issue

Sorin has become aware of cases of non-tuberculous mycobacteria endocarditis or deep infection following cardiac surgery during which the heater cooler device was used. There is a risk that surgical patients may experience invasive cardiovascular infection, including endocarditis, or other deep-surgical-site infections due to non-tuberculous mycobacteria, such as Mycobacterium chimaera. Because the symptoms may be slow to manifest, it is possible that many months may pass after completion of the surgical procedure before a surgical patient presents with an infection. In some cases, it is possible that infection could lead to death. Sorin's investigation into these cases is ongoing. To date, the investigation has not determined a causal connection between the heater cooler device and these cases. In some instances there has been a suggestion of such a link; however, infection following cardiac surgical procedures can be caused by numerous, other sources.

The heater cooler device which is provided non-sterile may develop highly contaminated water due to the failure to follow the Instructions for Use for water maintenance and water circuit disinfection. If contaminated water is used in the device **and** the user performs inadequate maintenance and/or fails to strictly adhere to the user instructions for cleaning of the heater cooler device, the device could become a source for contaminating the surgical environment. This condition can occur where there has been a build-up of biofilm within the water circuit of the device. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site.

Contamination of heater cooler units with other waterborne pathogens, like *Mycobacterium abscessus* and non-fermenting gram-negative bacteria, has also been detected in the water of certain heater cooler units. However, no cases of patient infection have been determined to be caused by heater cooler devices. Further, Sorin's investigations into the potential association of heater cooler units with infections by *Mycobacterium chimaera* and other pathogens are ongoing.

If there is a need for further communication based on the investigation results, we will provide you the information.

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Immediate Customer Action

- ✓ Sorin reminds its customers using heater cooler devices about the importance of adhering to correct maintenance of the device at all times and, in particular, to assure that the cleanliness of the water is maintained. **Attachment 1** of this notification includes the new Instructions for Use for the cleaning and disinfection of the Sorin heater cooler devices. Please discard the existing IFU and follow this new IFU which includes updated cleaning and disinfection instructions.
    - o Assure that your team understands Mycobacteria and the potential contamination risks for cardiac surgical procedures, for example, that Mycobacterium is widely distributed in the ecosystem including chlorinated drinking water from the tap, it is inherently resistant to chemical disinfectants and antibiotics, and under the right conditions, it has a propensity to form biofilm and it can also be aerosolized.

- ✓ Healthcare providers involved in the care of patients who have undergone open heart surgery should be vigilant for cases of endocarditis or other cardiovascular infection of unidentified origin with specific testing for slow-growing non-tuberculous Mycobacteria such as *Mycobacterium chimaera* performed as indicated.

- ✓ Verify that this letter has reached your local team and that the recommended monitoring has been considered for your cardiac surgery operating rooms and area. This includes the monitoring of the area water not only for typical microorganisms, but also for slow growing non-tuberculosis Mycobacteria that requires special monitoring practices.

Actions to be taken by the user on the device

- ✓ Review your inventory and identify any heater cooler devices per the attached list, **Attachment 2**.

- ✓ For each unit, determine if the device has been maintained according to the Instructions for Use. If yes, strictly adhere to the new Instructions for Use provided in **Attachment 1** of this notification.

  Note: It is recommended to implement a microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous Mycobacteria on a monthly basis (Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria should not be detectable in 100ml). The water in the device should meet microbiological drinking-water quality according to national drinking-water standards.

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✓ If the device has not been maintained according to the Instructions for Use, follow instructions in the table below:
Note: Please consult your Infection Control Manager for executing the following steps.

Step 1 / Submission of Test Sample
✓ Take two 100ml or greater water samples from one of the drain valves at the back of the device **prior to** the disinfection step: (1) for heterotrophic plate count measurement; and (2) for non-tuberculous mycobacteria analysis.
✓ Submit samples (1 & 2) to a microbiological lab for heterotrophic plate count measurement of the water and to determine if non-tuberculous mycobacteria are detectable.
✓ Perform disinfection of the water circuit of the heater cooler device(s) according to the new instructions for use provided in **Attachment 1** of this notification.
✓ Replace any accessories and products that are used in conjunction with the heater cooler device which may be potentially contaminated (e.g. tubing and connectors, graduated beaker, warming blanket) by new or re-processed parts.
✓ While awaiting test results from the microbiological lab, operate the heater cooler device outside of the operating room, if structurally possible, and proceed to **Step 2.** Note: For technical support regarding the installation outside the OR (max. distance, routing) please contact your local service representative.
✓ If it is not possible to move the heater cooler device outside the operating room, take the device out of service or proceed to **Step 3.**
Step 2 / Interim Process (If heater cooler device can be operated outside the operating room)
✓ Perform the water maintenance and disinfection of the water circuit of the device(s) according to the new instructions for use provided in **Attachment 1** of this notification.
✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior disinfection.
✓ When you receive the results from the lab go to **Step 4**

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Step 3 / Heater Cooler operated in operating room
✓ Place the heater cooler in a way that the flow conditions of the surgical side are not disturbed by the heater cooler device fans. o Maintain maximum distance from surgical field; o Position heater cooler such that the fan exhausts of the device are directed away from the surgical field; o Position heater cooler fan exhausts close to the suction exhaust (outtake) of the operating room. ✓ The water in the tank must be changed **every day**. ✓ In order to prevent microbial growth and to avoid biofilm build-up, add medical grade 3% hydrogen peroxide solution to the tank contents (follow instructions provided in the new IFU, which direct 150 ml for the heater cooler 3T or 50 ml for the heater cooler 1T). ✓ Perform a **weekly** disinfection as described in the new IFU to kill the waterborne pathogens such as non-tuberculous mycobacteria. ✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior to disinfection. ✓ Take microbiological air samples for non-tuberculous mycobacteria in the operating room when the heater cooler is running on a bi-weekly basis. ✓ When you receive the results from the lab go to **Step 4**
Step 4 / Review of Lab Analysis and Action
✓ If the microbial counts are within the specified limits (meet microbiological drinking-water quality and Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria are not detected in 100ml), the device can be placed back into the operating room. Continue to use and maintain the device according to the new IFU, **Attachment 1** ✓ Implement a microbiological monitoring of the water quality, including monitoring for non-tuberculous Mycobacteria on a monthly basis. ✓ If you find microbial counts in the water are greater than the limits specified above, contact your infection control manager to determine appropriate actions and immediately contact your service representative for support. ✓ If non-tuberculous mycobacteria are found in the air of the operating room, when the heater cooler is operated, remove the heater cooler from service and immediately contact your service representative for support. o For emergency surgeries please consult your infection control manager to determine appropriate actions.

For technical support please contact your local service representative.

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Please complete and return the attached Confirmation Form (see **Attachment 3**) by fax to «Number» or by email to «E-mail Address».

Transmission of this Field Safety Notice

Please assure within your organization that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them and also inform the below mentioned contact person.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

For questions regarding this Field Safety Notice, please contact Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agencies who are aware of these actions.

Thank you for your cooperation in this matter. Sorin Group is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

i.V. Christian Peis
Director Quality Assurance

Enclosures:

Attachment 1: New Instructions for Use

Attachment 2: Affected Product List

Attachment 3: Customer Response Form

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Attachment 2
Affected Product List

FIELD SAFETY NOTICE
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-50	Heater-cooler 1T, 230V	16S00808 - 16S02268
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please refer to Attachment 3 for affected Systems at your site.

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Attachment 3 - Customer Response Form

FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

According to our records you have the following affected products:

<Fill in the customer related codes and serial numbers only- Use Attachment 4_Product trace list (Excel File)>

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form to:

Sorin Site/ Distributor Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: << Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>

Section 1 - Please Complete:

1. We HAVE reviewed and understand the attached Field Safety Notice ☐ yes ☐ no
2. We DO NOT understand the attached Field Safety Notice and request more information ☐ yes ☐ no
3. WE HAVE discarded the old instruction for use ☐ yes ☐ no

Please contact us:

Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

Customer Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: << Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>
Submitted by .....
Signature .....
Date ...../...../.....

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Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

August 6, 2015

Customer Name
Address
City, State Zip

Subject: Update to the Field Safety Notice for Heater-Cooler System 3T

Dear Valued Customer:

You recently received a Field Safety Notice from Sorin Group regarding the Heater-Cooler System 3T (Reference # 9611109-06/03/15-002-C, dated June 15, 2015).

The purpose of this Field Safety Notice was to:

- Remind you of the importance of following disinfection and maintenance procedures.
- Inform you that if your Heater-Cooler 3T is not properly maintained and it becomes contaminated, there is a possibility that bacteria can be aerosolized when the device is operated serving as a potential source for contamination.
- Provide you with updated instructions for use regarding disinfection and maintenance procedures.

This letter is to inform you that the Heater-Cooler System 3T Operating Instructions provided with the Field Safety Notice dated June 15, 2015 were intended for distribution to English speaking countries in the European Union (EU) rather than for the United States.

Although the EU and USA cleaning and disinfection procedures are equivalent, the EU procedure includes additional chemicals only available in other countries. Additionally, the USA Operating Instructions include information specific to the U.S. such as English units of measure and an Indications for Use statement.

The USA Heater-Cooler System 3T Operating Instructions are attached to this letter.

For your convenience, the USA Heater-Cooler System 3T Operating Instructions are available on the Sorin Group website at www.sorin.com/3t . They can be viewed, saved or printed as you prefer.

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AT THE HEART OF MEDICAL TECHNOLOGY

Customer Actions:

- Please discard all existing Heater-Cooler System 3T Operating Instructions and replace them with the attached USA Heater-Cooler System 3T Operating Instructions.
  Note: The current USA Heater-Cooler System 3T Operating Instructions are CP_IFU_16-XX-XX_USA_014. This identification number is printed at the bottom of each page.
- Follow the actions detailed in the Heater-Cooler System 3T Field Safety Notice dated June 15, 2015.
- Please complete and return the attached Customer Response Form by fax to 303-467-6502 or by email to USFSN@sorin.com.

Contact Information:

Please contact your Sorin Group account representative if you have any questions. If further assistance is required, please contact:

Technical Services hotline at 1-800-221-7943, extension 6355

For your reference, we have also created a list of Frequently Asked Questions, Quick Start Instructions and a 3T Disinfection Video on our website at www.sorin.com/3t .

Sorin Group is committed to providing quality products and services. Thank you for your cooperation in this matter. This information will also be provided to the FDA.

Sincerely,

Christian Peis
Director Quality Assurance

Attachment 1: Affected Products List

Attachment 2: Customer Response Form

Attachment 3: USA Heater-Cooler System 3T Operating Instructions

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 1

Affected Product List

UPDATE TO THE FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please note, all Sorin Heater-Cooler System 3T Devices are affected. Refer to the Customer Response Form for your affected products.

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 2

Customer Response Form

UPDATE TO THE FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C
Including USA Heater-Cooler 3T System Operating Instructions

According to our records you have the following affected products:

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form: By fax to 303-467-6502 or by email to USFSN@sorin.com.

Section 1 - Please Complete this section:

We HAVE reviewed and understand this Field Safety Notice ☐ Yes ☐ No

WE HAVE implemented the proper Operating Instructions ☐ Yes ☐ No

Customer Name: _____
Contact Name: _____
E-mail: _____
Fax No.: _____
Phone Number: _____

Submitted by .....

Signature ..... Date ...../...../.....

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SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

ATTACHMENT 3

USA Heater-Cooler System 3T Operating Instructions

UPDATE TO THE FIELD SAFETY NOTICE

SORIN GROUP
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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Sorin Group Deutschland GmbH 12/29/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

DEC 29, 2015

WARNING LETTER

VIA UNITED PARCEL SERVICE

André-Michel Ballester
Chief Executive Officer
LivaNova (formerly Sorin Group S.p.A.)
Via Benigono Crespi, 17
Milano, 20159
Italy

Dear Mr. Ballester:

The United States Food and Drug Administration (FDA) conducted the following inspections at your facilities:

- Sorin Group Deutschland GmbH, Lindberghstrasse 25, Munchen, 80939, Germany, (Munchen Facility), dated August 24, 2015, through August 27, 2015; and
- Sorin Group USA, Inc., 14401 W. 65th Way, Arvada, Colorado 80004, U.S.A., (Arvada Facility), dated August 24, 2015, through September 1, 2015.

During the inspection at your Munchen facility, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Stockert Heater Cooler 3T thermal regulator devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

These inspections revealed that your firm's devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from Mr. Thierry Dupoux, Vice President, Sorin Group Cardiopulmonary BU, Sorin Group Deutschland GmbH, dated September 15, 2015, concerning our investigator's observations noted on the Form FDA 483s (FDA 483), List of Inspectional Observations, which was issued to your firm's Munchen, Germany facility. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. 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) [Munchen Facility]. For example:

a. Your firm created Design Change Order #8115, dated December 11, 2012, as part of the corrective actions to the FDA Warning Letter dated August 2, 2011, to the Munchen Facility, to address deficiencies in the design change procedures. The change order documents the decisions to change the design input for water quality to add new cleanliness criteria, test the cleaning instructions for use (IFU) to the new input, update the cleaning instructions for use, and validate the new IFU. However:

i. The changed design input is incomplete in that there is no information on how maintaining a cleanliness standard for drinking water applies to the requirement that "biofilm should not grow in the 3T devices". Additionally, there is no information on a water quality standard ensures that the device does not cause waterborne infection; and,

ii. The design validation for the change to the cleaning IFU is inadequate. In the IFU, end users are responsible for conducting the cleaning and disinfection procedure on devices at user facilities. There is no documentation that your firm tested the updated IFU under actual or simulated use conditions to ensure the usability of the cleaning IFU. Your firm has received complaints of patient deaths due to infection from non-tuberculosis mycobacteria (NTM), specifically *mycobacteria chimaera,* since January 2014, where the cause of the infection appeared to be 3T devices colonized with the mycobacteria. Your firm investigated the complaints and determined that the user facilities had not been following the cleaning IFUs, potentially contributing to patient infections.

b. Your firm issued Design Change Orders 9416, 9416-01, 9711, and 9690, corresponding to CAPA 2015-03, and submitted a recall in June, 2015 (#Z-2076/2081-2015), to update the cleaning and disinfection IFU after receiving complaints of patient deaths due to infections caused by the 3T device. As part of this design change, your firm contracted a laboratory to conduct a test on the cleaning procedure in the updated IFU. The resulting test report, dated April 7, 2015, describes the test protocol and results. However, your firm's test report does not demonstrate an adequate verification or validation of the new cleaning IFU because: (reduction) for bacteria, as required by your test procedure. In addition the acceptance criteria do not appear to correspond to the design inputs of drinking water quality, controlling biofilm, or that the device does not cause waterborne infection;

i. The acceptance criteria for the test do not demonstrate that the updated cleaning and disinfection instructions produce a **(b)(4)** level (reduction) for bacteria, as required by your test procedure. In addition the acceptance criteria do not appear to correspond to the design inputs of drinking water quality, controlling biofilm, or that the device does not cause waterborne infection;

ii. Puristeril is not available in the United States, and therefore your firm recommends using Clorox as a substitute in the IFUs. However, the test report does not demonstrate the amounts of Clorox described in the IFU are equivalent to Puristeril;

iii. Two of the challenge bacteria, **(b)(4)** and **(b)(4),** used in the test procedure were not used at a high enough concentration to demonstrate the **(b)(4)** level acceptance criteria;

iv. The exact disinfectant dilution is not clear, because the exact water amounts used were not measured. Water levels were determined by **(b)(4).** No validation for the accuracy of these **(b)(4)** for detecting water levels was documented in the test report;

v. There is no description for how the sampling locations, sampling methods, and machine conditions used represent worst case condition for finding bacteria;

vi. There is no statistical rationale documented in the test report for using testing **(b)(4),** to demonstrate that the cleaning instructions for use will consistently maintain water quality requirements inside 3T devices in the field or clinical setting; and,

vii. There is no documentation that your firm tested the updated IFUs for usability by the end user. Specifically, those responsible for conducting the cleaning and disinfection procedure on devices at user facility.

Your firm's response did not address this deficiency. We note that this is a repeat from a nonconformance noted in the Warning Letter issued to the Munchen facility on August 2, 2011.

2. 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) [Munchen facility]. For example, your firm designed and implemented a new cleaning, drying, and disinfection process using **(b)(4)** at the contract manufacturer, **(b)(4)**, as part of a corrective action. However, the new process was not adequately validated or verified prior to implementation on production units or monitored after implementation. Specifically:

a. Your firm contracted an "efficacy test" at a testing firm, **(b)(4)**, on November 17, 2014, to conduct an in-house validation of the use of the **(b)(4)** disinfection and drying process to eliminate a mycobacterium test strain from 3T devices to validate the new process. However, the efficacy test was not an adequate verification or validation of the disinfection and drying process because:

i. The efficacy test report documented testing to **(b)(4)** mixture; however, the disinfection and drying process **(b)(4)**. There was no documentation of justification for using a different concentration, and therefore the test does not accurately reflect the **(b)(4)** disinfection procedure;

ii. No controls were used in the efficacy test;

iii. Your firm did not provide documentation to describe if a **(b)(4)** was used **(b)(4)**; and

iv. Your firm did not provide documentation for how the bacteria were **(b)(4)**.

b. Your firm conducted further monitoring of manufactured devices after the **(b)(4)** disinfection and drying process was implemented. However, the monitoring was inadequate because the following required information for a cleaning and disinfection monitoring report was not documented:

i. The data for recovery efficiency of bacteria from the 3T devices;

ii. The data for complete bioburden: aerobic bacteria, anaerobic bacteria, spores, fungi, and yeast in the devices prior to disinfection. Only aerobic mesophilic bacteria are noted;

iii. The data for bacteriostasis or fungistasis;

iv. The concentration of **(b)(4)** used in sampling;

v. The time of exposure to the **(b)(4)**; and

vi. Whether **(b)(4)** was performed after **(b)(4)**.

c. Your firm's disinfection and drying procedure and validation protocol, "**(b)(4)** cleaning, disinfection, and drying process designed and implemented by your Munchen facility at the contract manufacturer **(b)(4)**. However, the procedure was not adequately validated to ensure that the process completely dries the device.

For example:

i. The protocol states that the transparent pump tubing **(b)(4)** The protocol did not indicate whether any **(b)(4)** after drying was acceptable; and

ii. The validation did not include key technical parameters required for validation of a disinfection process. For example:

a. The amount of **(b)(4)** at time 0 (start of experiment);

b. Data to provide a rationale for choosing **(b)(4)** dry the tanks and tubing;

c. Quantification of the term "visually dry" and how to measure dryness by a validated method;

d. Documentation of the **(b)(4)**; and

e. Documentation of environmental conditions for temperature and humidity during the **(b)(4)** device prior to sampling.

We reviewed your firm's response and conclude that it is not adequate. Your firm did not evaluate the potential impact of these violations on distributed devices, and take steps to mitigate the risks as needed.

Our inspection also revealed that your firm's devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR), but are not limited to, the following:

3. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17 (Arvada facility). For example:

Your firm's MDR procedure, "Standard Operating Procedure for Medical Device Reporting", **(b)(4)**, Rev. AA, updated on October 15, 2012, has the following deficiencies:

a. The procedure does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, the procedure omits definition of the term "reasonably suggests," found in 803.20(c)(1). The exclusion of this definition for this term from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a);

b. The procedure does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the procedure does not address how your firm will submit all information reasonably known to it for each event;

c. The procedure does not describe how it will address documentation and record-keeping requirements, including:

i. Documentation of adverse event related information maintained as MDR event files'

ii. Information that was evaluated to determine if an event was reportable;

iii. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable; and

iv. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

In addition, we have noticed deficiencies in your firm's (Munchen facility) MDR procedure, **"(b)(4)**, Rev. 003. Specifically, the MDR procedure does not have an effective date.

Please note, the MDR procedures at the Munchen and Arvada facilities include references to submitting MDRs to FDA using the following address: FDA, CDRH, Medical Device Reporting, P. O. Box 3002, Rockville, MD 20847-3002. Please note that effective August 14, 2015, MDRs should be submitted electronically and paper submissions will not be accepted, except under special circumstances, directed by FDA. For more information about electronic reporting, please refer to the eMDR website and the eMDR guidance document.
http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm (http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm)

Our inspection at your Munchen facility also revealed that the Heater Cooler 3T device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have 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). The Heater-Cooler System 3T is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

Specifically, your firm distributed the Heater-Cooler System 3T, cleared under K052601, with modified Instructions for Use (Versions 013 and 014) with respect to the operating, maintaining, cleaning and disinfecting of the device. Some of the modifications found in Versions 013 and 014 include: adding more instruction details, changes to the cleaning/disinfecting process (e.g., chemicals used and amounts used), and expansion to the process to include the entire circuit instead of only the tanks. These are significant labeling changes that can affect the safety or effectiveness of the device, and therefore require a new 510(k) in order to be assured that appropriate testing and validation of the cleaning/disinfecting protocols have taken place.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for the device is described on the Internet at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. (/MedicalDevices/default.htm)

The FDA will evaluate the information that you submit and decide whether your product may be legally marketed.

Our inspections also revealed that your firm's Heater-Cooler System 3T devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806 – Medical Devices; Reports of Corrections and Removals. Significant violations include, but are not limited to, the following:

Failure to submit a written report to FDA of any correction or removal of a device initiated to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 CFR 806.10. For example: A change order was initiated on December 20, 2011, related to a change consisting of updating the devices' IFU to indicate a new cleaning and disinfection procedure. Subsequently, the change was implemented in the IFU to indicate the use of a water filter and to add Hydrogen Peroxide to the water used in the devices. A letter was sent to your customers notifying them of the new IFU. The letter stated that the instructions for the device had been updated to assure the user can maintain the cleanliness of the water in the device, and that the 'Updated Instructions for Water Cleanliness' replaced the previous water cleaning instructions for the 3T Heater Cooler. Your firm did not submit a written report to FDA of the correction and removal, as required by 21 CFR 806.

Given the serious nature of the violations of the Act, the Heater Cooler 3T devices, and other devices manufactured by your Munchen facility are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these

devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office, in writing within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993.Refer to CMS case #484629 when replying. If you have any questions about the contents of this letter, please contact: Shumaya Ali, Acting Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email), or +1 (240) 402-4020 (phone), or +1 (301) 847-8139 (fax).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
CAPT Sean Boyd
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Cc:
Thierry Dupoux
Vice President of Quality Assurance and Regulatory Affairs
LivaNova (formerly Sorin Group Deutschland GmbH)
Lindberghstrasse 25
Munchen, 80939
Germany

Carrie Wood
Director
Customer Quality
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Arvada, CO 80004

More In 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)