IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IOWA

Jeri Pickrell, individually and on behalf of all similarly situated persons, Plaintiff, vs. LIVANOVA PLC (FKA SORIN GROUP), SORIN GROUP DEUTSCHLAND GMBH, and SORIN GROUP USA, INC. Defendants.	**CASE NO.** **COMPLAINT AND JURY DEMAND**

COME NOW Plaintiff Jeri Pickrell, individually and on behalf of all similarly situated persons, by and through her undersigned attorneys, and allege the following upon information and belief, except for those allegations pertaining to Plaintiff which are based on personal knowledge.

NATURE OF THE ACTION

1. Plaintiff Jeri Pickrell (hereinafter "Plaintiff") bring this action individually and on behalf of all persons similarly situated in the State of Iowa who were unknowingly exposed to a potentially fatal bacteria during open heart surgery.

2. Plaintiff and the Classwere exposed to *M. Chimaera* and / or *M.* Abscessus, subspecies of nontuberculous mycobacterium (collectively referred to as "NTM" herein), through a Sorin 3T Heater-Cooler System manufactured by the Defendants and used to regulate their blood temperature during surgeries at two hospitals, Mercy Medical Center ("Mercy") and University of Iowa Hospitals and Clinics ("UIHC").

3. As further described below, Defendant LivaNova knew or should have known that design and/or manufacturing defects in its Sorin 3T Heater-Cooler System causes bacterial

colonization, to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death.

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

JURISIDCTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties, 28 USCS § 1332(a)(2). Plaintiff are citizens and residents of the State of Iowa. Defendant LivaNova is a foreign corporation incorporated under the laws of England and Wales with a corporate headquarters in Milan, Italy, and with a principal place of business in the United States located in Arvada, Colorado. Defendant, Sorin Group Deutschland Gmbh, is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA Inc. has a principal place of business in Arvada, Colorado. Personal jurisdiction exists over Defendant LivaNova and Sorin Gourp DeutschlandGmbh in the U.S. due to the general and specific contacts it maintains in the U.S. Defendants LivaNova and Sorin Group Deutschland Gmbh maintains those contacts presently and did so at all times material to this action. The amount in controversy exceeds $75,000.

6. This Court additionally has subject matter over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). There are more than 4,100 putative class members, who are or were citizens of the State of Iowa at the time of their exposure, and Defendants LivaNova and Sorin Gourp DeutschlandGmbh are citizens of another state and/or foreign country. The aggregate of the Class Members' claims is more than $5 million dollars, exclusive

of interests and costs.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiffs' claim emanated from activities within this jurisdiction and Defendants do substantial business within this jurisdiction.

THE PARTIES

8. Plaintiff and proposed Class Representative Jeri Pickrell is an adult individual, a resident and citizen of Iowa residing in Greenfield, Iowa. Plaintiff had open heart surgery on June 19, 2016.As a result of the use of the Sorin 3T Heater-Cooler System during her surgery, Jeri Pickrell was exposed to NTM.

9. Defendant LivaNova, PLC ("LivaNova"), formerly known as Sorin Group, is a foreign for-profit corporation headquartered Milan, Italy. Defendant, Sorin Group Deutschland Gmbh, is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin Group USA Inc. has a principal place of business in Arvada, Colorado. LivaNova maintains a U.S. office in Arvada, Colorado. LivaNova is a global medical device company specializing in devices used in the treatment of cardiovascular diseases. LivaNova, Sorin Group Deutschland Gmbh, and Sorin Group USA, Inc. designed, manufactured, marketed and sold the Sorin 3T Heater-Cooler Systems used in Plaintiff and Class Members' surgeries.

GENERAL FACTUAL ALLEGATIONS

A. Two Iowa Hospitals Announce Patient Exposure to Deadly Bacteria

10. On or about February 2, 2016, UIHC announced that approximately 1,500 of its patients who had major heart, lung, or liver surgeries between January 1, 2012 and January 22,

2016 had been exposed to a rare and potentially fatal bacteria via Sorin 3T Heater-Cooler Systems used to regulate blood temperature.

11. On or about August 29, 2016, Mercy announced that 2,600 of its patients who had open heart surgery between July 1, 2012 and July 1, 2016 had been exposed to the same rare and potentially fatal bacteria during their surgeries.

12. In addition to announcements to the public, both hospitals reported that they sent letters to individual patients which informed them of the exposure and advised them to follow up with their physicians.

B. The Fatal Bacteria

13. The bacteria at issue are *M. Chimaera* and *M. Abscessus*. The bacteria are subspecies of nontuberculous mycobactermium ("NTM")[1], which occur naturally in the environment and rarely causes illness. However, NTM poses a unique health risk to those with compromised immune systems, and in particular those who have undergone invasive surgical procedures. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to five years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease. The recommended monitoring period after exposure is at least five years.

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

15. Because NTM symptoms are non-specific and manifestation may take several

[1] Discovery in this action may reveal that different strands of NTM, or other bacteria types altogether, have been transmitted to Plaintiff and putative Class Members through the same mechanism. As such, Plaintiff reserves her right to amend her Complaint with specific facts learned through discovery.

weeks to several years, a patient will most likely fail to link the infection to his or her prior heart surgery, particularly as more time elapses between surgery and initial symptomatology.

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

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

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

19. Upon information and belief, at least one individual who underwent open heart surgery at UIHC died as a result of an NTM infection.

20. The risk of NTM transmission with the 3T System is not unique to Mercy and UIHC. For example, in October and November 2015, two Pennsylvania hospitals notified approximately 3,600 patients who underwent open heart surgeries between October 1, 2011 and November 5, 2015 of their exposure to NTM through use of the 3T System. To date, there have been eleven confirmed NTM infections in Pennsylvania which have resulted in five deaths.

C. Medical Devices Identified as the Infection Source

21. The CDC has affirmatively linked the NTM infection risk at Mercy and UIHC to the Sorin 3T Heater-Cooler System used to regulate patient blood temperature during cardiovascular surgeries.

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

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

24. A Rapid Risk Assessment released by the European Centre for Disease Prevention and Control ("ECDC") in April 2015 notes that invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[2]

25. A public health investigation in Switzerland included microbiological examinations of environmental samples that identified *M. Chimaera* (a strand of NTM) contamination in heater-cooler units, including water samples from the units. Air sampling cultures were positive for M. Chimaera when the units were running, but negative when they were turned off.[3]

26. In July 2015, an article was published in the Journal of Clinical Infectious Diseases following patients in Europe who contracted NTM. The article concluded that the epidemiological and microbiological features of the prolonged outbreak in Europe provided evidence of the airborne transmission of *M. Chimaera* from contaminated heater-cooler units.

27. On October 15, 2015, the Food and Drug Administration ("FDA") issued a Safety Communication which noted that between January 2010 and August 2015, the agency received

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[2] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http:/lecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater- cooler-units-rapid-risk-assessment-30-April-20 15.pdf (last accessed on January 26, 2016).

[3] *Id.*

32 Medical Device Reports of patient infections associated with heater-cooler device contamination, eight in the U.S, and the remaining 24 predominantly from Western Europe.

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

29. On June 1, 2016, the FDA issued an updated Safety Communication which advised that there may be a higher risk of patient infection associated with surgeries that introduced a prosthetic product/material [e.g., heart valve, graft, LVAD], or heart transplants when the 3T was used and recommended that healthcare providers determine a method for patient follow-up and establish patient surveillance in cases of potential exposure, per the recommendations in CDC's Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units.

30. In October 2016, the FDA issued an updated Safety Communication which reported clusters of patients infected with M. chimaera were located in Iowa. Specifically, the Centers for Disease Control and Prevention (CDC) and National Jewish Health performed whole genome sequencing on clinical isolates from infected patients and samples taken from the 3T devices from hospitals representing geographically distinct regions within the U.S. (Pennsylvania and Iowa) where clusters of patient infections with *M. chimaera* were identified. Each of the isolates tested were associated with devices manufactured before September 2014. Samples of the water drained from the 3T devices and air samples collected while the devices were in operation were also tested. The results obtained strongly suggest that the tested 3T devices had a common source of *M. chimaera* contamination.

D. Defendant LivaNova's 3T Heater-Cooler System

31. The Sorin 3T Heater-Cooler Systems ("3T Systems") used at Mercy and UIHC during the relevant time periods were designed, manufactured, marketed and sold by Defendant LivaNova, formerly known as Sorin Group, to the hospitals in Iowa.

32. On July 15, 2015, the FDA issued a Class 2 Recall of the 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

33. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by LivaNova on June 15, 2015.

34. According to LivaNova's June 2015 Field Safety Notice, its hygiene concept was "enhanced" by introducing the following modifications:

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

b. Instead of three different procedures (every five days, every 2 weeks and every 3 months), only two different procedures (every 7 days and every 14 days) to make disinfection easier;

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

d. H202 in low dose for preservation;

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

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

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

35. However, a month prior to the recall, in May 2015, LivaNova determined that devices that had not been maintained according to the manufacturer's instructions for use

("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

36. Upon information and belief, LivaNova knew or should have known that design and/or manufacturing defects in its 3T System renders it prone to bacterial colonization, regardless of the cleaning and disinfection procedures used.

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

44. On December 29, 2015, the FDA sent LivaNova a warning letter advising the company that its 3T Systems were subject to refusal of admission into the U.S. until it resolved several FDA violations, including the FDA's determination that the 3T Heater-Cooler Systems were adulterated[4] and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions.

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

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

E. Iowa Hospitals Respond to the Crisis

47. Shortly after learning of the association between NTM infection and its 3T Heater- Cooler Systems, Mercy and UIHC created online resources for patients exposed to the bacteria.

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[4] Under the Federal Food, Drug and Cosmetic Act, a medical device is "adulterated" if the methods used in, or the facilities or controls used for her manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation

48. According to UIHC's website, medical services are currently being provided to exposed patients at no cost.[5]

49. According to Mercy's website, a toll-free number has been set up for patients to contact the hospital to learn if follow-up treatment is necessary.[6] Mercy's website does not indicate whether it intends to charge exposed patients for follow-up care.

50. It is unknown how long Mercy and UIHC intend to continue offering these services. It is likewise unknown if there are any limitations to the services being offered by Mercy and UIHC which may inhibit the early detection of NTM infections.

CLASS ACTION ALLEGATIONS

51. The Class claims all derive directly from a single course of conduct by the Defendant. The Defendant engaged in uniform and standardized conduct toward the Class. It did not differentiate, in degree of care or candor, its actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief, the same legal standards under Iowa and/or federal law govern. Accordingly, Plaintiff brings this lawsuit as a class action on her own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Fed. R. Civ. P. 23. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

Class Definition

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

> All individuals residing in the State of Iowa who underwent open heart surgery at:

[5] https://uihc.org/news/potential-infection-risk-major-heart-and-lung-surgeries (last accessed May 22, 2017).
[6] http://www.mercydesmoines.org/Portals/0/ntm-faqs.pdf (last accessed May 22, 2017).

(i) Mercy Medical Center between July 1, 2012 and July 1, 2016; or
(ii) University of Iowa Hospitals and Clinics between January 1, 2012;
and who are currently asymptomatic for nontuberculous mycobacterium (or "NTM") infection. Claims for actual injury from an NTM infection are excluded from the claims brought in this class action.

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

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

a. **Numerosity:** Upon information and belief, Plaintiff states that there are at least 4,100 individuals who underwent open heart surgery during the relevant time periods. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical.

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

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

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

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

iv. Whether the Defendant knew or should have known of their NTM exposure;

v. Whether their exposure to NTM was caused by the negligence of the Defendant;

vi. Whether the 3T System is defectively designed;

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

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

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

x. Whether the Defendant is legally responsible for implementing and maintaining a medical monitoring fund to provide NTM screening.

c. **Typicality:** Plaintiffs' claim is typical of the claims of Class Members because they each underwent surgeries at Mercy or UIHC during the time period in which the allegedly defective medical devices were used. Plaintiff alleges that her exposure to NTM occurred in substantially the same way. As such, the claims or defenses of the representative parties are typical of the claims or defenses of the class.

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

e. **Class Action Maintainable under Rule 23(b)(2):** A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only individual members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged

herein. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single form simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, the Defendant will remain free from responsibility for exposing at least 4,100 patients to a potentially deadly bacterium and Class Members, who have limited resources, will either be forced to fund their own medical screening or forgo the necessary screening due to financial constraints.

f. **Class Action Maintainable Under Rule 23(b)(3):** By negligently exposing Plaintiff and Class Members to NTM, the Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making the implementation and maintenance of a medical monitoring fund and declaratory relief the appropriate remedies for the Class.

g. **Ascertainability:** The Class Members are ascertainable as both Mercy and UIHC can identify every single class member from their respective contemporaneously kept medical records. Accordingly, nothing more than a ministerial act on the part of non-parties Mercy and UIHC will be necessary to ascertain all potential Class Members.

TOLLING OF THE STATUTE OF LIMITATIONS

Discovery Rule

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

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

57. Prior to Mercy and UIHC's announcements and correspondence advising that Plaintiff and Class Members may have been exposed to NTM, Plaintiff was wholly unaware of both her exposures to NTM and the fact that her exposures may have been caused by a defective medical device.

58. Any applicable statute of limitation has therefore been tolled by Plaintiffs' and Class Members' lack of knowledge of the facts alleged herein prior to October and November 2015.

COUNT I – MEDICAL MONITORING

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

60. The latency period for the manifestation of an NTM infection is estimated to be between anywhere from two weeks to five years after exposure.

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

62. When NTM is transmitted by the method described above, namely airborne transmission from a contaminated medical device to an individual undergoing invasive surgery,

it is widely acknowledged as a dangerous and potentially life-threatening bacteria.

63. Plaintiff and the Class Members' exposure to NTM was caused by Defendant.

64. LivaNova's negligence as follows:

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

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

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

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

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

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

65. Plaintiff and the Class Members' exposure to NTM was proximately caused by Defendant LivaNova's negligence as described herein.

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

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

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

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

COUNT II – DECLARATORY RELIEF PURUSANT TO 28 U.S.C. § 2201, *ET SEQ.*

70. Plaintiff incorporate by reference the preceding paragraphs as if fully set forth herein.

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

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

73. Plaintiff alleges that the Sorin 3T Heater-Cooler System is defective in that it is prone to bacterial colonization which may be transmitted to patients during surgery.

74. There are actual controversies between the Defendant and Plaintiff, including prospective Class members, concerning: 1) whether the 3T System is defective, 2) whether the Defendant knew, or should have known, of defects in its 3T System, and 3) whether the Defendant failed to adequately warn of the risk of bacterial colonization in its 3T System.

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

76. Plaintiff therefore seeks a declaration that the Sorin 3T Heater-Cooler System is defective, and that the Defendant must expeditiously notify the Class of such defects.

PRAYER FOR RELIEF

Plaintiff, on behalf of themselves and all others similarly situated, request the Court to enter judgment against the Defendant as follows:

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

B. A declaration that the Sorin 3T Heater-Cooler System is defective and unsafe for its intended use;

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

D. An award to Plaintiff and Class Members of damages, costs and disbursements in this action, including reasonable attorneys' fees, as permitted by law;

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

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

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

JURY TRIAL DEMANDED

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

Dated: May 22, 2017 SHINDLER ANDERSON GOPLERUD & WEESE PC

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