IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF IOWA

RONALD REED, HELEN ANN REED, and RONALD REED on behalf of ELIZABETH ANNE REED and ROSS REED, Plaintiffs, vs. LIVANOVA DEUTSCHLAND GMBH fka SORIN GROUP DEUTSCHLAND GMBH, and SORIN USA, INC. Defendants.	**CASE NO. 3:17-CV-00063** **COMPLAINT AND JURY DEMAND**

COME NOW Plaintiff Ronald Reed, Helen Ann Reed and Ronald Reed on behalf of Elizabeth Anne Reed and Ross Reed, by and through his undersigned attorneys, allege the following:

JURISIDCTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties, 28 USCS § 1332(a)(2). Plaintiffs Ronald Reed and Helen Ann Reed are citizens and residents of the State of Iowa, residing in Iowa City, Iowa. Defendant LivaNova Deutschland GMBH ("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 Deutschland GMBH ("Sorin"), is a foreign corporation headquartered in Munich, Germany. Defendant, Sorin USA, Inc. ("Sorin USA") has a principal place of business in Arvada, Colorado.

2. Personal jurisdiction exists over Defendant LivaNova and Sorin in the U.S.

due to the general and specific contacts it maintains in the U.S. Defendants LivaNova and Sorin maintains those contacts presently and did so at all times material to this action.

3. The amount in controversy exceeds $75,000.

4. 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.

NATURE OF THE ACTION

5. Plaintiffs Ronald Reed and Helen Ann Reed (hereinafter "Plaintiffs") at all relevant times were married. Plaintiffs have two children, Elizabeth Anne Reed and Ross Reed.

6. Plaintiff Ronald Reed had open heart surgery on June 19, 2013. As a result of the use of the Sorin 3T Heater-Cooler System during his surgery, Plaintiff Ronald Reed was exposed to the *Mycobacterium chimaera ("M. chimaera")*.

7. Defendant 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, and Sorin USA designed, manufactured, marketed and sold the Sorin 3T Heater-Cooler Systems used in Plaintiff's surgery.

GENERAL FACTUAL ALLEGATIONS

A. University of Iowa Hospitals and Clinics Announces Patient Exposure to Deadly Bacteria

8. Plaintiff Ronald Reed received a letter on February 2, 2016 informing him that he had been exposed to a bacterium which is associated with Nontuberculous Mycobacteria ("NTM").[1]

[1] UIHC letter dated 2/1/16 with Questions and Answers about NTM Exposure attached.

9. On or about February 2, 2016, the University of Iowa Hospitals and Clinics ("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.

B. The Fatal Bacteria

10. The bacteria at issue is *M. chimaera*. The bacteria is a sub-specie of nontuberculous mycobactermium ("NTM"), which occurs 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.

11. 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.

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

13. 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.

14. 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 long term.

15. 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.

16. Upon information and belief, at least two individuals who underwent open heart surgery at UIHC died as a result of an NTM infection.

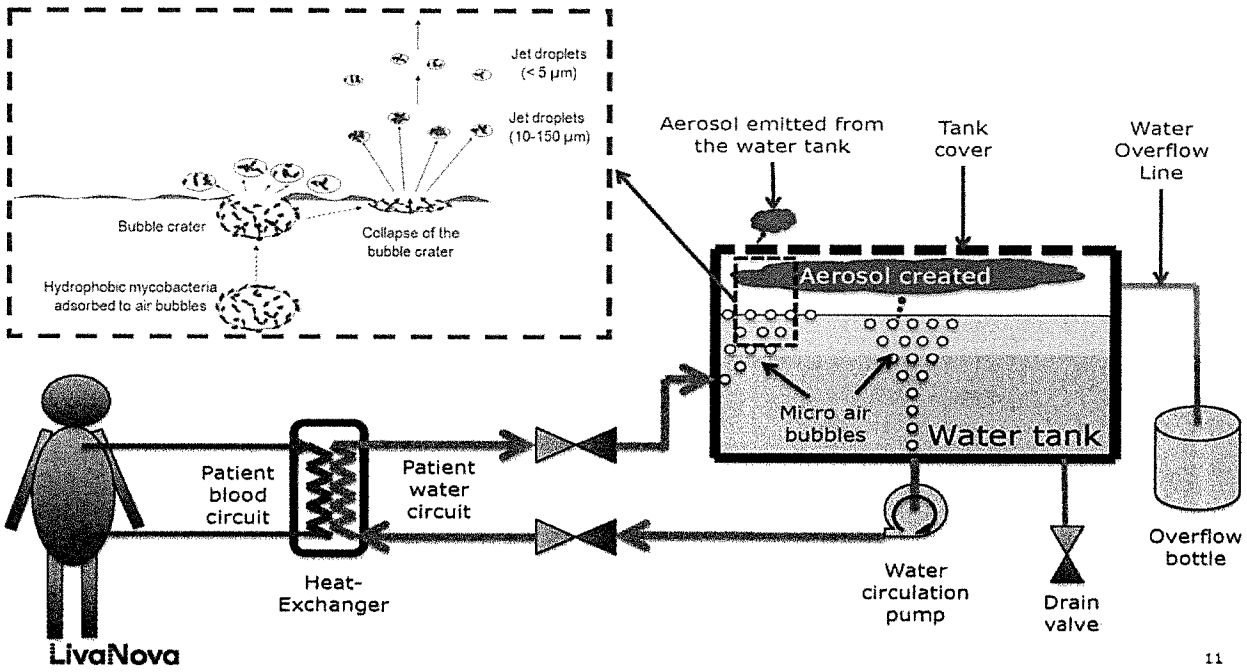
17. The risk of NTM transmission with the 3T System is not unique to UIHC. For example, in October and November 2015, two Pennsylvania hospitals notified approximately 3,600 patients who underwent open heart surgeries between October 1, 2011 and November 5, 2015 of their exposure to NTM through use of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

C. United States CDC and FDA Conclude Defendants' 3T Heater-Cooler Systems as the Infection Source

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

19. The Sorin 3T Heater-Cooler Systems ("3T") used at UIHC from January 1, 2012 to January 22, 2016 were designed, manufactured, marketed and/or sold by Defendants, Sorin and Sorin USA.

20. The 3T regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks and other areas where water pass through aerosolize a vapor containing NTM which exits out of the device and is pushed into the ambient air of the operating room through the System's exhaust fan. If placed in the operating room, the contaminated vapor from the 3T directly enters the sterile surgical field and the patient's open body.



(taken from Defendants' publicly available presentation to the FDA Circulatory Devices Panel on June 2, 2016).

21. Published articles dating back to the 1980s confirm that NTM is commonly found in water and has a high propensity to become airborne (aerosolize) through natural processes.[2]

22. The potential for contaminated water from heater-cooler devices to infect patients intraoperatively was recognized by the medical and scientific community as early as November 2002.[3]

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[2] *See e.g.*, Wendt, *et al.*, Epidemiology of Infection by Nontuberculous Mycobacteria, III. Isolation of Potentially Pathogenic Mycobacteria from Aerosols, American Review of Respiratory Disease, 1980 ("Field experiments have confirmed the existence of a natural mechanism for the transfer of significant numbers of mycobacteria from water to air."); Falkinham, Mycobacterial Aerosols and Respiratory Disease, Emerging Infectious Diseases, July 2003 ("Environmental opportunistic Mycobacteria are present in drinking water, resistant to disinfection, able to provoke inflammatory reactions, and readily aerosolized.").

[3] *See* The Heater-Cooler Unit—A Conceivable Source of Infection, Weitkemper, *et al.*, The Journal of the American Society of Extra-Corporeal Technology, 2002.

23. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[4]

24. 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.[5]

25. In April 2011 the FDA visited Defendant, Sorin, in Munchen, Germany for a plant inspection and to discuss safety concerns with several products, including the 3T approved in 2005 through the 510(k) process. The FDA advised the company that its 3Ts harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to avoid bacterial infections in patients exposed in the operating room.

26. Defendants conceded to the FDA that this particular patient risk was "not considered" because it was "not of concern."

27. During this inspection, the FDA advised the company that the bacterial growth charts it used to justify the original instruction for device disinfection every 14 days allowed bacterial overgrowth well in excess of safe standards in just one and a half days. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no

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[4] 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://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater- cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed on September 18, 2017).

[5] Subsequent studies have further confirmed that the 3T aerosolizes *M. chimaera* when powered on. *See e.g.*, Lyman, *et al.* Invasive Nontuberculous Mycobacterial Infections among Cardiothoracic Surgical Patients Exposed to Heater-Cooler Devices, Emerging Infectious Diseases, May 2017; Gotting, *et al.*, Heater-Cooler Units: Contamination of Crucial Devices in Cardiothoracic Surgery, Journal of Hospital Infection, February 2016; Sommerstein, *et al.*, Transmission of *Mycobacterium Chimaera* from Heater-Cooler Units during Cardiac Surgery Despite an Ultraclean Air Ventilation System, Emerging Infectious Diseases, June 2016.

information to support the cleaning methods it disseminated to U.S. purchasers.

28. 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.

29. More than four years later, on July 15, 2015, Defendants issued a Class 2 Recall of the 3T's instructions for use ("IFU") 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."

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

31. According to this Field Safety Notice, the company's hygiene concept was "enhanced"[6] by introducing the following modifications:

a. Use filtered tap water when filling the device;

b. To make disinfection easier, switch from three different cleaning procedures (every five days, every two weeks and every three months), to just two (every seven days and every fourteen days);

c. The option to use peracetic acid instead of Clorox for disinfection;

d. Use hydrogen peroxide in low dose for device preservation;

e. Include all external tubing, bottles and buckets in the disinfection process;

f. Change to polyethylene tubing that meets national drinking water standards; and

g. Unused heater-coolers should be disinfected bi-weekly.

[6] A month prior to the recall, in May 2015, Defendants informed customers that devices that had not been maintained according to the manufacturers' IFUs required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

32. 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." 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 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.

33. 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.

34. On December 29, 2015, the FDA sent Defendants a warning letter advising that 3Ts were subject to refusal of admission into the U.S. until they resolved several FDA violations, including the FDA's determination that the 3Ts were adulterated[7] 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. The FDA's findings were based on its inspections of the company's Munchen, Germany and Arvada, Colorado production facilities.

35. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been documented, validated and/or submitted to the FDA for approval.

[7] 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 their manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation.

36. 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.

37. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain 3Ts manufactured at Defendants' Munich, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

38. A June 1, 2016 FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the *M. chimaera* to which European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model – the 3T." The FDA cautioned U.S. purchasers of the 3T that if they purchased their units before September 2014 they may have been shipped from Defendants' factory contaminated with *M. chimaera*.[8]

39. The June 1, 2016, FDA Safety Communication also 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.

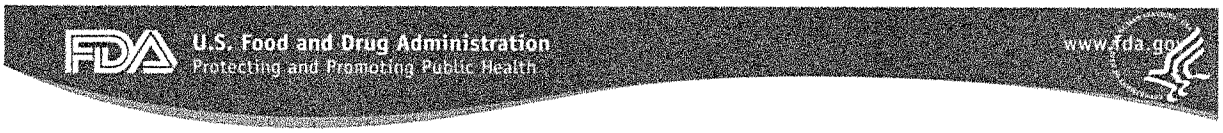
40. In June 2016, a study published in the Journal of Emerging Infectious Diseases

[8] June 1, 2016 FDA Safety Communication, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm (last accessed on September 18, 2017).

confirmed the airborne transmission of NTM via 3Ts due to the ability of the 3T's exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study, aerosolization from the 3T carried *M. chimaera* particles a distance of up to 5 meters from the device.

41. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the 3T.

42. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports ("MDR") it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the 3T.



MDRs by Manufacturer, Brand Name and User Facility (US vs. OUS)

MDRs by Manufacturer and UF				
Manufacturer and Brand Name	Total Number of MDRs	Number of User Facilities Represented in the MDRs		
		US	OUS	Total
LivaNova/Sorin** Stockert 3T	160	15	35	50
Maquet HCU20, HCU30 & HCU40	9	0	5*	5*
Cincinnati Sub-Zero 333W and Hemotherm	3	2*	0	2*
Terumo HX2	8	1*	0	1*
Total	180	16 (2*)	39 (1*)	55 (3*)

*Note that 3 UF reported devices from 2 different manufacturers
**LivaNova/Sorin has approximately 60% of the market share for this type of device

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43. During this Panel, Defendants' representatives admitted that the company was in

the process of retrofitting existing 3Ts with new design features, including, but not limited to, changing tubing materials from PVC to polyethylene to limit biofilm formation and the introduction of plugs in the water circuit to prevent sitting water.

44. Manufacturing and User Facility Device Experience ("MAUDE") reports, such as one reported to the FDA on July 7, 2016, evidence that even mechanical deep disinfection followed by the use of filtered water, new water hoses, and three cycles of Defendants' new cleaning procedure fail to eliminate high bacteria counts in the 3T.[9]

45. 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.[10]

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[9] *See also*, ECDC Rapid Risk Assessment, *supra* ("In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. chimaera* at the hospital tested positive three months after purchase and installation.").

[10] *See* CDC Morbidity and Mortality Weekly Report for October 14, 2016, available online at https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w (last accessed on September 18, 2017). Multiple studies have since linked the same strain of *M. chimaera* to patient infections following use of the 3T in geographically sequestered locations such as Australia, Canada, France, Germany, Hong Kong, Ireland, the Netherlands, Spain and Switzerland. *See e.g.,* Svensson, *et al.*, *Mycobacterium chimaera* in heater–cooler units in Denmark related to isolates from the United States and United Kingdom, Emerg Infect Dis., March 2017, available online at https://wwwnc.cdc.gov/eid/article/23/3/16-1941_article (last accessed on September 18, 2017); *see also* Walker, *et al.,* Microbiological Problems and Biofilms Associated with Mycobacterium Chimaera in Heater-cooler Units Used for Cardiopulmonary Bypass, Journal of Hospital Infection, April 26, 2017 (collecting data of global *M. Chimaera* infections).

46. That same day, the FDA issued an updated Safety Communication instructing hospitals throughout the country to discontinue using 3Ts manufactured before September 2014 due to evidence of "point source contamination at the production site".[11]

47. Subsequent studies published in 2017 further confirm "an ongoing international outbreak of *M. chimaera* infection following cardiac surgery" and that "all *M. chimaera* infections have been attributed to a specific make/model of HCU (Sorin 3T, LivaNova PLC, formerly Sorin Group Deutschland GmbH).[12]

48. Upon information and belief, Defendants knew or should have known that design and/or manufacturing defects in its 3T renders it prone to bacterial colonization and transmission, *regardless of the cleaning and disinfection procedures used.*[13]

D. Additional NTM Outbreaks

49. The risk of NTM transmission with the 3T is not unique to UIHC. In October and November 2015, two Pennsylvania hospitals notified approximately 3600 patients of their exposure to NTM through use of the 3T. On September 20, 2016, a third Pennsylvania hospital, Penn Presbyterian Medical Center in Philadelphia, announced patient infections linked to the 3T.

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[11] *See* October 13, 2016 "UPDATE: Mycobacterium Chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T Heater-Cooler System: FDA Safety Communication", available online at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm (last accessed on September 18, 2017).

[12] *See e.g.,* Walker, *et al, supra*; Lyman, *et al. supra* (detailing a Pennsylvania field investigation which "confirmed a prolonged outbreak of invasive MAC infections associated with cardiac surgery requiring cardiopulmonary bypass with exposure to 3T HCDs, similar to reports from Europe.")

[13] *See e.g.*, Garvey, *et al.*, Decontamination of Heater-cooler Units Associated with Contamination by Atypical Mycobacteria, Journal of Hosp. Infection, March 2016 (finding that Defendants' decontamination protocol was inadequate and that removal of internal tubing was required to achieve water quality in 3Ts); Marra, *et al.*, Mycobacterium Chimaera Infections Associated with Contaminated Heater-Cooler Devices for Cardiac Surgery: Outbreak Management, Clinical Infectious Diseases, April 19, 2017 ("Despite adherence to these [manufacturer] recommendations for use of sterile or filtered water, and regular water circuit disinfection and tubing changes, *M. Chimaera* contamination will persist…investigators using far more intensive attempts at disinfection have been unable to eradicate *M. Chimaera* from 3T HCDs.")(internal citations omitted).

50. Hospitals in at least 14 other U.S. states have reported patient infections and/or device contamination with NTM. For example, in May 2016, Swedish Medical Center in Seattle, Washington issued letters notifying certain cardiac bypass patients that it had tested and found NTM in several of its 3Ts.

51. Many hospitals have either discontinued using the 3T or, like UIHC, have moved the device into a separate room to prevent contaminated aerosols from reaching the surgical field.

FACTS REGARDING PLAINTIFF RONALD REED

52. On March 25, 2013, Plaintiff Ronald Reed underwent an ascending aorta graft repair with heart surgery at UIHC.

53. On March 10, 2015, Plaintiff Ronald Reed was seen by Dr. Michael Voigt in the Center for Digestive Diseases-Hepatology for unexplained weight loss of thirty pounds on referral from Plaintiff Ronald Reed's primary internist, Dr. John Kelley. Dr. Voigt reviewed a liver biopsy from February 27, 2015 that showed multiple granulomas distributed throughout the lobule, as well as portal areas. There were also extensive areas of necrosis surrounding the granulomas. Dr. Voigt reviewed a CT abdomen and pelvis without contrast dated February 20, 2015 which showed that the liver and spleen had increased significantly in size compared to CTs dated May 19, 2014 and March 24, 2013. The liver was measured at 22.5 cm and the spleen at 22.3 cm with the main portal vein at 19 mm in diameter. The gallbladder wall was thickening without pericholecystic fluid.

54. Dr. Voigt ordered an extensive workup for fungal and mycobacterial infections, including Coccidioides Histoplasma Aspergillus Blastomyces which were all negative. Plaintiff Ronald Reed's bone marrow biopsy did not show any lymphoma and the immunophenotyping

would be atypical for a hepatic/splenic lymphoma. Dr. Voigt concluded, in conjunction with Dr. Kelley, that Plaintiff Ronald Reed had idiopathic granulomatous disease without an underlying lymphoma or infection not precipitated by drug and that he did not have sarcoidosis.

55. Dr. Voigt reviewed additional test results and suggested to Dr. Kelley via correspondence dated May 16, 2015 that Plaintiff Ronald Reed was responding to steroid therapy, but noted that Plaintiff Ronald Reed seemed to be developing hypogammaglobulinemia and mild neutropenia.

56. Plaintiff Ronald Reed learned he had been exposed to the above bacterium which is associated with Nontuberculous Mycobacteria ("NTM") in February 2016.[14]

57. On or about February 2, 2016, the University of Iowa Hospitals and Clinics ("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.

58. Dr. Voigt saw Plaintiff Ronald Reed on February 5, 2016 at Dr. Kelley's request. Dr. Diekema noted that due to high dose steroids started in April 2015, Plaintiff Ronald Reed briefly improved. In September 2015, Plaintiff Ronald Reed was found to have granulomas of the retina on routine ophthalmologic examination. Plaintiff Ronald Reed's steroid dose was slowly weaned and Plaintiff Ronald Reed's condition deteriorated with weight loss, spleen enlargement and pancytopenia worsening.

59. Dr. Voigt considered lymphocytic leukemia due to his symptoms and response to steroid therapy. Dr. Voigt also noted that patients who underwent heart surgery in the past

[14] UIHC letter dated 2/1/16 with Questions and Answers about NTM Exposure attached.

several years are at risk of developing a Mycobacterium infection called Mycobacterium chimaera and this needed to be ruled out. Dr. Voigt ordered an AFB blood culture. Dr. Voigt referred Plaintiff Ronald Reed to Dr. MacFarlane for the possible large granular cell lymphocytic leukemia.

60. Plaintiff Ronald Reed saw Dr. MacFarlane on February 18, 2016. Plaintiff Ronald Reed reported difficulty maintaining his weight and four episodes of fever to 103° F with weakness, chills and sweats in the past year. Dr. MacFarlane also noted the possibility of an infection with Mycobacterium chimaera. Dr. MacFarlane suggested various medication changes and ordered additional testing.

61. Plaintiff Ronald Reed saw Dr. Daniel Diekema in Infectious Disease on February 25, 2016. Given the Plaintiff Ronald Reed's only risk factor as exposure to heart surgery and the time course with his constellation of signs and symptoms, Dr. Diekema felt Plaintiff Ronald Reed's condition was consistent with prior reports of disseminated infection due to *M. chimaera.* Dr. Diekema discussed therapeutic approach with Dr. Charles Daley at National Jewish and prescribed anti-mycobacterial therapy aimed at *M. chimaera.* Dr. Diekema also ordered tests to confirm the diagnosis.

62. The AFB blood culture test ordered by Dr. Voigt on February 5, 2016 returned positive for *M. chimaera.*

63. On April 6, 2016, Plaintiff Ronald Reed was seen by Dr. Michael Edmond for continued weight loss. Since Plaintiff Ronald Reed's last visit with Dr. Diekema, he had been admitted at Mercy Iowa City with nephrolithiasis. Plaintiff Ronald Reed's susceptibility profile of the *M. chimaera* organism was pending. Dr. Edmond planned to continue Plaintiff Ronald Reed on a low dose of prednisone until his aortic graft could be removed. Plaintiff Ronald Reed

was also seen by nephrology for continued kidney issues with changes in medications.

64. On April 13, 2016, Plaintiff Ronald Reed met with Dr. Diekema to discuss removal of his aortic graft. Dr. Diekema identified hospitals with aortic surgeons, such as the National Jewish and University of Colorado and the Mayo Clinic for potential referrals to consider treatment options.

65. On June 6, 2016, Dr. Diekema discussed with Plaintiff Ronald Reed the novelty of the clinical syndrome and approximately 60 cases reported worldwide with clinical management and outcome uncertain. Plaintiff Ronald Reed decided to continue with the anti-mycobacterial therapy and noted that repeat evaluation of his retinal involvement was pending.

66. Plaintiff Ronald Reed reported to Dr. Diekema on July 18, 2016 that his eye exam was stable. Dr. Diekema informed Plaintiff Ronald Reed that while removal of his graft material, if possible, would be desirable, the reported outcomes from other institutions have often been poor even with removal and crude mortality worldwide and is approximately 50%. In Dr. Diekema's opinion, removal would cause significant risk and ideally would be preceded by addition of amikacin (for cidal activity, to decrease likelihood of new graft material being infected), which may worsen his renal function and lead to dialysis dependence. Dr. Diekema recommended Plaintiff Ronald Reed continue his three-drug antimicrobial regimen, begin a slow prednisone taper, recheck AFB blood cultures with next blood draw and see Dr. Mohammad Bashir in the TCV program to discuss perioperative mortality for graft replacement and help assess graft integrity.

67. Dr. Bashir examined Plaintiff Ronald Reed and reviewed his medical history. Dr. Bashir discussed possible redo operative concerns with Patient. Given his history of renal insufficiency, second operation and thrombocytopenia, Dr. Bashir opined that a repeat operation

would be high risk with little benefit since Plaintiff Ronald Reed was doing well with little symptoms at that time.

68. Dr. Diekema ordered a repeat PET-CT after examining Plaintiff Ronald Reed on September 28, 2016. Plaintiff Ronald Reed reported that he had gained five pounds since the last visit and felt overall well. Plaintiff Ronald Reed's lab abnormalities persist and he continued to require immunosuppressive therapy to control the symptomatic inflammatory process. Plaintiff Ronald Reed's last three sets of follow up AFB blood cultures remain negative (from April, June and August). Plaintiff Ronald Reed described an increase in back/hip stiffness and pain. Due to reports of osteomyelitis and septic arthritis due to *M. chimaera*, Dr. Diekema ordered a repeat PET-CT.

69. Plaintiff Ronald Reed's PET-CT revealed increased uptake circumferentially around the graft, suspicious for progression of infection/inflammation and also was concerning for new development of L1/L2 osteomyelitis/discitis.

70. In late November 2016, Plaintiff Ronald Reed noticed changes in his vision with fuzziness and some problems with near vision. Dr. Diekema noted that Plaintiff Ronald Reed's ophthalmologist did not feel his findings were indicative of ethambutol toxicity. Plaintiff Ronald Reed's visual changes were stable, but he reported some trouble with small print and some intolerance of bright light.

71. On January 10, 2017, Plaintiff Ronald Reed met with Dr. Culver Boldt in Ophthalmology on referral by his local ophthalmologist and with Dr. Diekema's knowledge. Dr. Boldt diagnosed Plaintiff Ronald Reed with bilateral multifocal choroiditis, likely due to either the *M. chimaera* systemic infection or the ethambutol Plaintiff Ronald Reed had taken for the *M. chimaera* systemic infection. Dr. Boldt discussed symptoms of progressive *M. chimaera*

chorioretinitis or choroidal neurovascular membrane from scars.

72. On February 14, 2017, Dr. Boldt diagnosed Plaintiff Ronald Reed with vitritis of both eyes.

73. Dr. Boldt has since noted optic neuropathy and cataracts in both eyes. Dr. Boldt referred Plaintiff Ronald Reed to Dr. Matthew Thurtell, a neurological ophthalmologist.

74. On September 7, 2017, Dr. Thurtell diagnosed Plaintiff Ronald Reed with toxic optic nerve neuropathy, cecocentral scotomas, bilateral vision loss and profoundly impaired color vision loss.

75. Dr. Thurtell recommended Plaintiff Ronald Reed cease taking ethambutol due to optic nerve toxicity, likely due to either the M. chimaera systemic infection or the ethambutol Plaintiff Ronald Reed had taken for the M. chimaera systemic infection.

76. Dr. Diekema consulted with physicians at the Jewish Hospital to find a replacement antibiotic.

77. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Ronald Reed acquired an *M. chimaera* infection, forcing him to undergo painful medical procedures and treatment, including, but not limited to, multiple bone marrow biopsies, triple antibiotic therapy, long term steroid therapy and progressive vision loss.

78. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff Ronald Reed, Ronald Reed expended various sums of money for medical care and treatment.

79. As a direct and proximate result of Defendants' negligence and liability producing conduct as described herein, Plaintiff Ronald Reed suffered, and continues to

suffer, from vision loss and excruciating and agonizing physical and emotional pain.

80. Plaintiff Ronald Reed's life expectancy has been reduced.

81. Plaintiff Ronald Reed was in no way responsible for his injuries.

CAUSES OF ACTION
DIVISION I NEGLIGENCE- DESIGN DEFECT
COUNT 1: Plaintiff Ronald Reed

82. Plaintiff Ronald Reed incorporates by reference the preceding paragraphs as if fully set forth herein.

83. The 3T is a product within the meaning of Iowa products liability law.

84. The 3T was expected to reach, and did reach, users and/or consumers, including Plaintiff Ronald Reed, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

85. Under Iowa products liability law, Defendants, Sorin and Sorin USA owed Plaintiff Ronald Reed a duty to exercise reasonable care in designing and testing the 3T.

86. Defendants, Sorin and Sorin USA, designed the 3T for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

87. At all times material, the 3T was used in a manner intended and/or foreseeable to the Defendants.

88. A patient or consumer using the 3T would reasonably expect the device to be free of significant defects.

89. The 3T, as designed by the Defendants, colonizes bacteria, including *M. chimaera.*

90. The 3T, as designed by the Defendants, directly transmits bacteria, including *M. chimaera,* to patients during invasive surgery.

91. The foreseeable risks of using the 3T, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T.

92. Reasonable alternative designs existed for the 3T which would have eliminated or reduced the risk of bacterial colonization and/or transmission of such bacteria to patients undergoing invasive surgical procedures.

93. Reasonable and feasible alternative designs include, but are not limited to, measures to direct airflow away from the surgical field (i.e. a housing unit for the exhaust vent), reducing the force at which air is vented from the System to a rate of less than 1000 cubic feet per minute, water reservoir isolation by using closed loop fluid management, an open water design to prevent inaccessible airspace, removable lids and parts for easy disinfection, disposable tank liners to prevent biofilm formation, and internal pasteurization or UV features to kill bacteria.

94. The failure to use feasible, reasonable alternative designs that eliminate bacterial colonization and the aerosolization of bacteria into the ambient air of operating rooms renders the 3T unreasonably unsafe.

95. Defendants knew or should have known that NTM, or other harmful bacteria, could colonize within the 3T and be spread to patients during surgery through the exhaust vent.

96. Plaintiff Ronald Reed's *M. chimaera* infection was caused by Defendants' conduct as follows:

a) Failing to conduct adequate safety and efficacy testing before placing the 3T into the stream of commerce;

b) Failing to timely establish procedures for reviewing the design of the 3T after receiving information that patients were developing bacterial infections as a result of surgeries

using the 3T;

c) Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the 3T before their implementation as required under 21 CFR 820.30(i); and

d) Failing to design or redesign the 3T to eliminate or mitigate bacterial colonization and/or transmission of such bacteria.

97. Plaintiff Ronald Reed, was proximately harmed by the design defects in the 3T as described above.

WHEREFORE, Plaintiff Ronald Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 2: Plaintiff Helen Ann Reed

98. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

99. As a direct and proximate result of the negligence of Defendants, Plaintiff Helen Ann Reed has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of her husband, Ronald Reed.

WHEREFORE, Plaintiff Helen Ann Reed demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 3: Plaintiff Ronald Reed on behalf of Elizabeth Anne Reed

100. Plaintiff Ronald Reed incorporates by reference the preceding paragraphs as if fully set forth herein.

101. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's daughter, Elizabeth Anne Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of her father, Ronald Reed.

WHEREFORE, Plaintiff Ronald Reed, on behalf of Elizabeth Anne Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 4: Plaintiff Ronald Reed on behalf of Ross Reed

102. Plaintiff Ronald Reed incorporates by reference the preceding paragraphs as if fully set forth herein.

103. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's son, Ross Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of his father, Ronald Reed.

WHEREFORE, Plaintiff Ronald Reed, on behalf of Ross Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

DIVISION II: STRICT LIABILITY-MANUFACTURING DEFECT
COUNT 1: Plaintiff Ronald Reed

104. Plaintiff Ronald Reed incorporates by reference the preceding paragraphs as if fully set forth herein.

105. The 3T is a product within the meaning of Iowa products liability law.

106. The 3T was expected to reach, and did reach, users and/or consumers, including Plaintiff Ronald Reed, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

107. Defendants, Sorin and Sorin USA manufactured the 3T for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

108. At all times material, the 3T was used in a manner intended and/or foreseeable to the Defendants.

109. A reasonable patient or consumer of the 3T would expect that the device be free of significant defects.

110. The 3T, as manufactured by the Defendants, colonizes bacteria, including *M. chimaera.*

111. The 3T, as manufactured by the Defendants, directly transmits bacteria, including *M. chimaera,* to patients during invasive surgery.

112. The foreseeable risks of using the 3T, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T.

113. Plaintiff Ronald Reed's *M. chimaera* infection was caused by Defendants' conduct as follows:

a) Failing to timely establish procedures or practices to prevent the 3T from being contaminated with NTM on the production line or elsewhere at Defendants' production facilities;

b) Manufacturing and selling the 3T with NTM contamination that occurred on the production line or elsewhere at Defendants' production facilities; and

c) Failing to ensure proper workmanship, materials and labeling for the 3T.

114. Plaintiff Ronald Reed was proximately harmed by the manufacturing defects in the 3T as described above.

WHEREFORE, Plaintiff Ronald Reed demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 2: Plaintiff Helen Ann Reed

115. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

116. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's wife, Helen Ann Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of her husband, Ronald Reed.

WHEREFORE, Plaintiff Helen Ann Reed demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 3: Plaintiff Ronald Reed on behalf of Elizabeth Anne Reed

117. Plaintiffs incorporates by reference the preceding paragraphs as if fully set forth herein.

118. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's daughter, Elizabeth Anne Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of her father, Ronald Reed.

WHEREFORE, Plaintiff Ronald Reed, on behalf of Elizabeth Anne Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 4: Plaintiff Ronald Reed on behalf of Ross Reed

119. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

120. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's son, Ross Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of his father, Ronald Reed.

WHEREFORE, Plaintiff Ronald Reed, on behalf of Ross Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

DIVISION III: NEGLIGENCE- WARNINGS DEFECTS
COUNT 1: Plaintiff Ronald Reed

121. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

122. The 3T is a product within the meaning of Iowa products liability law.

123. The 3T was expected to reach, and did reach, users and/or consumers, including Plaintiff Ronald Reed without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

124. Defendants, Sorin and Sorin USA, owed Plaintiff Ronald Reed a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the 3T.

125. Defendants, Sorin and Sorin USA marketed, advertised and promoted the 3T for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

126. At all times material, the 3T was used in a manner intended and/or foreseeable to the Defendants.

127. A reasonable patient or consumer of the 3T would expect that the device be free of significant defects.

128. The 3T colonizes bacteria, including *M. chimaera*, and directly transmits such bacteria to patients during invasive surgery.

129. Defendants knew or should have known that NTM, or other harmful bacteria, could colonize within the 3T and be spread to patients during surgery through the exhaust vent.

130. The foreseeable risks of using the 3T, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the 3T.

131. Plaintiff Ronald Reed's *M. chimaera* infection was caused by Defendants' conduct as follows:

a) Failing to provide proper cleaning and disinfection procedures for the 3T;

b) Failing to conduct proper validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T;

c) Failing to warn patients like Plaintiff Ronald Reed and/or purchasers of the 3T that the device colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms;

d) Failing to timely notify known purchasers of the 3T that patients could be

exposed to NTM;

e) Failing to alert hospitals and patients to promptly test for NTM infection when patients present with fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss and fatigue after surgery using the 3T; and

f) Failing to timely notify known purchasers of the 3T to relocate the device from the operating room during surgery to prevent patient transmission of NTM.

132. Plaintiff Ronald Reed was proximately harmed by the warnings defects in the 3T as described above.

WHEREFORE, Plaintiff Ronald Reed demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 2: Plaintiff Helen Ann Reed

133. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

134. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's wife, Helen Ann Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of her husband, Ronald Reed.

WHEREFORE, Plaintiff Helen Ann Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 3: Plaintiff Ronald Reed on behalf of Elizabeth Anne Reed

135. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

136. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's daughter, Elizabeth Anne Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of her father, Ronald Reed.

WHEREFORE, Plaintiff Ronald Reed, on behalf of Elizabeth Anne Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

COUNT 4: Plaintiff Ronald Reed on behalf of Ross Reed

137. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

138. As a direct and proximate result of the negligence of Defendants, Plaintiff Ronald Reed's son, Ross Reed, has been, and will in the future be, deprived of the support, aid, society, comfort, and companionship of his father, Ronald Reed.

WHEREFORE, Plaintiff Ronald Reed, on behalf of Ross Reed, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Iowa, together with interest thereon, costs of suit and attorneys' fees.

PRAYER FOR RELIEF

Plaintiffs Ronald Reed and Helen Ann Reed request the Court to enter judgment against the Defendants as follows:

A. An award to Plaintiffs of compensatory and punitive damages, costs

and reasonable attorneys' fees, as permitted by law;

B. An award to Plaintiff Helen Ann Reed of past and future loss of consortium damages, costs and reasonable attorneys' fees, as permitted by law;

C. An award to Plaintiff Ronald Reed, on behalf of his daughter, Elizabeth Anne Reed of past and future loss of consortium damages, costs and reasonable attorneys' fees, as permitted by law;

D. An award to Plaintiff Ronald Reed, on behalf of his son, Ross Reed of past and future loss of consortium damages, costs and reasonable attorneys' fees, as permitted by law;

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

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

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

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all issues so triable.

Dated:

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
RONALD REED, HELEN ANN REED, and RONALD REED on behalf of ELIZABETH ANNE REED and ROSS REED

(b) County of Residence of First Listed Plaintiff Johnson, Iowa
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
[redacted]

DEFENDANTS
LIVANOVA DEUTSCHLAND GMBH fka SORIN GROUP DEUTSCHLAND GMBH, and SORIN USA, INC.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☒ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. Section 1332
Brief description of cause:
Personal injury caused by Manufacturing Defect and/or Warning Defects.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

DATE 10/16/17 [redacted]

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____