UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

RYAN PAUL MITCHELL, SR. AND DELACY LUCAS, INDIVIDUALLY AND ON BEHALF OF THEIR MINOR DAUGHTER, R. M. **VERSUS** **LIVANOVA, PLC AND SORIN GROUP USA, INC.**	**CIVIL ACTION** **NUMBER: 18-cv-6965** **SECTION:** **JUDGE _____** **("__")** **DIVISION:** **MAGISTRATE JUDGE** **_____** **("__")** **JURY TRIAL REQUESTED**

COMPLAINT FOR DAMAGES

The complaint of Ryan Paul Mitchell, Sr. and Delacy Lucas, individually and on behalf of their minor daughter, R. M., through undersigned counsel, with respect represents that:

PARTIES

1.

Plaintiffs, Ryan Paul Mitchell, Sr. and Delacy Lucas, individually and on behalf of their minor child, R. M. are both persons of the full age of majority and domiciled in the Parish of St. James, State of Louisiana.

2.

Plaintiffs are the lawful and natural parents of the minor, R. M., and at all times pertinent hereto, Plaintiffs had custody of their minor daughter, who resided with one of them.

3.

Made Defendants herein are:

a. LivaNova, PLC ("LivaNova"), f/k/a Sorin Group S.p.A. and/or Sorin Group Deutschland GmbH, is a public limited company incorporated under the laws of England and Wales. LivaNova is a medical technology company with a principal place of business located at 5 Merchant Square, North Wharf Road, London, UK W2 1AY but, at all times pertinent hereto, this Defendant was doing business in Louisiana and within the jurisdiction of this Honorable Court. Upon information and belief, LivaNova is the parent company of Sorin Group USA, Inc. and/or LivaNova, Inc.

b. Sorin Group USA, Inc. ("Sorin") is a Delaware corporation with its principal place of business located at 14401 West 65th Way, Arvada, Colorado 80004 but, at all times pertinent hereto, this Defendant was doing business in Louisiana and within the jurisdiction of this Honorable Court.

JURISDICTION AND VENUE

4.

Jurisdiction of this matter is based upon diversity of citizenship, 28 USC §1332(a)(1) and (2), with the amount in controversy, exclusive of interest and costs, exceeding the sum of $75,000.

5.

Venue is proper in this district pursuant to 28 USC §§1391(b)(2) and (c) as a substantial part of the events and/or omissions giving rise to this claim occurred in New Orleans, Orleans Parish, Louisiana and within the jurisdiction of this Honorable Court and, upon information and belief, at all times pertinent hereto Defendants conducted regular business in the Eastern District of Louisiana.

FACTS

6.

Plaintiffs reiterate, re-allege and re-aver all allegations in the preceding paragraphs as if fully set forth at length herein.

7.

On August 2, 2017, the minor, R. M., underwent an extracardiac non fenestrated Fontan circulation completion procedure at Children's Hospital in New Orleans, Louisiana and within the jurisdiction of this Honorable Court, during which the Stockert heater-cooler 3T thermal regulator device ("Stockert 3T") was used.

8.

Sorin is engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly, numerous medical devices, including the Stockert 3T, throughout the United States, including in the State of Louisiana.

9.

At all material times, the Stockert 3T was marketed and sold to hospitals in the State of Louisiana. In particular, the Stockert 3T was sold by Sorin to Louisiana Children's Medical Center ("LCMC") in New Orleans, Louisiana.

10.

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

11.

On or about September 19, 2005, Sorin Group Deutschland submitted a §510(k) pre-market notification of intent to market the Stockert 3T. *See* FDA §510(k) No. K052601.

12.

The §510(k) pre-market notification and approval process is regarded as a simplified application process that does not require an extensive review and approval by the United States Food and Drug Administration (FDA) because the entity applying for §510(k) approval certifies that the device is substantially equivalent to an already legally-marketed device.

13.

The §510(k) pre-market notification submitted by Sorin Group Deutschland states that the Stockert 3T is substantially equivalent in safety and effectiveness as three predicate devices.

14.

In the pre-market notification submitted to the FDA, Sorin Group Deutschland certified that the Stockert 3T "do[es] not raise new issues of safety or effectiveness."

15.

No clinical trials were conducted in connection with the submission of Stockert 3T §510(k) application process.

16.

On or about June 6, 2006, the FDA determined that the Stockert 3T was substantially equivalent to legally marketed predicate devices and approved the marketing of the Stockert 3T system.

17.

The FDA approved the Stockert 3T as a Class II medical device.

18.

Thereafter, LivaNova and/or Sorin began marketing and selling the Stockert 3T with Instructions for Use ("IFU").

19.

At all times relevant hereto, Sorin was required to develop, test, and validate safe cleaning and disinfection protocols, and to incorporate these protocols into the Stockert 3T device's labeling and IFU.

20.

The Stockert 3T device's labeling and IFU must provide sufficient instructions on how to clean and disinfect the device, and the instructions or protocol must be validated by the manufacturer prior to the device being marketed, as per Title 21, Code of Federal Regulations, Part 820.

21.

Upon information and belief, Sorin's validation of the Stockert 3T cleaning and/or disinfection procedures outlined in the IFU was conducted without considering the presence of mycobacteria. Furthermore, upon information and belief, Sorin's IFU did not consider cleaning guidelines or disinfection protocols for water quality outside of Germany.

22.

On or about January 28, 2014, Sorin received a report from a health professional that one or more patients experienced an infection after surgeries in which the Stockert 3T was used. The hospital's investigation found bacteria in the tanks of all Stockert 3T devices at the facility.

23.

On or about February 12, 2014, Sorin filed a MAUDE Adverse Event Report with the FDA.

24.

On or about June 19, 2014, Sorin received a report from a user facility's risk manager that

fifteen patients tested positive for an "atypical mycobacterium infection." Out of the fifteen patients who were identified as infected, four of them had died.

25.

On or about July 14, 2014, Sorin authored a letter entitled, "IMPORTANT INFORMATION Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices" (hereinafter "July 2014 'Import Information' letter").

26.

The July 2014 "Important Information" letter was sent "Attention: Hygiene Specialist, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

27.

The July 2014 "Import Information" letter states as follows:

> *"We would like to bring to the attention of our customers a newly identified risk for cardiac surgery patients. Some cardiac surgery patients have been infected with a slow growing Mycobacterium chimaera ... .It is important to assure that your staff is aware of the Mycobacteria risk and to review your hygiene & surgical practices in the cardiac surgery theatre. This review should include your sampling and monitoring programs for your water sources, solution preparations and systems that use water in the cardiac surgery theatre. Among these water systems, heater cooler device(s) need strict adherence to the cleaning, disinfection and maintenance according to the operating manual.... Without vigilant performance of the disinfection per the Operating Instructions, these organisms can multiply in a heater cooler device and potentially form biofilm…"*

28.

The July 2014 "Important Information" letter continues,

> *"One of the highest risks of contamination for the patient is a direct contact transfer of water/solution droplets containing mycobacteria into the surgical field. Another risk that should be reviewed is the air distribution within the cardiac surgery theatre as this can be a*

> *transmission method for mycobacteria. The air conditioning as well as ventilation units including the heater cooler device fans need to be considered in that analysis."*

29.

The July 2014 "Important Information" letter also states:

> *"During the investigation work it has been identified that some hospitals heater cooler devices are contaminated. By way of caution and as a safety measure, Sorin reminds its customers using heater cooler devices about the importance of adhering to the correct maintenance of the device at all times and in particular to assure that the cleanliness of the water in the device is maintained. If the water is not properly disinfected and maintained, microbiological growth can occur within the device and over time biofilm may form.*

30.

The July 2014 "Important Information'" letter states that "strict adherence to the instructions is mandatory for the safe use of the device."

31.

The July 2014 "Important Information" letter also enclosed some chapters of the latest version of the operating instructions for the Stockert 3T device ("2014 IFU").

32.

According to Part5.2 of the 2014 IFU, entitled, "Filling the water tanks," the "water tanks must be disinfected prior to operating the heater-cooler for the first time." Filtered tap water was to be used, and in order to prevent microbial growth, "100 ml of medical grade 3% hydrogen peroxide should be added to the filtered tap water." Every five days, 50 ml of hydrogen peroxide was to be added to the water tank, and the water "should be changed every two weeks."

33.

According to Part 6-2.1 of the 2014 IFU, entitled, "Disinfection of the water circuits," "[t]he water circuits must be disinfected prior to operating the heater-cooler for the first time, when

placing the unit in storage and if the hydrogen peroxide was not routinely performed. In order to prevent microbial growth, we recommend performing the disinfection cycle every 3 months."

34.

The disinfection procedure listed in Part 6.2.1 of the 2014 IFUs applies to the "water circuits," which include the pump, heating and cooling tanks, fittings and all interconnecting tubing.

35.

Part 6.2.1 of the 2014 IFU states, "[f]or disinfection of the water circuits, use Clorox® Regular-Bleach, Maranon or another SORIN GROUP approved disinfectant."

36.

On or about April 7, 2015, a laboratory contracted by LivaNova and/or Sorin completed testing designed to evaluate the effectiveness of the Stockert 3T's updated disinfection procedures in eliminating various bacteria, including mycobacteria chimaera.

37.

According to a White Paper authored by Sorin, "[w]ith the enhanced hygiene concept, it is possible to achieve a bacterial count lower than 100 CFU/ml and no mycobacteria in the water of the 3T heater-cooler."

38.

Sorin' s White Paper specifically notes that its test results, which demonstrated the efficacy of its "expanded hygiene concept," were limited to new devices only. The White Paper states as follows:

> *"Note: all of the above results have been obtained on a new device released from production. This means that the initial level of bacterial contamination was limited, and specifically, that no biofilm or any other environment favorable to bacterial growth was present. The efficacy of the same disinfectant on a highly*

> *contaminated device could not be demonstrated…."* (emphasis added).

39.

Upon information and belief, by April 2015, Sorin knew that their "enhanced hygiene concept"" was ineffective in eliminating all bacteria, including mycobacteria chimaera, from devices that were not new and/or were already contaminated.

40.

On or about April 30, 2015, the European Centre for Disease Prevention and Control Issued a Rapid Risk Assessment, which linked cardiac surgery-associated mycobacterium chimaera infections to heater-cooler units.

41.

According to Sorin, in May 2015, they set up a "deep disinfection service" at Sorin Group Deutschland facilities, after realizing that "existing disinfection procedures would not be sufficient to reduce the risk of bacterial contamination of a heater-cooler device if it had not been properly maintained (according to IFU) for a long period of time, thus allowing a biofilm to grow in the water circuit."

42.

On or about June 3, 2015, Sorin authored a Field Safety Notice entitled, "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices."

43.

The June 3, 2015 Field Safety Notice was sent "Attention: Hygiene Specialist, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

44.

The June 3, 2015 Field Safety Notice states as follows:

> *"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."*

45.

The June 3, 2015 Field Safety Notice also provided customers with updated Instructions for Use regarding disinfection and maintenance procedures.

46.

On or about June 11, 2015, the United Kingdom's Medicines and Healthcare Products Regulatory Agency issued a Medical Device Alert warning of the risk of mycobacterium infection in patients undergoing cardiac surgery, associated with heater-coolers used with cardiopulmonary bypass machines.

47.

On or about June 15, 2015, Sorin authored a Field Safety Notice entitled, "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices."

48.

The June 15, 2015, Field Safety Notice was sent "Attention: Hygiene Specialist, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

49.

The June 15,2015, Field Safety Notice states as follows:

> *"Sorin has become aware that the actual disinfection practices and its 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."*

50.

The June 15, 2015 Field Safety Notice also provided customers with updated Instructions for Use, dated February 2015, regarding disinfection and maintenance procedures.

51.

On or about August 6, 2015, Sorin authored a letter, entitled, "Update to the Field Safety Notice for Heater-Cooler System 3T."

52.

According to the letter, "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."

53.

Attached to the August 6, 2015, letter were the updated Instructions for Use for devices used in the United States ("2015 IFU").

54.

According to Part 5.2 of the 2015 IFU, entitled, "Filling the water tanks," filtered tap water was to be used, and in order to prevent microbial growth, "150 ml (5 US FL Oz.) of medical grade 3% hydrogen peroxide solution" was to be added to the tank contents.

55.

According to Part 6.3 of the 2015 IFU, entitled, "Disinfection of the water circuits," "[p]rior to operating the heater-cooler for the first time, when placing the system in storage and during regular operation, the water circuits must be disinfected at intervals of 14 days. The Heater-Cooler 3T water circuits include the pump, heating and cooling tanks, fittings and all interconnecting tubing."

56.

Part 6.3.1 of the 2015 IFU states, "[f]or disinfection of the water circuits, use Clorox Regular Bleach (active ingredient: 8.25% sodium hypochlorite), Minncare Cold Sterilant or another SORIN GROUP approved disinfectant."

57.

According to Part 6.3.1 of the 2015 IFU, either 6 fluid ounces of concentrated Clorox Regular Bleach or 15 fluid ounces of Minncare Cold Sterilant must be added to the Stockert 3T's water tank to properly disinfect the device.

58.

According to Part 6.4 of the 2015 IFU, entitled, "Changing the water," "[t]he water in the water circuits must be changed every 7 days. In order to prevent microbial growth, add 150ml (5 US fl. Oz.) of medical grade 3% hydrogen peroxide solution to the tank contents."

59.

According to Sorin' s "FAQs for the Heater-Cooler System 3T Disinfection Process," Sorin recommended water testing immediately and then every three weeks for units that were not

properly maintained. Sorin also recommended implementing a monthly water testing schedule for units that were properly maintained.

60.

In July 2015, the Bavarian Health and Food Safety Authority conducted an on-site investigation of Sorin's Munchen, German manufacturing facility. Environmental samples were taken from the production line, on-site tap water, and from a used and disassembled heater-cooler device in the manufacturer's service center. Six of twenty samples obtained were positive for mycobacteria chimaera.

61.

On or about October 15, 2015, the FDA issued a Safety Communication warning hospitals and health care professionals of the association between heater-cooler devices and nontuberculous mycobacterium ("NTM") infections.

62.

On or about October 21 and 27, 2015, the Centers for Disease Control and Prevention ("CDC") issued two communications to raise awareness among healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

63.

On or about December 11, 2015, the Pennsylvania Department of Health issued a Health Advisory on NTM infections among patients undergoing open-heart surgeries.

64.

According to the Health Advisory, "epidemiological and microbiological findings from investigations in Europe and Pennsylvania convincingly support the conclusion that exposure to

contaminated HCUs [heater-cooler units] is associated with NTM infection among patients undergoing open heart surgery on CPB (cardiopulmonary bypass)."

65.

On or about December 29, 2015, the FDA sent LivaNova a Warning Letter, after conducting inspections at the LivaNova and/or Sorin's Munchen and Arvada facilities.

66.

According to the Warning Letter, the inspections revealed that the Stockert 3T devices are adulterated under 21 U.S.C.§ 351(h) and misbranded under 21 U.S.C. § 352(o) and (t)(2).

67.

According to the Warning Letter, the FDA advised LivaNova that its failure to validate the Stockert 3T design changes to ensure the device's safety resulted in the device being illegally marketed.

68.

A Class II recall of the Stockert 3T device was issued by the FDA on March 17, 2016. The recall covers 1,125 units.

69.

The FDA "determined cause" for the recall is "device design."

70.

On April 28, 2016, an article entitled, "Contamination during production of heater-cooler units by Mycobacterium chimaera potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016" (hereinafter "Haller article") was published in the journal, *Eurosurveillance*.

71.

The Haller article presented the results of a surveillance of clinical cases and of contaminated heater-cooler devices, as well as environmental investigations in Germany prior to February 2016.

72.

According to the Haller article, "[d]uring environmental investigations, *M. chimaera* was detected in samples from used HCUs [heater-cooler units] from three different countries and samples from new HCUs as well as in the environment at the manufacturing site of one manufacturer in Germany." The manufacturing facility identified was LivaNova and/or Sorin's facility in Munchen, Germany.

73.

The Haller article concluded that "at least some of the five German cases with *M. chimaera* infection may have occurred due to contamination of the HCUs by *M. chimaera* at the manufacturing site."

74.

Further, the Haller article notes, "[a]ccording to the information provided by LivaNova and/or Sorin, HCUs manufactured before mid-August 2014 may have had environmental mycobacteria presence in the unit at the time of delivery."

75.

On or about June 1, 2016, the FDA issued a Safety Communication entitled, "Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stockert 3T-Heater-Cooler System."

76.

The FDA's Safety Communication notes that "[t]esting conducted by the manufacturer in August 2014 found *M chimaera* contamination on the production line and water supply at the 3T manufacturing facility."

77.

According to the FDA, the Haller article suggests "a direct link between the *M. chimaera* to which the European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model-the 3T."

78.

The FDA alerted health care facilities that if they purchased and used the 3T prior to September 2014, they must "be aware the units may have been shipped from the factory contaminated with *M chimaera*."

79.

On October 13, 2016, the CDC issued a press release warning hospitals about the risk of Mycobacterium infections when using the Stockert 3T.

80.

In the October 13, 2016 press release, the CDC specifically warned the hospitals to check to see what equipment was in use, ensure that they are maintained according to the latest manufacturer instructions, and alert affected patients and the clinicians who care for them.

81.

In response to the October 13, 2016 CDC press release, LivaNova, the parent company of Sorin, issued another Field Safety Notice Update that specifically noted that the CDC and the FDA recommended:

- Heater-cooler devices known or suspected to be contaminated with [Mycobacterium], based on the facility's testing program or other information known to the hospital, should be removed from service.

- Heater-cooler devices manufactured before September 2014 should only be used as directed by the FDA Safety Communication.

- Heater-cooler devices that are not known or suspected to be contaminated and manufactured during or after September 2014 should be used in accordance with the Operating Instructions and take into account additional precautions specified in the FDA Safety Communication.

    a. Following the Operating Instructions for heater-cooler devices and specifically those relating to cleaning and disinfecting. We continue to believe that following these operating instructions is essential to mitigating the potential risk posed by using these non-sterile devices. The FDA Safety Communication confirms the importance of following the applicable operating instructions.

    b. Conducting water quality monitoring per LivaNova's June 2015 3T Field Safety Notice "Cardiac Surgery Mycobacterium Risks."

82.

On December 2, 2016, LivaNova sent a letter warning facilities to review the November 1, 2016 recommendations from the FDA regarding the Stockert 3T.

83.

Following R. M.'s August 2, 2017 Fontan circulation procedure during which the Stockert 3T device was used, she developed yellowish drainage to her surgical incision site, and she subsequently required treatment for *mycobacterium abscessus*. R.M. was admitted to Children's Hospital on August 29, 2017 with a postoperative sternal wound infection and discharged on October 16, 2017. Over the course of her hospital stay at Children's Hospital, R.M. underwent

numerous procedures under general anesthesia, including an incision and drainage of her sternal wound, several replacements of wound VAC dressings and the placement of a Broviac catheter.

FIRST CAUSE OF ACTION
(PURSUANT TO THE LOUISIANA PRODUCTS LIABILITY ACT (LSA-R.S. 9:2800.52, *ET SEQ.)*

84.

Plaintiffs reiterate, re-allege, and re-aver all allegations in the preceding paragraphs as if fully set forth at length herein.

85.

Defendants, LivaNova and Sorin, under all applicable laws including, but not limited to, the Louisiana Products Liability Act, LSA-R.S. 9:2800.52 *et seq.*, are liable unto Plaintiffs for the injuries and damages to the minor, R. M., and for Plaintiffs' damages for developing, designing, manufacturing, testing, marketing, distributing, and selling a product, particularly the Stockert 3T, that was unreasonably dangerous in design.

SECOND CAUSE OF ACTION
(PURSUANT TO THE LOUISIANA PRODUCTS LIABILITY ACT (LSA-R.S. 9:2800.52, *ET SEQ.)*

86.

Plaintiffs reiterate, re-allege, and re-aver all allegations in the preceding paragraphs as if fully set forth at length herein.

87.

Defendants, LivaNova and Sorin, under all applicable laws including, but not limited to, the Louisiana Products Liability Act, LSA-R.S. 9:2800.52 *et seq.*, are liable unto Plaintiffs for the injuries and damages to the minor, R. M., and for Plaintiffs' damages for developing, designing,

manufacturing, testing, marketing, distributing, and selling a product, particularly the Stockert 3T, that was unreasonably dangerous in construction or composition.

THIRD CAUSE OF ACTION
(PURSUANT TO THE LOUISIANA PRODUCTS LIABILITY ACT (LSA-R.S. 9:2800.52, *ET SEQ.)*

88.

Plaintiffs reiterate, re-allege, and re-aver all allegations in the preceding paragraphs as if fully set forth at length herein.

89.

Defendants, LivaNova and Sorin, under all applicable laws including, but not limited to, the Louisiana Products Liability Act, LSA-R.S. 9:2800.52 *et seq.*, are liable unto Plaintiffs for the injuries and damages to the minor, R. M., and for Plaintiffs' damages for developing, designing, manufacturing, testing, marketing, distributing, and selling a product, particularly the Stockert 3T, that was unreasonably dangerous because adequate warnings about the product had not been provided.

FOURTH CAUSE OF ACTION
(PURSUANT TO THE LOUISIANA PRODUCTS LIABILITY ACT (LSA-R.S. 9:2800.52, *ET SEQ.)*

90.

Plaintiffs reiterate, re-allege, and re-aver all allegations in the preceding paragraphs as if fully set forth at length herein.

91.

Defendants, LivaNova and Sorin, under all applicable laws including, but not limited to, the Louisiana Products Liability Act, LSA-R.S. 9:2800.52 *et seq.*, are liable unto Plaintiffs for the injuries and damages to the minor, R. M., and for Plaintiffs' damages for developing, designing, manufacturing, testing, marketing, distributing, and selling a product, particularly the Stockert 3T,

that was unreasonably dangerous because the product did not conform to an express warranty of the manufacturer about the product.

INJURIES AND DAMAGES

92.

As a result of the fault of Defendants, the minor, R. M., was caused to be treated for a *mycobacterium abscessus* infection and other injuries and residuals, including, but not limited to, permanent scarring; she has been caused to suffer severe physical pain, mental anguish and emotional distress; she has required extensive and painful treatment, including several surgeries and the prolonged need for powerful antibiotics, for her injuries and the serious residuals thereof; she has suffered residual and permanent disabilities and impairments, physical, mental, and emotional; she has been handicapped in her everyday activities; she will continue to require additional medical treatment and related care in the future; all for which Plaintiffs, on behalf of their minor daughter, are entitled to recover from Defendants all amounts reasonable in the premises.

93.

As a result of the injuries and damages sustained by his minor daughter, R. M., Plaintiff, Ryan Paul Mitchell, Sr., has suffered and will continue to suffer the loss of his daughter's consortium, service and society, for which this Plaintiff is entitled to recover from Defendants pursuant to Article 2315(B) of the Louisiana Civil Code all amounts reasonable in the premises.

94.

As a result of the injuries and damages sustained by her minor daughter, R. M., Plaintiff, Delacy Lucas, has suffered and will continue to suffer the loss of her daughter's consortium, service and society, for which this Plaintiff is entitled to recover from Defendants pursuant to Article 2315(B) of the Louisiana Civil Code all amounts reasonable in the premises.

95.

Plaintiffs are also entitled to recover from Defendants all past and future medical, hospital, and related bills that have been and will be incurred for the medical care and treatment of their minor daughter, R. M., for her severe injuries and residuals and their lost wages resulting from the time they missed from their employments to provide care to R. M. and to take her to receive treatment from her healthcare providers.

JURY DEMAND

96.

Plaintiffs are entitled to and demand a trial by jury.

WHEREFORE, Plaintiffs, Ryan Paul Mitchell, Sr. and Delacy Lucas, individually and on behalf of their minor daughter, R. M., pray for the following relief:

a. That Defendants, LivaNova, PLC and Sorin Group USA, Inc., be served with a copy of this Complaint for Damages;

b. That after due proceedings had, there be judgment in favor of Plaintiffs, individually and on behalf of their minor daughter, R. M., and against Defendants, jointly, severally, and *in solido*, for all amounts reasonable in the premises;

c. For legal interest on all sums from date of judicial demand;

d. For all costs of these proceedings;

e. For all appropriate legal and equitable relief; and

f. For a trial by jury.

BY ATTORNEYS:

WALTERS, PAPILLION, THOMAS, CULLENS, LLC

s/David Abboud Thomas
David Abboud Thomas (LA Bar Roll No. 22701)
Hayden A. Moore (LA Bar Roll No. 35254)

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abboud@lawbr.net
haydenmoore@lawbr.net

PLEASE SERVE:

LivaNova, PLC
Service instructions will be provided

Sorin Group USA, Inc.
Through its registered agent for service of process:
C T Corporation System
3867 Plaza Tower Drive
Baton Rouge, Louisiana 70816

JS 44 (Rev. 06/17)

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

Ryan Paul Mitchell, Sr. and Delacy Lucas, individually and obo their minor daughter, R. M.

(b) County of Residence of First Listed Plaintiff St. James Parish
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
David Abboud Thomas -Walters, Papillion, Thomas, Cullens, LLC
12345 Perkins Road, Bldg. 1, Baton Rouge, LA 70810
225-236-3636

DEFENDANTS

LivaNova, PLC, f/k/a Sorin Group S.p.A. and/or Sorin Group Deutschland GmbH, and Sorin Group 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)*

Click here for: Nature of Suit Code Descriptions.

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
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 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
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 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 - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC 1332(a)(1) and (2)

Brief description of cause:
Defendants' product caused infection

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 2:18-cv-06357

DATE 07/25/2018

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

RYAN PAUL MITCHELL, SR AND DELACY LUCAS, INDIVIDUALLY AND ON BEHALF OF THEIR MINOR DAUGHTER, R. M.

Plaintiff(s)

v.

LIVANOVA, PLC AND SORIN GROUP USA, INC.

Defendant(s)

Civil Action No. 18-cv-6965

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Sorin Group USA, Inc.
Through its registered agent for service of process:
CT Corporation System
3867 Plaza Tower Drive
Baton Rouge, LA 70816

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

David Abboud Thomas
Walters, Papillion, Thomas, Cullens, LLC
12345 Perkins Road, Building One
Baton Rouge, LA 70810

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: