IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

Edward Ray Waddell, Individually, Plaintiff, vs. LivaNova PLC, Sorin Group Deutschland GmbH, and Sorin Group USA, Inc., Defendants.	Civil Action No. _____ **COMPLAINT** **(Jury Trial Requested)**

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

NATURE OF THE ACTION

1. Plaintiff was exposed to nontuberculous mycobacterium ("NTM") through a Sorin 3T Heater-Cooler System (the "Sorin 3T System") used to regulate his blood temperature during open chest surgeries at Greenville Health Hospital System ("Greenville Health").

2. As further described below, Defendants LivaNova PLC, Sorin Group Deutschland GmbH, and Sorin Group USA, Inc. knew or should have known that design and/or manufacturing defects in their Sorin 3T System cause bacterial colonization to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death. Additionally, Defendants knew or should have known of proper disinfectant and sterilization procedures to clean the Sorin 3T System to prevent the colonization and spreading of NTM bacteria.

3. Through this action, Plaintiff seeks damages for his injuries.

PARTIES TO THIS ACTION

4. Plaintiff Edward Ray Waddell is a resident and citizen of Greenville County, State of South Carolina. On December 26, 2013, Plaintiff Waddell underwent coronary stenting procedure. On January 2, 2014, he had an aortic valve replacement at the Greenville Health System Hospital ("GHS") in Greenville, South Carolina. The Sorin 3T System was used during this procedure, resulting in his NTM infection.

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

6. Defendant Sorin Group Deutschland GmbH ("Sorin") is a foreign for-profit corporation headquartered in Munich, Germany. Sorin designed, manufactured, and marketed the Sorin 3T System used in Plaintiff's surgeries.

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

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

JURISDICTON AND VENUE

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

9. This Court has personal jurisdiction over this action pursuant to Fed. R. Civ. P. 4 and S.C. Code Ann. § 36-2-803. Defendants are non-domiciliaries of South Carolina, conduct business in South Carolina, and maintain general and specific contacts in South Carolina. Defendants have committed tortious acts within South Carolina causing injury to a person within South Carolina. Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in South Carolina. Defendants are in the business of researching, designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, the Sorin 3T System in South Carolina.

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

GENERAL FACTUAL ALLEGATIONS

A. The Sorin 3T System

11. Defendants market and sell thermal regulator devices to be used on patients in the

operating room, including the Sorin 3T System.

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

13. The Sorin 3T System used during Plaintiff's surgery was designed, manufactured, marketed, and/or sold by Defendants.

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

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

16. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in

the letter is a violation of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with the Act's requirements, including but not limited to: Registration and Listing (21 C.F.R. part 807); Labeling (21 C.F.R. part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21 C.F.R. part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act; 21 C.F.R. 1000-1050).

B. The GHS Infection Outbreak

17. On or about June 20, 2014, GHS publically announced that approximately 14 patients had tested positive for a rare NTM infection known as Mycobacterium abscessus ("*M. abscessus*"). Most of those patients were exposed to the bacterium during open chest surgeries. At that time, GHS indicated that there had been three deaths resulting from the same infection. On or about June 26, 2014, GHS released a second statement indicating that there were 15 confirmed cases of patients with the infection.

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

19. On July 21, 2014, GHS confirmed that the patient death toll had increased to four. In the July 21, 2014 announcement, GHS stated that it sent out letters to "approximately 180 patients on whom specific cardiopulmonary surgical equipment had been used," since those patients were at risk after potentially being exposed to the *M. abscessus* bacterium, including Plaintiff Waddell.

C. The Bacteria

20. NTM occurs naturally in the environment. Because the Sorin 3T System aerosolized NTM into the operating room during open chest surgeries, patients were exposed to a greater amount of NTM than naturally occurring background levels.

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

22. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to four years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease.

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

24. Diagnosis of *M. abscessus* can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the bacterium can be found in the blood and isolated from a blood sample. Targeted cultures, screenings, and proper testing are usually not performed unless the physician has been made aware of this type of mycobacterium exposure.

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

26. While an NTM infection diagnosed early may be successfully treated by draining collections of pus or removing the infected tissue, coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time, there is a significant risk of death in cases diagnosed late and in individuals with considerably weakened immune systems.

D. Medical Devices Identified as the Infection Source

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

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

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

30. 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.

31. 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.

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

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.

E. Recall of the Sorin 3T System

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

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

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

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

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

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

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

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

d. H2O2 in low dose for preservation;

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

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

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

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

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

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

41. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

42. In the letter, the FDA identified various design change orders dating back to

December 11, 2012 that had never been submitted to the FDA for approval.

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

FACTS SPECIFIC TO THIS CASE

44. Defendants' Sorin 3T System was used during Plaintiff's aortic valve replacement and cardiac bypass grafting procedure performed at GHS on or about December 26, 2013. Plaintiff's surgeon, Dr. Barry Davis, used the device to assist in the cooling and re-warming of Plaintiff's blood. Plaintiff was subsequently discharged from the hospital.

45. Over the following days and weeks, Plaintiff's condition began to deteriorate. Initially, while there were no observable signs of infection around the incision site, Plaintiff began running a high-grade fever, displayed signs of increasing weakness, and developed pneumonia.

46. In April 2014, Plaintiff began treatment at GHS for a red rash and bubbling around his sternal wound and an area toward the superior aspect of his incision that appeared to be swollen and contain fluid. Plaintiff was placed on antibiotics and scheduled to undergo sternal debridement by Dr. Davis. Plaintiff underwent the sternal debridement, was fitted with a wound vac, and was continued on antibiotics while the wound contents were cultured.

47. Plaintiff had to undergo additional debridement, as well as a pectoralis major muscle flap procedure, which has severely affected the use of his arm.

48. The wound cultured out mycobacteria. Plaintiff was discharged home with the wound vac and was scheduled for home health care, as well as regular treatment by an infectious disease physician in addition to his cardiologist and a thoracic surgeon.

49. In the fall of 2015, Plaintiff was readmitted to GHS for delayed healing of his surgical

wound. While attempting to dress his wound, nurses found pus bubbling from the tissue at the incision site.

50. Due to the severity of Plaintiff's wound dehiscence and exposure of wires and sutures, he was again taken for a sternal debridement and wound flap procedure review. All the sutures and wiring had to be redone. Plaintiff also developed an aortic aneurysm from the infection.

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

52. Plaintiff continued treatment for the *M. abscessus* infection and was either hospitalized or received treatment at a physician's office in 2014, 2015, and 2016. Plaintiff's treatment by physicians for this *M. abscessus* infection is ongoing.

COUNT I - NEGLIGENCE

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

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

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

a. Failing to conduct adequate safety and efficacy testing before seeking to have

the Sorin 3T System put into the stream of commerce;

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

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

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

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

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

56. Defendants owed Plaintiff a duty of reasonable care to discover defects and/or errors in the Sorin 3T System and to inform and/or warn the FDA, the medical community, Plaintiff, and the public of a defect once it was discovered. Defendants violated these duties when they failed to do so, which further placed Plaintiff at risk for harm and injury.

57. The Sorin 3T System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution, and advertising from the system that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution, and advertising of the Sorin 3T System used at during Plaintiff's surgery at GHS was in violation of those requirements.

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

59. As a direct and proximate result of Defendants' negligent, careless, grossly negligent, and reckless conduct, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

COUNT II – STRICT PRODUCTS LIABILITY

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

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

62. As a direct and proximate result of Defendants' negligent, careless, grossly negligent, and reckless conduct, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

COUNT III – BREACH OF EXPRESS WARRANTY

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

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

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

66. As a direct and proximate result of Defendants' breaches of express warranties, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

COUNT IV – BREACH OF IMPLIED WARRANTY

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

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

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

70. Plaintiff, individually and/or by and through his healthcare providers, relied upon

Defendants' implied warranties of merchantability in consenting to have the heart procedure performed with assistance of the Sorin 3T System.

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

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

73. As a direct and proximate result of Defendants' breaches of implied warranties, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

COUNT V – NEGLIGENT MISREPRESENTATION

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

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

76. Defendants failed to adhere to FDA regulations by failing to appropriately report all information and knowledge in their possession regarding the dangers Defendants knew their product presented, including, but not limited to, the fact that colonization of mycobacteria inside

the Sorin 3T System could occur if specific disinfection and maintenance procedures were not implemented.

77. Had Defendants accurately and truthfully represented to the FDA, the medical community, Plaintiff, and the public the material facts relating to the risks of the Sorin 3T System, GHS would not have utilized the Sorin 3T System for the procedure during which Plaintiff contracted the *M. abscessus* infection resulting in his injuries.

78. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

COUNT VI – MISREPRESENTATION BY OMISSION

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

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

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

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

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

84. As a direct and proximate result of Defendants' misrepresentations by omission, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

COUNT VII – VIOLATION OF THE UNFAIR TRADE PRACTICES ACT

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

86. Defendants have engaged in unfair and deceptive acts or practices in violation of the South Carolina Unfair Trade Practices Act, S.C. Code § 39-5-10, *et seq.*, including but not limited to, utilizing deception, fraud, misrepresentation, concealment, omission, and suppression of research from investigations, adverse events reported to the FDA, and clinical trials regarding the safety, efficacy, instructions for use, and the unreasonably dangerous nature of the Sorin 3T System.

87. Defendants violated the Unfair Trade Practices Act by concealing, omitting, and failing to inform the FDA, Plaintiff, the medical community, and other purchasers of the failures,

adverse reactions, complications, and the insufficiency of the Instructions for Use as it related to the Sorin 3T System.

88. Defendants' unfair and deceptive acts and practices occurred during a course of conduct involving trade or commerce and had a public impact.

89. Defendants' conduct caused harm to the residents of South Carolina, and the conduct is subject to repetition and has been repeated on numerous occasions.

90. As a direct and proximate result of Defendants' violations of the Unfair Trade Practices Act, Plaintiff has suffered permanent and painful injuries, including but not limited to past and future mental anguish, past and future physical pain and suffering, past and future life care expenses, past and future permanent physical impairment, past and future medical and health care expenses, past and future loss of enjoyment of life, and loss of earnings or earning capacity for which Plaintiff is entitled to recover actual, consequential, punitive, and special damages in an amount to be determined by a jury at trial.

91. Plaintiff is entitled to an award of reasonable attorneys' fees and costs pursuant to S.C. Code § 39-5-140.

92. Defendants' unfair and deceptive acts and practices were a willful and knowing violation S.C. Code § 39-5-20. Plaintiffs is therefore entitled to an award of three times the actual damages sustained pursuant to S.C. Code § 39-5-140.

PUNITIVE DAMAGES

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

94. Defendants' acts, omissions, and violations as set forth herein constitute intentional, fraudulent, malicious, willful, wanton, and/or reckless conduct. Accordingly, Plaintiff is entitled to

an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the Court to enter judgment against Defendants as follows:

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

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

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

JURY TRIAL DEMAND

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

Respectfully submitted,

McGowan Hood & Felder, LLC

/s/ *James L. Ward, Jr.*

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