**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF FLORIDA**

LIFENET HEALTH,
A Virginia Corporation

Plaintiff,

v.

RTI SURGICAL, INC.,
A Delaware Corporation

Defendant.

Civil Action No. 3:18-cv-817-J-34JRK

**JURY TRIAL DEMANDED**

# COMPLAINT

LifeNet Health, by and through its undersigned counsel, states as follows for its complaint against the defendant, RTI Surgical, Inc. ("RTI" or "Defendant"):

## I. THE PARTIES

### A. LifeNet Health

1. LifeNet Health is a nonprofit corporation organized under 26 U.S.C. § 501(c)(3) and existing under the laws of the Commonwealth of Virginia and having a principal place of business at 1864 Concert Drive, Virginia Beach, Virginia 23453.

2. LifeNet Health's mission statement is "Saving Lives, Restoring Health and Giving Hope." Founded in 1982 as the Eastern Virginia Tissue Bank, LifeNet Health is one of the world's most trusted providers of transplant solutions, from organ and tissue procurement to innovative bio-implant technologies and cellular therapies.

3. Each year, LifeNet Health facilitates the transplantation of over 400 organs in the United States and distributes over 500,000 allograft bio-implants to meet the needs of hospitals

and patients in the United States and internationally. An allograft is human donor tissue, such as skin, bone, tendon, or cardiovascular tissue, intended for transplantation in a human recipient.

4. LifeNet Health is also extensively involved in promoting and facilitating tissue donation and bio-implant tissues. For example, LifeNet Health's Tissue Services Division is dedicated to training, educating, and maintaining relationships with more than 50 partners to promote tissue donation in their respective communities.

5. LifeNet Health also established its Wound Management & Surgical Reconstruction franchise to ensure the processing and delivery of skin/dermal allograft bio-implants for U.S. and international trauma and burn centers.

6. In addition, LifeNet Health's Bio-Implants Division has pioneered technologies related to all aspects of the allograft bio-implant production process, including disinfection, decellularization (the removal of cellular elements from an allograft bio-implant), fabrication, preservation, and sterilization.

7. LifeNet Health is also a member of several organizations related to tissue donation. For example, LifeNet Health is an accredited member of the American Association of Tissue Banks, and also a member organization of Donate Life America, a not-for-profit alliance of national organizations across the United States committed to increasing organ, eye, and tissue donation.

8. The patents asserted by LifeNet Health in this Complaint are a result of LifeNet Health's extensive research and development in the field of tissue and bio-implant technology.

**B. RTI Surgical, Inc.**

9. Upon information and belief, RTI is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 11621 Research Circle,

Alachua, FL 32615. RTI also has a regular and established place of business in this judicial district at 13901 Sutton Park Drive South, Suite 350C, Jacksonville, Florida 32224.

10. RTI is in the business of importing, manufacturing, selling, and/or offering for sale various medical products including skin/dermal products under the brand name Fortiva™ ("Fortiva"). RTI is also in the business of manufacturing, selling, and/or offering for sale various bone products including Capistrano Cervical Allograft Spacer System ("Capistrano"), Puros-S2 cervical ("Puros-S2"), AlloQuent-S ("AlloQuent"), CeSpace Cortical Cancellous Bone ("CeSpace"), Cornerstone ASR-Cortical Cancellous Block ("Cornerstone ASR"), and Elemax Cortical Cancellous Spacer ("Elemax").

11. Upon information and belief, Fortiva is a porcine (pig) skin xenograft (the "Infringing Soft Tissue Product").

12. Upon information and belief, Capistrano, Puros-S2, AlloQuent, CeSpace, Cornerstone ASR, and Elemax are allograft spine products (the "Infringing Bone Products").

## II. JURISDICTION AND VENUE

13. This action is a claim for patent infringement arising under the Patent Laws of the Unites States, 35 U.S.C. § 271 *et seq*.

14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a).

15. This Court has personal jurisdiction over RTI at least because RTI has substantial, continuing, and on-going contacts within the State of Florida and this judicial district, and RTI has sold and continues to sell the products at issue in this case in this State and judicial district.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) at least because RTI has a regular and established place of business in this judicial district. In addition, on information and belief, RTI has committed acts of infringement in the

State of Florida and in this judicial district, including but not limited to offering to sell and selling products that infringe one or more of LifeNet Health's asserted patents to customers located in this judicial district or for use in this judicial district.

## III. FACTS

### A. U.S. Patent No. 6,569,200

17. On June 5, 2001, U.S. Patent Application No. 09/874,862 (the "'862 application") was filed on behalf of inventors Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson. The '862 Application is a divisional application of U.S. Patent Application No. 09/107,459, filed June 30, 1998, now U.S. Patent No. 6,293,970 (the "'970 patent").

18. On May 27, 2003, the U.S. Patent and Trademark Office ("USPTO") issued the '862 application as U.S. Patent No. 6,569,200 (the "'200 patent"). A copy of the '200 patent is attached as Exhibit A.

19. LifeNet Health is the assignee of all right, title, and interest in and to the '200 patent and possesses all rights of recovery under the '200 patent.

20. The '200 patent is directed to, *inter alia*, "plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage," and methods for producing the same. *See* Exhibit A at Abstract.

21. As stated in the Abstract of the '200 patent, "[t]he invention replaces water in the molecular structure of the bone or soft tissue matrix with one or more plasticizers allowing for dehydration of the tissue, yet not resulting in an increase in brittleness of the plasticized product, and resulting in compressive and/or tensile properties similar to those of normal hydrated bone. Replacement of the chemical plasticizers by water prior to implantation is not required and thus, the dehydrated bone or soft tissue plasticized product can be placed directly into an implant site without significant preparation in the operating room." *Id.*

22. In 2010, with the launch of its Oracell® dermal implant, LifeNet introduced Preservon® grafts, processed using its proprietary bio-implant tissue-preservation technology based on the '200 patent family. This technology is an ambient temperature (room temperature) preservation method that simplifies the tissue-preparation and product-distribution processes and storage, saves valuable time in the operating room, and allows allograft tissue to retain its physical and biomechanical properties.

23. Starting in 2010 with the launch of its Oracell® dermal implant, LifeNet has marked its products incorporating the proprietary bio-implant tissue-preservation technology with the '200 patent number.

**B. U.S. Patent No. 9,579,420**

24. On February 8, 2010, U.S. Patent Application No. 12/701,634 (the "'634 application") was filed on behalf of inventors Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson (deceased) by plaintiff LifeNet Health.

25. On February 28, 2017, the USPTO issued the '634 application as U.S. Patent No. 9,579,420 (the "'420 patent"). A copy of the '420 patent is attached as Exhibit B.

26. The '420 patent claims priority through a series of applications to the '970 patent.

27. LifeNet Health is the assignee of all right, title, and interest in and to the '420 patent and possesses all rights of recovery under the '420 patent.

28. The '420 patent is one of several issued patents in the '970 patent family.

29. The invention of the '420 patent is also directed to, *inter alia*, "plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage," and methods for producing the same. *See* Exhibit B at Abstract.

**C. U.S. Patent No. 9,585,986**

30. On February 28, 2014, U.S. Patent Application No. 14/193,040 (the "'040 application") was filed on behalf of inventors Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson (deceased) by plaintiff LifeNet Health.

31. On March 7, 2017, the USPTO issued the '040 application as U.S. Patent No. 9,585,986 (the "'986 patent"). A copy of the '986 patent is attached as Exhibit C.

32. The '986 patent claims priority through a series of applications to the '970 patent.

33. LifeNet Health is the assignee of all right, title, and interest in and to the '986 patent and possesses all rights of recovery under the '986 patent.

34. The '986 patent is one of several issued patents in the '970 patent family.

35. The invention of the '986 patent is also directed to, *inter alia*, "plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage," and methods for producing the same. *See* Exhibit C at Abstract.

**D. U.S. Patent No. 6,458,158**

36. On October 27, 2000, U.S. Patent Application No. 09/699,029 (the "'029 application") was filed on behalf of inventors Billy G. Anderson and Lloyd Wolfinbarger, Jr.

37. On October 1, 2002, the USPTO issued the '029 application as U.S. Patent No. 6,458,158 (the "'158 patent"). A copy of the '158 patent is attached as Exhibit D.

38. The '158 patent is a continuation-in-part of U.S. Patent Application No. 09/286,975 (the "'975 application), filed on April 6, 1999, now abandoned. The '975 application is a continuation-in-part of U.S. Patent Application No. 09/225,299 (the "'299 application"), filed on January 5, 1999, now abandoned.

39. LifeNet Health is the assignee of all right, title, and interest in and to the '158 patent and possesses all rights of recovery under the '158 patent.

40. The invention of the ’158 patent is directed to “a composite bone graft for implantation in a patient.” *See* Exhibit D at Abstract.

**E. U.S. Patent No. 8,182,532**

41. On September 30, 2004, U.S. Patent Application No. 10/953,881 (the “’881 application”) was filed on behalf of inventors Billy G. Anderson (deceased) and Lloyd Wolfinbarger, Jr.

42. On May 22, 2012, the USPTO issued the ’881 application as U.S. Patent No. 8,182,532 (the “’532 patent”). A copy of the ’532 patent is attached as Exhibit E.

43. The ’532 patent claims priority through a series of applications to both the ’975 application and the ’299 application.

44. LifeNet Health is the assignee of all right, title, and interest in and to the ’532 patent and possesses all rights of recovery under the ’532 patent.

45. The invention of the ’532 patent is also directed to “a composite bone graft for implantation in a patient.” *See* Exhibit E at Abstract.

**F. Prior Litigation Regarding the ’200 Patent**

46. In September 2013, LifeNet Health filed suit in the U.S. District Court for the Eastern District of Virginia asserting infringement of the ’200 patent by LifeCell Corporation (“LifeCell”). *See* D.I. 1, Civil Action No. 2:13-cv-00486, September 6, 2013 (E.D. Va.) (the “’200 patent litigation”). LifeNet Health accused LifeCell’s porcine Strattice® product, among others, of infringing the ’200 patent.

47. After a ten-day jury trial, the jury found the ’200 patent to be valid and infringed by Strattice and other LifeCell products, and awarded damages to LifeNet Health in the amount of $34,741,971. *See* ’200 patent litigation, D.I. 369, 395. The U.S. Court of Appeals for the

Federal Circuit upheld the verdict in LifeNet Health's favor on appeal in a unanimous panel decision. *See LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316 (Fed. Cir. 2016).

48. On information and belief, RTI had knowledge of the '200 patent at least by virtue of the '200 patent litigation. On information and belief, RTI also had knowledge of the jury verdict and of the appellate decision of the '200 patent litigation.

**G. RTI's Infringing Soft Tissue Product**

49. Upon information and belief, RTI has been using, importing, manufacturing, selling, and/or offering for sale a porcine dermis tissue product under the brand name Fortiva.

50. RTI filed papers at the U.S. Food and Drug Administration ("FDA") and represented to the FDA that Fortiva "is substantially equivalent to the predicate device Strattice® (K070560) in intended use, material, design, and function." RTI March 5, 2013 510(k) Summary ("RTI 510(k)") (attached as Exhibit F) at 1. As discussed above, in the '200 patent litigation, Strattice was found to infringe claims 1-4, 7, 8, and 10 of the '200 patent, and this finding of infringement was upheld on appeal.

51. RTI makes a number of other claims about Fortiva in its FDA filings and in the Instructions for Use ("IFU") for Fortiva:

52. "Fortiva™ porcine dermis is an extracellular collagen matrix comprised of porcine dermal tissue that has been processed and terminally sterilized via gamma irradiation. The surgical mesh device is designed to perform as a scaffold that allows for neovascularization and permits replacement of the device with patient's tissue. The sterile device is supplied pre-hydrated in water and is provided in various sizes. The device is ready for immediate use without extra preparation (i.e., no rinsing, no soaking, etc.)" Fortiva IFU (attached as Exhibit G) at 2.

53. "This device is processed via the Tutoplast® tissue sterilization process which includes meticulous cleaning and solvent dehydration of the tissue. The process inactivates or removes potential pathogens, gently removes unwanted materials, such as cells, antigens and viruses. As part of the *Tutoplast* process, this device was terminally sterilized by gamma irradiation to a sterility assurance level (SAL) of $10^{-6}$. The sterilization validation method employed meets or exceeds requirements of the Association for the Advancement of Medical Instrumentation (AAMI) and International Organization for Standards (ISO)." Fortiva IFU, Exhibit G, at 2.

54. "The device is shipped at ambient temperature via expedited shipping methods. Keep the device in a clean, dry place between 10°C and 30°C and protected from direct sun exposure." Fortiva IFU, Exhibit G, at 2.

55. "The proposed device is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use. The proposed device is designed to perform as a scaffold that allows for neovascularization and permits replacement of the device with host tissue." RTI 510(k), Exhibit F, at 1.

56. "This device is comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and stored hydrated and ready to use. The device has the same technological characteristics as the predicate device [Strattice] in material, design, and function as listed in the table below:

| Characteristic | Proposed Device | Predicate Device |
|---|---|---|
| Intended Use | Surgical mesh scaffold to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. | Surgical mesh scaffold to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. |
| Material | Porcine Dermis | Porcine Dermis |
| Design | Terminally sterilized sheets in various sizes | Terminally sterilized sheets in various sizes |
| Function | Scaffold for soft tissue repair | Scaffold for soft tissue repair |
| Chemical composition | Not applicable to these devices. | |
| Energy Source | Not applicable to these devices. | |

."

RTI 510(k), Exhibit F at 2.

57. Upon information and belief, in view of the fact that RTI declared to the FDA that Fortiva "is substantially equivalent to the predicate device Strattice®" and in view of at least the claims made by RTI about Fortiva identified above, Fortiva meets each and every limitation of claims 1-4, 7, and 8 of the '200 patent.

58. Upon information and belief, and for those same reasons, Fortiva is a plasticized soft tissue graft suitable for transplantation into a human, as set forth in at least claims 1-4 of the '200 patent.

59. Upon information and belief, Fortiva is a cleaned soft tissue graft having an internal matrix, and one or more plasticizers contained in the internal matrix as set forth in claim 1. *See supra*, paragraphs 52 (Fortiva is "an extracellular collagen matrix comprised of porcine dermal tissue that has been processed"); 53 (Fortiva is processed by a method "which includes meticulous cleaning and solvent dehydration of the tissue." The processing "removes potential pathogens, gently removes unwanted materials, such as cells, antigens and viruses."); 55 (Fortiva "is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use."); 56 (Fortiva "has the

same technological characteristics as the predicate device [Strattice] in material, design, and function.").

60. Upon information and belief, the one or more plasticizers in Fortiva are not removed from the internal matrix of the plasticized soft tissue graft prior to transplantation into a human as set forth in claim 1. *See supra*, paragraphs 52 (Fortiva "is ready for immediate use without extra preparation (i.e., no rinsing, no soaking, etc.)"); 55 (Fortiva "is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use."); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

61. Upon information and belief, Fortiva is a plasticized soft tissue graft that is suitable for direct transplant into a human without rehydration, as set forth in claim 4. *See supra*, paragraphs 52 (Fortiva "is ready for immediate use without extra preparation (i.e., no rinsing, no soaking, etc.)"); 56 (Fortiva "is stored hydrated and ready to use."); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

62. Upon information and belief, RTI has been manufacturing, or causing to be manufactured, Fortiva, according to the method of claims 7 and 8 of the '200 patent. Upon information and belief, Fortiva is manufactured by impregnating a cleaned, soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft, where the one or more plasticizers are not removed from an internal matrix of the plasticized soft tissue graft prior to transplantation into a human as set forth in claim 7. *See supra*, paragraphs 52 (Fortiva "is ready for immediate use without extra preparation (i.e., no rinsing, no soaking, etc.)"); 53 (Fortiva is processed through a method that results in "solvent dehydration of the tissue"); 55 (Fortiva "is an

implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use."); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

63. Upon information and belief, Fortiva is a plasticized soft tissue graft suitable for transplantation into a human, as set forth in at least claims 1-4, 8, 9, 11, 13, and 14 of the '420 patent. Upon information and belief, Fortiva is a cleaned soft tissue graft having an internal matrix, and one or more plasticizers contained in the internal matrix as set forth in claim 1. *See supra*, paragraphs 52 (Fortiva is "an extracellular collagen matrix comprised of porcine dermal tissue that has been processed"); 53 (Fortiva is processed "which includes meticulous cleaning and solvent dehydration of the tissue." The processing "removes potential pathogens, gently removes unwanted materials, such as cells, antigens and viruses."); 55 (Fortiva "is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use."); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

64. Upon information and belief, Fortiva is a cleaned soft tissue graft comprising collagen fibers and the native orientation of the collagen fibers is maintained in the plasticized soft tissue graft as set forth in claim 1. *See supra*, paragraphs 52 (Fortiva is "an extracellular collagen matrix comprised of porcine dermal tissue that has been processed"); 53 (the cleaning process of Fortiva "gently removes unwanted materials"); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

65. Upon information and belief, Fortiva is a plasticized soft tissue graft that is suitable for direct transplant into a human without rehydration, as set forth in claim 4, is sterile, as set forth in claim 8, does not require refrigeration or freezing, as set forth in claim 9, and is suitable for storage at room temperature as set forth in claim 11. *See supra*, paragraphs 52, 55, 56 (stating that Fortiva is supplied ready to use without extra preparation required); 52, 53, 55, 56 (stating that Fortiva is sterilized); and paragraph 56 (stating that Fortiva is "shipped at ambient temperature" and is to be stored "between 10°C and 30°C").

66. Upon information and belief, RTI has been manufacturing, or causing to be manufactured, Fortiva, according to the method of claims 16-18, 28, 29, 34, and 35 of the '420 patent. Upon information and belief, Fortiva is manufactured by impregnating a cleaned soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft, wherein the cleaned soft tissue graft comprise collagen fibers, and the orientation of the collagen fibers is not altered by the step of impregnating, such that the native orientation of the collagen fibers is maintained in the plasticized soft tissue graft, as set forth in claim 16. *See supra*, paragraphs 52 (Fortiva is "an extracellular collagen matrix comprised of porcine dermal tissue that has been processed"); 53 (Fortiva is processed through a method that results in "solvent dehydration of the tissue" and the cleaning process of Fortiva "gently removes unwanted materials"); 55 (Fortiva "is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use."); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

67. Upon information and belief, Fortiva is a soft tissue graft as set forth in at least claim 11 of the '986 patent. Upon information and belief, Fortiva includes a soft tissue graft

obtained from a human or animal donor and a plasticizer, wherein cellular elements are substantially removed from said the tissue, the plasticizer is contained in the soft tissue, and the plasticized soft tissue has mechanical properties of natural soft tissue, as set forth in claim 11. *See supra*, paragraphs 52 (Fortiva is "an extracellular collagen matrix comprised of porcine dermal tissue that has been processed"; Fortiva "is ready for immediate use without extra preparation (i.e., no rinsing, no soaking, etc.)); 53 (Fortiva is processed through a method "which includes meticulous cleaning and solvent dehydration of the tissue. The process inactivates or removes potential pathogens, gently removes unwanted materials, such as cells, antigens and viruses."); 55 (Fortiva "is an implantable surgical mesh comprised of non-crosslinked porcine dermis that has been processed, terminally sterilized and is stored hydrated and ready to use. The proposed device is designed to perform as a scaffold that allows for neovascularization and permits replacement of the device with host tissue."); 56 (Fortiva "has the same technological characteristics as the predicate device [Strattice] in material, design, and function.").

**H. RTI's Infringing Bone Products**

**1. RTI's Infringement of the '158 and '532 Patents by Capistrano**

68. Upon information and belief, RTI has been using, manufacturing, selling, and offering for sale a bone product under the brand name Capistrano Cervical Allograft Spacer System. Exhibit H (RTI Form 10K, 2011) at 7[1]; Exhibit I (RTI Form 10K, 2012) at 7.

69. Upon information and belief, Capistrano is a cervical allograft spacer system machined from cortical and cancellous allograft bone and assembled using cortical pins to provide an optimal osteoconductive scaffold. Exhibit J (SeaSpine webpage re Capistrano), at 1, and Exhibit K (Health Management Website), at 1.

[1] Citations used herein refer to the page numbering in the bottom right hand corner of the document.

70. Below is a picture of Capistrano:

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Exhibit J (SeaSpine webpage: http://www.seaspine.com/products/capistrano/) at 2.

71. Upon information and belief, Capistrano is a composite bone graft as set forth in at least claims 1 and 2 of the '158 patent. Upon information and belief, Capistrano is a cervical allograft spacer system machined from cortical and cancellous allograft bone. Capistrano includes a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, as set forth in claim 1. *See supra*, paragraphs 69 (stating that Capistrano is "a cervical allograft spacer system machined from cortical and cancellous allograft bone"); and 70 (depicting the structure of the Capistrano graft).

72. Upon information and belief, Capistrano is a cervical allograft spacer system machined from cortical and cancellous allograft bone and assembled using cortical pins to provide an optimal osteoconductive scaffold. Capistrano has one or more bone pins for holding together the graft unit, wherein the first cortical bone portion and the second cortical bone portion are not in physical contact, and wherein the composite bone graft does not comprise an adhesive and the bone graft is not demineralized, as set forth in claims 1 and 2 of the '158 patent. *See supra*, paragraphs 69 (stating that Capistrano is "is a cervical allograft spacer system

machined from cortical and cancellous allograft bone and assembled using cortical pins to provide an optimal osteoconductive scaffold"); and 70 (depicting the structure of the Capistrano graft).

73. Upon information and belief, Capistrano is a load-bearing composite spinal bone graft for implantation into a host as set forth in at least claim 12 of the '532 patent. Upon information and belief, Capistrano includes (1) a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (2) a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (3) one or more osteoconductive substances disposed between the first cortical bone portion and the second cortical bone portion and configured to contact a portion of the host bone to form a graft unit; and (4) one or more non-adhesive mechanical connectors for holding together the load-bearing spinal bone graft unit, the spinal bone graft being configured for implantation into the anterior spinal column of the host, as set forth in claim 12. *See supra*, paragraphs 69 (stating that Capistrano is "is a cervical allograft spacer system machined from cortical and cancellous allograft bone and assembled using cortical pins to provide an optimal osteoconductive scaffold"); and 70 (depicting the structure of the Capistrano graft).

**2. RTI's Infringement of the '158 and '532 Patents by Puros-S2**

74. Upon information and belief, RTI has been using, manufacturing, selling, and offering for sale a bone product under the brand name Puros-S2 cervical. Exhibit L (RTI 10K, 2008), at 7.

75. Upon information and belief, the sterile Puros-S2 cervical implant is machined from cortical and cancellous bone and designed to maintain the height of the interbody space and provides an osteoconductive lattice for bony in-growth. Exhibit M (Puros S2 product webpage: http://www.zimmerbiomet.com/medical-professionals/spine/product/puros-s-s2-cervical-

interbody.html), at 1. Upon information and belief, Puros-S2 has the strength of cortical bone with an osteoconductive cancellous center. Exhibit M (Puros S2 product webpage: http://www.zimmerbiomet.com/medical-professionals/spine/product/puros-s-s2-cervical-interbody.html), at 2.

76. Below is a picture of Puros-S2:

Exhibit N (Puros S2 product webpage: http://www.zimmer.com/medical-professionals/products/spine/puros-s-s2-cervical-interbody.html), at 1.

77. Upon information and belief, Puros-S2 is a composite bone graft as set forth in at least claims 1 and 2 of the ’158 patent. Upon information and belief, Puros-S2 is a cervical implant, machined from cortical and cancellous bone and has the strength of cortical bone with an osteoconductive cancellous center. Puros-S2 includes a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, as set forth in claim 1. *See supra*, paragraphs 75 (stating that Puros-S2 is a “cervical implant, machined from cortical and cancellous bone”); 75 (stating that Puros-S2 has the “strength of cortical bone with an osteoconductive cancellous center”); and 76 (depicting the structure of the Puros-S2 graft).

78. Upon information and belief, Puros-S2 is a cervical implant, machined from cortical and cancellous bone and designed to maintain the height of the interbody space, and provides an osteoconductive lattice for bony in-growth. Puros-S2 has one or more bone pins for holding together the graft unit, wherein the first cortical bone portion and the second cortical bone portion are not in physical contact, and wherein the composite bone graft does not comprise an adhesive and the bone graft is not demineralized, as set forth in claims 1 and 2 of the '158 patent. *See supra*, paragraphs 75 (stating that Puros-S2 is a "cervical implant, machined from cortical and cancellous bone and designed to maintain the height of the interbody space, [and] provides an osteoconductive lattice for bony in-growth"); 75 (stating that Puros-S2 has the "strength of cortical bone with an osteoconductive cancellous center"); and 76 (depicting the structure of the Puros-S2 graft).

79. Upon information and belief, Puros-S2 is a load-bearing composite spinal bone graft for implantation into a host as set forth in at least claim 12 of the '532 patent. Upon information and belief, Puros-S2 includes (1) a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (2) a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (3) one or more osteoconductive substances disposed between the first cortical bone portion and the second cortical bone portion and configured to contact a portion of the host bone to form a graft unit; and (4) one or more non-adhesive mechanical connectors for holding together the load-bearing spinal bone graft unit, the spinal bone graft being configured for implantation into the anterior spinal column of the host, as set forth in claim 12. *See supra*, paragraphs 75 (stating that Puros-S2 is a "cervical implant, machined from cortical and cancellous bone and designed to maintain the height of the interbody space, [and] provides an

osteoconductive lattice for bony in-growth"); 75 (stating that Puros-S2 has the "strength of cortical bone with an osteoconductive cancellous center"); and 76 (depicting the structure of the Puros-S2 graft).

**3. RTI's Infringement of the '158 and '532 Patents by AlloQuent**

80. Upon information and belief, RTI has been using, manufacturing, selling, and offering for sale a bone product under the brand name AlloQuent-S. Exhibit L (RTI 10K, 2008), at 7.

81. Upon information and belief, AlloQuent is a premium assembled cervical allograft that combines the desirable features of a cortical and a cancellous allograft. Anti-migration ribs ensure secure placement while the cancellous center provides the optimum scaffold for new bone integration. The cortical planks provide structural integrity and protect against subsidence. Exhibit O (AlloQuent brochure: http://web.orthofix.com/Products/Products/AlloQuent/AlloQuent-Brochure.pdf) at 2.

82. Below is a picture of AlloQuent:


Exhibit P (AlloQuent – Quick Reference Guide) at 2.

83. Upon information and belief, AlloQuent is a composite bone graft as set forth in at least claims 1 and 2 of the '158 patent. Upon information and belief, AlloQuent is an assembled cervical allograft that combines the desirable features of a cortical and a cancellous allograft with anti-migration ribs that ensure secure placement while the cancellous center

provides the optimum scaffold for new bone integration. AlloQuent includes a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, as set forth in claim 1. *See supra*, paragraphs 81 (stating that AlloQuent is "a premium assembled cervical allograft that combines the desirable features of a cortical and a cancellous allograft. Anti-migration ribs ensure secure placement while the cancellous center provides the optimum scaffold for new bone integration. The cortical planks provide structural integrity and protect against subsidence."); and 82 (depicting the structure of the AlloQuent graft).

84. Upon information and belief, AlloQuent has anti-migration ribs that ensure secure placement while the cortical planks provide structural integrity and protect against subsidence. AlloQuent has one or more bone pins for holding together the graft unit, wherein the first cortical bone portion and the second cortical bone portion are not in physical contact, and wherein the composite bone graft does not comprise an adhesive and the bone graft is not demineralized, as set forth in claims 1 and 2 of the '158 patent. *See supra*, paragraphs 81 (stating that AlloQuent has "[a]nti-migration ribs [that] ensure secure placement while the cancellous center provides the optimum scaffold for new bone integration." And, "[t]he cortical planks provide structural integrity and protect against subsidence."); and 82 (depicting the structure of the AlloQuent graft).

85. Upon information and belief, AlloQuent is a load-bearing composite spinal bone graft for implantation into a host as set forth in at least claim 12 of the '532 patent. Upon information and belief, AlloQuent includes (1) a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (2) a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the

host bone; (3) one or more osteoconductive substances disposed between the first cortical bone portion and the second cortical bone portion and configured to contact a portion of the host bone to form a graft unit; and (4) one or more non-adhesive mechanical connectors for holding together the load-bearing spinal bone graft unit, the spinal bone graft being configured for implantation into the anterior spinal column of the host, as set forth in claim 12. *See supra*, paragraphs 81 (stating that AlloQuent is "a premium assembled cervical allograft that combines the desirable features of a cortical and a cancellous allograft. Anti-migration ribs ensure secure placement while the cancellous center provides the optimum scaffold for new bone integration. The cortical planks provide structural integrity and protect against subsidence."); and 82 (depicting the structure of the AlloQuent graft).

**4. RTI's Infringement of the '158 and '532 Patents by CeSpace**

86. Upon information and belief, RTI has been using, manufacturing, selling, and offering for sale a bone product under the brand name CeSpace Cortical Cancellous Bone. Exhibit Q (CeSpace Brochure) at 4; *see also* Exhibit L (RTI 10K, 2008), at 7 (identified as "Cervical/Lumbar Grafts").

87. Upon information and belief, CeSpace is a cortical cancellous allograft cervical spacer with porous cancellous bone that permits absorption of blood into the implant. Exhibit Q (CeSpace Brochure) at 4. CeSpace is composed of dense cortical bone that provides compressive strength and stability as part of the healing process. Exhibit Q (CeSpace Brochure) at 4.

88. Below is a picture of CeSpace:


Exhibit Q (CeSpace Brochure) at 4.

89. Upon information and belief, CeSpace is a composite bone graft as set forth in at least claims 1 and 2 of the ’158 patent. Upon information and belief, CeSpace is a cortical cancellous allograft cervical spacer with porous cancellous bone that permits absorption of blood into the implant. CeSpace includes a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, as set forth in claim 1. *See supra*, paragraphs 87 (stating that CeSpace is a cortical cancellous allograft cervical spacer with “porous cancellous bone [that] permits absorption of blood into the implant.”); and 88 (depicting the structure of the CeSpace graft).

90. Upon information and belief, CeSpace has one or more bone pins for holding together the graft unit, wherein the first cortical bone portion and the second cortical bone portion are not in physical contact, and wherein the composite bone graft does not comprise an adhesive and the bone graft is not demineralized, as set forth in claims 1 and 2 of the ’158 patent. *See supra*, paragraph 88 (depicting the structure of the CeSpace graft).

91. Upon information and belief, CeSpace is a load-bearing composite spinal bone graft for implantation into a host as set forth in at least claim 12 of the ’532 patent. Upon information and belief, CeSpace includes (1) a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (2) a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (3) one or more osteoconductive substances disposed between the first cortical bone portion and the second cortical bone portion and configured to contact a portion of the host bone to form a graft unit; and (4) one or more non-adhesive mechanical connectors for holding together the load-bearing spinal bone graft unit, the spinal bone graft being configured for implantation into the anterior spinal column of the host, as set forth in claim 12. *See supra*, paragraphs 87 (stating that CeSpace is a cortical cancellous allograft cervical spacer with “porous cancellous bone [that] permits absorption of blood into the implant.”); and 88 (depicting the structure of the CeSpace graft).

**5. RTI’s Infringement of the ’158 and ’532 Patents by Cornerstone ASR**

92. Upon information and belief, RTI has been using, manufacturing, selling, and offering for sale a bone product under the brand name Cornerstone ASR-Cortical Cancellous Block. Exhibit L (RTI 10K, 2008), at 7 and 9.

93. Upon information and belief, Cornerstone ASR has cortical lateral walls, with a cancellous center, combined by medial/lateral parallel cortical bone pins, where the cortical portion provides structural support and the cancellous portion provides a scaffold for bone in-growth. Exhibit R (Cornerstone Brochure) at 2.

94. Below is a picture of Cornerstone ASR:

Exhibit R (Cornerstone Brochure) at 2.

95. Upon information and belief, Cornerstone ASR is a composite bone graft as set forth in at least claims 1 and 2 of the '158 patent. Upon information and belief, Cornerstone ASR has cortical lateral walls, with a cancellous center where the cortical portion provides structural support and the cancellous portion provides a scaffold for bone in-growth. Cornerstone ASR includes a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, as set forth in claim 1. *See supra*, paragraphs 93 (stating that Cornerstone ASR has "cortical lateral walls, with a cancellous center" where the "cortical portion provides structural support" and the "cancellous portion provides [a] scaffold for bone in-growth."); and 94 (depicting the structure of the Cornerstone ASR graft).

96. Upon information and belief, Cornerstone ASR has cortical lateral walls, with a cancellous center, combined together by medial/lateral parallel cortical bone pins. Cornerstone ASR has one or more bone pins for holding together the graft unit, wherein the first cortical bone portion and the second cortical bone portion are not in physical contact, and wherein the

composite bone graft does not comprise an adhesive and the bone graft is not demineralized, as set forth in claims 1 and 2 of the '158 patent. *See supra*, paragraphs 93 (stating that Cornerstone ASR has "cortical lateral walls, with a cancellous center, combined together by medial/lateral parallel cortical bone pins"); and 94 (depicting the structure of the Cornerstone ASR graft).

97. Upon information and belief, Cornerstone ASR is a load-bearing composite spinal bone graft for implantation into a host as set forth in at least claim 12 of the '532 patent. Upon information and belief, Cornerstone ASR includes (1) a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (2) a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (3) one or more osteoconductive substances disposed between the first cortical bone portion and the second cortical bone portion and configured to contact a portion of the host bone to form a graft unit; and (4) one or more non-adhesive mechanical connectors for holding together the load-bearing spinal bone graft unit, the spinal bone graft being configured for implantation into the anterior spinal column of the host, as set forth in claim 12. *See supra*, paragraphs 93 (stating that Cornerstone ASR has "cortical lateral walls, with a cancellous center, combined together by medial/lateral parallel cortical bone pins," where the "cortical portion provides structural support" and the "cancellous portion provides [a] scaffold for bone in-growth."); and 94 (depicting the structure of the Cornerstone ASR graft).

**6. RTI's Infringement of the '158 and '532 Patents by Elemax**

98. Upon information and belief, RTI has been using, manufacturing, selling, and offering for sale a bone product under the brand name Elemax™ Cortical Cancellous Spacer ("Elemax").

99. Elemax is described as follows: "The Elemax® Cortical Cancellous Spacer is a precision-machined cervical allograft freeze-dried for room-temperature storage with the ability

to be rehydrated in 30 seconds." Exhibit S (Elemax Product Webpage: http://www.rtix.com/en_us/products/product-implant/elemax-cortical-cancellous-spacer), at 1. "Additional features include a cancellous center portion for osteoconductive potential, cortical sides to maximize implant compressive strength and stability, and 6° lordosis. This spacer also has a unique inserter feature to provide secure instrument attachment and to limit any additional width from the inserter grasping the graft." Exhibit S (Elemax Product Webpage: http://www.rtix.com/en_us/products/product-implant/elemax-cortical-cancellous-spacer), at 1.

100. Below is a picture of Elemax:

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Exhibit S (Elemax Product Webpage: http://www.rtix.com/en_us/products/product-implant/elemax-cortical-cancellous-spacer), at 1.

101. Upon information and belief, Elemax is a composite bone graft as set forth in at least claims 1 and 2 of the '158 patent. Upon information and belief, Elemax includes a first cortical bone portion, a second cortical bone portion, a cancellous bone portion disposed between the first cortical bone portion and the second cortical bone portion to form a graft unit, as set forth in claim 1. *See supra*, paragraphs 99 (stating that Elemax is a "Cortical Cancellous Spacer"); 99 (stating that Elemax has "a cancellous center portion for osteoconductive potential, [and] cortical sides to maximize implant compressive strength and stability"); and 100 (depicting the structure of the Elemax graft).

102. Upon information and belief, Elemax has one or more bone pins for holding together the graft unit, wherein the first cortical bone portion and the second cortical bone portion are not in physical contact, and wherein the composite bone graft does not comprise an adhesive and the bone graft is not demineralized, as set forth in claims 1 and 2 of the ’158 patent. *See supra*, paragraphs 99 (stating that Elemax has “a cancellous center portion for osteoconductive potential, [and] cortical sides); and 100 (depicting the structure of the Elemax graft).

103. Upon information and belief, Elemax is a load-bearing composite spinal bone graft for implantation into a host as set forth in at least claim 12 of the ’532 patent. Upon information and belief, Elemax includes (1) a first cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (2) a second cortical bone portion comprising one or more textured surfaces configured to contact a portion of the host bone; (3) one or more osteoconductive substances disposed between the first cortical bone portion and the second cortical bone portion and configured to contact a portion of the host bone to form a graft unit; and (4) one or more non-adhesive mechanical connectors for holding together the load-bearing spinal bone graft unit, the spinal bone graft being configured for implantation into the anterior spinal column of the host, as set forth in claim 12. *See* paragraphs 99 (stating that Elemax is a “Cortical Cancellous Spacer”); 99 (stating that Elemax has “a cancellous center portion for osteoconductive potential, [and] cortical sides to maximize implant compressive strength and stability”); and 100 (depicting the structure of the Elemax graft).

## IV. COUNT I: INFRINGEMENT OF THE ’200 PATENT

104. Plaintiff LifeNet Health realleges and incorporates by reference paragraphs 1 through 103 of this Complaint as though fully set forth herein. *See also*, Exhibit T (Exemplary

claim chart demonstrating the infringement of the ’200 patent by the Infringing Soft Tissue Product).

105. RTI has infringed and continues to infringe at least claims 1-4, 7, and 8 of the ’200 patent by, without LifeNet Health’s authority, importing, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States at least the Infringing Soft Tissue Product.

106. LifeNet Health has suffered monetary and other damages by reason of RTI’s infringement of the ’200 patent.

## V. COUNT II: INFRINGEMENT OF THE ’420 PATENT

107. Plaintiff LifeNet Health realleges and incorporates by reference paragraphs 1 through 103 of this Complaint as though fully set forth herein. *See also*, Exhibit U (Exemplary claim chart demonstrating the infringement of the ’420 patent by the Infringing Soft Tissue Product).

108. RTI has infringed and continues to infringe at least claims 1-4, 8, 9, 11, 13, 14, 16-18, 28, 29, 34 and 35 of the ’420 patent by, without LifeNet Health’s authority, importing, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States at least the Infringing Soft Tissue Product.

109. LifeNet Health has suffered monetary and other damages by reason of RTI’s infringement of the ’420 patent.

## VI. COUNT III: INFRINGEMENT OF THE ’986 PATENT

110. Plaintiff LifeNet Health realleges and incorporates by reference paragraphs 1 through 103 of this Complaint as though fully set forth herein. *See also*, Exhibit V (Exemplary claim chart demonstrating the infringement of the ’986 patent by the Infringing Soft Tissue Product).

111. RTI has infringed and continues to infringe at least claim 11 of the ’986 patent by, without LifeNet Health’s authority, importing, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States at least the Infringing Soft Tissue Product.

112. LifeNet Health has suffered monetary and other damages by reason of RTI’s infringement of the ’986 Patent.

## VII. COUNT IV: INFRINGEMENT OF THE ’158 PATENT

113. Plaintiff LifeNet Health realleges and incorporates by reference paragraphs 1 through 103 of this Complaint as though fully set forth herein. *See also*, Exhibit W (Exemplary claim chart demonstrating the infringement of the ’158 patent by the Infringing Bone Products).

114. RTI has infringed and continues to infringe at least claims 1 and 2 of the ’158 patent by, without LifeNet Health’s authority, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States at least the Infringing Bone Products.

115. LifeNet Health has suffered monetary and other damages by reason of RTI’s infringement of the ’158 patent by the Infringing Bone Products.

## VIII. COUNT V: INFRINGEMENT OF THE ’532 PATENT

116. Plaintiff LifeNet Health realleges and incorporates by reference paragraphs 1 through 103 of this Complaint as though fully set forth herein. *See also*, Exhibit X (Exemplary claim chart demonstrating the infringement of the ’532 patent by the Infringing Bone Products).

117. RTI has infringed and continues to infringe at least claims 12 of the ’532 patent by, without LifeNet Health’s authority, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States at least the Infringing Bone Products.

118. LifeNet Health has suffered monetary and other damages by reason of RTI’s infringement of the ’532 patent by the Infringing Bone Products.

## IX. PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff LifeNet Health requests relief against Defendant RTI as follows:

(a) A judgment that RTI has infringed the ’200, ’420,’986, ’158, and ’532 patents;

(b) A judgment and order requiring RTI to pay damages, including increased damages, under 35 U.S.C. § 284, together with costs and prejudgment and post-judgment interest;

(c) An order for a preliminary injunction under 35 U.S.C. § 283 requiring RTI to cease importing, manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States the Infringing Soft Tissue Product;

(d) An order for a permanent injunction under 35 U.S.C. § 283 requiring RTI to cease importing, manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States the Infringing Soft Tissue Product;

(e) A finding that this case is an exceptional case, and an order awarding Plaintiff its costs and reasonable attorney fees under 35 U.S.C. § 285; and

(f) Any and all such other and further relief as the Court may deem appropriate.

## X. JURY DEMAND

LifeNet Health hereby demands a trial by jury on all issues triable to a jury.

Dated: June 27, 2018

Respectfully submitted,

**LIFENET HEALTH**

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