

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

COLOPLAST A/S,

Plaintiff,

v.

CALDERA MEDICAL, INC.,

Defendant.

Civil No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

JURY DEMAND

Plaintiff Coloplast A/S, for its Complaint against Caldera, alleges as follows:

PARTIES

1. Plaintiff Coloplast A/S (“Coloplast”) is a Danish corporation headquartered in Humlebaek, Denmark. Coloplast has a subsidiary, Coloplast Corp., which operates in the United States and is headquartered in Minneapolis, Minnesota.

2. Defendant Caldera Medical, Inc. (“Caldera”) is a California corporation with its principal place of business at 5171 Clareton Drive, Agoura Hills, CA 91301.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

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

5. This Court has personal jurisdiction over Caldera because, on information and belief, Caldera transacts business and has continuous and systematic contacts in this

district, maintains an ongoing presence within this district, has purposefully availed itself of the privileges and benefits of the laws of the state of Minnesota, and has engaged in acts causing injury to Coloplast in Minnesota.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

PATENTS-IN-SUIT

7. On December 10, 2013, United States Patent No. 8,603,119 (“the ‘119 patent”), entitled “Surgical Implant Having Strands and Methods of Use,” was duly and legally issued by the United States Patent and Trademark Office. Coloplast was assigned and continues to hold all right, title, and interest in the ‘119 patent. A true and correct copy of the ‘119 patent is attached as Exhibit A to this Complaint.

8. On December 10, 2013, United States Patent No. 8,603,120 (“the ‘120 patent”), entitled “Low Mass Density Surgical Implant and Methods of Use,” was duly and legally issued by the United States Patent and Trademark Office. Coloplast was assigned and continues to hold all right, title, and interest in the ‘120 patent. A true and correct copy of the ‘120 patent is attached as Exhibit B to this Complaint.

9. On January 21, 2014, United States Patent No. 8,632,554 (“the ‘554 patent”), entitled “Low Mass Density Surgical Implant Having Strands and Methods of Use,” was duly and legally issued by the United States Patent and Trademark Office. Coloplast was assigned and continues to hold all right, title, and interest in the ‘554 patent. A true and correct copy of the ‘554 patent is attached as Exhibit C to this Complaint.

CALDERA'S INFRINGING PRODUCTS

10. On information and belief, Caldera makes, uses, offers to sell, and/or sells within the United States and/or imports into the United States products that infringe the '119, '120, and '554 patents, including, without limitation, the Vertessa Lite model numbers CAL-VYL, CAL-VL1020, CAL-VL1130, CAL-VL1022, CAL-VL422ST, CAL-VLY2643, CAL-VLY2654 (collectively, the "Vertessa Lite" or the "Vertessa Lite products"). Caldera specifically markets and sells the Vertessa Lite to medical professionals in the United States.

11. The Vertessa Lite is a surgical mesh implant for use in the treatment of pelvic organ prolapse, as described and claimed in the '119, '120, and '554 patents. An excerpt from Caldera's product brochure describes the Vertessa Lite as follows:

Vertessa[®] Lite
Polypropylene Mesh for Sacrocolpopexy
Lightweight, Flexible and Strong. The Perfect Balance.

Lightweight and flexible yet strong, inspiring the confidence you desire

- Vertessa Lite weighs 20.9 g/m².³
- Vertessa Lite is 31% stronger than market-leading light weight mesh.¹
- Suture pull-out strength is 32% greater than market-leading light weight mesh.¹
- Designed with reduced tensile and bending stiffness to decrease stress shielding effect on patient tissue.²

Designed specifically to meet your Sacrocolpopexy procedural needs

- Mesh can be trimmed to desired anatomical size without fraying or unravelling.³
- Unique blue mesh design for enhanced visibility.

<http://www.calderamedical.com/wp-content/uploads/VL-Brochure.pdf> (last visited on

May 26, 2016). *See also* <http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016).

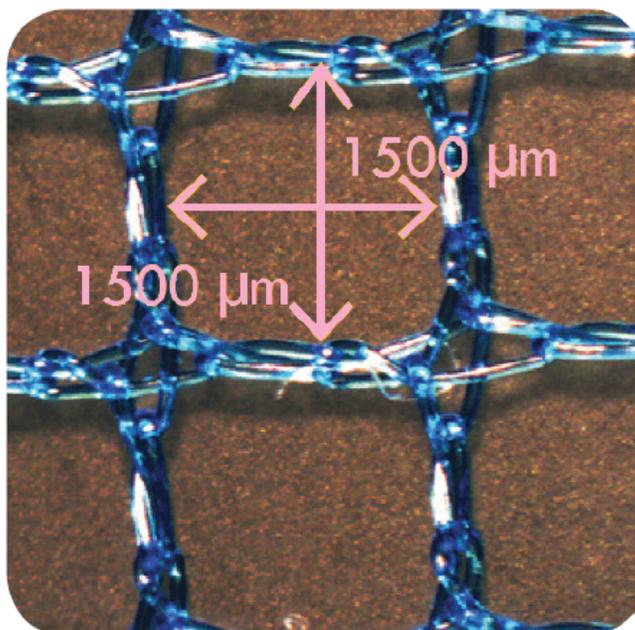
12. Similarly, Caldera's § 510(k) Summary to the Food and Drug Administration states that "Vertessa® Lite devices are designed to be used in women suffering from uterine or vaginal vault prolapse and are implanted or affixed using suture of the surgeon's choice. Vertessa® Lite devices [. . .] are comprised of [. . .] monofilament polypropylene warp knit blue mesh."

13. The Vertessa Lite contains all limitations of at least one claim of the '119 patent, including, without limitation, claim 8.

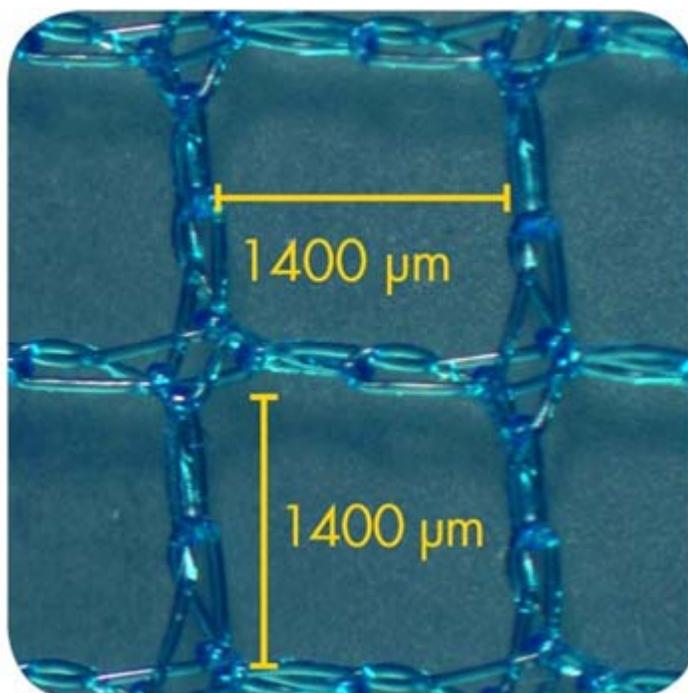
14. For example, the Vertessa Lite is "[a] surgical implant adapted to treat a prolapse in a patient[,]" as recited in claim 8 of the '119 patent. (Ex. A, Col. 19, l. 25.) *See, e.g.*, paragraph 12, *supra*, for features of Vertessa Lite that correspond to the preamble.

15. The Vertessa Lite further comprises "a knitted mesh having a mass density of less than 50 g/m²[.]" (Ex. A, Col. 19, l. 27.) Depictions of the mesh used in the Vertessa Lite show that the mesh is knitted together:

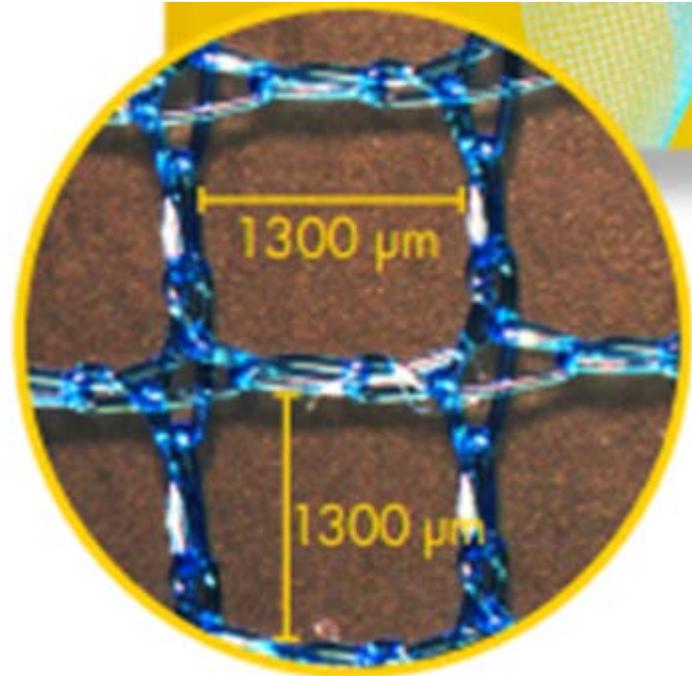
Caldera Medical Polypropylene Mesh



See <http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016) (annotated).



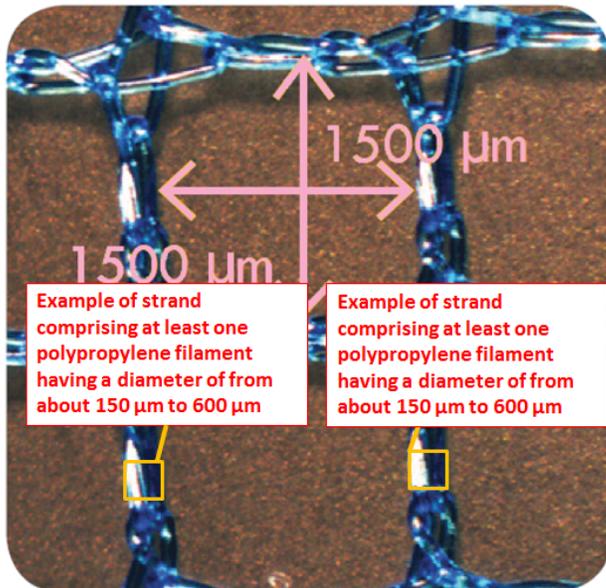
See Vertessa™ Lite Brochure, Rev. C.



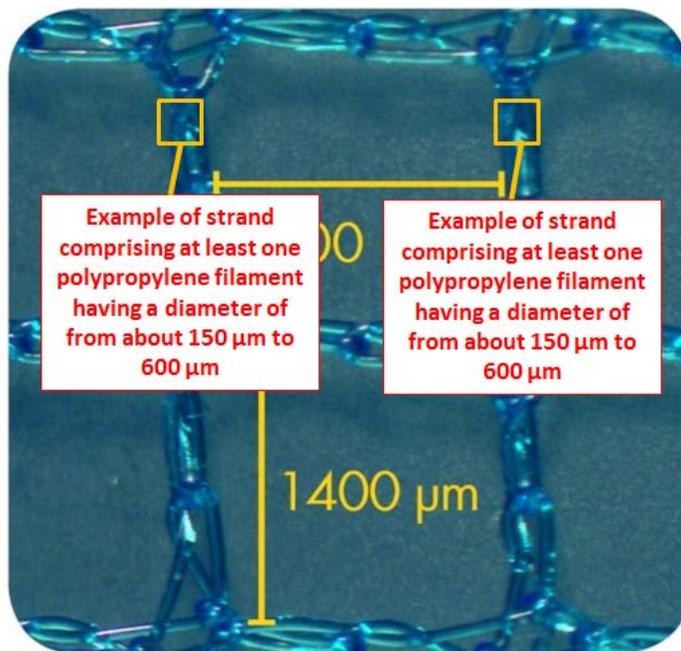
See Vertessa™ Lite Brochure, Rev. B. Caldera’s § 510(k) summary also explains that the “Vertessa® Lite devices [. . .] are comprised of [. . .] monofilament polypropylene warp knit blue mesh.” Caldera has represented that certain models of the Vertessa Lite product weigh 20.9 g/m². <http://www.calderamedical.com/wp-content/uploads/VL-Brochure.pdf> (last visited on May 26, 2016). Other models of the product have been represented by Caldera to weigh 22 g/m² and 23.8 g/m². See Vertessa™ Lite Brochure, Rev. B; Vertessa™ Lite Brochure, Rev. C.

16. The mesh used in the Vertessa Lite contains “strands comprising at least one polypropylene filament and having a diameter of from about 150 μm to 600 μm[.]” (Ex. A, Col. 19, ll. 29-31.) Depictions of the mesh used in the Vertessa Lite show that the strand has at least one polypropylene filament and having a diameter of from about 150 μm to 600 μm:

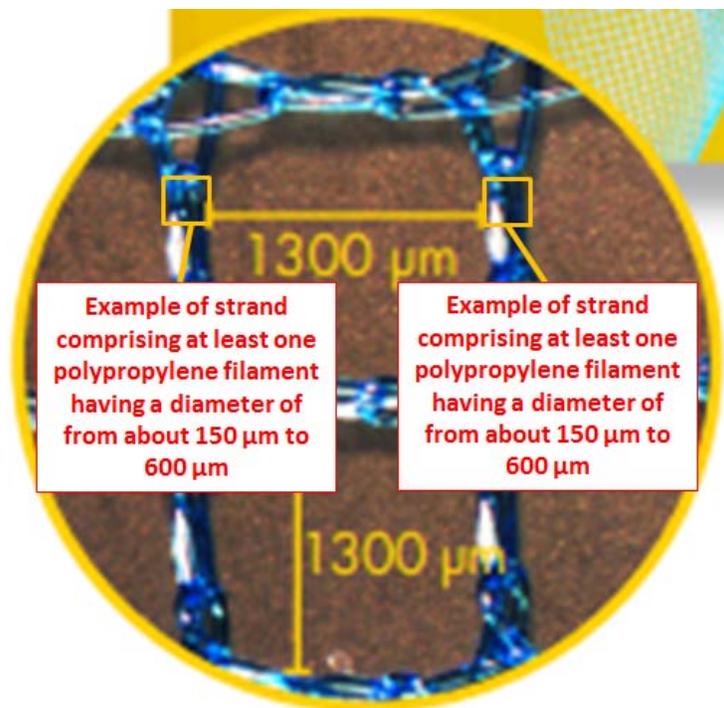
Caldera Medical Polypropylene Mesh



<http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016) (annotated).



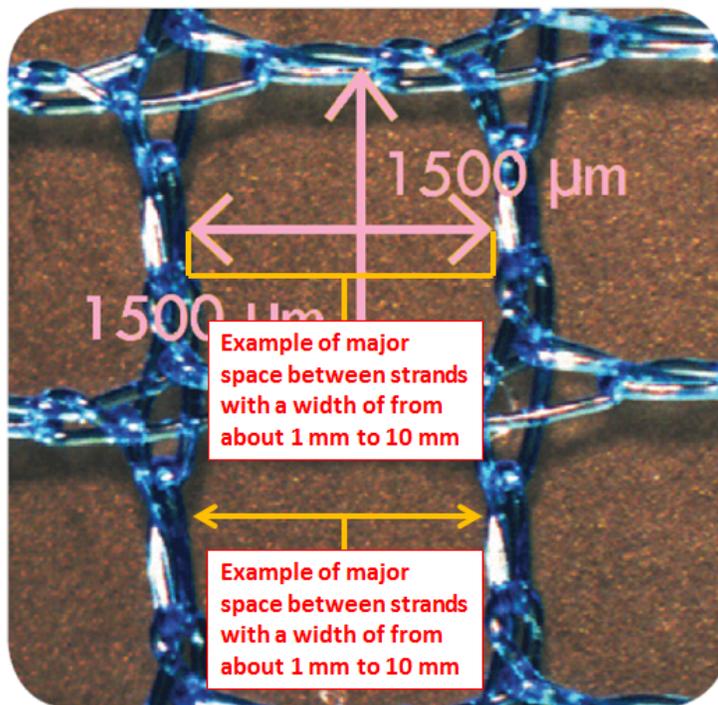
Vertessa™ Lite Brochure, Rev. C (annotated).



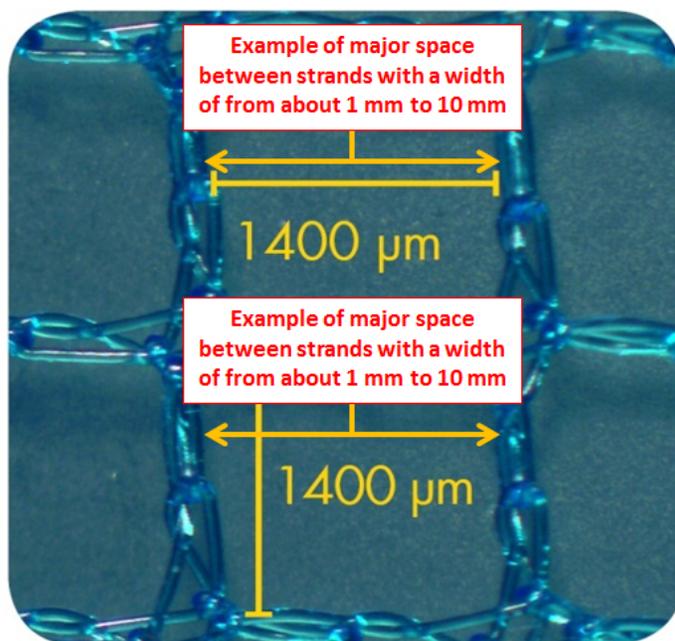
Vertessa™ Lite Brochure, Rev. B (annotated).

17. The mesh used in the Vertessa Lite contains “major spaces located between the strands to allow blood to pass through the surgical implant, wherein the major spaces have a width of from about 1 mm to 10 mm[.]” (Ex. A, Col. 19, ll. 32-35.) Depictions of the mesh used in the Vertessa Lite show that there that are major spaces located between the strands with a width from about 1 mm to 10 mm:

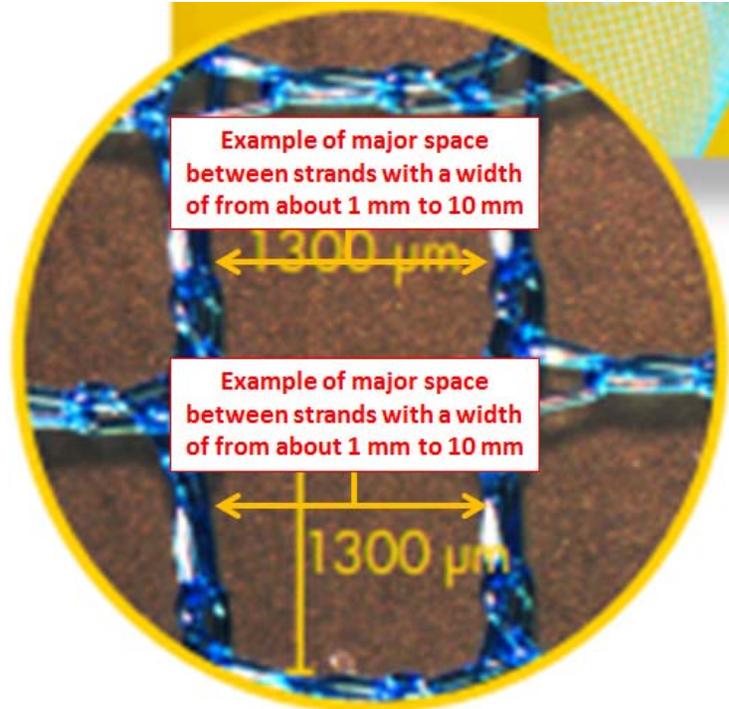
Caldera Medical Polypropylene Mesh



<http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016) (annotated).



Vertessa™ Lite Brochure, Rev. C (annotated).

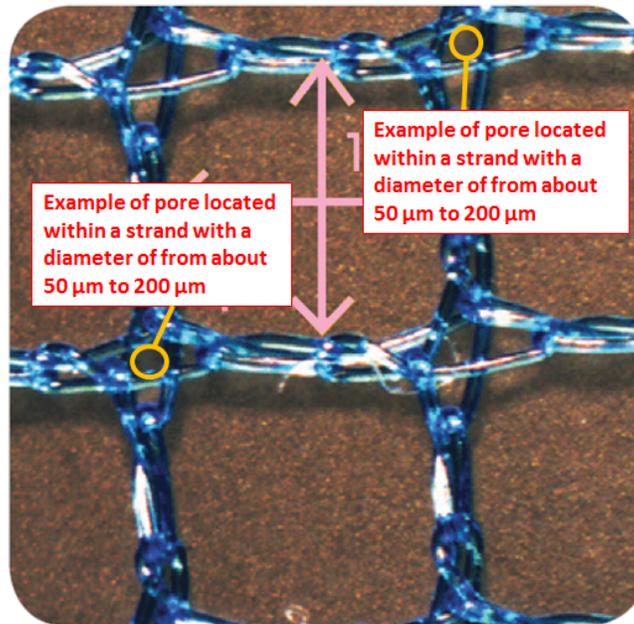


Vertessa™ Lite Brochure, Rev. B (annotated).¹ Caldera’s product brochure also explains that the major spaces “allows for macrophage movement and fibroblast in-growth.” <http://www.calderamedical.com/wp-content/uploads/VL-Brochure.pdf> (last visited on May 26, 2016).

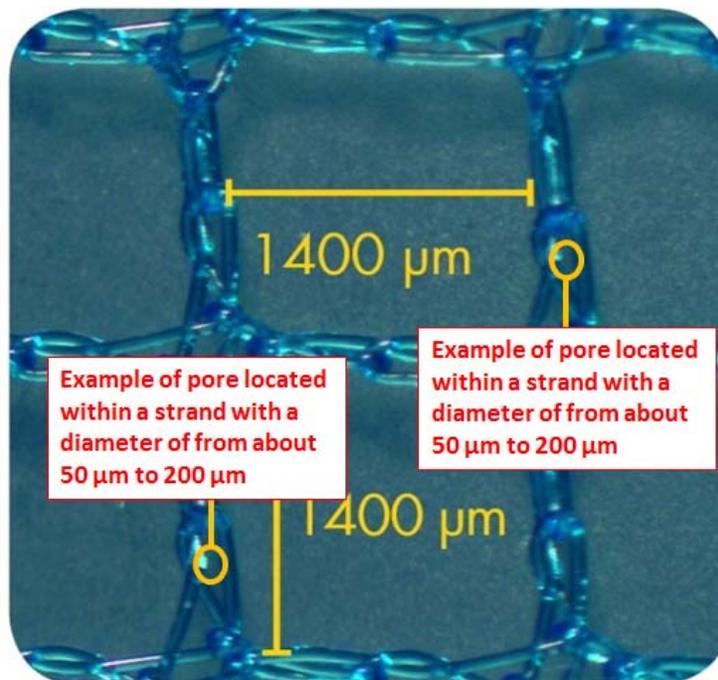
18. The mesh used in the Vertessa Lite contains “pores located within the strands to aid tissue ingrowth, wherein the pores have a diameter of from about 50 μm to 200 μm[.]” (Ex. A, Col. 19, ll. 36-38.) Depictions of the mesh used in the Vertessa Lite show that there are pores located within the strands with a diameter of from about 50 μm to 200 μm:

¹ 1,000 micrometers (“μm”) is equivalent to 1 millimeter (“mm”). As such, and as shown in the depictions of the mesh used in the Vertessa Lite products, each major space has a width of approximately 1.3 mm to 1.5 mm.

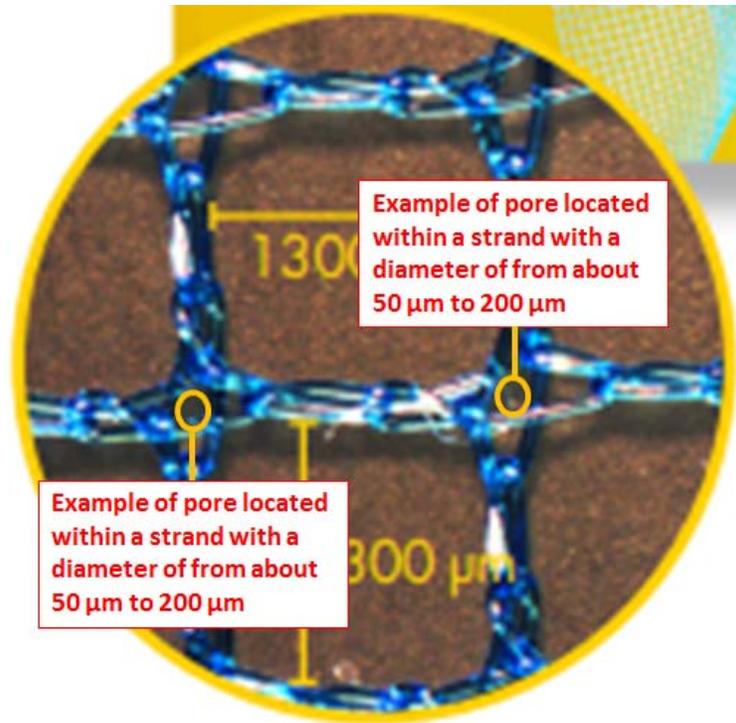
Caldera Medical Polypropylene Mesh



<http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016) (annotated).



Vertessa™ Lite Brochure, Rev. C (annotated).



Vertessa™ Lite Brochure, Rev. B (annotated).

19. The Vertessa Lite “is configured to be implanted in a region of the prolapse, wherein the prolapse is selected from the group consisting of urethrocoele prolapse, cystocoele prolapse, vault prolapse, uterine prolapse, enterocoele prolapse, and rectocoele prolapse, and wherein the knitted mesh is configured to be secured in place to treat the prolapse.” (Ex. A, Col. 19, ll. 39-45.) Caldera’s § 510(k) summary explains that the “Vertessa® Lite devices are designed to be used in women suffering from uterine or vaginal vault prolapse and are implanted or affixed using suture of the surgeon’s choice. Vertessa® Lite devices [. . .] are comprised of [. . .] monofilament polypropylene warp knit blue mesh.” *See, also, e.g.*, paragraph 12, *supra*, for features of Vertessa Lite that correspond to this claim element.

20. The Vertessa Lite contains all limitations of at least one claim of the ‘120

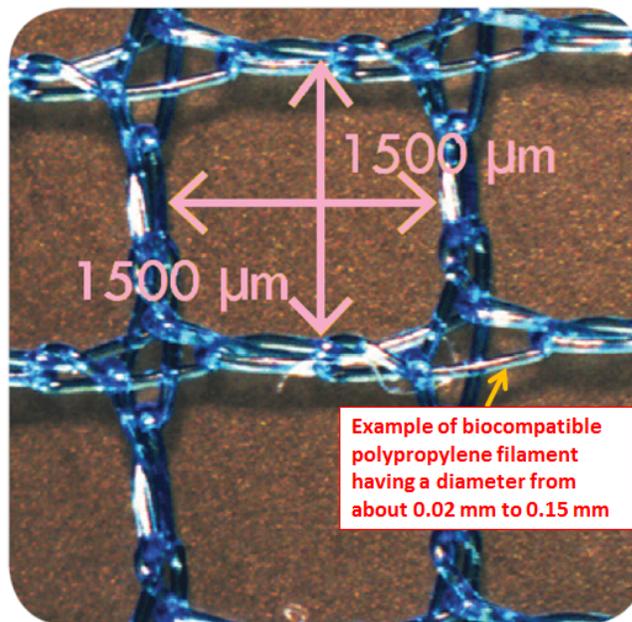
patent, including, without limitation, claim 8.

21. For example, the Vertessa Lite is “[a] surgical implant adapted to treat a prolapse in a patient[,]” as recited in claim 8 of the ‘120 patent. (Ex. B, Col. 19, l. 18.) *See, e.g.*, paragraphs 11-12 and 19, *supra*, for features of Vertessa Lite that correspond to the preamble.

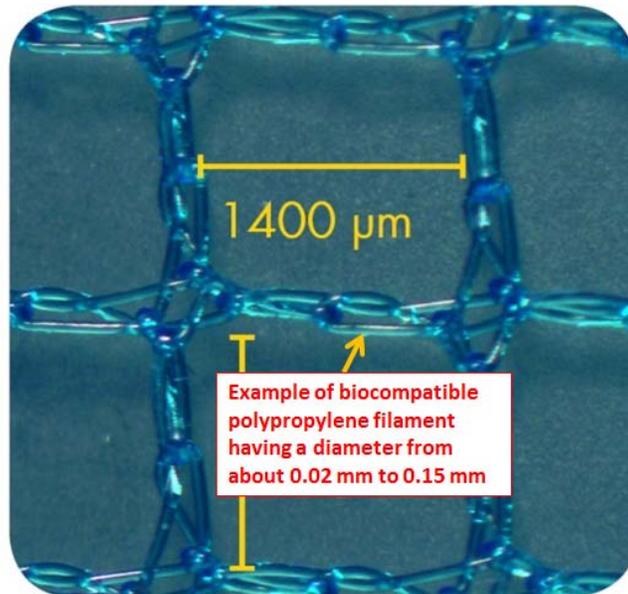
22. The Vertessa Lite further comprises “a knitted mesh having a mass density of less than 25 g/m²[.]” (Ex. B, Col. 19, l. 20.) *See, e.g.*, paragraph 15, *supra*, for features of Vertessa Lite that correspond to this claim element.

23. The mesh used in the Vertessa Lite contains “at least one biocompatible polypropylene filament and having a diameter of from about 0.02 mm to 0.15 mm[.]” (Ex. B, Col 19, ll. 22-23.) Depictions of the mesh used in the Vertessa Lite show that the polypropylene filament has a diameter of from about 0.02 mm to 0.15 mm:

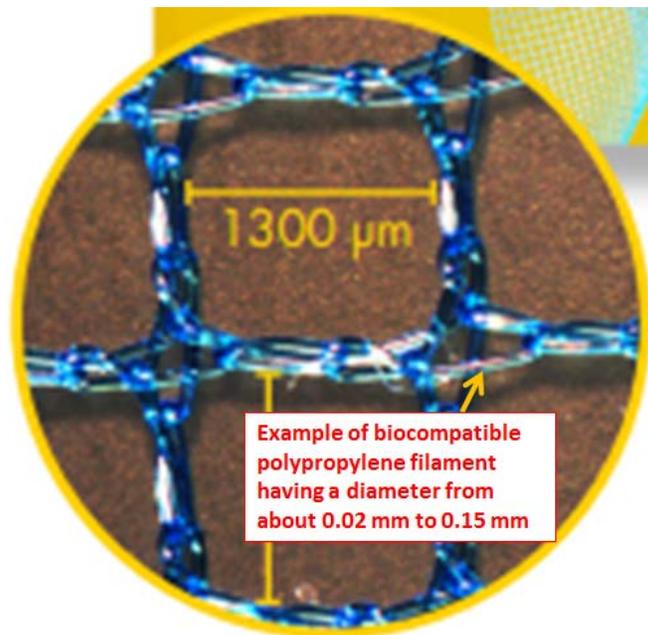
Caldera Medical Polypropylene Mesh



<http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016) (annotated).



Vertessa™ Lite Brochure, Rev. C (annotated).

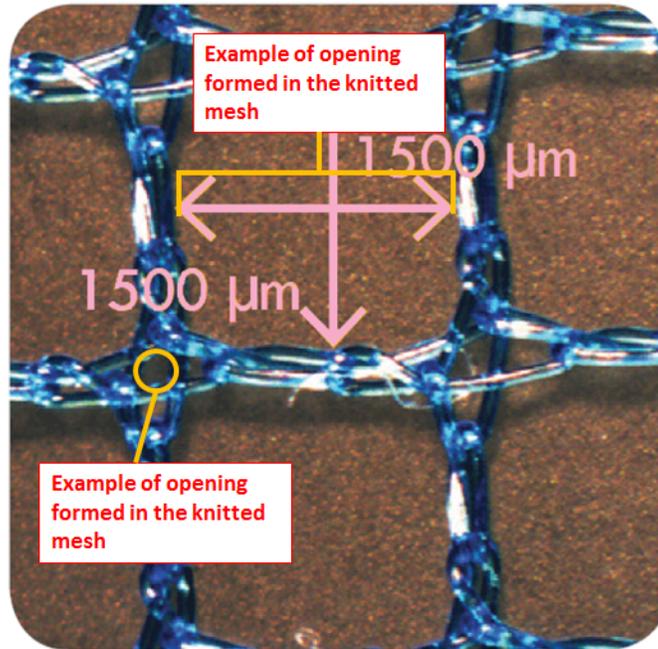


Vertessa™ Lite Brochure, Rev. B (annotated).

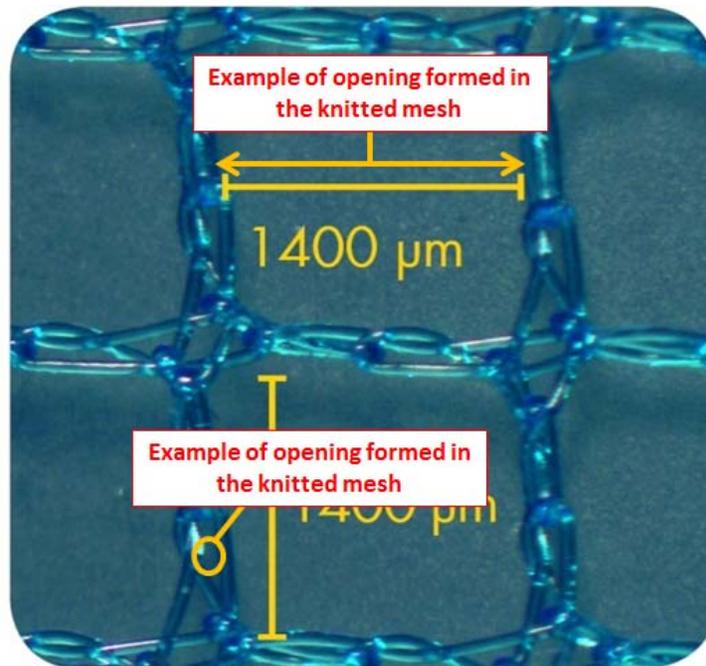
24. The mesh used in the Vertessa Lite contains “openings formed in the knitted mesh to allow blood to pass through the knitted mesh or allow fibroblast

throughgrowth[.]” (Ex. B, Col. 19, ll. 25-27.) Depictions of the mesh used in the Vertessa Lite show that openings are formed in the knitted mesh:

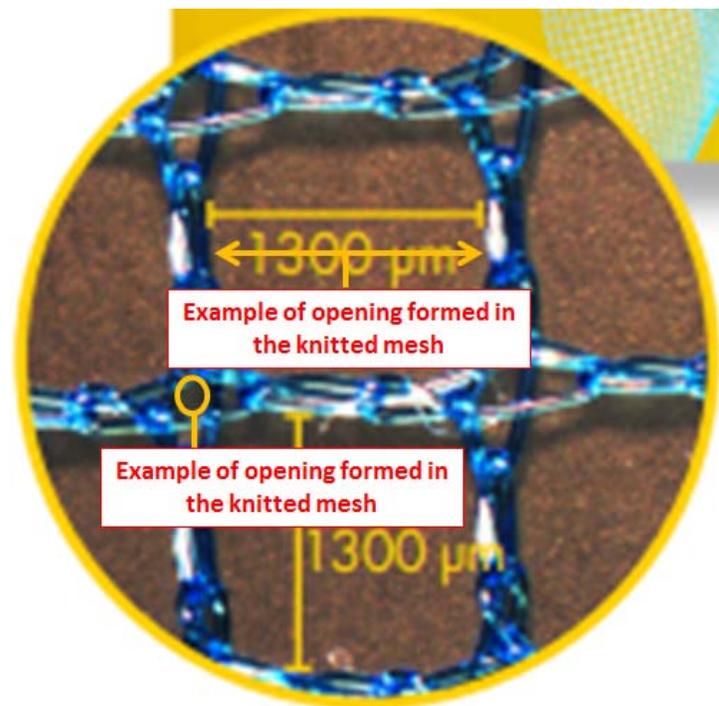
Caldera Medical Polypropylene Mesh



<http://www.calderamedical.com/medical-professionals/products/vertessa-lite-polypropylene-mesh-for-scp/> (last visited on May 26, 2016) (annotated).



Vertessa™ Lite Brochure, Rev. C (annotated).



Vertessa™ Lite Brochure, Rev. B (annotated). Caldera's product brochure also states that the openings "allow[] for macrophage movement and fibroblast in-growth."

<http://www.calderamedical.com/wp-content/uploads/VL-Brochure.pdf> (last visited on

May 26, 2016).

25. The openings in the mesh used in the Vertessa Lite include “at least one of pores having a diameter of from about 50 μm to 200 μm and major spaces having a width of from about 1 mm to 10 mm[.]” (Ex. B, Col. 19, ll. 28-30.) *See, e.g.*, paragraphs 17-18, 24, *supra*, for features of Vertessa Lite that correspond to this claim element.

26. The Vertessa Lite is also an implant that “is configured to be implanted in a region of the prolapse, wherein the prolapse is selected from the group consisting of urethrocoele prolapse, cystocoele prolapse, vault prolapse, uterine prolapse, enterocoele prolapse, and rectocoele prolapse, and wherein the knitted mesh is configured to be secured in place to treat the prolapse.” (Ex. B, Col. 19, ll. 31-37.) *See, e.g.*, paragraphs 11-12 and 19, *supra*, for features of Vertessa Lite that correspond to this claim element.

27. The Vertessa Lite contains all limitations of at least one claim of the ‘554 patent, including, without limitation, claim 7.

28. For example, the Vertessa Lite is “[a]n implant adapted to treat a prolapse in a patient[,]” as recited in claim 7 of the ‘554 patent. (Ex. C, Col. 19, l. 20.) *See, e.g.*, paragraphs 11-12 and 19, *supra*, for features of Vertessa Lite that correspond to the preamble.

29. The Vertessa Lite further comprises “a knitted mesh having a mass density of less than 25 g/m^2 [.]” (Ex. C, Col. 19, l. 22.) *See, e.g.*, paragraph 15, *supra*, for features of Vertessa Lite that correspond to this claim element.

30. The mesh used in the Vertessa Lite contains “strands comprising polypropylene and having a diameter of less than about 600 μm [.]” (Ex. C, Col. 19, ll. 24-25.) *See, e.g.*, paragraph 16, *supra*, for features of Vertessa Lite that correspond to this claim element.

31. The mesh used in the Vertessa Lite contains “major spaces located between adjacent ones of the strands, the major spaces having a width of from about 1 mm to 10 mm[.]” (Ex. C, Col. 19, ll. 26-28.) *See, e.g.*, paragraph 17, *supra*, for features of Vertessa Lite that correspond to this claim element.

32. The mesh used in the Vertessa Lite contains “pores located within the strands, the pores having a diameter of from about 50 μm to 200 μm .” (Ex. C, Col. 19, ll. 29-30.) *See, e.g.*, paragraph 18, *supra*, for features of Vertessa Lite that correspond to this claim element.

33. The Vertessa Lite is also an implant “configured to be implanted in a region of the prolapse, wherein the prolapse is selected from the group consisting of urethrocoele prolapse, cystocoele prolapse, vault prolapse, uterine prolapse, enterocoele prolapse, and rectocoele prolapse, and wherein the knitted mesh is configured to be secured in place to treat the prolapse[.]” (Ex. C, Col. 19, ll. 31-37.) *See, e.g.*, paragraphs 11-12 and 19, *supra*, for features of Vertessa Lite that correspond to this claim element.

34. Caldera has actual knowledge of the ‘119, ‘120, and ‘554 patents since at least March 25, 2015, when counsel for Coloplast informed Caldera that the Vertessa Lite products infringe the ‘119, ‘120, and ‘554 patents and provided copies of the

patents for Caldera's review.

35. On information and belief, the Vertessa Lite practices other independent and dependent claims of the '119, '120, and '554 patents.

36. On information and belief, additional surgical mesh implant products for use in the treatment of pelvic organ prolapse that Caldera makes, uses, offers to sell, and/or sells within the United States and/or imports into the United States infringe the '119, '120, and '554 patents also.

37. Coloplast reserves the right to identify other infringing products and/or additional claims of the '119, '120, and '554 patents found to be infringed during further discovery and investigation.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,603,119

38. Coloplast realleges and incorporates by reference paragraphs 1 through 37, *supra*, as if fully stated herein.

39. On information and belief, Caldera makes, uses, offers to sell, and/or sells in the United States and/or imports into the United States surgical mesh implant products for use in the treatment of pelvic organ prolapse, including, for example, the Vertessa Lite, that infringe, either literally or under the doctrine of equivalents, at least one claim of the '119 Patent.

40. Accordingly, Caldera has infringed and is infringing, either literally or under the doctrine of equivalents, the '119 patent in violation of 35 U.S.C. § 271(a).

41. Caldera's acts of infringement have caused and continue to cause damage to

Coloplast, and Coloplast is entitled to recover from Caldera the damages sustained by Coloplast in an amount subject to proof at trial. Caldera's acts of infringement will irreparably injure Coloplast unless and until such infringing activities are enjoined by this Court.

42. On information and belief, Caldera's infringement of the '119 patent has been and continues to be taking place with objective recklessness and despite an objectively high likelihood that Caldera's actions constitute infringement of a valid patent.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,603,120

43. Coloplast realleges and incorporates by reference paragraphs 1 through 42, *supra*, as if fully stated herein.

44. On information and belief, Caldera makes, uses, offers to sell, and/or sells in the United States and/or imports into the United States surgical mesh implant products for use in the treatment of pelvic organ prolapse, including, for example, the Vertessa Lite, that infringe, either literally or under the doctrine of equivalents, at least one claim of the '120 Patent.

45. Accordingly, Caldera has infringed and is infringing, either literally or under the doctrine of equivalents, the '120 patent in violation of 35 U.S.C. § 271(a).

46. Caldera's acts of infringement have caused and continue to cause damage to Coloplast, and Coloplast is entitled to recover from Caldera the damages sustained by Coloplast in an amount subject to proof at trial. Caldera's acts of infringement will

irreparably injure Coloplast unless and until such infringing activities are enjoined by this Court.

47. On information and belief, Caldera's infringement of the '120 patent has been and continues to be taking place with objective recklessness and despite an objectively high likelihood that Caldera's actions constitute infringement of a valid patent.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,632,554

48. Coloplast realleges and incorporates by reference paragraphs 1 through 47, *supra*, as if fully stated herein.

49. On information and belief, Caldera makes, uses, offers to sell, and/or sells in the United States and/or imports into the United States surgical mesh implant products for use in the treatment of pelvic organ prolapse, including, for example, the Vertessa Lite, that infringe, either literally or under the doctrine of equivalents, at least one claim of the '554 Patent.

50. Accordingly, Caldera has infringed and is infringing, either literally or under the doctrine of equivalents, the '554 patent in violation of 35 U.S.C. § 271(a).

51. Caldera's acts of infringement have caused and continue to cause damage to Coloplast, and Coloplast is entitled to recover from Caldera the damages sustained by Coloplast in an amount subject to proof at trial. Caldera's acts of infringement will irreparably injure Coloplast unless and until such infringing activities are enjoined by this Court.

52. On information and belief, Caldera's infringement of the '554 patent has been and continues to be taking place with objective recklessness and despite an objectively high likelihood that Caldera's actions constitute infringement of a valid patent.

PRAYER FOR RELIEF

WHEREFORE, Coloplast respectfully requests this Court:

A. To enter judgment that Caldera has infringed the '119, '120, and '554 patents in violation of 35 U.S.C. § 271;

B. To enter orders preliminarily and permanently enjoining Caldera, its officers, agents, servants, employees, attorneys, and all persons in active concert or participation with any of the foregoing, who receive actual notice by personal service or otherwise of the orders, from infringing the '119, '120, and '554 patents in violation of 35 U.S.C. § 271;

C. To award Coloplast its damages in an amount sufficient to compensate it for Caldera's infringement of the '119, '120, and '554 patents, together with pre-judgment and post-judgment interest and costs, pursuant to 35 U.S.C. § 284.

D. To find that Caldera's patent infringement has been willful and increase the damages awarded to Coloplast up to three times the amount passed, pursuant to 35 U.S.C. § 284.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Coloplast

respectfully requests a trial by jury of any and all issues on which a trial by jury is available under applicable law.

Dated: May 26, 2016

Respectfully submitted,

/s/ Ronn B. Kreps

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