

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOSTON SCIENTIFIC CORPORATION)	
and BOSTON SCIENTIFIC SCIMED, INC.,)	
Plaintiffs,)	
v.)	Civil Action No.
MICRO-TECH ENDOSCOPY USA INC.,)	
MICRO-TECH (NANJING) CO., LTD., and)	JURY TRIAL DEMANDED
HENRY SCHEIN INC.,)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendants Micro-Tech Endoscopy USA Inc. (“Micro-Tech USA”), Micro-Tech (Nanjing) Co., Ltd. (“Micro-Tech Nanjing”), and Henry Schein Inc. (“Henry Schein”; collectively “Defendants”), Plaintiffs Boston Scientific Corporation (“BSC”) and Boston Scientific SciMed, Inc. (“BSSI”; collectively “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for the infringement of United States Patent Nos. 9,980,725 (the “725 Patent”) entitled “Through the Scope Tension Member Release Clip” (attached as Exhibit A), 7,094,245 (the “245 Patent”) entitled “Device and Method for Through the Scope Endoscopic Hemostatic Clipping” (attached as Exhibit B), and 8,974,371 (the “371 Patent”) entitled “Through the Scope Tension Member Release Clip” (attached as Exhibit C) under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

PARTIES

2. Plaintiff BSC is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 300 Boston Scientific Way, Marlborough, Massachusetts 01752. BSC is a leading developer, manufacturer, and supplier of medical devices, including endoscopic products for the treatment of diseases of the digestive system.

3. Plaintiff BSSI is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business at One SciMed Place, Maple Grove, Minnesota 55311. Among other things, BSSI develops and manufactures endoscopic products for the treatment of diseases of the digestive system, including hemostatic clips that BSC distributes. BSSI is the owner by assignment of the '725, '245, and '371 Patents.

4. On information and belief, Defendant Micro-Tech USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 2855 Boardwalk Drive, Ann Arbor, Michigan 48104. Micro-Tech USA is in the business of, among other things, distributing medical instruments and devices.

5. On information and belief, Defendant Micro-Tech Nanjing is a corporation organized and existing under the laws of Jiangsu Province, China, with its principal place of business located at No. 10, Gaoke Third Road, National New & High Technology Industrial Development Zone, Nanjing, Jiangsu, PRC 210032. Micro-Tech Nanjing is in the business of, among other things, manufacturing, importing, and distributing medical devices.

6. On information and belief, Defendant Henry Schein is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 135 Duryea Road, Melville, New York 11747. Henry Schein is in the business of, among other things, distributing medical devices.

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States, including 35 U.S.C. § 271, *et seq.*

8. This Court has original jurisdiction over the subject matter of this Complaint under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over each of the Defendants.

10. Defendants Micro-Tech USA and Henry Schein are subject to general personal jurisdiction in the State of Delaware under *Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014) and in accordance with due process, as they are both incorporated in the State of Delaware.

11. Defendant Micro-Tech Nanjing is subject to specific jurisdiction in this District. It maintains purposeful minimum contacts with the United States (including in this District), including but not limited to making, selling, offering to sell, and/or importing into the United States (including in this District) for subsequent sale or use products, services, methods, or processes as discussed more fully herein, “such that maintenance of the suit does not offend traditional notions of fair play and substantial justice.” *Int’l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945) (internal citations omitted). These activities include, but are not limited to, manufacturing the SureClip™ Hemostasis Clip products for sale in the United States, as is evident, for example, on the face of the “Instructions for Use” for the SureClip™ (obtained from Defendant Micro-Tech USA’s website at <https://www.mtendoscopy.com/wp-content/uploads/2018/08/Sure-Clip-Repositionable-Hemostasis-Clip-Instructions-REV9.pdf>), a copy of which is attached as Exhibit D.

12. Venue in this district is proper under 28 U.S.C. § 1400(b). In particular, venue is proper as to Micro-Tech USA and Henry Schein because they are incorporated in Delaware and

thus reside in this District. Venue is proper as to Micro-Tech Nanjing as a foreign corporation under the “alien-venue rule.” *Brunette Machine Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); *In re HTC Corp.*, 889 F.3d 1349 (Fed. Cir. 2018).

FACTUAL BACKGROUND

13. Plaintiffs are leading developers, manufacturers, and suppliers of medical devices dedicated to helping medical care professionals deliver superior healthcare to their patients. Among the medical devices that Plaintiffs have developed and sold are the Resolution™ Clip and Resolution 360™ Clip, endoscopic hemostasis clips that are intended for use to, among other things, stop bleeding in the gastrointestinal tract. The Resolution™ Clip and Resolution 360™ Clip are designed to allow medical care professionals to precisely position the clip and securely lock it in place to quickly stop gastrointestinal bleeding.

14. Plaintiffs have made significant investments into the research, development, and testing of the design of hemostatic clips, including the technologies embodied by the Resolution™ Clip and Resolution 360™ Clip, and have made significant investments bringing those products to market.

15. Plaintiffs have applied for and obtained patents based on inventions arising out of the research and development of its hemostatic clips, including the following:

- a. On May 29, 2018, the U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’725 Patent to Russell F. Durgin, William C. Mers Kelly, Lance Alan Wolf, Brian Keith Wells, Vasiliy P. Abramov, and Gregory R. Furnish as inventors.
- b. On August 22, 2006, the USPTO duly and legally issued the ’245 Patent to Mark L. Adams, Russell F. Durgin, Vincent Turturro, Justin Grant, Norman May, and Roy H. Sullivan, III as inventors.
- c. On March 10, 2015, the USPTO duly and legally issued the ’371 Patent to Russell F. Durgin, William C. Mers Kelly, Lance Alan Wolf, Brian Keith Wells, Vasily P. Abramov, and Gregory R. Furnish as inventors.

16. BSSI is the lawful owner of all right, title and interest in and to the '725, '245, and '371 Patents.

17. Defendants have been directly competing with Plaintiffs, and are continuing to do so, by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use hemostatic clips that utilize Plaintiffs' patent technologies, including the SureClip™, SureClip™ MINI, and SureClip™ PLUS Hemostasis Clips. A true and correct copy of Micro-Tech USA's product catalog, with Henry Schein named as distributor (obtained from Defendant Henry Schein's website at <https://www.henryschein.com/us-en/images/medical/MicroTechCatalog.pdf>), is attached as Exhibit E. A true and correct copy of the SureClip™ Hemostasis Clip Product Information Sheet (obtained from Defendant Micro-Tech USA's website at https://www.mtendoscopy.com/wp-content/uploads/2018/08/SureClip_MPW30000_Rev6-1.pdf) is attached as Exhibit F.

18. Defendants are thus competitors of Plaintiffs in the endoscopic hemostatic clip market.

COUNT I

(Defendants' Infringement of the '725 Patent)

19. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

20. Defendants have had knowledge of the '725 Patent since at least the filing of this Complaint and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the SureClip™ Hemostasis Clip products would infringe one or more claims of the '725 Patent.

21. On information and belief, Defendants were aware that Plaintiffs' Resolution™ Clip products embody the claimed inventions of the '725 Patent and knew or should have known that Defendants' products, including the SureClip™ Hemostasis Clip products, infringe one or more claims of the '725 Patent.

22. Defendants have actively, knowingly, and intentionally infringed and continue to infringe, literally and/or through the doctrine of equivalents, the '725 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use in the United States products, services, methods, or processes that are covered by at least Claim 1 and Claim 12 of the '725 Patent. Such devices include, but are not limited to, the SureClip™ Hemostasis Clip products described above.

23. By way of example and not limitation, Claim 1 of the '725 Patent recites:

An apparatus for applying clips to tissue, comprising:

a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped;

a capsule comprising a proximal end and a distal end;

a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween;

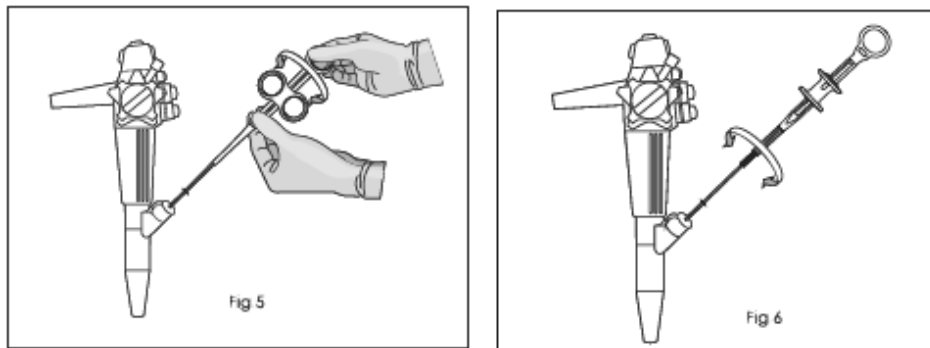
a control member a distal end of which is releasably coupled to the clip assembly via a separable yoke to transmit the clip assembly forces applied thereto to move the clip assembly between the closed and expanded configurations;

wherein the separable yoke includes first and second yoke arms extending distally from the control member on opposite sides of the clip assembly and the clip assembly includes a connecting member extending between the first and second yoke arms coupling the yoke to the clip assembly, the first and second yoke arms being configured to be separated from the connecting member when subjected to a predetermined force by the control member to uncouple the control member from the clip assembly.

24. By way of example and not limitation, the SureClip™ Hemostasis Clip products infringe Claim 1 of the '725 Patent as described below.

25. The SureClip™ Hemostasis Clip products are used for applying clips to tissue. *See, e.g.*, Exhibit D, p. 1 (“The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract”).

26. The SureClip™ Hemostasis Clip products contain a sheath sufficiently flexible to pass through the bends of an endoscope and navigate through the body until the distal end of the devices reach the target tissue. *See, e.g.*, Exhibit D, Figs. 5 and 6.



27. The SureClip™ Hemostasis Clip products contain a capsule (in box below) extending from a proximal end to a distal end. *See, e.g.*, Exhibit F, p. 1.

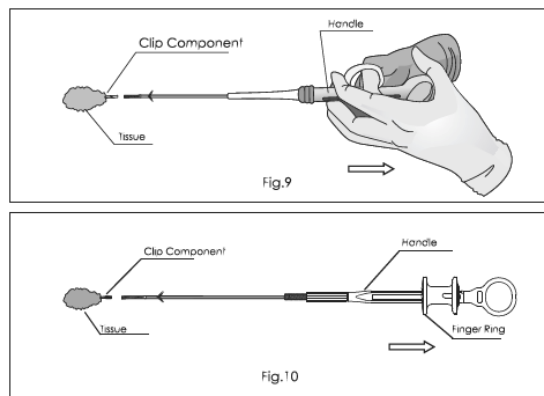


28. The SureClip™ Hemostasis Clip products contain clip arms (in box below) and a proximal pin and distal pin within the capsule; forces applied proximally to these clip arms through the control wire cause the clip arms to become drawn together; forces applied distally to

these clip arms through the control wire cause the clip arms to separate; forces are applied as needed to receive target tissue therebetween. *See, e.g.*, Exhibit F, p. 1.



29. The SureClip™ Hemostasis Clip products contain a pair of J hooks that extend distally from the distal end of the control wire; the J hooks are releasably connected to the clip assembly, such that application of a sufficient predetermined force will release the J hooks, and thus control wire, from the clip assembly. *See, e.g.*, Exhibit D, Figs. 9 and 10.



30. Defendants have been infringing and are continuing to infringe one or more of the claims of the '725 Patent through the aforementioned acts, without authorization from Plaintiffs.

31. Plaintiffs are entitled to recover damages adequate to compensate them for Defendants' infringement of the '725 Patent.

32. Defendants' infringement of the '725 Patent has caused and is continuing to cause Plaintiffs to suffer irreparable harm, and Plaintiffs are entitled to injunctive relief to prevent further infliction of such harm.

COUNT II

(Defendants' Infringement of the '245 Patent)

33. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

34. Defendants have had knowledge of the '245 Patent since at least the filing of this Complaint and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the SureClip™ Hemostasis Clip products would infringe one or more claims of the '245 Patent.

35. On information and belief, Defendants were aware that Plaintiffs' Resolution™ Clip products embody the claimed inventions of the '245 Patent and knew or should have known that Defendants' products, including the SureClip™ Hemostasis Clip products, infringe one or more claims of the '245 Patent.

36. On information and belief, Defendants have actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, others to infringe the '245 Patent by offering for sale and selling infringing hemostatic clips, with knowledge of the '245 Patent and knowledge that their customers and end users will use those clips in a manner that directly infringes, literally and/or under the doctrine of equivalents, one or more of the claims of the '245 Patent; and with the specific intent to encourage and facilitate those infringing acts through the creation and dissemination of promotional and marketing materials, instructional materials, product manuals, and technical materials, including by way of

example, the Instructions for Use, sales catalog, and Product Information Sheet for their SureClip™ Hemostasis Clip products attached as Exhibits D – F hereto.

37. By way of example and not limitation, Claim 1 of the '245 Patent recites:

A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising:

a clip, the clip having at least two clip legs;

a breakable link adapted to couple a control wire to the clip and adapted to be broken by a first predetermined tensile force applied by the control wire;

the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip;

an axially rigid sheath enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire;

a handle coupled to the axially rigid sheath; and

an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip;

wherein when the breakable link is broken, the control wire uncouples from the clip.

38. By way of example, and not limitation, the SureClip™ Hemostasis Clip products infringe Claim 1 of the '245 Patent as described below.

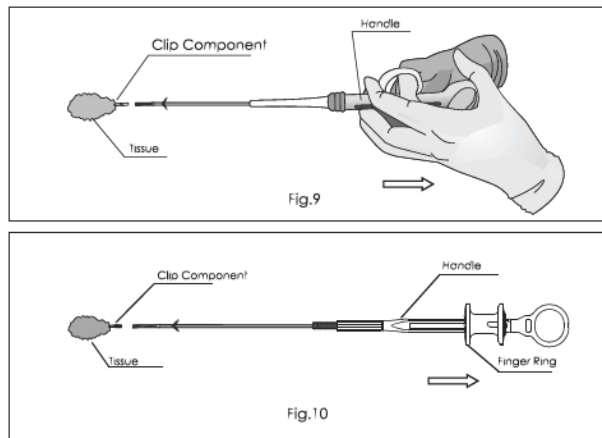
39. The SureClip™ Hemostasis Clip products are medical devices used to cause hemostasis of a blood vessel for use through an endoscope. *See, e.g.*, Exhibit D, p. 1 (“The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract”).

40. The SureClip™ Hemostasis Clip products contain a clip comprised of two clip arms (in box below) and a proximal pin and distal pin within the capsule; forces applied proximally to these clips arms through the control wire cause the clip arms to become drawn together; forces applied distally to these clip arms through the control wire cause the clip arms to

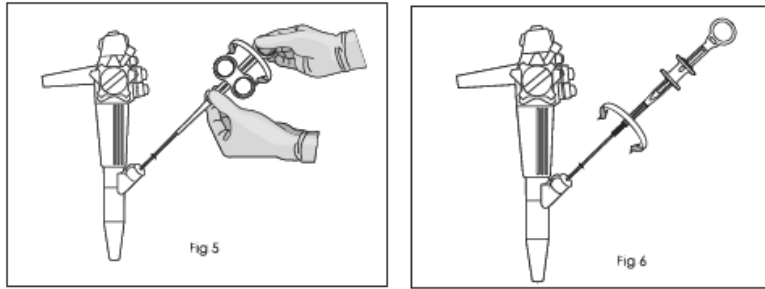
separate; forces are applied as needed to receive target tissue therebetween. *See, e.g.*, Exhibit F, p. 1. Such movement is reversibly operable prior to uncoupling. *See, e.g.*, Exhibit F, p. 2 (“SureClip’s unique design permits opening and closing the jaw prior to deployment.”).



41. The SureClip™ Hemostasis Clip products contain a pair of J hooks that extend distally from the distal end of a control wire; the J hooks are releasably connected to the proximal pin of the clip assembly, such that application of a sufficient predetermined force will release the J hooks from the clip assembly, thereby forming a breakable link that, when broken, uncouples the control wire from the clip. *See, e.g.*, Exhibit D, Figs. 9 and 10.

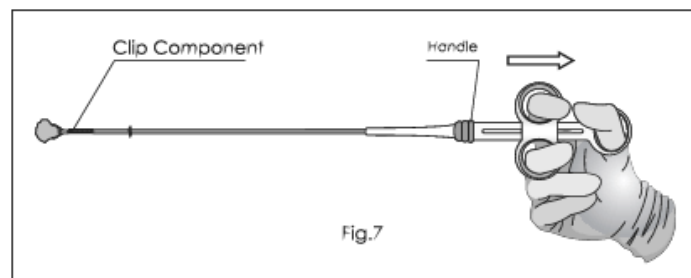


42. The SureClip™ Hemostasis Clip products contain a sheath sufficiently flexible to pass through the bends of an endoscope and navigate through the body until the distal end of the devices reaches the target tissue, which has sufficient axial rigidity to communicate a first force opposing a second force applied to the control wire. *See, e.g.*, Exhibit D, Figs. 5 and 6.



43. The SureClip™ Hemostasis Clip products contain a handle coupled to the sheath.

See, e.g., Exhibit D, Fig. 7.



44. The SureClip™ Hemostasis Clip products contain an actuator coupled to the control wire, whereby the actuator engages the control wire and causes the clip legs to open and close, and, upon application of a sufficient predetermined force, to decouple the clip mechanism from the control wire. *See, e.g., Exhibit D, Figs. 5–7, 9 and 10.*

45. Defendants have been infringing and are continuing to infringe one or more of the claims of the '245 Patent through the aforementioned acts, without authorization from Plaintiffs.

46. Plaintiffs are entitled to recover damages adequate to compensate them for Defendants' infringement of the '245 Patent.

47. Defendants' infringement of the '245 Patent has caused and is continuing to cause Plaintiffs to suffer irreparable harm, and Plaintiffs are entitled to injunctive relief to prevent further infliction of such harm.

COUNT III

(Defendants' Infringement of the '371 Patent)

48. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

49. Defendants have had knowledge of the '371 Patent since at least the filing of this Complaint and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the SureClip™ Hemostasis Clip products would infringe one or more claims of the '371 Patent.

50. On information and belief, Defendants were aware that Plaintiffs' Resolution™ Clip products embody the claimed inventions of the '371 Patent and knew or should have known that Defendants' products, including the SureClip™ Hemostasis Clip products, infringe one or more claims of the '371 Patent.

51. Defendants have actively, knowingly, and intentionally infringed and continue to infringe, literally and/or through the doctrine of equivalents, the '371 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use in the United States products, services, methods, or processes that are covered by at least Claim 11 of the '371 Patent. Such devices include, but are not limited to, the SureClip™ Hemostasis Clip products described above.

52. By way of example and not limitation, Claim 11 of the '371 Patent recites:

An apparatus for applying clips to tissue within a living body, comprising:

a capsule;

a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive tissue therebetween;

a control element including a connector element, extending between a proximal end which, during use, remains outside the body accessible to a user and a distal end removably connected to the clip assembly via the connector element, wherein the control element detaches from the connector element via a frangible link; and

a sheath extending from a proximal to a distal end and covering a portion of the control element, wherein the distal end of the sheath is releasably coupled to the capsule.

53. By way of example and not limitation, the SureClip™ Hemostasis Clip products infringe Claim 11 of the '371 Patent as described below.

54. The SureClip™ Hemostasis Clip products are used for applying clips to tissue within a living body. *See, e.g.*, Exhibit D, p. 1 (“The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract”).

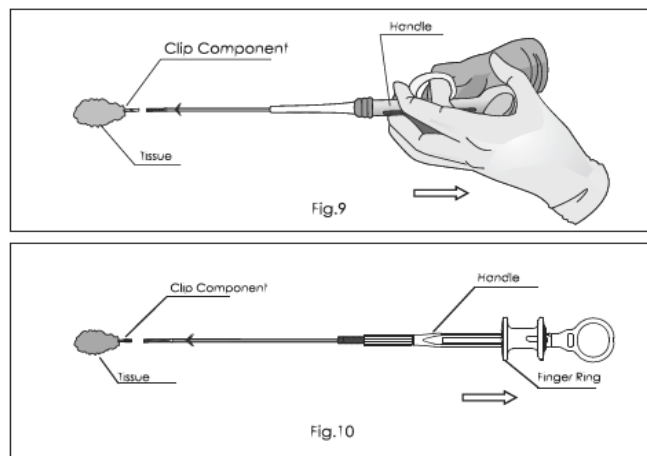
55. The SureClip™ Hemostasis Clip products contain a capsule (in box below). *See, e.g.*, Exhibit F, p. 1.



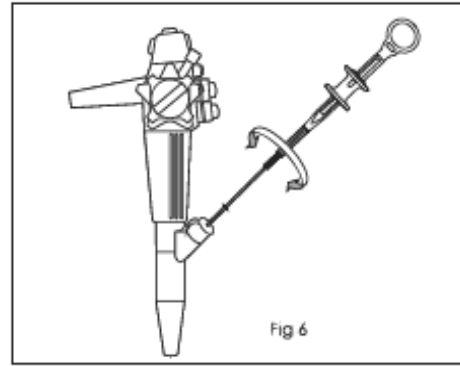
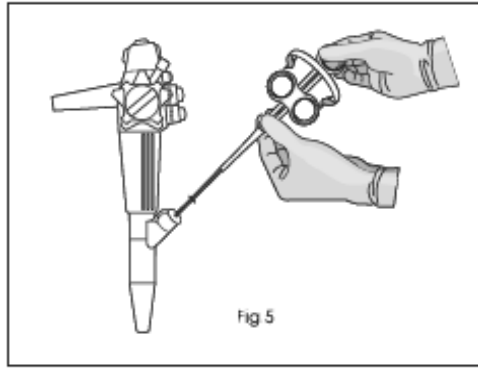
56. The SureClip™ Hemostasis Clip products contain clip assemblies that include two clip arms (in box below); forces applied proximally to these clip arms through the control wire cause the clip arms to become drawn together for application of clips to tissue; forces applied distally to these clip arms through the control wire cause the clip arms to separate from one another to receive target tissue therebetween. *See, e.g.*, Exhibit F, p. 1.



57. The SureClip™ Hemostasis Clip products contain a control element, the proximal end of which remains outside the body and accessible to the user. The distal end is removably connected to the clip assembly via the connector element, wherein the control element detaches from the connector element via a frangible link. *See, e.g., Exhibit D, Figs. 9 and 10.*



58. The SureClip™ Hemostasis Clip products contain a sheath that extends from a proximal to a distal end, covering at least a portion of the control element, and which is releasably coupled to the capsule. *See, e.g., Exhibit D, Figs. 5, 6, 9, and 10.*



59. Defendants have been infringing and are continuing to infringe one or more of the claims of the '371 Patent through the aforementioned acts, without authorization from Plaintiffs.

60. Plaintiffs are entitled to recover damages adequate to compensate them for Defendants' infringement of the '371 Patent.

61. Defendants' infringement of the '371 Patent has caused and is continuing to cause Plaintiffs to suffer irreparable harm, and Plaintiffs are entitled to injunctive relief to prevent further infliction of such harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that Defendants have infringed the '245, '725, and '371 Patents;
2. A judgment that Plaintiffs be awarded all appropriate damages under 35 U.S.C. § 284 for Defendants' past infringement, and any continuing or future infringement of the '245, '725, and '371 Patents, up until the date such judgment is entered, including interest, costs, and disbursements as justified under 35 U.S.C. § 284;
3. A permanent injunction, pursuant to 35 U.S.C. § 283, restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from any further infringement of the '245, '725, or '371 Patents for the full terms thereof, including any extensions;

4. A judgment that this case be declared exceptional within the meaning of 35 U.S.C. § 285 and that Plaintiffs be awarded their reasonable attorneys' fees against Defendants that they incur in prosecuting this action;

5. A judgment that Plaintiffs be awarded costs and expenses that they incur in prosecuting this action; and

6. A judgment and award of such further relief at law or in equity as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury on all claims and issues so triable.

DATED: November 26, 2018

YOUNG CONAWAY STARGATT & TAYLOR LLP

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