IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REX MEDICAL, L.P., Plaintiff, v. INTUITIVE SURGICAL, INC., INTUITIVE SURGICAL OPERATIONS, INC. and INTUITIVE SURGICAL HOLDINGS, LLC, Defendants.	**Civil Action No. 19-cv-5-MN** **JURY TRIAL DEMANDED** **FILED UNDER SEAL**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Rex Medical, L.P. ("Rex Medical" or "Plaintiff") asserts claims against Intuitive Surgical, Inc., Intuitive Surgical Operations, Inc., and Intuitive Surgical Holdings, LLC (collectively, "Intuitive" or "Defendants") for infringement of U.S. Patent No. 9,439,650 ("the '650 Patent" or "the Asserted Patent"). Rex Medical alleges as follows:

NATURE OF THE ACTION

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

THE PARTIES

2. Rex Medical is a limited partnership organized and existing under the laws of Pennsylvania with its principal place of business at 555 North Lane, Suite 5035, Conshohocken, PA 19428.

3. Defendant Intuitive Surgical, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 1020 Kifer Road, Sunnyvale, CA 94086.

4. Defendant Intuitive Surgical Operations, Inc. is a privately held corporation organized under the laws of the State of Delaware, with its principal place of business at 1020 Kifer Road, Sunnyvale, CA 94086.

5. Defendant Intuitive Surgical Operations, Inc. is a wholly-owned subsidiary of Defendant Intuitive Surgical, Inc.

6. Defendant Intuitive Surgical Holdings, LLC is a limited liability company organized under the laws of the State of Delaware, with its principal place of business at 1020 Kifer Road, Sunnyvale, CA 94086.

7. Defendant Intuitive Surgical Holdings, LLC is wholly-owned by Defendant Intuitive Surgical, Inc.

8. Upon information and belief, Intuitive manufactures and distributes surgical platforms and tools, including minimally invasive staplers for use in laparoscopic surgery.

9. Upon information and belief, Intuitive sells and offers to sell products and services throughout the United States, including in this judicial district, and introduces products and services into the stream of commerce that incorporate infringing technology, knowing that they would be sold in this judicial district and elsewhere in the United States.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code.

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this judicial district under 28 U.S.C. § 1400(b). Upon information and belief, each Defendant resides in the State of Delaware.

13. Upon information and belief, each Defendant is subject to this Court's general and specific personal jurisdiction because each Defendant is organized under the laws of the State of Delaware, and is thus a resident of Delaware.

BACKGROUND

Rex Medical and Its Tissue Stapling Inventions

14. Rex Medical was co-founded by Dr. James F. McGuckin Jr., M.D in 1996 to further the development of life-changing medical devices.

15. Rex Medical specializes in the development, manufacturing, and marketing of innovative, minimally invasive medical devices. Rex Medical targets its devices towards the cardiovascular, venous access, endosurgery, and oncology markets.

16. Rex Medical is ISO Certified.

17. Rex Medical's current President is Lindsay L. Carter. Mr. Carter joined Rex Medical in 2001 and was named President of the company in 2009.

18. Rex Medical owns several U.S. and foreign patents, including the Asserted Patent. The named inventors on the Asserted Patent are Dr. James F. McGuckin, Jr. and Peter W.J. Hinchliffe. Like Dr. McGuckin, Mr. Hinchliffe helped oversee the formation and development of Rex Medical, serving as Vice President of Research and Development from 1999-2002.

19. Rex Medical's mission has been, and remains, to improve patients' results through technological innovations.

20. Rex Medical has several innovative products in development that are unrelated to this litigation, including the Closer™ Vascular Sealing System, the Revolution™ Peripheral Atherectomy System, and the SplitWire™ Percutaneous Transluminal Angioplasty Scoring

Device. Rex Medical has patents pending related to each of these innovations. Additionally, Rex Medical currently distributes the Quadra-Fuse™ Multi-Pronged Injection Needle in partnership with Sillajen, a company focused on attacking and eradicating cancers.

Rex Medical's Tissue Stapling Patents

21. Rex Medical owns the Asserted Patent, which relates to Rex Medical's developments of an apparatus and method for stapling tissue during surgery. More specifically, Rex Medical developed a surgical stapling device and method that can be used for a variety of surgical procedures.

22. The need to remove parts or all of a tissue or organ can arise from a variety of reasons, such as gastro-esophageal lesions, stomach reduction, and gastro-esophageal reflux. The process of surgically removing parts of the tissue or organ is known as resection.

23. During a resection, the targeted tissue must be surgically cut away from the non-targeted tissue (i.e., the tissue that is to remain in the body) to remove the targeted tissue. Because some tissue is cut, there is a simultaneous need to seal the cut tissue so that the remaining, non-targeted tissue is not left open and exposed.

24. During a resection, a device used to grasp the targeted tissue may be needed to pull the targeted tissue away from the surrounding tissue, organs, and structures so the cutting and sealing devices can be used.

25. Rex Medical designed surgical stapling devices that can both cut and staple tissue almost simultaneously. These devices are particularly useful in laparoscopic surgery (also known as minimally invasive surgery). These devices are described in and covered by the '650 Patent.

26. The Asserted Patent is directed to systems apparatus and methods for stapling tissue during resection. The systems apparatus includes, for example, an operative head

comprising a pair of opposed tissue clamping jaws, which are moveable with respect to one another, holding one position when preparing to receive the targeted tissue, and a different, closed position when clamping the targeted tissue to cut and staple it. One of the jaws includes a stapling mechanism, which pushes the staple through the targeted tissue; the other jaw includes a staple forming anvil surface, which molds the staple's shape once the staple passes through the targeted tissue. The stapling mechanism includes slots, through which staples are fired, which are arranged in a row extending from a proximal end of the first jaw to a distal end of the first jaw. This first jaw works in combination with a control handle that remains outside the patient, even when the operative head is operating within the patient's stomach and esophagus. The control handle can include one or more actuators for moving the jaws relative to one another, and for operating the stapling mechanism.

27. The Asserted Patent allows the efficient sealing of cut tissue during resection.

The '650 Patent

28. Rex Medical is the assignee and owner of the right, title, and interest in and to the `650 Patent having acquired those rights on April 1, 2002, including the right to assert all causes of action arising under the '650 Patent and the right to any remedies for infringement of them.

29. The '650 Patent, entitled "Apparatus and Method for Resectioning Gastro-Esophageal Tissue," was issued by the United States Patent and Trademark Office on September 13, 2016. The '650 Patent issued from United States Patent Application No. 15/018,000 and claims priority to United States Provisional Application No. 60/265,469 ("the '469 Application"), filed on January 31, 2001. A copy of the '650 Patent is attached as **Exhibit A**.

30. The inventions of the '650 Patent are generally directed to a tissue stapling device that has two jaws to clamp targeted tissue and pass staples into the clamped tissue.

31. The ’650 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

The Infringing Products

32. Intuitive makes, uses, sells, offers for sale, and/or imports products under the *da Vinci Surgical System* brand. The *da Vinci Surgical System* includes surgical instruments used in conjunction with each other within the *da Vinci* system.

33. Intuitive’s *da Vinci Surgical System* includes the *da Vinci Xi* and *da Vinci X* versions.

34. Intuitive makes, uses, sells, offers for sale, and/or imports the SureForm 60 Stapler, the SureForm 45 Stapler, and the SureForm 45 Curved-Tip Stapler.

35. The SureForm 60 Stapler is compatible with the SureForm 60 reloads. Upon information and belief, the SureForm 60 reloads are inserted into the SureForm 60 Stapler.

36. The SureForm 60 Stapler is compatible with the *da Vinci Surgical System Xi* and *da Vinci Surgical System X*. The SureForm 60 Stapler is used to surgically staple tissue.

37. Upon information and belief, the SureForm 60 Stapler was first introduced into the market in 2018.

38. The SureForm 45 Stapler is compatible with the SureForm 45 reloads. Upon information and belief, the SureForm 45 reloads are inserted into the SureForm 45 Stapler.

39. The SureForm 45 Stapler is compatible with the *da Vinci Surgical System Xi* and *da Vinci Surgical System X*. The SureForm 45 Stapler is used to surgically staple tissue.

40. Upon information and belief, the SureForm 45 Stapler was first introduced into the market in 2019.

41. The SureForm 45 Curved-Tip Stapler is compatible with the SureForm 45 reloads. Upon information and belief, the SureForm 45 reloads are inserted into the SureForm 45 Curved-Tip Stapler.

42. The SureForm 45 Curved-Tip Stapler is compatible with the *da Vinci Surgical System Xi* and *da Vinci Surgical System X*. The SureForm 45 Curved-Tip Stapler is used to surgically staple tissue.

43. Upon information and belief, the SureForm 45 Curved-Tip Stapler was first introduced into the market in 2019.

SureForm 60 Stapler

44. The SureForm 60 Stapler is illustrated below.

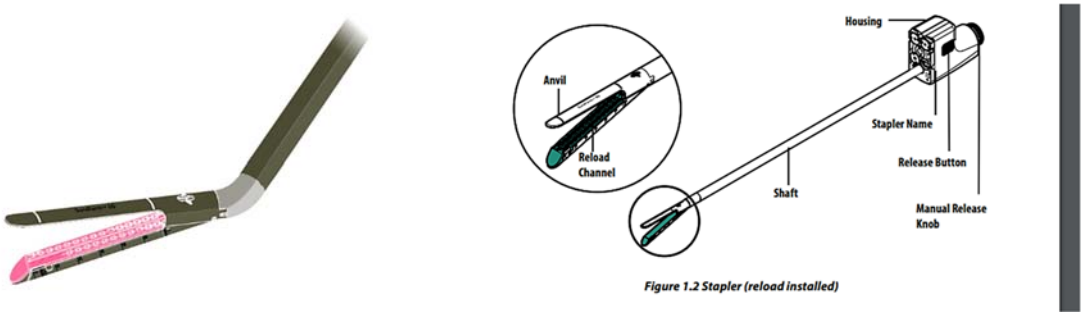


Figure 1.2 Stapler (reload installed)

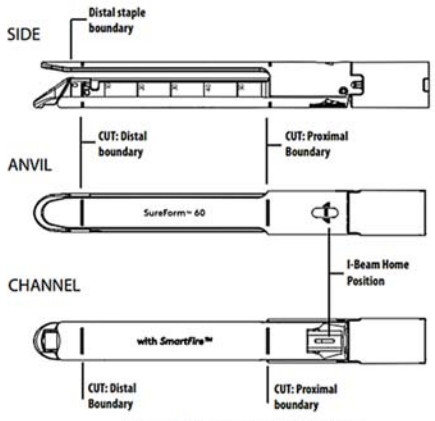


Figure 1.3 Etching on jaws explained

SureForm 60 Stapler User Manual (553910-05) at 1, 11.

45. The SureForm 60 Stapler is indicated for use in resection, transection, and/or creation of anastomoses in general, thoracic, gynecologic, urologic, and pediatric surgery. SureForm 60 Stapler User Manual (553910-05) at 6. The SureForm 60 Stapler allows multiple rows of staples and cuts the tissue along the middle of the staple line. SureForm 60 Stapler User Manual (553910-05) at 9.

46. The SureForm 60 Stapler is described as including two jaws, a shaft, and instrument housing. SureForm 60 Stapler User Manual (553910-05) at 10. Controls are used to position the jaws across the targeted tissue. One jaw holds and propels the staples when triggered; the other jaw forms the propelled staples in the targeted tissue. SureForm 60 Stapler User Manual (553910-05) at 10, 19–20.

SureForm 45 Stapler and SureForm 45 Curved-Tip Stapler

47. The SureForm 45 Stapler (left) and SureForm 45 Curved-Tip Stapler (right) are illustrated below.

RM0002533

48. Upon information and belief, the SureForm 60 Stapler, SureForm 45 Stapler, and SureForm 45 Curved-Tip Stapler do not differ in any material way other than the staple line length (60 mm, 45 mm, and 45 mm, respectively).

49. Upon information and belief, the staple line length does not affect the infringement analysis.

50. Thus, the representation in this Second Amended Complaint of the SureForm 60 Stapler is also representative of the SureForm 45 Stapler and SureForm 45 Curved-Tip Stapler, and vice versa.

51. Upon information and belief, the SureForm 45 Stapler and the SureForm 45 Curved-Tip Stapler do not differ in any way other than the additional curvature of one jaw of the SureForm 45 Curved-Tip Stapler. Upon information and belief, the additional curvature does not affect the infringement analysis.

52. Intuitive's *da Vinci Surgical Systems Xi* and *X* with SureForm 60 Stapler, the *da Vinci Surgical Systems Xi* and *X* with SureForm 45 Stapler, and the *da Vinci Surgical Systems Xi* and *X* with SureForm 45 Curved-Tip Stapler (collectively "the Accused Products") infringe at least the Asserted Patent.

COUNT I – INFRINGEMENT OF U.S. PATENT 9,439,650

53. Rex Medical realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 52 of the Second Amended Complaint as though fully set forth herein.

54. Upon information and belief, Intuitive has and continues to directly and indirectly infringe, literally and/or under the doctrine of equivalents, at least claim 6-12 of the '650 Patent by making, using, selling, importing, offering for sale, and/or providing and causing to be used the Accused Products.

55. Claim 6 of the '650 Patent is a claim that is dependent on claim 5, which is dependent on claim 4.

56. Claim 4 of the ’650 Patent claims an apparatus for stapling tissue comprising:

> a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue there between for stapling,
>
> a staple carrying portion of the first jaw defining slots through which staples are configured to pass;
>
> an anvil surface defined on the second jaw opposing the first jaw;
>
> at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment; and
>
> a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion, the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location.

57. Claim 5 of the ’650 Patent claims:

> The apparatus of claim 4, wherein the beam is configured to engage the first and second jaws one of entirely or substantially from therewithin to maintain the second distance and the alignment.

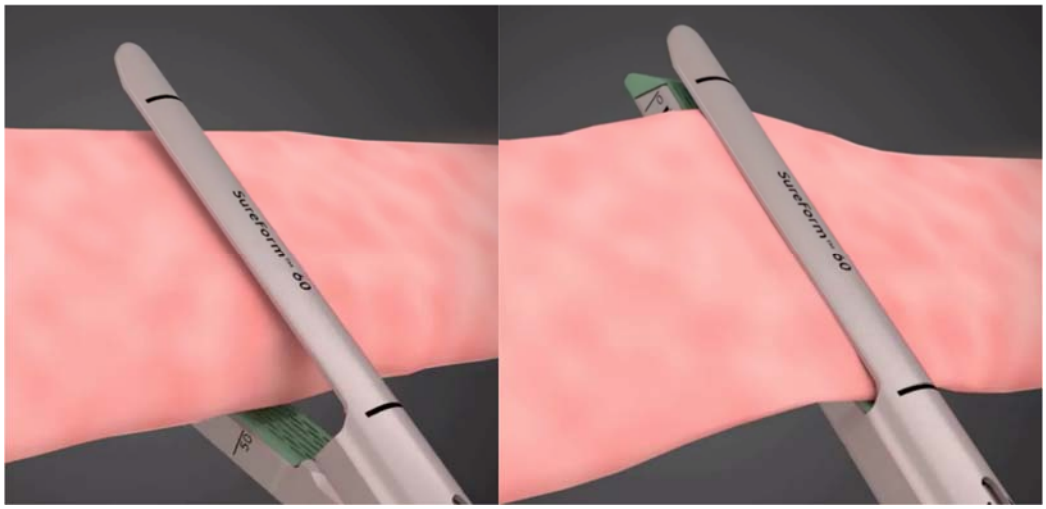
58. Claim 6 of the ’650 Patent—the claim that is asserted—claims:

> The apparatus of claim 5, wherein the beam comprises an upper portion and a lower portion and a web coupled between the upper portion and the lower portion, at least one of the lower portion or the upper portion configured to cause the staple pusher to move a staple as the beam moves from a proximal location to a distal location, the upper portion and the lower portion configured to cooperatively engage the first jaw and the second jaw to align the slots with a staple forming portion on the anvil Surface.

59. The Accused Products contain each of the above limitations. *See, e.g.*, **Exhibit B**.

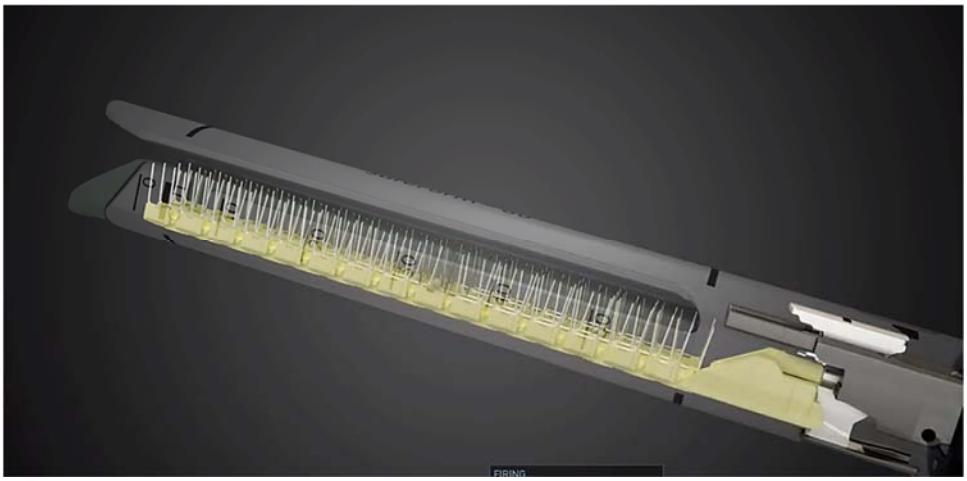
60. The Accused Products are apparatuses for stapling tissue.

61. The Accused Products have two jaws at least one of which is movable in relation to the other and can consequently be moved from a first configuration where the jaws are separated from each other at a first distance to receive tissue, to a second configuration where the jaws are clamped together at a second distance to hold tissue for stapling. Illustrations of the two jaws and their movements are below.



https://www.intuitivesurgical.com/davinci-sureform-60/ (last viewed December 30, 2018)

62. The Accused Products have a staple carrying portion of the first jaw with slots through which the staples are configured to pass. The Accused Products' "Reload channel" holds the staples and has slots that the staples pass through. SureForm 60 Stapler User Manual (553910-05) at 10.



https://www.intuitivesurgical.com/davinci-sureform-60/

63. The Accused Products have an anvil surface defined on the second jaw opposing the first jaw.

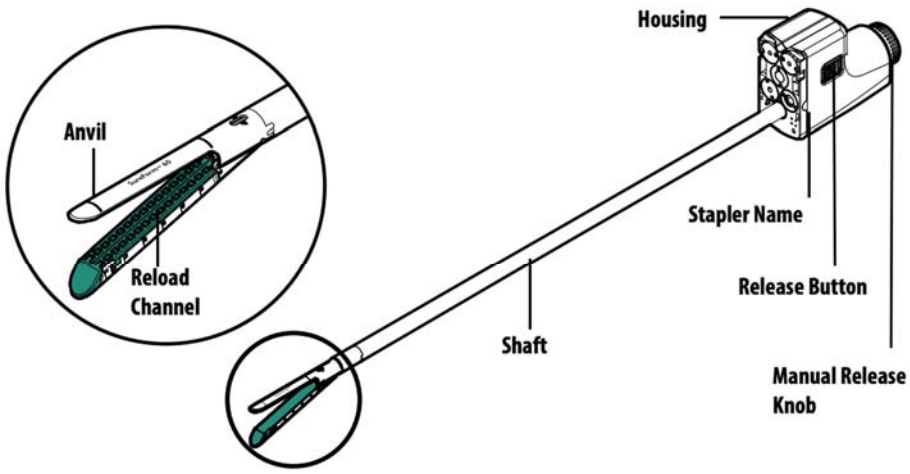
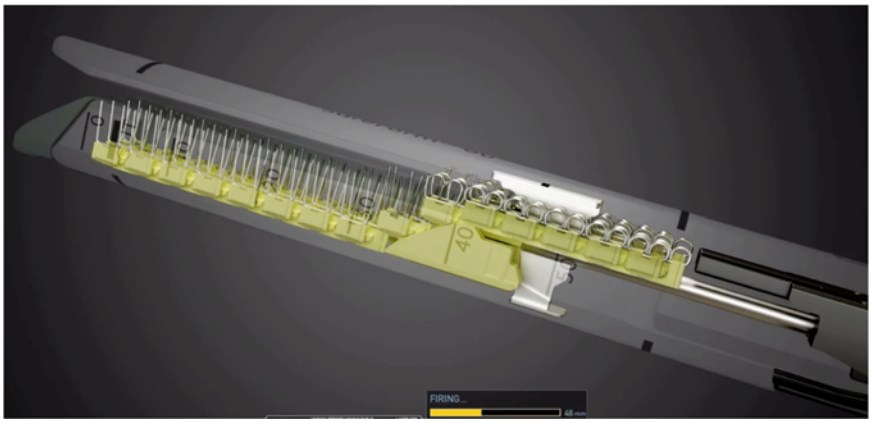


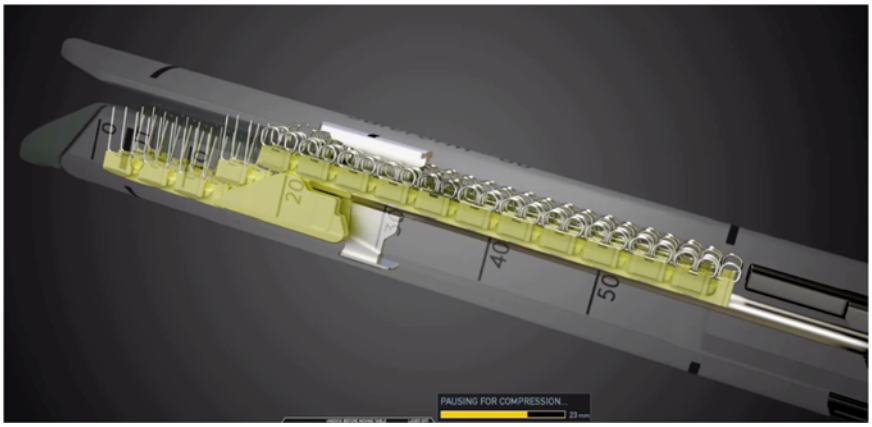
Figure 1.2 Stapler (reload installed)

SureForm 60 Stapler User Manual (553910-05) at 11.

64. Upon information and belief, the Accused Products have at least one of a gear and a cable operatively coupled to at least one of the jaws and configured to move at least one jaw from the first configuration to the second configuration such that the jaws are in alignment.

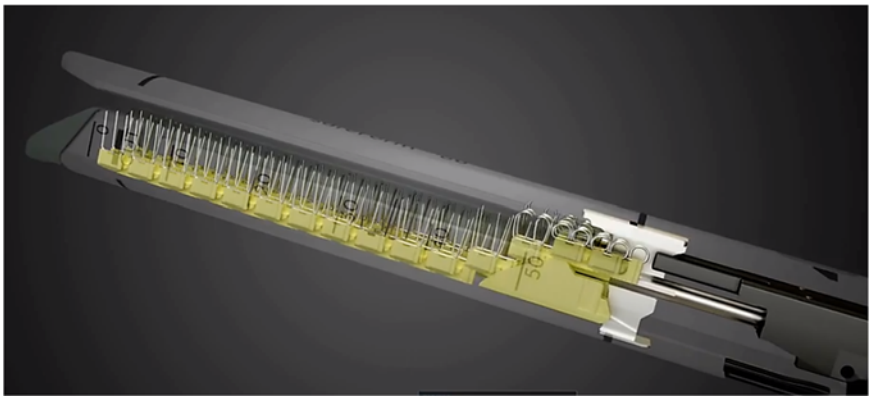
65. The Accused Products have a staple pusher that moves the staples from one position within the staple carrying portion, to a second position entirely outside the staple carrying portion. Illustrations of the pusher are below.





https://www.intuitivesurgical.com/davinci-sureform-60/

66. Upon information and belief, the Accused Products maintain the second distance and alignment of the jaws (i.e., when the jaws are close together)—while the staples are pushed out—by virtue of a beam configured to engage the first and second jaws from within the jaws while tissue is stapled from a proximal to a distal location. Illustrations of this beam and its location are below.



https://www.intuitivesurgical.com/davinci-sureform-60/

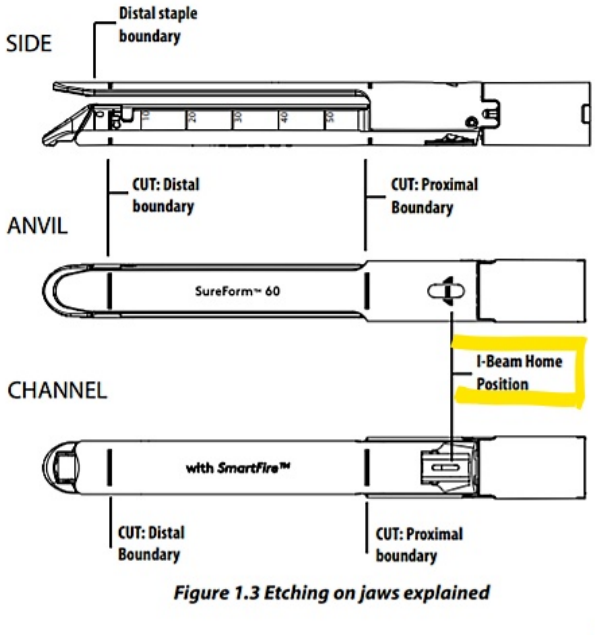
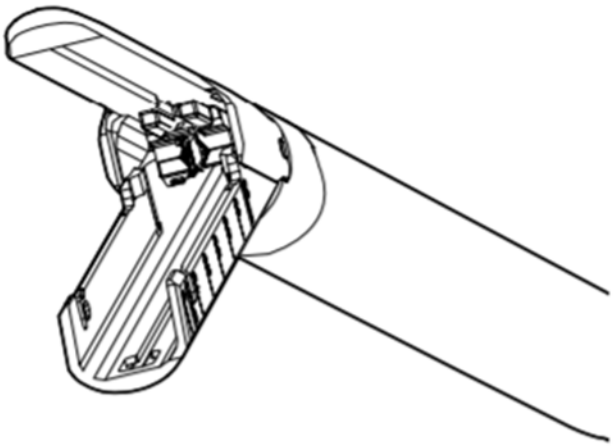


Figure 1.3 Etching on jaws explained

SureForm 60 Stapler User Manual (553910-05) at 11 (highlighting added).



SureForm 60 Stapler User Manual (553910-05) at 26.

3. If either the top of the anvil or the bottom of the channel are visible, keep turning the Manual Release Knob until the I-beam has returned to the home position, which indicates that the jaws are fully opened. See Figure 3.11.

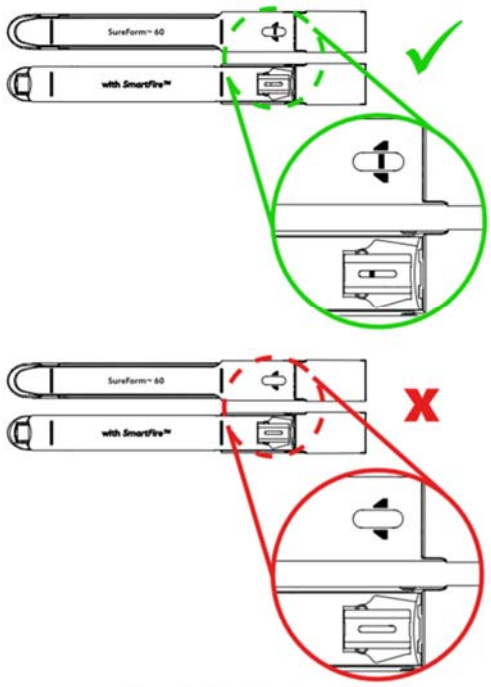
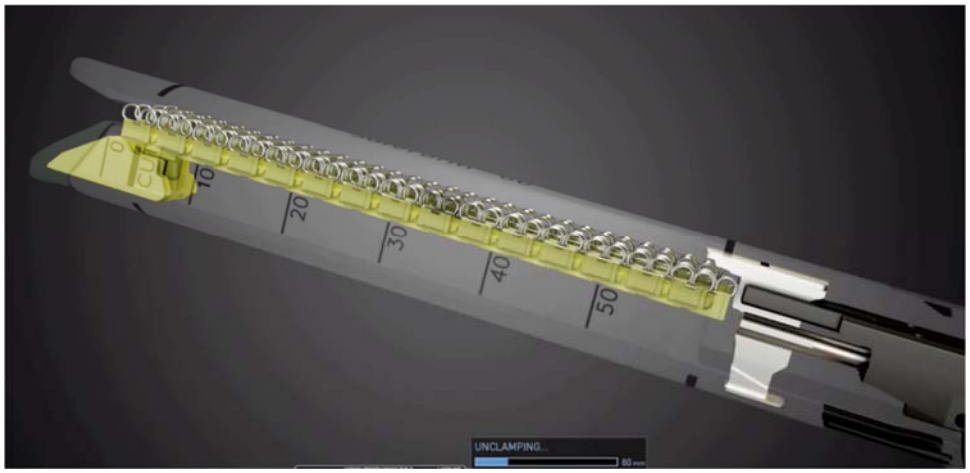


Figure 3.11 Check I-Beam Position

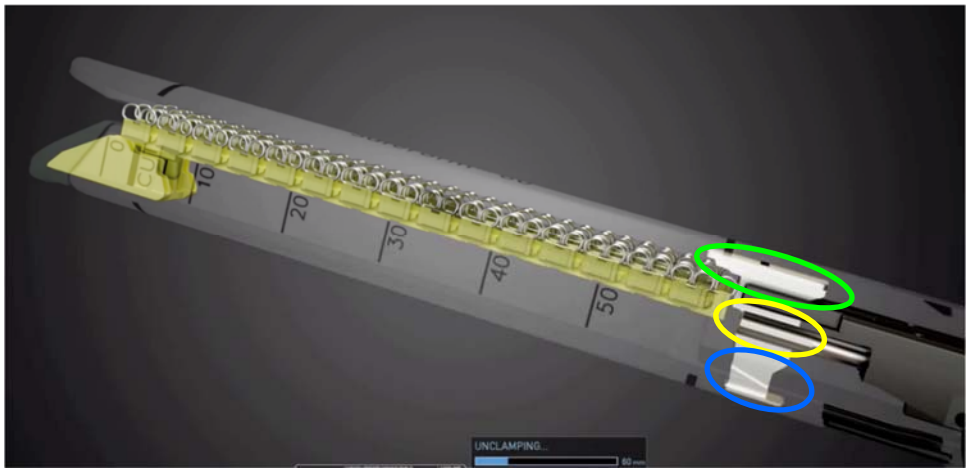
SureForm 60 Stapler User Manual (553910-05) at 34.

67. Upon information and belief, the Accused Products' beam is configured to engage the two jaws entirely or substantially from within the jaws to maintain the second distance and alignment (i.e., when the jaws are close together). An illustration of the beam is below.



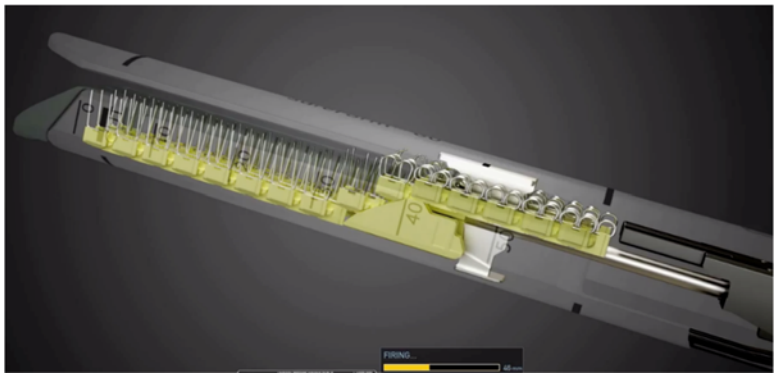
https://www.intuitivesurgical.com/davinci-sureform-60/

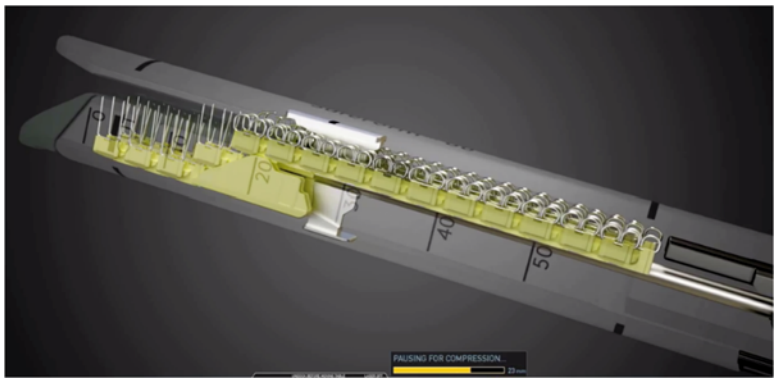
68. Upon information and belief, the beam comprises an upper portion and a lower portion, and a web coupled between the upper and lower portion.



https://www.intuitivesurgical.com/davinci-sureform-60/ (highlighting added)

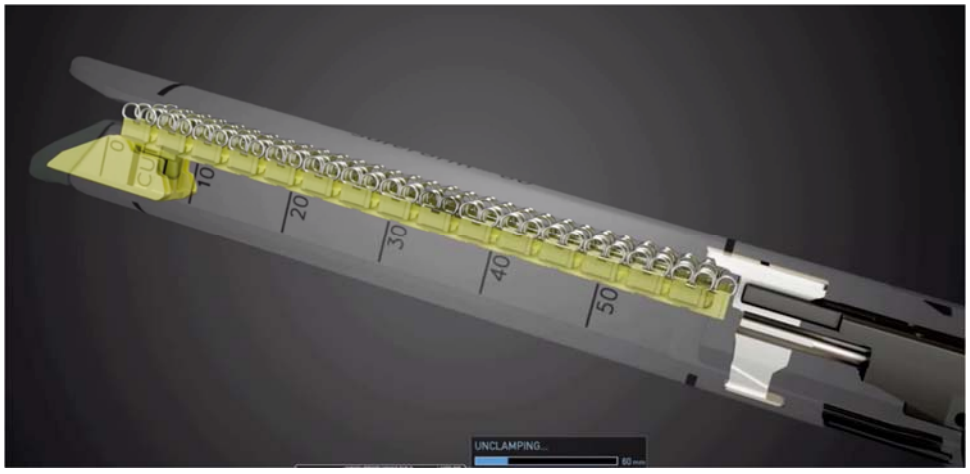
69. Upon information and belief, at least one of the beam's upper or lower portion is configured to cause the stapler pusher to move a staple as the beam moves from a proximal location to a distal location.





https://www.intuitivesurgical.com/davinci-sureform-60/

70. Upon information and belief, the beam's upper portion and lower portion are configured to cooperatively engage the two jaws to align the slots with a staple forming portion on the anvil surface.



https://www.intuitivesurgical.com/davinci-sureform-60/

71. The Accused Products also contain each of the claim limitations required by at least claims 7-12 of the ’650 Patent. *See, e.g.,* **Exhibit B**.

72. Intuitive has had knowledge of the ’650 Patent at least as early as January 3, 2019, as a result of service of the Complaint (D.I. 1) in this action. (*See* D.I. 4) The original Complaint explicitly alleged direct and indirect infringement of the ’650 Patent by certain of Intuitive’s Accused Products. Therefore, since at least January 3, 2019, Intuitive has had knowledge of the ’650 Patent, knowledge that its customer’s actions constituted infringement, and knowledge of Rex Medical’s direct and indirect infringement claims. As such, Intuitive is liable for inducing infringement under 35 U.S.C. § 271(b) and for contributory infringement under 35 U.S.C. § 271(c) based on its knowledge and actions since at least service of the original Complaint.

73. Upon information and belief, Intuitive has induced and continues to induce others to infringe at least one claim of the ’650 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Intuitive’s partners, clients, customers, and end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the ’650 Patent.

74. In particular, Intuitive’s actions that aid and abet others such as its partners, clients, customers, and end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

75. Upon information and belief, Intuitive is liable for contributory infringement of the ’650 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the

Accused Products to be especially made or adapted for use to infringe the ’650 Patent. The Accused Products are a material component for use in practicing the ’650 Patent and are specifically made and are not a staple article of commerce suitable for substantial non-infringing use.

76. As a consequence of each of Intuitive’s direct and indirect infringement, both literal and/or under the doctrine of equivalents, of the ’650 Patent, Rex Medical has been, and continues to be, damaged in an amount not yet determined and is entitled to recover damages pursuant to 35 U.S.C. § 284.

77. Upon information and belief, Intuitive’s infringement of the ’650 Patent will continue in the future, and Rex Medical will continue to suffer damages as a consequence unless Intuitive’s infringing acts are enjoined by this Court.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Rex Medical demands a trial by jury on all triable issues.

PRAYER FOR RELIEF

WHEREFORE, if Plaintiff Rex Medical is unsuccessful securing a reasonable royalty prior to service of this Second Amended Complaint, Plaintiff Rex Medical demands judgment for itself and against Intuitive as follows:

A. An adjudication that Intuitive has infringed the ’650 Patent;

B. An award of damages to be paid by Intuitive adequate to compensate Rex Medical for Intuitive’s past infringement of the Asserted Patent, and any continuing or future infringement through the date such judgment is entered, including pre-judgment and post-

judgment interest, costs, expenses, and an accounting of all infringing acts including, but not limited to, those acts presented at trial as well as those acts not presented at trial;

C. An adjudication that Intuitive's infringement has been willful and an award of treble damages;

D. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of Plaintiff Rex Medical's reasonable attorneys' fees; and

E. An award to Rex Medical of such further relief at law or in equity as the Court deems just and proper.

Dated: March 5, 2020

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market St., 12th Floor
Wilmington, DE 19801
Tel: 302-777-0300
Fax: 302-777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiff

OF COUNSEL:

Erik B. Milch
Stephen N. Scaife
COOLEY LLP
11951 Freedom Drive
One Freedom Square
Reston, VA 20190-5656
(703) 456-8000

Stephen C. Crenshaw
COOLEY LLP
1299 Pennsylvania Ave., N.W., Ste. 700
Washington, D.C. 20004-2400
(202) 842-7800

EXHIBIT A

US009439650B2

(12) **United States Patent**
McGuckin, Jr. et al.

(10) **Patent No.: US 9,439,650 B2**
(45) **Date of Patent: *Sep. 13, 2016**

(54) **APPARATUS AND METHOD FOR RESECTIONING GASTRO-ESOPHAGEAL TISSUE**

(71) Applicant: **REX MEDICAL, L.P.**, Radnor, PA (US)

(72) Inventors: **James F. McGuckin, Jr.**, Radnor, PA (US); **Peter W. J. Hinchliffe**, Downington, PA (US)

(73) Assignee: **REX Medical, L.P.**, Radnor, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/018,000**

(22) Filed: **Feb. 8, 2016**

(65) **Prior Publication Data**

US 2016/0151065 A1 Jun. 2, 2016

Related U.S. Application Data

(63) Continuation of application No. 13/856,819, filed on Apr. 4, 2013, now Pat. No. 9,271,727, which is a continuation of application No. 11/471,126, filed on Jun. 20, 2006, now Pat. No. 8,424,741, which is a continuation of application No. 10/855,908, filed on May 27, 2004, now Pat. No. 7,090,684, which is a continuation of application No. 10/062,760, filed on Jan. 31, 2002, now Pat. No. 6,835,199.

(60) Provisional application No. 60/265,469, filed on Jan. 31, 2001.

(51) **Int. Cl.**

A61B 17/068	(2006.01)
A61B 17/10	(2006.01)
A61B 17/072	(2006.01)
A61B 17/3205	(2006.01)
A61B 1/273	(2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61B 17/105*** (2013.01); ***A61B 17/068*** (2013.01); ***A61B 17/072*** (2013.01); ***A61B 17/07207*** (2013.01); ***A61B 17/3205*** (2013.01); *A61B 1/2736* (2013.01); *A61B 17/00234* (2013.01); *A61B 2017/00278* (2013.01); *A61B 2017/00827* (2013.01); *A61B 2017/07214* (2013.01); *A61B 2017/07221* (2013.01); *A61B 2017/2905* (2013.01); *A61B 2017/2923* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/1152
USPC 227/179.1, 180.1; 606/139
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,473,077 A	9/1984	Noiles
4,485,817 A	12/1984	Swigget

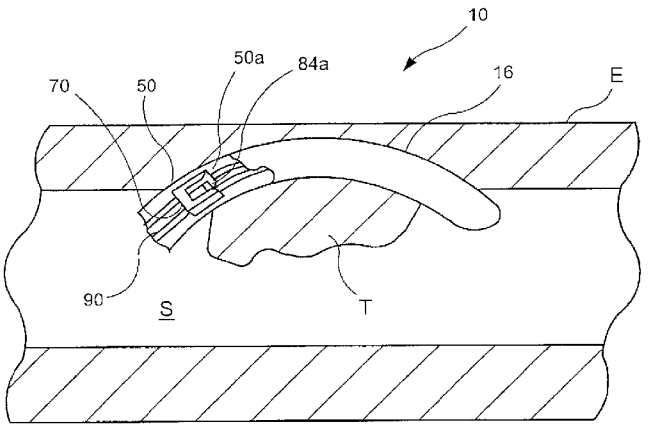
(Continued)

Primary Examiner — Nathaniel Chukwurah

(57) **ABSTRACT**

A system for stapling tissue comprises a flexible endoscope and an operative head including a pair of opposed, curved tissue clamping jaws sized to pass through an esophagus, the jaws being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration, a first one of the curved jaws including a stapling mechanism and a second one of the jaws including a staple forming anvil surface, the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof in combination with a control handle which, when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator for moving the jaws relative to one another and a second actuator for operating the stapling mechanism.

30 Claims, 11 Drawing Sheets



(51) **Int. Cl.**
A61B 17/00 (2006.01)
A61B 17/29 (2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,488,523	A	12/1984	Shichman	
4,505,414	A	3/1985	Filipi	
4,610,383	A	9/1986	Rothfuss et al.	
4,671,445	A	6/1987	Barker et al.	
5,040,715	A	8/1991	Green et al.	
5,100,419	A	3/1992	Ehlers	
5,139,513	A	8/1992	Segato	
5,190,203	A	3/1993	Rodak	
5,197,649	A	3/1993	Bessler et al.	
5,258,008	A	11/1993	Wilk	
5,271,543	A	12/1993	Grant et al.	
5,326,013	A	7/1994	Green et al.	
5,330,486	A	7/1994	Wilk	
5,355,897	A	10/1994	Pietrafitta et al.	
5,389,098	A *	2/1995	Tsuruta	A61B 17/00234 606/142
5,392,978	A	2/1995	Velez et al.	
5,395,030	A *	3/1995	Kuramoto	A61B 1/00087 227/179.1
5,403,326	A	4/1995	Harrison et al.	
5,411,508	A	5/1995	Bessler et al.	
5,425,738	A	6/1995	Gustafson	
5,433,721	A	7/1995	Hooven et al.	
5,441,507	A	8/1995	Wilk	
5,507,426	A *	4/1996	Young	A61B 17/07207 227/176.1
5,562,694	A	10/1996	Sauer et al.	
5,571,116	A	11/1996	Bolanos et al.	
5,582,611	A	12/1996	Tsuruta et al.	
5,582,615	A	12/1996	Foshee et al.	
5,645,209	A *	7/1997	Green	A61B 17/07207 227/175.2
5,657,921	A	8/1997	Young et al.	
5,662,260	A	9/1997	Yoon	
5,667,517	A	9/1997	Hooven	
5,868,760	A	2/1999	McGuckin, Jr.	
5,972,023	A	10/1999	Tanner et al.	
6,506,196	B1	1/2003	Laufer	
6,544,271	B1	4/2003	Adams et al.	
6,835,199	B2 *	12/2004	McGuckin, Jr.	A61B 17/07207 227/175.1
8,424,741	B2 *	4/2013	McGuckin, Jr.	A61B 17/07207 227/176.1

* cited by examiner

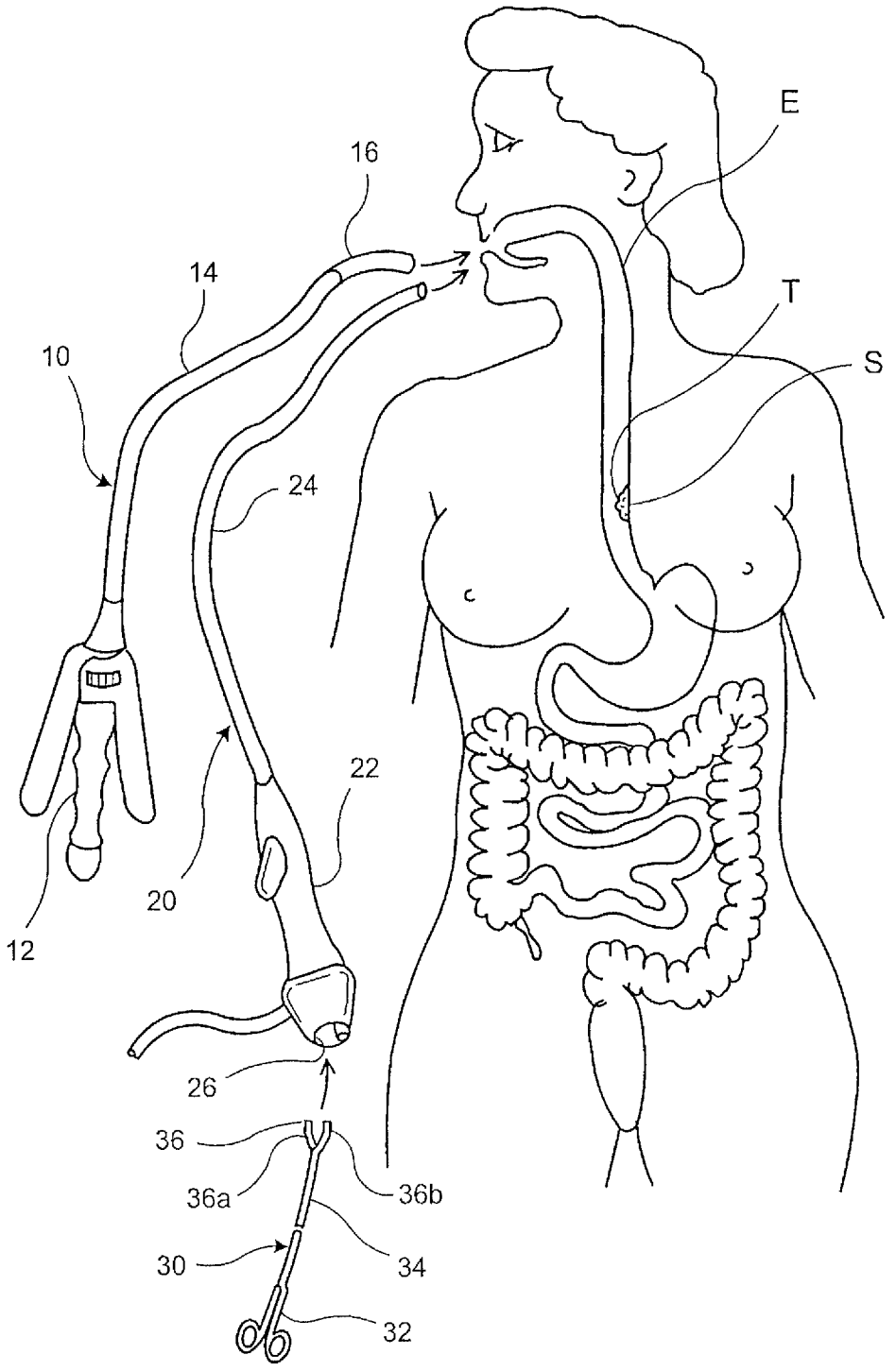


FIG. 1

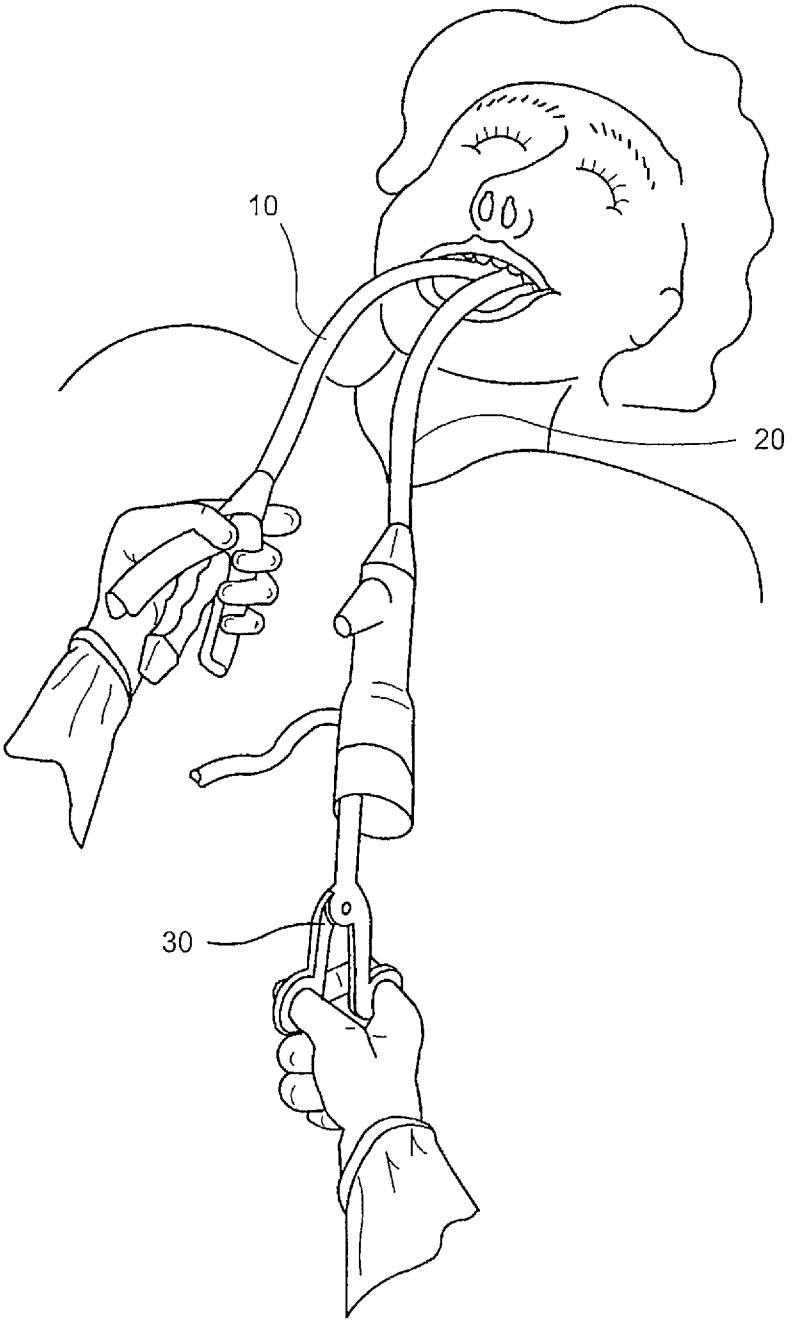
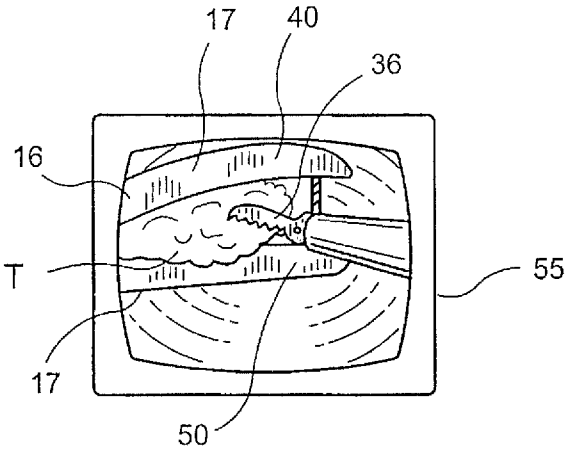
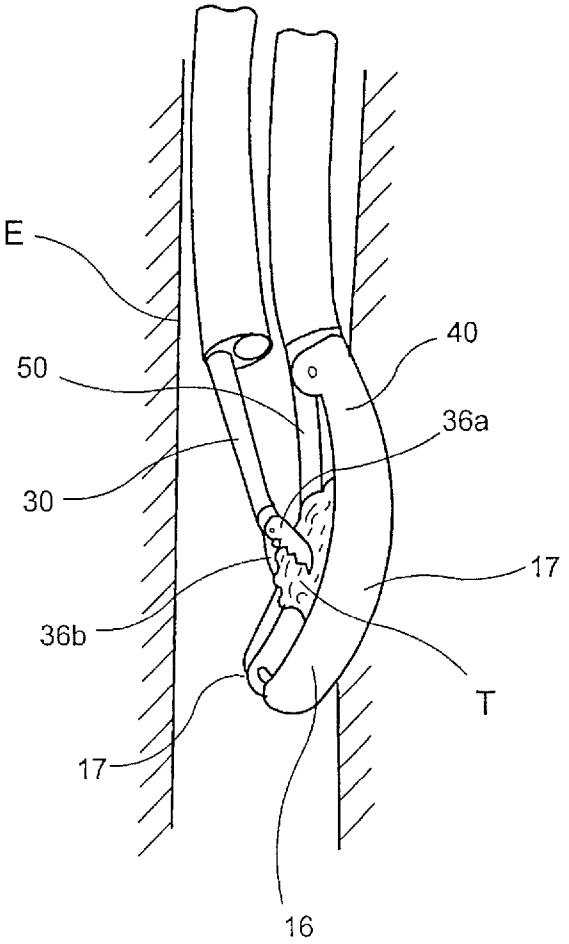


FIG. 2a



F I G. 2b



F I G. 2c

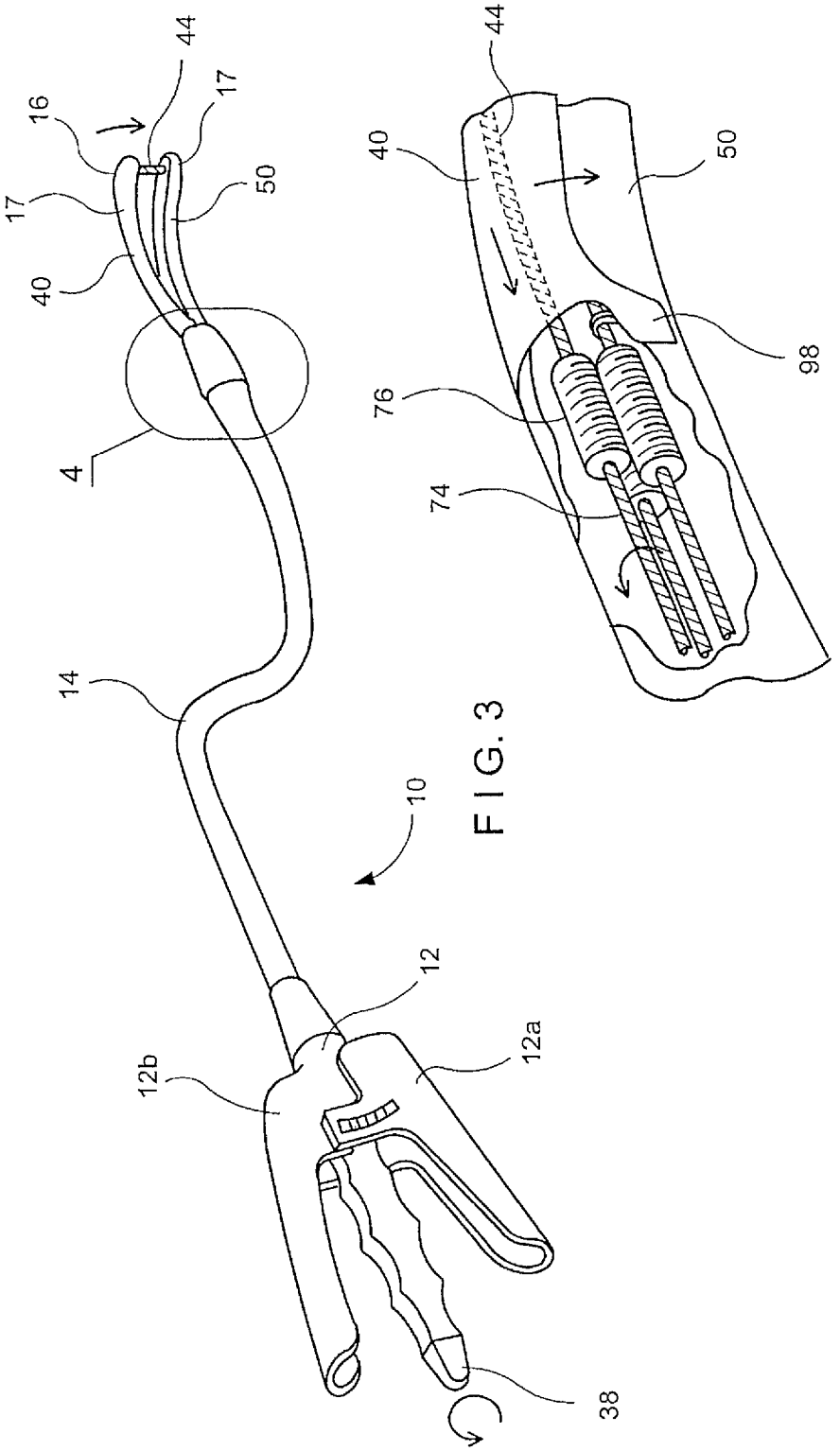


FIG. 3

FIG. 4

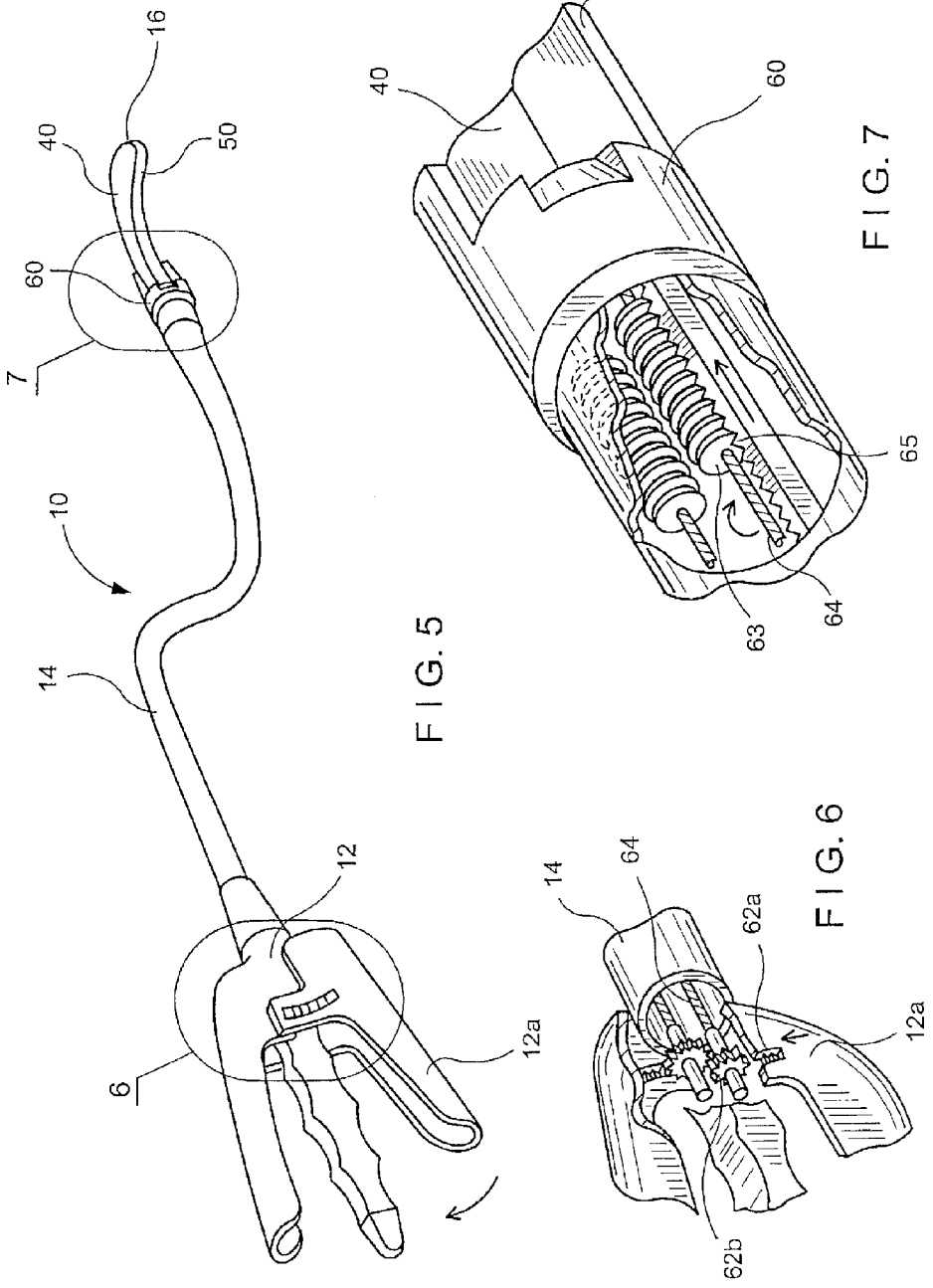


FIG. 5

FIG. 7

FIG. 6

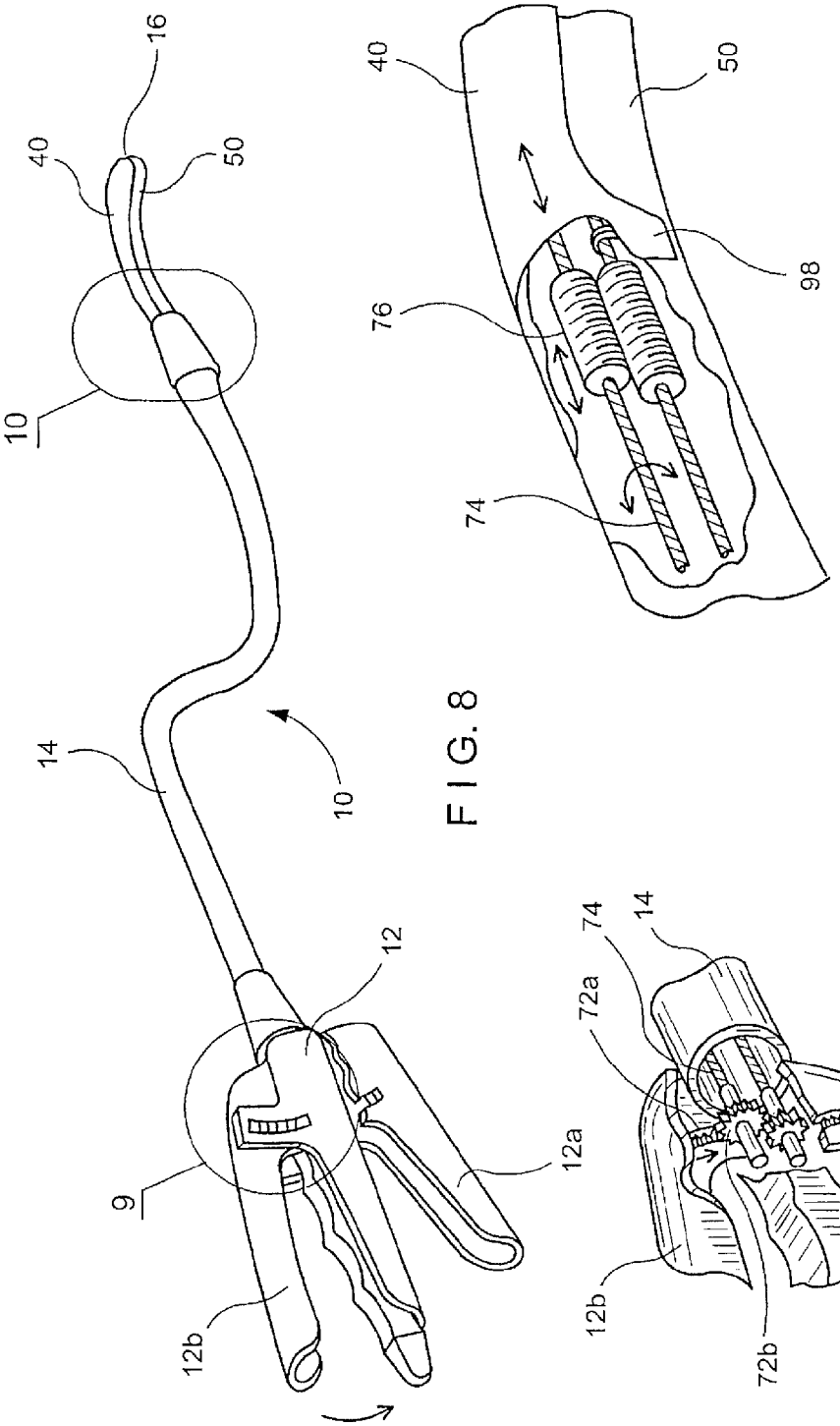


FIG. 8

FIG. 10

FIG. 9

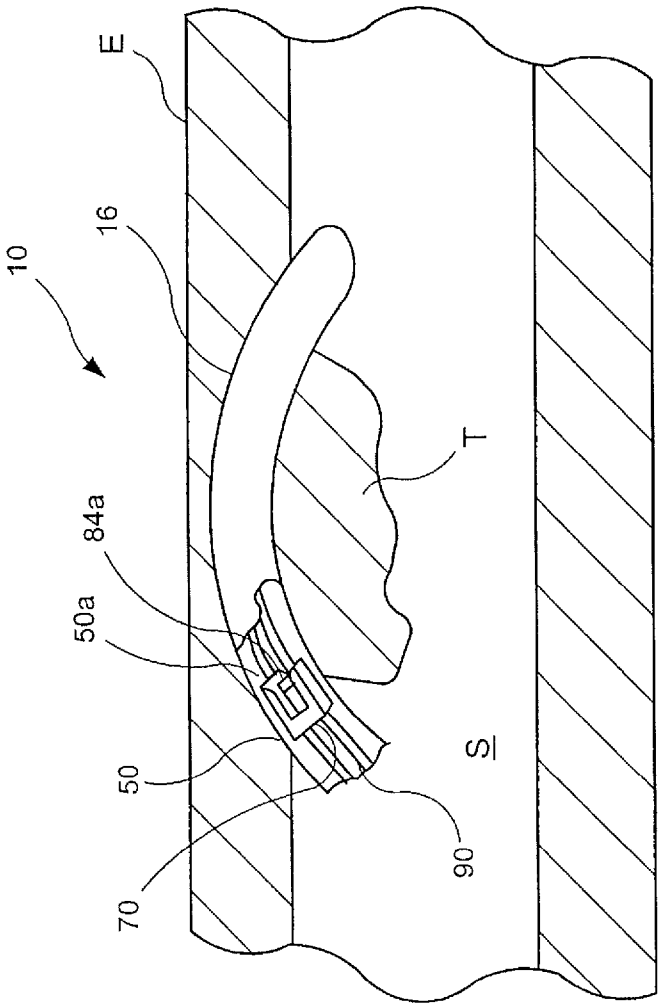


FIG. 11

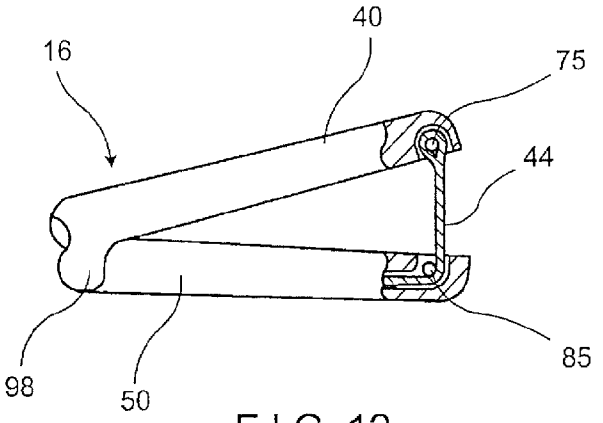


FIG. 12

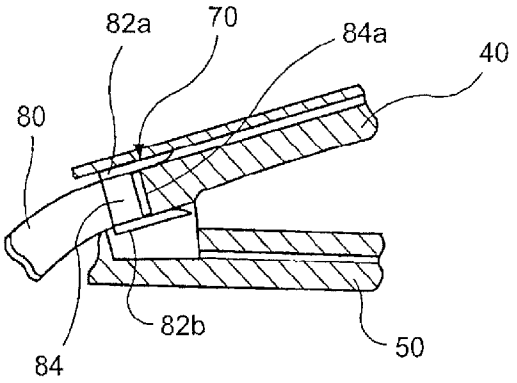


FIG. 13

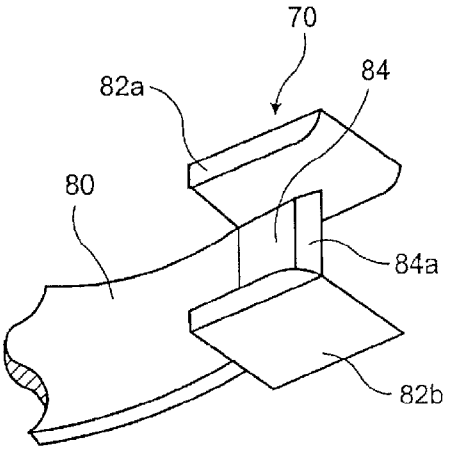


FIG. 14

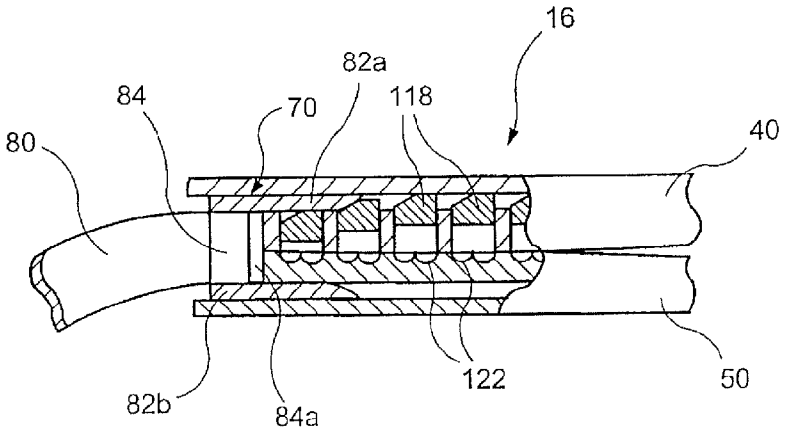


FIG. 15

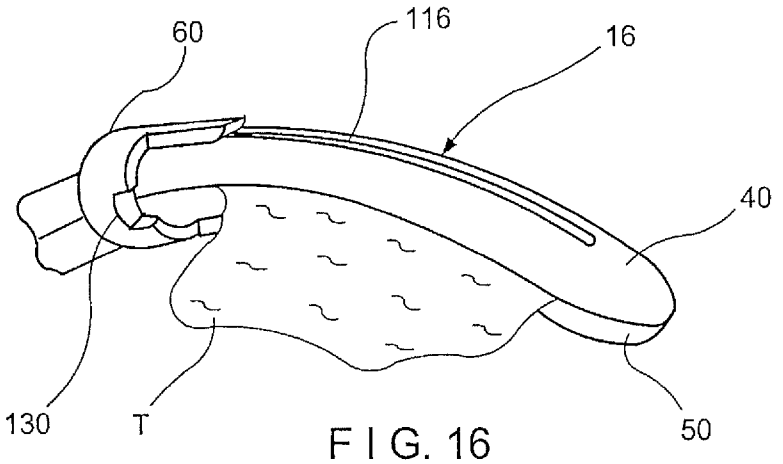


FIG. 16

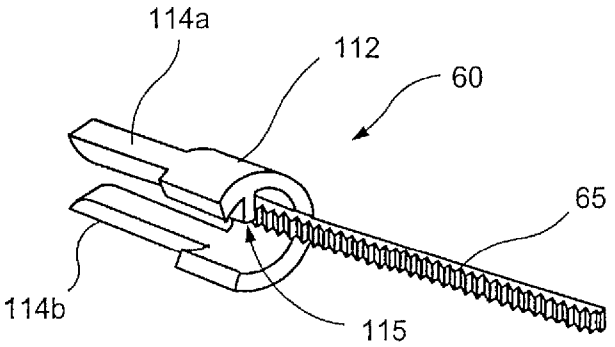


FIG. 17

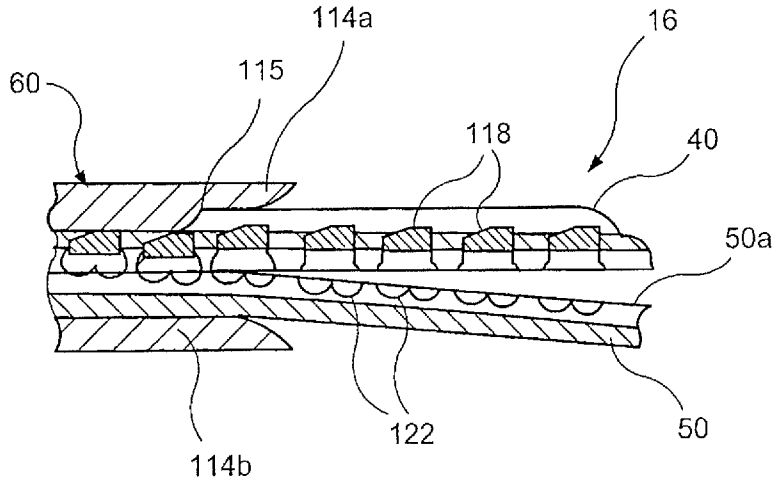


FIG. 18

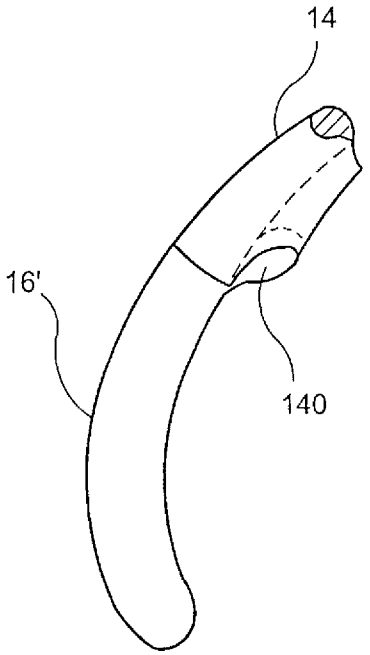


FIG. 19

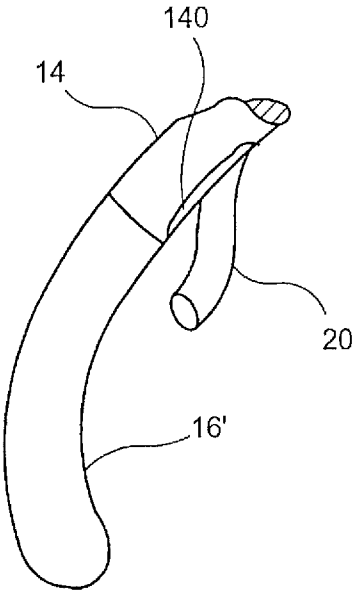


FIG. 20

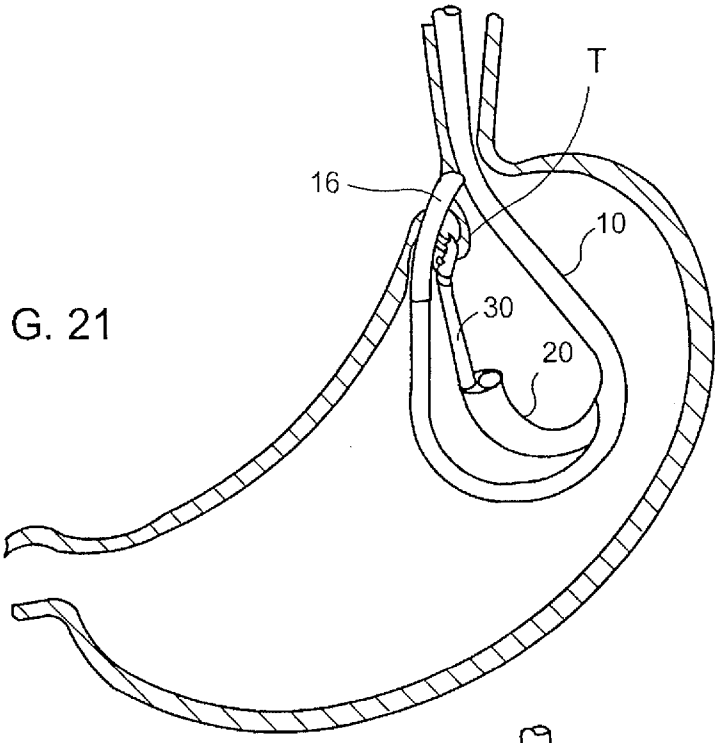


FIG. 21

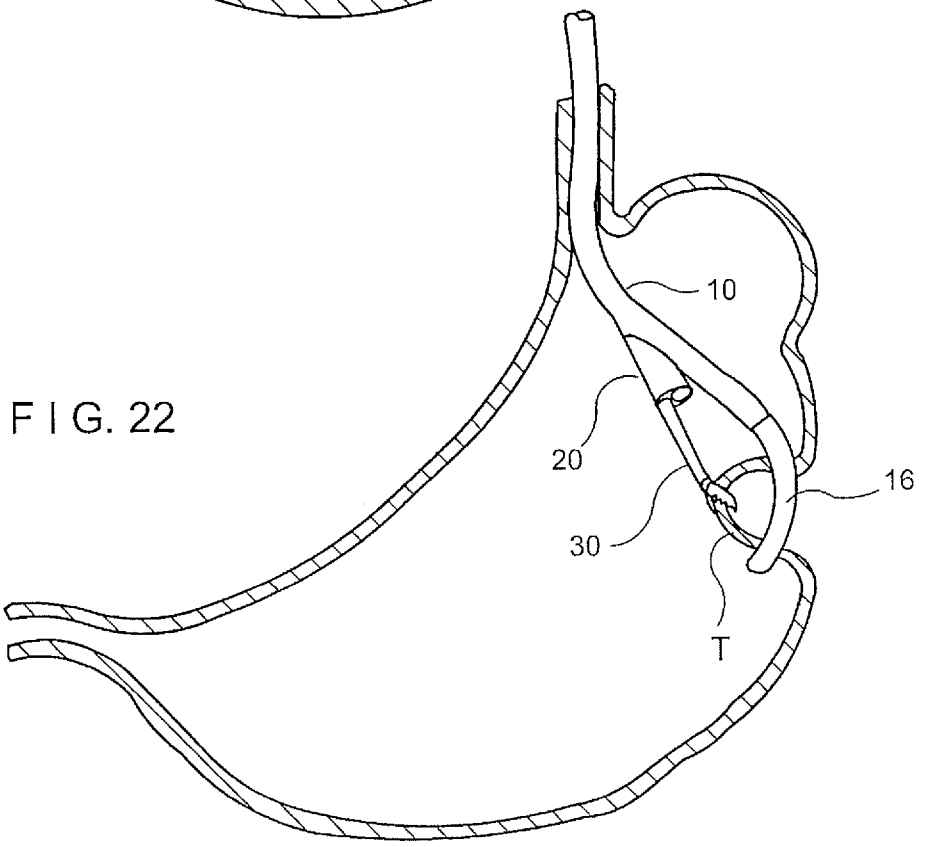


FIG. 22

APPARATUS AND METHOD FOR RESECTIONING GASTRO-ESOPHAGEAL TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims prority to and is a continuation of U.S. patent. application Ser. No. 13/856,819, filed Apr. 4, 2013, which is a continuation of U.S. patent application Ser. No. 11/741,126, filed Jun. 20, 2006, which is a continuation of U.S. patent application Ser. No. 10/855,908, filed May 27, 2004, which is a continuation of U.S. patent application Ser. No. 10/062,760, filed Jan. 31, 2002, which claims priority to U.S. Provisional Application No. 60/265,469, filed Jan. 31, 2001, all entitled "Apparatus and Method for Resectioning Gastro-Esophageal Tissue," the entire contents of each of which are incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to endoscopic devices for performing localized resections of gastro-esophageal lesions.

BACKGROUND OF THE INVENTION

Endoscopic surgical stapling apparatus are known in the art and are utilized to provide a variety of surgical procedures. For example, U.S. Pat. No. 5,040,715 to Green, et al. discloses an endoscopic stapling device configured to be inserted through a small entrance wound in the abdominal cavity to place rows of staples in body tissue. This device has a limited range of motion in that the stapling assembly at the distal end of the instrument can only be rotated about the central axis of the instrument.

An endoscopic stapling apparatus purporting to have a greater range of motion is disclosed in U.S. Pat. No. 5,326,013 to Green et al. This device has an articulating stapling assembly mounted for pivotal movement about an axis extending transverse to the central axis of the instrument. An endoscopic stapling device designed to be inserted through a small incision in a body wall and purporting to have an increased range of motion is described in U.S. Pat. No. 5,389,098 to Tsuruta et al. A stapling assembly of this device curves away from a central axis of the instrument to a 90.degree. angle so that it can more easily reach tissue spaced from the central axis. This device incises tissue clamped within the stapling assembly and places staggered lines of staples on both sides of the incision.

SUMMARY OF THE INVENTION

The present invention is directed to a system for stapling tissue comprising a flexible endoscope and an operative head including a pair of opposed, curved tissue clamping jaws sized to pass through an esophagus, the jaws being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration, a first one of the curved jaws including a stapling mechanism and a second one of the jaws including a staple forming anvil surface, the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof in combination with a control handle which, when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator for moving the jaws relative to one another and a second actuator for operating the stapling mechanism.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a perspective view of a system according to an illustrative embodiment of the present invention along with a partially cross-sectional view of a patient showing a target portion of tissue to be resected;

FIG. **2***a* shows the system of FIG. **1** inserted into the patient's body via the mouth;

FIG. **2***b* shows a display of the image of a stapling apparatus of the system of FIG. **1** provided to a user;

FIG. **2***c* shows a cross-sectional view of the patient's esophagus with the stapling apparatus of FIG. **3** in position adjacent to the target portion of tissue;

FIG. **3** shows a perspective view of the system of FIG. **1** with jaws of the stapling apparatus open;

FIG. **4** shows a partially cross-sectional view of a proximal end of the stapling apparatus of FIG. **3** showing control cables for operating the jaws configured as when the jaws are open;

FIG. **5** shows a perspective view of the system of FIG. **1** with jaws of the stapling apparatus closed with a lower actuator lever on a control handle being actuated;

FIG. **6** shows a partially cross-sectional view of the control handle of the system of FIG. **5** showing a coupling between control cables for operating the jaws and the lower actuator lever on the control handle;

FIG. **7** shows a partially cross-sectional view of a proximal end of the stapling apparatus of FIG. **5** showing control cables for operating a stapling pusher of the stapling apparatus configured as when the lower actuator lever is actuated;

FIG. **8** shows a perspective view of the system of FIG. **1** with jaws of the stapling apparatus closed with an upper actuator lever on the control handle being actuated;

FIG. **9** shows a partially cross-sectional view of a portion of the control handle of the system of FIG. **8** showing a coupling between control cables for operating the jaws and the upper actuator lever on the control handle;

FIG. **10** shows a partially cross-sectional view of a proximal end of the stapling apparatus of FIG. **5** showing control cables for operating a stapling pusher of the stapling apparatus configured as when the upper actuator lever is actuated;

FIG. **11** shows a partially cross-sectional view of a stapling assembly of the system of FIG. **1** grasping esophageal tissue;

FIG. **12** shows a partially cross-sectional view of the stapling assembly of the system of FIG. **1** illustrating a mechanism for grossly approximating the jaws of the stapling assembly;

FIG. **13** shows a partially cross-sectional view of the stapling assembly illustrating a mechanism for finely approximating the jaws in an initial position;

FIG. **14** shows a perspective view of an I-beam member of the fine approximation mechanism of FIG. **13**;

FIG. **15** shows a partially cross-sectional view of the stapling assembly with the fine approximation mechanism in a partially advanced position;

FIG. **16** shows a perspective view of the stapling assembly with a C-shaped clamp member thereof in an initial position;

FIG. **17** shows a perspective view of the C-shaped clamp member of FIG. **16** rotated 180.degree. removed from the jaws;

FIG. **18** shows a cross-sectional view of the stapling assembly with the C-shaped clamp member in a partially advanced position;

FIG. **19** shows an alternate embodiment of the system according to the present invention with a lateral endoscope receiving lumen;

FIG. **20** shows the system of FIG. **19** with an endoscope received therein;

FIG. **21** shows a system in accord with the present invention positioned within the stomach to perform a procedure for the treatment of reflux; and

FIG. **22** shows a system in accord with the present invention positioned within the stomach to perform a stomach reduction procedure.

DETAILED DESCRIPTION

A detailed description of illustrative embodiments of the present invention is provided in conjunction with the attached drawings. In the descriptions of the various embodiments and the corresponding drawings, like reference numerals refer to like elements.

A method and apparatus for resectioning anastomized lumenal tissue is disclosed in U.S. Pat. No. 5,868,760 to McGuckin et al., the disclosure of which is hereby incorporated by reference in its entirety. The disclosed apparatus includes a flexible tubular body and a distal operating capsule that may be inserted through either a naturally occurring body orifice or a surgical incision and guided to an operative site endoscopically or using radiologic imaging guidance. In use the target tissue is stapled, cut and captured within the operating capsule for removal from the body. The healthy tissue is thereby anastomized by surgical staples.

FIG. **1** shows a system for resecting esophageal tissue according to an illustrative embodiment of the present invention. A surgical stapling apparatus, designated generally by the reference numeral **10**, is utilized in conjunction with an endoscope **20** for providing remote vision of an operative area and to assist in guiding the stapling apparatus **10** to the operative area. An endoscopic grasping device **30** extends through a lumen in the endoscope **20** for use at the surgical site as would be understood by those of skill in the art. Those skilled in the art will further understand that, while the illustrative embodiments are described in conjunction with visual observation of the operative site via the endoscope **20**, these procedures may also be visualized through the use of Magnetic Resonance Imaging (MRI). In this case, components of the system and the instruments utilized therewith, such as the grasping device **30**, would be constructed from non-ferrous material such as titanium, as would be understood by those of skill in the art.

As shown in FIG. **1**, the stapling apparatus **10** includes a proximal handle portion **12**, an elongated flexible body portion **14** extending from the handle portion **12** and a generally C-shaped stapling assembly **16** operatively associated with a distal end of the flexible body portion **14**. The flexible body portion **14** and the stapling assembly **16** are preferably dimensioned and configured to traverse the natural curvature of the esophagus. As shown in FIGS. **2***b* and **2***c* and described in detail below, the stapling assembly **16** includes a pair of opposable jaws **17** defined by a staple carrying portion **40** and a staple forming portion **50**. Those skilled in the art will understand that, although the jaws **17** are described herein as rotating relative to one another between the open and closed positions, that these jaws **17** may be coupled by a mechanism which allows them to move linearly with respect to one another or in any other manner so long as they move between a first position in which the jaws **17** are separated from one another to receive tissue and a second position in which the jaws **17** are clamped together to hold tissue tightly therebetween for stapling.

Furthermore, those skilled in the art will understand that the system may operate with any of a variety of commercially available medical endoscopes which may include, for example, a proximal handle portion **22**, an elongated flexible body portion **24** through which one or more interior lumena extend for accommodating, for example, a fiber optic bundle or other image transmission structure, a working channel for the grasping device **30**, etc. Those skilled in the art will understand that the fiber optic bundle (or other image transmitting structure) allows a user to remotely visually monitor a field of view at the distal end of the endoscope (e.g., an operative site S within the esophagus E). As would be further understood by those of skill in the art, the tissue grasping device **30** may include a handle portion **32**, an elongated flexible body portion **34** and a pair of opposable jaws **36***a* and **36***b*.

In use as shown in FIGS. **2***a*-**2***c*, the surgical stapling apparatus **10** and the flexible endoscope **20** are introduced into a patient's mouth and advanced into the esophagus to the operative site S under visual guidance from the endoscope **20**. Once at the site S, the operator maneuvers the stapling assembly **16** into a desired position relative to the tissue to be resected. Those skilled in the art will understand that the stapling assembly **16** may be coupled to the handle portion **22** by a cable steering system (not shown) substantially as included in commercially available endoscopes to allow the remote maneuvering and positioning of the stapling assembly **16**. The jaws **17** of the stapling assembly **16** are then opened to a tissue receiving position as shown in FIG. **3** and the grasping device **30** is advanced from the distal end of the endoscope **20**. The jaws **36***a* and **36***b* are rotated away from one another by manipulation of the grasper handle portion **32** and the tissue T to be resected is grasped by closing the jaws **36***a*, **36***b*. The grasping device **30** is then withdrawn into the working channel of the endoscope **20** to pull the tissue T into position between the jaws **17** of the stapling assembly **16** and the jaws **17** are closed to clamp the tissue T in place between the staple carrying portion **40** and the staple forming portion **50**. Those skilled in the art will understand that the tissue T is preferably drawn between the jaws **17** so that a margin of healthy tissue is positioned between the staple carrying portion **40** and the staple forming portion **50** to ensure that all of the diseased or damaged tissue T is removed. Those skilled in the art will understand that this may be visually confirmed through the use of the vision system of the endoscope as shown in FIG. **2***b*.

As shown in FIG. **2***c*, once the tissue T has been properly positioned between the jaws **17**, the jaws **17** are grossly approximated and are then finely approximated using a translating clamping member **60**, illustrated in detail in FIGS. **16**-**18**. As shown in FIGS. **3**, **4** and **12**, an illustrative embodiment of the system according to the present invention includes an actuation cable **44** to facilitate gross approximation of the jaws **17** via actuation of an actuator knob **38**. The actuation cable **44** may be secured to the one of the jaws **17** including, for example, the staple carrying portion **40** and is operatively coupled to the other jaw **17** including the staple forming portion **50** by a member **85** which may, for example, be a spindle, capstan or other

member around which the cable **44** passes to change direction to generate the clamping force to draw the jaws **17** together. Furthermore, an overhanging flange **98** at a proximal end of the staple carrying portion **40** acts as a tissue shield preventing the target tissue T from entering into the joint between the jaws **17**.

As shown in FIGS. **3-7**, to actuate the clamping member **60** to finely approximate the jaws **17**, the lower clamping handle **12***a* is actuated in the direction of the arrow in FIG. **5** to cause the integral gear rack **62***a* to turn pinion gear **62***b* which rotates elongated drive cable **64**. As shown in FIG. **7**, the drive cable **64** is coupled to a drive screw **63** so that rotation of the drive cable **64** rotates the drive screw **63** moving the clamping member **60** distally as shown in FIG. **18**. This finely approximates the jaws **17** of the stapling assembly **16** whereby a tissue contacting surface of the staple carrying portion **40** and a tissue contacting surface of the staple forming portion **50** are brought into cooperative alignment, tightly clamping the tissue therebetween. Those skilled in the art will understand that alternative sources of power (e.g., electrical, hydraulic, pneumatic, etc.) may be applied to drive the jaws **17** and to drive all other mechanisms of the stapling assembly **16**.

As shown in FIG. **8**, once the jaws **17** have been brought into cooperative alignment with one another, the stapling assembly **16** may be actuated to fire staples through the, clamped tissue while simultaneously cutting away the tissue T from the stapled and anastamized tissue. The user actuates the stapling assembly **16** to drive staples through the margin of healthy tissue in one or more arcuate bands located radially outward of a line of tissue cutting. Alternatively, those skilled in the art will understand that the stapling operation may be separated from the tissue cutting operation so that no tissue is cut until the entire stapling operation has been successfully concluded.

Specifically, as shown in FIGS. **8-10**, the operator drives an I-beam member **70** through the stapling assembly **16** by operating the clamping handle **12***b* in the direction of the arrow in FIG. **8**, causing gear rack **72***a* to rotate pinion gear **72***b* which rotates a staple driving drive cable **74** as shown in FIG. **9**. The drive cable extends through the flexible body portion **14** to a linear drive screw **76** which drives a flexible pusher **80** coupled to the I-beam member **70** as shown in FIG. **10**.

As shown in FIGS. **11**, **13**, **14** and **15**, the I-beam member **70** includes upper and lower beam portions **82***a*, **82***b*, respectively, connected by a central web portion **84**. A leading edge **84***a* of the central web portion **84** may preferably define a cutting blade for incising tissue as the I-beam member **70** is moved distally as described below. As shown in FIG. **11**, an arcuate channel **90** within which the central web portion **84** travels, is defined in the opposing jaws **17** radially inward of the arcuate lines of staple carrying slots (not shown). Those skilled in the art will understand that the staple slots may be arranged in any number of rows, for example, from one to five such rows may be included and the slots of these rows may be staggered so that to ensure that the opening created by the resection is completely sealed.

As described above, actuation of the lower handle **12***a* causes the C-shaped clamp member **60** to move along an arc the length of the curved stapling assembly **16** to finely approximate the jaws **17** toward one another. As shown in FIGS. **13**, **14** and **15**, the clamp member **60** includes a body portion **112** from which depend upper and lower clamping beams **114***a* and **114***b*, respectively, for urging the jaws **17** toward one another.

In addition, as shown in FIGS. **16** and **17**, in one embodiment of the invention, the body **112** includes a radially depending driving stem **115** having a sloped leading edge configured to extend through an arcuate slot **116** formed in the staple carrying portion **40** for sequentially contacting each of a plurality of staple pushers **118**. The staple pushers **118** are positioned so that, when contacted by the driving stem **115**, each staple pusher **118** is driven through a corresponding one of the staple slots to drive a staple housed therein from the slot out of the staple carrying portion **40**, through both thicknesses of the folded portion of tissue clamped between the jaws **17** and against the staple forming surface **50***a* of the staple forming portion **50** to couple the two thicknesses of tissue to one another. In this embodiment, the clamping member **60** further includes an integral cutting blade **130** for forming an arcuate incision substantially concentric with and radially within an inner one of the arcs of staple slots. Furthermore, the cutting blade **130** is preferably positioned so that it trails the leading edge **115** so that tissue is stapled before it is cut.

As shown in FIG. **15**, according to a further embodiment of the invention, actuation of the upper actuation handle **12***b* causes the I-beam member **70** to move through the stapling assembly **16** to sequentially fire arcuate rows of staples while simultaneously cutting tissue away from the esophagus radially within the rows of staples. When the I-beam member **70** is driven by the pusher **80**, the sloped leading edge of the upper beam portion **82***a* contacts sequentially each of a plurality of staple pushers **118** to drive them through their respective staple slots to drive the staples housed therein from each slot out of the staple carrying portion **40**, through both thicknesses of the folded portion of tissue clamped between the jaws **17** and into the staple forming pockets **122** formed in the staple forming surface **50***a* of the staple forming portion **50** to couple the two thicknesses of tissue to one another. As the leading edge **84***a* of the central web portion **84** is proximal to the sloped leading edge, the incision trails the stapling action so that only tissue within the arc that has previously been stapled is severed.

As shown in FIGS. **19** and **20**, according to a further embodiment of the invention, a stapling assembly **16'** according to the present invention may include an endoscope receiving lumen **140** through which the endoscope **20** may be slidably inserted. This allows an operator to use to steering and vision capability of the endoscope **20** to locate the operative site S. Once the distal end of the endoscope **20** is positioned adjacent to the site S, the stapling assembly **16'** may be slid along the endoscope **20** to the operative site S and the steering capability of the distal end of the endoscope **20** may be employed to achieve a desired position and orientation of the stapling assembly **16'** relative to the tissue T. Other than the endoscope receiving lumen **140**, the construction of the rest of the system of FIGS. **19** and **20** may be substantially in accord with that of any of the previously described embodiments.

Furthermore, as shown in FIGS. **21** and **22**, the system according to the present invention may also be used to perform resections within the stomach. For example, the stapling apparatus **10** may be used to correct gastro-esophageal reflux ("GERD") or to perform a stomach reduction procedure. Specifically, as shown in FIG. **21**, a system according to the invention may be inserted through the esophagus into a patient's stomach and the operator may position the jaws **17** under visual control via the endoscope **20** adjacent to a junction between the esophagus and the stomach. The operator then uses the steering capability of

the endoscope **20**, received within the endoscope lumen **140** to direct the jaws **17** toward a portion of stomach tissue to be fastened to the esophagus. Specifically, the operator grasps a portion of the stomach using the grasping device **30** and urges the tissue T toward the esophagus to create a fold of tissue with an outside surface of the stomach tissue adjacent to or in contact with an outer surface of the esophagus. This fold is then clamped by the jaws **17** and stapled together to reduce the diameter of the opening from the esophagus to the stomach. The tissue radially within the stapled tissue is then resected.

Similarly as shown in FIG. **22**, to perform a stomach reduction, an operator inserts a system according to the present invention into the stomach via the esophagus as described above in regard to FIG. **21** and locates a portion of tissue to be folded over on itself to reduce the size of the stomach. This tissue T is grasped by the grasping device **30** and drawn between the jaws **17** which clamp the tissue T together folded onto itself and staples the fold together. Those skilled in the art will understand that, for a stomach reduction procedure, the folded tissue radially within the staples may, if desired, be left in place without resection so that the operation may be reversed at a later date. Thus, for such a stomach reduction procedure where the folded, stapled tissue will be left in place within the stomach, the stapling apparatus **10** need not include a tissue cutting mechanism. Rather, the stapling apparatus **10** need only include structure for approximating the jaws **17** and for driving staples through the gripped fold of tissue. In this case, the C-shaped clamp member **60** would be constructed without the cutting blade **130**.

The above described embodiments are for purposes of illustration only and the various modifications of these embodiments which will be apparent are considered to be within the scope of the teachings of this invention which is to be limited only by the claims appended hereto.

What is claimed is:

1. An apparatus, comprising:

a head having:

a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are spaced apart at a first distance and a second configuration in which the first jaw and the second jaw are spaced apart at a second distance,

a stapling assembly of the first jaw having slots through which staples are configured to be passed in a row extending from a proximal end of the first jaw to a distal end of the first jaw,

an anvil surface of the second jaw configured to form a staple,

a first adjustment assembly configured for gross movement of the first jaw and second jaw,

a second adjustment assembly configured for fine adjustment of the first jaw and the second jaw; and

a handle coupled to the head and having one or more actuators configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration, and to actuate the stapling assembly.

2. The apparatus of claim **1**, wherein at least one of the first jaw and the second jaw is curved.

3. The apparatus of claim **1**, wherein the second adjustment assembly is one of a clamp coupled around the first jaw and the second jaw, and an I-beam including a web that extends through at least one of the first jaw and the second jaw.

4. An apparatus for stapling tissue, comprising:

a first jaw and a second jaw, at least one of the first jaw and the second jaw being movable with respect to the other of the first jaw and the second jaw from a first configuration in which the first jaw and the second jaw are separated from each other at a first distance to receive tissue and a second configuration in which the first jaw and the second jaw are clamped together at a second distance to hold tissue therebetween for stapling,

a staple carrying portion of the first jaw defining slots through which staples are configured to pass;

an anvil surface defined on the second jaw opposing the first jaw;

at least one of a gear and a cable operatively coupled to at least one of the first jaw and the second jaw and configured to move at least one of the first jaw and the second jaw from the first configuration to the second configuration such that the first jaw and the second jaw are in alignment; and

a staple pusher configured to cause a staple to move from a first position at least partially within the staple carrying portion to a second position entirely outside the staple carrying portion, the second distance and the alignment being maintained by a beam configured to engage the first and second jaws from within the first and second jaws while tissue is stapled from a proximal location to a distal location.

5. The apparatus of claim **4**, wherein the beam is configured to engage the first and second jaws one of entirely or substantially from therewithin to maintain the second distance and the alignment.

6. The apparatus of claim **5**, wherein the beam comprises an upper portion and a lower portion and a web coupled between the upper portion and the lower portion, at least one of the lower portion or the upper portion configured to cause the staple pusher to move a staple as the beam moves from a proximal location to a distal location, the upper portion and the lower portion configured to cooperatively engage the first jaw and the second jaw to align the slots with a staple forming portion on the anvil surface.

7. The apparatus of claim **6**, further comprising a cutting blade on the web.

8. The apparatus of claim **5**, wherein the beam is configured as a cutting blade.

9. The apparatus of claim **4**, wherein the first jaw and the second jaw are pivotably coupled at a pivot point, a portion of the first jaw defining a flange that extends past a surface of the second jaw when the first jaw and second jaw are in the first configuration and the second configuration.

10. The apparatus of claim **4**, further comprising one or more actuators including at least one of an actuator handle, a lever, a trigger, a knob or a cable.

11. The apparatus of claim **4**, wherein at least a portion of the apparatus is powered.

12. The apparatus of claim **4**, wherein at least a portion of the first jaw and the second jaw is curved.

13. An apparatus, comprising:

a head portion having a first jaw and a second jaw configured to move between a first configuration for receiving tissue and a second configuration for stapling tissue,

the first jaw defining a cavity configured to receive a plurality of staples and a plurality of slots configured to pass staples therethrough;

the second jaw having a staple-forming surface; and

a beam whose opposite end portions are connected by a central web portion and are configured to clamp and align the first and second jaws from therewithin when in the second configuration as the beam moves distally along a channel defined in a tissue contacting surface of each of the first and second jaws; and

a control handle configured to actuate receiving, clamping and stapling of tissue, and

a shaft coupling the control handle to the head portion.

14. The apparatus of claim **13**, wherein:

the beam is configured to enable at least one of firing staples and cutting tissue.

15. The apparatus of claim **13**, wherein the slots through which staples are passed are arranged in a first row extending from a proximal end of the first jaw to a distal end thereof such that two or more staples are fired in a row orthogonal to a direction of movement of the beam one of simultaneously or serially.

16. The apparatus of claim **15**, wherein additional slots are arranged in a second row substantially parallel to the first row of slots.

17. The apparatus of claim **13**, wherein the head portion is one of fixedly coupled or movably coupled to the shaft.

18. The apparatus of claim **13**, wherein tissue is cut between the first row and the second row upon firing of one or more staples through the slots.

19. The apparatus of claim **13**, wherein one of the opposite end portions of the beam is configured to enable firing of the plurality of staples.

20. The apparatus of claim **13**, wherein the beam includes a cutting blade and is configured to clamp and align the first and second jaws one of entirely or substantially from therewithin.

21. The apparatus of claim **13**, wherein one end portion of the beam is configured to cause one or more staple pushers to be pushed for firing the plurality of staples as the beam travels towards a distal end of the head portion.

22. The apparatus of claim **13**, wherein the control handle includes at least one of an actuation handle, a lever, a trigger, a knob and a cable.

23. The apparatus of claim **13**, wherein at least a portion of the apparatus is powered.

24. The apparatus of claim **23**, wherein the apparatus is powered electrically, hydraulically or pneumatically.

25. The apparatus of claim **13**, wherein at least a portion of the shaft is flexible.

26. The apparatus of claim **13**, wherein at least a portion of the first jaw and the second jaw is curved.

27. An apparatus for stapling tissue, comprising:

a stapling head including first and second jaws, at least one of the first and second jaws being movable to approximate with respect to the other of the first and second jaws, the first jaw including a staple carrying portion and defining slots configured to pass staples therethrough and the second jaw including a staple forming portion; and

a beam having upper and lower portions connected by a central web portion, the upper and lower portions being configured to engage the first and second jaws from therewithin, respectively, and the central web portion being configured to travel along a channel defined in each tissue contacting surface of the first and second jaws to clamp tissue therebetween for stapling.

28. The apparatus of claim **27**, further comprising:

a control handle configured to actuate driving of staples through the slots and to approximate the first and second jaws; and

a shaft coupling the control handle to the stapling head.

29. The apparatus of claim **27**, wherein the beam is further configured as a cutting blade and is configured to engage the first and second jaws one of entirely or substantially from therewithin.

30. The apparatus of claim **27**, further comprising an endoscope receiving lumen.

* * * * *

EXHIBIT B

FILED UNDER SEAL

REDACTED