IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

REX MEDICAL, L.P.,	
Plaintiff,	Civil Action No.
v.	
MEDTRONIC, PLC and COVIDIEN, LP,	JURY TRIAL DEMANDED
Defendants.	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Rex Medical, L.P. ("Rex Medical" or "Plaintiff") asserts claims against Medtronic, plc ("Medtronic") and Covidien, LP ("Covidien") (collectively "Defendants") for infringement of U.S. Patent Nos. 9,439,650 ("the '650 Patent") and 10,136,892 ("the '892 Patent") (collectively, "the Asserted Patents"). 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

- 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,
 Pennsylvania 19428.
- 3. Upon information and belief, Medtronic is a corporation organized under the laws of Ireland with its principal place of business at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland, and Operational Headquarters located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. *See* https://www.medtronic.com/ie-en/about/locations.html.

- 4. Upon information and belief, Covidien is a limited partnership organized and existing under the laws of Delaware with its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048.
 - 5. Upon information and belief, Covidien is a subsidiary of Medtronic.
- 6. Upon information and belief, Medtronic and/or Covidien manufactures and distributes surgical platforms and tools, including surgical staplers.
- 7. Upon information and belief, Medtronic acquired Covidien plc on January 26, 2015, resulting in the combination of Medtronic, Inc. and Covidien plc as a subsidiary of Medtronic plc. Upon information and belief, at least since January 26, 2015, Medtronic makes, uses, sells, offers for sale, and/or imports Covidien products.
- 8. Upon information and belief, in acquiring Covidien plc and its subsidiaries,
 Medtronic assumed all liabilities arising from Covidien plc's and Covidien LP's past and present
 acts and omissions.
- 9. Upon information and belief, Covidien operates within the "Minimally Invasive Therapies Group" of Medtronic. Upon information and belief, Medtronic receives revenue from Covidien's actions and products.
- 10. Upon information and belief, Defendants sell and offer to sell products and services throughout the United States, including in this judicial district, and introduce 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

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

- 12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).
- 13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b). Upon information and belief, Medtronic is a foreign defendant under §§ 1391(c) and 1400(b), and is thus subject to jurisdiction within any judicial district. Upon information and belief, Covidien resides in this judicial district.
- 14. Upon information and belief, Medtronic is subject to this Court's specific personal jurisdiction because Medtronic has sufficient minimum contacts within the State of Delaware and this District, pursuant to due process and/or the Delaware Long Arm Statute, as Medtronic purposefully availed itself of the privileges of conducting business in the State of Delaware and in this District, because Medtronic regularly conducts and solicits business within the State of Delaware and within this District, and because Rex Medical's causes of action arise directly from Medtronic's business contacts and other activities in the State of Delaware and this District.
- 15. Upon information and belief, Covidien is subject to this Court's general and specific personal jurisdiction because Covidien has sufficient minimum contacts within the State of Delaware and this District, pursuant to due process and/or the Delaware Long Arm Statute, as Covidien purposefully availed itself of the privileges of conducting business in the State of Delaware and in this District, because Covidien regularly conducts and solicits business within the State of Delaware and within this District, and because Rex Medical's causes of action arise directly from Covidien's business contacts and other activities in the State of Delaware and this District. Further, this Court has personal jurisdiction over Covidien because Covidien is organized in Delaware and has purposely availed itself of the privileges and benefits of the laws of the State of Delaware.

BACKGROUND

Rex Medical and Its Tissue Stapling Inventions

- 16. Rex Medical was co-founded by Dr. James F. McGuckin Jr., M.D in 1996 to further the development of life-changing medical devices.
- 17. 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.
 - 18. Rex Medical is ISO Certified.
- 19. 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.
- 20. Rex Medical owns several U.S. and foreign patents, including the Asserted Patents. The named inventors on the Asserted Patents 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.
- 21. Rex Medical's mission has been, and remains, to improve patients' results through technological innovations.
- 22. Rex Medical has several innovative products in development that are unrelated to this litigation, including the CloserTM Vascular Sealing System, the RevolutionTM Peripheral Atherectomy System, and the SplitWireTM 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

- 23. Rex Medical owns the Asserted Patents, which relate 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.
- 24. 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.
- 25. 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.
- 26. 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.
- 27. Rex Medical designed surgical stapling devices that can both cut and staple tissue almost simultaneously. These devices are useful in both laparoscopic surgery (also known as minimally invasive surgery) and open resection surgery. These devices are described in and covered by the '650 Patent and the '892 Patent.

- 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. These jaws work 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.
- 29. The Asserted Patents allow the efficient sealing of cut tissue during resection.
 The '650 Patent
- 30. 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.
- 31. 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 Ex. A.

- 32. 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.
- 33. The '650 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

The '892 Patent

- 34. Rex Medical is the assignee and owner of the right, title, and interest in and to the '892 Patent having acquired those rights on April 1, 2002, including the right to assert all causes of action arising under the '892 Patent and the right to any remedies for infringement of them.
- 35. The '892 Patent, entitled "Apparatus and Method for Resectioning Gastro-Esophageal Tissue," was issued by the United States Patent and Trademark Office on November 27, 2018. The '892 Patent issued from United States Patent Application No. 15/617,835, filed on June 8, 2017 and claims priority to the '469 Application, filed on January 31, 2001. A copy of the '892 Patent is attached as Ex. B.
- 36. The inventions of the '892 Patent are generally directed to a tissue stapling device that has two jaws to clamp targeted tissue and pass staples into the clamped tissue.
- 37. The '892 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

The Infringing Products

- 38. Defendants make, use, sell, offer for sale, and/or import products under the Endo GIATM brand. Upon information and belief, these products were Covidien products, which Medtronic acquired through its acquisition of Covidien plc.
- 39. Defendants make, use, sell, offer for sale, and/or import several tissue stapling devices under the Endo GIATM brand, including the Endo GIATM 30 mm Reload with Tri-

StapleTM Technology, the Endo GIATM Curved Tip Reload with Tri-StapleTM Technology, the Endo GIATM Black Reload with Tri-StapleTM Technology, the Endo GIATM Radial Reload with Tri-StapleTM Technology, and the Endo GIATM Reinforced Reload (45 mm AMT and/or 60 mm AXT) with Tri-StapleTM Technology.

- 40. Upon information and belief, each of the products specifically referenced in paragraph 39 are used with at least one or more of the following stapling systems: the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler, the Endo GIATM Universal Staplers and Reloads system, and/or the Endo GIATM Ultra Universal Staplers and Reloads system.
- 41. Defendants make, use, sell, offer for sale, and/or import the Signia[™] Stapling System, the iDrive[™] Ultra Powered Stapler, the Endo GIA[™] Universal Staplers and Reloads system, and/or the Endo GIA[™] Ultra Universal Staplers and Reloads system.
- 42. Upon information and belief, the products specifically referenced in paragraph 39 are essential to the use and operability of at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler, the Endo GIATM Universal Staplers and Reloads system, and/or the Endo GIATM Ultra Universal Staplers and Reloads system.
- 43. Upon information and belief, each of the products specifically referenced in paragraph 39 are used to surgically staple tissue in minimally invasive surgery and/or open resection surgery.
- 44. Upon information and belief, each of the products specifically referenced in paragraph 39 have the same general operation, function, and design.
- 45. Upon information and belief, each of the systems specifically referenced in paragraph 41 have the same general operation, function, and design.

- 46. Upon information and belief, the Endo GIA™ 30 mm Reload with Tri-Staple™ Technology was introduced into the market in 2012 at the latest.
- 47. Upon information and belief, the Endo GIA™ Curved Tip Reload with Tri-Staple™ Technology was introduced into the market in 2011.
- 48. Upon information and belief, the Endo GIATM Black Reload with Tri-StapleTM Technology was introduced into the market in 2011.
- 49. Upon information and belief, the Endo GIA™ Radial Reload with Tri-Staple™ Technology was introduced into the market in 2012.
- 50. Upon information and belief, the Endo GIATM Reinforced Reload with Tri-StapleTM Technology was introduced into the market in 2014.
- 51. The products and systems specifically referenced in paragraphs 39 and 41 are found on Medtronic's website. https://www.medtronic.com/covidien/en-us/products/surgical-stapling.html
- 52. Upon information and belief, at least Medtronic owns, operates, controls, and/or manages various Internet websites, including, without limitation, at least https://www.medtronic.com/us-en/index.html, https://www.medtronic.com/covidien/en-us/products/surgical-stapling.html, https://www.medtronic.com/covidien/en-us/support.html, and the respective links to webpages that can be found from these pages. Consequently, Medtronic

stapling/signia-stapling-system.html, and https://www.medtronic.com/covidien/en-

¹ Some, but not all, additional websites can be found at the following URLs: https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-reinforced-reload.html, https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-curved-tip-reload.html, https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-black-reload.html, https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-radial-reload.html, https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html, https://www.medtronic.com/covidien/en-us/products/surgical-stapling/idrive-ultra-powered-stapling-system.html, https://www.medtronic.com/covidien/en-us/products/surgical-

manages and controls the content that can be found on each webpage. Each of these websites display "©2019 Medtronic;" Defendant Medtronic refers to itself as "Medtronic" to the United States Securities and Exchange Commission and others, *see* Ex. C.

- 53. Upon information and belief, Medtronic—through at least its ownership, operation, control, and management of at least the various websites referenced in paragraph 52 and footnote 1—offers for sale and sells the infringing products accused in this Complaint; encourages the sale of such products in an infringing manner; instructs and directs others on how to use such products in an infringing manner; provides support and assistance in using such products in an infringing manner; encourages and entices the use of such products in an infringing manner; and otherwise disseminates and aids and abets the infringement of products accused in this Complaint.
- 54. For example, Medtronic offers at least "Surgical Stapling Product Training & Support," (*e.g.*, https://www.medtronic.com/covidien/en-us/support/products/surgical-stapling.html), training and use videos, (*e.g.*, https://www.medtronic.com/covidien/en-us/support/products/surgical-stapling/idrive-ultra-powered-stapling-system.html), and data to inform consumers, (*e.g.*,

https://www.medtronic.com/content/dam/covidien/library/us/en/product/surgical-stapling/endo-gia-30-mm-reload-info-sheet.pdf).

55. Upon information and belief, Covidien does not maintain, operate, control, and manage its own website. For example, typing the URL "www.covidien.com" into the URL search bar takes the browser to Medtronic's website. Thus, Covidien relies, at least in part, on Medtronic's website.

us/products/surgical-stapling/laparoscopic-staplers.html#endo-gia-ultra-universal-staplers-and-reloads-thumb.

Endo GIATM 30 mm Reload with Tri-StapleTM Technology

56. The Endo GIA™ 30 mm Reload with Tri-Staple™ Technology is illustrated below.



https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html



https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html

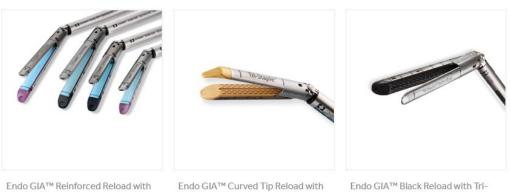


https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html

- 57. The Endo GIA™ 30 mm Reload with Tri-Staple™ Technology is described as a surgical tissue stapling device to be used in minimally invasive surgery.

 https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html.
- 58. At least the Endo GIATM 30 mm Reload with Tri-StapleTM Technology (the "30 mm Product") infringes at least the Asserted Patents. The 30 mm Product can be found on Medtronic's website at: https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html.
- 59. Upon information and belief, in addition to the 30 mm Product, at least each of the following products—individually or in conjunction with the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler, the Endo GIATM Universal Staplers and Reloads system, and/or the Endo GIATM Ultra Universal Staplers and Reloads system—infringe at least the Asserted Patents: the Endo GIATM Curved Tip Reload with Tri-StapleTM Technology, the Endo GIATM Black Reload with Tri-StapleTM Technology, the Endo GIATM Radial Reload with Tri-StapleTM Technology, and the Endo GIATM Reinforced Reload with Tri-StapleTM Technology (collectively (including the 30 mm Product) the "Accused Products").

60. Upon information and belief, the Accused Products have the same general operation, function, and design.



Endo GIA™ Reinforced Reload with Tri-Staple™ Technology

Endo GIA™ Curved Tip Reload with Tri-Staple™ Technology

Endo GIA™ Black Reload with Tri-Staple™ Technology



Endo GIA™ Radial Reload with Tri-Staple™ Technology



Endo GIA™ 30 mm Reload with Tri-Staple™ Technology

https://www.medtronic.com/covidien/en-us/products/surgical-stapling.html

- 61. Upon information and belief, the 30 mm Product is representative of and emblematic of the other Accused Products. Consequently, the 30 mm Product's features discussed in this Complaint are an adequate representation of the Accused Products.
- 62. The Accused Products are capable of being used, and are used, as part of the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler, the Endo GIATM Universal Staplers and Reloads system, and/or the Endo GIATM Ultra Universal Staplers and Reloads system.

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

- 63. Rex Medical realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 62 of the Complaint as though fully set forth herein.
- 64. Upon information and belief, Defendants have and continue to directly and indirectly infringe, literally and under the doctrine of equivalents, at least claims 6, 19, and 21 of the '650 Patent by making, using, selling, importing, offering for sale, and/or providing and causing to be used the Accused Products.
- 65. Claim 6 of the '650 Patent is a claim that is dependent on claim 5, which is dependent on claim 4.
 - 66. 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.

67. 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.

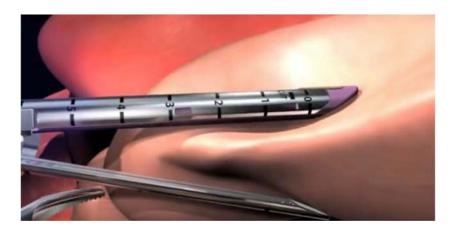
68. Claim 6 of the '650 Patent—the claim that is asserted—claims:

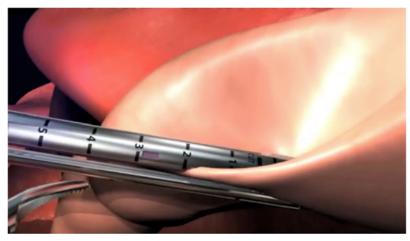
The apparatus of claim 5, wherein the beam comprises an upper portion and a lower portion and a web coupled between the upper portion and the lower portion, at least one of the lower portion or the upper portion configured to cause the staple pusher to move a staple as the beam moves from a proximal 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.

- 69. The 30 mm Product contains each of the above limitations. See, e.g., Ex. D.
- 70. The 30 mm Product is an apparatus for stapling tissue.
- 71. The 30 mm Product has 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.



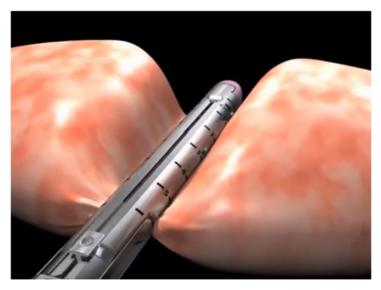
https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html

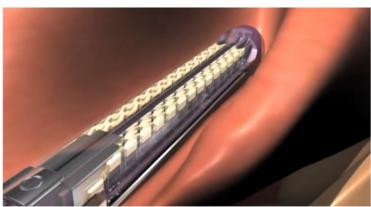


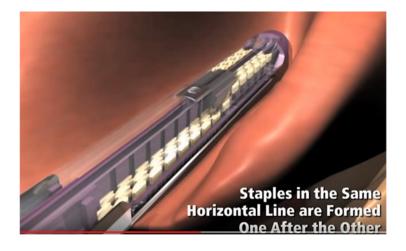


https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s

72. The 30 mm Product has a staple carrying portion of the first jaw with slots through which the staples are configured to pass.









https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

73. The 30 mm Product has an anvil surface defined on the second jaw opposing the first jaw.



https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html



https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

74. Upon information and belief, the 30 mm Product, by itself or used in conjunction with the Endo GIATM Ultra Universal Staplers and Reloads system,² has 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.



²

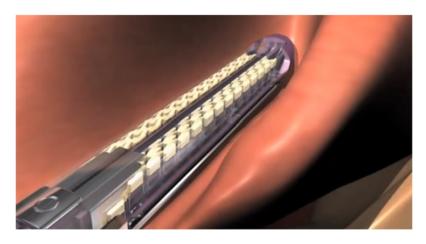
² Upon information and belief, the 30 mm Product by itself has at least one of a gear and a cable operatively coupled to at least one of the jaws, and configured to move at least one jaw from the first configuration to the second configuration such that the jaws are in alignment, or, in addition to the Endo GIATM Ultra Universal Staplers and Reloads system, the 30 mm Product in conjunction with at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler system, and/or the Endo GIATM Universal Staplers and Reloads system has 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.

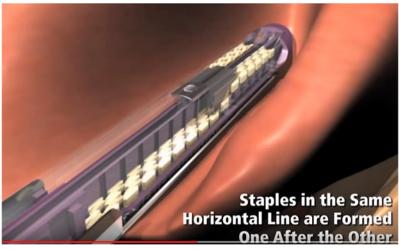


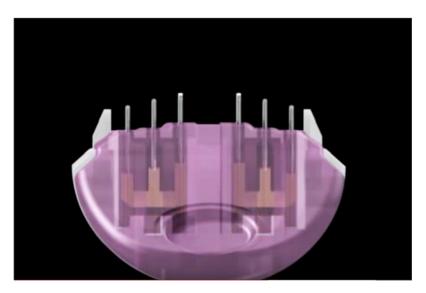


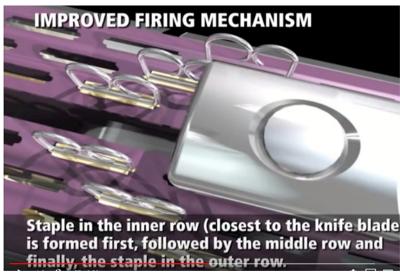
https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s

75. The 30 mm Product has 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.



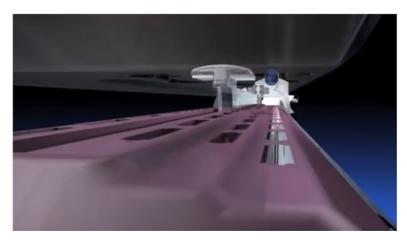






https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

76. Upon information and belief, the 30 mm Product maintains the second distance and alignment of the jaws (i.e., when the jaws are close together) 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. Defendants advertise the "improved design of the stronger fixed anvil and I-beam incorporated into" its staplers. https://www.medtronic.com/covidien/en-us/products/surgical-stapling/tri-staple-technology.html. Illustrations of this beam are below.



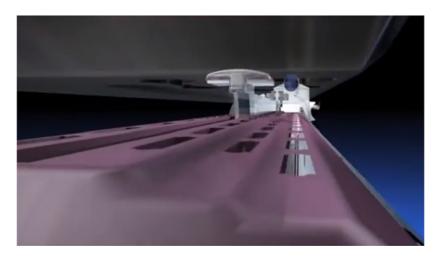






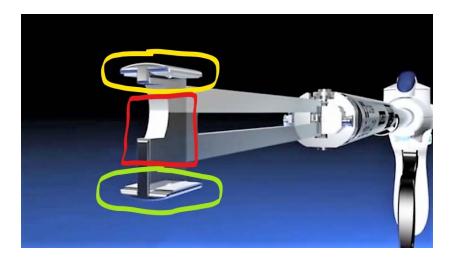
https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

77. Upon information and belief, the 30 mm Product's 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.



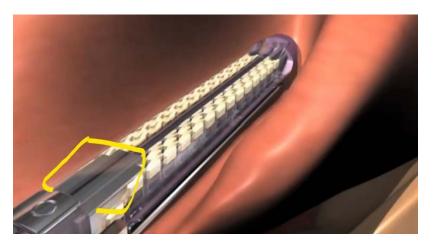
https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s

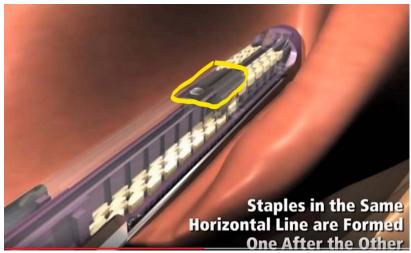
78. The beam comprises an upper portion and a lower portion, and a web coupled between the upper and lower portion.



https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (highlighting added)

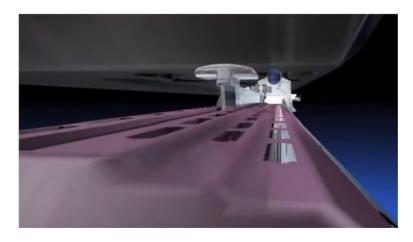
79. Upon information and belief, at least one of the beam's upper or lower portion is configured to cause the stapler pusher to move a staple as the beam moves from a proximal location to a distal location.

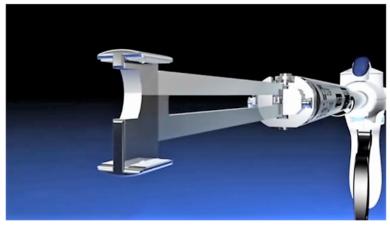




https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original) (highlighting added)

80. 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.youtube.com/watch?v=CXMvYBM0lcU&t=10s

- 81. Claim 19 of the '650 Patent is a claim that is dependent on claim 13.
- 82. Claim 13 of the '650 Patent claims 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.

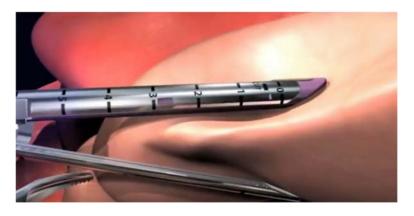
83. Claim 19 of the '650 Patent—the claim that is asserted—claims:

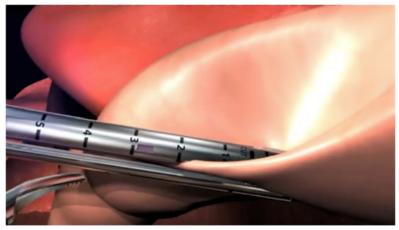
The apparatus of claim 13, wherein one of the opposite end portions of the beam is configured to enable firing of the plurality of staples.

- 84. The 30 mm Product contains each of the above limitations. See, e.g., Ex. D.
- 85. The 30 mm Product is an apparatus that has a head portion with two jaws that are configured to move between a first configuration to receive tissue and a second configuration to staple tissue.



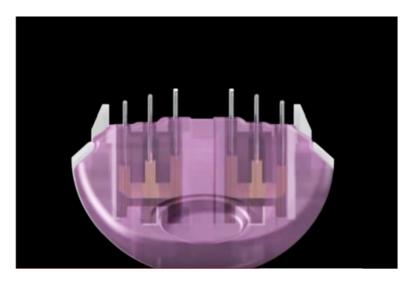
https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html





 $https://www.youtube.com/watch?v=\!CXMvYBM0lcU\&t=\!10s$

86. The 30 mm Product has a jaw with a cavity configured to receive a plurality of staples, and has a plurality of slots configured to pass staples through it.





https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s

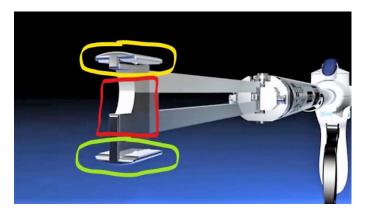
87. The 30 mm Product has a second jaw, which has a staple-forming surface.

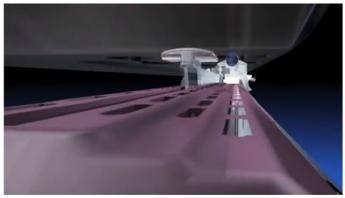




https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

88. Upon information and belief, the 30 mm Product has a beam whose opposite end portions are connected by a central web portion and are configured to clamp and align the two jaws from therewithin when in the second configuration as the beam moves distally along a channel defined in a tissue contacting surface of each jaw. Illustrations of this beam and its location and path are below.





https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (highlighting added)

89. The 30 mm Product, used in conjunction with the Endo GIATM Ultra Universal Staplers and Reloads system,³ has a control handle configured to actuate receiving, clamping,

³ Upon information and belief, in addition to the Endo GIATM Ultra Universal Staplers and Reloads system, at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler system, and/or the Endo GIATM Universal Staplers and Reloads system have a control handle configured to actuate receiving, clamping, and stapling of tissue.

and stapling of tissue. The 30 mm Product used in conjunction with the Endo GIATM Ultra Universal Staplers and Reloads system is illustrated below.









https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

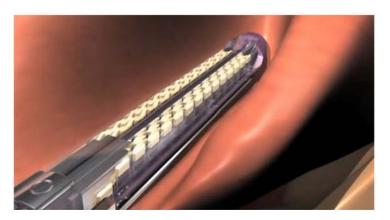
90. The 30 mm Product, used in conjunction with the Endo GIA™ Ultra Universal Staplers and Reloads system,⁴ has a shaft coupling the control handle to the head portion.

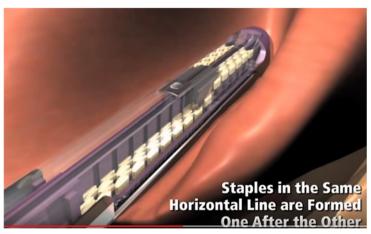


⁴ Upon information and belief, in addition to the Endo GIATM Ultra Universal Staplers and Reloads system, at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler system, and/or the Endo GIATM Universal Staplers and Reloads system have a shaft coupling the control handle to the head portion.

https://www.medtronic.com/content/dam/covidien/library/us/en/product/surgical-stapling/endo-gia-reloads-with-tri-staple-technology-and-endo-gia-ultra-universal-staplers-brochure.pdf

91. The 30 mm Product's beam is configured so that one of the opposite end portions of the beam is configured to enable firing of the plurality of staples.





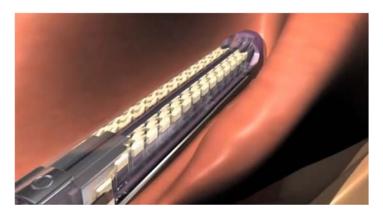


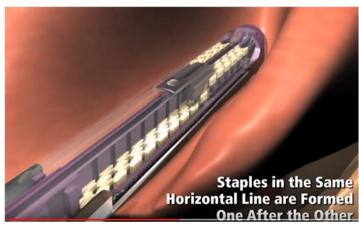
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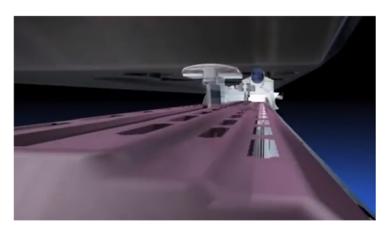
- 92. Claim 21 of the '650 Patent is a claim that is also dependent on claim 13.
- 93. Claim 21 of the '650 Patent claims:

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.

- 94. The 30 mm Product contains each of the above limitations. See, e.g., Ex. D.
- 95. The 30 mm Product's beam is configured so that one end portion of the beam causes one or more staple pushers to be pushed for firing the plurality of staples as the beam travels toward a distal end of the head portion.









https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original)

96. Upon information and belief, since at least September 13, 2016, Medtronic and/or Covidien had knowledge of the '650 Patent and 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, Defendants' partners, clients, customers, and end users, whose use of the Accused Products constitute direct infringement of at least one claim of the '650 Patent. Specifically, Rex Medical, through its counsel, sent Covidien representatives a letter informing Covidien of the '650 Patent on September 13, 2016. Ex. E. Additionally, Rex Medical informed Medtronic of the '650 Patent no later than November 16, 2016. Ex. F.

- 97. In particular, Defendants' 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.
- 98. Medtronic's and/or Covidien's infringement of the '650 Patent has been, and continues to be, willful. Medtronic and/or Covidien knew of the '650 Patent and knew that it was infringing the '650 Patent at least as early as September 13, 2016. Despite Rex Medical's indication to Defendants that Rex Medical was willing to engage in meaningful licensing discussions, Defendants declined, choosing instead to infringe in willful disregard of Rex Medical's patent rights.
- 99. Upon information and belief, Defendants are 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. As well, upon information and belief, Medtronic assumed the liability of Covidien's 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.
- 100. As a consequence of Defendants' direct and indirect infringement, both literal and 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.

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

COUNT II – INFRINGEMENT OF U.S. PATENT 10,136,892

- 102. Rex Medical realleges and incorporates by reference the allegations set forth in the foregoing paragraphs 1 through 101 of the Complaint as though fully set forth herein.
- 103. Upon information and belief, Defendants have and continue to directly and indirectly infringe, literally and under the doctrine of equivalents, at least claims 1 and 5 of the '892 Patent by making, using, selling, importing, offering for sale, and/or providing and causing to be used the Accused Products.
 - 104. Claim 1 of the '892 Patent claims 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 one or more rows extending from a proximal end of the first jaw to a distal end of the first jaw, and an anvil surface of the second jaw being configured to form a staple;

a first adjustment assembly configured for gross movement of the first jaw or the second jaw;

a second adjustment assembly including a beam configured for fine movement of the first jaw or the second jaw to maintain a fixed distance there between, wherein the beam is operatively coupled to a pusher and includes a central web portion connecting an upper beam portion and a lower beam portion, the central web portion including a cutting blade which is generally more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion, and the pusher being configured to cause a staple pusher to move for firing as the beam moves distally;

a handle 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; and a shaft coupling the handle to the head; wherein

at least one of the upper beam portion and the lower beam portion is a generally flat plate orthogonally attached to an end of the central web portion and is configured to engage the first jaw or the second jaw entirely from within the first jaw or the second jaw for clamping and alignment; and

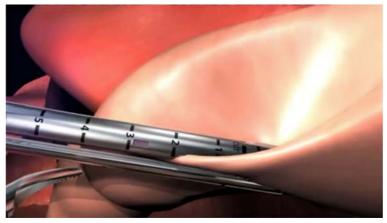
the pusher and the central web portion are coplanar with a channel defined in a tissue contacting surface of each of the first jaw and the second jaw when the beam moves distally.

- 105. The 30 mm Product contains each of the above limitations. See, e.g., Ex. G.
- 106. The 30 mm Product is an apparatus that has a head with two jaws where at least one jaw is movable in regards to the other resulting in the jaws holding a configuration at one distance and, upon at least one jaw moving, the jaws holding a second configuration at a second distance.



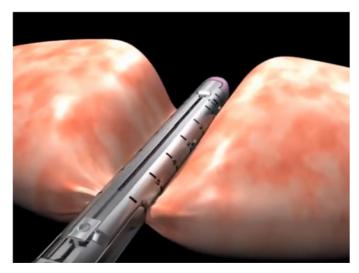
https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html

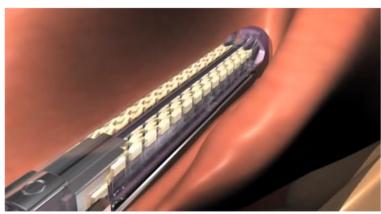


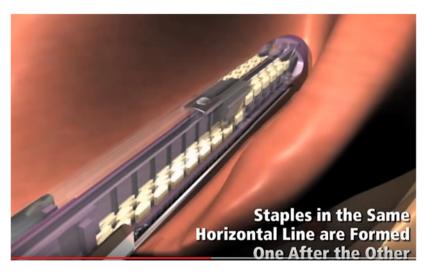


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107. The 30 mm Product has a stapling assembly in the first jaw, with slots through which staples are passed in one or more rows extending from a proximal end of the first jaw to a distal end of the first jaw.









108. The 30 mm Product has a second jaw with an anvil surface configured to form a staple.



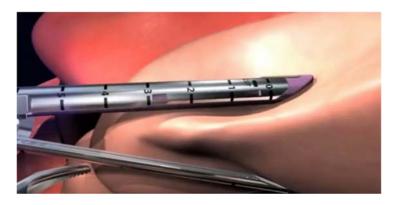
https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html

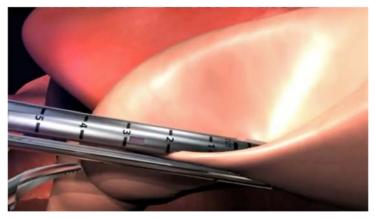




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109. The 30 mm Product has an adjustment assembly configured for gross movement of at least one jaw.

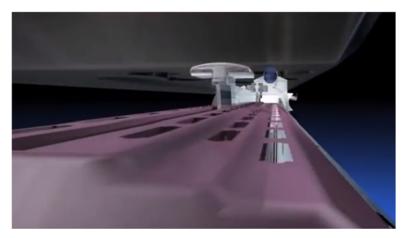


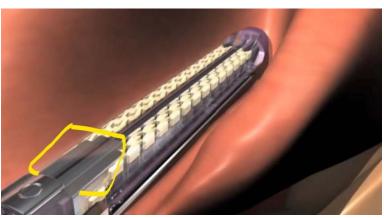


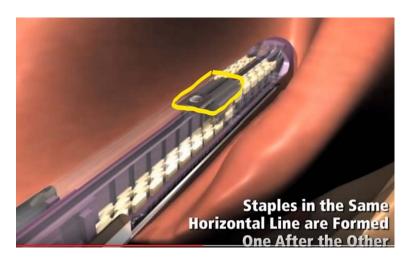
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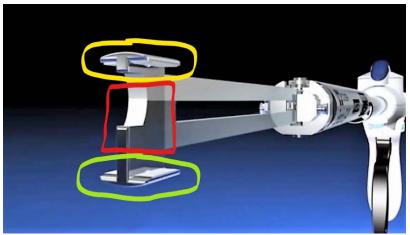
110. Upon information and belief, the 30 mm Product has a second adjustment assembly that includes a beam configured for fine adjustment of one of the two jaws to maintain a fixed distance between the jaws, where the beam is coupled to a pushing bar and includes a central web portion connecting an upper beam portion and a lower beam portion.









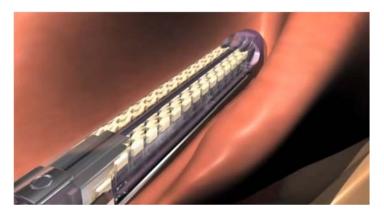


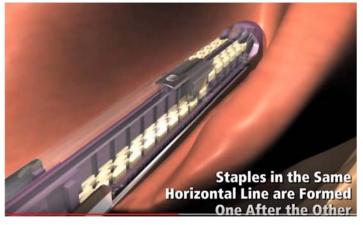
https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (annotations in original) (highlighting added)

111. Upon information and belief, the beam's central web portion includes a cutting blade that is generally more distal than at least the trailing edge of the upper beam portion or the lower beam portion.



112. The pusher is configured to cause a staple pusher to move for firing as the beam moves distally.

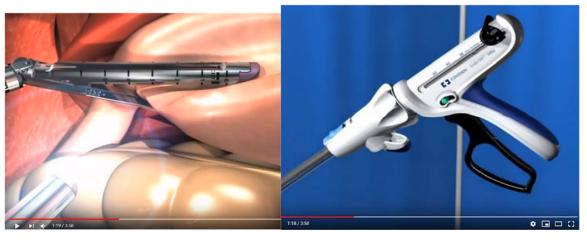




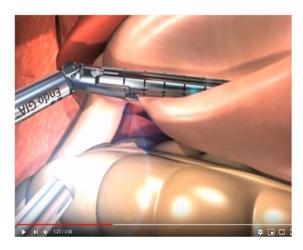
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113. The 30 mm Product, used in conjunction with the Endo GIATM Ultra Universal Staplers and Reloads system,⁵ has a handle with at least one actuator configured to move at least one of the jaws from the first configuration to the second configuration, and to actuate the stapling assembly. The 30 mm Product used in conjunction with the Endo GIATM Ultra Universal Staplers and Reloads system is illustrated below.





⁵ Upon information and belief, in addition to the Endo GIATM Ultra Universal Staplers and Reloads system, at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler system, and/or the Endo GIATM Universal Staplers and Reloads system have a handle with at least one actuator configured to move at least one of the jaws from the first configuration to the second configuration, and to actuate the stapling assembly.





114. The 30 mm Product, used in conjunction with the Endo GIA™ Ultra Universal Staplers and Reloads system,⁶ has a shaft coupling the handle to the head.

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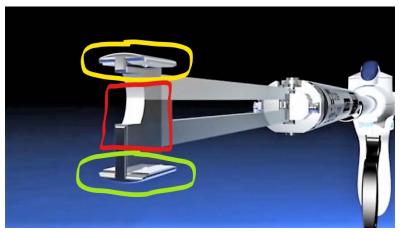
⁶ Upon information and belief, in addition to the Endo GIA™ Ultra Universal Staplers and Reloads system, at least the Signia™ Stapling System, the iDrive™ Ultra Powered Stapler system, and/or the Endo GIA™ Universal Staplers and Reloads system have a shaft coupling the handle to the head.



https://www.medtronic.com/content/dam/covidien/library/us/en/product/surgical-stapling/endo-gia-reloads-with-tri-staple-technology-and-endo-gia-ultra-universal-staplers-brochure.pdf

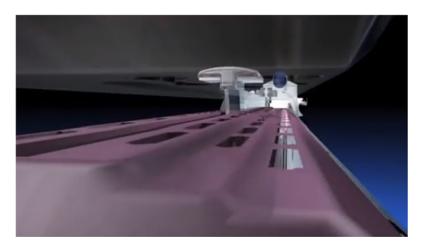
115. Within the 30 mm Product, at least one of the upper beam portion and the lower beam portion is a generally flat plate orthogonally attached to an end of the central web portion and is configured to engage one of the jaws entirely from within the jaw for clamping and alignment.

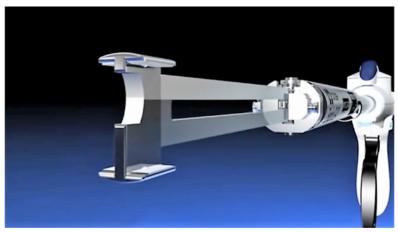




https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (highlighting added)

116. The pusher and central web portion are coplanar with a channel defined in a tissue contacting surface of each of the two jaws when the beam moves distally.







https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s

117. Claim 5 of the '892 Patent claims 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 sealing tissue;

a beam having an upper beam portion and a lower beam portion connected by a central web portion having a leading edge including a cutting blade that is more distal than at least one of a trailing edge of the upper beam portion and a trailing edge of the lower beam portion, wherein the upper beam portion and the lower beam portion are configured to clamp and align the first jaw and the second jaw at least partially from within the first jaw and the second jaw when in the second configuration as the central web portion moves distally along a channel defined in a tissue contacting surface of each of the first jaw and the second jaw;

a pusher operatively coupled to the beam and configured to move the beam distally;

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

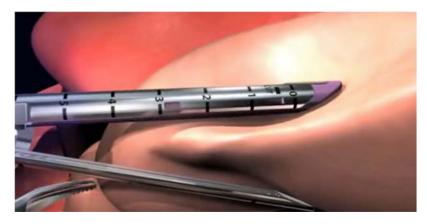
a shaft coupling the control handle to the head portion;

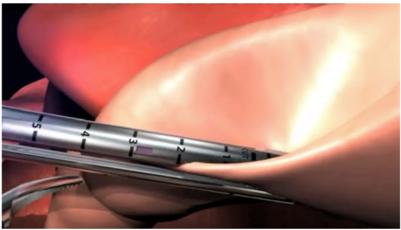
wherein at least one of the upper beam portion and the lower beam portion is orthogonally attached to an end of the central web portion, and the pusher is coplanar with the central web portion and the channel.

- 118. The 30 mm Product contains each of the above limitations. See, e.g., Ex. G.
- 119. The 30 mm Product is an apparatus with a head portion with two jaws that are configured to move between a first configuration for receiving tissue and a second configuration for sealing tissue.



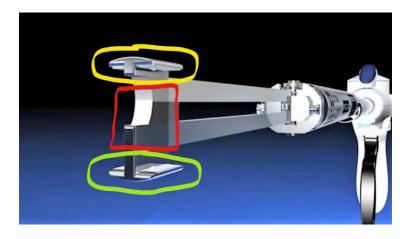
https://www.medtronic.com/covidien/en-us/products/surgical-stapling/endo-gia-30-mm-reload.html





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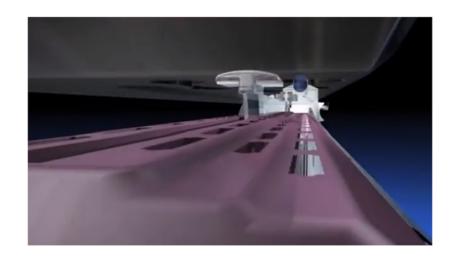
120. The 30 mm Product has a beam with an upper portion and a lower portion connected by a central web portion.

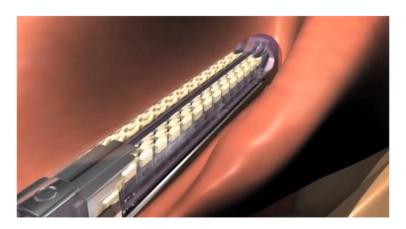


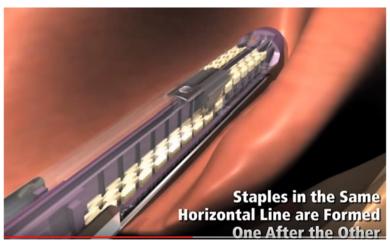
https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (highlighting added)

121. Upon information and belief, the central web portion has a leading edge with a cutting blade that is more distal than at least one of a trailing edge of the upper beam portion and the lower beam portion, where the upper and lower portions are configured to clamp and align the jaws at least partially from within the first jaw and the second jaw when in the second configuration as the central web portion moves distally along a channel defined in a tissue contacting surface of each of the jaws.



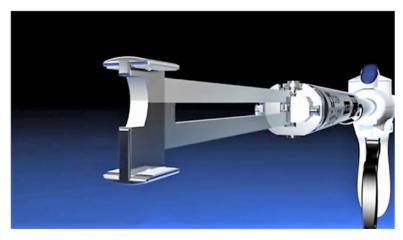


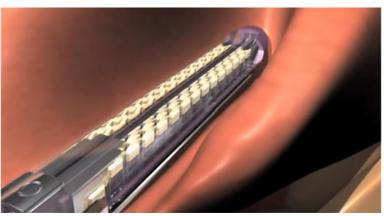


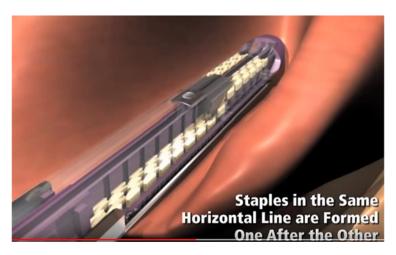




122. The 30 mm Product has a pusher operatively coupled to the beam and configured to move the beam distally.



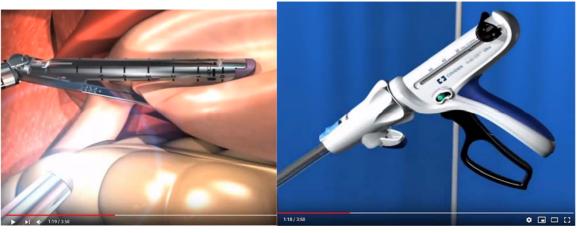




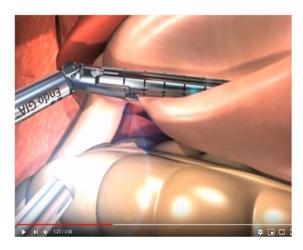
 $https://www.youtube.com/watch?v=CXMvYBM0lcU\&t=10s \ (annotations \ in \ original)$

123. The 30 mm Product, used in conjunction with the Endo GIA™ Ultra Universal Staplers and Reloads system,⁷ has a control handle configured to actuate receiving, clamping, and sealing of tissue. The 30 mm Product used in conjunction with the Endo GIA™ Ultra Universal Staplers and Reloads system is illustrated below.





⁷ Upon information and belief, in addition to the Endo GIATM Ultra Universal Staplers and Reloads system, at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler system, and/or the Endo GIATM Universal Staplers and Reloads system have a control handle configured to actuate receiving, clamping, and sealing of tissue.





124. The 30 mm Product, used in conjunction with the Endo GIA™ Ultra Universal Staplers and Reloads system,⁸ has a shaft coupling the control handle to the head portion.

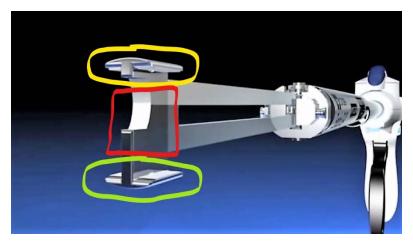
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⁸ Upon information and belief, in addition to the Endo GIATM Ultra Universal Staplers and Reloads system, at least the SigniaTM Stapling System, the iDriveTM Ultra Powered Stapler system, and/or the Endo GIATM Universal Staplers and Reloads system have a shaft coupling the control handle to the head portion.

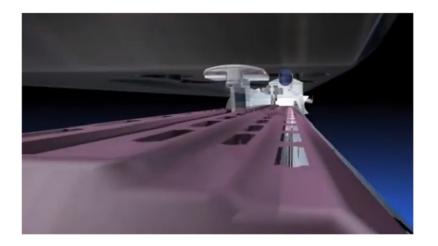


https://www.medtronic.com/content/dam/covidien/library/us/en/product/surgical-stapling/endo-gia-reloads-with-tri-staple-technology-and-endo-gia-ultra-universal-staplers-brochure.pdf

125. Within the 30 mm Product, at least one of the upper beam portion and the lower beam portion is orthogonally attached to an end of the central web portion and the pusher is coplanar with the central web portion and the channel.







https://www.youtube.com/watch?v=CXMvYBM0lcU&t=10s (highlighting added)

- 126. Upon information and belief, since at least the date of filing this complaint, Medtronic and/or Covidien had knowledge of the '892 Patent and has induced and continues to induce others to infringe at least one claim of the '892 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, Defendants' partners, clients, customers, and end users, whose use of the Accused Products constitute direct infringement of at least one claim of the '892 Patent.
- 127. In particular, Defendants' 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.
- 128. Upon information and belief, Defendants are liable for contributory infringement of the '892 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 '892 Patent. Upon information and belief, Medtronic assumed the liability of Covidien's contributory infringement of the '892 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 '892 Patent. The Accused Products are a material component for use in practicing the '892 Patent and are specifically made and are not a staple article of commerce suitable for substantial non-infringing use.

- 129. As a consequence of Defendants' direct and indirect infringement, both literal and under the doctrine of equivalents, of the '892 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.
- 130. Upon information and belief, Defendants' infringement of the '892 Patent will continue in the future, and Rex Medical will continue to suffer damages as a consequence unless Defendants' 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 Complaint, Plaintiff Rex Medical demands judgment for itself and against Defendants as follows:

- A. An adjudication that Defendants have infringed the '650 Patent and the '892 Patent;
- B. An award of damages to be paid by Defendants adequate to compensate Rex Medical for Defendants' past infringement of the Asserted Patents, 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 Defendants' 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: June 13, 2019 Respectfully submitted,

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