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(54) Title: SURGICAL INSTRUMENT WITH FLUID FILLABLE BUTTRESS

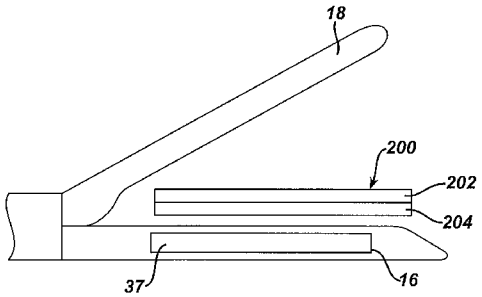

FIG. 10

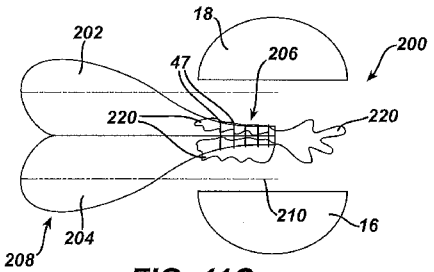

FIG. 11C

(57) Abstract: An apparatus comprises a surgical instrument and a buttress configured to hold a fluid adhesive. In some versions, the buttress contains a two-part fluid adhesive where two fluid materials form a fluid adhesive when combined. In some versions, the buttress is configured to be compressed by the surgical instrument thereby pressurizing a portion of the buttress. Thereafter, the buttress may be severed and the pressurized region may be operable to urge the fluid adhesive to a tissue site.

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— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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SURGICAL INSTRUMENT WITH FLUID FILLABLE BUTTRESS

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BACKGROUND

[0001] In some settings, endoscopic surgical instruments may be preferred over traditional open surgical devices since a smaller incision may reduce the post-operative recovery time and complications. Consequently, some endoscopic surgical instruments may be suitable for placement of a distal end effector at a desired surgical site through a cannula of a trocar. These distal end effectors may engage tissue in a number of ways to achieve a diagnostic or therapeutic effect (e.g., endocutter, grasper, cutter, stapler, clip applier, access device, drug/gene therapy delivery device, and energy delivery device using ultrasound, RF, laser, etc.). Endoscopic surgical instruments may include a shaft between the end effector and a handle portion, which is manipulated by the clinician. Such a shaft may enable insertion to a desired depth and rotation about the longitudinal axis of the shaft, thereby facilitating positioning of the end effector within the patient. Positioning of an end effector may be further facilitated through inclusion of one or more articulation joints or features, enabling the end effector to be selectively articulated or otherwise deflected relative to the longitudinal axis of the shaft.

Examples of endoscopic surgical instruments include surgical staplers. Some such staplers are operable to clamp down on layers of tissue, cut through the clamped layers of tissue, and drive staples through the layers of tissue to substantially seal the severed layers of tissue together near the severed ends of the tissue layers. Merely exemplary surgical staplers are disclosed in U.S. Pat. No. 4,805,823, entitled “Pocket Configuration

for Internal Organ Staplers," issued February 21, 1989; U.S. Pat. No. 5,415,334, entitled "Surgical Stapler and Staple Cartridge," issued May 16, 1995; U.S. Pat. No. 5,465,895, entitled "Surgical Stapler Instrument," issued November 14, 1995; U.S. Pat. No. 5,597,107, entitled "Surgical Stapler Instrument," issued January 28, 1997; U.S. Pat. No. 5,632,432, entitled "Surgical Instrument," issued May 27, 1997; U.S. Pat. No. 5,673,840, entitled "Surgical Instrument," issued October 7, 1997; U.S. Pat. No. 5,704,534, entitled "Articulation Assembly for Surgical Instruments," issued January 6, 1998; U.S. Pat. No. 5,814,055, entitled "Surgical Clamping Mechanism," issued September 29, 1998; U.S. Pat. No. 6,978,921, entitled "Surgical Stapling Instrument Incorporating an E-Beam Firing Mechanism," issued December 27, 2005; U.S. Pat. No. 7,000,818, entitled "Surgical Stapling Instrument Having Separate Distinct Closing and Firing Systems," issued February 21, 2006; U.S. Pat. No. 7,143,923, entitled "Surgical Stapling Instrument Having a Firing Lockout for an Unclosed Anvil," issued December 5, 2006; U.S. Pat. No. 7,303,108, entitled "Surgical Stapling Instrument Incorporating a Multi-Stroke Firing Mechanism with a Flexible Rack," issued December 4, 2007; U.S. Pat. No. 7,367,485, entitled "Surgical Stapling Instrument Incorporating a Multistroke Firing Mechanism Having a Rotary Transmission," issued May 6, 2008; U.S. Pat. No. 7,380,695, entitled "Surgical Stapling Instrument Having a Single Lockout Mechanism for Prevention of Firing," issued June 3, 2008; U.S. Pat. No. 7,380,696, entitled "Articulating Surgical Stapling Instrument Incorporating a Two-Piece E-Beam Firing Mechanism," issued June 3, 2008; U.S. Pat. No. 7,404,508, entitled "Surgical Stapling and Cutting Device," issued July 29, 2008; U.S. Pat. No. 7,434,715, entitled "Surgical Stapling Instrument Having Multistroke Firing with Opening Lockout," issued October 14, 2008; and U.S. Pat. No. 7,721,930, entitled "Disposable Cartridge with Adhesive for Use with a Stapling Device," issued May 25, 2010. The disclosure of each of the above-cited U.S. Patents is incorporated by reference herein. While the surgical staplers referred to above are described as being used in endoscopic procedures, it should be understood that such surgical staplers may also be used in open procedures and/or other non-endoscopic procedures.

[0002] While various kinds of surgical stapling instruments and associated components have been made and used, it is believed that no one prior to the inventor(s) has made or used the invention described in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0004] FIG. 1A depicts a perspective view of an articulating surgical instrument with an end effector in a nonarticulated position;

[0005] FIG. 1B depicts a perspective view of the surgical instrument of FIG. 1A with an end effector in an articulated position;

[0006] FIG. 2 depicts a perspective view of an opened end effector of the surgical instrument of FIGS. 1A-1B;

[0007] FIG. 3A depicts a side cross-sectional view of the end effector of FIG. 2, taken along line 3-3 of FIG. 2, with the firing bar in a proximal position;

[0008] FIG. 3B depicts a side cross-sectional view of the end effector of FIG. 2, taken along line 3-3 of FIG. 2, but showing the firing bar in a distal position;

[0009] FIG. 4 depicts an end cross-sectional view of the end effector of FIG. 2, taken along line 4-4 of FIG. 2;

[00010] FIG. 5 depicts an exploded perspective view of the end effector of FIG. 2;

[00011] FIG. 6 depicts a perspective view of the end effector of FIG. 2, positioned at tissue and having been actuated once in the tissue;

[00012] FIG. 7 depicts a perspective view of a retainer cap with the end effector of FIG. 2;

[00013] FIG. 8 depicts a perspective underside view of the retainer cap of FIG. 7;

[00014] FIG. 9 depicts a side view of the retainer cap with the end effector of FIG. 7;

[00015] FIG. 10 depicts a side view of an exemplary end effector with a buttress;

[00016] FIG. 11A depicts a front view of the buttress of FIG. 10 in an uncompressed state;

[00017] FIG. 11B depicts a front view of the buttress of FIG. 10 with an anvil and lower jaw clamped around buttress;

[00018] FIG. 11C depicts a side view of the buttress of FIG. 10 after being severed with liquid being urged from the buttress;

[00019] FIG. 12A depicts a front, cross-sectional view of the buttress of FIG. 10 being compressed;

[00020] FIG. 12B depicts a front, cross-sectional view of the buttress of FIG. 10 after being severed;

[00021] FIG. 13 depicts a perspective view of a surgical instrument with the buttress of FIG. 10 with liquid having been urged from the buttress;

[00022] FIG. 14 depicts a perspective view of an exemplary end effector with an exemplary alternative version of a buttress;

[00023] FIG. 15 depicts a cross sectional view of the exemplary end effector of FIG. 14 clamping tissue with a pair of buttresses;

[00024] FIG. 16 depicts a cross sectional view of the pair of buttresses of FIG. 14 after being sliced by a cutting edge;

[00025] FIG. 17 depicts a cross sectional view of an exemplary alternative buttress having a plurality of adhesive regions;

[00026] FIG. 18 depicts a cross sectional view of an exemplary alternative buttress having a plurality of adhesive capsules; and

[00027] FIG. 19 depicts a cross sectional view of an exemplary capsule forming chamber for forming the plurality of adhesive capsules of FIG. 18.

[00028] The drawings are not intended to be limiting in any way, and it is contemplated that various embodiments of the invention may be carried out in a variety of other ways, including those not necessarily depicted in the drawings. The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention, and together with the description serve to explain the principles of the invention; it being understood, however, that this invention is not limited to the precise arrangements shown.

DETAILED DESCRIPTION

[00029] The following description of certain examples of the invention should not be used to limit the scope of the present invention. Other examples, features, aspects, embodiments, and advantages of the invention will become apparent to those skilled in the art from the following description, which is by way of illustration, one of the best modes contemplated for carrying out the invention. As will be realized, the invention is capable of other different and obvious aspects, all without departing from the invention. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[00030] I. Exemplary Surgical Stapler

[00031] FIGS. 1-6 depict an exemplary surgical stapling and severing instrument (10) that is sized for insertion, in a nonarticulated state as depicted in FIG. 1A, through a trocar

cannula passageway to a surgical site in a patient for performing a surgical procedure. Surgical and stapling and severing instrument (10) includes handle portion (20) connected to implement portion (22), the latter further comprising shaft (23) distally terminating in an articulating mechanism (11) and a distally attached end effector (12). Once articulation mechanism (11) and distally end effector (12) are inserted through the cannula passageway of a trocar, articulation mechanism (11) may be remotely articulated, as depicted in FIG. 1B, by articulation control (13). Thereby, end effector (12) may reach behind an organ or approach tissue from a desired angle or for other reasons. It should be understood that terms such as "proximal" and "distal" are used herein with reference to a clinician gripping handle portion (20) of instrument (10). Thus, end effector (12) is distal with respect to the more proximal handle portion (20). It will be further appreciated that for convenience and clarity, spatial terms such as "vertical" and "horizontal" are used herein with respect to the drawings. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

[00032] End effector (12) of the present example includes a lower jaw (16) and a pivotable anvil (18). Handle portion (20) includes pistol grip (24) toward which closure trigger (26) is pivotally drawn by the clinician to cause clamping, or closing, of the anvil (18) toward lower jaw (16) of end effector (12). Such closing of anvil (18) is provided through an outmost closure sleeve (32), which longitudinally translates relative to handle portion (20) in response to pivoting of closure trigger (26) relative to pistol grip (24). A distal closure ring (33) of closure sleeve (32) is indirectly supported by frame (34) of implement portion (22). At articulation mechanism (11), a proximal closure tube (35) of closure sleeve (32) communicates with the distal portion (closure ring) (33). Frame (34) is flexibly attached to lower jaw (16) via articulation mechanism (11), enabling articulation in a single plane. Frame (34) also longitudinally slidingly supports a firing drive member (not shown) that extends through shaft (23) and communicates a firing motion from firing trigger (28) to firing bar (14). Firing trigger (28) is farther outboard of closure trigger (26) and is pivotally drawn by the clinician to cause the stapling and

severing of clamped tissue in end effector (12), as will be described in greater detail below. Thereafter, release button (30) is depressed to release the tissue from end effector (12).

[00033] FIGS. 2-5 depict end effector (12) employing an E-beam firing bar (14) to perform a number of functions. As best seen in FIGS. 3A-3B, firing bar (14) includes a transversely oriented upper pin (38), a firing bar cap (44), a transversely oriented middle pin (46), and a distally presented cutting edge (48). Upper pin (38) is positioned and translatable within an anvil pocket (40) of anvil (18). Firing bar cap (44) slidably engages a lower surface of lower jaw (16) by having firing bar (14) extend through channel slot (45) (shown in FIG. 3B) that is formed through lower jaw (16). Middle pin (46) slidingly engages a top surface of lower jaw (16), cooperating with firing bar cap (44). Thereby, firing bar (14) affirmatively spaces end effector (12) during firing, overcoming pinching that may occur between anvil (18) and lower jaw (16) with a minimal amount of clamped tissue and overcoming staple malformation with an excessive amount of clamped tissue.

[00034] FIG. 2 shows firing bar (14) proximally positioned and anvil (18) pivoted to an open position, allowing an unspent staple cartridge (37) to be removably installed into a channel of lower jaw (16). As best seen in FIGS. 4-5, staple cartridge (37) of this example includes a cartridge body (70), which presents an upper deck (72) and is coupled with a lower cartridge tray (74). As best seen in FIG. 2, a vertical slot (49) is formed through part of staple cartridge (37). As also best seen in FIG. 2, three rows of staple apertures (51) are formed through upper deck (70) on one side of vertical slot (49), with another set of three rows of staple apertures (51) being formed through upper deck (70) on the other side of vertical slot (49). Referring back to FIGS. 3-5, a wedge sled (41) and a plurality of staple drivers (43) are captured between cartridge body (70) and tray (74), with wedge sled (41) being located proximal to staple drivers (43). Wedge sled (41) is movable longitudinally within staple cartridge (37); while staple drivers (43) are movable vertically within staple cartridge (37). Staples (47) are also positioned within cartridge

body (70), above corresponding staple drivers (43). In particular, each staple (47) is driven vertically within cartridge body (70) by a staple driver (43) to drive staple (47) out through an associated staple aperture (51). As best seen in FIGS. 3A-3B and 5, wedge sled (41) presents inclined cam surfaces that urge staple drivers (43) upwardly as wedge sled (41) is driven distally through staple cartridge (37).

[00035] With end effector (12) closed as depicted in FIG. 3A, firing bar (14) is advanced in engagement with anvil (18) by having upper pin (38) enter a longitudinal anvil slot (42). A pusher block (80) is located at the distal end of firing bar (14), and is configured to engage wedge sled (41) such that wedge sled (41) is pushed distally by pusher block (80) as firing bar (14) is advanced distally through staple cartridge (37). During such firing, cutting edge (48) of firing bar (14) enters vertical slot (49) of staple cartridge (37), severing tissue clamped between staple cartridge (37) and anvil (18). As shown in FIGS. 3A-3B, middle pin (46) and pusher block (80) together actuate staple cartridge (37) by entering into a firing slot within staple cartridge (37), driving wedge sled (41) into upward camming contact with staple drivers (43) that in turn drive staples (47) out through staple apertures (51) and into forming contact with staple forming pockets (53) on the inner surface of anvil (18). FIG. 3B depicts firing bar (14) fully distally translated after completing severing and stapling tissue.

[00036] FIG. 6 shows end effector (12) having been actuated through a single stroke through tissue (90). As shown, cutting edge (48) has cut through tissue (90), while staple drivers (43) have driven three alternating rows of staples (47) through the tissue (90) on each side of the cut line produced by cutting edge (48). Staples (47) are all oriented substantially parallel to the cut line in this example, though it should be understood that staples (47) may be positioned at any suitable orientations. In the present example, end effector (12) is withdrawn from the trocar after the first stroke is complete, spent staple cartridge (37) is replaced with a new staple cartridge, and end effector (12) is then again inserted through the trocar to reach the stapling site for further cutting and stapling. This process may be repeated until the desired amount of cuts and staples (47) have been

provided. Anvil (18) may need to be closed to facilitate insertion and withdrawal through the trocar; and anvil (18) may need to be opened to facilitate replacement of staple cartridge (37).

[00037] It should be understood that cutting edge (48) may sever tissue substantially contemporaneously with staples (47) being driven through tissue during each actuation stroke. In the present example, cutting edge (48) just slightly lags behind driving of staples (47), such that a staple (47) is driven through the tissue just before cutting edge (48) passes through the same region of tissue, though it should be understood that this order may be reversed or that cutting edge (48) may be directly synchronized with adjacent staples. While FIG. 6 shows end effector (12) being actuated in two layers (92, 94) of tissue (90), it should be understood that end effector (12) may be actuated through a single layer of tissue (90) or more than two layers (92, 94) of tissue. It should also be understood that the formation and positioning of staples (47) adjacent to the cut line produced by cutting edge (48) may substantially seal the tissue at the cut line, thereby reducing or preventing bleeding and/or leaking of other bodily fluids at the cut line. Various suitable settings and procedures in which instrument (10) may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00038] It should be understood that instrument (10) may be configured and operable in accordance with any of the teachings of U.S. Pat. No. 4,805,823; U.S. Pat. No. 5,415,334; U.S. Pat. No. 5,465,895; U.S. Pat. No. 5,597,107; U.S. Pat. No. 5,632,432; U.S. Pat. No. 5,673,840; U.S. Pat. No. 5,704,534; U.S. Pat. No. 5,814,055; U.S. Pat. No. 6,978,921; U.S. Pat. No. 7,000,818; U.S. Pat. No. 7,143,923; U.S. Pat. No. 7,303,108; U.S. Pat. No. 7,367,485; U.S. Pat. No. 7,380,695; U.S. Pat. No. 7,380,696; U.S. Pat. No. 7,404,508; U.S. Pat. No. 7,434,715; and/or U.S. Pat. No. 7,721,930. As noted above, the disclosures of each of those patents are incorporated by reference herein. Additional exemplary modifications that may be provided for instrument (10) will be described in greater detail below. Various suitable ways in which the below teachings may be incorporated into instrument (10) will be apparent to those of ordinary skill in the art.

Similarly, various suitable ways in which the below teachings may be combined with various teachings of the patents cited herein will be apparent to those of ordinary skill in the art. It should also be understood that the below teachings are not limited to instrument (10) or devices taught in the patents cited herein. The below teachings may be readily applied to various other kinds of instruments, including instruments that would not be classified as surgical staplers. Various other suitable devices and settings in which the below teachings may be applied will be apparent to those of ordinary skill in the art in view of the teachings herein.

[00039] II. Exemplary Cover

[00040] FIGS. 7-9 show an exemplary staple cartridge (37) retainer cap (180), which may be attached to staple cartridge (37). It should be understood that retainer cap (180) may be configured and operable in accordance with any of the teachings of U.S. Patent Application Serial No. 12/894,369, entitled "Implantable Fastener Cartridge Comprising a Support Retainer", filed on September 30, 2010, the entire disclosure of which is incorporated by reference herein. Retainer cap (180) is operable to prevent, or at least inhibit, a clinician's thumb, for example, from contacting the tips of staples (47) positioned within staple cartridge (37) when staple cartridge (37) is inserted into lower jaw (16) of end effector (12). In addition or in the alternative, it may prevent staples (47) from inadvertently falling out of the cartridge. Referring now to FIGS. 7 and 8, retainer cap (180) of the present example includes bottom surface (181) and top surface (182), which can provide a pushing surface for the clinician to apply a downward force thereto, for example. In one merely exemplary use, the clinician may grab handle portion (184) of retainer cap (180), align support portion (110) of staple cartridge (37) with lower jaw (16) of end effector (12), and at least partially insert staple cartridge (37) within lower jaw (16) of end effector (12). Thereafter, the clinician can completely seat staple cartridge (37) in lower jaw (16) of end effector (12) by applying the downward force to top surface (182) of retainer cap (180) which can transmit the downward force directly to support portion (110). In the present example, retainer cap (180) comprises proximal

supports (187) which extend downwardly and contact deck surface (111) of the support portion. Retainer cap (180) further comprises distal support portion (183), which abuts nose (103). When a downward force is applied to retainer cap (180), the downward force can be transmitted through proximal supports (187) and/or distal support portion (183). In some exemplary versions, at least some of the supports may not be in contact with the top of support portion (110) before the downward force is applied to retainer cap (180); however, in some versions, retainer cap (180) can be operable to flex, or move, downwardly until retainer cap (180) touches the top of support portion (110). At such point, the downward flexure, or movement, of retainer cap (180) can be impeded, or at least substantially impeded, from flexing further.

[00041] As described above, retainer cap (180) can be attached to staple cartridge (37) and can be used to manipulate the position of staple cartridge (37). In some versions, retainer cap (180) can comprise any suitable number of gripping members which can be operable to releasably hold retainer cap (180) to support portion (110) of staple cartridge (37), for example. For instance, in the present example, retainer cap (180) comprises latch arms (188, 189). Latch arms (189) extend around the sides of nose (103) and engage bottom surface (109) (FIG. 7) of nose (103). Similarly, latch arms (188) extend around the sides of lock projections (108) extending from support portion (110) and engage the bottom surfaces of lock projections (108). These latch arms (188) are operable to position retainer cap (180) over the zone or region in which the staples (47) are stored within support portion (110). In any event, once staple cartridge (37) has been suitably positioned, retainer cap (180) can be detached from staple cartridge (37). Of course, any other suitable components or features may be used to provide releasable coupling of retainer cap (180) to staple cartridge (37). In some versions, the clinician may apply an upward lifting force to handle (184) in order to detach the distal end of retainer cap (180) from distal end (102) of staple cartridge (37). In at least one such embodiment, latch arms (188, 189) may flex outwardly as handle (184) is lifted upwardly such that latch arms (188, 189) may flex around lock projections (108) and nose (103), respectively. Thereafter, the proximal end of retainer cap (180) may be lifted away from proximal end

(101) of staple cartridge (37) and retainer cap (180) may be moved away from staple cartridge (37). With retainer cap (180) removed and with staple cartridge (37) properly seated in lower jaw (16) of end effector (12), instrument (10) may then be used in a surgical procedure.

[00042] III. Exemplary Fillable Buttress

[00043] A buttress (200), as shown in FIGS. 10-13, may be used with the end effector portion of the exemplary surgical cutter shown in FIGS. 1-6. It will be appreciated that use of buttress (200) as will be described below may facilitate quicker recovery to the surgical site where tissue has been severed and stapled by, for example, stabilizing areas where staples (47) have been applied. In some exemplary versions, buttress (200) may be used with retainer cap (180) described above, or alternatively, buttress (200) may be used directly with surgical severing and stapling instrument (10) described above without the use of retainer cap (180).

[00044] FIG. 10 shows that buttress (200) comprises a first fluid fillable member (202) or bladder and a second fluid fillable member (204) or bladder. In some exemplary versions, first fluid fillable member (202) may be attached to anvil (18) by an adhesive and second fluid fillable member (204) may be attached to upper deck (72) of staple cartridge (37) positioned in lower jaw (16). In other exemplary versions, first fluid fillable member (202) and second fluid fillable member (204) may be adhered together and adhered to anvil (18). In other exemplary versions, first fluid fillable member (202) and second fluid fillable member (204) may be adhered together and adhered to upper deck (72) of staple cartridge (37). In some exemplary versions, rather than using an adhesive to attach first fluid fillable member (202) or second fluid fillable member (204) to anvil (18) and/or lower jaw (16), a clip or other suitable mechanical or liquid fastening system may be used as would be apparent to one of ordinary skill in the art in view of the teachings herein. The present example of FIG. 10 shows buttress (200) as it is about to be positioned between anvil (18) and lower jaw (16).

[00045] First fluid fillable member (202) and second fluid fillable member (204) contains a two-part liquid (220) such that when the two parts of liquid (220) come in contact with one another, as will be described below, they form a coagulant that buttresses the surgical site affected by surgical stapling and severing instrument (10) shown in FIGS. 1-6. In some exemplary versions, first fluid fillable member (202) is filled with fibrin while second fluid fillable member (204) is filled with thrombin, but it should be understood that any suitable material may be used. In some versions, first fluid fillable member (202) and second fluid fillable member (204) may both comprise liquid (220) that may be operable to buttress a surgical site without necessarily combining with another compound. In yet other exemplary versions, rather than two fluid fillable members, any suitable number of fluid fillable members may be used as would be apparent to one of ordinary skill in the art in view of the teachings herein. For example, three or more fluid fillable members may be used, or a single fluid fillable member may be used. Furthermore, buttress (200) may be prefilled with liquid (220) or alternatively the user or physician may fill buttress (200) with liquid (220) prior to use of surgical stapling and severing instrument (10). In some other exemplary versions, liquid (220) may comprise a hemostatic agent, a biologically safe glue, or any other suitable adhesive material as would be apparent to one of ordinary skill in the art in view of the teachings herein.

[00046] In the exemplary version, buttress (200) has a generally flat, rectangular shape configured to fit in between anvil (18) and lower jaw (16). Buttress (200) has a size at least slightly larger than the width of anvil (18) or lower jaw (16). In some exemplary versions, buttress (200) may have a size significantly larger than anvil (18) or lower jaw (16). However, any suitable shape or size for buttress (200) may be used as would be apparent to one of ordinary skill in the art in view of the teachings herein. Furthermore, buttress (200) comprises a semi self-supportive structure such that buttress (200) can maintain its generally flat shape when buttress (200) is not being compressed as will be discussed below.

[00047] FIGS. 11A-C show a side view of buttress (200) showing how liquid (220) contained within first fluid filled portion (202) and second fluid filled portion (204) may be urged out of buttress (200). In the exemplary version, buttress (200) may be placed between anvil (18) and lower jaw (16) wherein buttress (200) remains mostly flat as shown in FIG. 11A. As also seen in FIG. 11A, liquid (220) remains in a substantially unpressurized state. In some exemplary versions, buttress (200) may be preloaded to be placed between anvil (18) and lower jaw (16) such that buttress (200) adheres to staple cartridge (not shown) contained in lower jaw (16). In other exemplary versions, the user or physician can load buttress (200) between anvil (18) and lower jaw (16) prior to use in a surgical setting. For example, in some exemplary versions the user may remove retaining cap (180) described above in FIGS. 7-9 and replace retaining cap (180) with buttress (200) prior to clamping anvil (18) and lower jaw (16) around the tissue of the surgical site. In other merely exemplary versions, buttress (200) may be coupled to retaining cap (180), wherein retaining cap (180) is removed prior to use, leaving only buttress (200) between anvil (18) and lower jaw (16). Other configurations for buttress (200) and retaining cap (180) may be used as would be apparent to one of ordinary skill in the art in view of the teachings herein.

[00048] FIG. 11B shows buttress (200) as it would appear when clamped by anvil (18) and lower jaw (16) resulting in a compressed region (206) and a pressurized region (208). In pressurized region (208), liquid (220) is forced under pressure. As seen in FIG. 11B, anvil (18) and lower jaw (16) have been clamped tightly around buttress (200) prior to buttress (200) being severed or stapled.

[00049] As seen in FIGS. 11C, phantom lines (210) show the outline of buttress (200) prior to anvil (18) and lower jaw (16) compressing buttress (200). Anvil (18) and lower jaw (16) may be clamped to sandwich buttress (200). Liquid (220) contained within buttress (200) remains pressurized in pressurized region (208). While FIGS. 11B-11C show pressurized region (208) on one side of compressed region (206), it will be appreciated that an opposite pressurized region (208) could be formed on an opposite

side of compressed (206). Buttress (200) comprises a generally elastic material configured to expand such that pressurized region (208) may be filled with most or all of the fluid in buttress (208) without breaking or popping under pressure. Pressurized region (208) accordingly expands beyond the region defined by phantom lines (210) to accommodate the increase in pressure and liquid of pressurized region (208).

[00050] As cutting edge (48) discussed above in reference to FIGS. 1-6 severs tissue (90), cutting edge (48) also severs buttress (200) resulting in buttress (200) being severed as shown in FIG. 11C. Almost simultaneously, buttress (200) is also stapled, and buttress (200) is thus ruptured by staples (47), thereby allowing buttress (200) to begin releasing liquid (220). Upon severing of buttress (200), liquid (220) is urged out of pressurized region (208) of buttress (200) and into the tissue of the surgical area thereby aiding in buttressing tissue (90) once tissue (90) is severed and stapled. Furthermore, staples (47) are deployed which, as stated above, further rupture buttress (200), thereby allowing liquid (220) to be squeezed out through regions of buttress (200) ruptured by staples (47) as well. In some exemplary versions, buttress (200) may comprise a dissolvable material such that buttress (200) may be left in tissue (90) without harming the patient. In other exemplary versions, buttress (200) may be removed from the surgical site once liquid (220) is released from buttress (200).

[00051] FIGS. 12A-B show a front cross-sectional view of buttress (200) as it is being compressed between two layers of tissue (290). In some exemplary versions, buttress (200) may be sandwiched between tissue (290) or in some alternative versions, buttress (200) may be pressed against either the top surface or bottom surface of tissue (290). In some exemplary versions, the outer surface of buttress (200) may comprise an adhesive coating to allow buttress (200) to adhere to tissue (290) prior to release of liquid (220). FIG. 12B shows buttress (200) after being severed and stapled by staples (247) where pressurized region (208) containing liquid (220) urges liquid (220) through compressed region (206) into surrounding tissue (290). In some versions, liquid (220) may also be urged through ruptures caused by staples (247).

[00052] FIG. 13 shows surgical severing and stapling instrument (10) as it is being used to sever and staple tissue (90). As can be seen in the present example, buttress (200) has been severed between anvil (18) and lower jaw (16). Furthermore, liquid (220) has been urged from buttress (200) into the surrounding tissue (90). While liquid (220) may comprise any suitable liquid, in the present example, liquid (220) comprises a coagulant, such as, for example, fibrin and thrombin. Liquid (220), once urged from buttress (200) is operable to aid in coagulation of the portions of tissue (90) where staples (47) have been inserted into tissue (90).

[00053] IV. Exemplary Buttress with Fillable Region

[00054] FIGS. 14-16 show a buttress (300) that may be used with end effector (12) of the instrument (10) shown in FIGS. 1-6. Buttress (300) comprises a barrier portion (302) and an adhesive region (304). Barrier portion (302) extends around the outer perimeter of adhesive region (304) thereby defining a first half (306) and a second half (308) of buttress (300). First half (306) and second half (308) are positioned such that vertical slot (49) is positioned roughly between first half (306) and second half (308). A cut line (314) extends between first half (306) and second half (308) as seen in FIG. 15 such that cutting edge (48) may cut barrier portion (302) along cut line (314). Of course, cut line (314) may be omitted. For instance, buttress (300) may be provided in discrete pieces on each side of vertical slot (49). Furthermore, it will be appreciated that buttress (300) may be configured as a single unit without the use of separate halves (306, 308). Similarly, while a single buttress (300) is used in the present example, it should be understood that two or more buttresses (300) may be used as would be apparent to one of ordinary skill in the art in view of the teachings herein. For example, FIG. 15 shows a cross sectional view of tissue (90) being clamped between two buttresses (300) – one buttress (300) on deck (72) of cartridge (37) and one buttress (300) on the underside of anvil (18).

[00055] Buttress (300) of the present example is constructed of a foam material, though it should be understood that any suitable materials may be used. By way of example only, buttress (300) may comprise a bio-absorbable fabric. Adhesive region (304) comprises

an adhesive (310) held within an adhesive layer membrane (312). Adhesive (310) may comprise any suitable adhesive material as would be apparent to one of ordinary skill in the art in view of the teachings herein. For example, adhesive (310) may comprise cyanoarylates, anti-microbial agents, and/or healing agents. In yet other exemplary versions, adhesive regions (304) of halves (306, 308) may comprise two or more agents such that adhesive properties are only activated when the agents are combined after halves (306, 308) are punctured. Other suitable materials for adhesive (310) will be apparent to one of ordinary skill in the art in view of the teachings herein. Membrane (312) connected to barrier portion (302) forms a bubble configured to hold a fluid adhesive (310). For example, FIG. 15 shows membrane (312) enclosing adhesive (310). Membrane (312) may be constructed of a bio-absorbable plastic and/or other bio-absorbable material. Membrane (312) may further be constructed of any suitable material as would be apparent to one of ordinary skill in the art in view of the teachings herein.

[00056] As noted above, barrier portion (302) forms a lip around adhesive region (304) such that any fluids in adhesive region (304) are held within the perimeter defined by barrier portion (302). For example, as shown in FIGS. 15-16, tissue (90) that is clamped between two buttresses (300) is positioned such that adhesive regions (304) face toward tissue (90). Anvil (18) is clamped against lower jaw (16) such that buttresses (300) squeeze tissue (90), thereby forming a seal between barrier portion (302) and tissue (90). As seen in FIG. 15, staples (47) pierce through membrane (312) of adhesive region (304). As a result, adhesive region (304) ruptures and adhesive (310) flows out. Barrier portion (302) has a cup-like shape configured to hold adhesive (310) against tissue (90) after adhesive (310) leaves adhesive region (304); while substantially preventing adhesive (310) from flowing out of buttress (300) to surrounding tissue. FIG. 16 shows adhesive (310) after it has flown out from adhesive region (304) and formed an adhesive layer (316). Also in FIG. 16, cutting edge (48) has sliced along cut line (314) severing tissue (90). It will be appreciated that staples (47) operably hold buttresses (300) pressed against tissue (90).

[00057] FIG. 17 shows an exemplary alternative version of buttress (400) having a plurality of adhesive regions (404) spaced apart within barrier portion (402). Adhesive regions (404) comprise plastic modules operable to burst when punctured and/or when sufficiently compressed. Each adhesive regions (404) has an adhesive (410) contained therein. It will be appreciated that all of the adhesive regions (404) need not necessarily contain the same adhesives (410). For example, some adhesive regions (404) may comprise one type of adhesive (410) and/or therapeutic material whereas other adhesive regions (404) may comprise a different type of adhesive (410) and/or therapeutic material. Of course, any other suitable medical fluids may be included in regions (404) in addition to or in lieu of adhesives.

[00058] FIG. 18 shows yet another exemplary version of buttress (500) having a foam region (504), with adhesive capsules (510) embedded and/or seeded into foam region (504). Foam region (504) is contained within barrier portion (502). Foam region (504) may substantially prevent adhesive capsules (510) from inadvertently leaving buttress (500) before buttress (500) is deployed at a surgical site. Foam region (504) may also substantially prevent adhesive that is released from capsules (510) from escaping the surgical site after buttress (500) is deployed at the surgical site. Furthermore, foam region (504) may substantially prevent the adhesive (510) of capsules (510) from sticking to anvil (18) and/or cartridge (18), before and/or after buttress (500) is deployed at the surgical site.

[00059] Adhesive capsules (510) may be constructed from any suitable method as would be apparent to one of ordinary skill in the art in view of the teachings herein. FIG. 19 shows one exemplary way of making adhesive capsules (510) using a capsule forming chamber (550). Chamber (550) comprises a dispenser (552) and coating medium (556). It will be appreciated that any non-reactive gas may be contained within chamber (550). Dispenser (552) dispenses adhesive material (554), which falls as adhesive drops before entering coating medium (556). Coating medium (556) may comprise a plastic, but any suitable material may be used as would be apparent to one of ordinary skill in the art in

view of the teachings herein. Adhesive material (554) contacts coating medium (556) and becomes covered with a coating, thereby forming adhesive capsules (510) at the bottom of coating medium (556). Thereafter, adhesive capsules (510) may be removed from chamber (550) and placed into foam region (504) as shown in FIG. 18. Of course, adhesive capsules (510) may be formed from any other suitable method as would be apparent to one of ordinary skill in the art in view of the teachings herein.

[00060] It should be understood that any one or more of the teachings, expressions, embodiments, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, embodiments, examples, etc. that are described herein. The following-described teachings, expressions, embodiments, examples, etc. should therefore not be viewed in isolation relative to each other. Various suitable ways in which the teachings herein may be combined will be readily apparent to those of ordinary skill in the art in view of the teachings herein. Such modifications and variations are intended to be included within the scope of the claims.

[00061] Versions of the devices described above may have application in conventional medical treatments and procedures conducted by a medical professional, as well as application in robotic-assisted medical treatments and procedures.

[00062] Versions of described above may be designed to be disposed of after a single use, or they can be designed to be used multiple times. Versions may, in either or both cases, be reconditioned for reuse after at least one use. Reconditioning may include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, some versions of the device may be disassembled, and any number of the particular pieces or parts of the device may be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, some versions of the device may be reassembled for subsequent use either at a reconditioning facility, or by a user immediately prior to a procedure. Those skilled in the art will appreciate that reconditioning of a device may utilize a variety of techniques for disassembly,

cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[00063] By way of example only, versions described herein may be sterilized before and/or after a procedure. In one sterilization technique, the device is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and device may then be placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation may kill bacteria on the device and in the container. The sterilized device may then be stored in the sterile container for later use. A device may also be sterilized using any other technique known in the art, including but not limited to beta or gamma radiation, ethylene oxide, or steam.

[00064] Having shown and described various versions in the present disclosure, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, versions, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

I/We Claim:

1. An apparatus, comprising:

(a) a surgical cutter comprising a distal end and a proximal end, wherein the proximal end comprises a handle, wherein the distal end comprises an anvil and a lower jaw, wherein the anvil and the lower jaw are configured to clamp tissue, wherein the surgical cutter is configured to sever tissue clamped by the anvil and the lower jaw; and

(b) a buttress filled with a liquid, wherein the buttress is configured to be placed between the anvil and the lower jaw, wherein the buttress comprises a compressive portion and a pressure portion, wherein the compressive portion is configured to be squeezed by the distal end of the surgical cutter by the anvil and the lower jaw clamping the compressive portion, wherein the pressure portion is configured to be pressurized with the liquid in response to clamping on the compression portion, wherein the buttress is configured to be severed and stapled by the surgical cutter substantially contemporaneously with when the surgical cutter severs tissue, wherein the pressure portion is configured to urge the liquid through the compressive portion once the buttress is severed.

2. The apparatus of claim 1, wherein the liquid comprises a two-part adhesive configured to have adhesive properties only once the two parts of the two-part adhesive are combined.

3. The apparatus of claim 1, wherein the buttress comprises an elastic material.

4. The apparatus of claim 1, wherein the anvil defines an anvil width, wherein the buttress defines a buttress width that is wider than the anvil width.

5. The apparatus of claim 1, wherein the buttress comprises a resilient material.

6. The apparatus of claim 1, wherein the buttress has a generally rectangular shape.

7. The apparatus of claim 1, wherein the buttress is configured to be pre-loaded into the surgical cutter.

8. The apparatus of claim 1, wherein the buttress straddles the lower jaw such that a substantially equal portion of the buttress extends outward from the lower jaw.

9. The apparatus of claim 1, wherein the buttress is configured to be coupled to the lower jaw.

10. The apparatus of claim 1, wherein the buttress comprises two substantially similarly shaped fluid filled members, wherein each of the two fluid filled members comprise a liquid adhesive.

11. The apparatus of claim 10, wherein each of the two fluid filled members comprises different liquid components.

12. The apparatus of claim 1, further comprising a surgical stapler in communication with the surgical cutter, wherein the surgical stapler comprises one or more staples, wherein the surgical stapler is configured to staple a portion of tissue, wherein the one or more staples are configured to rupture the buttress.

13. The apparatus of claim 1, wherein the buttress comprises a dissolvable material.

14. The apparatus of claim 1, wherein the buttress comprises a two-part fluid coagulant, wherein one of the two-part fluids comprises fibrin, wherein the other of the two-part fluids comprises thrombin.

15. The apparatus of claim 1, wherein the buttress comprises an adhesive on the outside of the buttress operable to adhere the buttress to a portion of the surgical cutter.

16. An apparatus comprising:

(a) a surgical instrument comprising a cutter and a stapler, wherein the surgical instrument further comprises an anvil and a lower jaw operable to

compress tissue as the tissue is cut and stapled, wherein the cutter is configured to cut at least a portion of the tissue, wherein the stapler is configured to staple at least a portion of the tissue; and

(b) a pair of bladders, wherein at least a portion of the pair of bladders is positioned between the anvil and the lower jaw, wherein the pair of bladders comprises a first bladder and a second bladder, wherein the first bladder contains a first coagulant component, wherein the second bladder contains a second coagulant component, wherein the cutter is operable to simultaneously rupture both the first bladder and the second bladder, thereby mixing at least a portion of the first coagulant component with at least a portion of the second coagulant component.

17. The apparatus of claim 16, wherein at least one of the pair of bladders further contains a fluid adhesive.

18. The apparatus of claim 16, wherein the anvil and the lower jaw is configured to compress at least a portion of the pair of bladders.

19. The apparatus of claim 16, wherein each of the pair of bladders comprises an elastic material.

20. A method for pressurizing and severing one or more bladders to distribute a fluid to simultaneously severed tissue using a surgical instrument, wherein the surgical instrument comprises an anvil and a lower jaw, wherein the surgical instrument further comprises a knife moveable in relation to the anvil and the lower jaw, wherein the one or more bladders are positionable between the anvil and the lower jaw, wherein at least a portion of the one or more bladders contains the fluid, the method comprising:

(a) aligning tissue between the anvil and the lower jaw;

(b) compressing a portion of the one or more bladders between the anvil and

the lower jaw;

(c) actuating a portion of the surgical instrument, wherein the act of actuating a portion of the surgical instrument is operable to move the knife in relation to the anvil and the lower jaw;

(d) severing tissue with the knife;

(e) severing the one or more bladders with the knife; and

(f) distributing the fluid to an area proximate to the severed tissue.

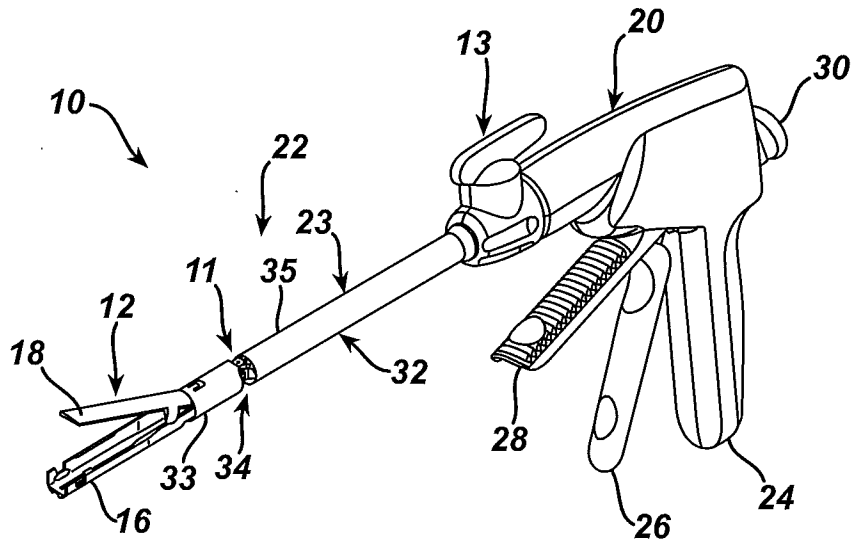
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FIG. 1A

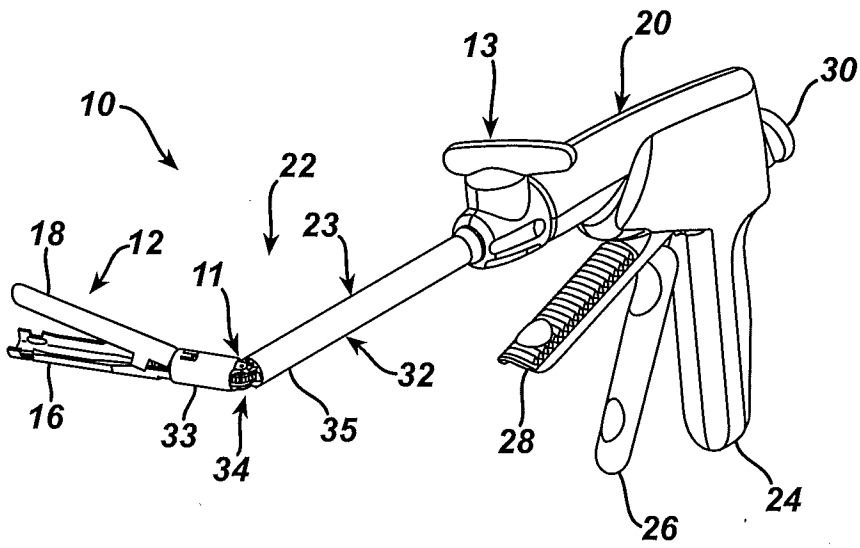
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FIG. 1B

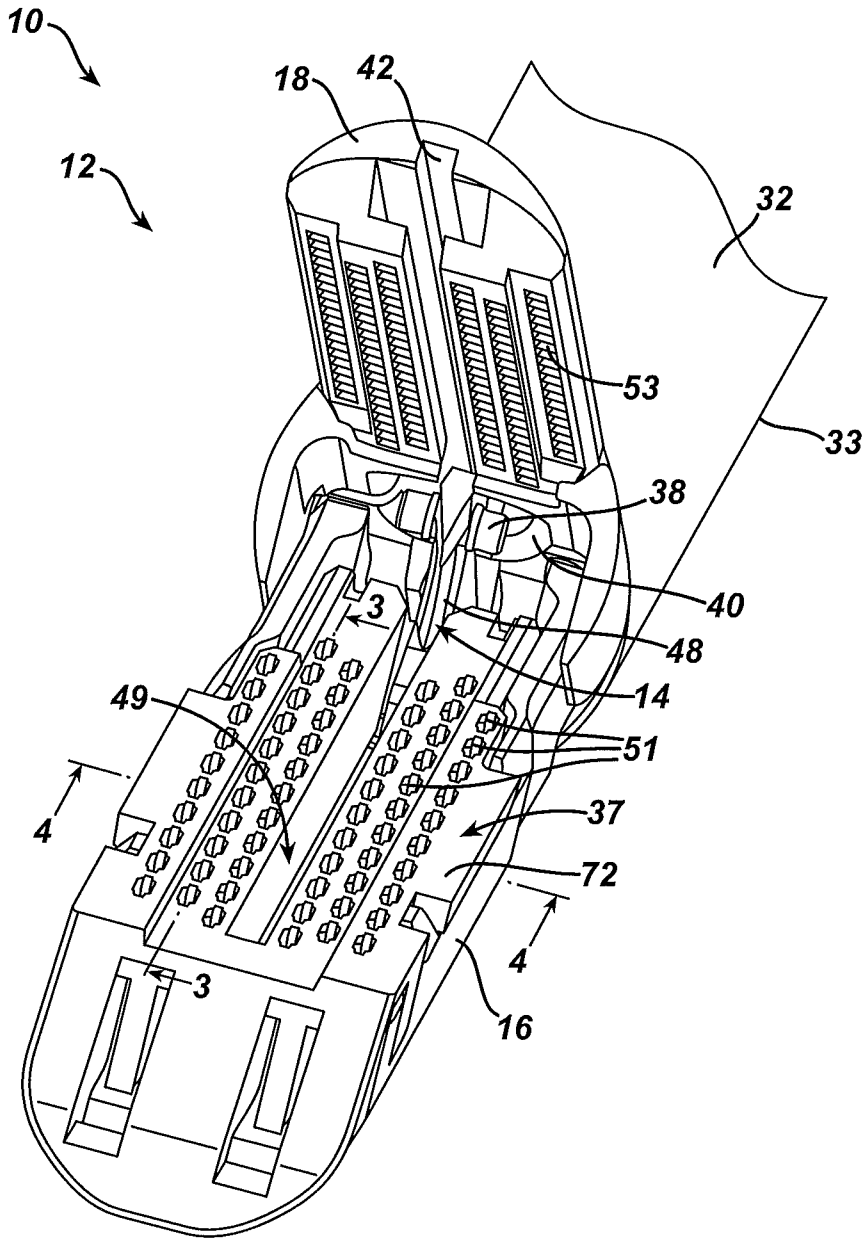

FIG. 2

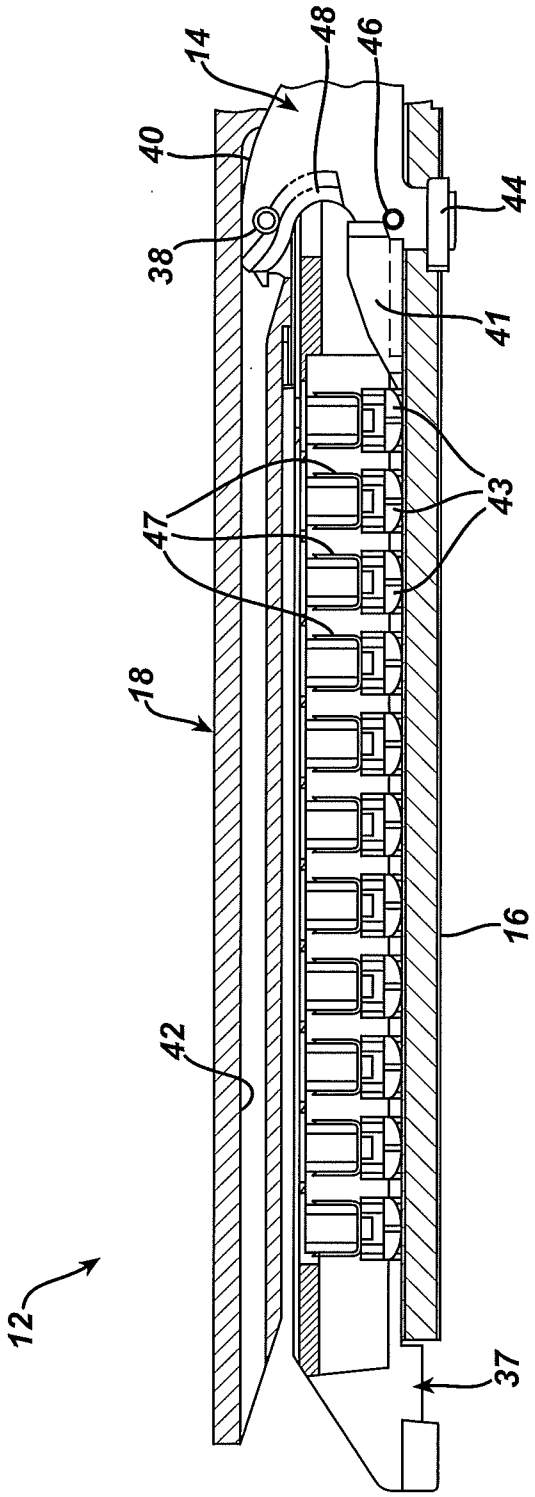

FIG. 3A

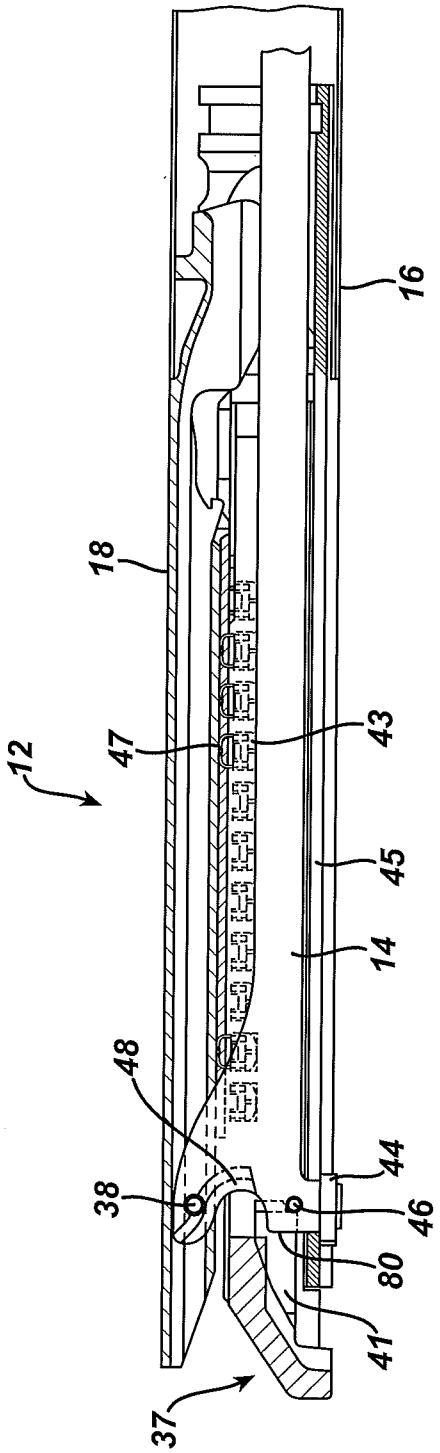

FIG. 3B

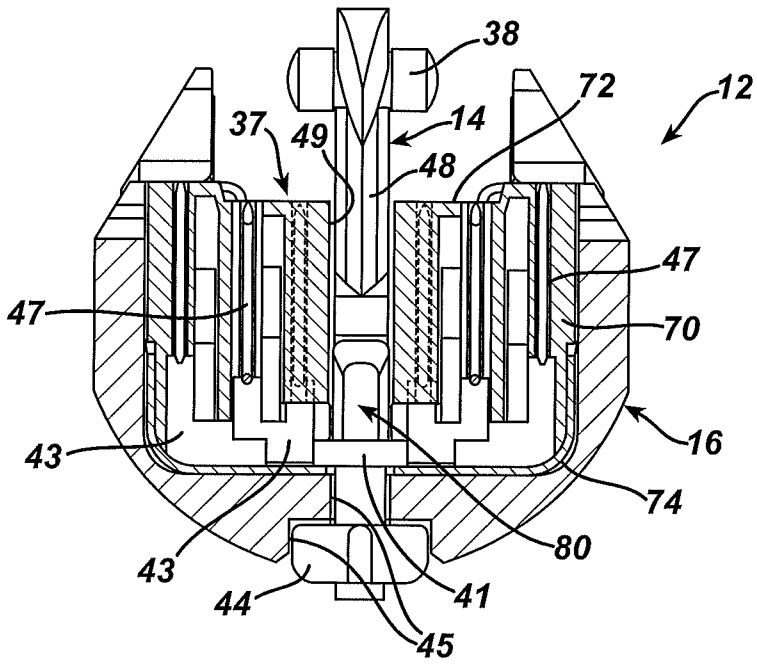

FIG. 4

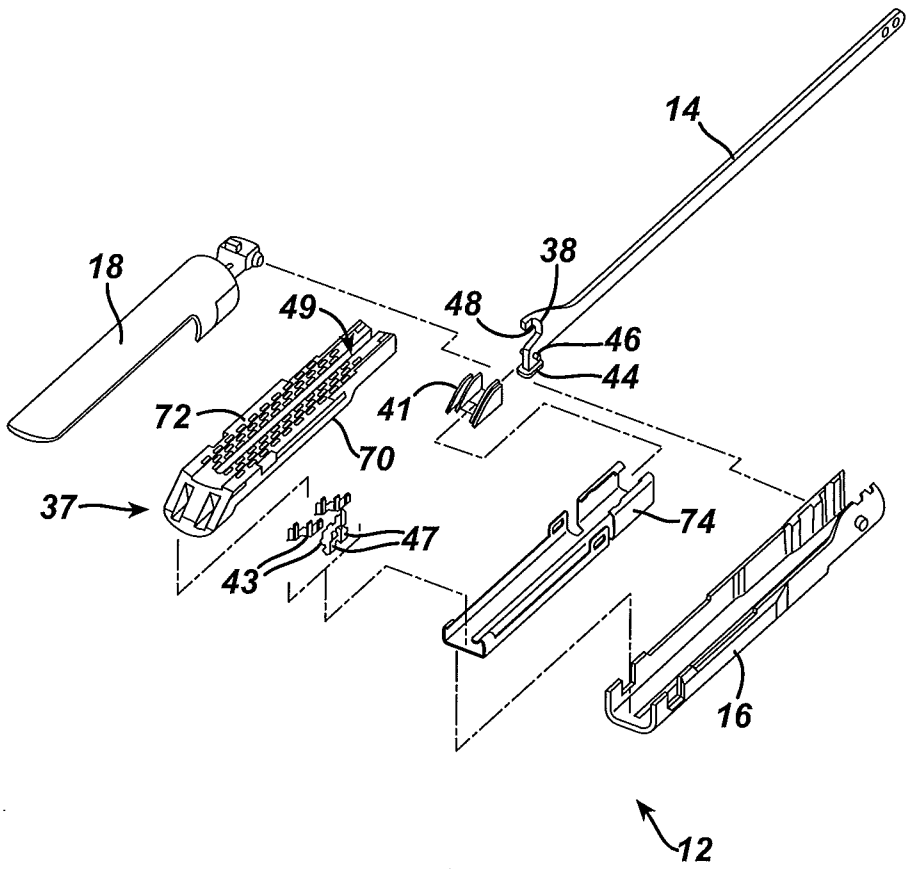

FIG. 5

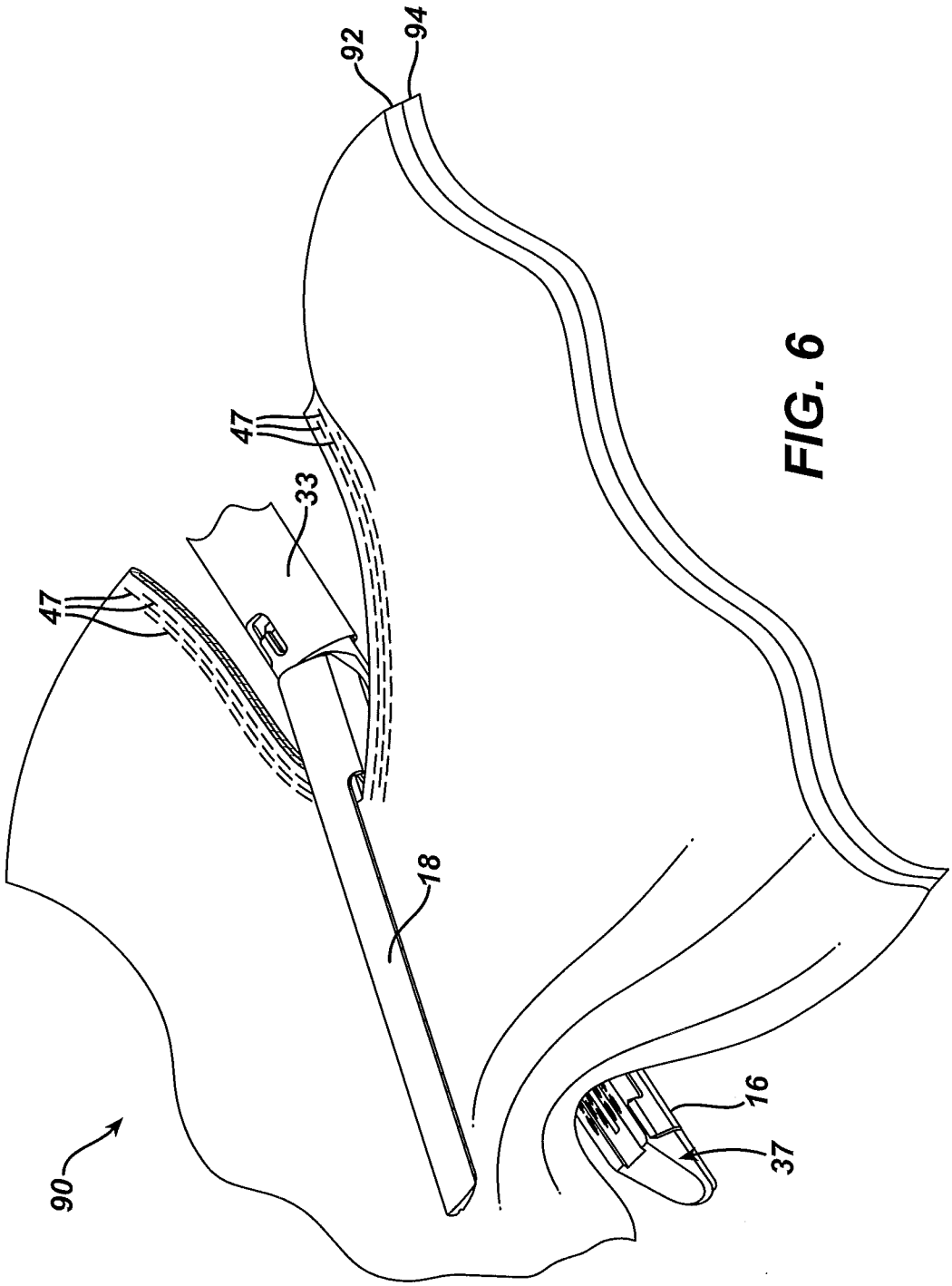

FIG. 6

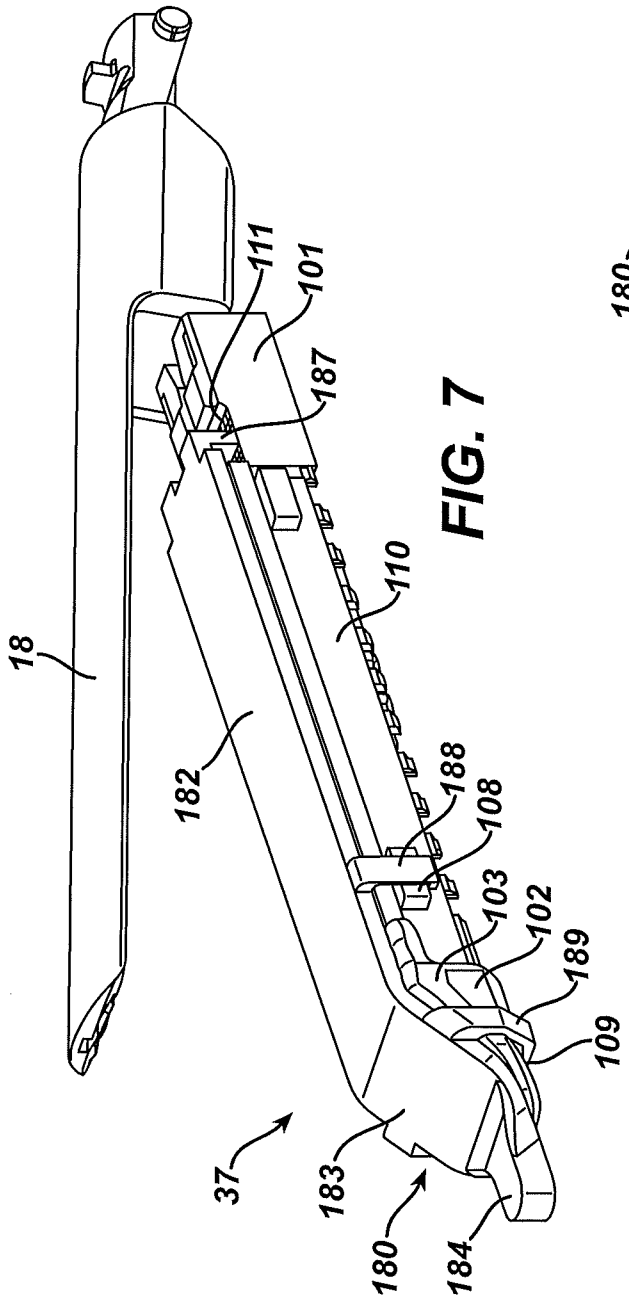
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FIG. 7

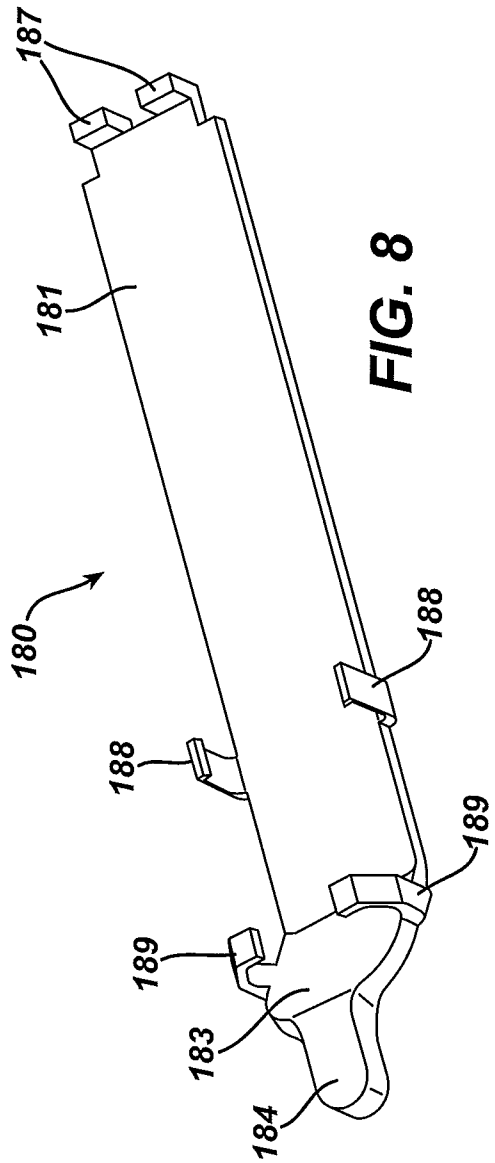
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FIG. 8

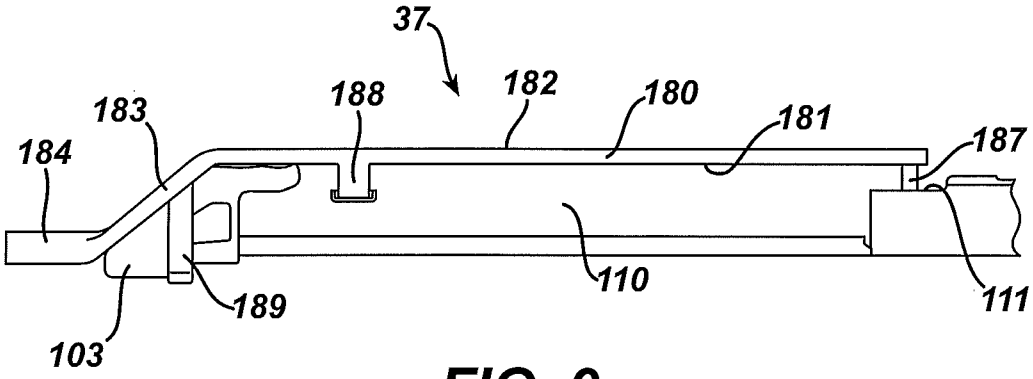
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FIG. 9

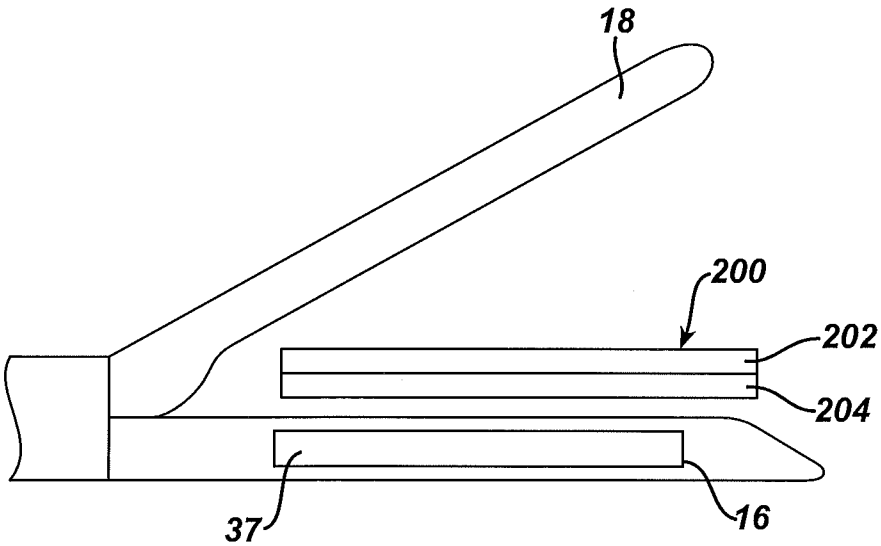
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FIG. 10

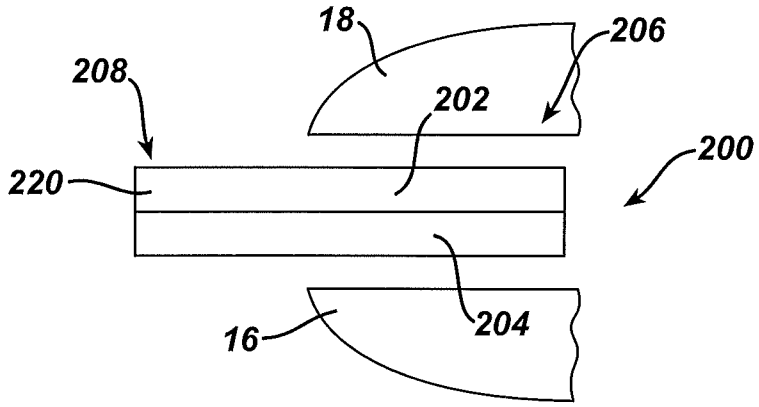

FIG. 11A

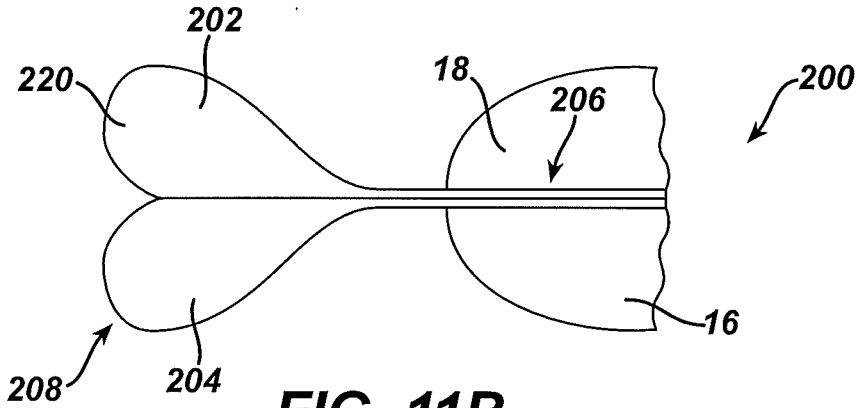

FIG. 11B

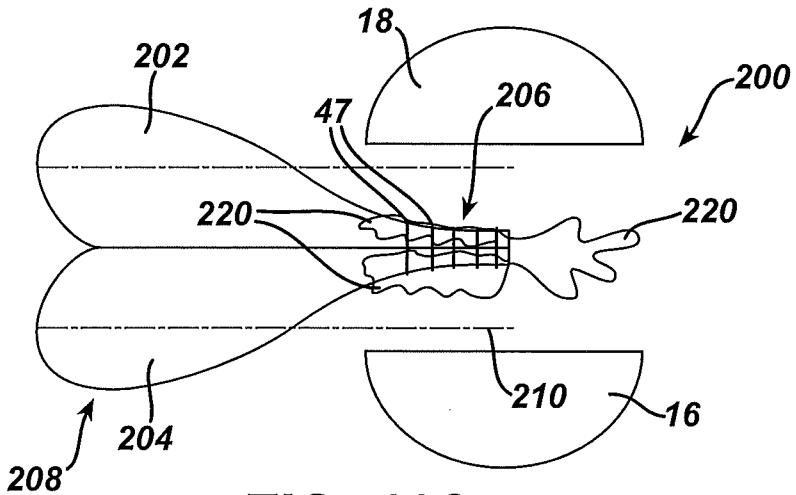

FIG. 11C

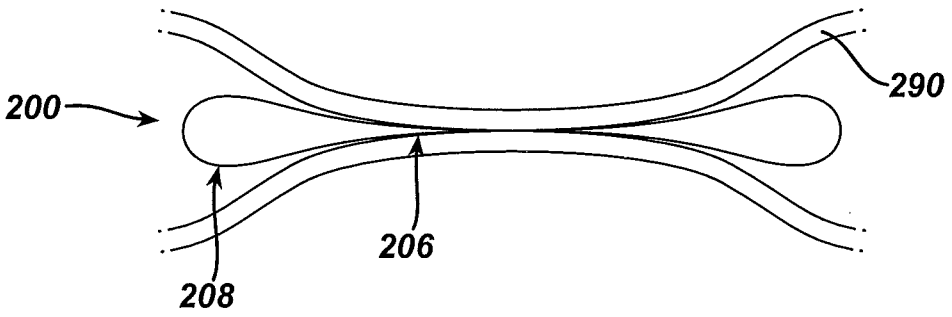

FIG. 12A

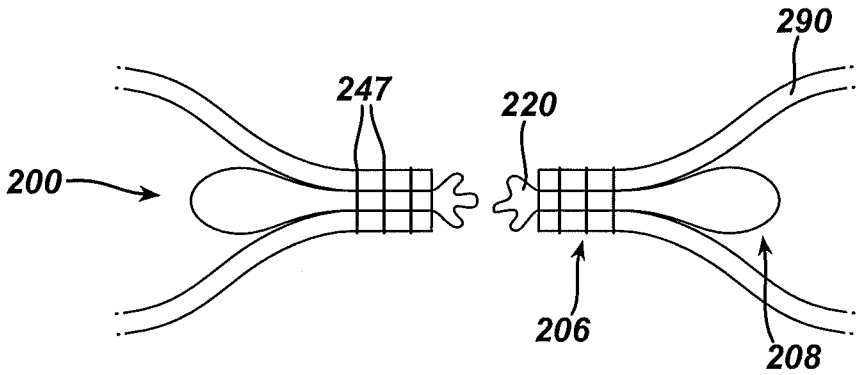

FIG. 12B

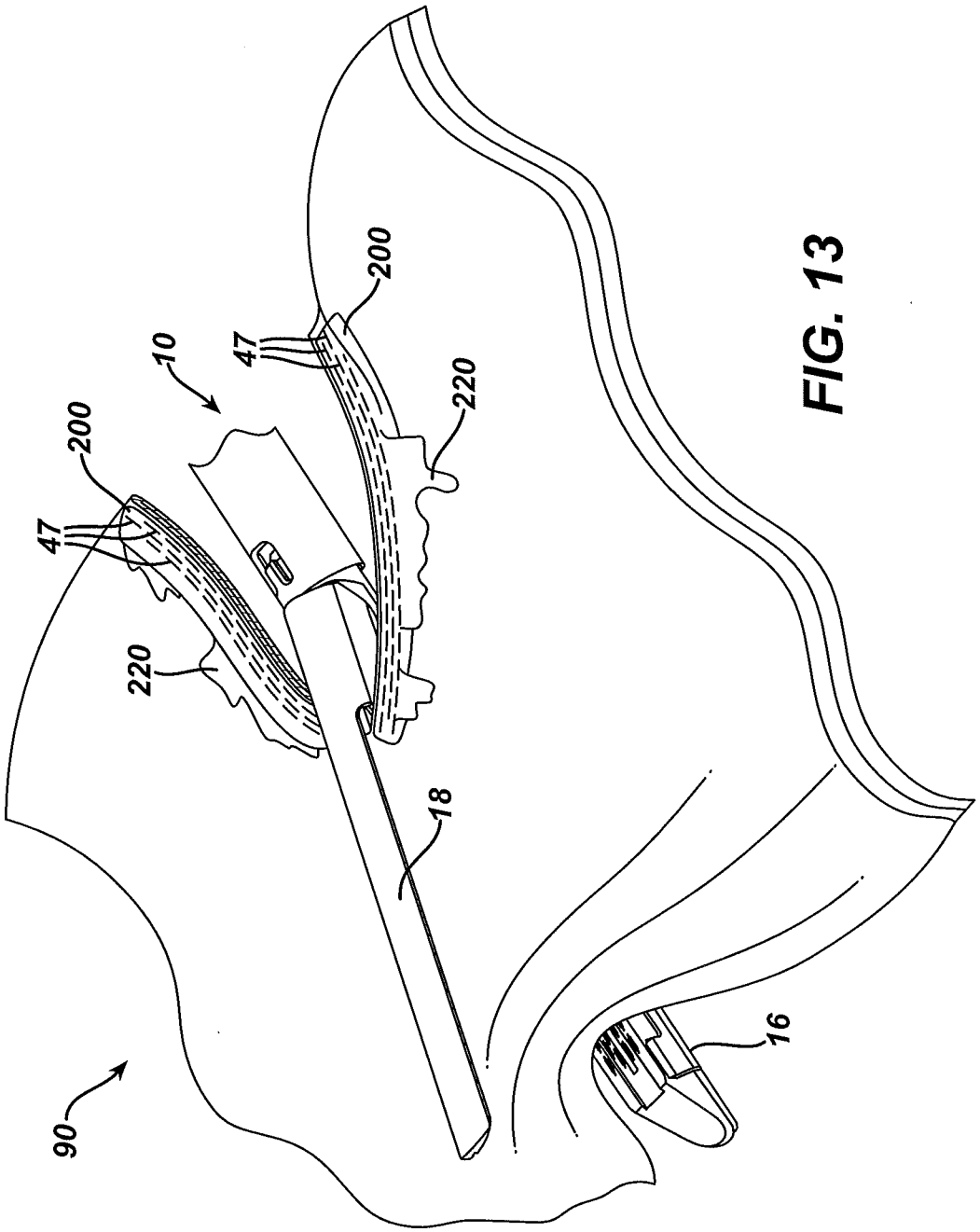

FIG. 13

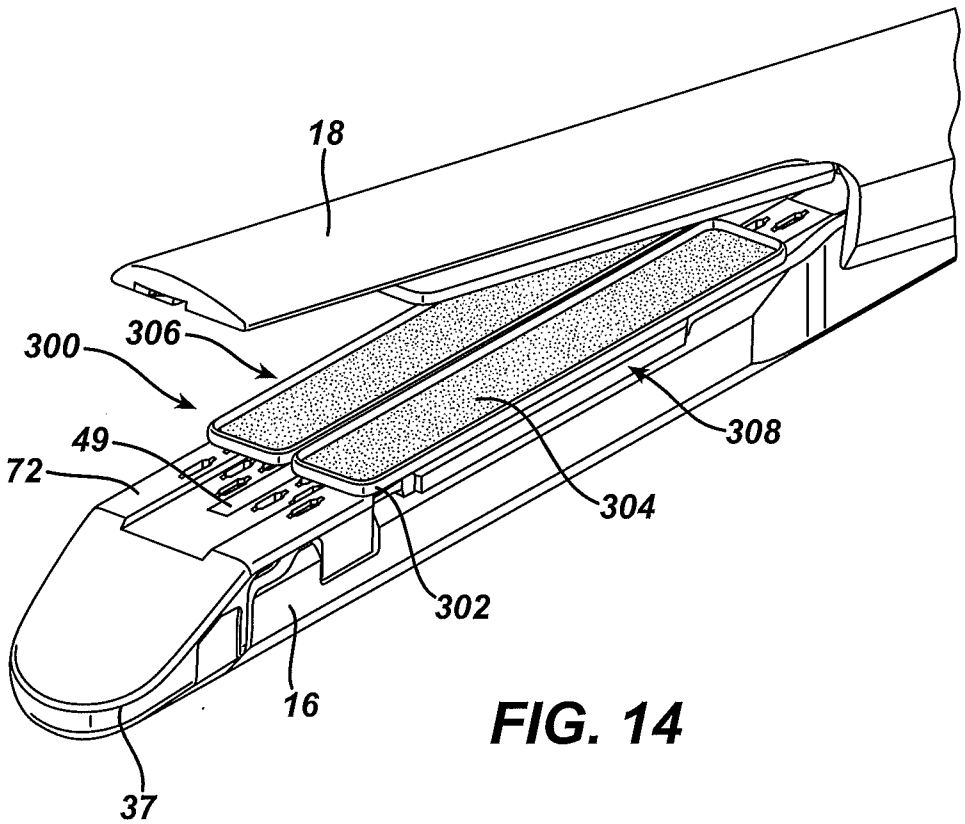

FIG. 14

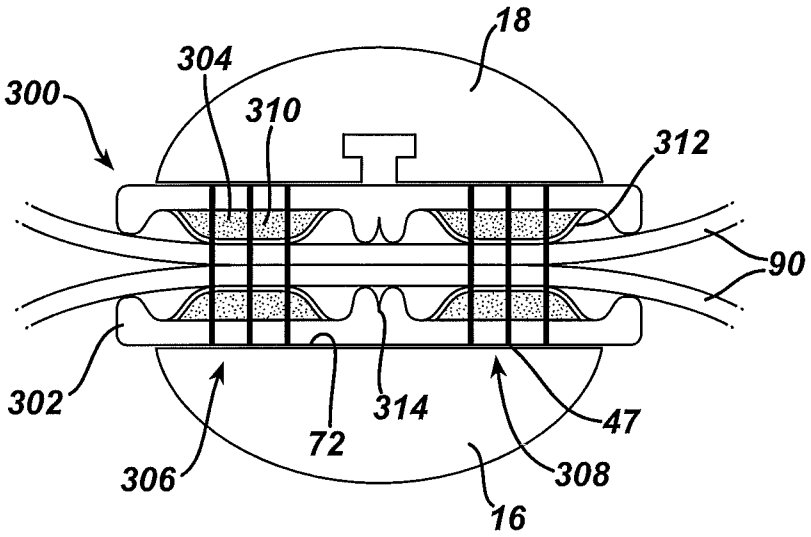
18
304
300
310
312
90
302
72
314
47
306
308
16

FIG. 15

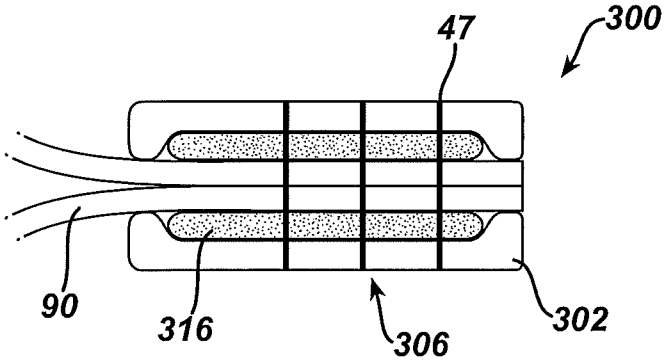
47
300
90
316
306
302

FIG. 16

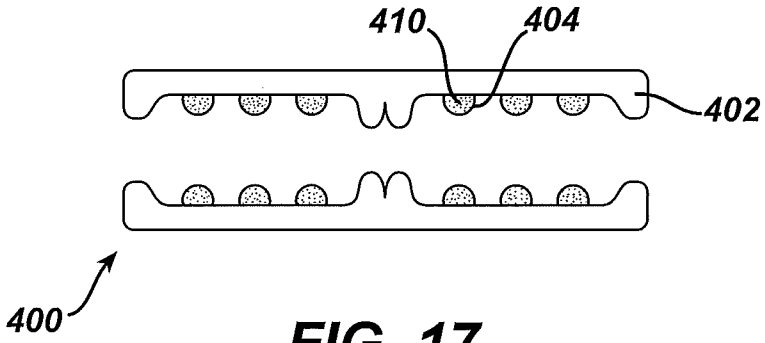

FIG. 17

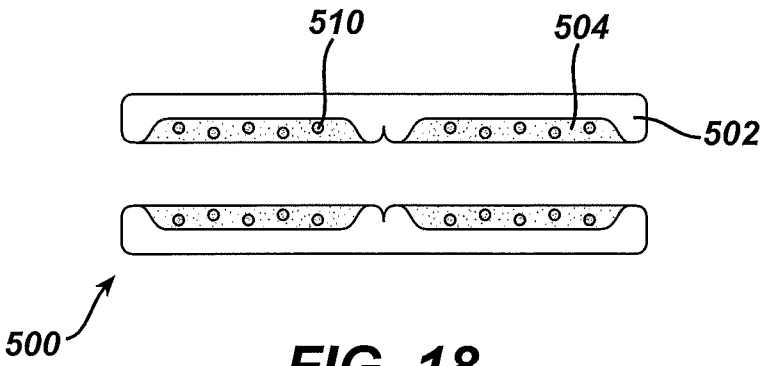

FIG. 18

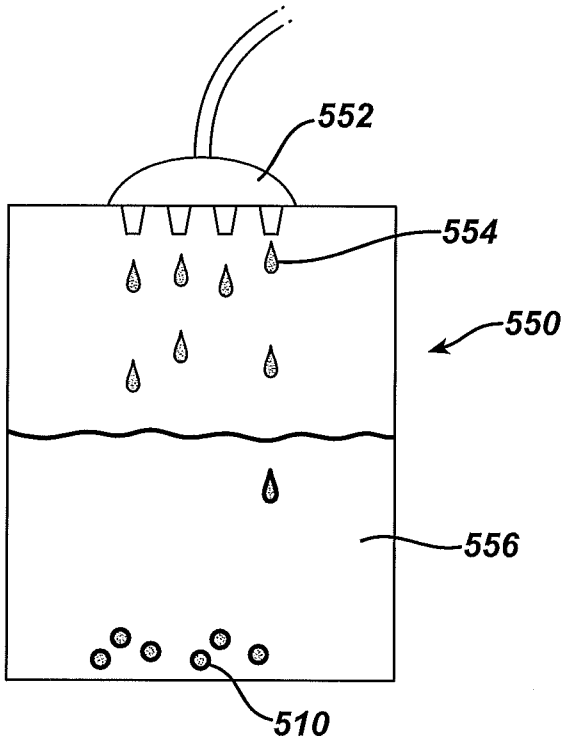

FIG. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/054401

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/072
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/120994 A1 (MURRAY MICHAEL A [US] ET AL) 14 May 2009 (2009-05-14) paragraphs [0016] - [0018], [0034], [0035], [0042]; figures 2,3	1-15
A	US 2011/042442 A1 (VIOLA FRANK J [US] ET AL) 24 February 2011 (2011-02-24) paragraph [0094]	11,14
A	US 2006/108393 A1 (HEINRICH RUSSELL [US] ET AL) 25 May 2006 (2006-05-25) paragraph [0094]	11,14
X,P	WO 2011/143184 A1 (ETHICON ENDO SURGERY INC [US]; HULL JOANNE [US]; HABERSTICH WELLS D [U) 17 November 2011 (2011-11-17) claim 16; figure 7	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 November 2012	07/12/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Barton, Simon

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/054401

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:

Claim 20 relates to a method excluded as a method of treatment by surgery, see Rules 39,67 EPC

2. [X] Claims Nos.: 16-19
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 20

Claim 20 relates to a method excluded as a method of treatment by surgery, see Rules 39,67 EPC

Continuation of Box II.2

Claims Nos.: 16-19

The presence of two independent device claims 1,16 with various selections of features renders unclear the definition of the claimed invention, contrary to the requirements of Article 6 PCT. The search is limited to claim 1 and to claims dependent thereon, to the extent that the dependent claims can be considered clearly to further define the invention of claim 1.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/054401

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009120994 A1	14-05-2009	NONE	
US 2011042442 A1	24-02-2011	AU 2007200915 A1	11-10-2007
		CA 2579683 A1	24-09-2007
		EP 1836974 A2	26-09-2007
		JP 2007252910 A	04-10-2007
		JP 2012183321 A	27-09-2012
		US 2006271104 A1	30-11-2006
		US 2011042442 A1	24-02-2011
US 2006108393 A1	25-05-2006	AU 2005295477 A1	27-04-2006
		CA 2584019 A1	27-04-2006
		EP 1804682 A2	11-07-2007
		JP 4801083 B2	26-10-2011
		JP 2008516698 A	22-05-2008
		JP 2009082727 A	23-04-2009
		US 2006108393 A1	25-05-2006
		US 2011036889 A1	17-02-2011
		US 2011147432 A1	23-06-2011
		US 2011147435 A1	23-06-2011
		WO 2006044800 A2	27-04-2006
WO 2011143184 A1	17-11-2011	AU 2011251988 A1	15-11-2012
		US 2011278346 A1	17-11-2011
		WO 2011143184 A1	17-11-2011