



- (51) **International Patent Classification:**
A61B 17/122 (2006.01)
- (21) **International Application Number:**
PCT/IB2016/054408
- (22) **International Filing Date:**
24 July 2016 (24.07.2016)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
62/196,323 24 July 2015 (24.07.2015) US
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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,

BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

- (54) **Title:** THICKNESS-ADJUSTABLE HEMOSTATIC CLIPS, CLIP APPLIERS, AND APPLICATIONS THEREOF

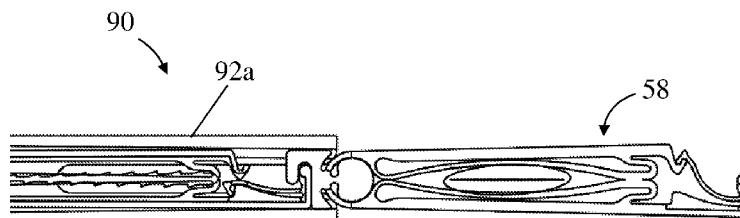


FIG. 11F

- (57) **Abstract:** Hemostatic clips, clip applicators, and applications thereof, for ligating bodily organs or tissues in a subject. The clip and clip applicators are configured to structurally conform to various thicknesses of bodily organs or tissues. In exemplary embodiments, the hemostatic clip includes pivotally linked clip arm members, wherein at least one has an outer rigid clip arm member, and an inner clip arm member being resilient and elastic. The clip includes a locking mechanism for locking together the clip arms. The hemostatic clip shifts from a non-stressed fully opened configuration to a stressed locked configuration with compressive forces being applied to a bodily organ or tissue. Inner resilient clip arm member of the clip facilitates structural conformity to various thicknesses of bodily organs or tissues, and provides an efficient, long lasting, and safe tissue ligation.



THICKNESS-ADJUSTABLE HEMOSTATIC CLIPS, CLIP APPLIERS, AND APPLICATIONS THEREOF

5 RELATED APPLICATION

This application claims the benefit of priority under 35 USC 119(e) of U.S. Provisional Patent Application No. 62/196,323, filed July 24, 2015, entitled "Thickness-Adjustable Hemostatic Clips, Clip Appliers, And Methods Of Use", the contents of which are incorporated herein by reference in their entirety.

10 FIELD OF THE INVENTION

The present invention, in some embodiments thereof, relates to surgical type hemostatic clips, clip appliers, and applications thereof, suitable for ligating bodily organs or tissues in a subject.

15 BACKGROUND

During many surgical procedures blood vessels or other tubular structure have to be ligated and cut. Prior art includes various teachings about devices and techniques applicable for ligating bodily organs or tissues, such as blood vessels, among other possible bodily organs or tissues in a subject. Hemostatic clips are well known and commonly used in such teachings. Prior art also includes various teachings about using medical devices and procedures for applying surgical clips. For example, PCT Int'l. Appl. Pub. No. WO 2015/040621 A1, of same applicant/assignee as the present invention, discloses a laparoscopic clip applier which includes multiple clips housed in a rigid sleeve, where the arms of the clips are oriented lengthwise in the sleeve, and a deployment mechanism for deploying the clips from a distal end of the sleeve via a perforation made by a needle provided with the distal end of the sleeve.

In spite of extensive teachings in the field and art of the invention, and in view of significant limitations and potential problems associated with such teachings, there is an on-going need for developing and implementing new or/and improved hemostatic clips, clip appliers, and applications thereof, that are effective in overcoming such limitations or problems in medical procedures of, or involving, ligating bodily organs or tissues in a subject.

30 SUMMARY OF THE INVENTION

The present invention, in some embodiments thereof, relates to surgical type hemostatic clips, clip appliers, and applications thereof, for ligating bodily organs or tissues in a subject. In exemplary embodiments, the present invention relates to a thickness-adjustable hemostatic clip and clip applier. In

exemplary embodiments, the clip applier is suitable for using the herein disclosed thickness-adjustable hemostatic clip. Exemplary embodiments of the present invention also relate to a method for ligating a bodily organ or tissue in a subject, for example, using the herein disclosed thickness-adjustable hemostatic clip and the clip applier.

5 In exemplary embodiments, the hemostatic clip of the invention includes pivotally linked first and second clip arm members, wherein at least one of the clip arm members has an outer rigid clip arm member and an inner clip arm member being resilient and elastic. In exemplary embodiments, the hemostatic clip further includes a locking mechanism configured for locking together the clip arms. In exemplary embodiments, the hemostatic clip shifts from a non-stressed fully opened configuration to a
10 stressed locked configuration in which compressive forces are being applied to the bodily organ or tissue. In exemplary embodiments, the inner resilient clip arm member disposed within the herein disclosed hemostatic clip facilitates structural conformity of the clip to various thicknesses of bodily organs or tissues, and provides an efficient, long lasting, and safe tissue ligation. Such exemplary features, among others, of the herein disclosed invention may provide important advantages over currently known and
15 used hemostatic clips, clip appliers, and applications thereof, for ligating bodily organs or tissues in a subject.

According to an aspect of some embodiments of the present invention, there is provided a thickness-adjustable hemostatic clip comprising: a first clip arm having a first clip arm distal end; a second clip arm having a second clip arm distal end, the second clip arm opposes and is pivotally linked to the
20 first clip arm at a shared proximal end, and the second clip arm is movable relative to the first clip arm from a non-stressed fully opened clip configuration wherein the first clip arm distal end is distanced from the second clip arm distal end by a predetermined distance, to a stressed locked clip configuration wherein the first clip arm distal end is in proximity with or contacts the second clip arm distal end; wherein at least one of the first and second clip arms includes an outer rigid clip arm member connected to an inner
25 resilient elastic clip arm member having a tissue contacting surface; and a locking mechanism configured for applying resistive force to the first clip arm distal end or to the second clip arm distal end, thereby locking the first clip arm distal end to the second clip arm distal end during the locked clip configuration, so as to prevent self-opening of the hemostatic clip.

According to such an embodiment of the hemostatic clip, the first and second clip arms, when
30 deployed in the locked clip configuration, are configured for applying compression and clamping forces to a bodily organ or tissue via the inner resilient elastic clip arm member while allowing the inner resilient elastic clip arm member to compress or shift laterally towards a respective the outer rigid clip arm member, such that in response to the deployment, the first and second clip arms are conformable to a compressed and clamped shape of the bodily organ or tissue while exerting clamping forces thereto.

According to some embodiments of the invention, the outer rigid arm member is configured to prevent deformation thereof in response to elastic deformation of the inner resilient elastic clip arm member and to limit expansion of the inner resilient elastic clip arm member.

According to some embodiments of the invention, the outer rigid clip arm member joins the inner resilient elastic clip arm member at two separate joining portions, whereby the outer and inner clip arm members enclose a gap extending between the joining portions, the gap separates a roof surface of the outer rigid clip arm member away from a roof-contact surface of the inner resilient elastic clip arm member. According to some embodiments of the invention, the inner resilient elastic clip arm member is configured for laterally bending or protruding towards an opposing inner arm member. According to some
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embodiments of the invention, the gap is sized for accommodating the inner resilient elastic clip arm member conforming to tissue and outwardly bending toward the outer rigid clip arm member, until at least part of the roof-contact surface contacts at least part of the roof surface.

According to some embodiments of the invention, a first and a second of the at least one inner resilient elastic clip arm member are configured to apply a pressure of up to about 150 gr/mm² to the
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bodily organ or tissue, wherein the applied pressure is constant or linearly rising in relation to thickness of tissue located between the first and second inner resilient elastic clip arms, under the compression and clamping forces applied to the bodily organ or tissue before being restricted in expansion by each the outer rigid clip arm member.

According to some embodiments of the invention, a first and a second of the at least one inner resilient elastic clip arm members are configured to apply a compressive pressure above 150 gr/mm² to
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the bodily organ or tissue, wherein the applied pressure rapidly rises in relation to thickness of compressed material of the first and second inner resilient elastic clip arm members or of compressed tissue therebetween when the first and second inner resilient elastic clip arm members are in close contact with respective the outer rigid clip arm members.

According to some embodiments of the invention, a first and a second of the at least one inner resilient elastic clip arm members are configured to apply a compressive pressure of at least 5 gr/mm² when separated by a distance of at least 0.1 mm therebetween.
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According to some embodiments of the invention, a first and a second of the at least one inner resilient elastic clip arm members are configured to apply a compressive pressure in a range of between
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about 10 gr/mm² and about 150 gr/mm² when separated by a distance in a range of between about 0.2 mm and about 0.8 mm therebetween.

According to some embodiments of the invention, a first and a second of the at least one inner resilient elastic clip arm members are configured for approaching each other and reducing a gap therebetween, while continuously conforming to the compressed shape of the bodily organ or tissue

clamped therebetween in response to gradual shrinking of the bodily organ or tissue during or/and after necrosis thereof.

According to some embodiments of the invention, each inner resilient elastic clip arm member is configured for evenly distributing pressure exerted on the bodily organ or tissue in contact therewith in response to the deployment.

According to some embodiments of the invention, the locking mechanism comprises a hook having a first end connected to the first clip arm distal end. According to some embodiments of the invention, the hook comprises a second end having a hook flange with a follower surface, wherein the hook first end is adapted for slidably engaging a cam surface provided on the second clip arm distal end, in response to the first and second clip arms moving from the opened clip configuration to the locked clip configuration. According to some embodiments of the invention, the first and second clip arms shift into the locked clip configuration following the hook flange reaching and fitting into a niche positioned beyond the cam surface. According to some embodiments of the invention, the first and second clip arms, and the locking mechanism, are integrally structured and manufactured from a single piece of material.

According to some embodiments of the invention, the hemostatic clip further comprises an interconnecting mechanism configured for sequentially chaining lengthwise, one after another, a plurality of the hemostatic clip, wherein a hemostatic clip proximal end includes a tail coupler connectable to a head coupler provided at the first clip arm distal end or at the second clip arm distal end.

According to some embodiments of the invention, opposing two of the inner resilient elastic clip arm members are configured to apply a compressive pressure of at least 5 gr/mm^2 when separated by a distance of at least 0.1 mm therebetween. According to some embodiments of the invention, opposing two of the inner resilient elastic clip arm members are configured to apply a compressive pressure in a range of between about 10 gr/mm^2 and about 150 gr/mm^2 when separated by a distance in a range of between about 0.2 mm and about 0.8 mm therebetween. According to some embodiments of the invention, opposing two of the inner resilient elastic clip arm members are configured for approaching each other and reducing a gap therebetween while being continuously conformable to the compressed and clamped shape of the bodily organ or tissue clamped therebetween, in response to gradual shrinking of the bodily organ or tissue during or/and after necrosis thereof.

According to some embodiments of the invention, the inner resilient elastic clip arm member is configured for evenly distributing pressure exerted on periphery of the bodily organ or tissue in contact therewith in response to the deployment and compressing of a ligated bodily organ or tissue.

According to an aspect of some embodiments of the present invention, there is provided a clip applier for deploying hemostatic clips onto a bodily organ or tissue in a subject, the clip applier comprising: at least one thickness-adjustable hemostatic clip, including a distal-most thickness-adjustable hemostatic

clip, comprised of: a first clip arm having a first clip arm distal end; a second clip arm having a second clip arm distal end, movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip; and a locking mechanism configured for locking the first clip arm distal end to the second clip arm distal end, so as to prevent self-opening of the hemostatic clip; wherein at least one of the first and second clip arms includes an outer rigid clip arm member connected to an inner resilient elastic clip arm member having a tissue contacting surface, such that when deployed, the clip arm members are configured for applying clamping forces to a bodily organ or tissue via each inner resilient elastic clip arm member while allowing each inner resilient elastic clip arm member to compress or shift laterally towards a respective rigid outer clip arm member, such that in response to the deployment, the first and second clip arms conform to a compressed shape of the bodily organ or tissue; and a trigger mechanism including an inner sleeve and configured for sliding and advancing the inner sleeve from a retracted position that uncovers the distal-most hemostatic clip, to a protruding position that covers the distal-most hemostatic clip.

According to such an embodiment of the hemostatic clip applier, the inner sleeve, when advanced to the protruding position over the first and second clip arms of the distal-most hemostatic clip effects moving of the first and second clip arms to approach each other so as to self-lock the first and second clip arms by the locking mechanism of the distal-most hemostatic clip.

According to some embodiments of the invention, the distal-most hemostatic clip includes a first and a second of the at least one inner resilient elastic clip arm member, and a first and a second of the respective outer rigid clip arm member, wherein the inner sleeve includes two opposing tracks sized and shaped for accommodating corresponding runner surfaces of the respective outer rigid clip arm members in contact therewith, when in the protruding position, thereby confining and defining a maximal achievable gap between the first and second inner resilient elastic clip arm members for the deployment, when the first and second inner resilient elastic clip arm members contact the respective outer rigid clip arm members.

According to some embodiments of the invention, the distal-most hemostatic clip includes a first and a second of the at least one inner resilient elastic clip arm member, and wherein the hemostatic clip and the trigger mechanism are shaped and sized for forcing the first and second inner resilient elastic clip arm members to align in a predetermined formation in which distance between the first and second clip arm distal ends is equal to or less than a predetermined opening that allows shifting of the first and second clip arms into the locked clip configuration upon the inner sleeve reaching the protruding position. According to some embodiments of the invention, the opposing tracks are parallel to each other.

According to an aspect of some embodiments of the present invention, there is provided a clip applier for ligating a bodily organ or tissue in a subject, the clip applier comprising: at least one hemostatic

clip, including a distal-most hemostatic clip comprised of: a first clip arm having a first clip arm distal end; a second clip arm having a second clip arm distal end, the second clip arm opposes and is pivotally linked to the first clip arm at a shared proximal end, and the second clip arm is movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip; and a locking mechanism configured to lock together the first and second clip arm distal ends to a closed clip height being smaller than an opened clip height of a non-stressed fully opened clip configuration; and a clip pressing mechanism, including a sliding press, and configured for selectively moving the sliding press across the distal-most hemostatic clip between a fully retracted position proximal to the distal-most hemostatic clip, and a fully protruded position across the distal-most hemostatic clip, so as to limit the opened clip height of the distal-most hemostatic clip to a maximal opened clip height being equal to or less than the closed clip height.

According to such an embodiment of the hemostatic clip applier, when the clip applier is deployed, shifting the sliding press from a retracted position to the fully protruded position effects gradual closing of the hemostatic clip by decreasing distance between the first and second clip arm distal ends, at least until reaching the closed-clip height, so as to activate the locking mechanism to lock together the first and second clip arm distal ends at the closed clip height, for facilitating ligation of the bodily organ or tissue.

According to some embodiments of the invention, the sliding press includes a tubular member. According to some embodiments of the invention, the tubular member is in a form of an inner sleeve axially slidable in a lumen of an outer sleeve, wherein the inner sleeve is configured to be withdrawn proximal to distal end of the outer sleeve when the clip pressing mechanism is in the fully retracted position, and is configured to protrude at least partially distal to the outer sleeve distal end when the clip pressing mechanism is in the protruding position. According to some embodiments of the invention, the outer sleeve is in a form of a needle or/and the outer sleeve distal end includes a sharp edge. According to some embodiments of the invention, the tubular member includes an inner lumen dimensioned for limiting opening of the distal-most hemostatic clip to the maximal opened clip height.

According to some embodiments of the invention, the clip applier is configured such that retracting the sliding press to the fully retracted position when the first and second clip arm distal ends are locked together into a locked configuration via the locking mechanism, effects release and ejection of the distal-most hemostatic clip therefrom.

According to some embodiments of the invention, the clip applier further comprises a biasing mechanism provided between the first and second clip arms, and configured for compressing a ligated bodily organ or tissue while being deformed to outer periphery of the compressed ligated bodily organ or tissue. According to some embodiments of the invention, the biasing mechanism is part of the distal-most hemostatic clip. According to some embodiments of the invention, the biasing mechanism comprises an

inner clip arm member, wherein each of the first and second clip arms includes an outer clip arm member connected to a corresponding the inner clip arm member, wherein each inner clip arm member has a tissue contacting surface being conformable or/and displaceable in response to the compressing of the ligated bodily organ or tissue.

5 According to some embodiments of the invention, the distal-most hemostatic clip, when in the locked configuration, is configured for applying compression and clamping forces to the bodily organ or tissue via each the inner clip arm member while allowing the tissue contacting surface to at least partially conform to the outer clip arm member or/and to a compressed and clamped shape of the bodily organ or tissue, in response to ligating of the bodily organ or tissue, wherein each the outer arm clip member is
10 configured for preventing deformation thereof in response to the conformity of the inner arm clip member tissue contacting surface.

According to some embodiments of the invention, the inner clip arm member is compactable or/and bendable towards the outer clip arm member in response to the conformity. According to some embodiments of the invention, the outer clip arm member joins the inner clip arm member at two separate
15 joining portions, whereby the outer and inner clip arm members enclose a gap extending between the joining portions, the gap separates a roof surface of the outer clip arm member away from a roof-contact surface of the inner clip arm member. According to some embodiments of the invention, the inner clip arm member is configured for laterally bending or protruding towards an opposing inner clip arm member. According to some embodiments of the invention, the gap is sized for accommodating the inner clip arm
20 member conforming to tissue and outwardly bending toward the outer clip arm member, until at least part of the roof-contact surface contacts at least part of the roof surface.

According to some embodiments of the invention, a first and a second of the at least one inner clip arm member are configured to apply a pressure of up to about 150 gr/mm² to the bodily organ or tissue, wherein the applied pressure is constant or linearly rises in relation to thickness of tissue located
25 between the first and second inner clip arms, under the compression and clamping forces applied to the bodily organ or tissue before being restricted in expansion by each the outer clip arm member.

According to some embodiments of the invention, a first and a second of the at least one inner clip arm members are configured to apply a compressive pressure above 150 gr/mm² to the bodily organ or tissue, wherein the applied pressure rapidly rises in relation to thickness of compressed bodily tissue
30 or organ of the first and second inner clip arm members or of compressed tissue therebetween when the first and second inner clip arm members are in close contact with respective the outer clip arm members.

According to some embodiments of the invention, a first and a second of the at least one inner clip arm members are configured to apply a compressive pressure of at least 5 gr/mm² when separated by a distance of at least 0.1 mm therebetween. According to some embodiments of the invention, a first

and a second of the at least one inner clip arm members are configured to apply a compressive pressure in a range of between about 10 gr/mm² and about 150 gr/mm² when separated by a distance in a range of between about 0.2 mm and about 0.8 mm therebetween. According to some embodiments of the invention, a first and a second of the at least one inner clip arm members are configured for approaching each other and reducing a gap therebetween while continuously conforming to the compressing of the bodily organ or tissue clamped therebetween in response to gradual shrinking of the bodily organ or tissue during or/and after necrosis thereof.

According to some embodiments of the invention, each inner clip arm member is resilient elastic and configured for resisting shaping thereof. According to some embodiments of the invention, each inner clip arm member is configured for evenly distributing pressure exerted on periphery of the bodily organ or tissue in contact therewith in response to the compressing of the ligated bodily organ or tissue.

According to an aspect of some embodiments of the present invention, there is provided a method for ligating a bodily organ or tissue in a subject, the method comprising: providing a distal-most hemostatic clip configured for surrounding the bodily organ or tissue, wherein the distal-most hemostatic clip comprises a first clip arm having a first clip arm distal end and a second clip arm having a second clip arm distal end, the second clip arm opposes and is pivotally linked to the first clip arm at a shared proximal end, and the second clip arm is movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip; providing a biasing mechanism between the first and second clip arms and allowing the biasing mechanism to occupy a space between the first and second clip arms and the bodily organ or tissue; gradually closing the hemostatic clip over the bodily organ or tissue by forcibly decreasing distance between the first and second clip arm distal ends; and locking together the first and second clip arm distal ends to a closed clip height, via activating a locking mechanism; wherein the gradually closing or/and the locking effects the biasing mechanism into compressing and clamping the bodily organ or tissue, while being deformed at least partially into an outer periphery of the compressed and clamped bodily organ or tissue.

According to some embodiments of the invention, the providing includes providing the distal-most hemostatic clip in a clip applicator, the clip applicator comprises a clip pressing mechanism, including a sliding press, and configured for selectively moving the sliding press across the distal-most hemostatic clip between a fully retracted position proximal to the distal-most hemostatic clip, and a fully protruded position across the distal-most hemostatic clip, so as to limit an opened clip height of the distal-most hemostatic clip to a maximal opened clip height.

According to some embodiments of the invention, the method further comprises releasing and ejecting the distal-most hemostatic clip from the clip applicator. According to some embodiments of the invention, the releasing and ejecting includes retracting the sliding press to the fully retracted position

after the first and second clip arm distal ends are locked together via the locking mechanism. According to some embodiments of the invention, the moving of the sliding press to the fully protruded position over the hemostatic clip initiates the activating of the locking mechanism.

5 According to some embodiments of the invention, the gradually closing the hemostatic clip includes the moving of the sliding press from the retracted position to the fully protruded position. According to some embodiments of the invention, the maximal opened clip height is equal to or less than the closed clip height.

10 According to some embodiments of the invention, each of the first and second clip arms comprises an outer arm member, wherein the biasing mechanism includes at least one resilient elastic inner clip arm member connected to a corresponding the inner clip arm member, wherein each inner clip arm member has a tissue contacting surface being conformable or/and displaceable in response to compressing of a ligated bodily organ or tissue.

15 According to some embodiments of the invention, the gradually closing or/and the locking includes applying compression forces to the bodily organ or tissue via the at least one inner clip arm member while allowing the tissue contacting surface to at least partially conform to the outer clip arm member or/and to a compressed and clamped shape of the bodily organ or tissue.

20 According to some embodiments of the invention, the inner clip arm member is configured for being compactable or/and bendable towards the outer clip arm member in response to the conformity, or/and the outer clip arm member connected thereto is configured for preventing deformation thereof in response to conformity of the inner clip arm member. According to some embodiments of the invention, the outer clip arm member joins the inner clip arm member at two separate joining portions, whereby the outer and inner clip arm members enclose a gap extending between the joining portions, the gap separates a roof surface of the outer clip arm member away from a roof-contact surface of the inner clip arm member.

25 According to some embodiments of the invention, the compressing and clamping the bodily organ or tissue while being deformed to the outer periphery thereof includes allowing the inner clip arm member to laterally bend or protrude towards a second opposing inner clip arm member. According to some embodiments of the invention, the gap is sized for accommodating the inner clip arm member conforming to tissue outwardly bending toward the outer clip arm member, until at least part of the roof-contact surface
30 contacts at least part of the roof surface.

According to some embodiments of the invention, the compressing and clamping the bodily organ or tissue includes applying a constant or linearly increasing compressive pressure of up to about 150 gr/mm² to the compressed and clamped bodily organ or tissue, wherein the applied pressure is constant or linearly rises in relation to thickness of tissue located between the first and second clip arms. According

to some embodiments of the invention, the compressing and clamping the bodily organ or tissue includes applying a compressive pressure above 150 gr/mm² to the bodily organ or tissue following full conformity of shape thereof to the corresponding outer clip arm member, wherein the applied pressure is constant or linearly rises in relation to thickness of tissue located between the first and second clip arms.

5 Unless otherwise defined, all technical or/and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods or/and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the
10 materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that
15 the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIGs. 1A - 1D are schematic side views showing a hemostatic clip, in a non-stressed fully opened
20 configuration (FIG. 1A), a closed and unlocked without a bodily organ or tissue configuration (FIG. 1B), a locked configuration without a bodily organ or tissue (FIG. 1C), and a stressed locked configuration (FIG. 1D), in accordance with some embodiments of the invention;

FIGs. 2A - 2B are schematic side views of an exemplary hemostatic clip, in a non-stressed fully opened configuration (FIG. 2A), and a locked configuration without a bodily organ or tissue (FIG. 2B), in
25 accordance with some embodiments of the invention;

FIGs. 3A - 3C is a schematic side view of an exemplary hemostatic clip which is thickness adjustable and conforms various tissue thicknesses upon ligating a bodily tissue or organ, in accordance with some embodiments of the invention;

FIG. 4 is a schematic isometric view of an exemplary hemostatic clip, in accordance with some
30 embodiments of the invention;

FIG. 5 is a photographic image of an exemplary hemostatic clip held in, and shown relative to, human fingers, in accordance with some embodiments of the invention;

FIGs. 6A - 6D are schematic side cut views of a portion of a clip applier which includes a hemostatic clip confined within a sleeve, wherein the clip is stressed locked and the sleeve is in a fully

protruded configuration (FIG. 6A), the clip is in a fully opened non-stressed configuration and the sleeve is in a retracted configuration (FIG. 6B), the clip is in a closed and about to be locked, and the sleeve is in a partially protruded configuration (FIG. 6C), and the clip is in a stressed locked configuration and the sleeve is in a partially retracted configuration (FIG. 6D), in accordance with some embodiments of the invention;

FIG. 7 is a schematic side cut view of another exemplary clip applier, in accordance with some embodiments of the invention;

FIG. 8 is a photographic image of an exemplary hemostatic clip confined within a sleeve of a hemostatic clip, when held in between human fingers, in accordance with some embodiments of the invention;

FIG. 9 is a side cut view illustration of a clip applier which includes a handle for operating the hemostatic clips of the invention;

FIG. 10 is a flow diagram of an exemplary embodiment of a method of ligating a bodily organ or tissue in a subject, using the herein disclosed hemostatic clip applier and hemostatic clip, in accordance with some embodiments of the invention; and

FIGs. 11A - 11G schematically illustrate steps (procedures / processes) of implementing the herein disclosed exemplary method of ligating a bodily organ or tissue in a subject, highlighting an exemplary clip applier during various stages of tissue ligation, in accordance with some embodiments of the invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to surgical type hemostatic clips, clip appliers, and applications thereof, for ligating bodily organs or tissues in a subject. In exemplary embodiments, the present invention relates to a thickness-adjustable hemostatic clip and clip applier. In exemplary embodiments, the clip applier is suitable for using the herein disclosed thickness-adjustable hemostatic clip. Exemplary embodiments of the present invention also relate to a method for ligating a bodily organ or tissue in a subject, for example, using the herein disclosed thickness-adjustable hemostatic clip and the clip applier.

In exemplary embodiments, the hemostatic clip of the invention includes pivotally linked first and second clip arm members, wherein at least one of the clip arm members has an outer rigid clip arm member and an inner clip arm member being resilient and elastic. In exemplary embodiments, the hemostatic clip further includes a locking mechanism configured for locking together the clip arms. In exemplary embodiments, the hemostatic clip shifts from a non-stressed fully opened configuration to a stressed locked configuration in which compressive forces are being applied to the bodily organ or tissue.

In exemplary embodiments, the inner resilient clip arm member disposed within the herein disclosed hemostatic clip facilitates structural conformity of the clip to various thicknesses of bodily organs or tissues, and provides an efficient, long lasting, and safe tissue ligation. Such exemplary features, among others, of the herein disclosed invention may provide important advantages over currently known and used hemostatic clips, clip applicators, and applications thereof, for ligating bodily organs or tissues in a subject.

Hemostatic clips are effective tools for ligating a blood vessel, or, other bodily organ or tissue. However, currently used clips or/and clip applicators are frequently associated with failure to effectively ligate a blood vessel, thereby causing continued bleeding in a subject. The inventors observed that a significant limitation and problem associated with currently employed hemostatic clips is non-conformity of the structural configuration of the clips to various thicknesses of blood vessels. Such structural non-conformity is associated with blood vessels being either too thin or too thick for the hemostatic clip to effect full ligation of the blood vessel. For example, structural non-conformity of a hemostatic clip to a relatively thin blood vessel results in a gap being formed between two arms of a closed hemostatic clip. Consequently, the clip may become loose, thereby, not effectively ligating the blood vessel or the tubular structure, and may even slide off the cut end of the blood vessel. Alternatively, for example, applying a clip to a relatively thick tissue, such as a larger vessel or other tubular structure in the subject's body, may result in excessive pressure being exerted upon the vessel wall, possibly tearing the vessel, causing premature necrosis and bleeding, or/and preventing closure of the clip on the vessel or tubular structure altogether.

While some prior art hemostatic clips may be associated with such complications caused by ineffective tissue ligation due to incompatibility to tissue thickness, the present invention aims to overcome this limitation and provides a hemostatic clip and clip applicator which are thickness adjustable, hence facilitate efficient ligations to various tissue thicknesses.

It is understood that the invention is not limited to the particular methodology, protocols, and anatomy, etc., described herein, as these may vary as the skilled artisan will recognize. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only, and is not intended to limit the scope of the invention. The following exemplary embodiments may be described in the context of exemplary bodily organ or tissue ligating procedures for ease of description and understanding. However, the invention is not limited to the specifically described devices and methods, and may be adapted to various clinical applications without departing from the overall scope of the invention.

An aspect of some embodiments of the present invention relates to a thickness-adjustable hemostatic clip including: a first clip arm having a first clip arm distal end and a second clip arm having a second clip arm distal end. The second clip arm opposes and is pivotally linked to the first clip arm at a

shared proximal end, and the second clip arm is movable relative to said first clip arm from a non-stressed fully opened clip configuration to a stressed locked clip configuration, wherein in the non-stressed fully opened clip configuration the first clip arm distal end is distanced from the second clip arm distal end by a predetermined distance, and in the stressed locked clip configuration the first clip arm distal end is in proximity with or contacts the second clip arm distal end. At least one of said first and second clip arms includes an outer rigid clip arm member connected to an inner resilient elastic clip arm member having a tissue contacting surface. The hemostatic clip further includes a locking mechanism configured for applying resistive force to the first clip arm distal end or to the second clip arm distal end, thereby locking the first clip arm distal end to the second clip arm distal end during the locked configuration, so as to prevent self-opening of the hemostatic clip. The first and second clip arms, when deployed in the locked clip configuration, while ligating a bodily organ or tissue, are configured for applying compression and clamping forces to the bodily organ or tissue via at least one of the inner resilient elastic clip arm member while allowing at least a portion of the inner resilient elastic clip arm member to compress or shift laterally towards a respective outer rigid clip arm member, such that in response to the clip deployment and ligating, the first and second clip arms are conformable to a compressed and clamped shape of said bodily organ or tissue.

Referring now to the drawings, FIGs. 1A - 1D are schematic side views showing a hemostatic clip according to some embodiments of the invention. Simplified illustrations of the hemostatic clip 10 of the invention for ligating the bodily organ or tissue which is bodily organ or tissue thickness-adjustable is shown. The hemostatic clip 10 includes a first clip arm 12 and a second clip arm 14 linked at a shared proximal end 26. The first clip arm 12 includes a first clip arm distal end 16 and the second clip arm 14 includes a second clip arm distal end 18. At least one of clip arms 12 and 14 includes an outer rigid clip arm member 24. At least one of clip arms 12 and 14 include an inner resilient elastic clip arm member 20. In some embodiments, at least one of clip arms 12 and 14 includes an outer rigid clip arm member 24 connected to an inner resilient elastic clip arm member 20. In some embodiments, each of clip arms 12 and 14 includes an outer rigid clip arm member 24 connected to an inner resilient elastic clip arm member 20. Inner resilient elastic clip arm member 20 may include a tissue contacting surface 22. Hemostatic clip 10 further includes a locking mechanism 28 including locking units 28a and 28b.

Hemostatic clip 10 may have a length within a range of between about 2 mm to about 50 mm.

The diameter of hemostatic clip may be less than about 7 mm, less than about 5 mm, less than about 4 mm, less than about 3 mm, less than about 2 mm or less than about 1 mm. Each possibility represents another exemplary embodiment of the invention.

Inner resilient elastic clip arm member 20 is configured such that various ranges of tissues thicknesses may be efficiently ligated by the hemostatic clip of the invention. In some embodiments, the

hemostatic clip 10 is suitable for ligating a bodily tissue or organ having a thickness within a range of between about 0.1 mm and about 10 mm, which may be compressible up to a compressed thickness within a range of between about 0.1 mm and 1 mm, where applicable.

5 Hemostatic clip 10 may exhibit a configuration selected from the group consisting of: non-stressed fully opened, closed and unlocked configuration, and stressed locked.

The following examples describe in details hemostatic clip 10 in the various configurations.

Referring to FIG. 1A, clip 10 is shown in a non-stressed fully opened configuration. In the fully opened configuration, first clip arm distal end 16 is distanced from second clip arm distal end 18 by a predetermined distance. In some embodiments, the term "predetermined distance" is interchangeable
10 with the term "closed clip height". In some embodiments, the predetermined distance is the maximal distance or height displayed between first clip arm distal end 16 and second clip arm distal end 18.

In some embodiments, the predetermined distance may display a height/distance value within the range of between about 0.3 mm to about 5 mm.

Referring to FIG. 1B, clip 10 is shown in a closed and unlocked without a bodily tissue or organ
15 ligated thereby. Compressive forces (shown by arrows) are operated on hemostatic clip 10 when confined within restricting boundaries, such as imposed by a sleeve of a clip applier, for example. The clip applier and the compressive forces operated on the hemostatic clip will be described in more details below. In the closed and unlocked without a bodily organ and tissue configuration, clip arm distal end 16 and clip arm distal end 18 are in close proximity and may or may not contact each other.

20 Referring to FIG. 1C, clip 10 is shown in a locked configuration. Locking mechanism 28 is locked and resistive forces (shown by arrows) are operated on the hemostatic clip. Clip arm distal end 16 and clip arm distal end 18 are in close proximity and may or may not contact each other.

Referring to FIG. 1D, clip 10 is shown in a stressed locked configuration. In this configuration first and second clip arms 12 and 14 apply compression and clamping forces towards a bodily organ or tissue
25 30 via at least one of inner resilient elastic clip arm member 20. The at least one of the inner resilient elastic clip arm member 20 conforms to the outer compressed shape, curvature or/and dimensions (e.g. thickness and/or shape) of bodily organ or tissue 30. For example, in response to ligating a bodily organ or tissue, at least a portion of the inner resilient elastic clip arm member 20 compresses laterally towards a respective outer rigid clip arm member 24. Optionally, additionally or alternatively, inner resilient elastic
30 clip arm member 20 laterally bends or protrudes towards an opposite inner resilient elastic clip arm member or clip arm. In response to ligating a bodily organ or tissue, outer rigid clip arm member 24 prevents deformation of clip arms 12 and 14. Locking mechanism 28 is closed and thereby opening of the hemostatic clip by resistive forces operated on the hemostatic clip is prevented. Clip arm distal end 16 and clip arm distal end 18 are in close proximity and may or may not contact each other.

According to some embodiments, clip arms 12 and 14 may be in close proximity in one of the following hemostatic clip 10 configurations: closed and unlocked configuration (no bodily tissue or organ being ligated), and stressed locked configuration (with a bodily tissue or organ being ligated). According to some embodiment, clip arm distal ends 16 and 18 may be in close proximity in one of the following hemostatic clip 10 configurations: closed and unlocked configuration (no tissue being ligated), and stressed locked configuration.

The term "close proximity" means that a space is present between first clip arm 12 and second clip arm 14. In some embodiment, the space diameter may depend on the clip configuration and/or the bodily tissue or organ dimensions (i.e. shape and thickness).

Ligating a bodily tissue or organ includes transition of the hemostatic clip from a non-stressed fully opened configuration (FIG. 1A) to a stressed locked configuration (FIG. 1D). Accordingly, and during ligating a bodily tissue or organ, the second clip arm 14 is movable relative to the first clip arm 12. By "movable relative to" it is meant that either one or both first clip arm 12 and second clip arm 14 are movable towards each other.

Ligating a bodily tissue or organ includes gradually closing hemostatic clip 10 over bodily organ or tissue 30, by forcibly decreasing distance between clip arm 12 and clip arm 14, or between clip arm distal end 16 and clip arm distal end 18. Ligating a bodily tissue or organ further includes locking together by locking mechanism 28 first and second clip arm distal ends 16 and 18.

Inner resilient elastic clip arm member 20 is configured to conform to various thicknesses of bodily organs or tissues. By "conform" or "conformity" it is meant that inner resilient elastic clip arm member 20 is shaped in response to ligating a bodily tissue or organ. In some embodiments, inner resilient elastic clip arm member 20 is bendable.

In some embodiments, inner resilient elastic clip arm member 20 is made of an elastic material. In some embodiments, inner resilient elastic clip arm member 20 is made of a biocompatible material.

Exemplary suitable elastic materials are, but not limited to, elastic type polymers, elastic metals, elastic metal alloys (e.g. nickel-titanium, stainless steel, cobalt chrome, Titanium), or a combination thereof.

During ligating a bodily organ or tissue, inner resilient elastic clip arm member 20 continuously conforms, optionally only partly, to the clamped bodily organ or tissue, while exerting compressing / clasping affecting pressure thereto, until full bodily organ or tissue ligation is accomplished. In some embodiments, inner resilient elastic clip arm member 20 evenly distributes pressure exerted on the bodily organ or tissue being ligated. In some embodiments, when only one of clip arms 12 and 14 includes an inner resilient elastic clip arm member 20, the inner resilient elastic clip arm distributes, optionally evenly,

pressure exerted on the bodily organ or tissue between the inner resilient elastic clip arm member 20 and an opposite clip arm member.

In some embodiments, inner resilient clip arm member 20 includes a tissue contacting surface 22. The tissue contacting surface 22 may be made from a material similar or not to the material inner resilient clip arm member 20 is made of. In some embodiments, inner resilient clip arm member 20 facilitates bodily organ or tissue grasping. In some embodiments, tissue contacting surface 22 may be disposed with serrations, teeth or rough surface.

Outer rigid clip arm member 24 is configured to support any deformation of inner resilient member 20 in response to bodily organ or tissue ligation. Outer rigid clip arm member 24 is further configured to limit expansion of inner resilient elastic clip arm member 20.

In accordance with those embodiments, outer rigid clip arm member 24 may be made of any suitable material as long as deformation in response to ligating a bodily tissue or organ of outer rigid clip arm member 24 is prevented. Some exemplary suitable materials are, but not limited to: Ni-Ti alloy, Titanium, or a combination thereof.

Shared proximal end 26 facilitates connection between clip arms 12 and 14. Shared proximal end 26 may be shaped and of any suitable structure that connects clip arms 12 and 14. For example, shared proximal end 26 may connect clip arms 12 and 14 by a hinge which may be integrally formed with at least one of clip arms 12 and 14 (an exemplary shared proximal end is described below with reference to FIG. 4).

Clip arms 12 and 14 are configured to apply compression and/or clamping forces towards the bodily organ or tissue via at least one of inner resilient elastic clip arm members 20 in response to ligating a bodily organ or tissue. In some embodiments, the pressure applied is constant. In some embodiments, the pressure applied linearly rises in relation to the stage of the bodily organ or tissue ligation. In some embodiments, the pressure applied depends on the bodily organ or tissue thickness. Optionally, during the course of ligation and prior to becoming restricted in expansion by outer rigid clip arm member 24, at least one of inner resilient elastic clip arm members 20 applies a pressure of up to about 300 gr/mm², or optionally, up to about 150 gr/mm², to the bodily organ or tissue.

Further optionally, when in close contact with outer rigid clip arm member 24, the at least one of inner resilient elastic clip arm members 20 applies a pressure of above 150 gr/mm² or of above 300 gr/mm² on the bodily organ or tissue.

Further optionally, the at least one inner resilient elastic clip arm members 20 applies a compressive pressure of at least 5 gr/mm², at least 10 gr/mm² or at least 15 gr/mm² when a distance of at least 0.1 mm separates between a first and a second inner resilient elastic clip arm members 20, or between a first inner resilient elastic clip arm member 20 and an opposite clip arm member. In some

embodiments, the at least one inner resilient elastic clip arm member 20 applies a compressive pressure in a range of between about 10 gr/mm² to about 150 gr/mm², when a distance in a range of between about 0.2 mm and about 0.8 mm separates between a first and a second inner resilient elastic clip arm member 20, or between a first inner resilient elastic clip arm member 20 and an opposite clip arm member.

5 Locking mechanism 28 includes locking units 28a and 28b, each is optionally provided at a different clip arm. Locking mechanism 28 is configured for applying resistive forces to at least one of first clip arm distal end 16 and second clip arm distal end 18, thereby locking the first clip arm distal end 16 to the second clip arm distal end 18. Further, locking mechanism 28 is configured to prevent self-opening of the hemostatic clip. Locking units 28a and 28b may each extend from first clip arm distal end 16 and first
10 clip arm distal end 18, respectively. Locking units 28a and 28b may each be integrally structured and manufactured from a single piece of material of first clip arm 12 and first clip arm 14.

Reference is now made to FIGs. 2A - 2B, which illustrate a schematic side view of an exemplary hemostatic clip 32 operative with some embodiments of the invention. Hemostatic clip 32 is an exemplary hemostatic clip 10 which includes inner resilient elastic clip arm member 48 (correspond to inner resilient
15 elastic clip arm member 20 of hemostatic clip 10) at each of first clip arm 34 and second clip arm 36 (correspond respectively to first clip arm 12 and second clip arm 14 of hemostatic clip 10). Further, hemostatic clip 10 demonstrates joint portion 44 which joins together inner resilient elastic clip arm member 48 with outer rigid clip arm member 46 (corresponds to outer rigid clip arm 24 of hemostatic clip 10). Similar to hemostatic clip 10, first clip arm 34 and second clip arm 36 of hemostatic clip 32 are linked
20 at a shared proximal end 42 (corresponds to shared proximal end 26 of hemostatic clip 10) and include a first clip arm distal end 38 (corresponds to first clip arm distal end 16 of hemostatic clip 10) and a second clip arm distal end 40 (corresponds to second clip arm distal end 18 of hemostatic clip 10), respectively. Further similar to hemostatic clip 10, locking mechanism 50 locks together first and second clip arm members 34 and 36. Inner resilient elastic clip arm member 48 may include a tissue contacting surface
25 (not shown, corresponds to tissue contacting surface 22 of hemostatic clip 10).

Joint portion 44 may be integral to at least one of clip arm members 34 and 36. Joint portion 44 may be a separate element connecting clip arm members 34 and 36. Joint portion 44 may be made from a material similar to rigid clip arm member 46. Alternatively, joint portion 44 may be made from the same material similar to inner resilient elastic clip arm member 48, including but not limited to at least one of Ni-
30 Ti alloy, Titanium, or other elastic biocompatible metal or polymer.

Outer rigid clip arm member 46 and inner resilient elastic clip arm member 48 enclose a gap that separates an inner surface of the outer rigid clip arm member 46 from a roof-contact surface of the inner resilient elastic clip arm member 48. In some embodiments, and depending on the dimensions of the bodily organ or tissue (i.e. shape and/or thickness) to be ligated and/or configuration of the hemostatic

clip (i.e. non-stressed fully opened, closed and unlocked without a bodily organ or tissue, and stressed locked), the gap, per each clip arm, is about 0.8 mm or less in maximal height, optionally about 0.5 mm or less, or optionally about 0.4 mm.

Inner resilient elastic clip arm members 48 present on each of clip arm 34 and clip arm 36 may have a space therebetween or may contact each other. The space depends on the clip's configuration (i.e. non-stressed fully opened, closed and unlocked without a bodily organ or tissue, or stressed locked) and/or the bodily tissue or organ dimensions. For example, when hemostatic clip 32 is closed and unlocked without a bodily organ or tissue or stressed locked the space diameter may be about 0.1 mm or less.

Referring to FIG. 2A, side view of hemostatic clip 32 in a non-stressed fully opened configuration is shown. Referring to FIG. 2B, side view of hemostatic clip 32 in a stressed locked configuration is shown.

Reference is now made to FIGs. 3A - 3C, which schematically illustrate a side view of the hemostatic clip 32 in accordance of an embodiment of the invention. Similar to hemostatic clip 10, hemostatic clip 32 is thickness adjustable and is compatible to various tissue thicknesses. The gap enclosed between outer rigid clip arm member 46 and inner resilient elastic clip arm member 48 is sized for accommodating various bodily tissue or organ thicknesses and may be reshaped according to the conformity of the inner resilient elastic clip arm member 48 to the bodily tissue or organ.

Referring to FIG. 3A, which illustrates thin bodily organ or tissue 52 conformity of hemostatic clip 32, the gap enclosed by outer rigid clip arm member 46 and inner resilient elastic clip arm member 48 may be slightly narrowed following tissue ligation.

Referring to FIG. 3B, which illustrates moderate thickness tissue 54 conformity of hemostatic clip 32, the gap enclosed by outer rigid clip arm member 46 and inner resilient elastic clip arm member 48 may be moderately narrowed and/or inner resilient elastic clip arm member 48 may outwardly bend toward the outer rigid clip arm member 46.

Referring to FIG. 3C, which illustrates thick tissue conformity 56 of hemostatic clip 32, the gap enclosed by outer rigid clip arm member 46 and inner resilient elastic clip arm member 48 may be substantially narrowed or completely diminished. Optionally, inner resilient elastic clip arm member 48 may outwardly bend toward the outer rigid clip arm member 46 until at least part of the roof contact surface of inner resilient elastic clip arm member 48 contacts at least part of the inner surface of outer rigid clip arm member 46.

Reference is now made to FIG. 4, which is an isometric view of hemostatic clip 58. Hemostatic clip 58 is an exemplary hemostatic clip 32 and includes a first clip arm 60 (corresponds to clip arm 34 of hemostatic clip 32) and a second clip arm 62 (corresponds to clip arm 36 of hemostatic clip 32), each includes inner resilient clip arm member 64 (corresponds to inner resilient clip arm 48 of hemostatic clip

32). The inner resilient clip arm member 64 includes a tissue contacting surface 36 disposed with teethes. Clip arms 60 and clip arm 62 are connected via an integrally formed hinge 68. Hemostatic clip 58 further includes a barrier 70 for blocking tissue from entering into hinge 68.

Hemostatic clip 58 includes a locking mechanism 72 which includes a hook first end 72a connected to first clip arm distal end 74 and a hook second end 72b connected to second clip arm distal end 76. The hook is having a hook flange 72c positioned on first clip arm distal end 74 which is adapted for slidably engaging a cam surface 72e provided on the second clip arm distal end 76. Locking mechanism 72 is activated in response to the first clip arm 60 and the second clip arm 62 shifting from the non-stressed fully opened configuration to the stressed locked configuration. First and second clip arms 60 and 62 shift into the stressed locked configuration following hook flange 72e reaching and fitting into a niche 72d positioned beyond flange 72c.

In some embodiments, first and second clip arms 60 and 62, and locking mechanism 72, are integrally structured and manufactured from a single piece of material. In some embodiments, first and second clip arms 60 and 62, and locking mechanism 72, are manufactured from different materials.

In some embodiments, the material may be any suitable material, including, but not limited to polymers, metals, metal alloys (e.g. nickel-titanium, stainless steel, cobalt chrome, Titanium), or a combination thereof.

Hemostatic clip 58 may further include an interconnecting mechanism 78 configured for sequentially chaining lengthwise, one after another, a plurality of hemostatic clips 58. Interconnecting mechanism 78 includes a head coupler 78b that may be positioned at the distal end of clip arm 60 or clip arm 62. Interconnecting mechanism 78 further includes a tail coupler 78a that may be positioned at the proximal end of clip 58. When a plurality of clips 58 are aligned sequentially and lengthwise, head coupler 78a of one clip 58 may connect another clip 58 via tail coupler 78b of the other clip 58 and thereby chain one after another, a plurality of hemostatic clips 58.

Reference is made to FIG. 5, which is a photographic image of an exemplary hemostatic clip 80 held in human fingers. The image shows the relative size of the hemostatic clip relative to that of human fingers.

An aspect of some embodiments of the present invention is provision of a clip applier for deploying hemostatic clips onto a bodily organ or tissue in a subject. In exemplary embodiments, the clip applier includes: at least one thickness-adjustable hemostatic clip, including a distal-most thickness-adjustable hemostatic clip, with: a first clip arm having a first clip arm distal end; a second clip arm having a second clip arm distal end, movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip; and a locking mechanism configured for

locking the first clip arm distal end to the second clip arm distal end, so as to prevent self-opening of the hemostatic clip.

In such exemplary embodiments, at least one of the first and second clip arms includes an outer rigid clip arm member connected to an inner resilient elastic clip arm member having a tissue contacting surface, such that when deployed, the clip arm members are configured for applying clamping forces to a bodily organ or tissue via each inner resilient elastic clip arm member while allowing each inner resilient elastic clip arm member to compress or shift laterally towards a respective rigid outer clip arm member. In response to the deployment, the first and second clip arms conform to a compressed shape of the bodily organ or tissue.

Additionally, in such exemplary embodiments, the clip applier also includes a trigger mechanism having an inner sleeve and configured for sliding and advancing the inner sleeve from a retracted position that uncovers the distal-most hemostatic clip, to a protruding position that covers the distal-most hemostatic clip. According to such embodiments, the inner sleeve, when advanced to the protruding position over the first and second clip arms of the distal-most hemostatic clip, effects moving of the first and second clip arms to approach each other so as to self-lock the first and second clip arms by the locking mechanism of the distal-most hemostatic clip.

Another, related, aspect of some embodiments of the present invention is provision of a clip applier for ligating a bodily organ or tissue in a subject. In exemplary embodiments, the clip applier includes: at least one hemostatic clip, including a distal-most hemostatic clip, with: a first clip arm having a first clip arm distal end; a second clip arm having a second clip arm distal end, the second clip arm opposes and is pivotally linked to the first clip arm at a shared proximal end, and the second clip arm is movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip; and a locking mechanism configured to lock together the first and second clip arm distal ends to a closed clip height being smaller than an opened clip height of a non-stressed fully opened clip configuration

In such exemplary embodiments, the clip applier further includes a clip pressing mechanism, having a sliding press, and configured for selectively moving the sliding press across the distal-most hemostatic clip between a fully retracted position proximal to the distal-most hemostatic clip, and a fully protruded position across the distal-most hemostatic clip, so as to limit the opened clip height of the distal-most hemostatic clip to a maximal opened clip height being equal to or less than the closed clip height.

According to such exemplary embodiments, when the clip applier is deployed, shifting the sliding press from a retracted position to the fully protruded position effects gradual closing of the hemostatic clip by decreasing distance between the first and second clip arm distal ends, at least until reaching the

closed-clip height, so as to activate the locking mechanism to lock together the first and second clip arm distal ends at the closed clip height, for facilitating ligation of the bodily organ or tissue.

Reference is now being made to FIGs. 6A - 6D, which illustrate a clip applier 84 for deploying hemostatic clips onto a bodily organ or tissue. The description below refers to clip 58 for exemplary reasons only, however, the description equally applies for deploying any of the clips described herein. Clip applier 84 may house approximately 20 hemostatic clips, or any number of clips below 20 clips.

Clip applier 84 may include a housing, optionally in a form of a cannula, or an outer sleeve 86b, that is configured for housing multiple clips or/and for facilitating a passage or entry for applying clips to internal organs or tissues, optionally from outside treated subject's body. In some embodiments, the outer sleeve 86b may be in the form of a needle with a sharp edge for enabling piercing through a body cavity wall. In accordance with those embodiments, outer sleeve includes a first distal sharp end and a second distal blunt end.

As shown, a sliding press in a form of an inner sleeve 86a is provided, being capable of sliding and retracting from a fully protruded configuration in which clip 58 is fully covered and is in a stressed locked configuration (FIG. 6A) to a retracted position that uncovers hemostatic clip 58 (FIG. 6B), optionally motion is relative to a static position for outer sleeve 86b. In some embodiments, inner sleeve 86a may have a diameter which is sufficiently narrow to facilitate a closed and unlocked configuration of clip 58. For example, the diameter of inner sleeve 86a may be in a range between 0.2 mm and 5 mm.

Optionally, alternatively or additionally, inner sleeve 86a is capable of sliding and advancing from a retracted position that in which hemostatic clip 58 uncovered or partially uncovered (FIGs. 6B and 6C), to a protruding position that covers hemostatic clip 58 and thereby effects locking of clip 58 (FIG. 6D). Locking clip 58 is mediated following gradual advancing and sliding to a protruding position of sleeve 86a (FIGs. 6C and 6D) which gradually covers first and second clip arms 60 and 62 of hemostatic clip 58. Sleeve 86a effects moving of the first and second clip arms 60 and 62 to approach each other so as to self-lock hemostatic clip 58 by locking mechanism 72.

In some embodiments, inner sleeve 86a includes opposing tracks (not shown). In some embodiments, opposing tracks are sized and shaped for accommodating runner surfaces of the outer rigid 61 of clip arm members 60 and 62 in contact therewith. In some embodiments, opposing tracks are parallel to each other.

In some embodiments, inner sleeve 86a includes a slot 83 provided along each side thereof, opened to distal opening thereof. Slots 83 are required in order to pass inner sleeve 86a about a length of a captured / ligated organ or tissue without causing damage or even be in contact thereto during travel (distal-protruding or proximal-retracting, relative to hemostatic clip 58). In some embodiments, length of each slit 83 is equal to or greater than most or all hemostatic clip 58, optionally at least its functionally

effective length between hinge 70 and locking mechanism 72. In some embodiments, height of each slit 83 is equal to or greater than a maximal compressed length of a ligated tissue when hemostatic clip 58 is in a locked configuration or/and accumulated height of all gaps between inner 64 and outer 62 clip arm members, optionally about 5 mm or more, or optionally about 8 mm or more.

5 In some embodiments, a trigger mechanism 86 (comprising at least inner sleeve 86a) is shaped and sized for forcing first and second inner resilient elastic clip arm members 64 to align in a predetermined formation in which distance between the first and second clip arm distal ends 74 and 76 is equal to or less than a predetermined opening. In some embodiments, the term "predetermined opening" is interchangeable with the term "predetermined distance".

10 Reference is now being made to FIG. 7, which illustrates another exemplary clip applier 90 for deploying hemostatic clips onto a bodily organ or tissue and ligating the bodily organ or tissue. The description below refers to hemostatic clip 88 (described in details below) for exemplary reasons only, however, the description of FIG. 7 equally applies for deploying any of the clips described herein.

15 Similar to clip applier 84, clip applier 90 may house multiple hemostatic clips 88. In some embodiments, hemostatic clips are positioned in clip applier 90 in a closed and unlocked configuration. Clip applier 90 includes a clip pressing mechanism, including sliding press 92, configured for laterally sliding and advancing. In some embodiments, sliding press 92 includes a tubular member 92a which is in a form of an inner sleeve (optionally similarly to inner sleeve 86a) and is capable of axially sliding in a lumen of an outer sleeve 92b. In some embodiments, tubular member 92a and outer sleeve 92b are
20 movable one towards the other. Outer sleeve 92b may be in a form of a needle or may include a sharp edge in its distal end. In some embodiments, tubular member 92a includes an inner lumen dimensioned for limiting opening of hemostatic clip 88 to the opened configuration.

Clip applier 90 may include a biasing mechanism 94 provided within hemostatic clip 88. Biasing mechanism 94 is provided between the first and second clip arms 96 and 98. Biasing mechanism 94 is
25 configured for compressing the ligated bodily organ or tissue when hemostatic clip 88 is being locked. Biasing mechanism 94 may include an inner clip arm member 94a. In some embodiments, inner clip arm member 94a corresponds and/or is essentially similar to inner resilient elastic clip arm members 20 and/or 48 and/or 64 of hemostatic clips 10, 32 and 58, respectively. The remaining elements of hemostatic clip 88 are essentially similar to the elements of hemostatic clips 10, 32 and 58.

30 Reference is made to FIG. 8, which is a photographic image of an exemplary clip 88 confined within tubular member 92a held in between human fingers. The image shows the relative size of the clip and clip applier relative to that of human fingers. In some embodiments, tubular member 92a includes a slot 93 provided along each side thereof, opened to distal opening thereof. In some embodiments, length of each slit 93 is equal to or greater than most or all hemostatic clip 88, optionally at least its functionally

effective length between hinge and locking mechanism of clip 88. In some embodiments, height of each slot 93 is equal to or greater than a maximal compressed length of a ligated tissue when hemostatic clip 88 is in a locked configuration, or/and optionally about 5 mm or more, or optionally about 8 mm or more.

Reference is made to FIG. 9, which illustrates a clip applier 90 which further includes a handle 96 and a trigger 98 configured for operating the hemostatic clips of the invention. The description below refers to hemostatic clip 58 and clip applier 90 for exemplary reasons only, however, the description of FIG. 9 equally applies any of the clips and clip appliers described herein. Handle 96 may include a mechanism for maneuvering tubular member 92a with respect to the clips housed in the tubular member 92a. The tubular member 92a maneuvering mechanism may include a trigger 98, extending from handle 96, for moving tubular member 92a, to deploy any of the clips described above. The most distally positioned clip 58 housed in tubular member 92a may be exposed from the distal end of tubular member 92a and positioned for deployment via any suitable clip advancement method. The handle and its operating system have been disclosed by the inventor of the present invention in International Patent Application, Publication No. WO 2015/040621.

Another aspect of some embodiments of the present invention is a method of ligating a bodily organ or tissue in a subject. The herein disclosed bodily organ or tissue ligating method may be practiced and implemented using any of the herein illustratively described exemplary embodiments of the hemostatic clip applier (and, components and features thereof), for example, clip applier 84 shown in at least FIGs. 6A - 6D, and clip applier 90 shown in at least FIGs. 7 and 9. Moreover, the herein disclosed bodily organ or tissue ligating method may be practiced and implemented using any of the herein illustratively described exemplary embodiments of the hemostatic clip (and, components and features thereof), for example, clip 10, clip 32, clip 58, clip 80, clip 88, shown in the figures.

FIG. 10 is a flow diagram of an exemplary embodiment (indicated as, and referred to by, reference number 100), including the indicated exemplary steps (procedures / processes) thereof, of a method of ligating a bodily organ or tissue in a subject. In FIG. 10, the exemplary embodiment 100 of the bodily organ or tissue ligating method includes exemplary steps (procedures / processes) represented by separate blocks (frames) which are assigned reference numbers, for example, 104, 108, 112, etc.. As shown in FIG. 10, in a non-limiting manner, and in some embodiments, such as exemplary embodiment 100, the method of ligating a bodily organ or tissue in a subject includes the following exemplary steps (procedures / processes).

In 104, there is providing a distal-most hemostatic clip configured for surrounding the bodily organ or tissue, wherein the distal-most hemostatic clip includes a first clip arm having a first clip arm distal end and a second clip arm having a second clip arm distal end, the second clip arm opposes and is pivotally

linked to the first clip arm at a shared proximal end, and the second clip arm is movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip.

In 108, there is providing a biasing mechanism between the first and second clip arms and allowing the biasing mechanism to occupy a space between the first and second clip arms and the bodily organ or tissue.

In 112, there is gradually closing the hemostatic clip over the bodily organ or tissue by forcibly decreasing distance between the first and second clip arm distal ends.

In 116, there is locking together the first and second clip arm distal ends to a closed clip height, via activating a locking mechanism.

In exemplary embodiments of the bodily organ or tissue ligating method, the steps (procedures) of gradually closing the hemostatic clip or/and of locking together the clip arm distal ends effect the biasing mechanism into compressing and clamping the bodily organ or tissue, while being deformed at least partially into an outer periphery of the compressed and clamped bodily organ or tissue.

In exemplary embodiments of the bodily organ or tissue ligating method, a hemostatic clip and a clip applier, as described herein are provided. A hemostatic clip being most distally positioned within a clip applier is provided with the two arms of the clip being opened. In some embodiments, the clip may be in a fully closed configuration. The clip is then provided to surround a bodily organ or tissue. The hemostatic clip is gradually closed over the bodily organ or tissue by forcibly decreasing a distance between a first and a second clip arms distal ends, and by activating a locking mechanism to thereby lock together the first and second clip arm distal ends to a closed clip configuration.

In exemplary embodiments, the gradually closing or/and locking may be effected by a biasing mechanism of the hemostatic clip which compresses and clamps an outer periphery of the bodily organ or tissue to thereby deform and ligate the bodily organ or tissue. In exemplary embodiments, a biasing mechanism includes at least one inner resilient arm member connected to a clip arm member. In exemplary embodiments, gradually closing and/or locking may further be effected by shifting sliding press provided in the clip applier from a fully retracted position, proximal to the distal-most hemostatic clip, to a fully protruded position, distal to the distal-most hemostatic clip. In exemplary embodiments, shifting from a fully retracted position, proximal to the distal-most hemostatic clip, causes the height between the distal ends of the two clip arms to be reduced and limited to the closed and locked position of the clip. In exemplary embodiments, shifting the sliding press to the fully protruded position over the hemostatic clip initiates activating of the locking mechanism of the hemostatic clip. In exemplary embodiments, the distal-most hemostatic clip is ejected from the clip applier. In exemplary embodiments, the releasing and ejecting is effected by retracting the sliding press to the fully retracted position.

Reference is made to FIGs. 11A - 11G, which schematically illustrate steps (procedure / processes) of practicing and implementing the herein disclosed exemplary method of ligating a bodily organ or tissue in a subject, using, for example, clip applier 90. The description below refers to hemostatic clip 58 for exemplary purpose only. In a non-limiting manner, the below description equally applies to
5 deploying any of the clips described herein.

Referring to FIG. 11A, clip 58 is shown in a fully opened configuration. Tubular member 92a is in a retracted configuration. Clip 58 is opened to its maximal opened clip height.

Referring to FIGs. 11B - 11D, tubular member 92a may be moved across distal most hemostatic clip 58 to gradually shift to a fully protruded position. Shifting the tubular member 92a from a retracted
10 position to the fully protruded position effects gradual closing of the hemostatic clip 58 over a bodily organ or tissue by decreasing distance between the first and second clip arm distal ends 74 and 76, at least until reaching a closed-clip height, so as to activate locking mechanism 72 to lock together the first and second clip arm distal ends 74 and 76.

Referring to FIGs. 11E - 11G, ejection of the distal-most hemostatic clip 58 is shown. Retraction
15 of tubular member 92a to the fully retracted position when the first and second clip arm distal ends 74 and 76 are locked together effects release and ejection of the distal-most hemostatic clip 58.

Each of the following terms written in singular grammatical form: 'a', 'an', and 'the', as used herein, means 'at least one', or 'one or more'. Use of the phrase 'one or more' herein does not alter this intended meaning of 'a', 'an', or 'the'. Accordingly, the terms 'a', 'an', and 'the', as used herein, may also refer to,
20 and encompass, a plurality of the stated entity or object, *unless otherwise specifically defined or stated herein*, or, *unless the context clearly dictates otherwise*. For example, the phrases: 'a unit', 'a device', 'an assembly', 'a mechanism', 'a component', 'an element', and 'a step or procedure', as used herein, may also refer to, and encompass, a plurality of units, a plurality of devices, a plurality of assemblies, a plurality of mechanisms, a plurality of components, a plurality of elements, and, a plurality of steps or procedures,
25 respectively.

Each of the following terms: 'includes', 'including', 'has', 'having', 'includes', and 'including', and, their linguistic / grammatical variants, derivatives, or/and conjugates, as used herein, means 'including, but not limited to', and is to be taken as specifying the stated component(s), feature(s), characteristic(s), parameter(s), integer(s), or step(s), and does not preclude addition of one or more additional
30 component(s), feature(s), characteristic(s), parameter(s), integer(s), step(s), or groups thereof. Each of these terms is considered equivalent in meaning to the phrase 'consisting essentially of'.

The term 'method', as used herein, refers to steps, procedures, manners, means, or/and techniques, for accomplishing a given task including, but not limited to, those steps, procedures, manners,

means, or/and techniques, either known to, or readily developed from known steps, procedures, manners, means, or/and techniques, by practitioners in the relevant field(s) of the disclosed invention.

Throughout this disclosure, a numerical value of a parameter, feature, characteristic, object, or dimension, may be stated or described in terms of a numerical range format. Such a numerical range format, as used herein, illustrates implementation of some exemplary embodiments of the invention, and does not inflexibly limit the scope of the exemplary embodiments of the invention. Accordingly, a stated or described numerical range also refers to, and encompasses, all possible sub-ranges and individual numerical values (where a numerical value may be expressed as a whole, integral, or fractional number) within that stated or described numerical range. For example, a stated or described numerical range 'from 1 to 6' also refers to, and encompasses, all possible sub-ranges, such as 'from 1 to 3', 'from 1 to 4', 'from 1 to 5', 'from 2 to 4', 'from 2 to 6', 'from 3 to 6', etc., and individual numerical values, such as '1', '1.3', '2', '2.8', '3', '3.5', '4', '4.6', '5', '5.2', and '6', within the stated or described numerical range of 'from 1 to 6'. This applies regardless of the numerical breadth, extent, or size, of the stated or described numerical range.

Moreover, for stating or describing a numerical range, the phrase 'in a range of *between* about a first numerical value *and* about a second numerical value', is considered equivalent to, and meaning the same as, the phrase 'in a range of *from* about a first numerical value *to* about a second numerical value', and, thus, the two equivalently meaning phrases may be used interchangeably. For example, for stating or describing the numerical range of room temperature, the phrase 'room temperature refers to a temperature in a range of between about 20 °C and about 25 °C', and is considered equivalent to, and meaning the same as, the phrase 'room temperature refers to a temperature in a range of from about 20 °C to about 25 °C'.

The term 'about', as used herein, refers to $\pm 10\%$ of the stated numerical value.

It is to be fully understood that certain aspects, characteristics, and features, of the invention, which are, for clarity, illustratively described and presented in the context or format of a plurality of separate embodiments, may also be illustratively described and presented in any suitable combination or sub-combination in the context or format of a single embodiment. Conversely, various aspects, characteristics, and features, of the invention which are illustratively described and presented in combination or sub-combination in the context or format of a single embodiment, may also be illustratively described and presented in the context or format of a plurality of separate embodiments.

Although the invention has been illustratively described and presented by way of specific exemplary embodiments, and examples thereof, it is evident that many alternatives, modifications, or/and variations, thereof, will be apparent to those skilled in the art. Accordingly, it is intended that all such

alternatives, modifications, or/and variations, fall within the spirit of, and are encompassed by, the broad scope of the appended claims.

5 All publications, patents, and or/and patent applications, cited or referred to in this disclosure are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent, or/and patent application, was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this specification shall not be construed or understood as an admission that such reference represents or corresponds to prior art of the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

WHAT IS CLAIMED IS

1. A thickness-adjustable hemostatic clip comprising:
 - a first clip arm having a first clip arm distal end;
 - a second clip arm having a second clip arm distal end, said second clip arm opposes and is pivotally linked to said first clip arm at a shared proximal end, and said second clip arm is movable relative to said first clip arm from a non-stressed fully opened clip configuration wherein said first clip arm distal end is distanced from said second clip arm distal end by a predetermined distance, to a stressed locked clip configuration wherein said first clip arm distal end is in proximity with or contacts said second clip arm distal end;
 - wherein at least one of said first and second clip arms includes an outer rigid clip arm member connected to an inner resilient elastic clip arm member having a tissue contacting surface; and
 - a locking mechanism configured for applying resistive force to said first clip arm distal end or to said second clip arm distal end, thereby locking said first clip arm distal end to said second clip arm distal end during said locked clip configuration, so as to prevent self-opening of the hemostatic clip;
 - wherein said first and second clip arms, when deployed in said locked clip configuration, are configured for applying compression and clamping forces to a bodily organ or tissue via said inner resilient elastic clip arm member while allowing said inner resilient elastic clip arm member to compress or shift laterally towards a respective said outer rigid clip arm member, such that in response to said deployment, said first and second clip arms are conformable to a compressed and clamped shape of said bodily organ or tissue while exerting clamping forces thereto.
2. The hemostatic clip of claim 1, wherein said outer rigid arm member is configured to prevent deformation thereof in response to elastic deformation of said inner resilient elastic clip arm member and to limit expansion of said inner resilient elastic clip arm member.
3. The hemostatic clip of claim 1, wherein said outer rigid clip arm member joins said inner resilient elastic clip arm member at two separate joining portions, whereby said outer and inner clip arm members enclose a gap extending between said joining portions, said gap separates a roof surface of said outer rigid clip arm member away from a roof-contact surface of said inner resilient elastic clip arm member.
4. The hemostatic clip of claim 3, wherein said inner resilient elastic clip arm member is configured for laterally bending or protruding towards an opposing inner arm member.

5. The hemostatic clip of claim 3, wherein said gap is sized for accommodating said inner resilient elastic clip arm member conforming to tissue and outwardly bending toward said outer rigid clip arm member, until at least part of said roof-contact surface contacts at least part of said roof surface.
6. The hemostatic clip of claim 1, wherein a first and a second of said at least one inner resilient elastic clip arm member are configured to apply a pressure of up to about 150 gr/mm² to said bodily organ or tissue, wherein said applied pressure is constant or linearly rising in relation to thickness of tissue located between said first and second inner resilient elastic clip arms, under said compression and clamping forces applied to said bodily organ or tissue before being restricted in expansion by each said outer rigid clip arm member.
7. The hemostatic clip of claim 1, wherein a first and a second of said at least one inner resilient elastic clip arm members are configured to apply a compressive pressure above 150 gr/mm² to said bodily organ or tissue, wherein said applied pressure rapidly rises in relation to thickness of compressed material of said first and second inner resilient elastic clip arm members or of compressed tissue therebetween when said first and second inner resilient elastic clip arm members are in close contact with respective said outer rigid clip arm members.
8. The hemostatic clip of claim 1, wherein a first and a second of said at least one inner resilient elastic clip arm members are configured to apply a compressive pressure of at least 5 gr/mm² when separated by a distance of at least 0.1 mm therebetween.
9. The hemostatic clip of claim 1, wherein a first and a second of said at least one inner resilient elastic clip arm members are configured to apply a compressive pressure in a range of between about 10 gr/mm² and about 150 gr/mm² when separated by a distance in a range of between about 0.2 mm and about 0.8 mm therebetween.
10. The hemostatic clip of claim 1, wherein a first and a second of said at least one inner resilient elastic clip arm members are configured for approaching each other and reducing a gap therebetween, while continuously conforming to said compressed shape of said bodily organ or tissue clamped therebetween in response to gradual shrinking of said bodily organ or tissue during or/and after necrosis thereof.

11. The hemostatic clip of claim 1, wherein each said inner resilient elastic clip arm member is configured for evenly distributing pressure exerted on said bodily organ or tissue in contact therewith in response to said deployment.
12. The hemostatic clip of claim 1, wherein said locking mechanism comprises a hook having a first end connected to said first clip arm distal end.
13. The hemostatic clip of claim 12, wherein said hook comprises a second end having a hook flange with a follower surface, wherein said hook first end is adapted for slidably engaging a cam surface provided on said second clip arm distal end, in response to said first and second clip arms moving from said opened clip configuration to said locked clip configuration.
14. The hemostatic clip of claim 13, wherein said first and second clip arms shift into said locked clip configuration following said hook flange reaching and fitting into a niche positioned beyond said cam surface.
15. The hemostatic clip of claim 1, wherein said first and second clip arms, and said locking mechanism, are integrally structured and manufactured from a single piece of material.
16. The hemostatic clip of claim 1, further comprising an interconnecting mechanism configured for sequentially chaining lengthwise, one after another, a plurality of the hemostatic clip, wherein a hemostatic clip proximal end includes a tail coupler connectable to a head coupler provided at said first clip arm distal end or at said second clip arm distal end.
17. A clip applier for deploying hemostatic clips onto a bodily organ or tissue in a subject, the clip applier comprising:
at least one thickness-adjustable hemostatic clip, including a distal-most thickness-adjustable hemostatic clip, comprised of:
a first clip arm having a first clip arm distal end;
a second clip arm having a second clip arm distal end, movable relative to said first clip arm from a non-stressed fully opened clip configuration of said distal-most hemostatic clip; and
a locking mechanism configured for locking said first clip arm distal end to said second clip arm distal end, so as to prevent self-opening of the hemostatic clip;

wherein at least one of said first and second clip arms includes an outer rigid clip arm member connected to an inner resilient elastic clip arm member having a tissue contacting surface, such that when deployed, said clip arm members are configured for applying clamping forces to a bodily organ or tissue via each said inner resilient elastic clip arm member while allowing each said inner resilient elastic clip arm member to compress or shift laterally towards a respective said rigid outer clip arm member, such that in response to said deployment, said first and second clip arms conform to a compressed shape of said bodily organ or tissue;

and

a trigger mechanism including an inner sleeve and configured for sliding and advancing said inner sleeve from a retracted position that uncovers said distal-most hemostatic clip, to a protruding position that covers said distal-most hemostatic clip;

wherein, said inner sleeve, when advanced to said protruding position over said first and second clip arms of said distal-most hemostatic clip effects moving of said first and second clip arms to approach each other so as to self-lock said first and second clip arms by said locking mechanism of said distal-most hemostatic clip.

18. A clip applier for ligating a bodily organ or tissue in a subject, the clip applier comprising:
at least one hemostatic clip, including a distal-most hemostatic clip comprised of:

a first clip arm having a first clip arm distal end;

a second clip arm having a second clip arm distal end, said second clip arm opposes and is pivotally linked to said first clip arm at a shared proximal end, and said second clip arm is movable relative to said first clip arm from a non-stressed fully opened clip configuration of said distal-most hemostatic clip; and

a locking mechanism configured to lock together said first and second clip arm distal ends to a closed clip height being smaller than an opened clip height of a non-stressed fully opened clip configuration;

and

a clip pressing mechanism, including a sliding press, and configured for selectively moving said sliding press across said distal-most hemostatic clip between a fully retracted position proximal to said distal-most hemostatic clip, and a fully protruded position across said distal-most hemostatic clip, so as to limit said opened clip height of said distal-most hemostatic clip to a maximal opened clip height being equal to or less than said closed clip height;

wherein, when the clip applier is deployed, shifting said sliding press from a retracted position to said fully protruded position effects gradual closing of said hemostatic clip by decreasing distance

between said first and second clip arm distal ends, at least until reaching said closed-clip height, so as to activate said locking mechanism to lock together said first and second clip arm distal ends at said closed clip height, for facilitating ligation of the bodily organ or tissue.

19. The clip applier of claim 18, wherein said sliding press includes a tubular member.

20. The clip applier of claim 19, wherein said tubular member is in a form of an inner sleeve axially slidable in a lumen of an outer sleeve, wherein said inner sleeve is configured to be withdrawn proximal to distal end of said outer sleeve when said clip pressing mechanism is in said fully retracted position, and is configured to protrude at least partially distal to said outer sleeve distal end when said clip pressing mechanism is in said protruding position.

21. The clip applier of claim 20, wherein said outer sleeve is in a form of a needle or/and said outer sleeve distal end includes a sharp edge.

22. The clip applier of claim 18, wherein said tubular member includes an inner lumen dimensioned for limiting opening of said distal-most hemostatic clip to said maximal opened clip height.

23. The clip applier of claim 18, configured such that retracting said sliding press to said fully retracted position when said first and second clip arm distal ends are locked together into a locked configuration via said locking mechanism, effects release and ejection of said distal-most hemostatic clip therefrom.

24. The clip applier of claim 23, further comprising a biasing mechanism provided between said first and second clip arms, and configured for compressing a ligated bodily organ or tissue while being deformed to outer periphery of said compressed ligated bodily organ or tissue.

25. The clip applier of claim 24, wherein said biasing mechanism is part of said distal-most hemostatic clip.

26. The clip applier of claim 25, wherein said biasing mechanism comprises an inner clip arm member, wherein each of said first and second clip arms includes an outer clip arm member connected to a corresponding said inner clip arm member, wherein each said inner clip arm member has a tissue contacting surface being conformable or/and displaceable in response to said compressing of said ligated bodily organ or tissue.

27. The clip applicator of claim 26, wherein said distal-most hemostatic clip, when in said locked configuration, is configured for applying compression and clamping forces to the bodily organ or tissue via each said inner clip arm member while allowing said tissue contacting surface to at least partially conform to said outer clip arm member or/and to a compressed and clamped shape of the bodily organ or tissue, in response to ligating of the bodily organ or tissue, wherein each said outer arm clip member is configured for preventing deformation thereof in response to said conformity of said inner arm clip member tissue contacting surface.

28. A method for ligating a bodily organ or tissue in a subject, the method comprising:

providing a distal-most hemostatic clip configured for surrounding the bodily organ or tissue, wherein said distal-most hemostatic clip comprises a first clip arm having a first clip arm distal end and a second clip arm having a second clip arm distal end, said second clip arm opposes and is pivotally linked to said first clip arm at a shared proximal end, and said second clip arm is movable relative to said first clip arm from a non-stressed fully opened clip configuration of said distal-most hemostatic clip;

providing a biasing mechanism between said first and second clip arms and allowing said biasing mechanism to occupy a space between said first and second clip arms and the bodily organ or tissue;

gradually closing said hemostatic clip over the bodily organ or tissue by forcibly decreasing distance between said first and second clip arm distal ends; and

locking together said first and second clip arm distal ends to a closed clip height, via activating a locking mechanism;

wherein said gradually closing or/and said locking effects said biasing mechanism into compressing and clamping the bodily organ or tissue, while being deformed at least partially into an outer periphery of said compressed and clamped bodily organ or tissue.

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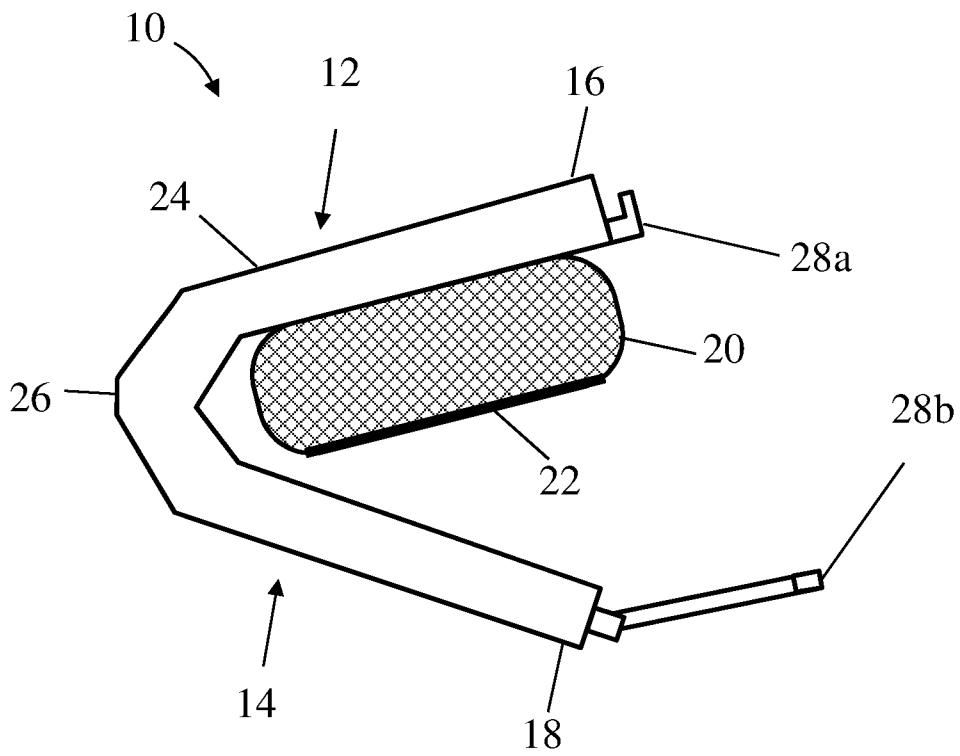


FIG. 1A

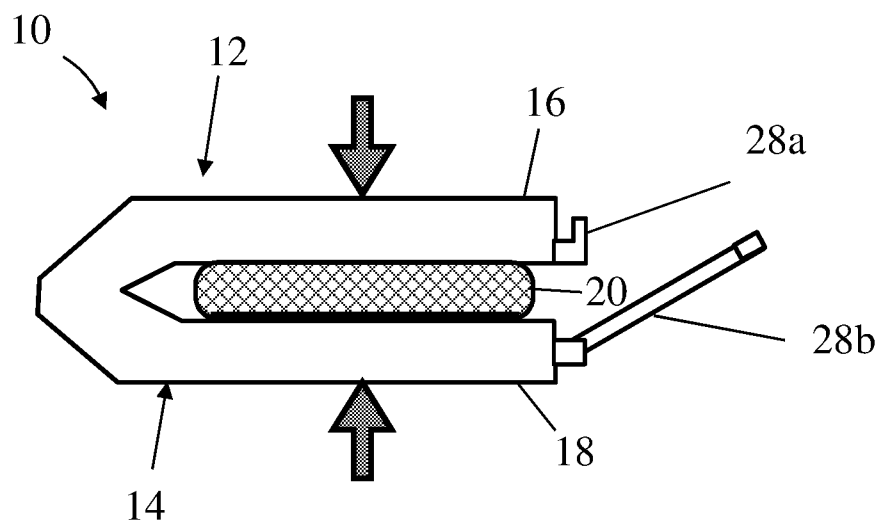


FIG. 1B

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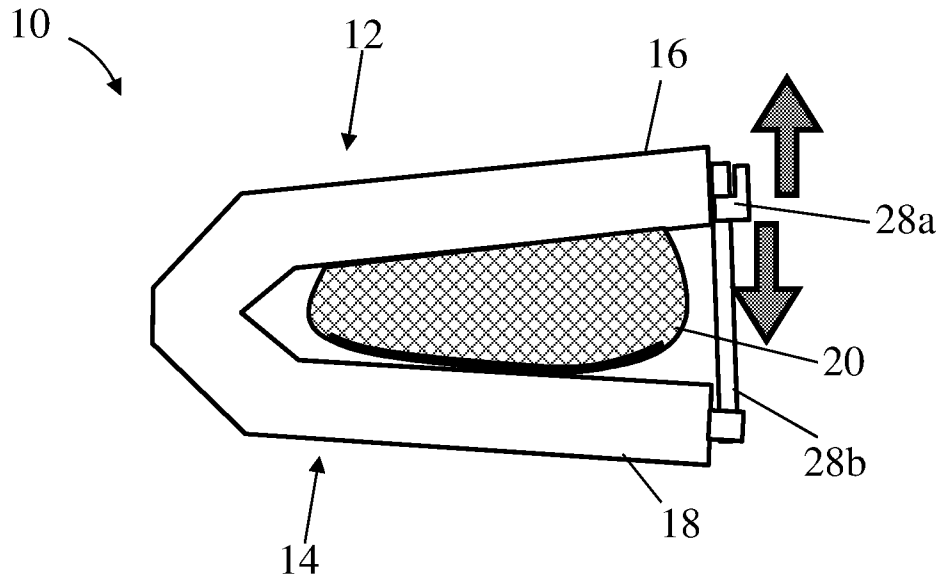


FIG. 1C

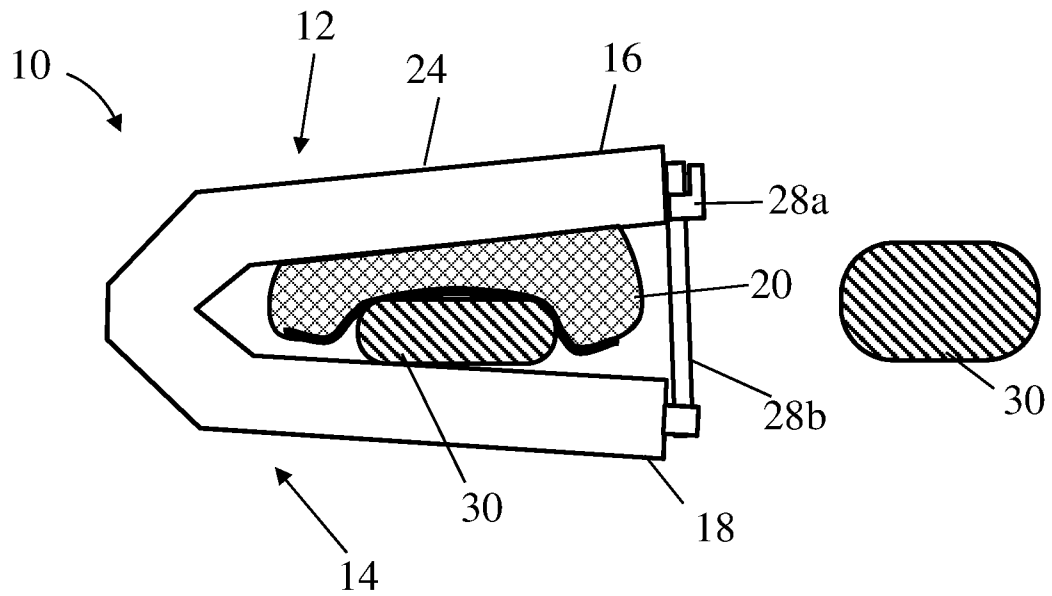


FIG. 1D

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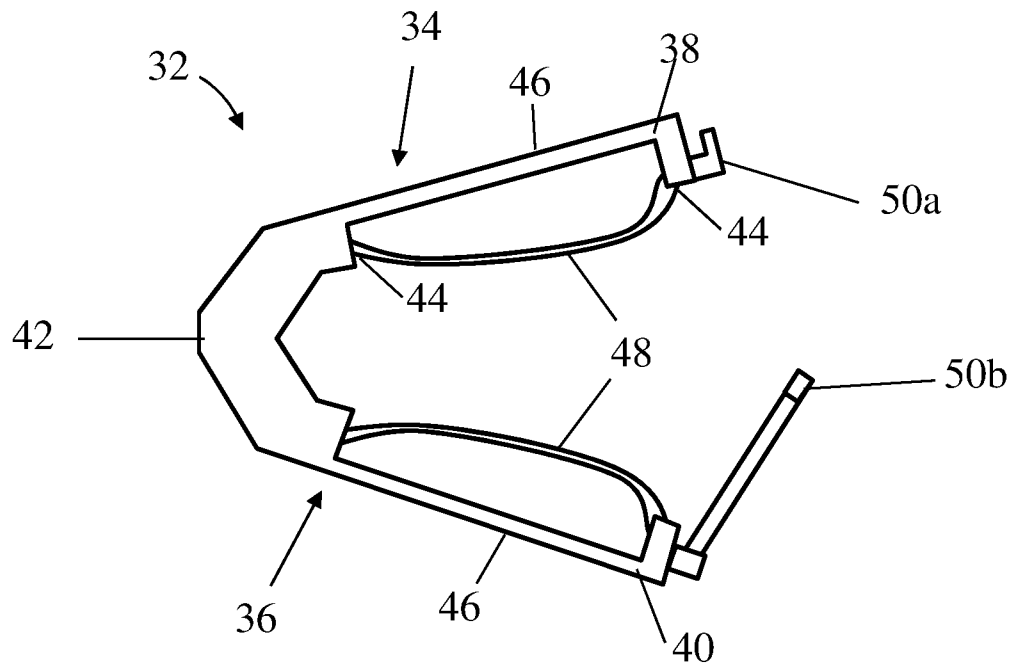


FIG. 2A

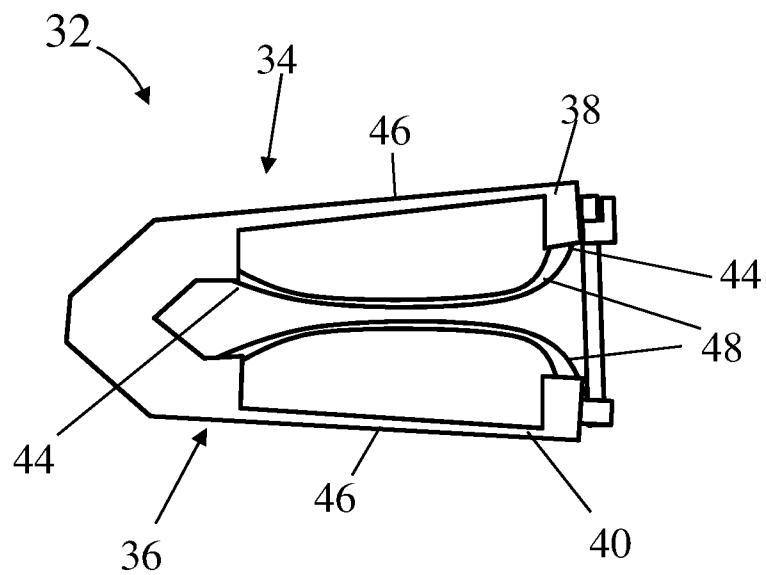


FIG. 2B

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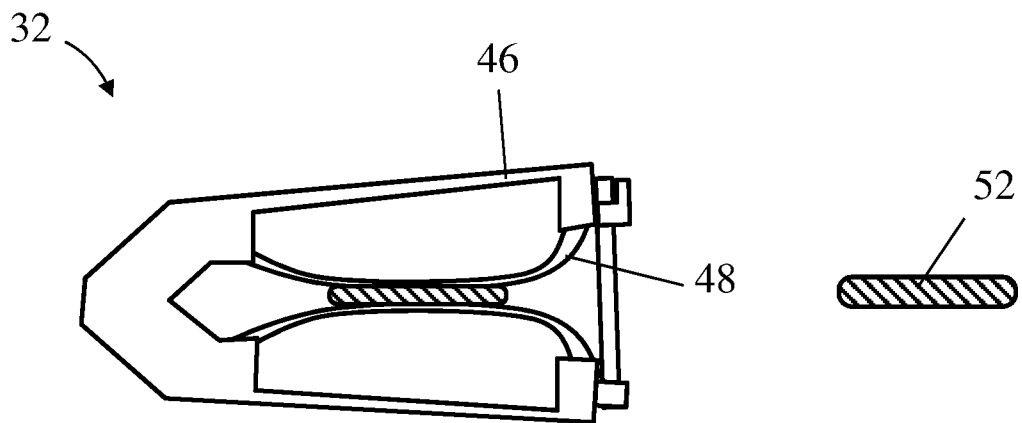


FIG. 3A

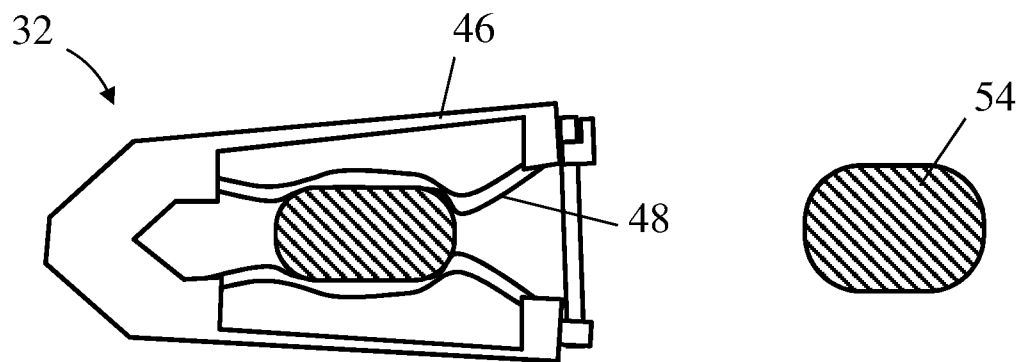


FIG. 3B

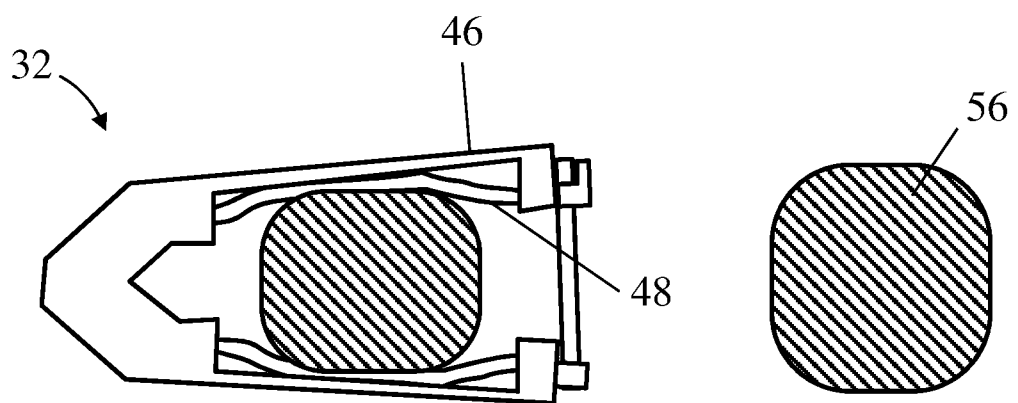


FIG. 3C

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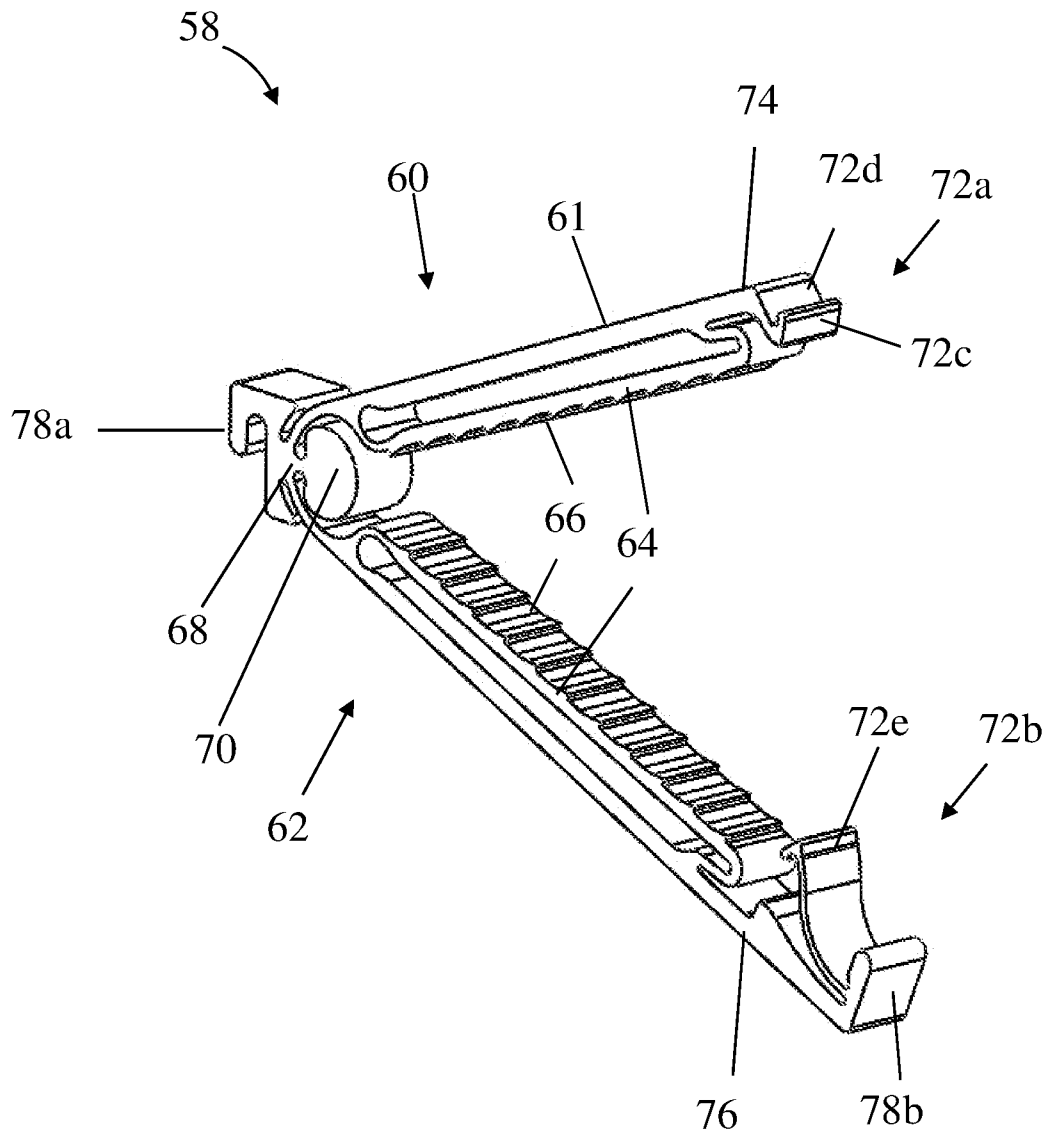


FIG. 4

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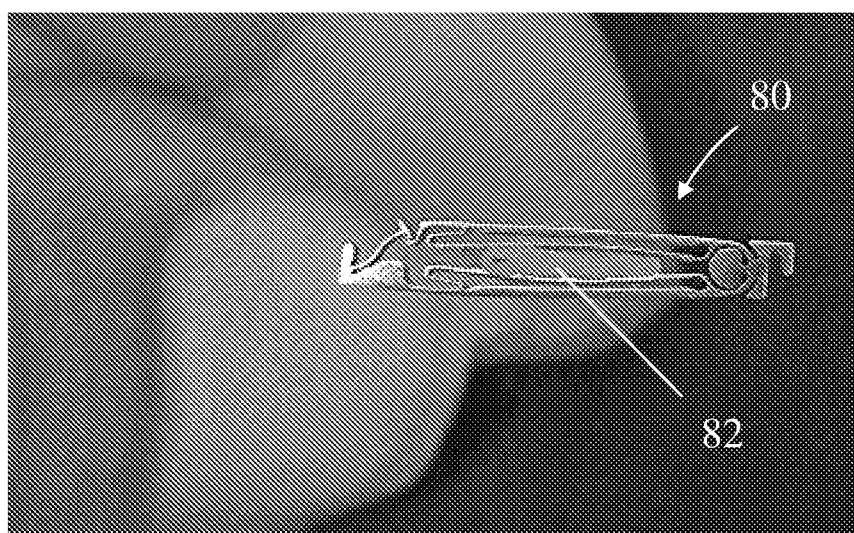


FIG. 5

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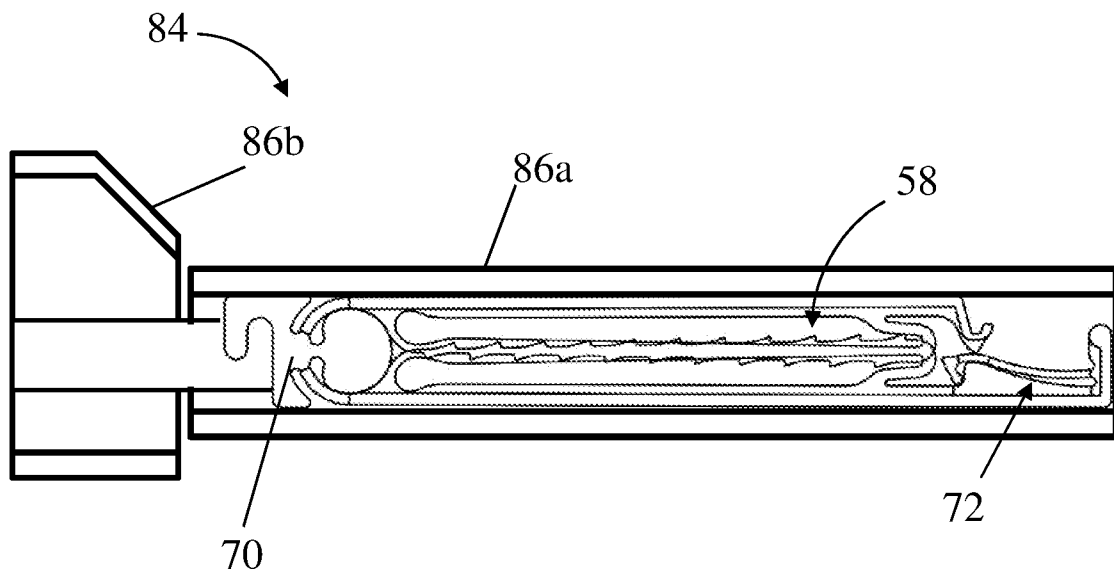


FIG. 6A

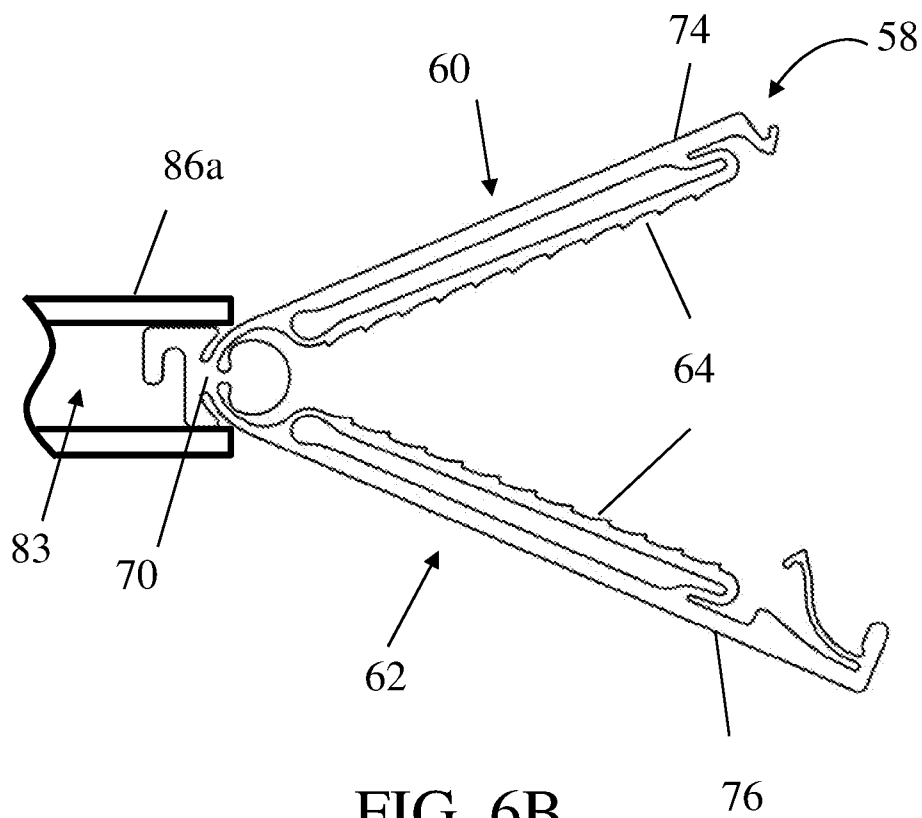


FIG. 6B

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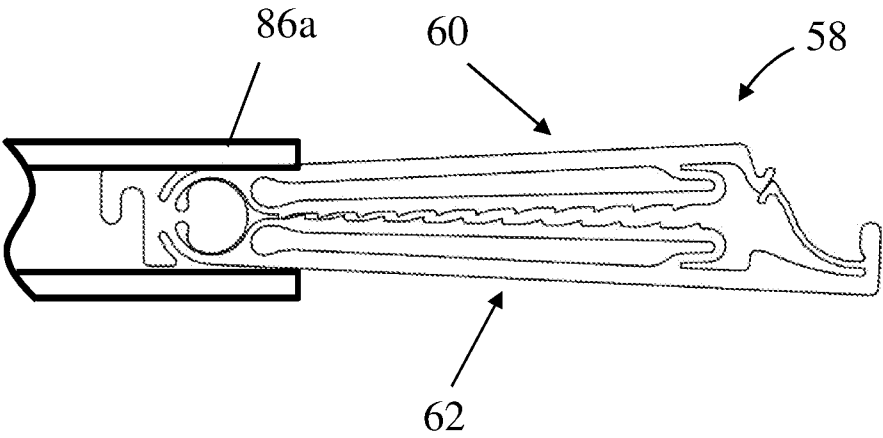


FIG. 6C

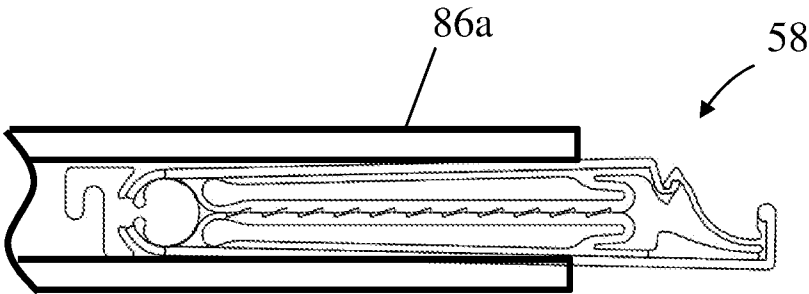


FIG. 6D

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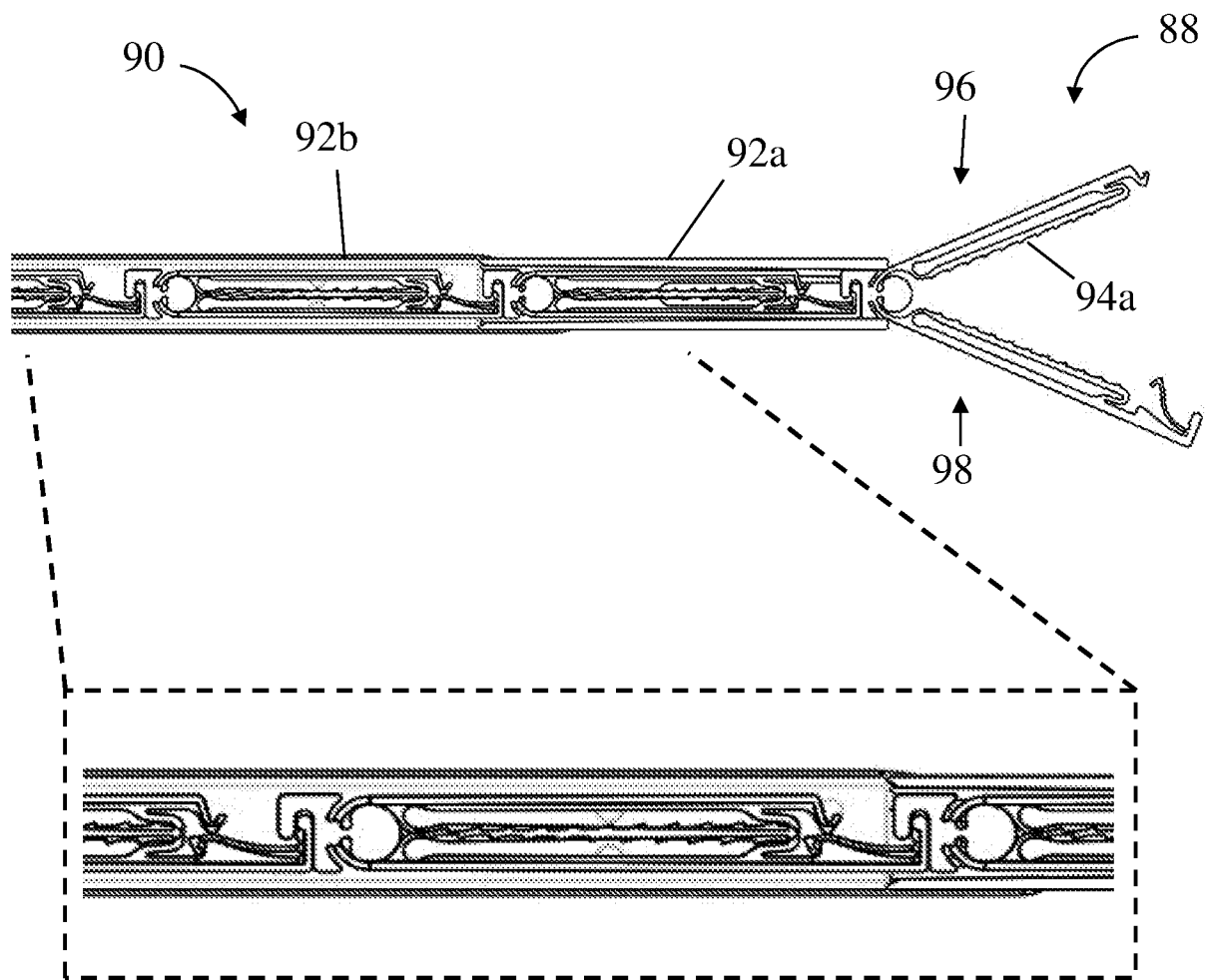


FIG. 7

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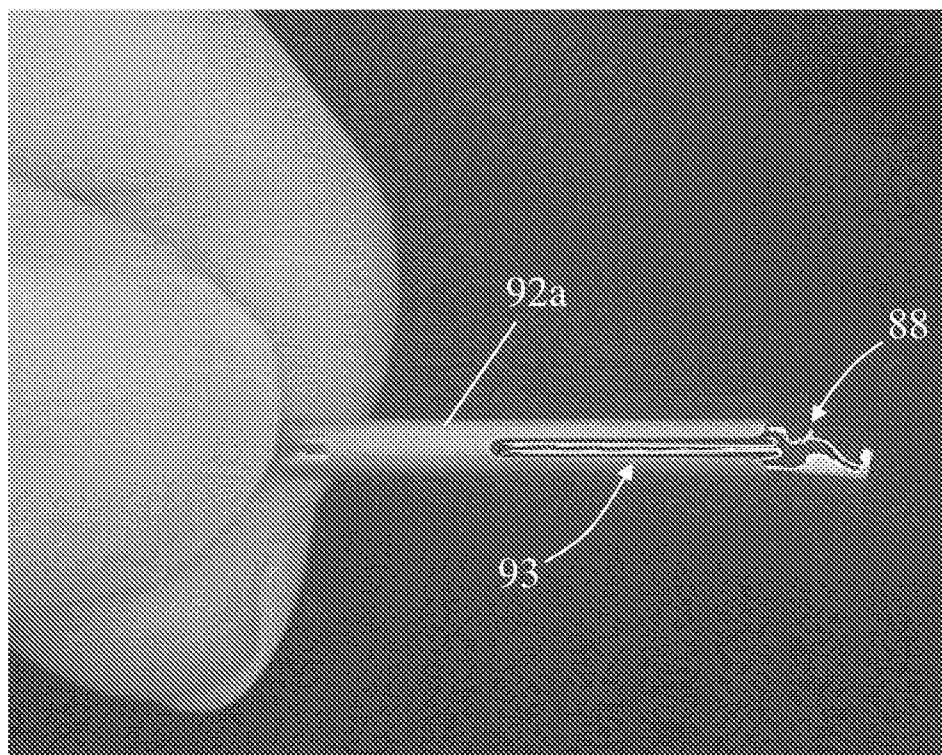


FIG. 8

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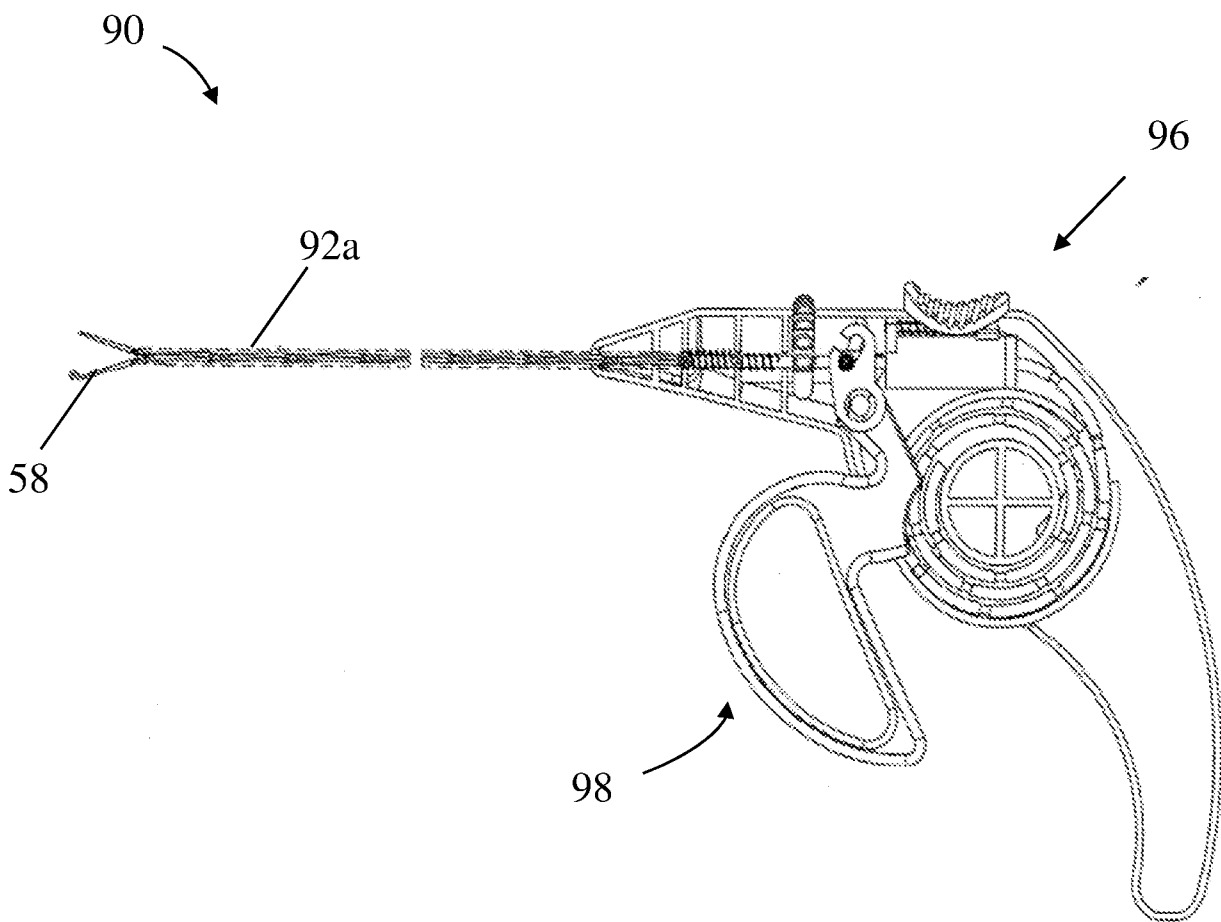


FIG. 9

12/15

100

FIG. 10

{Ligating a bodily organ or tissue in a subject.}

104

Providing a distal-most hemostatic clip configured for surrounding the bodily organ or tissue. The distal-most hemostatic clip includes a first clip arm having a first clip arm distal end and a second clip arm having a second clip arm distal end, the second clip arm opposes and is pivotally linked to the first clip arm at a shared proximal end, and the second clip arm is movable relative to the first clip arm from a non-stressed fully opened clip configuration of the distal-most hemostatic clip.



108

Providing a biasing mechanism between the first and second clip arms and allowing the biasing mechanism to occupy a space between the first and second clip arms and the bodily organ or tissue.



112

Gradually closing the hemostatic clip over the bodily organ or tissue by forcibly decreasing distance between the first and second clip arm distal ends.

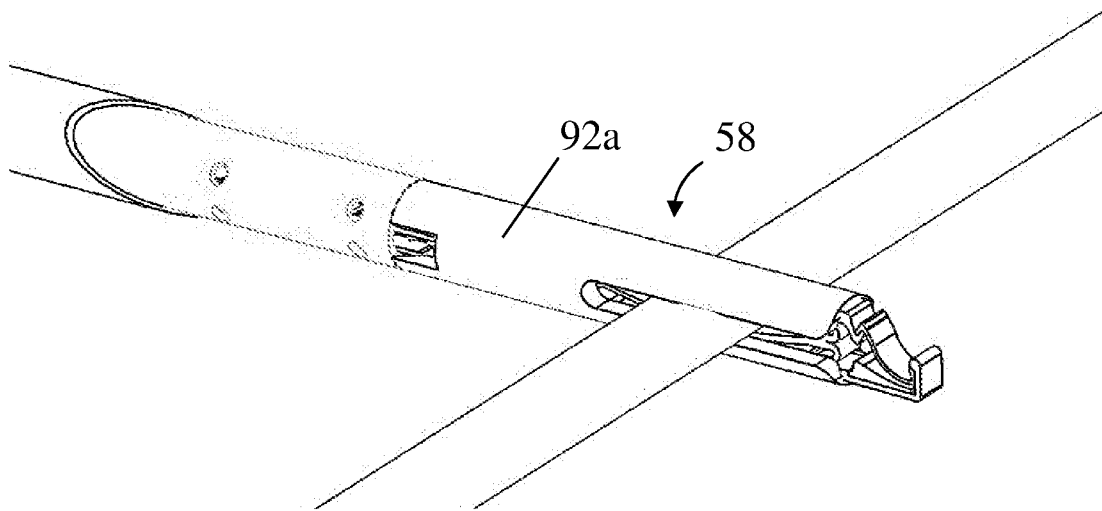
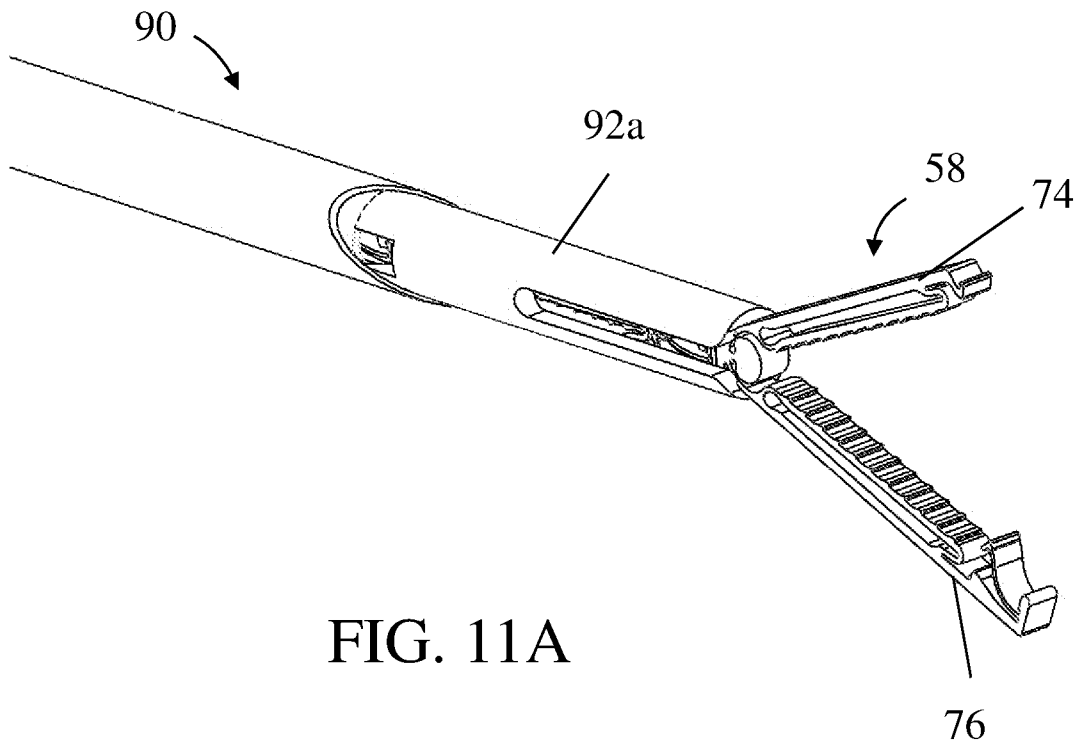


116

Locking together the first and second clip arm distal ends to a closed clip height, via activating a locking mechanism.

Gradually closing or/and locking effects the biasing mechanism into compressing and clamping the bodily organ or tissue, while being deformed at least partially into an outer periphery of the compressed and clamped bodily organ or tissue.

13/15



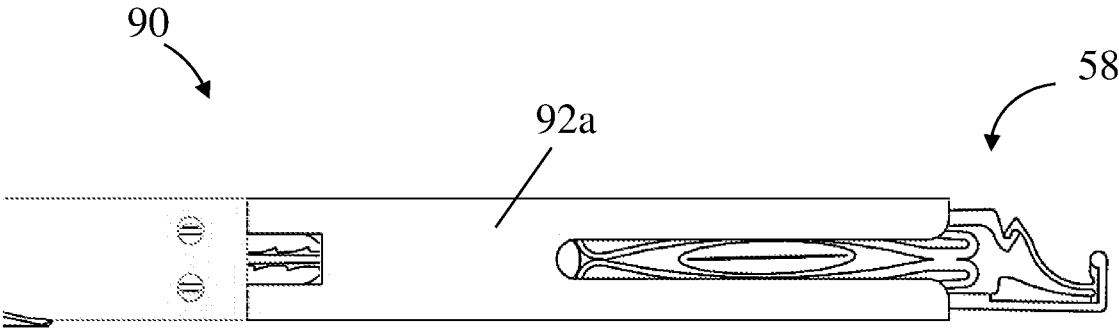


FIG. 11C

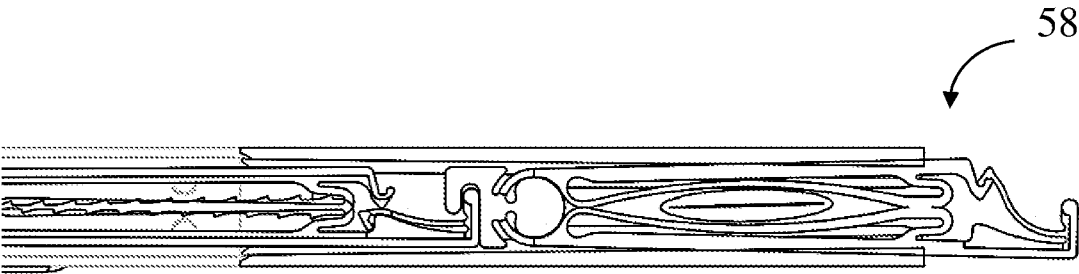


FIG. 11D

15/15

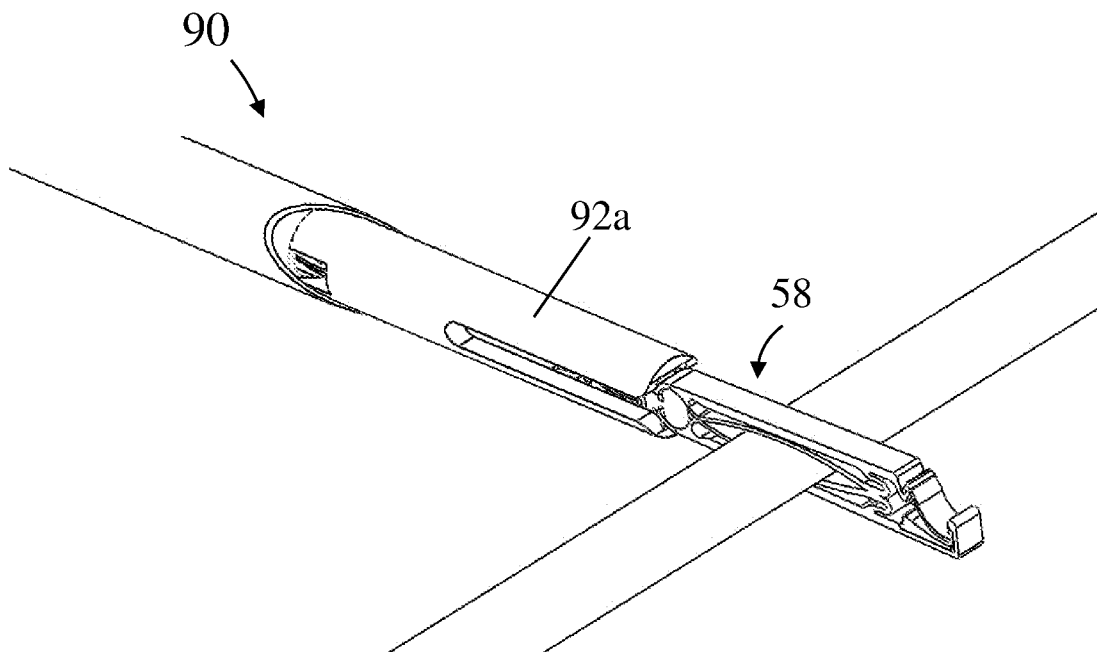


FIG. 11E

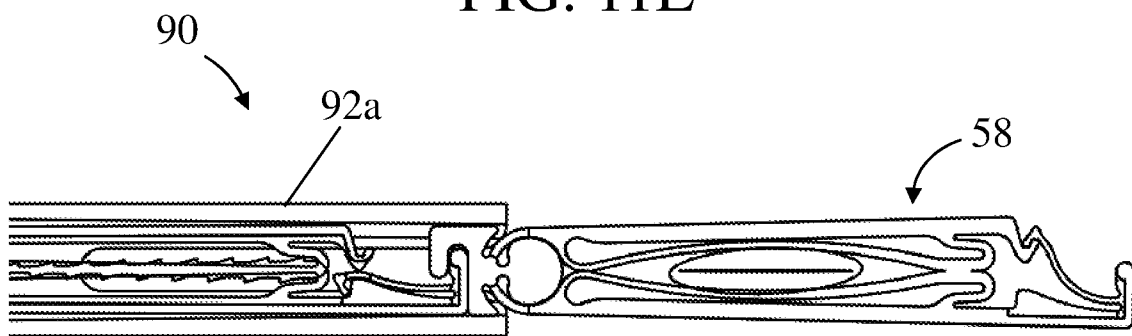


FIG. 11F



FIG. 11G