



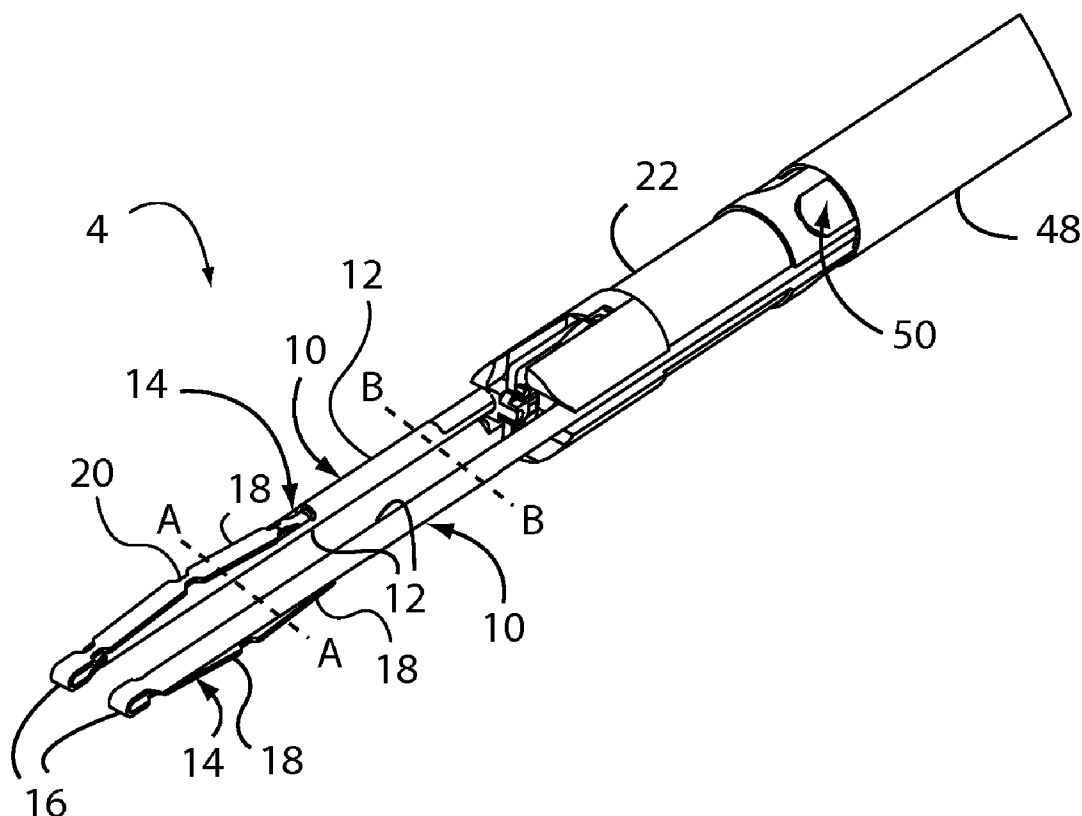
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(19) **United States**(12) **Patent Application Publication**
Bender et al.(10) **Pub. No.: US 2009/0039138 A1**(43) **Pub. Date: Feb. 12, 2009**(54) **VASCULAR CLOSURE SYSTEM WITH
SPLAYABLE STAPLE**(75) Inventors: **Theodore M. Bender**, San Francisco, CA (US); **Zachary Warder-Gabaldon**, Palo Alto, CA (US); **Matthew B. Newell**, Portola Valley, CA (US); **Bernard A. Hausen**, Menlo Park, CA (US); **Bryan D. Knodel**, Flagstaff, AZ (US)Correspondence Address:
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REDWOOD CITY, CA 94063 (US)(73) Assignee: **Cardica, Inc.**, Redwood City, CA (US)(21) Appl. No.: **12/254,743**(22) Filed: **Oct. 20, 2008****Related U.S. Application Data**

(63) Continuation of application No. 11/282,177, filed on Nov. 18, 2005, now Pat. No. 7,458,978, which is a continuation-in-part of application No. 11/093,003, filed on Mar. 28, 2005, now Pat. No. 7,344,544.

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A61B 17/064 (2006.01)
(52) **U.S. Cl.** **227/179.1; 606/219**
(57) **ABSTRACT**

A medical device for closing an opening in tissue may include a staple with a plurality of tines, where the staple is deformable from an initial configuration to a splayed configuration and then to a closed configuration; a cradle that includes a distal stop and a proximal stop proximal to the distal stop extending therefrom, where the cradle holds a portion of the staple between the proximal stop and the distal stop, and where the proximal stop and distal stop are spaced apart from one another a fixed distance substantially equal to the thickness of the portion of the staple held therebetween, where that portion of the staple substantially contacts both stops in the initial configuration; and a housing, where the cradle is movable relative to that housing.



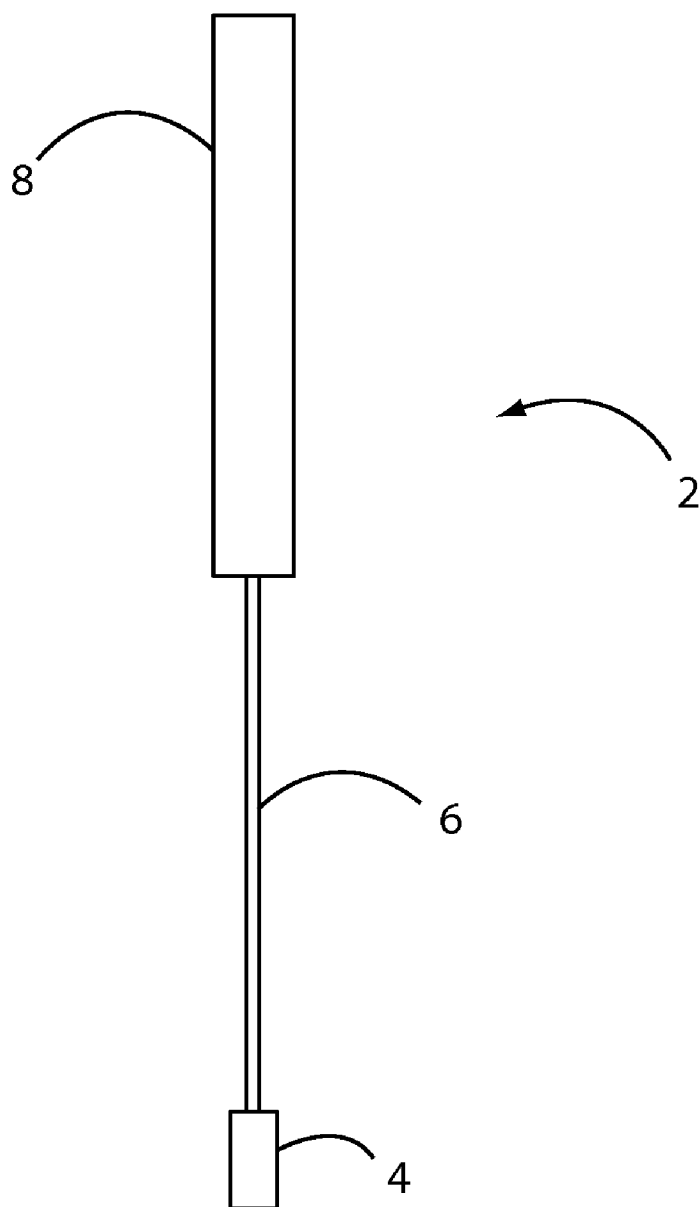


FIG. 1

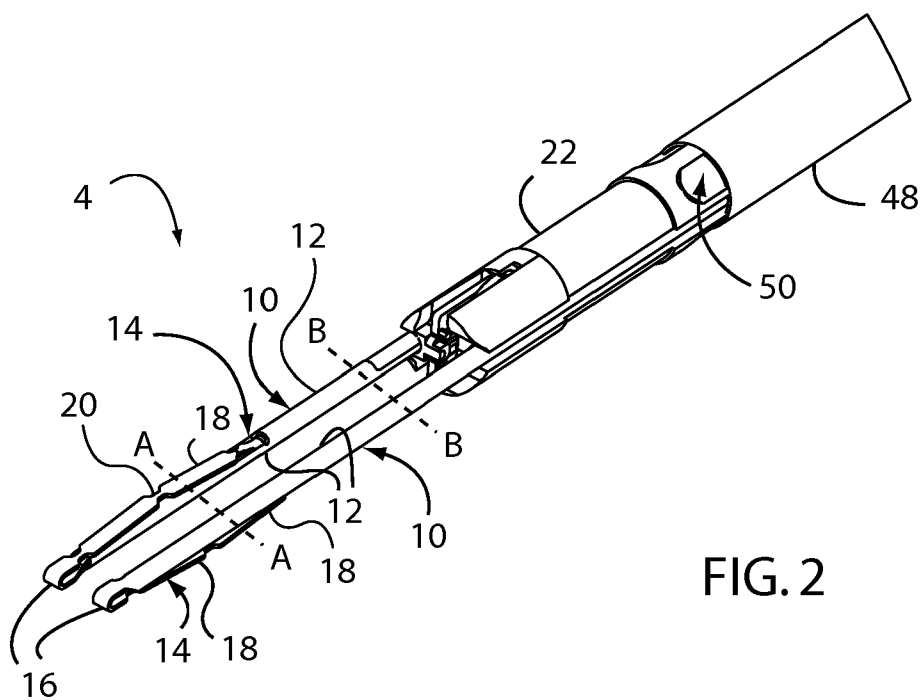


FIG. 2

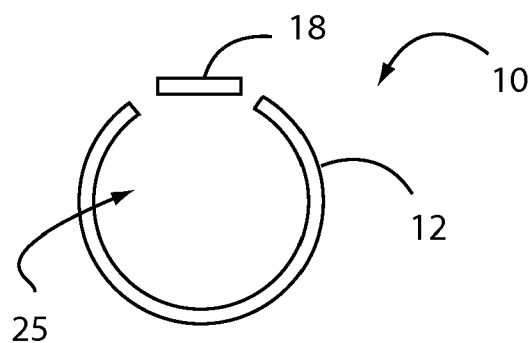


FIG. 3A

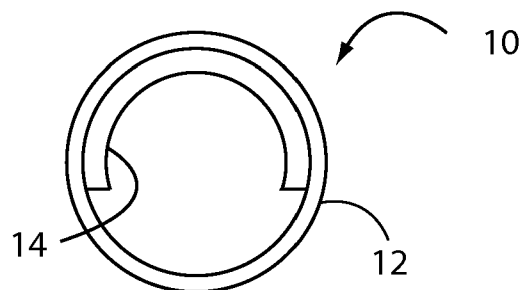


FIG. 3B

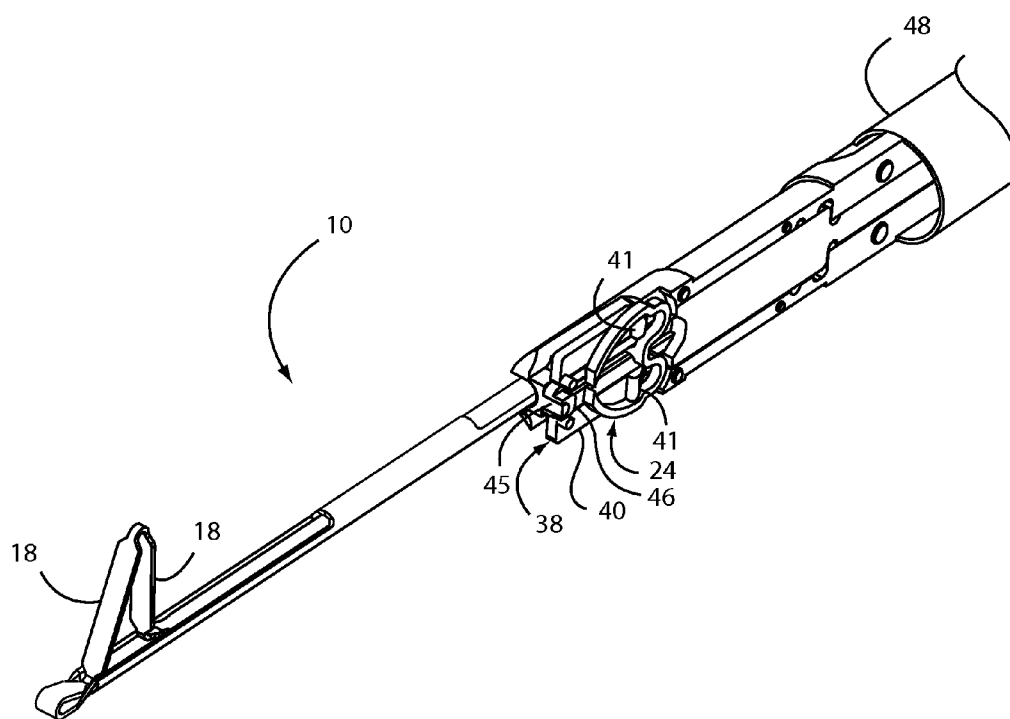


FIG. 4

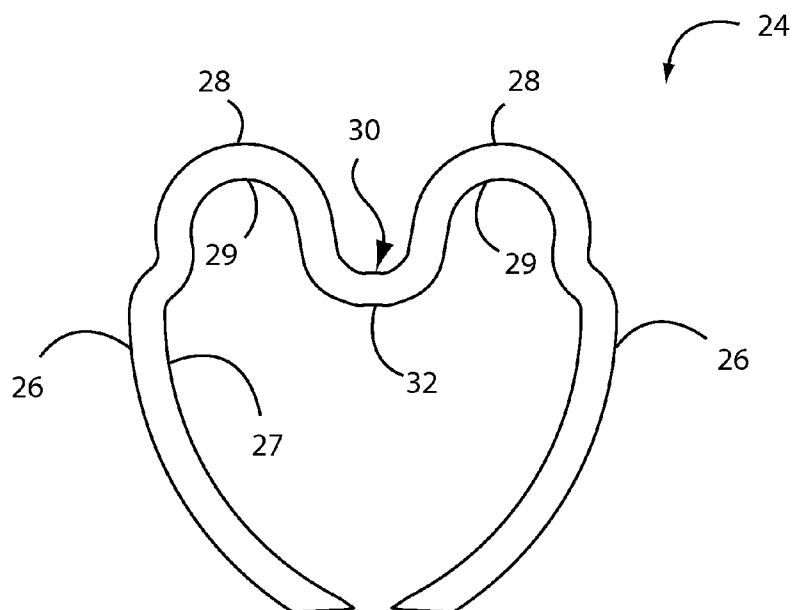


FIG. 5

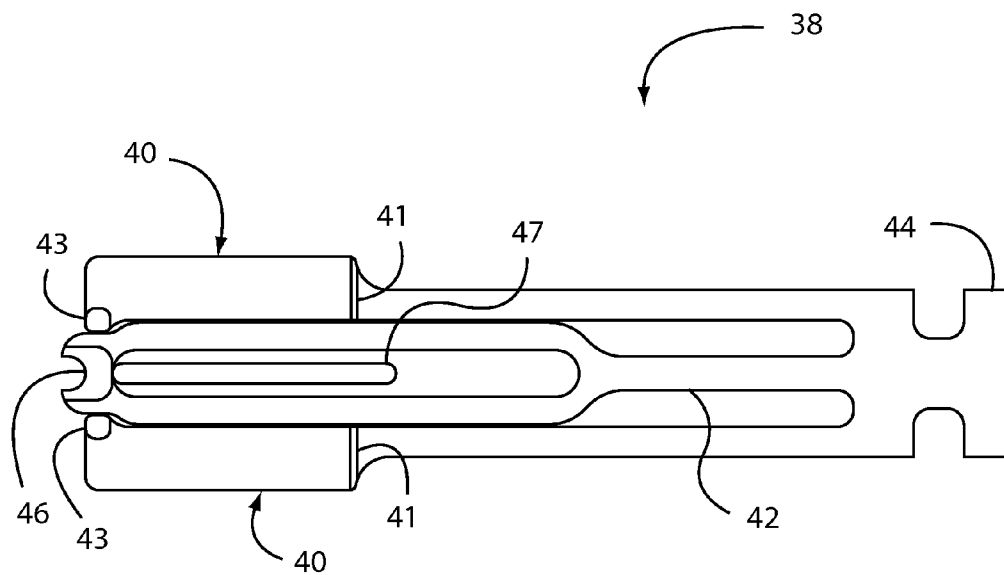


FIG. 6

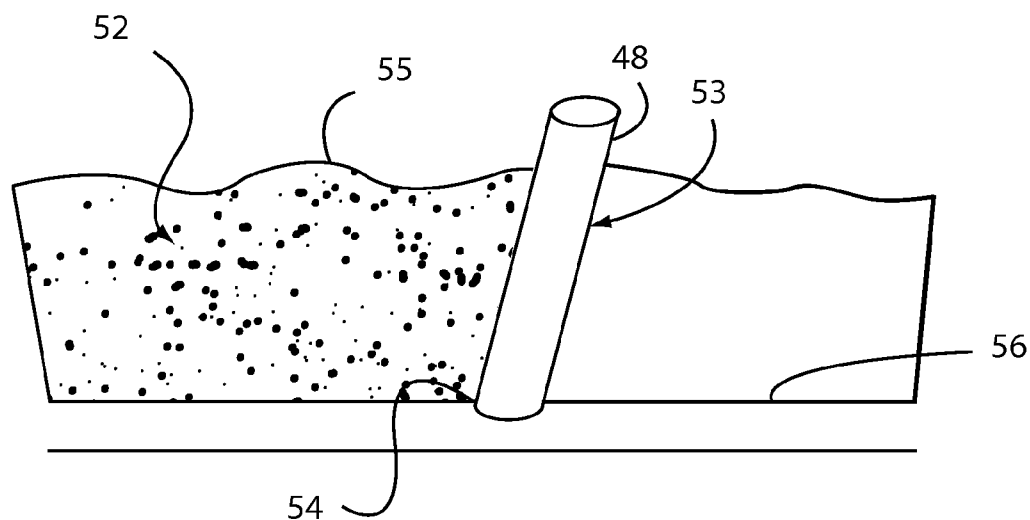


FIG. 7

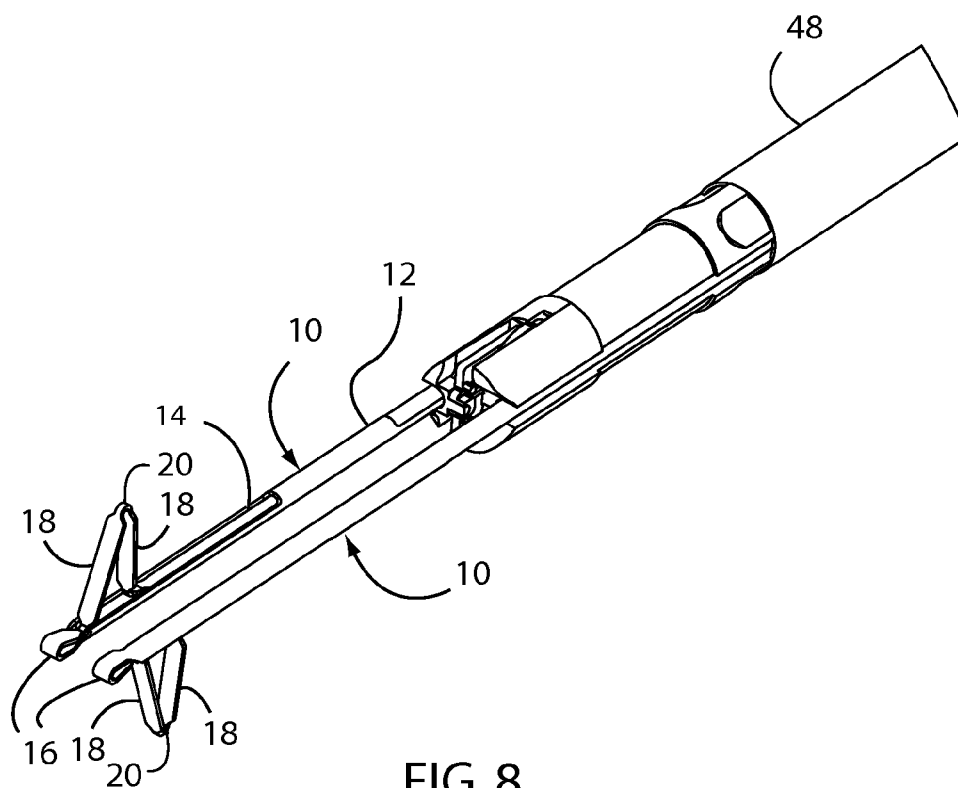


FIG. 8

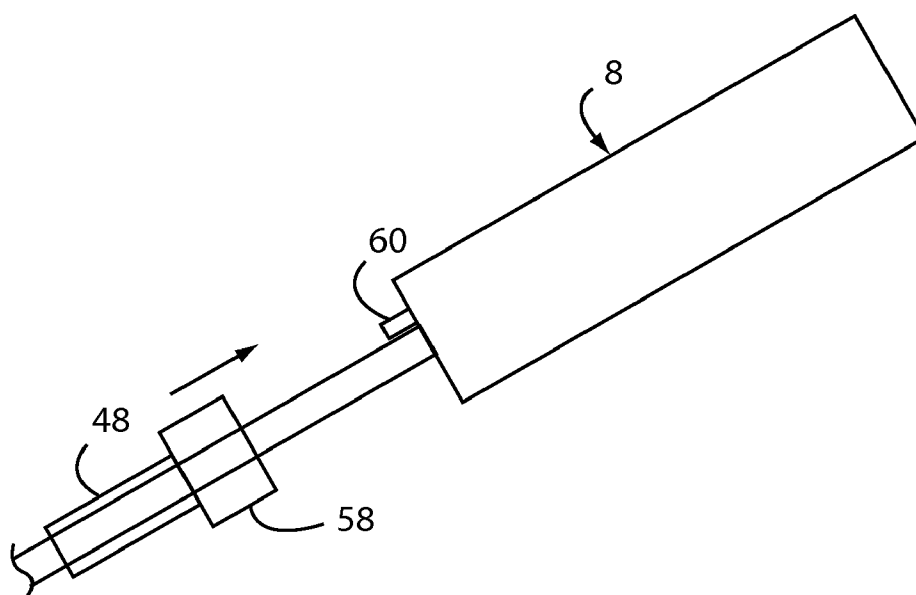
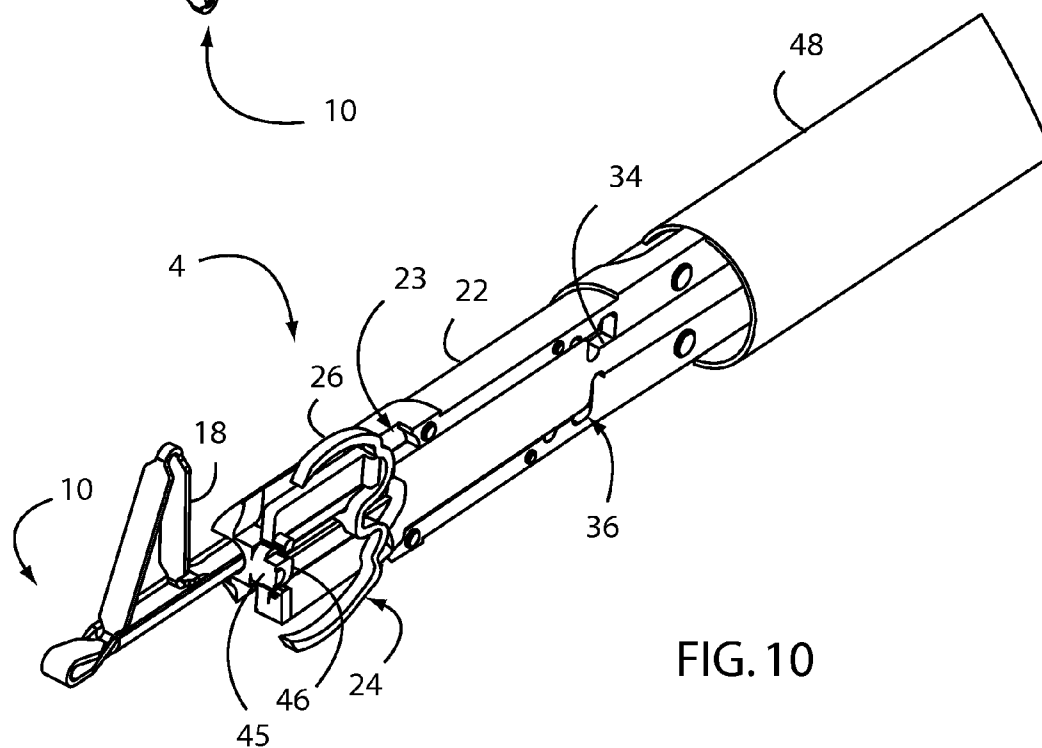
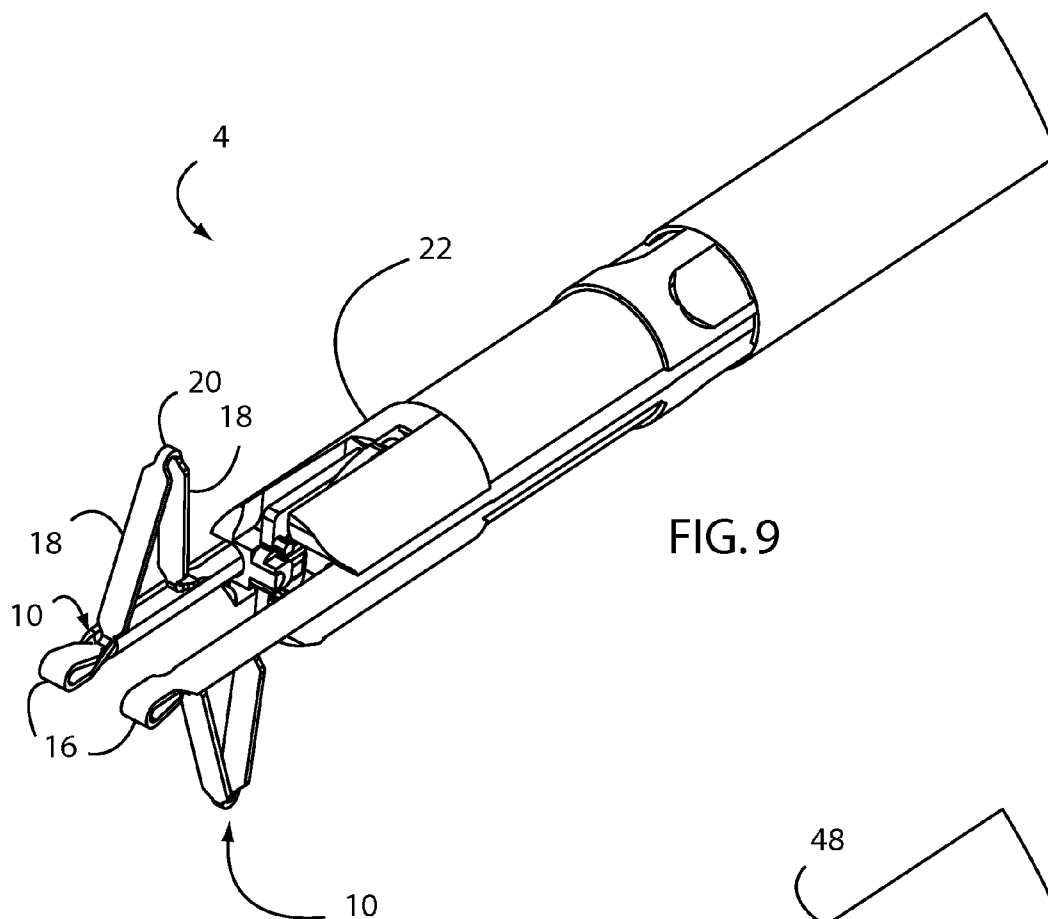


FIG. 8A



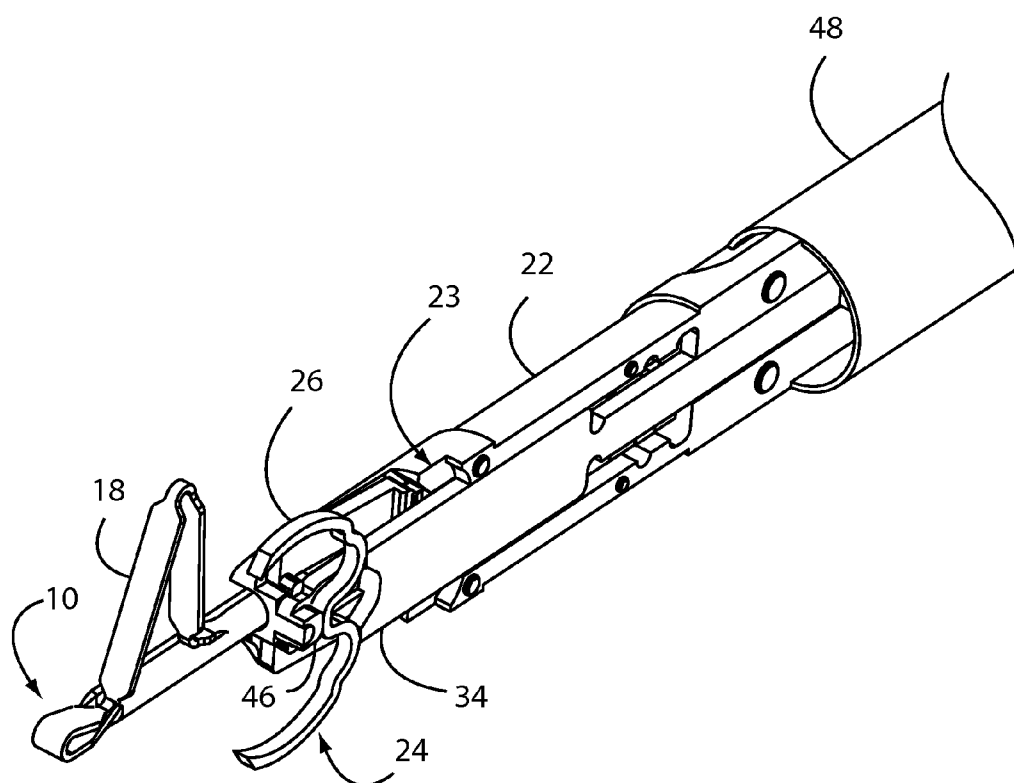
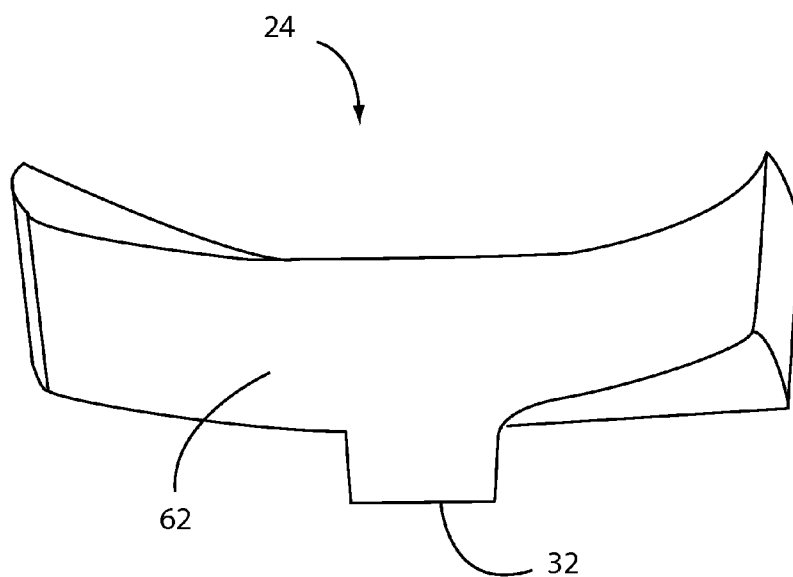
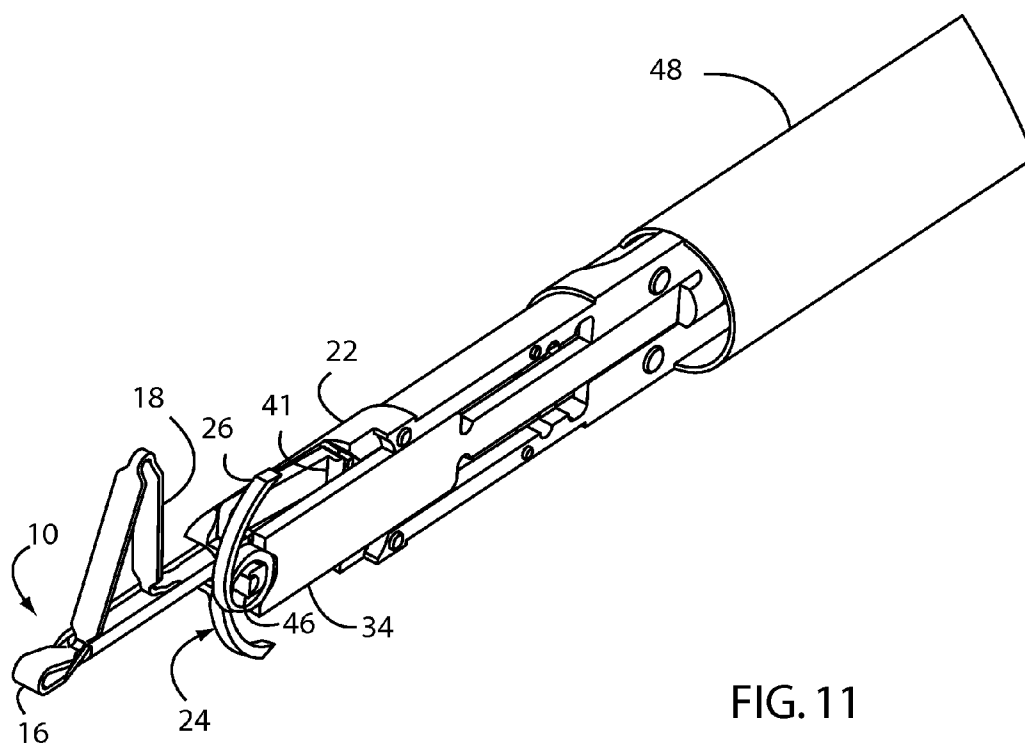


FIG. 10A



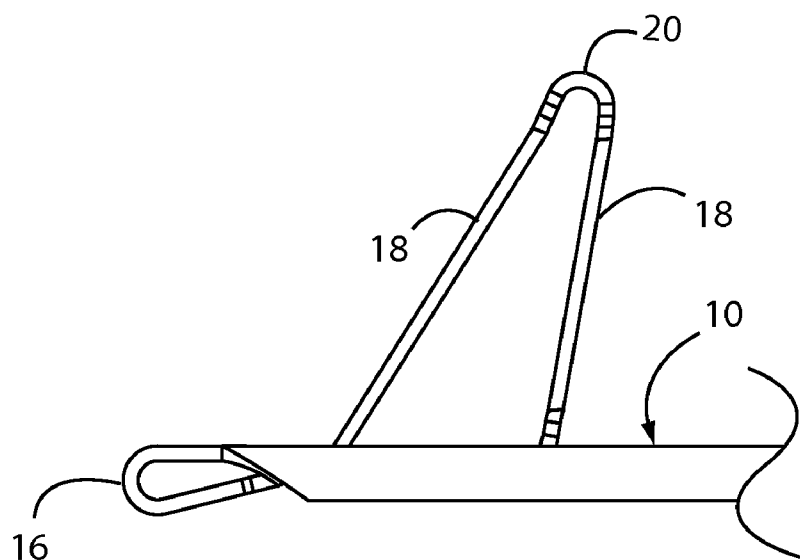


FIG. 13A

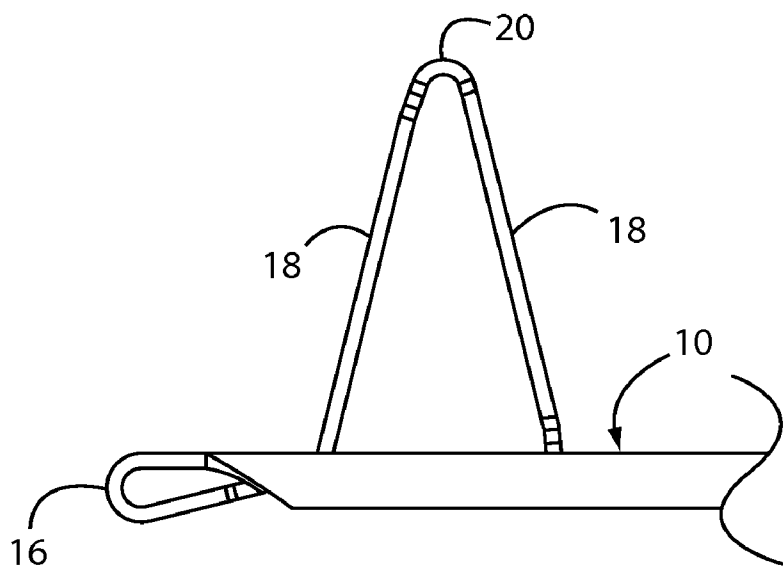


FIG. 13B

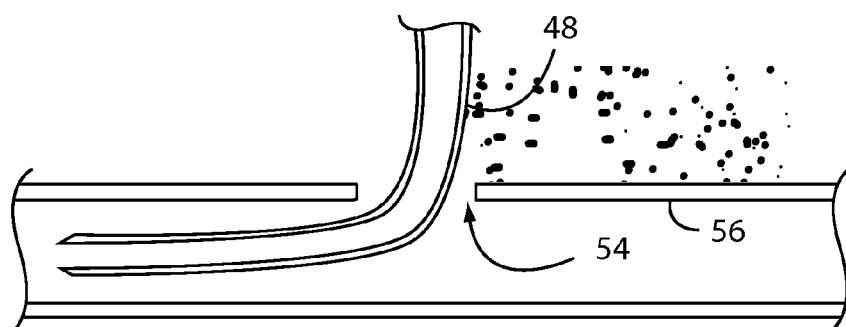


FIG. 14

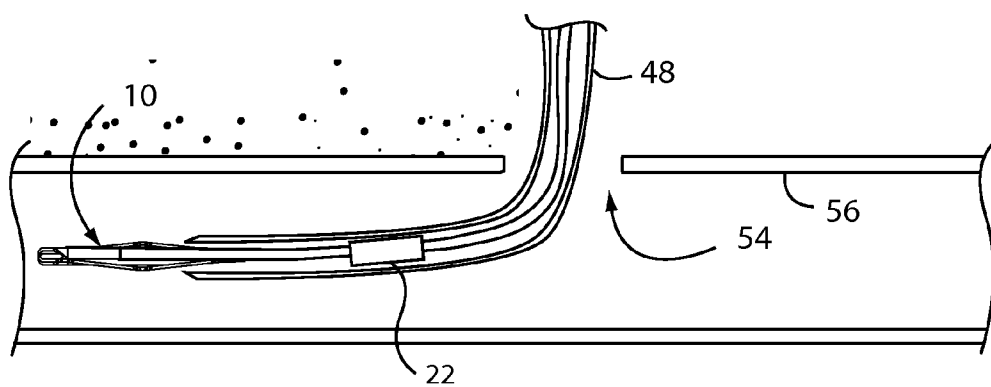


FIG. 15

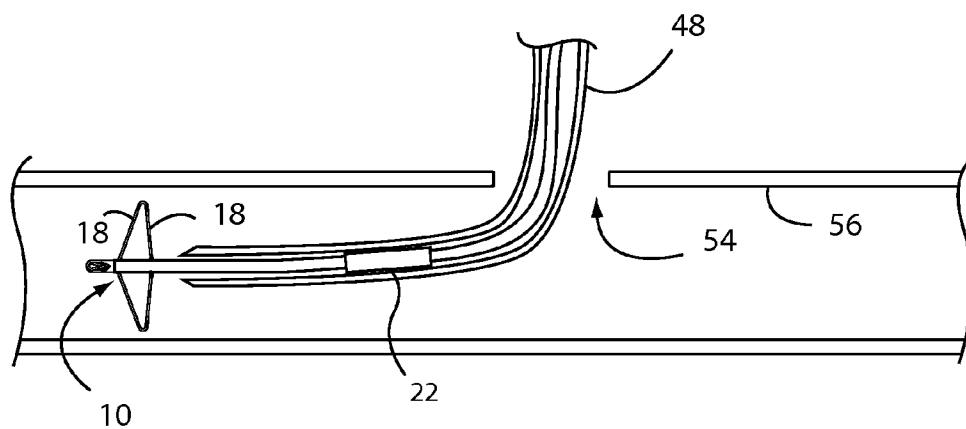


FIG. 16

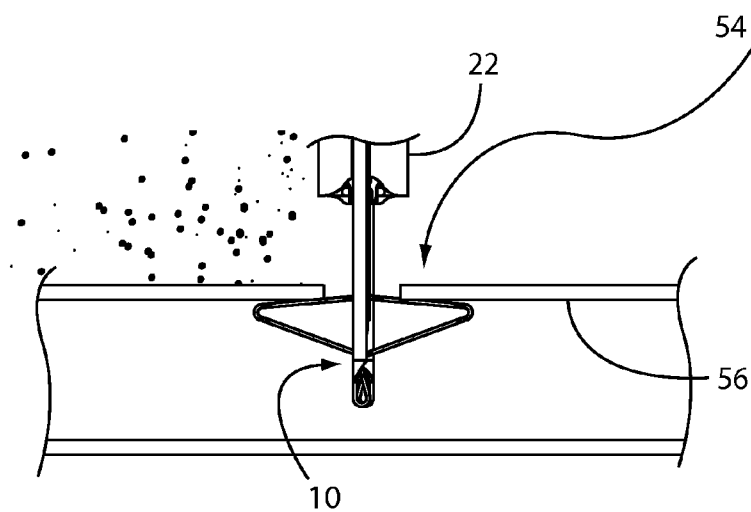


FIG. 17

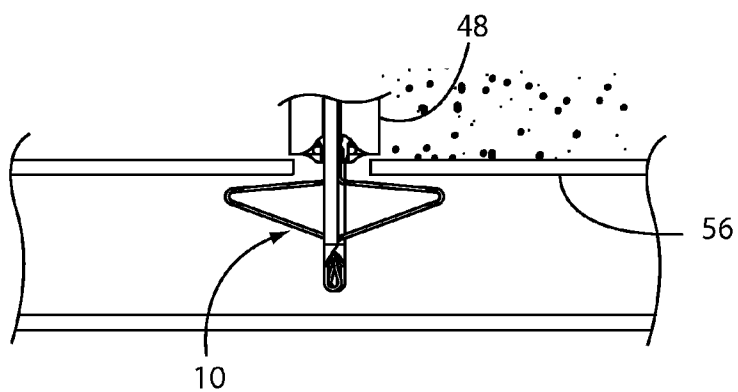
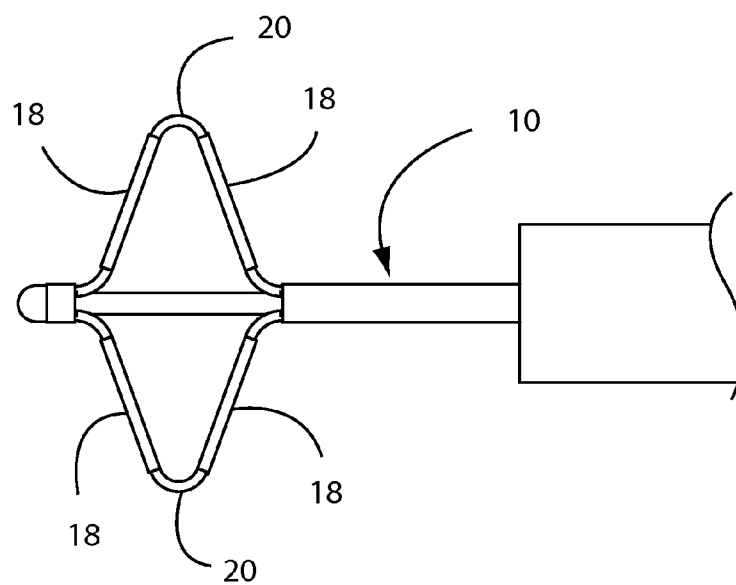
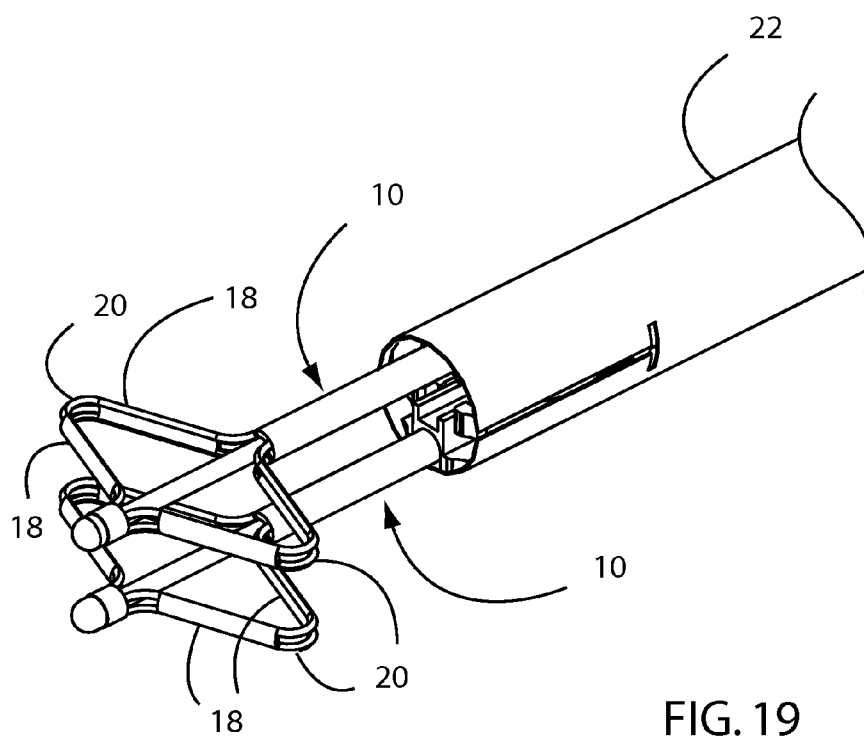


FIG. 18



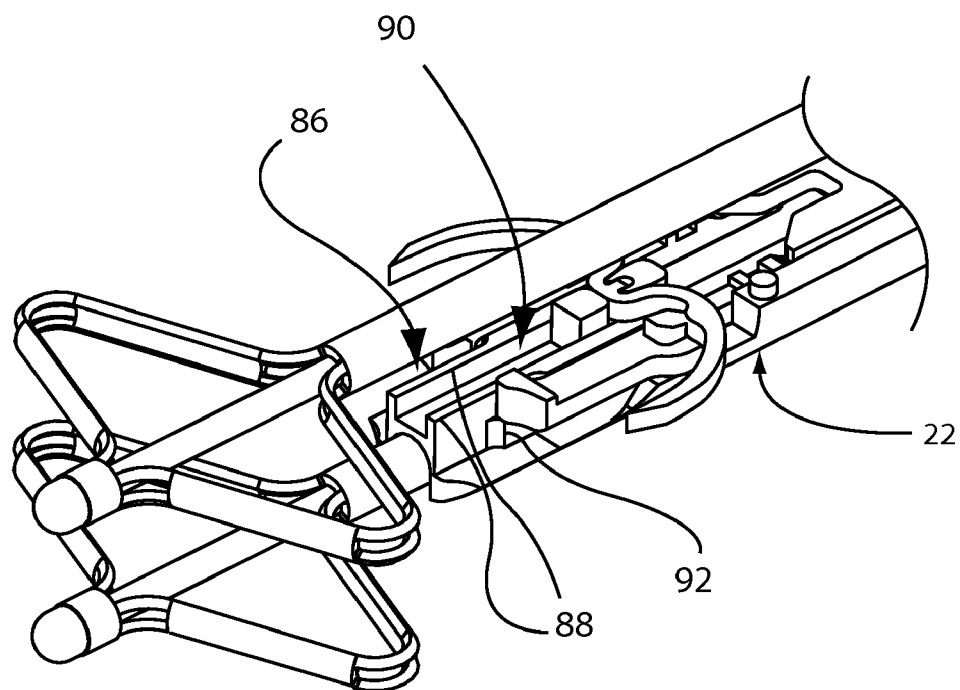


FIG. 21

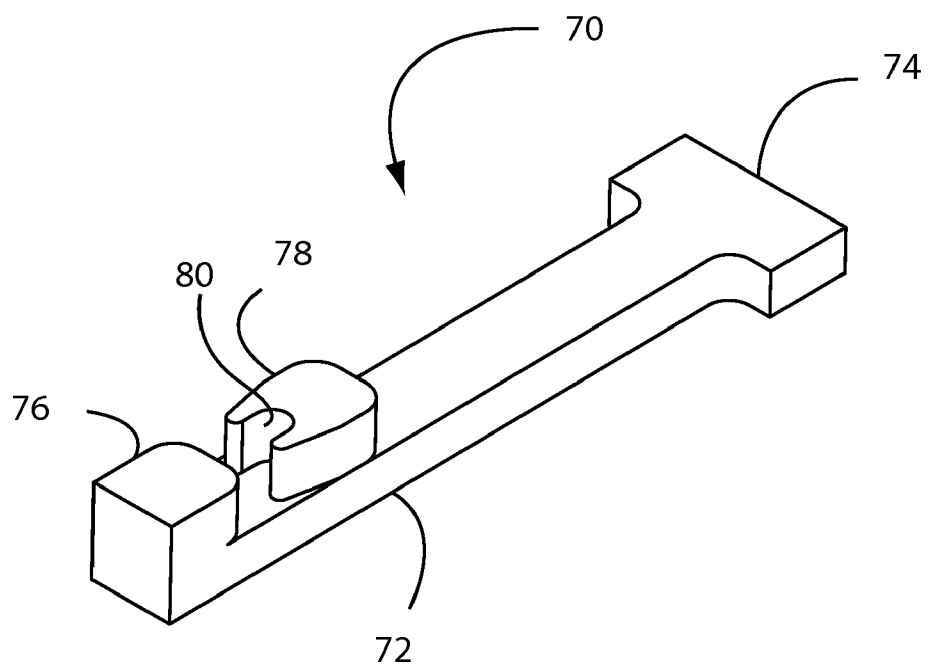


FIG. 22A

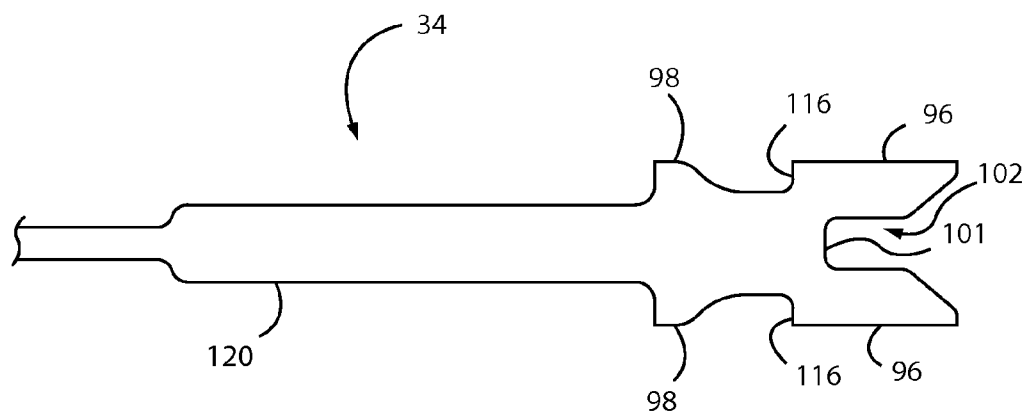


FIG. 22B

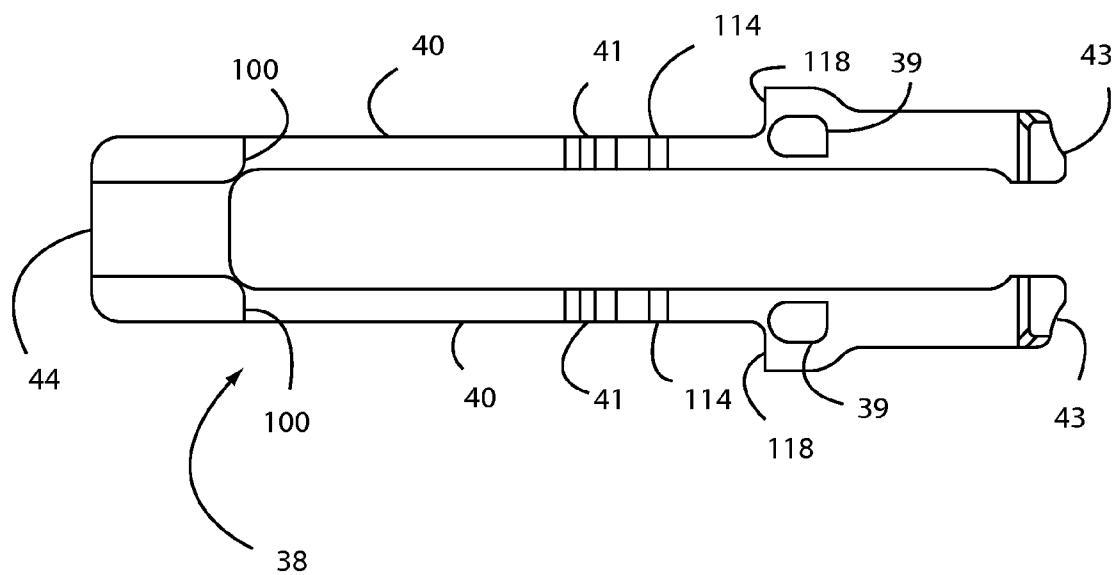


FIG. 22C

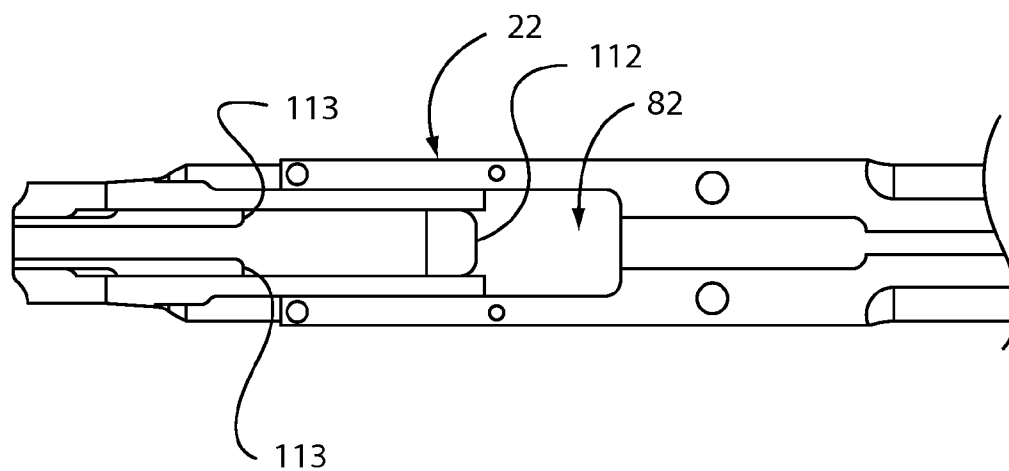


FIG. 22D

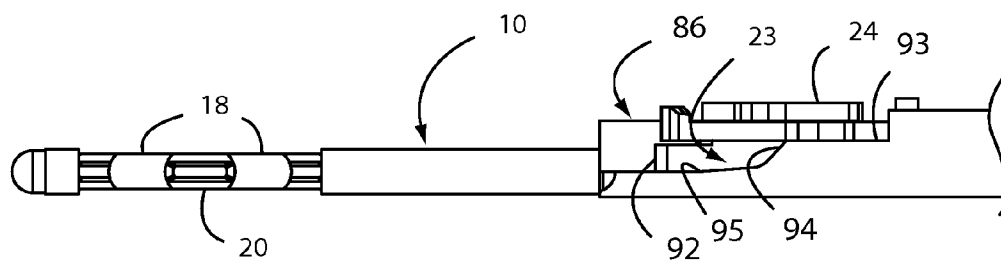


FIG. 23

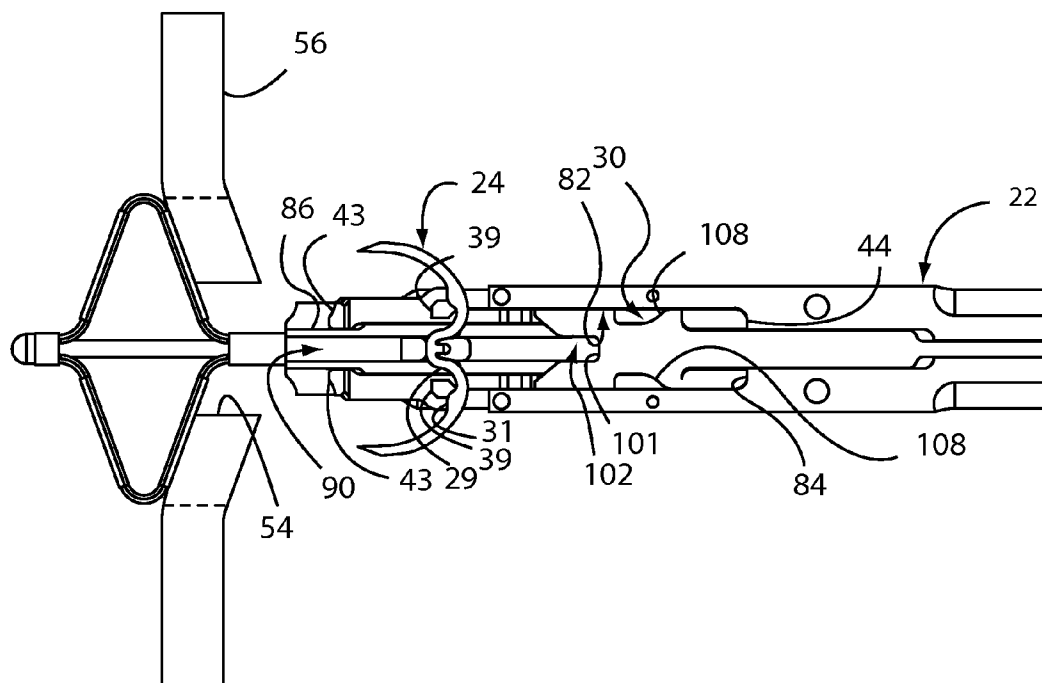


FIG. 24

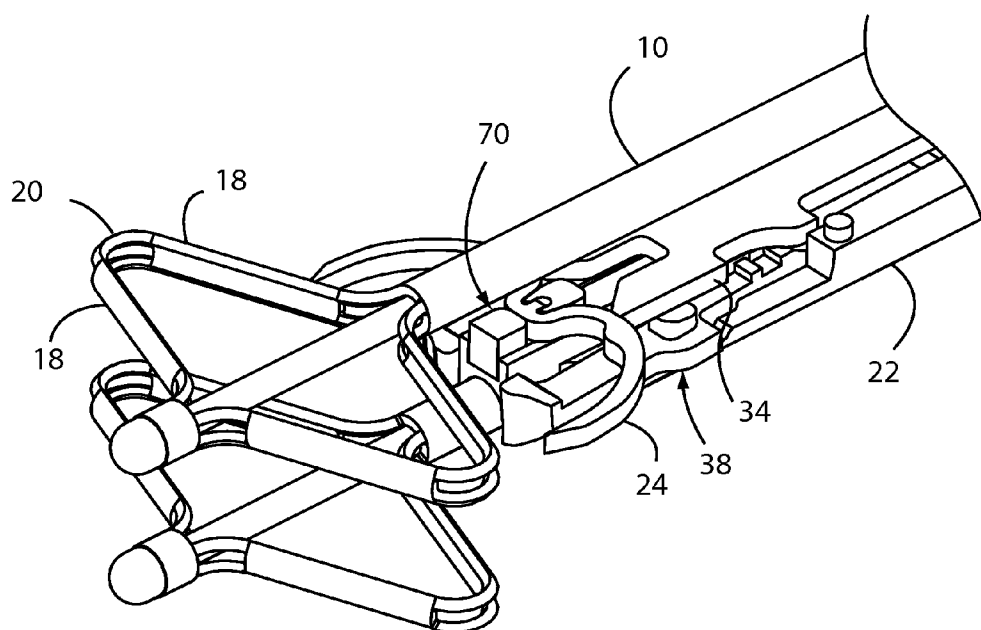


FIG. 25

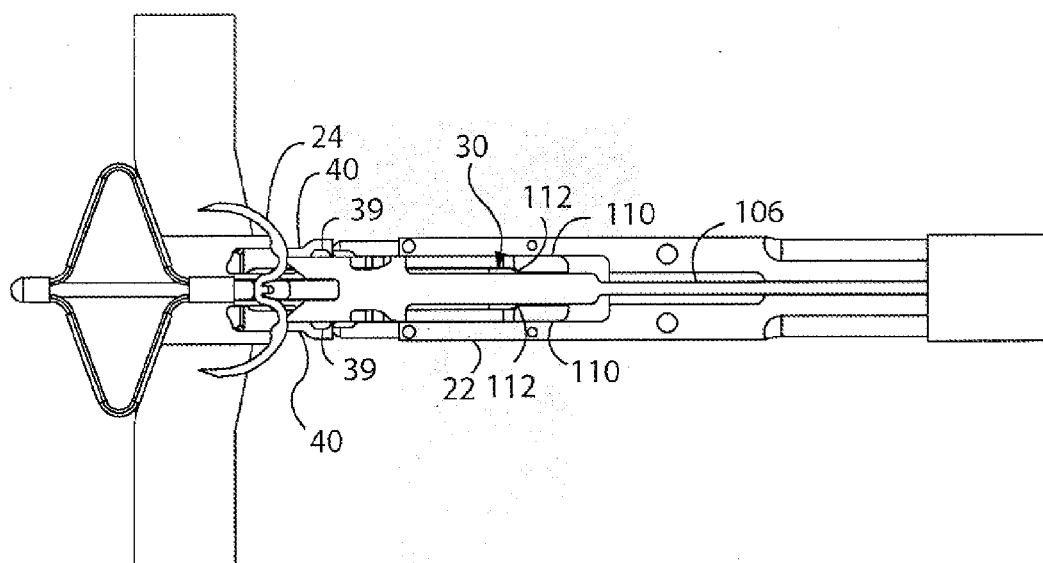


FIG. 26

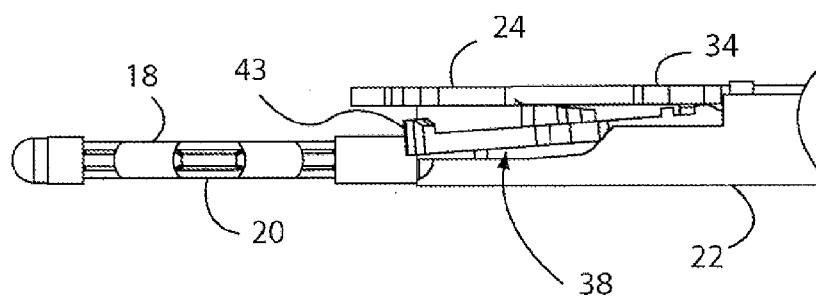


FIG. 27

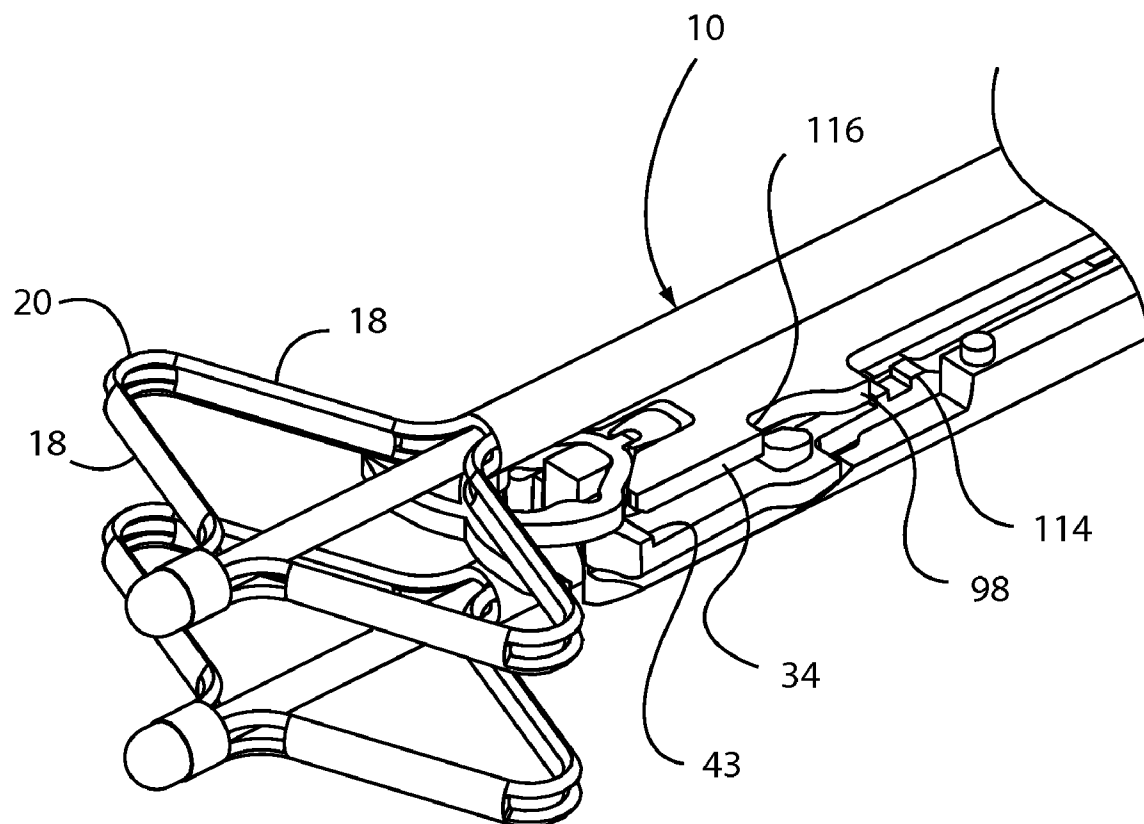


FIG. 28

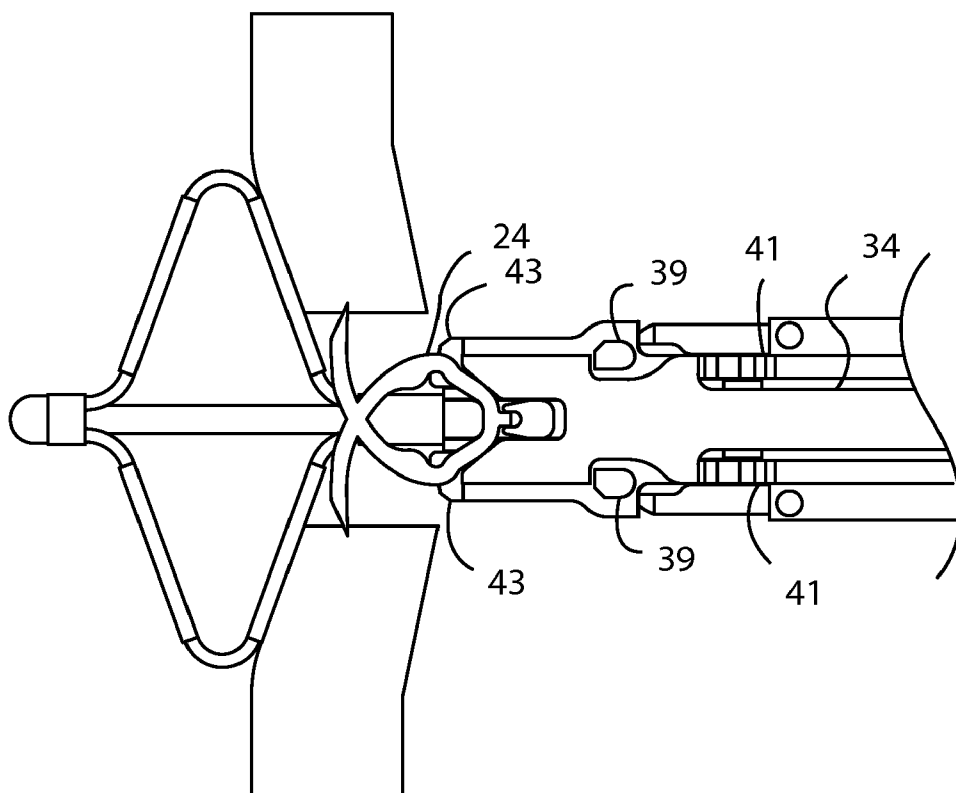


FIG. 29

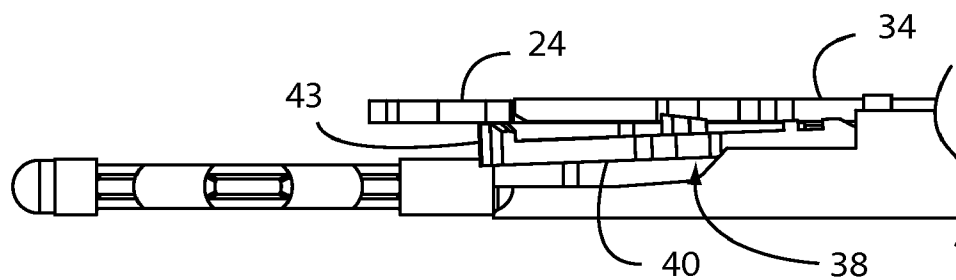


FIG. 30

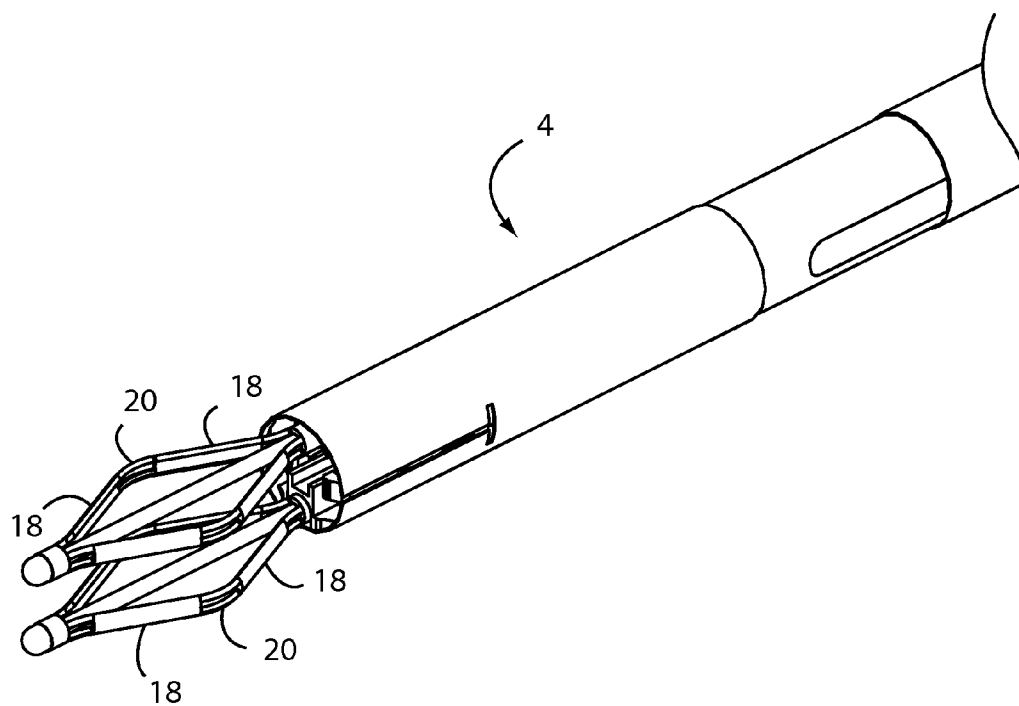


FIG. 31

VASCULAR CLOSURE SYSTEM WITH SPLAYABLE STAPLE

[0001] This application is a continuation of U.S. patent application Ser. No. 11/282,177, filed Nov. 18, 2005; which in turn is a continuation-in-part of U.S. patent application Ser. No. 11/093,003, filed Mar. 28, 2005, now U.S. Pat. No. 7,344,544; the contents of which are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to a system for closing an opening in tissue.

BACKGROUND

[0003] Millions of people each year undergo catheterization for reasons including stent placement, angioplasty, angiography, atrial ablation, placement of abdominal aortic aneurysm grafts and/or stents, and other interventional cardiologic and vascular procedures. In a femoral artery catheterization, an opening is made in the wall of the femoral artery, and a sheath is placed in that opening through which a guidewire and one or more tools may be inserted for performing treatment on the patient.

[0004] After the sheath is removed, the opening in the femoral artery must be closed. Compression is typically used to do so. Anticoagulation therapy is stopped, and manual pressure is applied to the site for up to an hour until clotting seals the access site. The patient then must remain motionless for up to 24 hours, generally with a sandbag or other heavy weight on the site to continue the compression. Many patients find this procedure, and the resultant bruising and pain, to be more unpleasant than the actual interventional procedure that was performed.

[0005] Several types of closure devices and techniques have been developed in an attempt to facilitate closure of the opening in the femoral artery. However, acceptance of these devices and techniques has been limited for several reasons, including complexity of use, complication rates similar to traditional closure, and cost. One type of device utilizes suture to close the opening. However, such devices are typically complex mechanically and consequently are complex to operate. Further, such devices often require an auxiliary knot-pushing tool to be used, further increasing complexity. Other devices are ring-shaped or shaped in a convoluted or tortuous manner, and are complicated and expensive to manufacture. Another closure technique involves inserting a plug or slurry of collagen or other chemical composition into the opening and/or the pathway in the leg between the opening and the skin. However, compression and lengthy bed rest are generally still required with chemical closure techniques, just as with traditional closure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a schematic view of a vascular closure system that includes an end effector, a shaft and a handle.

[0007] FIG. 2 is a perspective view of the end effector having butterfly members in a first, collapsed configuration.

[0008] FIG. 3a is a cross-section view of a butterfly member of the end effector along the line A-A in FIG. 2.

[0009] FIG. 3b is a cross-section view of a butterfly member of the end effector along the line B-B in FIG. 2.

[0010] FIG. 4 is a perspective cross-section view of the end effector in a first configuration.

[0011] FIG. 5 is a side view of the staple of FIG. 4 in a first configuration.

[0012] FIG. 6 is a side view of paddles and a finger that are utilized within the end effector.

[0013] FIG. 7 is a schematic view of tissue having a catheterization sheath positioned therein.

[0014] FIG. 8 is a perspective view of the end effector having butterfly members in a second, expanded configuration.

[0015] FIG. 8A is a schematic view of the handle and shaft of the vascular closure system and their relationship with a sheath.

[0016] FIG. 9 is a perspective view of the end effector after the butterfly members have been moved proximally.

[0017] FIG. 10 is a perspective cutaway view of the end effector in a second configuration, as the staple is splayed.

[0018] FIG. 10A is a perspective view of the end effector in a third configuration, after the splayed staple has been shuttled distally.

[0019] FIG. 11 is a perspective view of the end effector in a fourth configuration, as the staple is closed.

[0020] FIG. 12 is a top view of an embodiment of a staple.

[0021] FIG. 13A is a side view of the distal end of one exemplary butterfly member.

[0022] FIG. 13B is a side view of the distal end of a different exemplary butterfly member.

[0023] FIG. 14 is a side view of a first step in the operation of the closure system.

[0024] FIG. 15 is a side view of a second step in the operation of the closure system.

[0025] FIG. 16 is a side view of a third step in the operation of the closure system.

[0026] FIG. 17 is a side view of a fourth step in the operation of the closure system.

[0027] FIG. 18 is a side view of a fifth step in the operation of the closure system.

[0028] FIG. 19 is a perspective view of the end effector having exemplary butterfly members in a second, expanded configuration.

[0029] FIG. 20 is a top view of the end effector of FIG. 19.

[0030] FIG. 21 is a cutaway perspective view of an exemplary end effector in a first configuration.

[0031] FIG. 22A is a perspective view of a cradle utilized in the end effector of FIG. 21.

[0032] FIG. 22B is a top view of a driver utilized in the end effector of FIG. 21.

[0033] FIG. 22C is a top view of a paddle assembly utilized in the end effector of FIG. 21.

[0034] FIG. 22D is a top view of an inner surface of the housing of the end effector of FIG. 21.

[0035] FIG. 23 is a side cutaway view of the end effector of FIG. 21.

[0036] FIG. 24 is a top cutaway view of the end effector of FIG. 21.

[0037] FIG. 25 is a cutaway perspective view of the end effector of FIG. 21 in a second configuration.

[0038] FIG. 26 is a top cutaway view of the end effector of FIG. 25.

[0039] FIG. 27 is a side cutaway view of the end effector of FIG. 25.

[0040] FIG. 28 is a cutaway perspective view of the end effector of FIG. 21 in a third configuration.

[0041] FIG. 29 is top cutaway view of the end effector of FIG. 28.

[0042] FIG. 30 is a side cutaway view of the end effector of FIG. 28.

[0043] FIG. 31 is a perspective view of the end effector of FIG. 25, showing the butterfly members in a partially-expanded configuration.

[0044] The use of the same reference symbols in different figures indicates similar or identical items.

DETAILED DESCRIPTION

Closure System

[0045] Referring to FIG. 1, a closure system 2 includes an end effector 4 connected to a shaft 6, which in turn is connected to a handle 8. The end effector 4 may be one or more separate components that are connected to the shaft 6, or may be fabricated integrally with the distal end of the shaft 6. Referring also to FIG. 7, the end effector 4 is sized to pass through a standard sheath 48 placed in a passage 53 in tissue 52 for a standard catheterization procedure. The end effector 4 may include a housing 22. The housing 22 may be split into multiple parts, such as a top half and a bottom half. Referring to FIGS. 2, 21 and 24, for example, a bottom half of the housing 22 is shown. The housing 22 may include internal functional features such as stops, grooves and rails that are described in greater detail below. Alternately, the housing 22 may include left and right halves rather than top and bottom halves. Alternately, the housing 22 may be configured in any other suitable manner.

[0046] Referring also to FIG. 2, the end effector 4 includes at least one butterfly member 10. Each butterfly member 10 acts to register tissue such as the wall of a blood vessel to the end effector 4, as described in greater detail below. At least one butterfly member 10 may extend substantially distally from a housing 22 or other component of the end effector 4. Alternately, at least one butterfly member 10 extends at least partially in a different direction. Each butterfly member 10 may be configured in any manner that allows it to move from a first, collapsed configuration to a second, expanded configuration, and back to the collapsed configuration. As one example, at least one butterfly member 10 includes a first element 12, and a second element 14 connected to the distal end of the first element 12. The first element 12 is not substantially deformable, and at least part of the second element 14 is deformable to an expanded configuration. Alternately, either or both of the elements 12, 14 is deformable to an expanded configuration. The elements 12, 14 may be shaped and configured in any suitable manner. As one example, referring also to FIGS. 3a-3b, the first element 12 may have a semicircular cross-section or other curved cross-section along at least part of its length. Such a cross section increases the moment of inertia of the first element 12 and thereby increases its stiffness. At least part of the first element 12 may be partially tubular, hollow, or otherwise include an area configured to receive a portion of the second element 14, or vice versa. At least part of the first element 12 may be substantially coaxial with the second element 14. The distal end 16 of at least one butterfly member 10 may be blunt in order to prevent or minimize any disturbance to the tissue structure into which the butterfly member 10 is inserted. For example, the distal end of at least one butterfly member 10 may be curved at the junction between the elements 12, 14. At least one butterfly member 10 may have a longitudinal axis in the

collapsed configuration that is offset from and substantially parallel to the longitudinal axis of the end effector 4 and/or the shaft 6. The use of the term “axis” in this document is not limited to use with respect to structures that are cylindrical or radially symmetrical, and the use of the term “axis” in conjunction with a structure does not and cannot limit the shape of that structure. Alternately, at least one butterfly member 10 is oriented differently relative to the longitudinal axis of the end effector 4 and/or the shaft 6.

[0047] The second element 14 may include two substantially planar segments 18 longitudinally spaced from one another and connected to one another by a hinge element 20 between them, such that one segment 18 is positioned distal to the other segment. The segments 18 need not be planar. For example, at least one segment 18 may be curved. At least one segment 18 may have a radius of curvature substantially the same as a remainder of the second element 14. The hinge element 20 may be a living hinge, such as a narrower area between the two segments 18 that bends to allow movement between the segments 18. Alternately, the hinge element 20 may be any structure or mechanism that allows for relative movement between the segments 18. At least one of the segments 18 may be curved or otherwise non-planar. One of the planar segments 18 may extend to a location at or in proximity to the distal end 16 of the corresponding butterfly member 10. The segments 18 may be angled relative to one another when the butterfly member 10 is in the first, collapsed configuration. For example, the most-distal segment 18 may be angled relative to the longitudinal axis of the corresponding butterfly member 10 such that the distal end of that segment 18 is closer to that longitudinal axis than the proximal end of that segment 18, and the most-proximal segment 18 may be angled relative to the longitudinal axis of the corresponding butterfly member 10 such that the proximal end of that segment 18 is closer to that longitudinal axis than the distal end of that segment 18. Alternately, the segments 18 may be angled differently relative to one another. The angle between the segments 18 allows the hinge 20 to deform or otherwise move upon application of force to the second element 14, as described in greater detail below. The segments 18 may be angled relative to one another a greater amount when the butterfly member 10 is in the second, expanded configuration than in the first, collapsed configuration. Alternately, the segments 18 may be substantially parallel to one another and/or lie in substantially the same plane as one another. Referring to FIG. 13A, the segments 18 each may be substantially the same length, such that they form a symmetrical shape upon actuation of the butterfly member 10. Alternately, referring to FIG. 13B, the segments 18 may differ in length, such that they form a non-symmetrical shape upon actuation of the butterfly member 10. Thus, in the expanded configuration, the distal end of at least one butterfly member 10 may have a single expanded feature formed by the connected segments 18.

[0048] Alternately, referring to FIGS. 19-20, in the expanded configuration, the distal end of at least one butterfly member 10 may have more than one expanded feature formed by connected segments 18. That is, at or near the distal end of the second element 14 of at least one butterfly member 10, two or more sets of segments 18 may be provided. Each set of segments 18 may include two segments 18 connected by a hinge 20 that may include two or more separate elements. Alternately, the segments may be connected differently. As shown in FIGS. 19-20, two sets of segments 18 are provided

on each butterfly member 10, spaced opposite one another near the distal end of the corresponding butterfly member 10. However, the two sets of segments 18 may be oriented differently relative to one another. Further, more than two sets of segments 18 may be provided on at least one butterfly member 10. The sets of segments 18 need not be arranged radially symmetrically or in any other particular arrangement relative to the remainder of the corresponding butterfly member 10. Each segment 18 in a set may be substantially the same length and/or shape as the other, or may differ in length and/or shape from the other.

[0049] Referring also to FIG. 2, the first element 12 may extend into the housing 22 of the end effector 4 through a notch, aperture or other opening. The first element 12 may instead extend along a groove or other receiving area of the housing 22, rather than or in addition to extending into the housing 22. The first element 12 is movable relative to the housing 22. Alternately, the first element 12 is fixed substantially to the housing 22. The first element 12 may extend through the shaft 6 to the handle 8. The proximal end of the first element 12 extends substantially proximally from the housing 22 in any suitable amount.

[0050] A proximal portion of the second element 14 may extend into a center area 26 of a proximal portion of the first element 12. That center area 26 of the first element 12 may be referred to as the lumen of the first element 12 for convenience, even though the first element 12 may be open along part of its perimeter, or may have a cross-section other than circular, at any portion of its length. The longitudinal axis of the lumen 26 may be substantially coincident with the longitudinal axis of the first element 12, or may be offset from or otherwise aligned relative to the longitudinal axis of the first element 12. The second element 14 may be movable relative to that lumen 26, such as by sliding substantially along or substantially parallel to the longitudinal axis of the lumen 26. Alternately, the second element 14 does not extend into the lumen 26 of the first element 12. Alternately, the second element 14 does not include a lumen 26. For example, both the first element 12 and the second element 14 may be substantially flat, or gently curved. The elements 12, 14 may be adjacent to one another, or spaced apart from one another, along at least part of their length, particularly where neither element 12, 14 includes a lumen 26. At least one of the elements 12, 14 may be configured to move, such as by sliding, relative to at least part of the other element 12, 14. Alternately, at least part of the second element 14 includes a lumen 26 therein, and a portion of the first element 12 may extend into that lumen 26.

[0051] The first element 12 and the second element 14 may both be parts of an integral whole, shaped to constitute the butterfly member 10. For example, the butterfly member 10 may be stamped from a sheet of metal, such as stainless steel. The butterfly member 10 may then be folded, where the first element 12 is on one side of the fold and the second element 14 is on the other side of the fold. At least a portion of each member 12, 14 may be folded into a semicircular or other shape as viewed longitudinally, before or after the folding. Each butterfly member 10 may be fabricated from any suitable material. As one example, at least one butterfly member 10 may be fabricated from any material, such as nickel-titanium alloy, that is elastically or superelastically deformable between the first configuration and the second configuration. As another example, at least one butterfly member 10 may be fabricated from any material, such as stainless steel or

plastic, that is plastically deformable between the first configuration and the second configuration. At least part of at least one butterfly member 10 may be plastically deformable between the collapsed configuration and the expanded configuration. At least part of the butterfly member 10 may be annealed, such that it can be plastically deformed without fracturing. Both of the elements 12, 14 may be substantially rigid, such that they are capable of transmitting both compressive and tensile force.

[0052] Referring also to FIG. 4, a staple 24 is initially positioned within a space inside the end effector 4. Alternately, the staple 24 is positioned differently within the end effector 4, or is positioned at the end of the end effector 4 rather than within it. The staple 24 may be sized and shaped in any suitable manner. As one example, referring also to FIG. 5, the staple 24 may have a curved M-shape. However, the staple 24 may have any other suitable shape. The staple 24 may have two tines 26, each extending at least partially in the distal direction. The tines 26 may be curved, and may each have a shape and radius of curvature such that the tines 26 are generally not parallel to one another. The radius of curvature may be substantially coincident with the path of travel of the tines 26 during closure of the staple 24. The staple 24 may be substantially bilaterally symmetrical, although it may be asymmetrical if desired. The staple 24 may be a substantially continuous solid. As used in this document, the term "solid" means that a structure has no slots, holes, apertures or other enclosed or bounded openings defined therein.

[0053] The distal end of each tine 26 may have a substantially pointed or sharpened distal end. However, the distal ends of the tines 26 need not be pointed or sharpened, particularly if the cross-sectional area of each tine 26 is small. Advantageously, each tine 26 has a single distal end that is not bifurcated or otherwise forked or split. The body of the staple 24 extends proximally from the distal end of one tine 26 and curves or angles toward the longitudinal centerline of the staple 24. This curve may extend outward from the longitudinal centerline of the staple 24, then toward the longitudinal centerline of the staple 24. Alternately, the tine 26 may curve differently. The body of the staple 24 reaches a peak 28, then extends distally and toward the longitudinal centerline of the staple 24. The body of the staple 24 then reaches a trough 30, then extends proximally and away from the longitudinal centerline of the staple to a second peak 28. The body of the staple 24 continues distally to form the second tine 26, and ends at the distal end of the second tine 26. Alternately, the staple 24 may be shaped differently. For example, the staple 24 may have more than two tines 26. A valley 29 is the area on the staple 24 on the other side of the staple 24 from a peak 28. For example, where a peak 28 of the staple 24 includes a convex curve oriented proximally, the corresponding valley 29 is a concave curve opening distally. Advantageously, the staple 24 is substantially solid. The peaks 28 and the trough 30 may be referred to collectively as the base of the staple 24. More generally, the part of the staple 24 connecting the tines 26 together is the base of the staple 24, regardless of its particular shape.

[0054] The staple 24 may include at least one tab 32 extending therefrom in any suitable direction, such as substantially perpendicular to the body of the staple 24. Advantageously, the tab 32 extends from the trough 30 of the staple 24 or from a location in proximity to the trough 30. The staple 24 may include any suitable number of tabs 32. Each tab 32 is sized and positioned to engage a corresponding substantially-long-

gitudinal groove (not shown) in the housing 22. Thus, the tab 32 registers the staple 24 to the housing 22. Alternately, instead of or in addition to a tab 32, the staple 24 may include at least one slot (not shown) that is sized and positioned to engage a corresponding substantially-longitudinal rib (not shown) defined on the housing 22. Alternately, any other structure or mechanism may be used to register the staple 24 to the housing 22.

[0055] The staple 24 may lie substantially in a single plane. That is, the staple 24 is shaped such that a single plane extends through and substantially bisects the entire staple 24. Alternately, the staple 24 does not lie substantially in a single plane. The longitudinal and lateral dimensions of the staple 24 overall may both be substantially larger than the height of the staple 24. Alternately, the staple 24 may be sized differently. Referring also to FIG. 12, the proximal surface 62 of the staple 24 optionally may be curved relative to a plane perpendicular to the longitudinal axis of the staple 24. For example, the proximal surface 62 of the staple 24 may take the shape of a twisted plane. The proximal surface 62 of the staple 24 may be twisted such that a line perpendicular to that proximal surface 62 on one side of the longitudinal centerline of the staple 24 is skewed relative to a line perpendicular to that proximal surface 62 on the other side of the longitudinal centerline of the staple 24, and both such lines are skewed relative to the longitudinal centerline of the staple 24.

[0056] The staple 24 may be plastically deformable. If so, the staple 24 may be fabricated from stainless steel, titanium or any other suitable plastically-deformable material. Alternately, the staple 24 may be elastically deformable. If so, the staple 24 may be fabricated from nickel-titanium alloy or any other suitable elastic or superelastic material. The staple 24 may be fabricated from a single wire or other piece of material, having a rectangular, circular or other cross-section. The cross-section of the staple 24 may be substantially constant along the entire staple 24, or may vary at different locations along the staple 24. For example, the cross-sectional area of the staple 24 at certain locations may be less than at other locations, in order to promote bending in those locations having a lesser cross-sectional area.

[0057] Referring also to FIG. 10, a driver 34 is located proximally to the staple 24, and is movable relative to the staple 24 such as by sliding. At least a portion of the driver 34 may be positioned within the housing 22. The housing 22 may be at least partially hollow in order to accommodate the driver 34. Advantageously, the housing 22 includes a passage 36 therein along which at least part of the driver 34 may slide or otherwise move. At least part of the passage 36 may guide the driver 34 during at least part of its motion. The driver 34 may be configured in any suitable manner. As one example, the driver 34 is an elongated member having a bifurcated distal end, where each bifurcation is configured to engage a corresponding peak 28 of the staple 24. Alternately, the distal end of the driver 34 is shaped differently. The driver 34 may be substantially flat, and may have a thickness substantially equal to that of the staple 24. Alternately, the driver 34 is shaped and/or configured differently, in any suitable manner. Optionally, the staple 24 may be fabricated integrally with the driver 34. If so, the staple 24 is frangible from the driver 34, such that the staple 24 separates from the driver 34 at a suitable time during or after deployment. Fabrication of the staple 24 integrally with the driver 34 may facilitate manufacturing.

[0058] Referring to FIGS. 4 and 6, a paddle assembly 38 may be located at least partially within the passage 36, at or near the distal end thereof. The paddle assembly 38 may include one or more paddles 40 and/or one or more fingers 42. As one example, two paddles 40 are utilized, and a finger 42 is positioned between the paddles 40, where the paddles 40 and the finger 42 are cantilevered from a base 44 of the paddle assembly 38. At least one paddle 40 may include a ridge 41 raised relative to a remainder of the paddle 40. The ridge 41 may be substantially linear, and may be substantially perpendicular to the longitudinal axis of the paddle 40. The ridge 41 may be shaped as a ramp, with greater thickness at its proximal edge than at its distal edge. The surface of the ramp may be straight, curved or complex. Alternately, the ridge 41 may be a bump, shaped such as a section of a cylinder. Alternately, the ridge 41 may be shaped and/or oriented in any other suitable manner. At least one paddle 40 may include a post 43 at or near its distal end. Each post 43 may be substantially cylindrical, or may be shaped in any other suitable manner. Each post 43 extends from a remainder of the paddle 40, and may be oriented substantially perpendicular to the longitudinal axis of the paddle 40. The finger 42 may be substantially linear, and extend substantially along a plane defined by the base 44 of the paddle assembly 38. The distal end of the finger 42 may extend substantially as far distally as the distal ends of the paddles 40, or may extend distally any other suitable distance. A projection 46 extends from a location at or near the distal end of the finger 42 substantially perpendicular to the longitudinal axis of the finger 42. Alternately, the projection 46 extends in a different direction. When the end effector 4 is in an initial position, the distal end of the driver 34 may be in contact with, or in proximity to, the base 44 of the paddle assembly 38. The projection 46 may include a concave depression or other surface configured to slide along a post 45 extending from the housing 22. The post 45 may guide and/or stabilize the projection 46.

[0059] Alternately, the paddle or paddles 40 may be angled or curved relative to the driver 34 such that the driver 34 would contact at least one paddle 40 if the driver 34 moved distally. At least one paddle 40 may be angled or curved toward the staple 24, such that the outer edge of that paddle 40 contacts an inner surface 27 of a tine 26 of the staple 24. That is, the paddle 40 may be angled, curved or otherwise shaped such that at least part of the paddle 40 is positioned between the tines 26 of the staple 24 and is distal to at least part of the staple 24 when the staple 24 is in an initial position. As a result, the paddle or paddles 40 may act both to restrain the staple 24 against distal motion and to hold the staple 24 in its initial configuration.

[0060] When the end effector 4 is in the initial position, the staple 24 is also in an initial position. In the initial position, each ridge 41 of each paddle 40 may be positioned distal to a corresponding valley 29 of the staple 24. Further, when the end effector 4 is in the initial position, the distal end of the driver 34 may be positioned against or in proximity the peaks 28 of the staple 24, thereby substantially restraining the staple 24 against motion in the proximal direction. The staple 24 may be held substantially in place while the end effector 4 is in the initial position in any suitable manner. For example, the staple 24 may be gently friction-fit against a portion of the housing 22.

[0061] Referring also to FIG. 1, the shaft 6 extends proximally from the end effector 4. The shaft 6 may be flexible or rigid. The shaft 6 may be articulated in at least one location, if

desired. Referring also to FIG. 7, the shaft 6 and the end effector 4 are both sized to pass through a standard sheath 48 used in a catheterization procedure. One or more blood leakage indicators 50 may be defined in the shaft 6. At least one blood leakage indicator 50 may be a groove or depression extending along at least part of the length of the shaft 6, and extending distally far enough that the distal end of the blood leakage indicator 50 is distal to the distal end of the sheath 48 when the closure system 2 is in use. Optionally, the shaft 6 may include a cutaway, trough or other feature (not shown) to allow the guidewire (if any) used in the catheterization procedure to remain in place during actuation of the closure system 2. Alternately, the closure system 2 may include or be configured to follow a second guidewire separate from the one utilized to perform a medical procedure.

[0062] The handle 8 is connected to the shaft 6, such as to the proximal end of the shaft 6. The shaft 6 may be fabricated such that the handle 8 is simply the proximal end of the shaft 6. Alternately, the shaft 6 and the handle 8 may be two separate items that are connected together in any suitable manner. The handle 8 may include any mechanism, mechanisms, structure or structures configured to actuate the end effector 4. For example, as described later in this document, the handle 8 may be configured to actuate the butterfly members 10 and the driver 34. Thus, any suitable mechanism or mechanisms that are configured to actuate the butterfly members 10 and the driver 34 may be used. A rod (not shown) may be attached to the driver 34, extending through the shaft 6 to the handle 8. The rod may be rigid enough to transmit force distally, and may be flexible enough to move along the shaft 6 where the shaft 6 is flexible. Alternately, a cable may be connected to the driver 34, and that cable may be directed around an axle, nose or other feature (not shown) of the end effector 4 in order to convert proximal motion of the cable to distal motion of the driver 34. Alternately, the driver 34, and/or any other suitable component of the end effector 4, may extend through the shaft 6 to the handle 8, in order to be actuated directly by the handle 8, and may connect directly to a mechanism, mechanisms, structure or structures in the handle 8 configured to actuate the end effector 4. Alternately, a butterfly cable (not shown) may be connected to the proximal end of each butterfly member 10. Each butterfly member 10 may be connected to an individual butterfly cable, or at least two butterfly members 10 may be connected to the same butterfly cable. Each butterfly cable may be connected to either element 12, 14 of at least one corresponding butterfly member 10. Motion of the butterfly cable results in motion of the corresponding element 12, 14.

[0063] The handle 8 may also include a source of stored energy for actuating the end effector 4. The source of stored energy may be mechanical (such as a spring), electrical (such as a battery), pneumatic (such as a cylinder of pressurized gas) or any other suitable source of stored energy. The source of stored energy, its regulation, and its use in actuating the end effector 4 may be as described in the U.S. patent application Ser. No. 11/054,265, filed on Feb. 9, 2005, which is herein incorporated by reference in its entirety. The handle 8 may instead, or also, include a connector or connectors suitable for receiving stored energy from an external source, such as a hose connected to a hospital utility source of pressurized gas or of vacuum, or an electrical cord connectable to a power source.

[0064] Alternately, the closure system 2 may include at least two separate components: a butterfly deployment tool connected to and configured to place the butterfly members

10, and a staple placement tool which is connected to the end effector 4 and configured to place the staple 24. In this embodiment, the closure system 2 includes two or more separate tools, in contrast to the closure system 2 disclosed above that is a single integrated tool. The staple placement tool may be slidable relative to the butterfly deployment tool, or vice versa. As one example, at least a portion of the butterfly deployment tool may be tubular, and at least a portion of the staple placement tool may be configured to slide within the lumen of the tubular portion of the butterfly deployment tool. As another example, the butterfly deployment tool and/or the staple placement tool may include a groove defined therein, where the other tool includes a rail, rib or other structure configured to slide along that groove. Separating the functions of butterfly deployment and staple placement may facilitate the deployment of multiple staples 24, as described in greater detail below.

[0065] Operation

[0066] Referring to FIGS. 7 and 14, in the course of a standard catheterization procedure, a sheath 48 is inserted through a passage 53 in tissue 52 such that one end of the sheath 48 enters an opening 54 in a blood vessel 56. The passage 53 extends between the epidermis 55 of the patient and the opening 54 in the blood vessel 56. The sheath 48 may be advanced any suitable distance into the blood vessel 56, as determined by the physician performing the procedure. When the sheath 48 is in place, at least one blood leakage indicator 50 is exposed to blood within the blood vessel 56, allowing blood to flow outward therethrough. As an example of a catheterization procedure, the blood vessel 56 may be a femoral artery, and the tissue 52 may be the tissue of the leg between the surface of the leg and the femoral artery. However, the blood vessel 56 may be a different blood vessel, and the tissue 52 may be different tissue in the vicinity of that different blood vessel. During the catheterization procedure, any suitable tools are utilized to perform the desired treatment on the patient, such as the placement of one or more stents in the coronary arteries or peripheral vessels of the patient. After the treatment has been performed, the tools utilized to perform that treatment are removed from the patient via the sheath 48, and the sheath 48 is left in place.

[0067] Referring also to FIG. 2, the end effector 4 of the closure system 2 is inserted into the sheath 48. The end effector 4 may be advanced along the sheath 48 in any suitable manner. As one example, the end effector 4 is manually pushed along the sheath 48 by the physician or other user by applying a force to the shaft 6 and/or the handle 8 after the end effector 4 has entered the sheath 48. Each butterfly member 10 initially may be in its first, collapsed configuration as the end effector 4 is advanced along the sheath 48. The end effector 4 continues to advance distally into the sheath 48 until at least the distal end 16 of at least one butterfly member 10 is distal to the distal end of the sheath 48. That is, the end effector 4 is advanced along the sheath 48 until at least the distal end 16 of at least one butterfly member 10 is outside of the lumen of the sheath 48. This position of the end effector 4 relative to the sheath 48 may be referred to as the standby position. The sheath 48 has a known length, and at least part of the end effector 4 is advanced along the lumen of the sheath 48 a distance greater than the length of the sheath 48. Thus, the particular position of the distal end of the sheath 48 in the lumen of the blood vessel 56 need not be known in order for the end effector 4 to be advanced to the standby position. Optionally, one or more markings may be placed on the shaft

6, such that when those one or more markings enter the lumen of the sheath 48, the end effector 4 has been advanced to the standby position. The marking or markings on the shaft 6 are placed at a distance from the distal end of the end effector 4 that is greater than the length of the sheath 48.

[0068] Optionally, a guidewire (not shown) utilized in the catheterization procedure may remain in the lumen of the sheath 48, and the end effector 4 and shaft 6 may follow that guidewire in any suitable manner. As one example, where a cutaway, groove or other feature is defined in the end effector 4 and/or shaft 6, that feature may slide along the guidewire. Optionally, the guidewire used in the catheterization procedure is removed from the lumen of the sheath 48 prior to the introduction of the end effector 4 into the sheath 48, and a second, thinner guidewire configured for use with the closure system 2 is inserted through the lumen of the sheath 48 and into the lumen of the blood vessel 56. The original guidewire may be removed before or after the placement of the second guidewire. The second, thinner guidewire, if used, may be more convenient to remove from the opening 54 in the blood vessel 56 after the staple 24 has been closed.

[0069] After the end effector 4 is in the standby position, at least one butterfly member 10 is actuated to move from its first, collapsed configuration to its second, expanded configuration. This actuation may be performed in any suitable manner. Referring also to FIG. 8, as one example, the second element 14 of each butterfly member 10 is held substantially in place, and the first element 12 of each butterfly member 10 is pulled proximally in any suitable manner. As one example, the elements 12, 14 each extend through the shaft 6 to the handle 8, and a mechanism or mechanisms in the handle 8 push or otherwise move the first element 12 proximally. As another example, the first element 12 is connected to a cable or other force transmission member, and the handle 8 exerts a proximal force on that cable, which in turn moves the first element 12 proximally.

[0070] Proximal motion of the first element 12 relative to the second element 14 exerts a compressive force on the segments 18, substantially in the longitudinal direction. Because at least one segment 18 is angled, curved or otherwise offset from the longitudinal direction, that longitudinal force results in a moment that acts on at least part of at least one segment 18. As a result of that moment, each segment 18 rotates outward from the longitudinal centerline of the first element 12 about the hinge member 20 as well as about the point of connection between each segment 18 and a remainder of the first element 12. The hinge member 20 allows the segments 18 to rotate relative to one another at a defined point, by providing a weakened area or other feature that is configured to bend upon the application of a force that is less than the amount of force needed to bend the segments 18 themselves. The deflection of the segments 18 as a result of the application of moments thereto may be plastic deformation. Alternately, that deflection may be elastic deformation. After the segments 18 of a butterfly member 10 complete their deflection, that butterfly member 10 is in the second, expanded configuration. Alternately, the segments 18 are bendable, rather than deformable. Alternately, a single segment 18, rather than two separate segments, is provided. As another example, the first element 12 of each butterfly member 10 is held substantially in place, and the second element 14 of each butterfly member 10 is pushed distally, such as by a rod or other rigid linkage attached to the end of each second element 14. This motion of the second element 14 relative to

the first element 12 exerts a compressive force on the segments 18, which then deform to the second, expanded configuration substantially as described above.

[0071] The sheath 48 may be removed from the tissue 52 of the patient prior to the expansion of at least one butterfly member 10. Referring also to FIG. 16, the closure system 2 may be configured such that removal of the sheath 48 from the tissue of the patient causes or allows expansion of at least one butterfly member 10. For example, referring also to FIG. 8A, the sheath 48 may include or be connected to a ring 58 or other structure at its proximal end. The handle 8 may include a button 60 at its distal end. The shaft 6 is positioned within the lumen of the sheath 48. As the sheath 48 is slid proximally out of the tissue 52 of the patient along the shaft 6, the ring 58 contacts the button 60, moving it from a first position to a second position. This motion of the button 60 may actuate a mechanism or mechanisms within the handle 8 to allow at least one butterfly member 10 to move to an expanded configuration and/or to cause at least one butterfly member 10 to move to an expanded configuration. Each butterfly member 10 in the expanded configuration is located within the lumen of the blood vessel 56. Alternately, the sheath 48 remains in place as at least one butterfly member 10 moves to the expanded configuration. Alternately, the actuation of at least one butterfly member 10 to move to the expanded configuration may be completely independent of the position of the sheath 48 relative to the handle 8 or any other component of the closure system 2.

[0072] Next, referring also to FIG. 17, the closure system 2 is moved proximally until the expanded butterfly member or members 10 contact the inner wall of the blood vessel 56, in proximity to the opening 54. The butterfly members 10 are held substantially stationary relative to the housing 22 as the closure system 2 is moved proximally. The closure system 2 may be moved proximally in any suitable manner. As one example, the handle 8 is manually moved proximally, causing the expanded butterfly member or members 10 to contact the inner wall of the blood vessel 56. When the closure system 2 reaches the position in which a segment 18 of each expanded butterfly member 10 contacts the inner wall of the blood vessel 56, the blood leakage indicator or indicators 50 have moved out of the lumen of the blood vessel 56 through the opening 54, and into the passage 53 in the tissue 52. As a result, the flow of blood through the blood leakage indicator or indicators 50 decreases or stops, indicating to the operator that the butterfly member or members 10 are positioned against the inner surface of the wall of the blood vessel 56.

[0073] Referring also to FIGS. 9 and 18, each butterfly member 10 is then moved proximally while the housing 22 is held in a substantially constant position. The butterfly members 10 are moved such that each butterfly member 10 is maintained in an expanded configuration as it moves proximally. As a result, the expanded portion of each butterfly member 10 pulls the wall of the blood vessel 56 toward the distal end of the housing 22, capturing the wall of the blood vessel 56 and registering the opening 54 in the blood vessel 56 to the distal end of the housing 22. The expanded portion of each butterfly member 10 may be wider than the opening 54 to facilitate this motion of the wall of the blood vessel 56. Advantageously, the expanded portion of each butterfly member 10 may be moved within one-half millimeter of the distal end of the housing 22. However, the distance that the expanded portion of each butterfly member 10 is moved may be more or less. Alternately, at least one butterfly member 10

is moved relative to a force, rather than a distance. That is, a particular force is exerted proximally on the butterfly member 10, causing it to move proximally until the force exerted on the butterfly member 10 by the wall of the blood vessel 56 in the distal direction is substantially equal to the force exerted on the butterfly member 10 in the proximal direction. Thus, the wall of the blood vessel 56 is moved into position in preparation for stapling. The wall of the blood vessel 56 is held in position against the distal end of the housing by compressive force exerted against the housing 22 by the expanded portion of each butterfly member 10. The movement of each butterfly member 10 may be accomplished in any suitable manner. For example, at least one element 12, 14 of at least one butterfly member 10 extends to the handle 8, and at least one of those elements 12, 14 is actuated directly by a mechanism or mechanisms associated with the handle 8. As another example, both the first and the second elements 12, 14 of at least one butterfly member 10 may be moved proximally by a cable or cables attached to the elements 12, 14. Alternately, the expanded portion of each butterfly member 10 is held substantially stationary, and the housing 22 is advanced distally. Such motion of the housing 22 may be accomplished in a manner similar to that described above with regard to the motion of the butterfly members 10. For example, each butterfly member 10 may be held substantially stationary relative to the handle 8, which in turn is held substantially stationary relative to the blood vessel 56. A force in the proximal direction is then exerted on the housing 22, such as via a member capable of transmitting compressive force, where that member extends through the shaft 6 to the handle 8.

[0074] Next, referring also to FIG. 10, the driver 34 advances distally. The driver 34 may be actuated to advance distally in any suitable manner. As one example, the driver 34 is urged distally when the handle 8 exerts a distal force on a member (not shown) or other structure or mechanism connected to the driver 34. The handle 8 may exert such a force in any suitable manner, as described above. As another example, the driver 34 extends through the shaft 6 to the handle 8, and the driver 34 is actuated directly by a mechanism or mechanisms associated with the handle 8. As another example, a cable is connected to the driver 34, and that cable is directed around a nose, axle or other feature (not shown) of the end effector 4 distal to the driver 34 in order to convert proximal motion of the cable to distal motion of the driver 34.

[0075] As the driver 34 advances distally, the driver 34 exerts a force in the distal direction on the staple 24. Each ridge 41 restrains the corresponding valley 29 of the staple 24 substantially against distal motion, such that the longitudinal position of the peaks 28 and the trough 30 of the staple are substantially unchanged as the driver 34 begins to exert a distal force on the staple 24. However, the tines 26 are not substantially restrained against motion resulting from application of force in the distal direction. The distal force exerted on at least one peak 28 of the staple 24 by the driver 34 urges each valley 29 of the staple 24 against the corresponding ridge 41 of the paddle 40. Each ridge 41 is positioned sufficiently far from the longitudinal centerline of the staple 24 such that a moment is generated about that ridge 41 that is applied to the corresponding peak 28 of the staple 24. This moment causes the corresponding tine 26 of the staple 24 to move outward from the longitudinal centerline of the staple 24. Each ridge 41 may be shaped, sized, positioned or otherwise configured

in any manner that results in such a moment and the resultant motion of the tines 26 of the staple 24.

[0076] Thus, as the driver 34 exerts a force on the staple 24, the distal ends of the tines 26 of the staple 24 move apart from one another, each in a direction away from the longitudinal centerline of the staple 24. This deformation of the staple may be referred to as "splaying." During splaying of the staple 24, the tines 26 themselves may remain substantially undeformed; rather, a portion of the staple 24 in proximity to each peak 28 and/or the trough 30 may deform. Alternately, at least one tine 26 may deform during splaying of the staple 24. Further, as the distal ends of the tines 26 move away from the longitudinal centerline of the staple 24, at least part of each tine 26 may move outside the distal end of the housing 22 through a slot 23 or other opening in the housing 22. As a result, the tines 26 of the staple 24 may move apart from one another a distance greater than the diameter of the housing 22. Where the staple 24 is made from a plastically-deformable material such as stainless steel, the staple 24 deforms plastically as it splays from its initial configuration to the splayed configuration. Plastic deformation is deformation that remains after the load that caused it is removed, or that would remain if the load were removed. Alternately, the staple 24 is elastically-deformable from its initial configuration to the splayed configuration. The staple 24 may be spring-loaded inwards to the initial configuration, such that the staple 24 springs outward and returns to the splayed configuration upon application of force or upon movement to a position relative to the housing 22 such that the staple 24 is free to spring outward. Alternately, the staple 24 does not deform or move to a splayed configuration at all; rather, it transitions directly from the initial configuration to a closed configuration as described below. If the staple 24 does not deform or move to a splayed configuration, then the tines 26 may be spaced apart as far as possible within the housing 22 when the staple 24 is in the initial configuration, such that the tines 26 are farther apart from one another than shown in FIG. 5.

[0077] Alternately, where at least one paddle 40 is angled or curved relative to the driver 34 as described above, as each tine 26 moves its inner surface 27 contacts an outer edge of the paddle 40. Such contact between each tine 26 and the corresponding paddle 40 causes the staple 24 to splay. That is, at least one tine 26 of the staple 24 moves away from the longitudinal centerline of the staple 24.

[0078] After the staple 24 has deformed to a splayed configuration, as shown in FIG. 10, the driver 34 continues to apply a force in the distal direction on the staple 24. This force pushes the splayed staple 24 at least partially onto each ridge 41, in turn causing the paddle 40 associated with each ridge 41 to deflect away from the longitudinal centerline of the driver 34, which at this point in the operation of the closure system 2 is substantially coaxial with the longitudinal centerline of the staple 24. The staple 24 then moves distal to the ridge or ridges 41. As the staple 24 moves distally, the driver 34 encounters each ridge 41. Contact between the driver 34 and each ridge 41 holds each paddle 40 in a position deflected away from the longitudinal centerline of the driver 34. After the staple 24 has moved distally to the ridge or ridges 41, it may advance rapidly toward the distal end of the housing 22, as the portion of the paddle 40 distal to each ridge 41 is out of the path of travel of the staple 24. Further, as the staple 24 advances, the tab 32 in the staple 24 slides along a substantially longitudinal groove 47 defined in the finger 42. The groove 47 may extend completely through the finger 42, or

may be a depression defined in the finger 42. The tab 32 may extend into the groove 47 of the finger 42. Interaction between the tab 32 of the staple 24 and the groove 47 may maintain the staple 24 in a desired orientation during its splaying, shuttling forward, closing and/or ejecting. Alternately, the tab 32 and/or a different registration element of the staple 24 rides along a corresponding registration element defined in the housing 22. The motion of the staple 24 between its splaying and the entry of the tines 26 into tissue 56 may be referred to as “shuttling.” During shuttling, the compressive force that deformed the staple 24 into the splayed configuration is substantially removed from the staple 24, because the staple 24 is free to move forward; the force exerted by the driver 34 on the staple 24 moves it distally rather than further deforming it.

[0079] Referring also to FIGS. 7 and 10A, as the driver 34 continues to move distally, it pushes the distal ends of the tines 26 out of the distal end of the housing 22, and the distal ends of the tines 26 then penetrate the wall of the blood vessel 56. The speed of the shuttling of the staple 24 may be controlled to facilitate penetration of the wall of the blood vessel 56. The staple 24 is in the splayed configuration as the distal ends of the tines 26 penetrate the wall of the blood vessel 56. The distal ends of the tines 26 are positioned further apart from one another when the staple 24 is in the splayed configuration than when the staple 24 is in the initial configuration, thereby allowing capture of tissue across a width greater than that of the housing 22 between the tines 26 as they enter and penetrate tissue 56. The staple 24 in the splayed configuration penetrates tissue 56 on opposite sides of the opening 54. The staple 24 may be positioned substantially across the center of the opening 54. Alternately, more than one staple 24 is deployed to close the opening 54. Optionally, when each butterfly member 10 is moved proximally, such that the expanded feature formed by each set of segments of that butterfly member 10 is moved proximally into contact with the wall of the blood vessel 56, a portion of the wall of the blood vessel 56 may be tented. That is, a portion of the wall of the blood vessel 56 may be pulled or stretched in a proximal direction. As a result, the splayed staple 24 may capture a greater amount of tissue between the distal ends of the tines 26 than if the wall of the blood vessel 56 was not tented.

[0080] As the driver 34 continues to move distally, it continues to move the staple 24 distally. As the staple 24 moves distally, the trough 30 of the staple encounters the projection 46 that extends from the finger 42. The projection 46 is positioned in the path of the staple 24 in order to contact the trough 30 of the staple 24 as it moves distally. That contact causes distal motion of the staple 24 to substantially stop. However, the driver 34 continues to exert a force in the distal direction on the staple 24, such as on the peaks 28 of the staple 24.

[0081] After the staple 24 substantially ceases its distal motion, the driver 34 continues to apply a distal force to the staple 24. Each peak 28 of the staple 24 is offset from the longitudinal centerline of the staple 24. Further, the longitudinal centerline of the staple 24 substantially intersects or approaches close to intersection with the projection 46. As a result, each peak 28 of the staple 24 is offset from the projection. The force exerted by the driver 34 distally on each peak 28 of the staple 24, which is offset from the longitudinal centerline of the staple 24, results in a moment about the projection 46, which acts as an anvil. Each tine 26 of the staple 24 that experiences that moment moves toward the longitudinal centerline of the staple 24. In the course of this motion,

the distal ends of the tines 26 may first move toward the longitudinal centerline of the staple 24 and toward one another, cross each other, then move away from the longitudinal centerline of the staple 24 and away from one another. The tines 26 need not substantially change shape as they move; rather, they may rotate about a pivot point located at or near the trough 30. Alternately, one or both of the tines 26 may deform as they move. The radius of curvature of each tine 26 may be substantially coincident with its path of travel during closure of the staple 24. Deformation of the staple 24 as a result of contact between the staple 24 and the projection 46 may be referred to as “closing” the staple 24.

[0082] Referring also to FIG. 11, as the driver 34 continues to move distally, the staple 24 continues to deform against the projection 46. This deformation may be plastic deformation from the splayed configuration to a final, closed configuration. The staple 24 and/or any other component of the end effector 4 may be shaped or otherwise configured such that the tines 26 swipe past one another as the staple 24 moves to the closed configuration. Referring also to FIG. 12, as one example, the staple 24 is shaped such that the application of force longitudinally thereto causes the tines 26 to move in a direction that has a component of motion perpendicular to the longitudinal direction, thereby moving the tines 26 such that they swipe past each other. The staple 24 may be curved in any manner to allow for such motion of the tines 26. For example, the proximal surface 62 of the staple 24 may take the shape of a twisted plane, as described above. Contact between the driver 34 and the proximal surface 62 of the staple thus causes the tines 26 to move apart from one another in a direction perpendicular to the direction in which the legs move toward one another as the staple 24 moves to a closed configuration, such that the tines 26 swipe past one another as the staple 24 closes. That is, because the force applied to the proximal surface 62 of the staple 24 is substantially in the longitudinal direction, and the proximal surface 62 of the staple 24 is twisted such that lines perpendicular to that proximal surface 62 on opposite lateral sides of the staple 24 are skewed in opposite directions relative to the longitudinal direction, the force applied to the staple 24 tilts the tines 26 in opposite directions. Thus, when the staple 24 is closed, the tines 26 may be both offset from and substantially adjacent to one another. Alternately, at least two tines 26 of the staple 24 are configured to interfere with or otherwise engage one another when the staple 24 is in the closed position. Alternately, at least two tines 26 may be substantially parallel to one another and spaced apart from one another when the staple 24 is in the closed position.

[0083] Alternately, the distal ends of the tines 26 of the staple 24 are shaped substantially conically. As the staple 24 closes, the conical tips of the tines 26 come into contact with one another. As a result of the angle of the side of each conical tip, this contact causes the tines 26 to slide adjacent to one another instead of interfering with one another. Alternately, the distal end of each tine 26 is substantially planar, where each plane is oriented in a different direction. As a result, when the distal ends of the tines 26 encounter one another, contact between the differently-oriented planes at the distal ends of the tines pushes the tines 26 out of plane relative to one another. Alternately, the tines 26 of the staple 24 are fabricated such that they are out of plane with one another when the staple 24 is in the initial configuration, such that the tines 26 do not substantially interfere with one another during deployment. Alternately, the tines 26 of the staple 24 are

plastically deformed out of plane with one another by contact with the paddle 40 while the staple 24 is splayed open and/or being closed. Alternately, the staple 24 and/or the end effector 4 are configured to prevent the tines 26 from interfering with one another as the staple 24 closes.

[0084] When deformation of the tines 26 of the staple is complete, the staple 24 is in the closed configuration. In that closed configuration, at least part of each tine 26 of the staple is located within the lumen of the blood vessel 56. The tines 26 may be positioned such that a part of each tine 26 is positioned against an inner surface of the blood vessel 56. Alternately, the tines 26 may be positioned differently relative to the wall of the blood vessel 56. In the closed configuration, the staple 24 holds opposite sides of the opening 54 together, substantially closing the opening 54. Where the staple 24 is frangibly connected to the driver 34, force is exerted on the staple 24 when the staple 24 approaches or reaches the closed configuration, in order to separate the staple 24 from the driver 34 such as by fracturing. The force on the staple 24 may be provided in any suitable manner. As one example, the connection between the staple 24 and the driver 34 may be shaped and sized such that the forces exerted on the staple 24 to deform it to the closed configuration also cause the staple 24 to separate from the driver 34. Alternately, the staple 24 is not separated from the driver 34 until the staple 24 is ejected from the housing 22. Alternately, the staple 24 is separated from the driver 34 at any other suitable time during the deployment process.

[0085] In the course of deflecting the staple 24 to the closed configuration, the driver 34 moves to a distalmost position. The distalmost position of the driver 34 may be controlled in any suitable manner. As one example, the distalmost position of the driver 34 is controlled by the handle 8. As another example, contact between the distal end of the driver 34 and at least one post 43 extending from a corresponding paddle 40 prevents the driver 34 from moving further in the distal direction, thereby defining the distalmost position of the driver 34.

[0086] After the staple 24 has been closed, the driver 34 is moved proximally. As the driver 34 moves proximally, it continues to engage at least one ridge 41 extending from each paddle 40, such that the paddles 40 continue to be deflected away from their original, rest position. As the driver 34 continues to move proximally, the distal end of the driver 34 moves over and then proximal to each ridge 41. After the distal end of the driver 34 has moved proximal to each ridge 41, the driver 34 no longer pushes the corresponding paddle 40 from its original position. Consequently, each paddle 40 moves back toward its original position. Advantageously, the deflection of each paddle 40 away from its original position is substantially elastic, such that in the deflected position each paddle 40 is biased toward its initial position. Alternately, at least one paddle 40 is plastically deformed away from its original position as the driver 34 moves distally, and each such paddle 40 does not return to its original position when the distal end of the driver 34 moves proximal to the corresponding ridge 41. If so, when the driver 34 retracts proximally, a feature on the driver 34 and/or a separate member (not shown) plastically deform the paddle 40 back toward its initial position in order to eject the staple, as described below. Alternately, at least one paddle 40 is not deflectable from a cantilevered base, but instead is movable relative to the housing 22 in any suitable direction.

[0087] As each paddle 40 moves back toward its original position, it exerts a force on the closed staple 24 along the

projection 46, urging the staple 24 along the projection 46 away from the finger 42 and toward the free end of the projection 46. When each paddle 40 moves close to or completely into its initial position, it has moved far enough to push the closed staple 24 off the free end of the projection 46. The closed staple 24 is then free to exit the housing 22 of the end effector 4.

[0088] Next, each butterfly member 10 is deformed from the expanded configuration back to the collapsed configuration. This deformation may be performed by reversing the steps described above for deforming the butterfly member 10 from the collapsed configuration to the expanded configuration. Where at least one butterfly member 10 elastically deformed from the collapsed configuration to the expanded configuration, force exerted on that butterfly member 10 to maintain the butterfly member in the expanded configuration is simply released, allowing the butterfly member 10 to return to the collapsed configuration.

[0089] After each butterfly member 10 returns to the collapsed position, the end effector 4 is moved proximally, and the butterfly members 10 then exit from the opening 54. Advantageously, where two butterfly members 10 are used, one butterfly member 10 is located on each side of the closed staple 24. As the end effector 4 is moved away from the opening 54, the staple 24 exits the distal end of the housing 22, as it grasps the tissue 56 with greater force than any remaining frictional forces or other incidental forces holding it to the housing 22. The guidewire, if used, is then removed from the blood vessel 56. Alternately, the guidewire is removed at a different time. The guidewire is pulled out of the blood vessel 56 adjacent to the closed staple 24 and between the edges of what had been the opening 54 in the blood vessel 56. Thus, a smaller-diameter guidewire may be advantageous, as it may leave a smaller gap in tissue between the edges of what had been the opening 54 in the blood vessel, such that the wall of the blood vessel can rebound more quickly to close that gap. After the end effector 4 is removed from the patient, the sheath 48 is removed if it is still present in the patient. The procedure is complete, and the opening 54 is substantially closed.

[0090] Where the closure system 2 includes a separate butterfly deployment tool connected to and configured to place the butterfly members 10, and a separate staple placement tool which is connected to the end effector 4 and configured to place the staple 24, each of the two separate components is substantially as described above with regard to the single, integrated tool, with minor variations. First, the butterfly deployment tool is inserted through the opening 54 in the blood vessel 56 and actuated such that a part of each butterfly member 10 is in the expanded configuration and seated against the inner surface of the wall of the blood vessel 56. Then, the staple placement tool is slid along the butterfly deployment tool toward the opening 54 in any suitable manner, and actuated substantially as described above. The staple placement tool is then withdrawn. Optionally, a second staple placement tool then may be advanced toward the opening 56 and actuated. The second staple placement tool may be used in the event that the first staple placement tool did not close the opening 56 to the satisfaction of the physician, in order to place a second staple for additional security, or for any other reason. After the staple placement tool is withdrawn, the

butterfly deployment tool is withdrawn, the opening 56 is substantially closed, and the procedure is complete.

Operation

Alternate Embodiment

[0091] Alternately, the closure system 2 is configured to hold the staple 24 substantially in the same longitudinal position while it is splayed, and advance the staple 24 distally after splaying is complete. Such a closure system 2 operates generally as described above. For clarity and brevity, this section of the document describes the significant differences in structure and operation between the different embodiments of the closure system 2.

[0092] Referring to FIGS. 21-24, the staple 24 may be held substantially in the same longitudinal position both before and during its splaying. Any suitable structure, mechanism or combination thereof may be used to hold the staple 24 in position. As one example, referring particularly to FIG. 22A, a cradle 70 may be provided. Advantageously, the cradle 70 is fabricated as a single part, such as by molding or machining. However, the cradle 70 may be assembled from two or more discrete parts. The cradle 70 may have any suitable shape. As one example, the cradle 70 may include a relatively flat and thin base 72. The proximal end 74 of the cradle 70 may be wider than the base 72, such that the base 72 and the proximal end 74 of the cradle 70 form a shape like the capital letter T. Alternately, the proximal end 74 of the cradle 70 may have substantially the same width as the base 72, or the proximal end 74 of the cradle 70 may be narrower than the base 72. A distal stop 76 may project upward from the base 72. That is, the distal stop 76 may project from the base 72 in a direction that extends away from the longitudinal centerline of the base 72, where that direction need not be perpendicular. A proximal stop 78 may project upward from the base 72 at a location proximal to and spaced apart from the distal stop 76. The proximal stop 78 may project from the base 72 in a direction that extends away from the longitudinal centerline of the base 72, where that direction need not be perpendicular.

[0093] The stops 76, 78 are shaped, and spaced apart from one another, in a manner that allows a portion of the staple 24 to be held therebetween. As one example, the proximal stop 78 may be configured to receive the tab 32 of the staple 24, such as within a notch defined in the proximal stop 78. As another example, the distal stop 76 may be configured to receive the tab 32 of the staple 24, such as within a notch defined in the distal stop 76. Where the staple 24 includes multiple tabs 32, each tab 32 may be received by a different stop 76, 78. Alternately, at least one stop 76, 78 may include a tab (not shown) which is received by the staple 24. The distal end of the proximal stop 78 may be spaced apart from the proximal end of the distal stop 76 a distance substantially equal to, or a distance greater than, the thickness of the staple 24 at a location on the staple 24 near the tab 32.

[0094] The staple 24 may be constrained laterally as well, both before and during its splaying. Referring to FIGS. 22C and 24, a splay post 39 may extend from each paddle 40, positioned distal to and against a corresponding valley 29 of the staple 24. The staple 24 may be shaped such that at least one valley 29 of the staple 24 includes at least one bump 31 that is positioned lateral to the corresponding splay post 39, when the staple 24 is in the initial position. In this way, contact between each splay post 39 and the staple 24 substantially prevents motion of the staple 24 in the lateral direction. Alter-

nately, the staple 24 may be allowed to move in the lateral direction. The upper surface of the splay post 39 may be sloped upwardly in the distal direction. Alternately, the upper surface of the splay post 39 may be substantially flat, or shaped or oriented in any other suitable manner.

[0095] Referring also to FIGS. 21 and 23-24, the staple 24 may be constrained against upward and/or downward motion as well, both before and during its splaying. Contact between the staple 24 and the paddles 40 may constrain the staple 24 against downward motion toward the paddles 40. Contact between the staple 24 and the housing 22 and/or a component within the housing 22 may constrain the staple 24 against motion upward away from the paddles 40. Alternately, the staple 24 may be allowed to move upward or downward. As used in this document, the terms "up" or "upper" refer to a direction perpendicular to the longitudinal centerline of the housing 22 and perpendicular to the plane in which the paddle assembly 38 substantially resides, in the direction away from the paddle assembly 38 toward the driver 34, as shown in FIG. 23. The terms "down" or "downward" refer to the opposite direction. These terms are used solely for convenience in describing the components and operation of the closure system 2, and do not limit the construction of the closure system 2 or its orientation in use.

[0096] At least one paddle 40 may be configured differently than described above. The paddle assembly 38 may be slidable in a direction substantially along or substantially parallel to the longitudinal centerline of the housing 22. Alternately, the paddle assembly 38 may be slidable in one or more directions instead of or in addition to the direction substantially along or substantially parallel to the longitudinal centerline of the housing 22. The housing 22 may include a cavity 82 defined therein, where that cavity 82 includes a proximal wall 84. The cavity 82 advantageously is open at its distal end, in order to allow the staple 24 to be ejected from it. The base 44 of the paddle assembly 38 may be in contact with the proximal wall 84 of the housing 22 before and during the splaying of the staple 24. In this way, the proximal wall 84 of the cavity 82 acts as a hard stop to ensure that the paddle assembly 38 is in a known location before and during the splaying of the staple 24. Alternately, the base 44 of the paddle assembly 38 may be positioned differently relative to the proximal wall 84 of the cavity 82 before and/or during the splaying of the staple 24. Optionally, the paddle assembly 38 may include two or more separate, spaced-apart paddles 40 that are not directly connected to one another. Optionally, the housing 22 itself may be omitted, and a frame or other open structure may be utilized in its place.

[0097] A guide 86, such as a track, rail or other suitable structure or mechanism, may extend along at least part of the cavity 82 within the housing 22. The guide 86 may be straight, and may be aligned substantially along or substantially parallel to the longitudinal centerline of the housing 22. Alternately, the guide 86 may be shaped and/or aligned differently. The guide 86 may include two walls 88 spaced apart from one another that define a trough 90 between them. Alternately, the guide 86 may be configured differently. The trough 90 is sized and shaped to receive at least a portion of the cradle 70 therein and allow it to slide along the trough 90. Alternately, the guide 86 may be omitted, and the cradle 70 may move relative to the housing 22 in a different manner. One or more ledges 92 may be positioned against the outer surface of at least one wall 88. The outer surface of a wall 88 is the lateral surface of that wall 88 that is not facing the trough 90. Alternately, at least part of

at least one ledge 92 is spaced apart from the corresponding wall 88. Each ledge 92 may have a substantially flat upper surface, or may have an upper surface shaped in any other suitable shape or manner. Each ledge 92 may extend substantially along the corresponding wall 88 to a location spaced apart from the distal end of that wall 88, or to any other suitable location.

[0098] The housing 22 may have at least one slot 23 defined therein, as described above. As viewed from the side, referring to FIG. 23, the slot 23 may be shaped to include a substantially flat first surface 93 defined in the housing 22, and a slot ramp 94 defined in the housing 22 that slopes downward in the distal direction from the first surface 93. The slot 23 may also include a substantially flat second surface 95 defined in the housing 22 that extends distally from the distal end of the slot ramp 94. Advantageously, two slots 23 may be provided, spaced laterally from one another in the housing 22, where each slot 23 may include the first surface 93, slot ramp 94, and second surface 95. At least one slot 23 may be bilaterally symmetrical, such that the upper portion of the slot 23 includes a slot ramp (not shown) that slopes upward in the distal direction. A thin seal (not shown) may be provided on the distal portion of the housing 22, to prevent or minimize blood leakage prior to splaying and deployment of the staple 24. Such a seal may be a thin cylindrical polyimide film that fits snugly over the distal portion of the housing 22, or may take a different form.

[0099] At least a portion of the driver 34 may be positioned within the housing 22. The driver 34 is configured to engage the paddle assembly 38 and the staple 24. The driver 34 may include at least one rear flange 98 that is positioned distal to a corresponding first stop 100 defined on a paddle 38 in the initial configuration of the closure system 2. The first stop 100 may be a surface of a boss, or any other suitable structure. Initially, each rear flange 98 may be in contact with the corresponding first stop 100, but need not be.

[0100] The distal end of the driver 34 may be bifurcated as shown in FIGS. 10 and 24, for example, such that each bifurcation 96 is positioned to contact a corresponding peak 28 of the staple 24 upon advancement of the driver 34, as described in greater detail below. The space between the bifurcations 96 may define an opening 102 that is at least as wide as the proximal stop 78 of the cradle 70. Alternately, that opening 102 is narrower than the proximal stop 78 of the cradle 70. The proximal end of the opening 102 may be referred to as the driver stop 101. In other respects, the driver 34 may be configured in at least some aspects as described above, or in any other suitable manner.

[0101] Referring also to FIG. 22D, a hard stop 104 may be defined in the housing 22 proximal to the proximal end 74 of the cradle 70. In the initial configuration, the proximal end of the cradle 70 may be positioned against the hard stop 104. Contact between the proximal end 74 of the cradle 70 and the hard stop 104 in the housing 22 prevents the cradle 70 from moving proximally beyond the hard stop 104. Contact between the staple 24, the stops 76, 78, and the splay post or posts 39 holds the cradle 70 substantially in place in the initial configuration, and prevents the cradle 70 from sliding out of the distal end of the housing 22. Alternately, the cradle 70 may be held in place initially in any other suitable manner.

[0102] The operation of the closure system 2 described in this section is generally as described above, with the major differences set forth below. The end effector 4 of the closure system 2 is inserted into the sheath 48. Referring to FIG. 31,

at least one butterfly member 10 is in a first, partially-expanded configuration when it is inserted into the sheath 48. In the partially-expanded configuration, the width of the expanded portion of the butterfly member 10 is less than the diameter of the lumen of the sheath 48, such that it can be inserted into and moved along the sheath 48. At least one butterfly member 10 is advanced into the lumen of the blood vessel 56. Then, at least one butterfly member 10 is actuated to move from its first, partially-expanded configuration to its second, fully-expanded configuration. Next, substantially as described above, the closure system 2 is moved proximally until the fully-expanded butterfly member or members 10 contact the inner wall of the blood vessel 56, in proximity to the opening 54. In this position, the housing 22 may at least partially plug the opening 54 in the blood vessel 56. The wall of the blood vessel 56 is pulled proximally as a result of the proximal motion of the fully-expanded butterfly member or member 10, such that the wall of the blood vessel 56 is in tension. The butterfly member or members 10 are then moved distally relative to the housing 22. In this way, the wall of the blood vessel 56 moves back into position as tension is released. Alternately, the butterfly member or members 10 may be moved in any other suitable sequence relative to the wall of the blood vessel 56.

[0103] Next, the staple 24 is splayed. Alternately, the staple 24 may be splayed at any other suitable time during the actuation of the closure system 2. The trough 30 and/or tab 32 of the staple 24 may be held in substantially the same position during splaying of the staple 24. Alternately, the trough 30 and/or tab 32 of the staple 24 may be held in substantially the same longitudinal position during splaying of the staple 24, and may be allowed to move at least partially in a different direction. Alternately, additional or different parts of the staple 24 may be held in substantially the same position, or allowed to move in at least one dimension, during splaying. As one example, the trough 30 of the staple 24 is held between the posts 76, 78 of the cradle 70. The tab 32 of the staple 24 may be received in the notch 80 of the proximal post 78 of the cradle. The driver 34 is moved proximally in any suitable manner, as described above, while the cradle 70 remains in substantially the same longitudinal position relative to the housing 22. The cradle 70 is held substantially in the same longitudinal position in any suitable manner. As one example, contact between the proximal end 74 of the cradle 70 and the hard stop 104 in the housing 22 prevents the cradle 70 from moving proximally as a result of friction against the driver 30 or any other force. Contact between the staple 24, the stops 76, 78, and the splay post or posts 39 may prevent the cradle 70 from moving distally.

[0104] As the driver 30 moves proximally, at least one rear flange 98 of the driver 30 contacts a corresponding first stop 100 on the paddle assembly 38, where the first stop 100 is located proximal to the rear flange 98. This contact transmits proximal force from the driver 30 to the paddle assembly 38, causing the paddle assembly 38 to move proximally. As the paddle assembly 38 moves proximally, the splay post or posts 39 move proximally as well. Referring also to FIGS. 5 and 24, each splay post 39 is positioned distal to a corresponding valley 29 of the staple 24. Each such splay post 39 may be positioned initially in contact with the corresponding valley 29 of the staple 24, or spaced apart from that valley 29. As the splay post 39 moves proximally, it comes into contact with the corresponding bump 31 in the valley 29 of the staple 24 if it is not already in contact with that bump 31, and then applies a

force in the proximal direction to that bump 31. Contact between the trough 30 and/or tab 32 of the staple 24 and the proximal stop 78 restrains that trough 30 and/or tab 32 substantially against proximal motion. However, the tines 26 are not substantially restrained against force resulting from the motion of the paddle assembly 38. As the splay post or posts 39 apply proximal force to the staple 24, the staple 24 transmits that proximally-directed force to the proximal stop 78 of the cradle 70. However, as a result of contact between the proximal end 74 of the cradle 70 and the hard stop 104, the cradle 70 is prevented from moving proximally due to that force. Each splay post 39 exerts a proximal force on and/or adjacent to the corresponding bump 31 of the staple 24. This proximal force is offset from the longitudinal centerline of the staple 24, along which the proximal stop 78 is positioned. Thus, the proximal force exerted on and/or adjacent to the corresponding bump 31 of the staple 24 generates a moment about the proximal stop 78. This moment causes the corresponding tine 26 of the staple 24 to bend outward from the longitudinal centerline of the staple 24. Alternately, at least one bump 31 of the staple 24 is omitted, and the corresponding splay post 39 simply exerts a force on the valley 29 of the staples 24. Alternately, the staple 24 is configured in any other suitable manner, and each splay post 39 delivers a proximal force to a suitable location on the staple 24 to cause splaying.

[0105] As a result of that moment or moments, the distal ends of the tines 26 of the staple 24 move apart from one another, each in a direction away from the longitudinal centerline of the staple 24. This deformation of the staple may be referred to as "splaying." Referring to FIGS. 21 and 24, the staple 24 is shown in the splayed configuration. When splaying is complete, the proximal end of the paddle assembly 38 may contact the proximal wall 84 of the cavity 82 within the housing 22. As a result, the paddle assembly 38 is restrained against motion further in the proximal direction, and thus further splaying of the staple 24 is constrained as well. That is, the degree to which the staple 24 is splayed may be controlled by controlling the distance along which the paddle assembly 38 is moved proximally. Alternately, splaying of the staple 24 to a particular splaying configuration and/or the proximal motion of the paddle assembly 38 may be controlled in any other suitable manner. During splaying of the staple 24, the tines 26 themselves may remain substantially undeformed; rather, a portion of the staple 24 in proximity to each peak 28 and/or the trough 30 may deform. Alternately, at least one tine 26 may deform during splaying of the staple 24. Further, as the distal ends of the tines 26 move away from the longitudinal centerline of the staple 24, at least part of each tine 26 may move laterally outside of the housing 22 through a slot 23 or other opening in the housing 22. As a result, the tines 26 of the staple 24 may move apart from one another a distance greater than the diameter of the housing 22. Where the staple 24 is made from a plastically-deformable material such as stainless steel, the staple 24 deforms plastically as it splays from its initial configuration to the splayed configuration. Plastic deformation is deformation that substantially remains after the load that caused it is removed, or that would substantially remain if the load were removed. Alternately, the staple 24 is elastically deformable or superelastically deformable from its initial configuration to the splayed configuration. Alternately, the staple 24 may be spring-loaded inwards to the initial configuration, such that the staple 24 springs outward and returns to the splayed configuration upon application of force or upon movement to a position relative to the housing 22

such that the staple 24 is free to spring outward. Alternately, the staple 24 does not deform or move to a splayed configuration at all; rather, it transitions directly from the initial configuration to a closed configuration as described below. If the staple 24 does not deform or move to a splayed configuration, then the tines 26 may be spaced apart as far as possible within the housing 22 when the staple 24 is in the initial configuration, such that the tines 26 are farther apart from one another than shown in FIG. 5. Splaying of the staple 24 may be performed at a location spaced apart from the distal end of the housing 22.

[0106] Next, referring also to FIGS. 25-26, the paddle assembly 38 is advanced distally in any suitable manner, such as by advancing a rod or other member 106 that is connected to or part of the driver 30. As the driver 30 advances distally, the distal end of at least one bifurcation 96 encounters the ridge 41 defined in the corresponding paddle 40. As described above, each paddle 40 may be deflectable in a direction away from the longitudinal centerline of the driver 30. As at least one bifurcation 96 contacts the corresponding ridge 41, the paddle 40 from which that ridge 41 extends may be restrained against deflection in a direction away from the longitudinal centerline of the driver 30. As a result, the bifurcation 96 is able to exert a distal force on the ridge 41 without the ridge 41 deflecting out of contact with it. The paddle 40 may be restrained against deflection in any suitable manner. As one example, contact between the paddle assembly 38 and at least one ledge 92 prevents at least part of the paddle assembly 38 from deflecting out of plane when the driver 30 contacts at least one ridge 41. That is, the driver 30 is positioned on one side of the paddle assembly 38, with at least one ledge 92 positioned on the other side of the paddle assembly 38. Contact between the driver 30 and the paddle assembly 38 prevents at least part of the paddle assembly 38 from moving toward the driver 30, and contact between the paddle assembly 38 and at least one ledge 92 prevents at least part of the paddle assembly 38 from moving away from the driver, such that the paddle assembly 38 as a whole advances distally.

[0107] As the paddle assembly 38 advances distally, the cradle 70 advances with it, carrying the splayed staple 24 distally as well. As described above, such distal advancement may be referred to as "shuttling." The cradle 70 and the splayed staple 24 may be advanced by continued motion of the driver 30 in the distal direction, or in any other suitable manner. During shuttling, the staple 24 may substantially retain the shape to which it was deformed during splaying. Alternately, the splayed staple 24 may change shape during shuttling, such as by contact with the housing 22, one or more components in the housing 22, or tissue outside the housing 22. Shutting may result from continued motion of the driver 30 in the distal direction. Optionally, at least one butterfly member 10 may be moved toward the housing 22 before or during shuttling, in order to bring the wall of the blood vessel 56 closer to the housing 22. Alternately, the splayed staple 24 is not shuttled distally; rather, the splayed staple 24 is held substantially in place, and one or more butterfly members 10 move toward the housing 22 to bring the wall of the blood vessel to the splayed staple 24 until that tissue is penetrated by the tines 26 of the staple 24.

[0108] As the paddle assembly 38 moves distally, at least one paddle 40 moves past the distal end of the corresponding ledge 92. As a result, at least the distal end of at least one paddle 40 is no longer substantially constrained against motion in the direction toward the ledge or ledges 92. The

paddle 40 may become substantially free of that constraint as a consequence of the shape of the paddle 40 and/or the corresponding ledge 92. As one example, at least one paddle 40 may be curved such that its distal tip extends inward a greater distance than a portion of the paddle 40 located immediately proximal to that distal tip, where the distance that the paddle 40 is curved inward is greater than the width of the ledge 92. Consequently, when the distal tip of the paddle 40 moves distal to the ledge 92, the distal tip of the paddle 40 moves out of contact with the ledge 92 and is free to move downward. Further, a portion of the paddle 40 proximal to the distal tip is also free to move downward, because that portion does not extend inward far enough to contact the ledge 92. Thus, as the paddle assembly 38 moves distally, at least part of at least one paddle 40 becomes deflectable away from the longitudinal axis of the driver 30. Alternately, the paddle assembly 38 engages at least one ledge 92 and/or other structure in a different manner that allows at least one paddle 40 to deflect away from the longitudinal axis of the driver 30 at a point during the translation of the paddle assembly 38. For example, the ledge 92 may be sloped downward.

[0109] The driver 30 continues to advance distally. When the paddles 40 are freed to become movable in a downward direction, the continued distal motion of each bifurcation 96 exerts a force against the surface of the corresponding ridge 41 that pushes that ridge 41, and hence the corresponding paddle 40, downward. Alternately, at least one paddle 40 is pushed downward in a different manner. The downward deflection of the ridge 41 allows the corresponding bifurcation 96 to slide over it. Optionally, at least one bifurcation 96 of the driver 34 may encounter the upper surface of the corresponding splay post 39, as the driver 34 continues to move distally. Contact between at least one bifurcation 96 and at least one splay post 39 thus may act to hold and/or move the corresponding paddle 40 downward. Where the upper surface of the splay post 39 is angled upward in the distal direction, contact between it and the corresponding driver 34 that is moving in the distal direction may assist in deflecting the paddle 40 downward. As the driver 30 slides over the ridge or ridges 41, friction therebetween may cause the paddle assembly 38 to continued to move distally. Alternately, by the time the driver 30 slides over the ridge or ridges 41, the paddle assembly 38 is already in its distalmost position such that the paddle assembly 38 does not continue to move in the distal direction.

[0110] As the driver 30 continues to advance distally, the distal end of the driver 30 contacts the proximal end of the staple 24. Each bifurcation 96 may contact a different peak 28 of the staple 24. Contact between the driver 30 and the staple 24 exerts a distal force on the staple 24, which in turn transmits that distal force to the distal stop 76 of the cradle 70. Because the cradle 70 is free to translate along the trough 90 in the housing 22, as described above, and because the trough 90 is oriented substantially longitudinally, the distal force transmitted to the cradle 70 via the staple 24 acts to move the cradle 70 distally, rather than to deform the staple 24. Alternately, the staple 24 may be deformed at least slightly as the cradle 70 advances distally. Alternately, the cradle 70 may be advanced in any other suitable manner.

[0111] The paddle assembly 38 substantially ceases its distal motion, coming to a stop at a distalmost location. The paddle assembly 38 may cease distal motion before, during or after the distal motion of the cradle 70 is completed. The paddle assembly 38 can be controlled to stop at its distalmost

location in any suitable manner. As one example, the paddle assembly may include a base 44 at or near its proximal end that connects the paddles 40. A paddle assembly stop 112 may be defined in the housing 22 or connected to the housing 22 at a location distal to the base 44, such that contact between the paddle assembly stop 112 and the base 44 prevents further distal motion of the paddle assembly 38. The position of the paddle assembly stop 112 in the housing 22 thereby controls the distance that the paddle assembly 38 can travel, and determines the distalmost position of the paddle assembly 38.

[0112] As the driver 30 continues to move distally, the cradle 70 continues to move distally as well, as does the staple 24, which remains in the splayed configuration. As the staple 24 moves distally, at least one tine 26 may encounter and penetrate the wall of the blood vessel 56. At least one tine 26 may also contact and/or engage body tissue outside of the blood vessel 56 as well. The cradle 70 then reaches its distalmost position, and is controlled to stop its motion in the distal direction, in any suitable manner. As one example, a cradle stop 113 is defined in the housing 22 distal to the proximal end 74 of the cradle 70. The proximal end 74 of the cradle 70 may be wider than the base 72 or other remainder of the cradle 70, such that the base 72 is able to slide distally without contacting the cradle stop 113 in the housing 22. The cradle stop 113 in the housing 22 is positioned further laterally than the lateral edge of the base 72, such that the proximal end 74 of the cradle 70 contacts the cradle stop 113 when the cradle 70 reaches its distalmost position. In this way, distal motion of the cradle 70 is arrested. As another example, a stop may be located at the distal end of the trough 90 along which the cradle 70 travels, such that contact between the distal end of the cradle 70 and that stop substantially halts the distal travel of the cradle 70.

[0113] With the paddle assembly 38 and the cradle 70 both at their distalmost positions, the driver 30 continues its advance distally, and thereby continues to apply a force to the staple 24 in the distal direction. With the cradle 70 substantially restrained against distal motion, the distal stop 76 of the cradle 70 substantially prevents the trough 30 of the staple 24 from moving in the distal direction. Each peak 28 of the staple 24 is offset from the longitudinal centerline of the staple 24. Further, the longitudinal centerline of the staple 24 substantially intersects the distal stop 76 of the cradle 70. As a result, each peak 28 of the staple 24 is laterally offset from the distal stop 76 of the cradle 70. The force exerted by the driver 34 distally on each peak 28 of the staple 24, which is laterally offset from the longitudinal centerline of the staple 24, results in a moment about the distal stop 76 of the cradle 70, which acts as an anvil. Each tine 26 of the staple 24 that experiences that moment moves toward the longitudinal centerline of the staple 24. In the course of this motion, the distal ends of the tines 26 may first move toward the longitudinal centerline of the staple 24 and toward one another. Deformation of the staple 24 as a result of contact between the staple 24 and the distal stop 76 of the cradle 70 may be referred to as "closing" the staple 24.

[0114] Referring also to FIGS. 28-29, as the driver 34 continues to move distally, the staple 24 continues to deform against the distal stop 76 of the cradle 70. This deformation may be plastic deformation from the splayed configuration to a final, closed configuration. The staple 24 and/or any other component of the end effector 4 may be shaped or otherwise configured such that the tines 26 swipe past one another as the staple 24 moves to the closed configuration. As one example,

the staple 24 may be configured as described above with regard to FIG. 12. As another example, the staple 24 may be configured in any manner such that, when the staple 24 is closed, the tines 26 are both offset from and substantially adjacent to one another. As another example, at least two tines 26 of the staple 24 are configured to interfere with or otherwise engage one another when the staple 24 is in the closed position. Alternately, at least two tines 26 may be substantially parallel to one another and spaced apart from one another when the staple 24 is in the closed position. The tines 26 need not substantially change shape as they move; rather, they may rotate about a pivot point located at or near the trough 30. Alternately, one or both of the tines 26 may deform as they move. The radius of curvature of each tine 26 may be substantially coincident with its path of travel during closure of the staple 24.

[0115] During deformation of the staple 24 from the splayed configured to the closed configuration, the distal portion of the paddle assembly 38 is in a position deflected downward away from the staple 24 as a result of contact between the driver 34 and at least one ridge 41 of the paddle assembly 38. When the staple 24 is in the closed configuration, the posts 43 of the paddle assembly 38 are positioned directly underneath at least part of the staple 24. Alternately, the posts 43 are positioned differently relative to the closed staple 24. Thus, the posts 43 do not interfere with or participate in the closing of the staple 24. Alternately, the posts 43 are configured to assist in the closing of the staple 24.

[0116] The driver 34 continues to move distally until formation of the staple 24 is substantially complete. That is, the formed staple 24 is firmly secured to tissue, and is deformed substantially to its formed configuration, such that contact between the driver 34 and the staple 24 prevents further distal motion of the driver 34. Alternately, referring also to FIG. 22B, the driver 34 may continue to move distally until the driver stop 101 at the proximal end of the opening 102 between the bifurcations 96 contacts the proximal stop 78 of the cradle 70. As described above, the cradle 70 is in its distalmost position and is constrained substantially against distal motion, and contact between the driver stop 101 and the proximal stop 78 of the cradle 70 consequently halts the distal motion of the driver 34 at a distalmost position of the driver 34. Deformation of the staple 24 to the closed configuration may be completed before the driver 34 reaches its distalmost position, or may be completed substantially at the point when the driver 34 reaches its distalmost position.

[0117] Before, or when, the driver 34 reaches its distalmost position, at least one rear flange 98 of the driver 34 may move distal to a detent 114 on the upper surface of the corresponding paddle 40. Further, the rear surface 116 of at least one bifurcation 96 may move distal to a corresponding splay post 39 on the upper surface of the paddle 40. Additionally, the body 120 of the driver 34 proximal to the rear flange or flanges 98 may be narrower than the space between the paddles 40 of the paddle assembly 38. The ridge 41 may be discontinuous, such that part of the ridge 41 is located on one paddle 40 and part of the ridge 41 is located on the other paddle 40. Thus, when the driver 34 reaches its distalmost position, the driver 34 may no longer exert a downward force on the paddles 40 deflecting them away from the longitudinal centerline of the driver 34. As a result, the paddles 40 may begin to move back toward their original position, or may move completely back to their original position, depending on their stiffness. Alternately,

the driver 34 may still exert such a force when the driver 34 is in the distalmost position.

[0118] After the staple 24 has been closed, the driver 34 is moved proximally. The driver 34 may be moved proximally in substantially the same manner in which it was moved distally, such as by application of a force substantially in the proximal direction along the rod 106 or other member connected to the driver 34. As the driver 34 moves proximally, at least one rear flange 98 of the driver 34 may contact the detent 114 of the corresponding paddle 40, because the paddle 40 has moved back toward its original position. Referring also to FIG. 22B, the rear surface 116 of at least one bifurcation 96 of the driver 34 may contact the splay post 39 of the corresponding paddle 40, because the paddle 40 has moved back toward its original position. As a result, as the driver 34 moves proximally it exerts a proximal force on the paddle assembly 38, which in turn begins to move proximally. Alternately, the detent 114 may be omitted, and contact between at least one bifurcation 96 and the corresponding splay post 39 acts to move the paddle assembly 38 proximally.

[0119] At least one paddle 40 may include a ramp engagement flange 118. The ramp engagement flange 118 extends laterally outward from a remainder of the paddle 40 a sufficient distance such that it contacts the corresponding slot ramp 94 defined in the housing 22 as the paddle assembly 38 moves proximally. As at least one paddle 40 moves proximally, contact between the ramp engagement flange 118 and the slot ramp 94 urges the corresponding paddle 40 back toward its original position. Such contact facilitates motion of the paddle 40, and allows the paddle 40 to be constructed to exert a relatively small bias toward its original position when it is in the deflected position. Alternately, at least one ramp engagement flange 118 may be omitted.

[0120] As each paddle 40 moves back toward its original position, each corresponding post 43 contacts the closed staple 24 and exerts a substantially upward force on the closed staple 24 substantially along the distal stop 76 of the cradle 70. The posts 43 thus may be referred to as ejection posts. This force urges the staple 24 along the distal stop 76 toward the free end of that distal stop 76. When each paddle 40 moves close to or completely into its initial position, it has moved far enough for the post or posts 43 to push the closed staple 24 off the free end of the distal stop 76. The closed staple 24 is then free to exit the housing 22 of the end effector 4. Alternately, one or more posts 43 may be omitted, and at least one paddle 40 or other component of the paddle assembly 38 contacts the closed staple 24 to urge it along the distal stop 76. The butterfly member or member 10 are moved from the fully-expanded configuration to a third, collapsed configuration, and then removed from the opening 54 in the blood vessel 56 substantially as described above. The butterfly member or members 10 may be moved from the fully-expanded configuration to the collapsed configuration before, during or after ejection of the closed staple 24. Alternately, the butterfly member or members 10 are moved from the fully-expanded configuration to the partially-expanded configuration before their withdrawal. Any additional steps in completing the procedure may be performed substantially as described above. The sequence of actions in the operation of the closure system 2 may be varied from the exemplary description above. Such actions may be performed in a different order, may be performed substantially simultaneously or may partially overlap, or may be performed in any other suitable manner. As one example, the sequence of operations relating to deployment

and retraction of the butterfly members **10** may be performed differently relative to the splaying and/or deployment of the staple **24**, or vice versa.

[0121] Operation: Closure of Other Tissue Openings

[0122] Referring to FIGS. **1-2**, the closure system **2** may be used to close any suitable opening in tissue. If so, the operation of the closure system **2** is substantially as described above. As one example, the closure system **2** may be used to close a trocar port or other surgical opening in the body of the patient. For such a use, and other uses on or near the surface of the body, the splaying step and any structures and mechanisms associated with splaying the staple **24** may be omitted, because adequate space exists outside of the patient for placing the closure system **2** in a suitable position with the tines of the splayed staple **24** extending out of the housing **22**. As another example, the closure system **2** may be used to close a wound in the body of the patient, whether on the skin of the patient or in the interior of the patient's body. As another example, the closure system **2** may be used to repair a hernia at any suitable location in the patient's body.

[0123] Optionally, the closure system **2** may be configured to deploy two or more staples **24**, simultaneously or sequentially. Multiple staples **24** may be useful where a larger hole, such as a trocar port, is to be closed. Where multiple staples are used, multiple drivers **34**, paddles **40** and/or cradles **70** may be utilized. If so, the closure system **2** is operated substantially as described above as to each individual staple **24** and associated structures and mechanisms within the closure system **2**.

[0124] While the invention has been described in detail, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention. It is to be understood that the invention is not limited to the details of construction, the arrangements of components and/or the details of operation set forth in the above description or illustrated in the drawings. Headings and subheadings are for the convenience of the reader only. They should not and cannot be construed to have any substantive significance, meaning or interpretation, and should not and cannot be deemed to be limiting in any way, or indicate that all of the information relating to any particular topic is to be found under or limited to any particular heading or subheading. The contents of each section of this document are merely exemplary and do not limit the scope of the invention or the interpretation of the claims. Therefore, the invention is not to be restricted or limited except in accordance with the following claims and their legal equivalents.

What is claimed is:

1. A medical device for closing an opening in tissue, comprising:

a staple including a plurality of tines, wherein said staple is deformable from an initial configuration to a splayed configuration and then to a closed configuration;

a cradle that includes a distal stop and a proximal stop proximal to said distal stop extending therefrom; wherein said cradle holds a portion of said staple between said proximal stop and said distal stop; and wherein said proximal stop and said distal stop are spaced apart from one another a fixed distance substantially equal to the thickness of said portion of said staple held therebetween, such that said portion of said staple substantially contacts both said proximal stop and said distal stop in said initial configuration; and

a housing, wherein said cradle is movable relative to said housing.

2. The medical device of claim **1**, wherein said staple includes a tab extending therefrom, and wherein at least one of said proximal stop and said distal stop is shaped to receive said tab.

3. The medical device of claim **1**, wherein said housing includes a guide therein along which said cradle is movable.

4. The medical device of claim **3**, wherein said guide is a track defined in said housing.

5. The medical device of claim **3**, wherein said guide is substantially linear and substantially parallel to the longitudinal centerline of said housing.

6. The medical device of claim **1**, further comprising a paddle assembly movable relative to said housing, wherein said paddle assembly includes at least one paddle with a splay post extending therefrom; each said splay post positioned distal to said staple.

7. The medical device of claim **6**, wherein said paddle assembly is movable by sliding substantially longitudinally.

8. The medical device of claim **6**, further comprising a driver movable relative to said cradle and said paddle assembly.

9. The medical device of claim **1**, further comprising a seal attached to the distal end of said housing.

10. The medical device of claim **1**, wherein said staple is plastically deformable.

11. A medical device for closing an opening in tissue, comprising:

a staple including a plurality of tines extending from a base, wherein said base includes at least two peaks spaced apart from the longitudinal centerline of said staple, and a trough located between said peaks, wherein the longitudinal centerline of said staple passes through said trough;

a cradle that holds at least a part of said staple;

a paddle assembly movable relative to said cradle, said paddle assembly including at least two spaced-apart paddles; and

a driver bifurcated at the distal end thereof into two spaced-apart branches;

wherein said driver is movable relative to said cradle and said paddle assembly; and wherein said driver is movable distally such that each said branch contacts and exerts a distal force on a corresponding said peak of said staple.

12. The medical device of claim **11**, further comprising a housing within which at least part of said staple, said cradle, said paddle assembly and said driver are located.

13. The medical device of claim **12**, wherein at least one stop is defined in said housing, wherein said stop limits motion of at least one of the group that includes said staple, said cradle, said paddle assembly and said driver.

14. The medical device of claim **12**, wherein at least one ledge is defined in said housing; wherein said paddle assembly is movable distally along a travel length, and wherein each said ledge supports a corresponding said paddle along less than the entire said travel length.

15. The medical device of claim **11**, further comprising an ejection post extending upward from at least one said paddle.

16. A medical device for closing an opening in tissue, comprising:

a staple including two tines, wherein said staple is splayable from an first configuration to a second configuration, and wherein said staple is then closeable to a third configuration;

two ridges spaced laterally apart from one another, each said ridge configured to contact a distally-oriented surface of a corresponding said tine of said staple and restrain said staple against motion in the distal direction; and

a driver configured to contact a proximally-oriented surface of said staple, wherein relative longitudinal motion of said ridges and said driver splays said staple to said second configuration.

17. The medical device of claim **16**, further comprising a cradle that holds said staple, and wherein relative longitudinal motion of said driver and said cradle closes said staple to said third configuration.

18. The medical device of claim **17**, wherein said ridges are configured to move out of contact with said staple after said relative longitudinal motion of said ridges and said driver splays said staple to said second configuration, and before said relative longitudinal motion of said driver and said cradle closes said staple to said third configuration.

19. The medical device of claim **16**, further comprising a bifurcated paddle assembly, wherein each said ridge extends from a bifurcation of said bifurcated paddle assembly.

20. The medical device of claim **16**, wherein said staple is generally M-shaped, and has two peaks, each said peak oriented in the proximal direction and located at a proximal-most location of said staple; wherein said staple includes two valleys, each said valley located longitudinally opposite a corresponding said peak and oriented in the distal direction; and wherein each said ridge contacts said staple at a corresponding said valley.

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