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(54) DEVICE, TOOLS AND METHODS FOR PERFORMING ANASTOMOSIS

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Related U.S. Application Data

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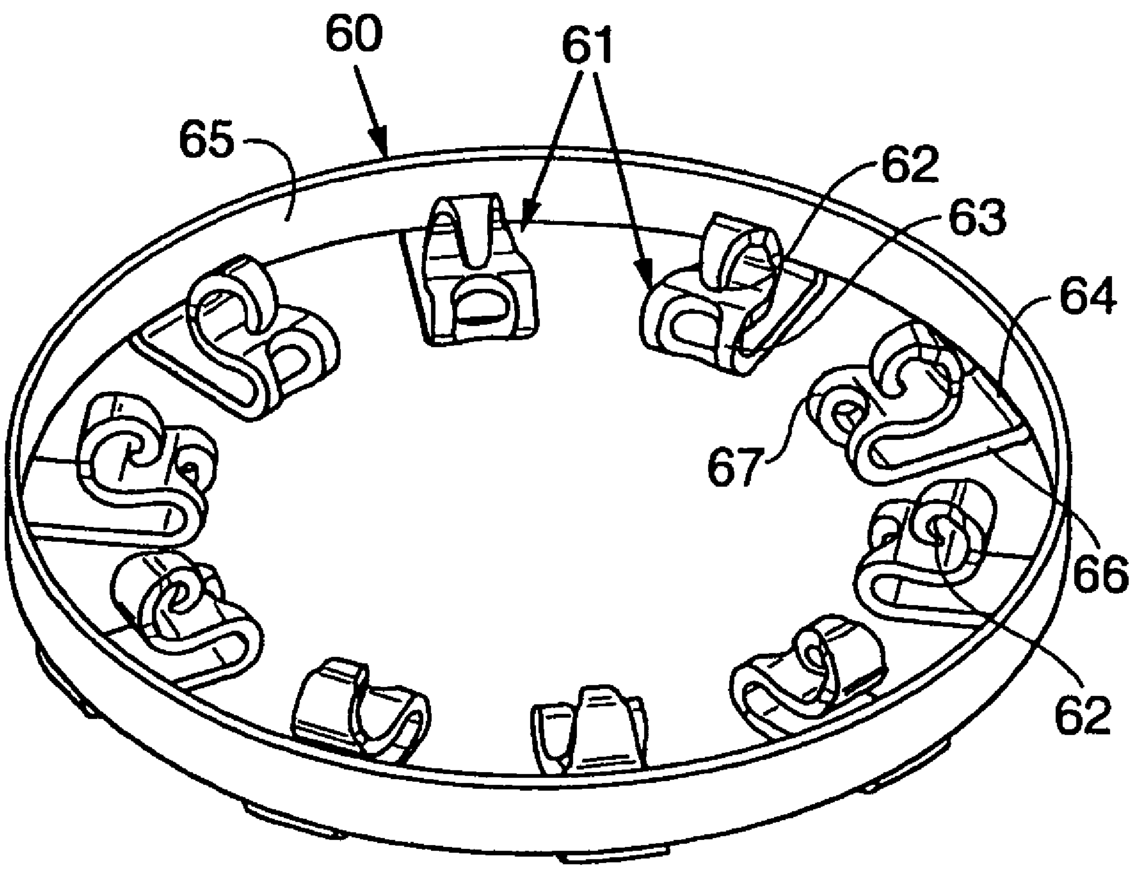
(52) U.S. Cl. 606/153

(57) ABSTRACT

Devices for use in anastomosis, methods and apparatus for installing the devices around long incisions or other orifices in tubular members such as vessels (tissue or artificial graft, or combinations), organs, ducts and the like, and method for performing anastomosis. The devices evert the walls of the tubular members to which they are attached so that an anastomosis performed with the devices joins the two members by contacting the inner walls of the members.



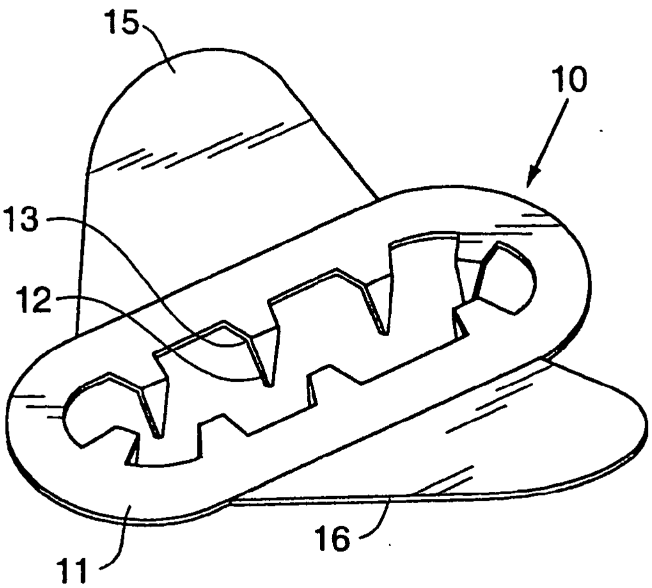


FIG. 1

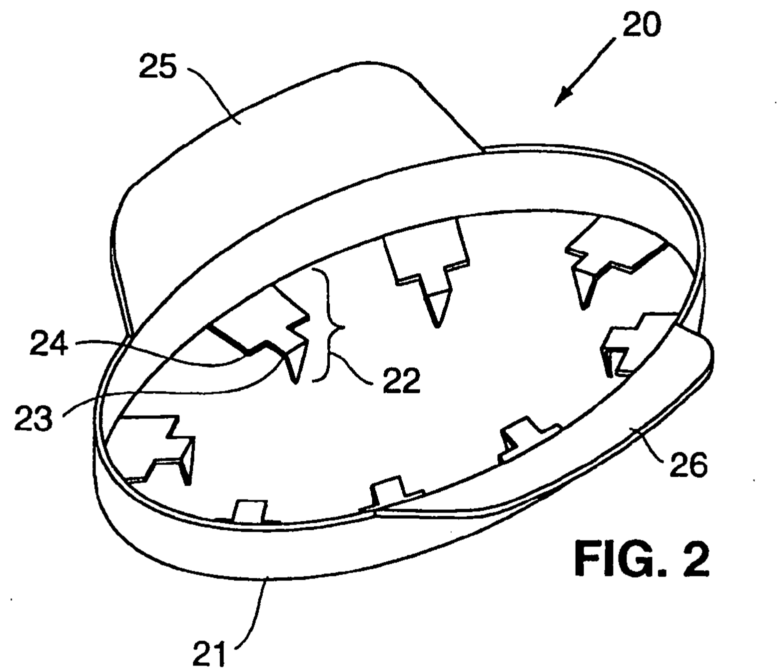


FIG. 2

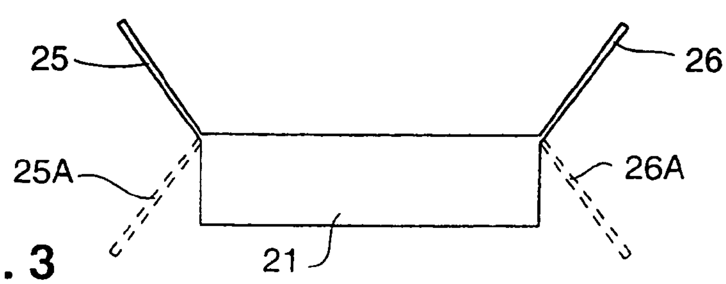
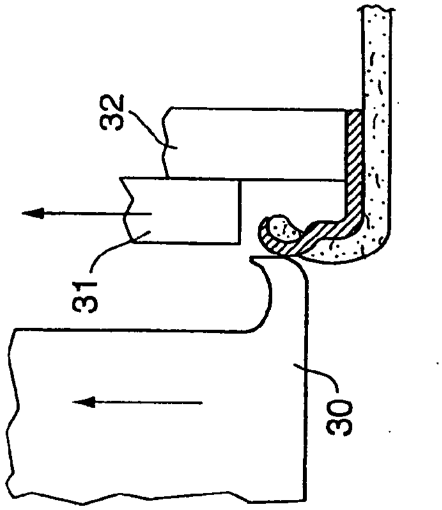


FIG. 3



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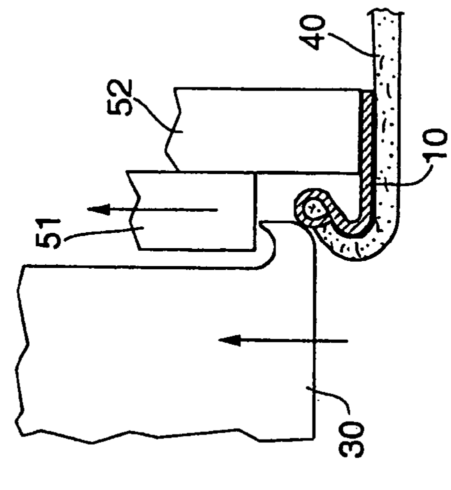

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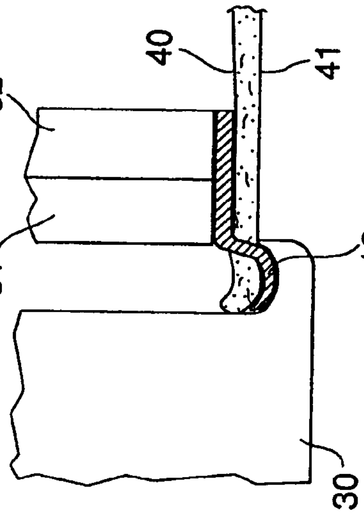
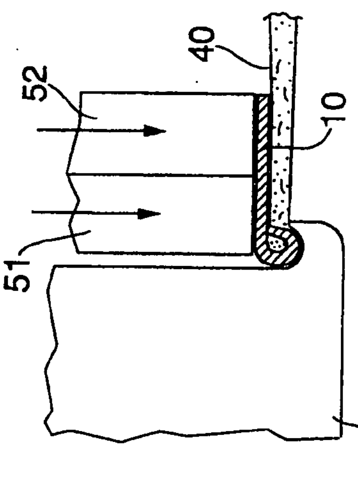


FIG. 5



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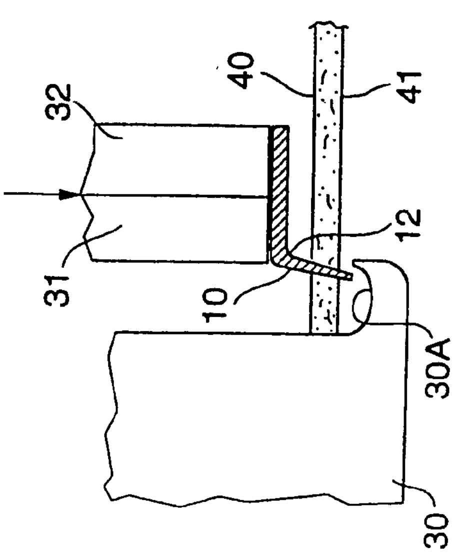

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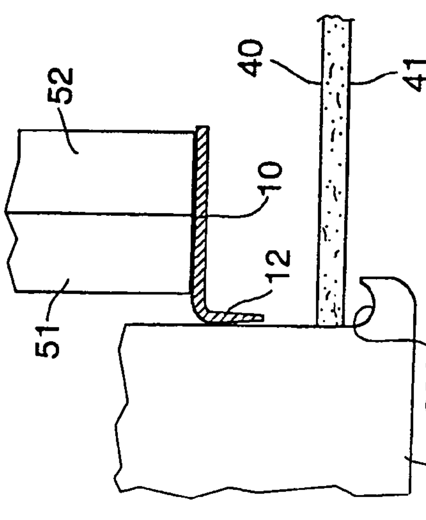

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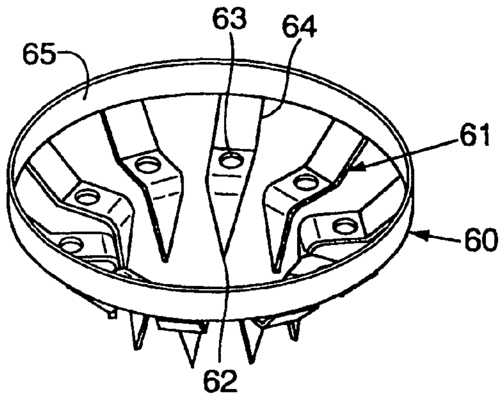

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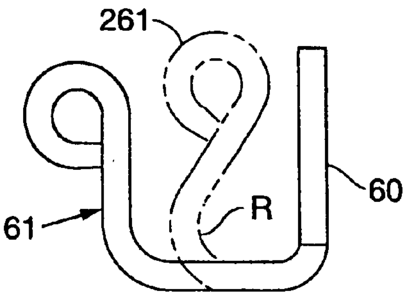

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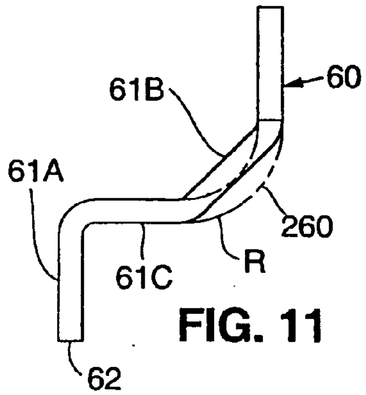

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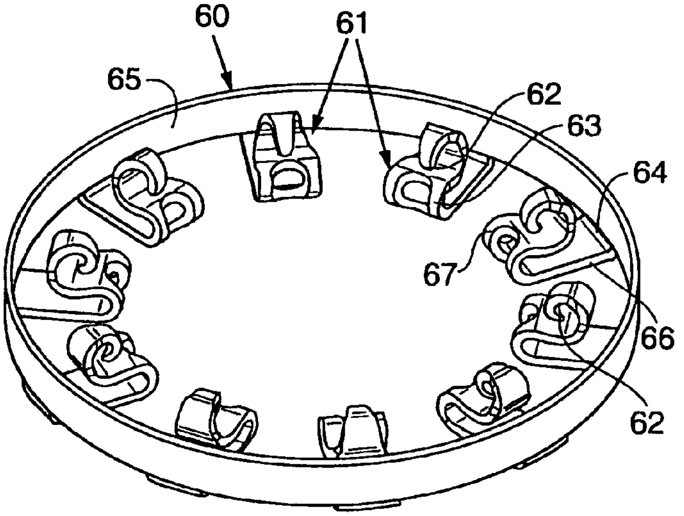

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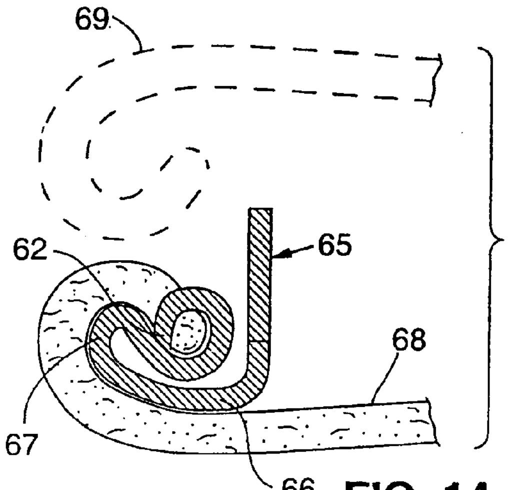

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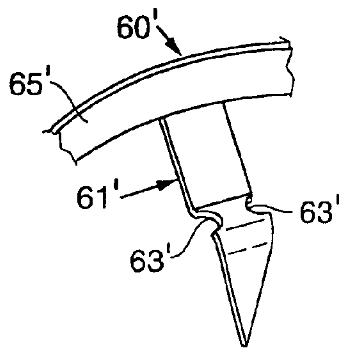

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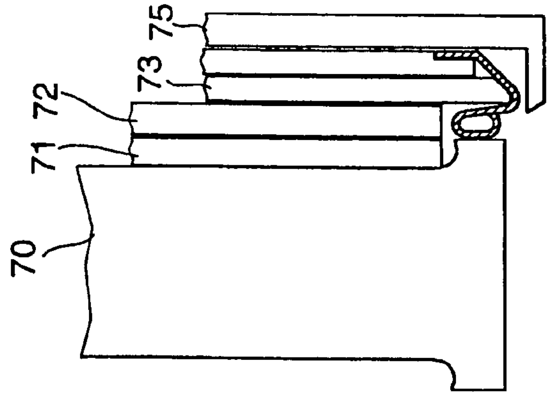

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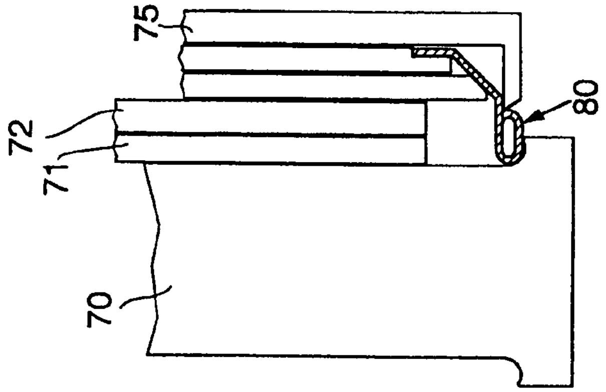

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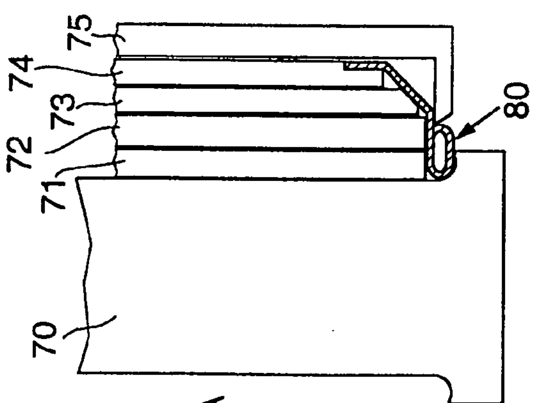

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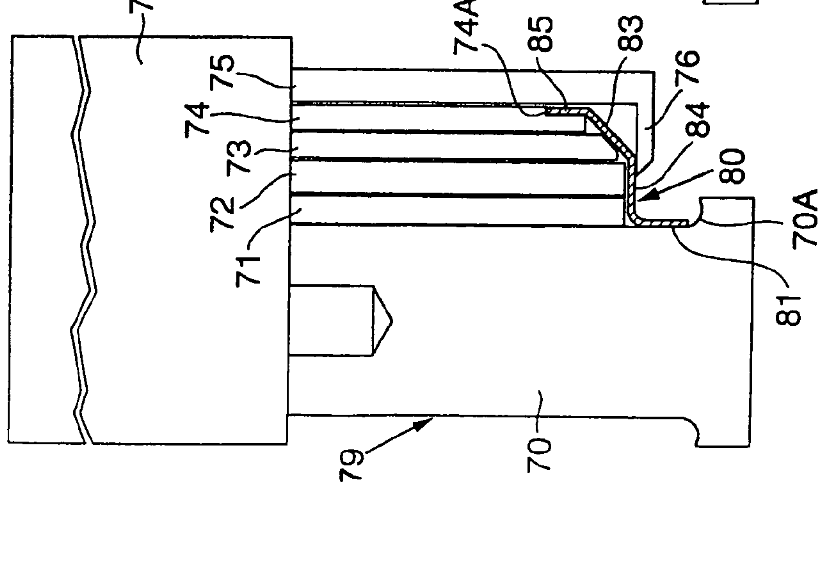

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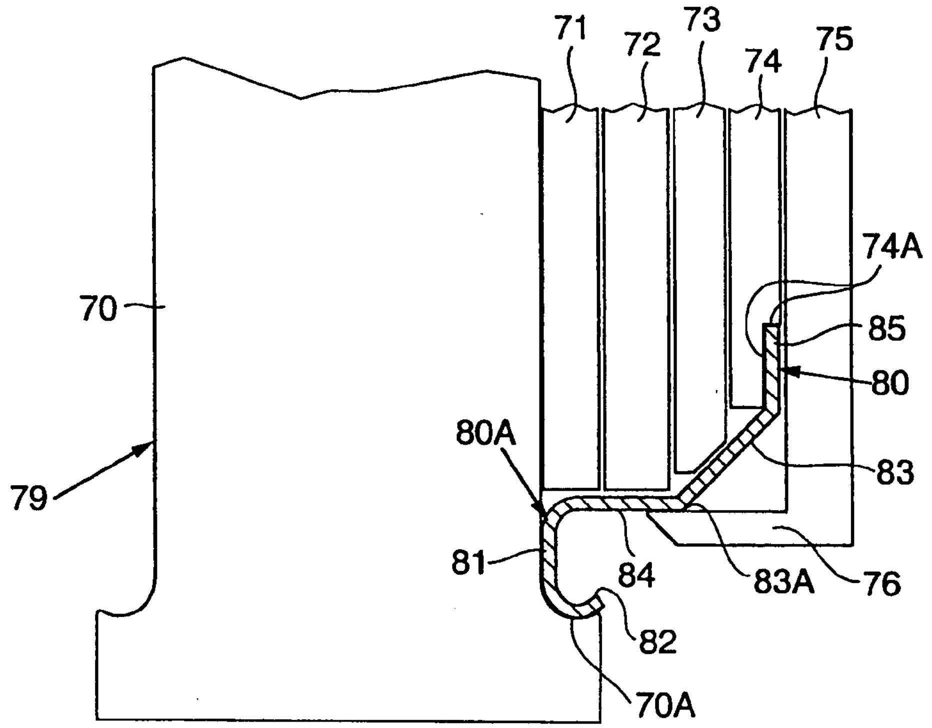

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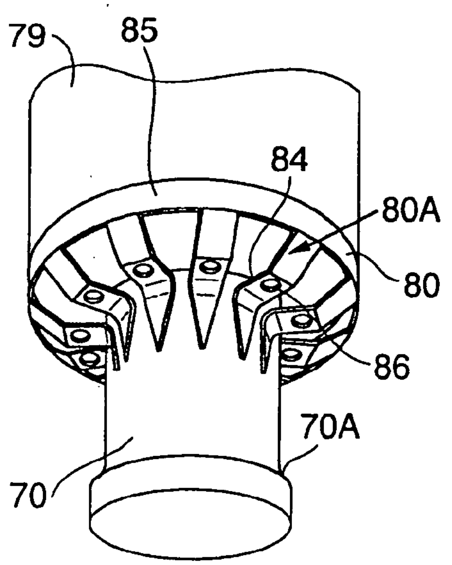

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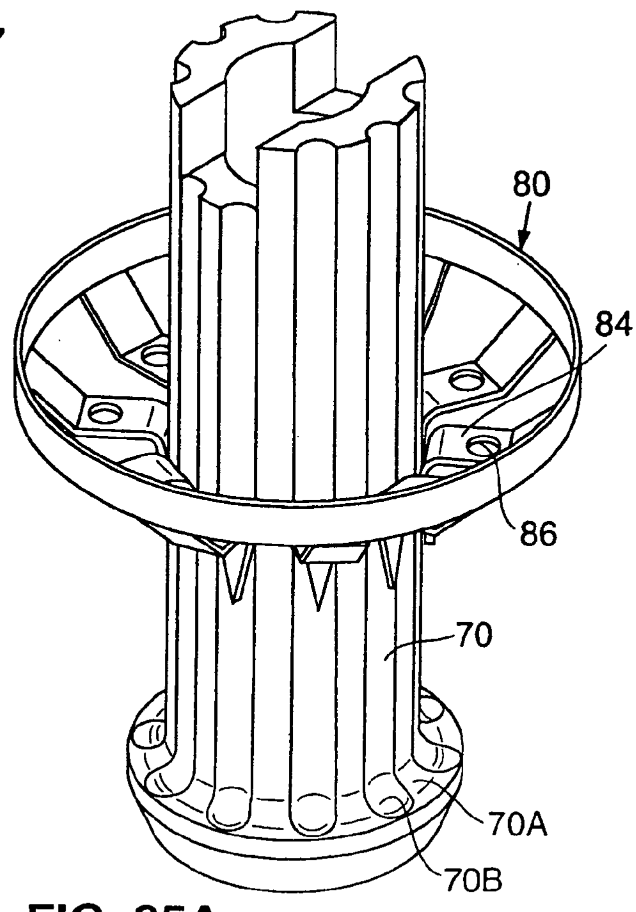
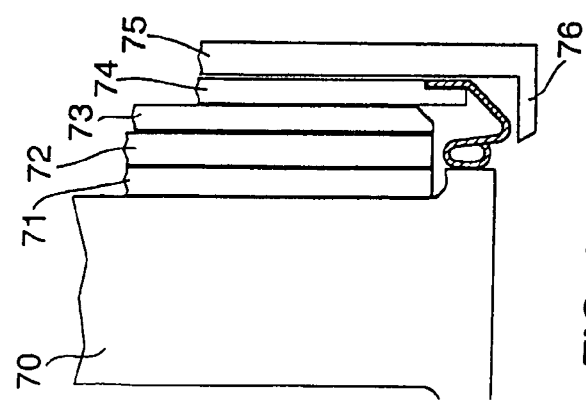


FIG. 25A



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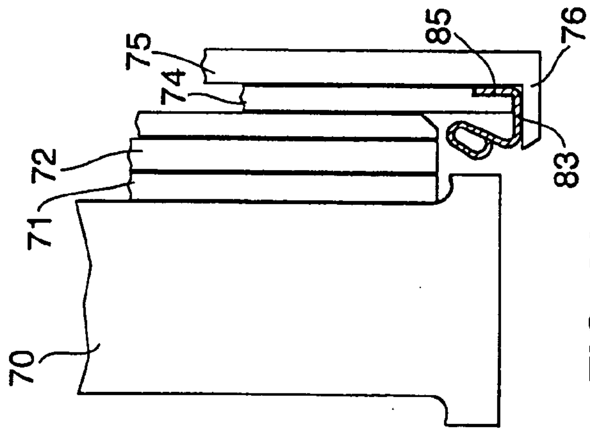

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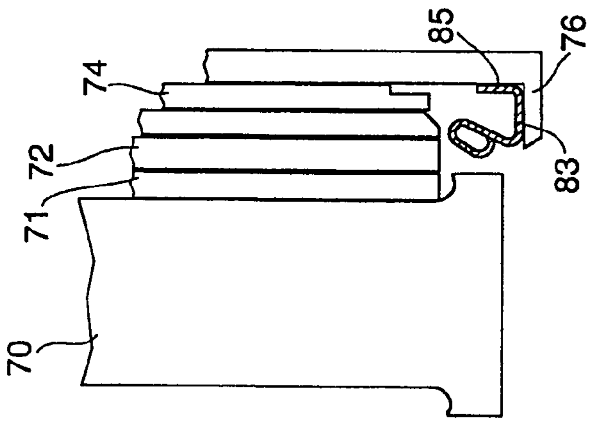

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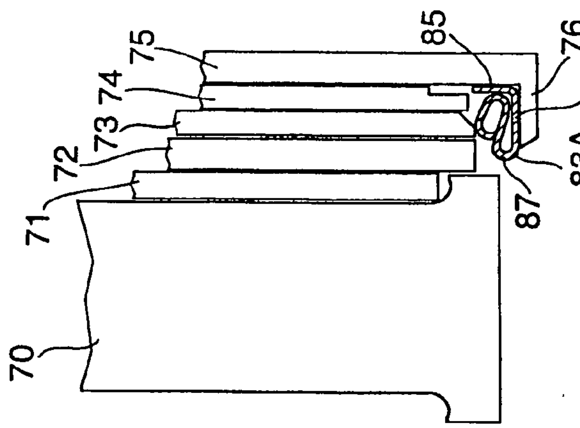

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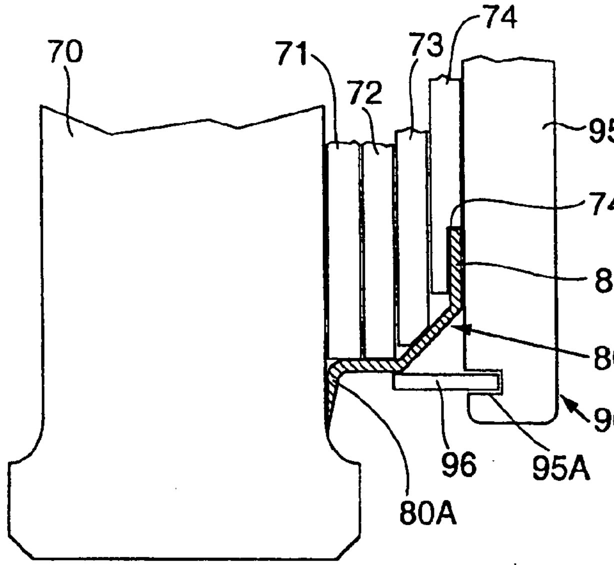

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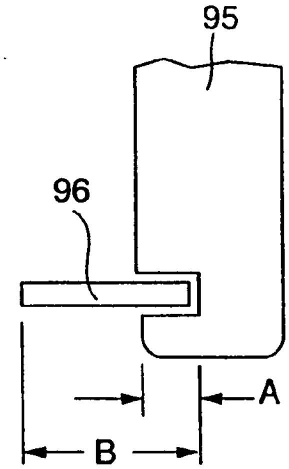

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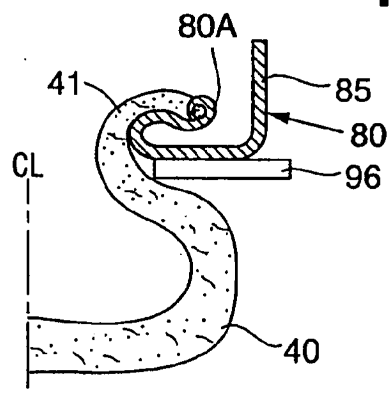

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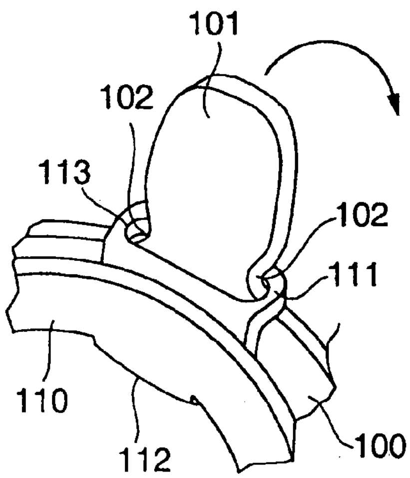

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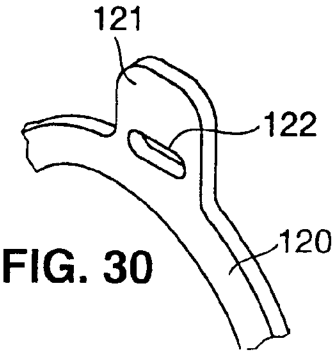

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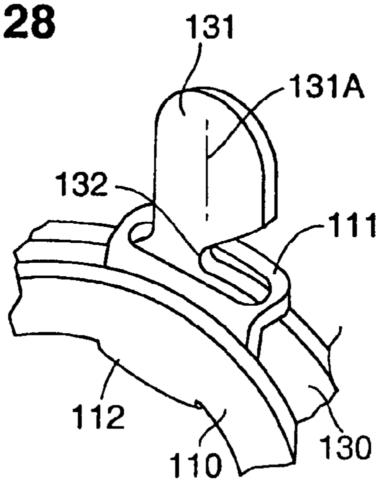

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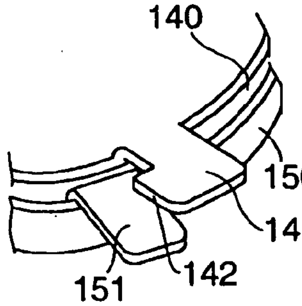

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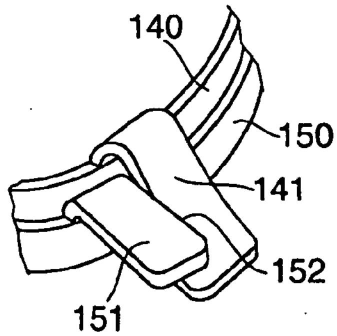

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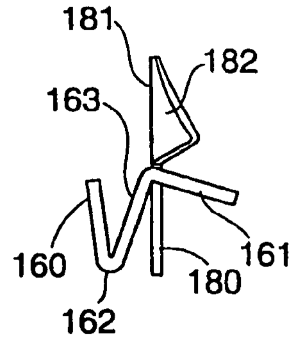

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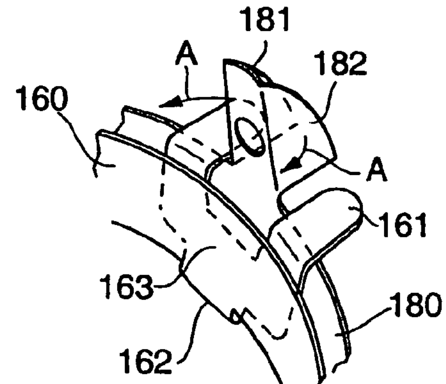

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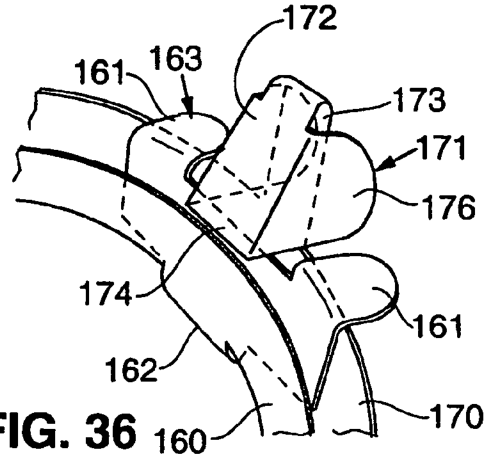

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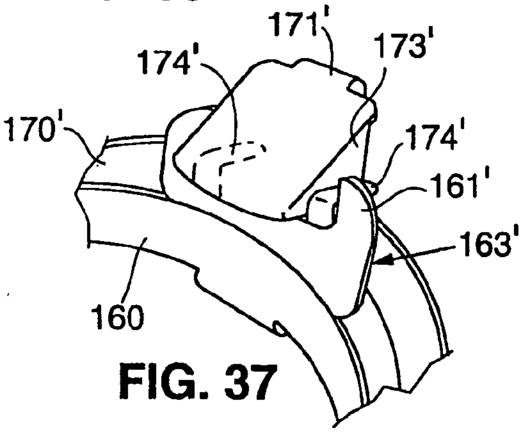

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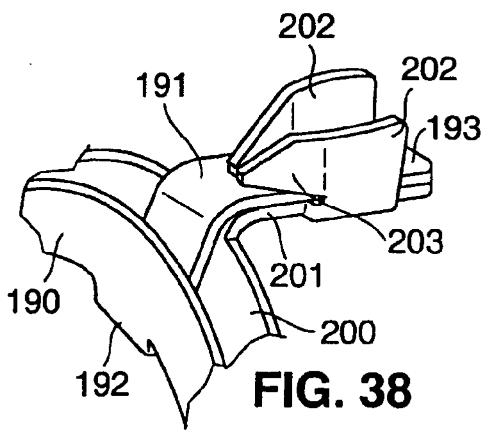

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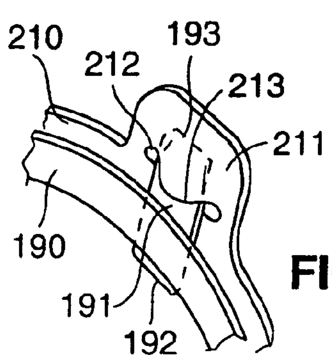

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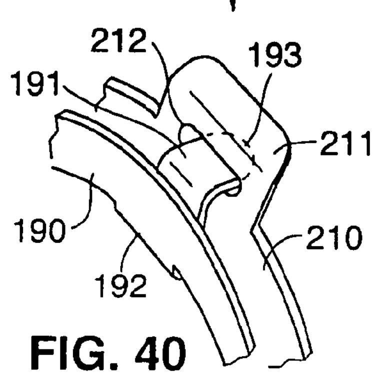

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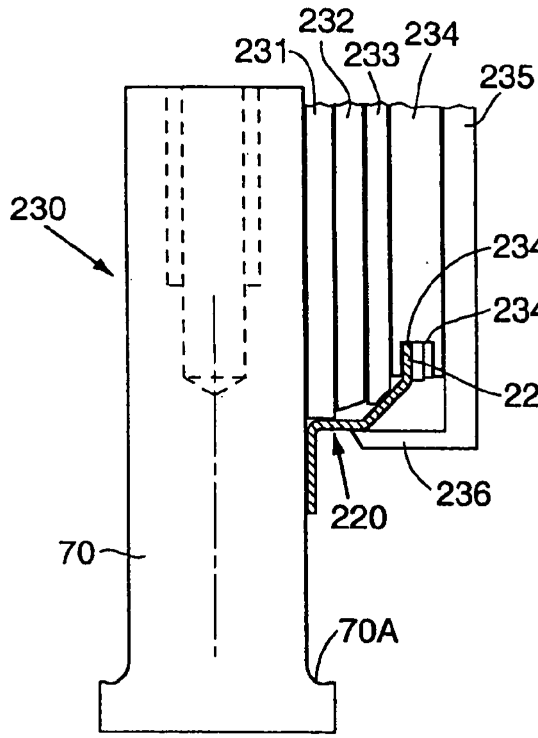
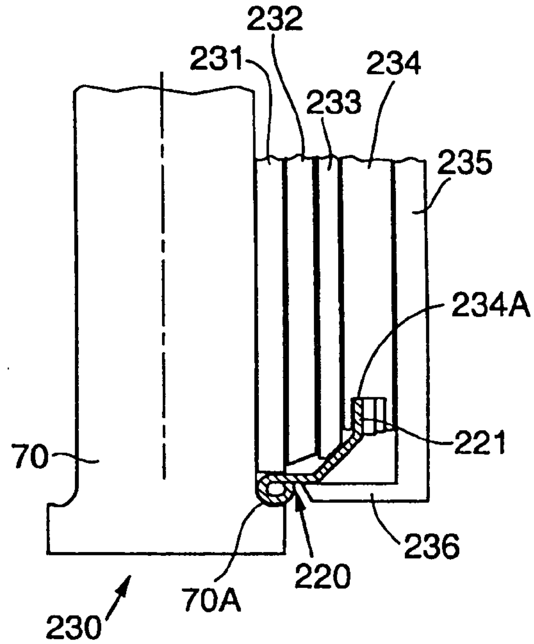


FIG. 41



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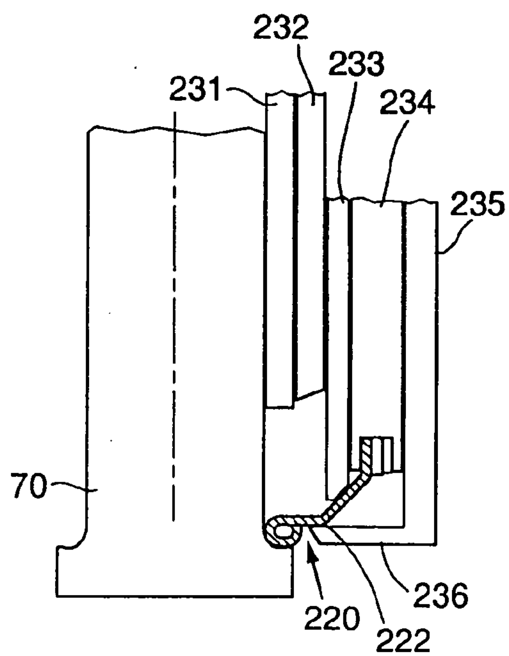

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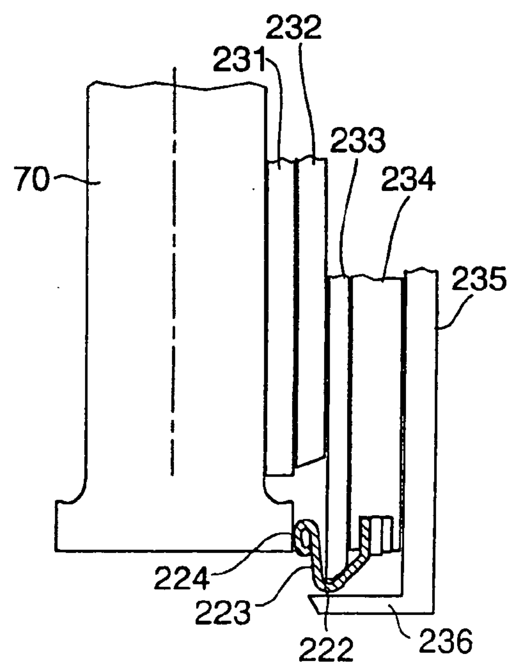

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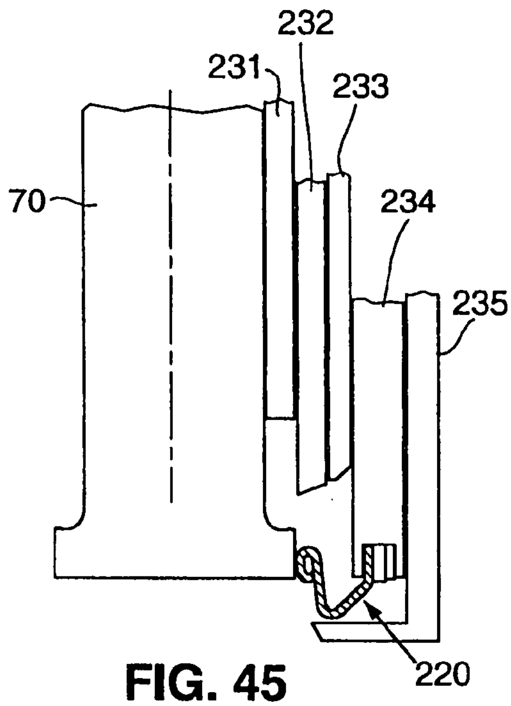

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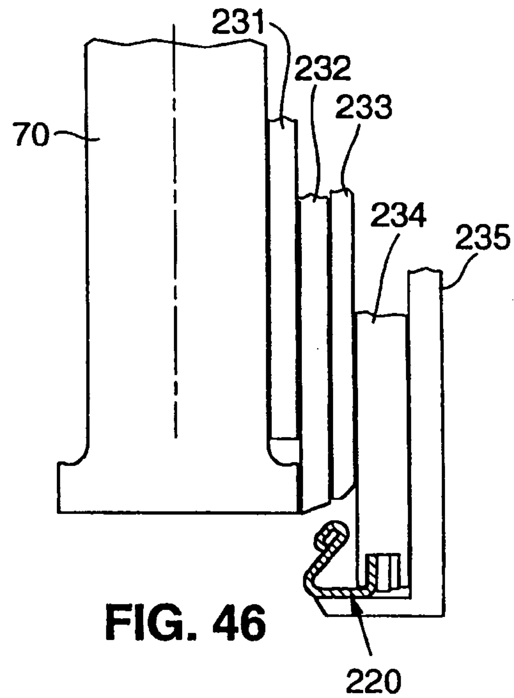

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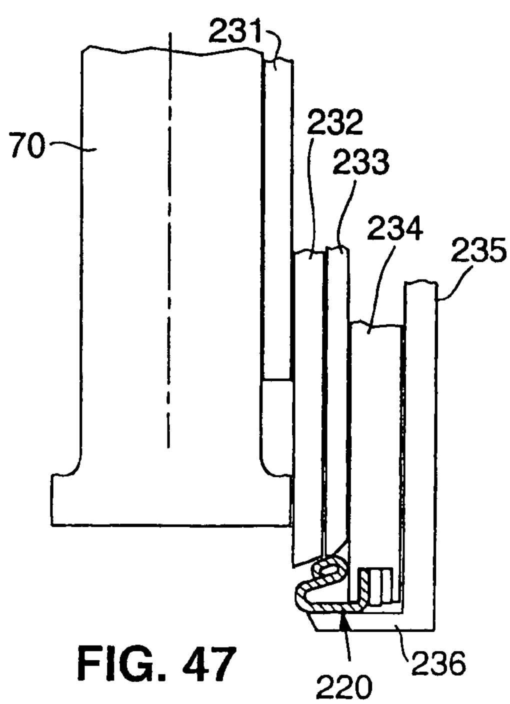

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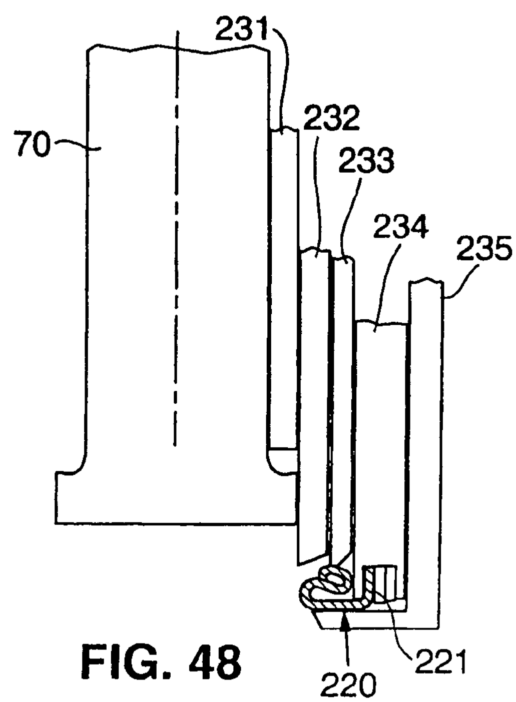

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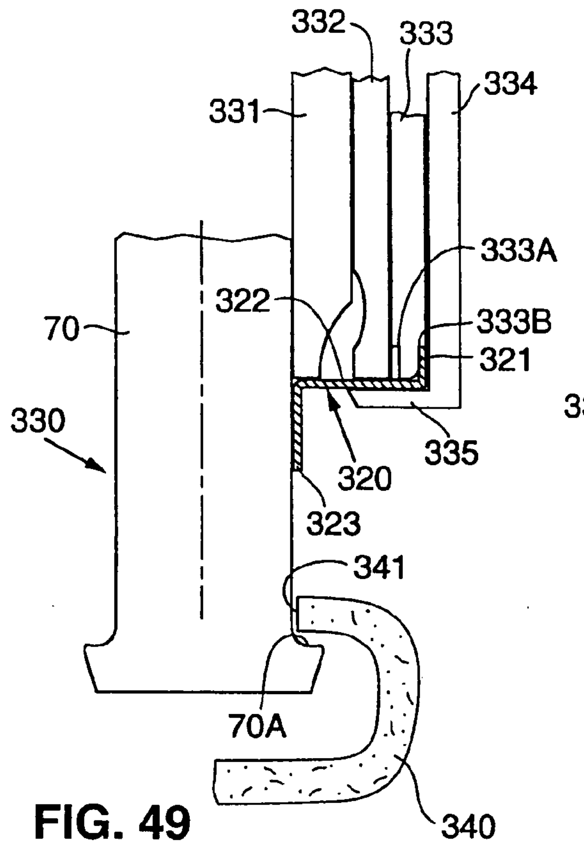


FIG. 49

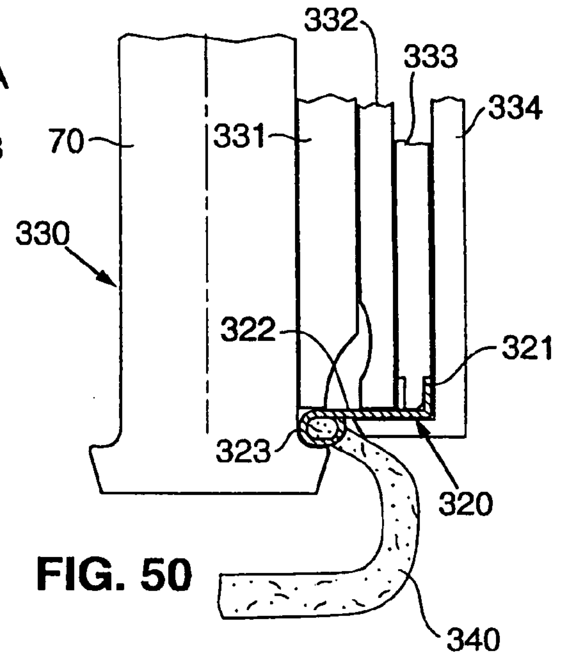


FIG. 50

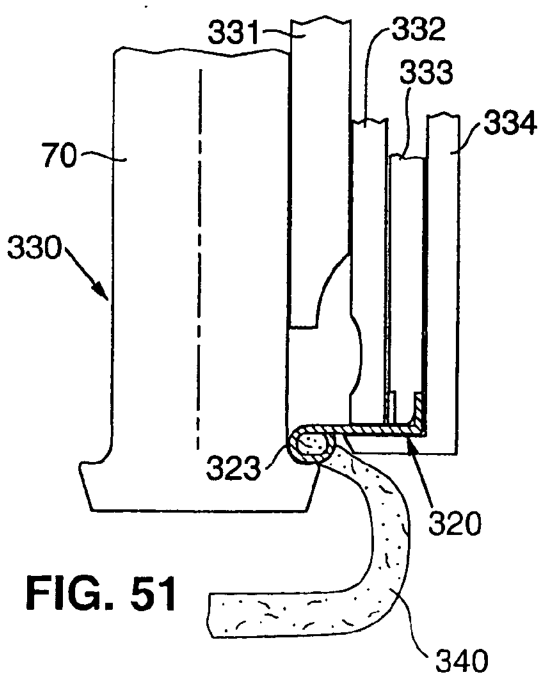


FIG. 51

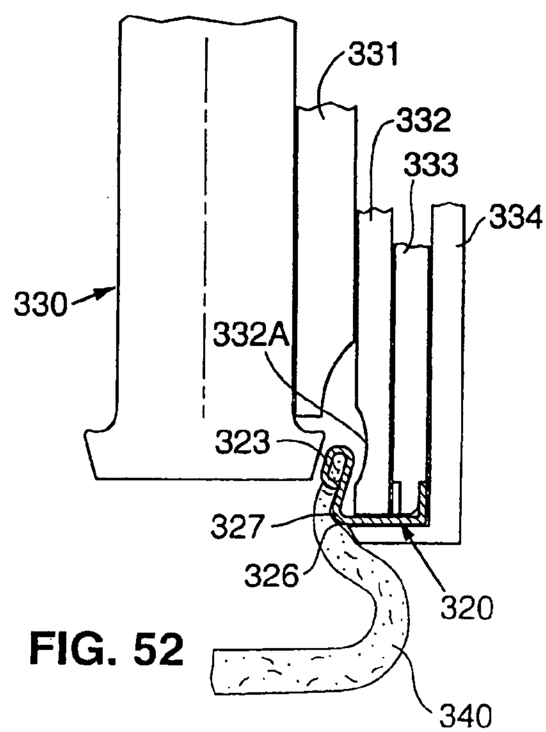


FIG. 52

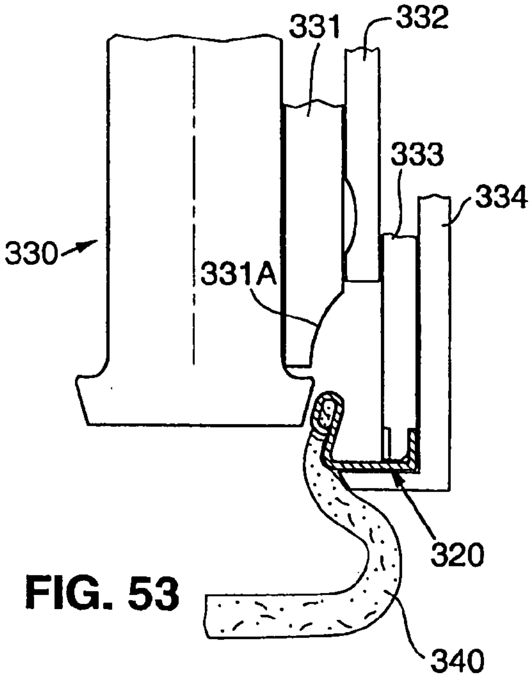


FIG. 53

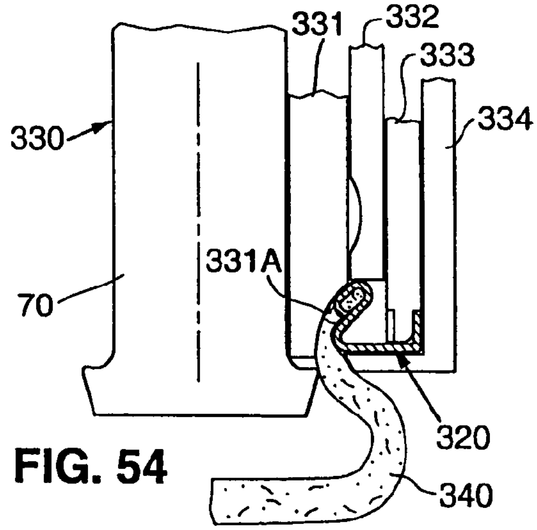
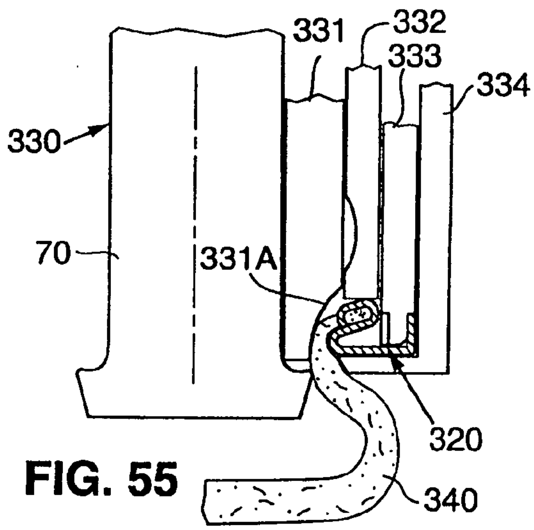


FIG. 54



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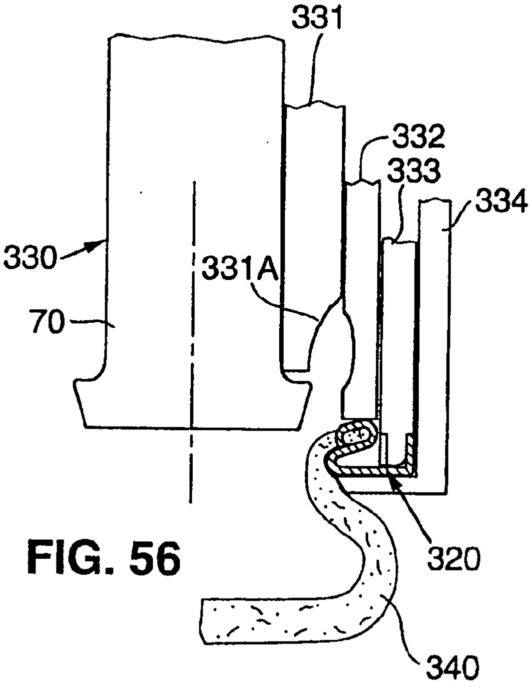

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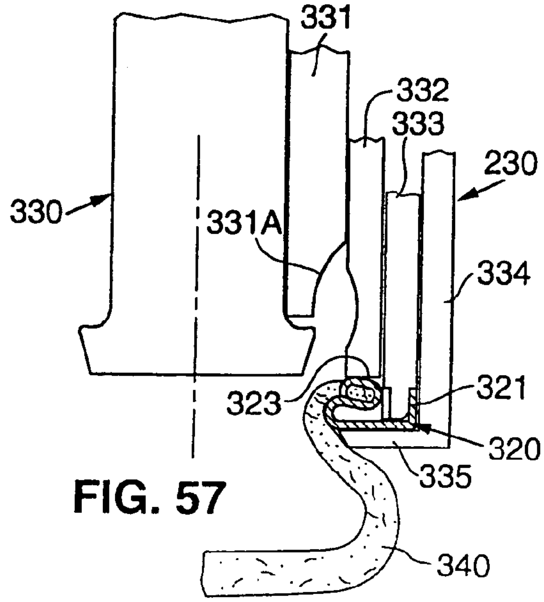

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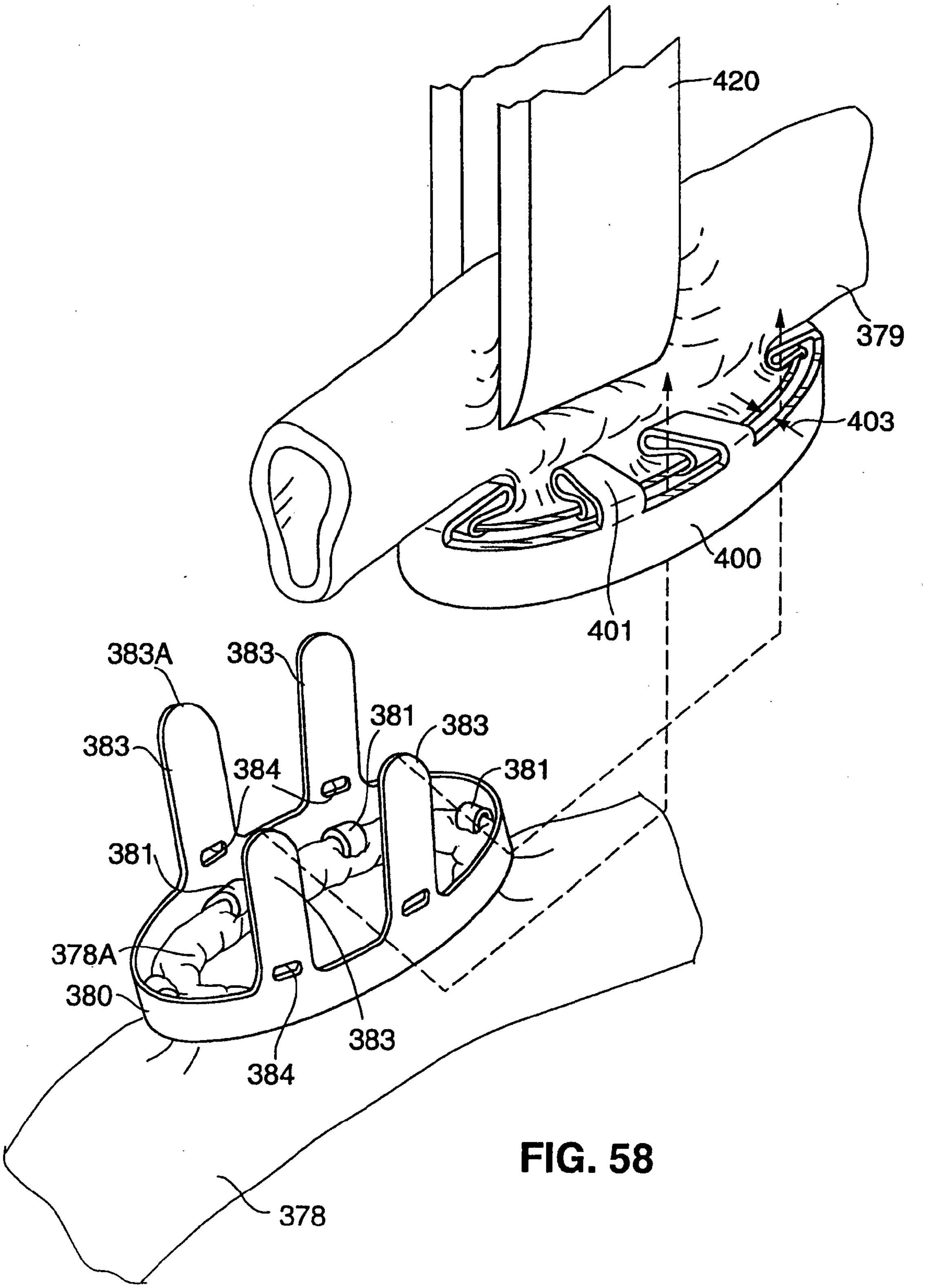
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FIG. 58

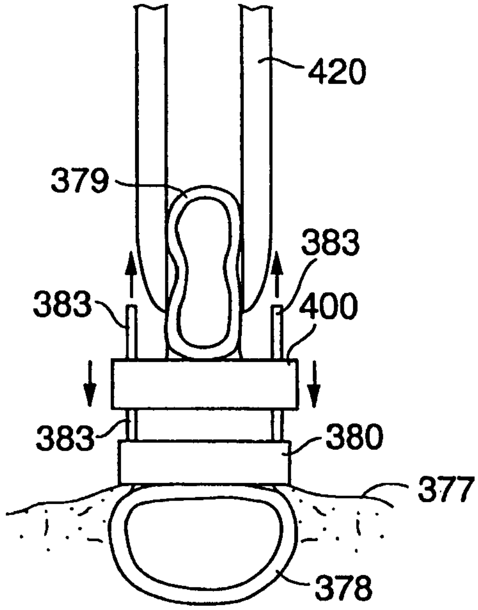


FIG. 59

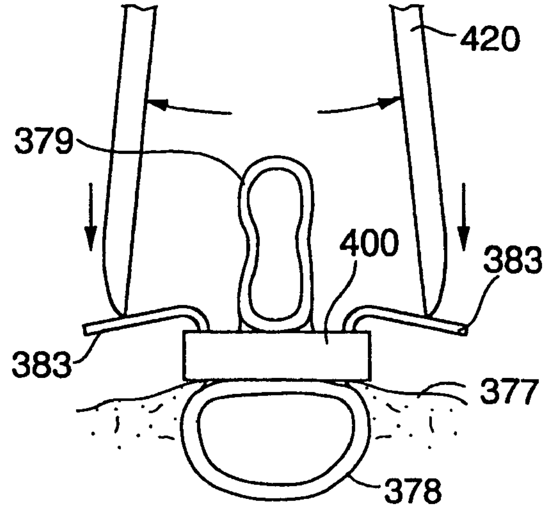


FIG. 60

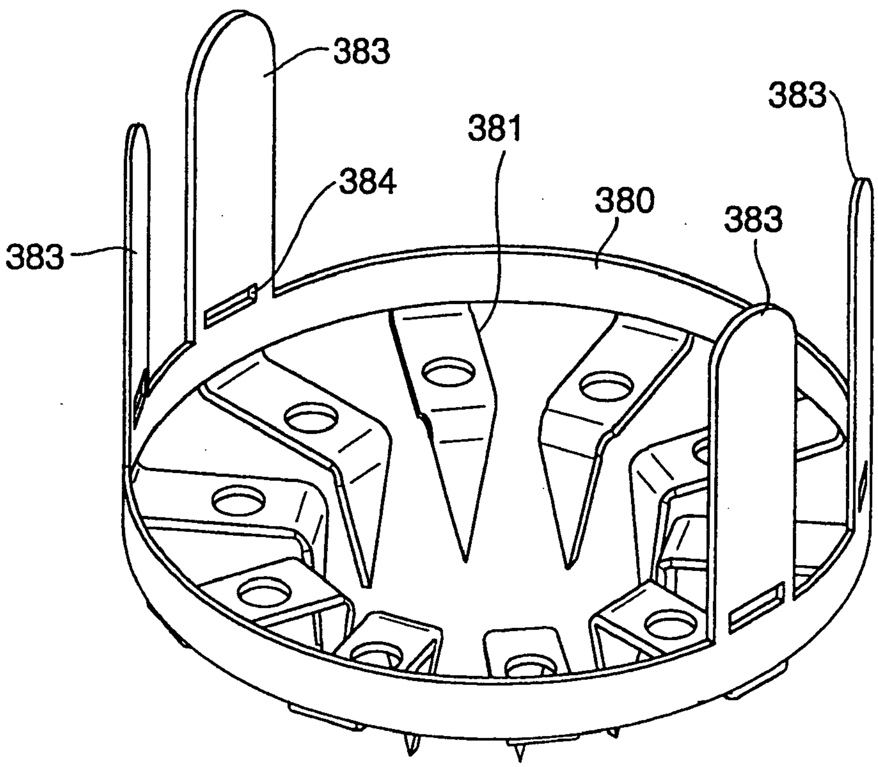


FIG. 61

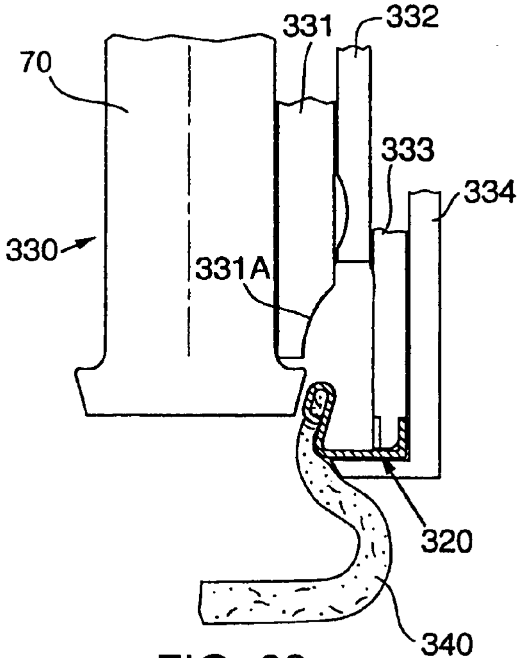


FIG. 62

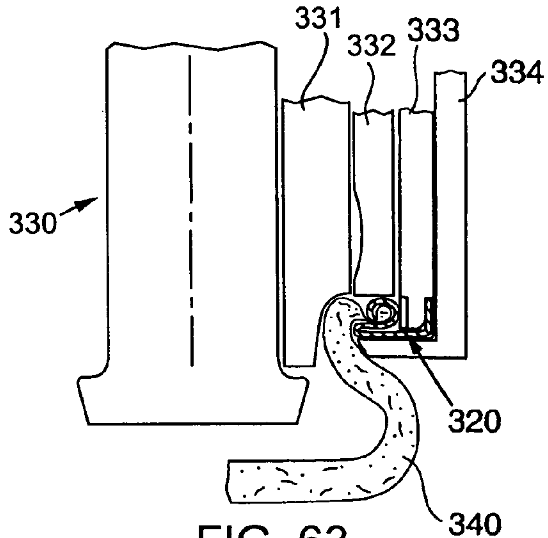


FIG. 63

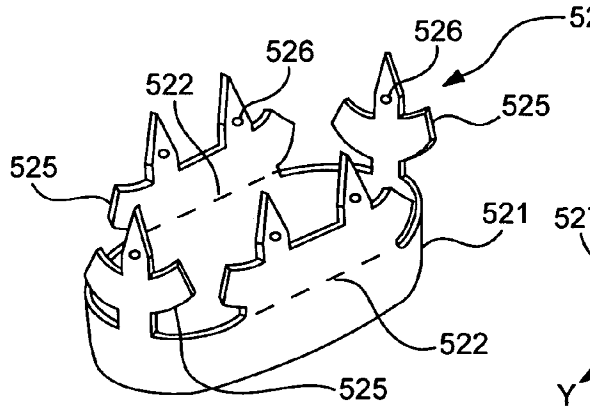


FIG. 64A

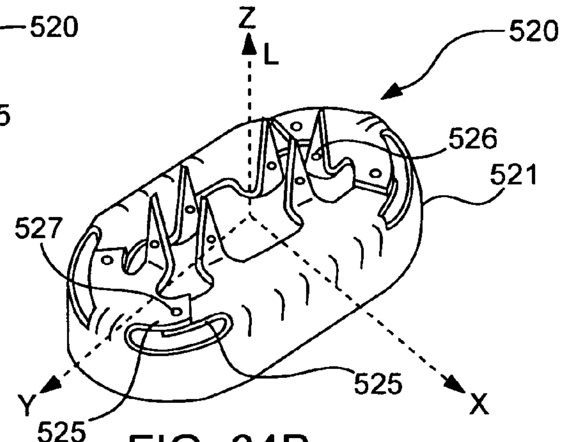


FIG. 64B

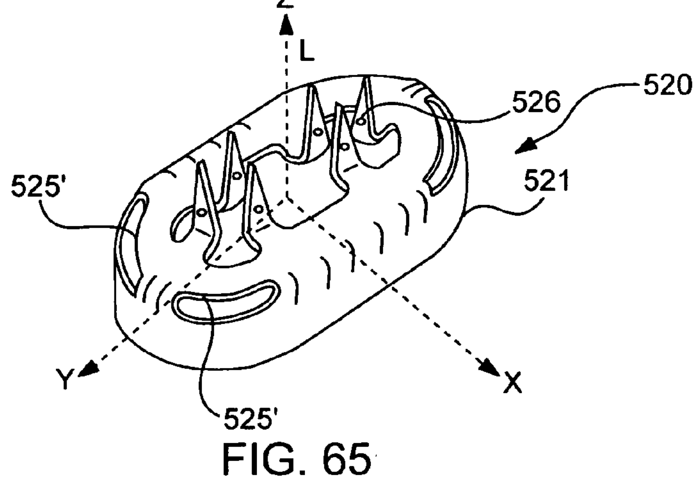


FIG. 65

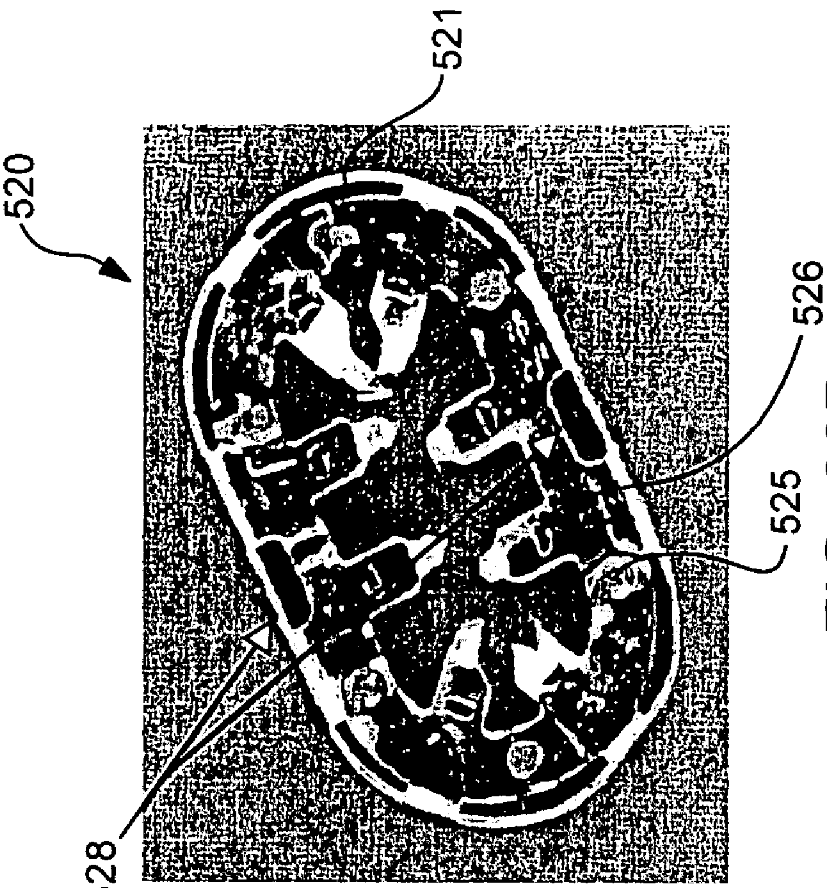


FIG. 66B

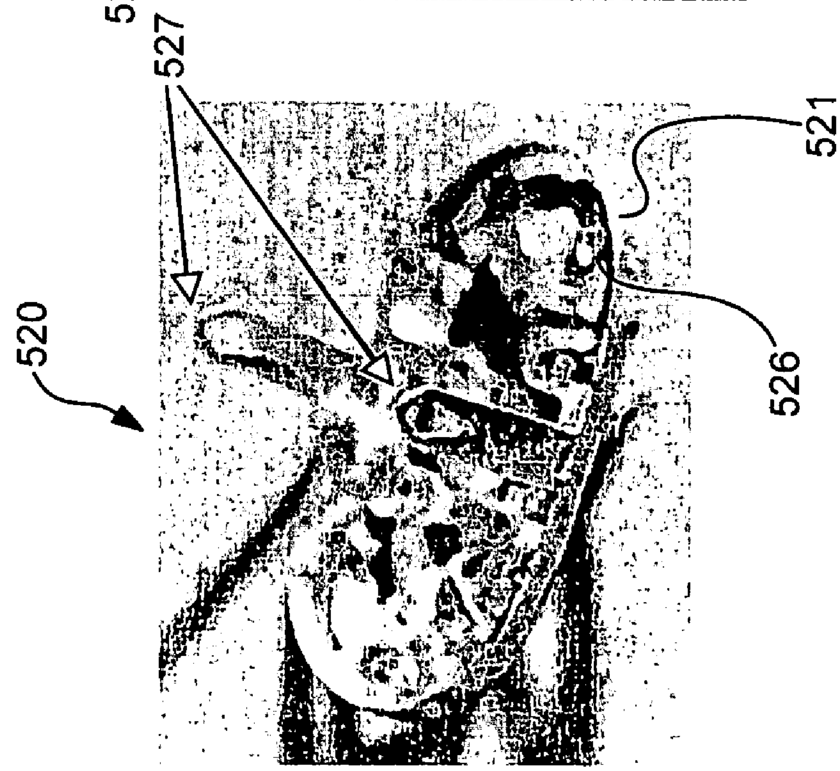


FIG. 66A

FIG. 67

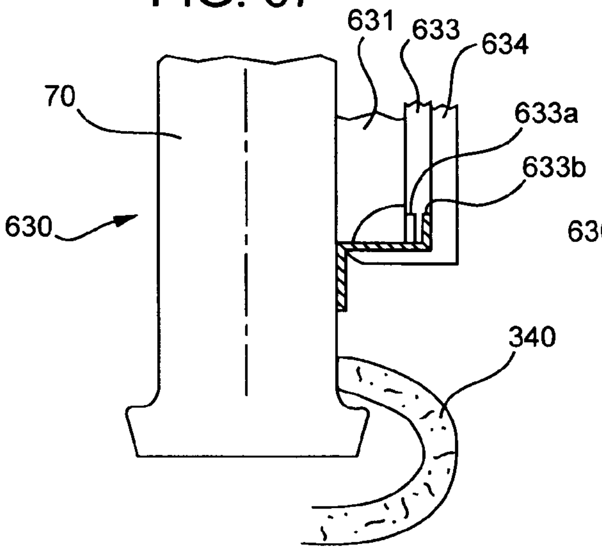


FIG. 68

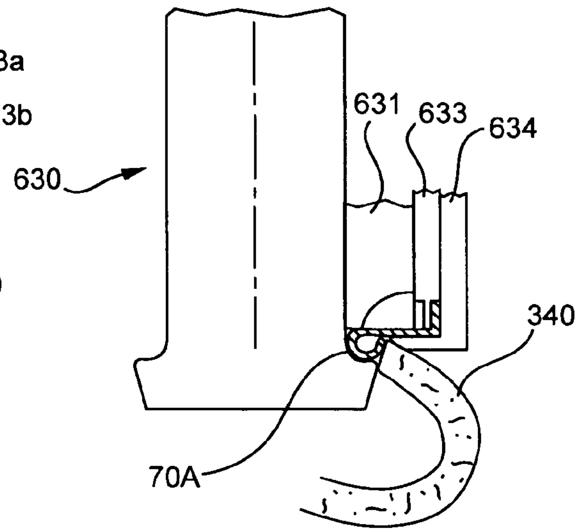
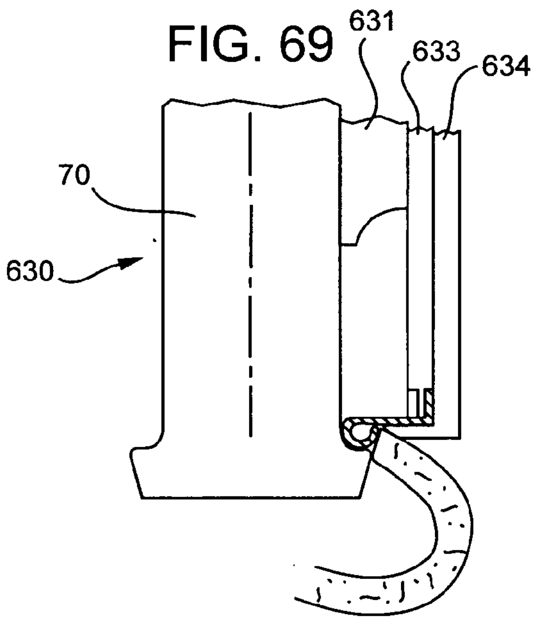


FIG. 69



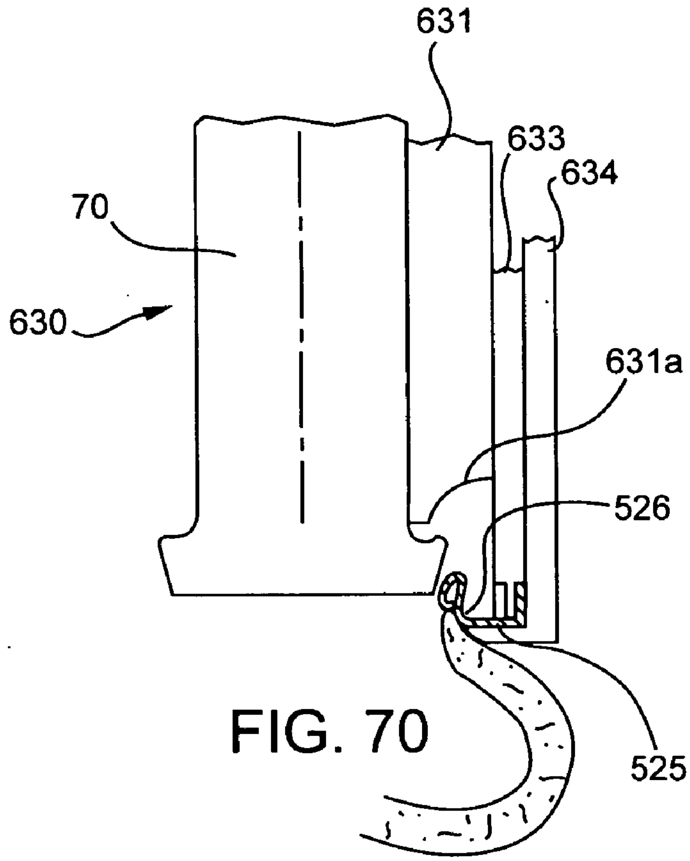


FIG. 70

(6)

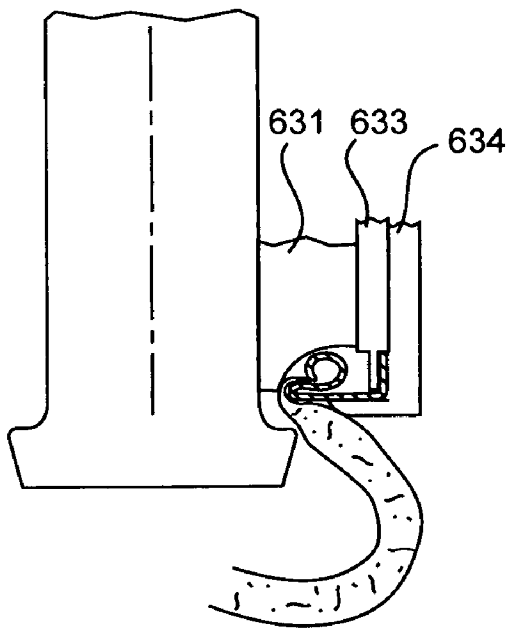


FIG. 71

DEVICE, TOOLS AND METHODS FOR PERFORMING ANASTOMOSIS

CROSS-REFERENCE

[0001] This application is a continuation-in-part application of application Ser. No. 09/794,670, filed Feb. 27, 2001, pending, which is incorporated herein, in its entirety, by reference thereto, and to which application we claim priority under 35 USC §120.

TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates to devices, apparatus and methods for performing anastomosis without hand-suturing.

BACKGROUND OF THE INVENTION

[0003] In the United States, many coronary artery bypass graft (CABG) procedures are performed on patients annually. Each of these procedures may include one or more graft vessels which are hand sutured. Until recently, coronary artery bypass procedures have been performed with the patient on cardiopulmonary bypass while the heart is stopped with cardioplegia and the surgery is performed on an exposed, stationary heart. Interest in developing a minimally invasive CABG procedure is increasing.

[0004] A few pioneering surgeons are now performing minimally invasive procedures in which a coronary artery bypass is performed through a small incision in the chest wall, sometimes on a beating heart, i.e., without heart-lung bypass and cardioplegia.

[0005] Until recently all bypass graft procedures have been performed by hand suturing the tiny vessels together with extremely fine sutures under magnification. There is a need (which is addressed by the present invention) for methods and apparatus useful for performing anastomosis during CABG surgery on a beating heart, without hand-suturing.

[0006] The present invention can be used to perform end-to-end anastomosis (in which the open end of a vessel or other organ is attached to (and in fluid communication with) the open end of another vessel or other organ without hand-suturing, end-to-side anastomosis (in which the open end of one vessel or other organ is attached to the side wall of a second organ in fluid communication with an incision or other orifice in the second organ's side wall) without hand-suturing, or side-to-side anastomosis (in which incisions or other orifices in the side walls of two vessels or other organs are aligned in fluid communication with each other and the aligned tissue is attached together) without hand-suturing.

SUMMARY OF THE INVENTION

[0007] In a class of embodiments the invention includes devices for performing anastomosis, tools for installing the devices and joining them to perform the anastomosis, and methods for installing the devices and for performing anastomoses.

[0008] An anastomosis device for attachment around an orifice in a first tubular member and for everting the wall of the tubular member around a perimeter of the orifice, in preparation for anastomosis with a second tubular tissue or organ is provided, in which the device includes a ring portion sized to extend around the orifice; and malleable tines extending radially inward from the ring portion and having tine tips bent at an angle with respect thereto. The tine tips are adapted to extend into the orifice, adjacent the perimeter of the orifice, and are deformable to grasp the wall defining the perimeter of the orifice, from inside the tubular tissue or organ. The tines are further deformable to evert the wall around the perimeter of the orifice.

[0009] The tines may each have a weakened portion adjacent the tine tip, so that the tines preferentially fold or bend at the weakened portions in response to being subjected to bending force.

[0010] A structurally reinforced device is described to further include extensions extending from the tines adjacent the ring portion. Adjacent extensions overlap one another when they and the tines are folded over during forming of the device.

[0011] The overlapping extensions may be fixed with respect to one another, thereby reinforcing the tines to provide increased bending strength.

[0012] The tines may extend substantially perpendicularly from the ring portion, and the tine tips may extend substantially perpendicularly from the tines.

[0013] The ring portion may include at least a pair of fastener elements adapted to mate with another device in performing the anastomosis. For a mating pair of devices, one device may have at least at least a pair of malleable tabs extending from the ring portion, and the other device may have an equal number of docking slots arranged to receive the malleable tabs for fastening the two devices together.

[0014] A method of attaching an anastomosis device to a tubular structure to be joined by anastomosis is provided to include: inserting an anvil having a bend forming surface into an orifice formed through a wall of the tubular structure; advancing an anastomosis device having a ring portion with tines extending radially inward therefrom over the anvil, wherein the tines further include tine tips extending therefrom, substantially perpendicularly to the anvil as the device is advanced over the anvil; continuing to advance the device until the tine tips extend into the orifice and past the inner wall surface of the tubular structure; driving the tine tips against the bend forming surface of the anvil by continuing to advance the device, wherein the tine tips are curled under the wall of the tubular structure, thereby gripping the wall between the tine tips and the tines which form a curled tine structure.

[0015] Further preparation of the tubular member for anastomosis may include retracting the anvil while holding an opposing force on the ring portion, wherein the anvil contacts the curled tine structure and bends the tines in an opposite direction to the direction of bending of the tine tips, thereby everting the wall of the tubular structure that peripherally surrounds the orifice.

[0016] Still further, at least one additional member having a bend forming surface may be advanced over the anvil to contact the curled tine structure and further bend the tines in the opposite direction to further evert the wall of the tubular structure.

[0017] The method everts the wall of the tubular structure to an extent that the inside surface of the wall is exposed to be contacted during the anastomosis.

[0018] A pair of anastomosis devices adapted to form an anastomosis between first and second tubular members having first and second orifices is provided. The first device of the pair is adapted for attachment around the orifice in the first tubular member and for everting the wall of the first tubular member at a perimeter of the orifice, and the second device is adapted for attachment around the orifice in the second tubular member and for everting the wall of the second tubular member at the perimeter of the orifice.

[0019] The first device includes a ring portion sized to extend around the orifice of the first tubular member; and malleable tines extending radially inward from the ring portion and having tine tips bent at an angle with respect to the radially extending tines and adapted to extend into the orifice, adjacent the perimeter of the orifice. The tine tips are deformable to grasp the wall at the perimeter of the orifice, from inside the tubular member and the tines are further deformable to evert the tissue around the wall forming the perimeter of the orifice.

[0020] The second device includes a ring portion sized to extend around the orifice of the second tubular member and sized to fit concentrically over the ring portion of the first device. The second device further includes malleable tines extending radially inward from the ring portion and having tine tips bent at an angle with respect to the radially extending tines and adapted to extend into the orifice of the second tubular member, adjacent the perimeter of the orifice. The tine tips of the second device are deformable to grasp the wall at the perimeter of the orifice, from inside the second tubular member and the tines are further deformable to evert the wall forming the perimeter of the orifice.

[0021] After attaching the first and second devices to the first and second tubular members, respectively, the second device is joined with the first device in a manner wherein the second ring portion concentrically surrounds the first ring portion, thereby contacting the everted inner wall surface of the first tubular member with the everted inner wall surface of the second tubular member. Alternatively, if the first and second devices have flat surfaces, such as the device shown in **FIG. 1**, for example, the everted inner wall surfaces over the first and second devices meet face to face, thereby bringing the everted surfaces into direct contact when the first and second devices are joined.

[0022] One of the first and second devices may include at least a pair of mounting tabs extending from the ring portion thereof, or from features extending from the ring portion, and the other device may include at least a pair of docking slots formed in the ring portion thereof, or formed in features extending from the ring portion, and arranged to mate with the mounting tabs for locking the first and second devices to complete the anastomosis. Alternatively, each ring portion could include one or more mounting tabs and one or more docking slots, as long as the other ring portion has appropriately arranged mounting tabs and docking slots to mate with those of the first ring portion. Further alternatively, the first and second devices may be joined by one or more ligating clips, sutures, suture clips, or any form of biocompatible external connecting elements, or may be joined using tissue glue, by tissue welding, or by metal welding, such as by means of a laser.

[0023] A method of performing an anastomosis is provided, to include the steps of: inserting an anvil having a bend forming surface into an orifice formed through a wall of a first tubular member; advancing a first anastomosis device having a ring portion with tines extending radially inward therefrom over the anvil, wherein the tines further include tine tips extending therefrom, substantially perpendicularly to the anvil as the device is advanced over the anvil; continuing to advance the first device and driving the tine tips against the bend forming surface of the anvil by continuing to advance the device, wherein the tine tips are curled under the wall of the tubular member, thereby gripping the wall between the tine tips and the tines which form a curled tine structure; everting the wall of the first tubular member along a perimeter of the orifice by bending the tines in an opposite direction to the direction of bending of the tine tips; inserting an anvil having a bend forming surface into an orifice formed through a wall of a second tubular member; advancing a second anastomosis device having a ring portion sized to fit concentrically over the first ring portion and having second tines extending radially inward therefrom, over the anvil, wherein the second tines further include second tine tips extending therefrom, substantially perpendicularly to the anvil as the second device is advanced over the anvil; continuing to advance the second device and driving the second tine tips against the bend forming surface of the anvil by continuing to advance the second device, wherein the second tine tips are curled under the wall of the second tubular member, thereby gripping the wall of the second tubular member between the second tine tips and the second tines which form a second curled tine structure; everting the wall of the second tubular member along a perimeter of the orifice by bending the tines in an opposite direction to the direction of bending of the second tine tips; sliding the second ring portion concentrically over the first ring portion, thereby contacting the everted wall of the second tubular member with the everted wall of the first tubular member, so that the inner wall surfaces of the first and second tubular members make contact; and fastening the first and second devices together to maintain contact between the everted wall surfaces and to maintain the second ring portion in a position concentrically surrounding the first ring portion.

[0024] These and other advantages, and features of the invention will become apparent to those persons skilled in the art upon reading the details of the devices, apparatus and methods as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] **FIG. 1** is a perspective view of an embodiment of the inventive ring for use in performing anastomosis without hand sutures.

[0026] **FIG. 2** is a perspective view of another embodiment of the inventive ring for use in performing anastomosis without hand sutures.

[0027] **FIG. 3** is a side elevational view of the ring of **FIG. 2**.

[0028] **FIG. 4** is a side cross-sectional view of a portion of the ring of **FIG. 1** and a portion of an apparatus for installing it, at an early stage of installation of the ring around an incision in the sidewall of a blood vessel.

[0029] **FIG. 5** is a side cross-sectional view of a portion of the ring of **FIG. 1** and a portion of an apparatus for installing it, at an intermediate stage of installation of the ring around an incision in the sidewall of a blood vessel.

[0030] **FIG. 6** is a side cross-sectional view of a portion of the ring of **FIG. 1** and a portion of an apparatus for installing it, at a late stage of installation of the ring around an incision in the sidewall of a blood vessel.

[0031] **FIG. 7** is a side cross-sectional view of a portion of the ring of **FIG. 1** and a portion of an alternative apparatus for installing it, at an early stage of installation of the ring around an incision in the sidewall of a blood vessel.

[0032] **FIG. 8** is a side cross-sectional view of a portion of the ring of **FIG. 1** and a portion of the **FIG. 7** installation apparatus, at an intermediate stage of installation of the ring around an incision in the sidewall of a blood vessel.

[0033] **FIG. 9** is a side cross-sectional view of a portion of the ring of **FIG. 1** and a portion of the **FIG. 7** installation apparatus, at a late stage of installation of the ring around an incision in the sidewall of a blood vessel.

[0034] **FIG. 10** is a perspective view of an embodiment of the inventive anastomosis ring, with its tines **(61)** in their initial configuration.

[0035] **FIG. 11** is a side cross-sectional view of a portion of ring **60** of **FIG. 10**, and of a portion (shown in phantom view) of another ring (identified by reference numeral **260**) which is a variation on ring **60**.

[0036] **FIG. 12** is a side cross-sectional view of portions of rings **60** and **260** of **FIG. 11**, after the tines thereof have been curled and formed in accordance with the invention.

[0037] **FIG. 13** is a perspective view of the ring of **FIG. 10**, with each of its tines **61** in its final configuration.

[0038] **FIG. 14** is a side cross-sectional view of a portion of ring **60** (with one tine **61** in the **FIG. 13** configuration) installed in tissue of a first vessel at the edge of an incision, and a second vessel (shown in phantom view) aligned with the first vessel.

[0039] **FIG. 15** is a perspective view of a portion of a variation on ring **60** of **FIG. 10**, with one of its tines **(61')** in its initial configuration.

[0040] **FIG. 16** is a side cross-sectional view of a portion of an embodiment **(80)** of the inventive ring and a portion of a tool **(79)** for installing this ring, in the configuration in which they would be at an early stage (to be referred to as a "first" stage) of installing the ring around an opening of an organ.

[0041] **FIG. 17** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a second stage of installing the ring around an opening of an organ.

[0042] **FIG. 18** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a third stage of installing the ring around an opening of an organ.

[0043] **FIG. 19** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a fourth stage of installing the ring around an opening of an organ.

[0044] **FIG. 20** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a fifth stage of installing the ring around an opening of an organ.

[0045] **FIG. 21** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a sixth stage of installing the ring around an opening of an organ.

[0046] **FIG. 22** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a seventh stage of installing the ring around an opening of an organ.

[0047] **FIG. 23** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at an eighth stage of installing the ring around an opening of an organ.

[0048] **FIG. 24** is a side cross-sectional view of ring **80** and tool **79** of **FIG. 16**, in the configuration in which they would be at a ninth stage of installing the ring around an opening of an organ.

[0049] **FIG. 25** is a simplified perspective view of the distal end of tool **79** (of **FIG. 16**), without sleeve **75**, and with ring **80** mounted thereon.

[0050] **FIG. 25A** is a perspective view of ring **80** around a fluted implementation of anvil **70**.

[0051] **FIG. 26** is side cross-sectional view of a portion of ring **80** of (of **FIGS. 16-25**) and a portion of another embodiment of the inventive tool **(90)** for installing this ring around an opening of an organ.

[0052] **FIG. 27** is a detail view of a portion of the apparatus shown in **FIG. 26**.

[0053] **FIG. 28** is a side cross-sectional view of a portion of ring **80** and a portion of tool **90**, which have been installed (using tool **90**) around an incision in a blood vessel.

[0054] **FIG. 29** is a perspective view of portions of two aligned anastomosis rings (rings **100** and **110**) having tab fasteners for fastening the rings together.

[0055] **FIG. 30** is a perspective view of a portion of a variation on anastomosis ring **100** (of **FIG. 29**) having a tab fastener which is a variation on fastener **101** of **FIG. 29**.

[0056] **FIG. 31** is a perspective view of portions of two aligned anastomosis rings (rings **130** and **110**) having tab fasteners, one of which (tab **131**) is a variation on fastener **101** of **FIG. 29**.

[0057] **FIG. 32** is a perspective view of portions of two aligned anastomosis rings (rings **140** and **150**) having a different type of tab fasteners for fastening the rings together, with the fasteners in an open (unlocked) configuration.

[0058] **FIG. 33** is a perspective view of the elements shown in **FIG. 32**, after these elements have been moved relative to each other into a closed (locked) configuration to fasten the rings together.

[0059] **FIG. 34** is a side cross-sectional view of portions of two aligned anastomosis rings (rings **160** and **180**) having spring fasteners for fastening the rings together.

[0060] **FIG. 35** is a perspective view of portions of the aligned anastomosis rings **160** and **180** shown in **FIG. 34**.

[0061] **FIG. 36** is a perspective view of portions of two aligned anastomosis rings (rings **160** and **170**) having spring fasteners of another type for fastening the rings together.

[0062] **FIG. 37** is a perspective view of a portion of a variation on ring **170** of **FIG. 36**.

[0063] **FIG. 38** is a perspective view of portions of two aligned anastomosis rings (rings **190** and **200**) having spring fasteners of another type for fastening the rings together.

[0064] **FIG. 39** is a perspective view of portions of two aligned anastomosis rings (rings **190** and **210**) having tab fasteners for fastening the rings together, with the fasteners in an unlocked position.

[0065] **FIG. 40** is a perspective view of portions of aligned rings **190** and **210** of **FIG. 39**, with the tab fasteners in a locked position.

[0066] **FIG. 41** is a side cross-sectional view of a portion of an embodiment (**220**) of the inventive ring and a portion of a tool (**230**) for installing this ring, in the configuration in which they would be at an early stage (to be. referred to as a "first" stage) of installing the ring around an opening of an organ.

[0067] **FIG. 42** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at a second stage of installing the ring around an opening of an organ.

[0068] **FIG. 43** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at a third stage of installing the ring around an opening of an organ.

[0069] **FIG. 44** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at a fourth stage of installing the ring around an opening of an organ.

[0070] **FIG. 45** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at a fifth stage of installing the ring around an opening of an organ.

[0071] **FIG. 46** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at a sixth stage of installing the ring around an opening of an organ.

[0072] **FIG. 47** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at a seventh stage of installing the ring around an opening of an organ.

[0073] **FIG. 48** is a side cross-sectional view of ring **220** and tool **230** of **FIG. 41**, in the configuration in which they would be at an eighth stage of installing the ring around an opening of an organ.

[0074] **FIG. 49** is a side cross-sectional view of a portion of an embodiment (**320**) of the inventive ring and a portion of an embodiment of the inventive tool (**330**) for installing the ring, in the configuration in which they would be at an early stage (to be referred to as a "first" stage) of installing the ring around an opening of an organ.

[0075] **FIG. 50** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a second stage of installing the ring around an opening of an organ.

[0076] **FIG. 51** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a third stage of installing the ring around an opening of an organ.

[0077] **FIG. 52** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a fourth stage of installing the ring around an opening of an organ.

[0078] **FIG. 53** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a fifth stage of installing the ring around an opening of an organ.

[0079] **FIG. 54** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a sixth stage of installing the ring around an opening of an organ.

[0080] **FIG. 55** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a seventh stage of installing the ring around an opening of an organ.

[0081] **FIG. 56** is a side cross-sectional view of ring **320** and tool **330** of FIG. **49**, in the configuration in which they would be at an eighth stage of installing the ring around an opening of an organ.

[0082] **FIG. 57** is a side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at an ninth stage of installing the ring around an opening of an organ.

[0083] **FIG. 58** is a perspective view of two of the inventive anastomosis rings (**380** and **400**), each installed in an incision in a different blood vessel, and a pair of forceps **420** gripping one of the blood vessels.

[0084] **FIG. 59** is a cross-sectional view of the apparatus and tissue of **FIG. 58**, after ring **400** has been lowered onto docking tabs **383** of ring **380**.

[0085] **FIG. 60** is a cross-sectional view of the apparatus and tissue of **FIG. 59** after rings **380** and **400** have been aligned, while docking tabs **383** are being folded into a locking configuration

[0086] **FIG. 61** is a perspective view of ring **380** of **FIG. 58**, in its pre-installation configuration.

[0087] **FIG. 62** is a partial, side cross-sectional view of ring **320** and tool **330** of **FIG. 49**, in the configuration in which they would be at a fifth stage of installing the ring around an opening of an organ, in a modified procedure relative to that described with regard to **FIGS. 49-57**.

[0088] **FIG. 63** is a partial, side cross-sectional view of ring **320** and tool **330** of **FIG. 62** in the configuration in which they would be after final bending and rotation by the modified procedure.

[0089] **FIG. 64A** is a perspective view of an anastomosis device after partial forming.

[0090] FIG. 64B is a perspective view of the device of FIG. 64A after reinforcing to increase bending strength in the base area of the tines.

[0091] FIG. 65 is a perspective view of a reinforced device formed as an integral unit, which does include overlying reinforcement areas and thus does not require joining of overlying reinforced areas.

[0092] FIGS. 66A and 66B are perspective views of a mating pair of devices having been reinforced according to the techniques described with regard to FIGS. 64A, 64B and 65.

[0093] FIG. 67 is a side cross-sectional view of a portion of a reinforced device and a portion of a delivery tool modified for delivery of a reinforced device according to the present invention, in a configuration in which they would be at an early stage (a "first" stage) of installing the device around an opening of an organ.

[0094] FIG. 68 is a side cross-sectional view similar to FIG. 67, but in a second stage configuration.

[0095] FIG. 69 is a side cross-sectional view similar to FIG. 68, but in a third stage configuration.

[0096] FIG. 70 is a side cross-sectional view similar to FIG. 69, but in a fourth stage configuration of the installation process.

[0097] FIG. 71 is a side cross-sectional similar to FIG. 70, but in a fifth stage configuration of the installation.

DETAILED DESCRIPTION OF THE INVENTION

[0098] Definitions

[0099] The term "grab" is used herein in a broad sense to denote any operation of grabbing, gripping, grasping, or otherwise capturing the relevant tissue (such that the captured tissue can be moved by moving the thing which captures the tissue), and to denote either "grab and pierce" or "grab without piercing."

[0100] The expression "malleable" element is used herein to denote an element that, when deformed from a first shape into a second shape, will not relax back into the first shape from the second. A flexible element can be elastic or malleable (the term "flexible" is used in a broad sense encompassing both the narrower terms "malleable" and "elastic").

[0101] FIG. 1 is a sectional view of an example of an anastomosis device 10 having been compressed and slid into a delivery tube 20 for purposes of performing a sutureless anastomosis. Delivery tube 20 may be a cannula, catheter or any other tube which is generally recognized as acceptable for invasive use in a surgical procedure in a patient, and which is properly dimensioned to reduce the diameter of the ends of device 10 to a biased state, such that when removing device 10 from tube 20, device 10 will return to its original unloaded state, as a result of the biasing force. The walls of tube 20 should be as thin as possible while still proving sufficient hoop strength to retain device in the constrained or compressed state.

[0102] After loading device 10 into tube 20 as shown in FIG. 1, a graft 30 is next inserted through tube 20 and through an interior passageway provided through device 10, as shown in FIG. 2. Thus, device 10 is also substantially tubular in its conformation when loaded in tube 20. Graft 30 may be a vessel of the patient upon which the anastomosis is to be performed, a synthetic graft, an allograft, a xenograft, or a combination of living tissue and synthetic material, for example. In the case where graft 30 is a tissue vessel, the loading configuration shown in FIG. 2 is advantageous because the intima or interior walls of the graft 30 do not come into contact with device 10.

[0103] which is an embodiment of the inventive ring for use in performing anastomosis without hand sutures. Ring 10 is integrally formed from metal, and includes a central ring portion 11, and tines 12 and docking features 15 and 16 which extend out from ring portion 11. Preferably, each of docking features 15 and 16 is implemented so as to add stiffness to ring portion 11, and to define at least one snap feature (or other fastener) for using in fastening together ring 10 (after it has been installed in a vessel or other organ) with another anastomosis ring. Tines 12 are malleable. Ring portion 11 can be implemented to be flexible but is preferably rigid. Ring portion 11 is substantially flat in a plane perpendicular to the central axis of ring 10.

[0104] Each tine 12 is manufactured to be generally flat, and is then bent so as to define a bent edge 13 between ring portion 11 and a distal tine portion which terminates at a sharp distal end. In the initial configuration, the distal tine portions are oriented at least substantially perpendicularly to the plane of ring portion 11. Each tine 12 is preferably tapered, with its width decreasing from its relatively wide proximal end (at portion 11) to its sharp distal end. Each tine 12 also has a hinge or weak section (sometimes referred to herein as a "weak portion") at a location that is separated from (but typically near to) edge 13. Such weak portions are not labeled in FIG. 1. The number of tines is variable and depends on the size of the ring and the size of the tines. The number should be sufficient to ensure that all of the tissue surrounding the orifice is grasped and everted.

[0105] The method for installing ring 10 (and variations thereon) in an opening (e.g., incision) in a vessel or other organ will be described below in detail, but is generally as follows. An anvil is inserted through the opening into the organ, and ring 10 is positioned with the sharp tips of tines 12 contacting the tissue surrounding the opening. An installation tool is then operated to drive tines 12 against the anvil, causing tines 12 to penetrate through the tissue into contact with the anvil and then begin to curl (or to begin to curl against the anvil and then penetrate the tissue as they continue to curl) so as to engage (and grab) the tissue and optionally also to begin to evert the tissue that surrounds the opening. Then, the anvil is retracted through ring portion 1*k* thereby causing each tine 12 to fold or buckle about its hinge (or weak portion) and thus move into a folded (or buckled) and curled configuration. The tines grab the tissue surrounding the opening and thus evert the incised tissue edges as they fold or buckle in response to action of the anvil. In some cases, additional shaping forces are exerted on the tines to move them from their folded (or buckled) and curled configuration into a final configuration. Retraction of the anvil does not significantly deform ring portion 11 although it does deform tines 12 relative to ring portion 11. When tines 12 have been deformed into their final configuration and the anvil has retracted out of engagement with ring 10, ring 10 is fully installed at the opening of the organ with ring portion **111** surrounding the opening (so that fluid can flow through the opening), ring **10** holding tissue around the opening so as to expose its intima, and docking features **15** and **16** exposed so that features **15** and **16** can be aligned with and fastened to docking features of another ring that has been installed at an incision in (or opening of) another organ to produce an anastomosis that joins the two organs.

[0106] **FIG. 2** is a perspective view of an anastomosis ring **20**, which is another embodiment of the inventive ring for use in performing anastomosis without hand sutures. Ring **20** is integrally formed from metal, and. includes a central ring portion **21**, and tines **22** and docking features **25** and **26** which extend out from ring portion **21**, Ring **20** differs from above-described ring **10** primarily in that its central ring portion **21** is tubular (in the sense that it surrounds a central axis, has substantially greater length (parallel to the central axis) than width (perpendicular to the central axis), and defines a circular or oblong cross-section in a plane perpendicular to the central axis) rather than flat, and in that tines **22** have slightly different shape than tines **12**. Tines **22** are malleable. Ring portion **21** can be implemented to be flexible but is preferably rigid.

[0107] Docking features **25** and **26** can be identical to above-described docking features **15** and **16** of **FIG. 1**. As shown in **FIG. 3**, features **25** and **26** are bent upward (at an obtuse angle) relative to ring portion **21**. Alternatively, the docking features can be bent downward (at an acute angle) relative to ring portion **21**, as are alternative docking features **25**A and **26**A shown in phantom view in **FIG. 3**.

[0108] When two rings **20** (or **10**) have been installed, each in an opening of a different organ, an anastomosis to join the organs is accomplished as follows:

> **[0109]** the two rings are aligned with each other to cause one ring (and the tissue held thereby) to meet the other ring (and the tissue held thereby) such that there is a plane (denoted herein as a "sealing plane") between the two rings; and the aligned rings are then fastened together.

[0110] With reference to **FIG. 2**, each tine **22** of ring **20** is generally flat. Each tine **22** has a relatively wide proximal portion between ring portion **11** and shoulder **24**, and a narrower distal portion beyond shoulder **24**. Each tine is bent at an edge **23** to define a distal portion (distally beyond edge **23**) and a proximal portion (between edge **23** and ring portion **11**). Each proximal portion defines a shoulder **24**. The width of the distal portion decreases in tapered fashion from edge **23** to a sharp distal end. The distal portions of tines **22** (distal to bent edges **23**) are oriented at least substantially perpendicularly to the plane of ring portion **21**. During installation, each tine **22** curls tightly from its tip to its edge **23** in response to being advanced against an anvil of an installation tool. Later during installation, each tine **22** tends to fold or buckle at shoulder **24** (rather than at other locations along the tine) in response to retraction of the anvil upward (when viewed as in **FIG. 2**) through ring portion **21**, so that shoulder **24** defines a hinge (or weak portion) of tine **22**. In some implementations, each tine **22** also has an additional hinge or weak portion (not labeled) at a location which is separated from (but typically near to) shoulder **24** and separated from edge **23**.

[0111] More generally, in embodiments of the inventive ring in which each tine (in its pre-installation configuration) has a proximal portion that extends radially inward toward the ring's central axis and a distal portion orientated at least substantially parallel to the ring's central axis (e.g., the embodiments of **FIGS. 1 and 2**), the distal portion is preferably tapered to its sharp tip to guarantee a tight curl when curling against the anvil of the installation tool during installation. The proximal portion need not be tapered (although the proximal portion of each tine of ring **10** is shown to be tapered in **FIG. 1**). In typical implementations, the proximal portion of each tine is not tapered (as in **FIG. 1**) and instead defines a shoulder (e.g., shoulder **24** of each tine of **FIG. 2**) or other hinge or weak portion (e.g., a hole), so that when the anvil of the installation tool is retracted (so as to fold or buckle the tines radially outward and thereby evert tissue being grabbed by the tines), each tine will preferentially fold or buckle at the shoulder (or other hinge or weak portion) of its proximal portion in response to the force exerted by the retracting anvil.

[0112] The method for installing ring **20** (and variations thereon) in an opening (e.g., an incision) in a vessel or other organ will be described below in detail, and is basically the same as the method for installing ring **10**. An anvil is inserted through the opening into the organ, and ring **20** is positioned with the sharp tips of tines **22** engaging the tissue surrounding the opening. An installation tool is then operated to drive tines **22** against the anvil, causing tines **22** to penetrate through the tissue into contact with the anvil and then begin to curl (or to begin to curl against the anvil and then penetrate the tissue, as they continue to curl) so as to engage (and grab) the tissue and optionally also to begin to evert the tissue that surrounds the opening. Then, the anvil is retracted through ring portion **21**, thereby causing each tine **22** to fold or buckle about one or more hinges (or weak portions) thereof and move into a folded (or buckled) and curled configuration. The tines grab the tissue surrounding the opening and thus evert the incised tissue edges as they fold or buckle in response to action of the anvil. In some cases, additional shaping forces are exerted on the tines to move them from their folded (or buckled) and curled configuration into a final configuration. Retraction of the anvil does not significantly deform ring portion **21** although it does deform tines **22** relative to ring portion **21**. When tines **22** have been deformed into their final configuration and the anvil has retracted out of engagement with ring **20**, ring **20** is fully installed at the opening of the organ with ring portion **21** surrounding the opening (so that fluid can flow through the opening), ring **20** holding tissue around the opening so as to expose its intima, and docking features **25** and **26** exposed.

[0113] The tines of each embodiment of the inventive ring (including ring **10** or **20**) are preferably wide and flat so that each has a relatively wide surface oriented parallel to the edge of the opening at which the ring is to be installed. This allows the tines efficiently to exert everting force on the tissue around the opening without tearing or otherwise causing trauma to the tissue, while at the same time the tines can be easily formed in response to exertion of moderate forces thereon (e.g., forces which fold or buckle the tines about their hinges or weak portions).

[0114] Ring **10** can be installed using an installation tool comprising anvil **30** and independently translatable sleeves **31** and **32** (as shown in **FIGS. 4, 5, and 6**) at the site of an incision in the side wall of a blood vessel having exterior surface **40** and interior surface (inside lining or "intima") **41**. Only the right half of the distal portion of each of elements **30, 31**, and **32**, and the right edge of the incision (whose axis of symmetry extends perpendicular to the plane of **FIG. 4**) are shown in **FIGS. 4, 5**, and **6**. **FIG. 4** shows ring **10** and the installation tool at an early stage of the installation process, **FIG. 5** shows them at a later stage, and **FIG. 6** shows them at a still later stage. When anvil **30** has retracted (upward) into the position shown in **FIG. 6**, ring **10** has been installed with ring portion **11** extending around the incision, tines **12** grabbing the tissue around the incision, and tines **12** having been deformed so as to evert the incised edges of the tissue to expose the intima **41** of the blood vessel as shown in **FIG. 6**.

[0115] More specifically, as shown in **FIG. 4**, anvil **30** is inserted into the incision. Sleeves **31** and **32** are then advanced distally to drive tines **12** of ring **10** into the tissue, so that the tines penetrate the tissue and engage the tine-forming surface **30**A of anvil **30**, and so that the tines begin to curl radially inward (toward the central axis of anvil **30**) as they advance against anvil surface **30**A. Then, as shown in **FIG. 5**, while sleeves **31** and **32** press ring **10**'s flat ring portion **11** in the distal direction against the vessel's exterior surface **40**, anvil **30** is retracted in the proximal direction (toward the top of **FIG. 5**) to cause surface **30**A to begin to bend the distal portion of each tine **12** toward the top of **FIG. 5** relative to the rest of ring **10**. Since the tines **12** extend through the tissue, the tines grab the tissue as they bend, and the bending of the tines causes the incised tissue edges to begin to evert. Then, as shown in **FIG. 6**, sleeve **31** is retracted in the proximal direction while anvil **30** continues to retract in the proximal direction. In response to the force exerted on tines **12** by retracting anvil **30** (when sleeve **31** has retracted proximally), each tine **12** folds or buckles at its hinge (or weak portion) radially outward (away from the central axis of anvil **30**) as it continues to grab the tissue, thereby completing the eversion of the incised tissue edges as shown in **FIG. 6**. After such folding or buckling of tines **12**, sleeve **32** is withdrawn or retracted in the proximal direction, leaving ring **10** installed at the incision with tines **12** holding the incised tissue edges in the desired everted state (for joining to tissue of another vessel or other organ). Optionally, a final step is performed in which an another element (not shown in **FIGS. 4-6**) of the installation tool is advanced into engagement with ring **10** (or the tissue that has been grabbed thereby), or in which anvil **30** is again advanced into the incision and sleeves **31** and **32** are then advanced against anvil **30**, to further bend the tines **12** relative to the rest of ring **10** and thereby further evert the incised tissue edges.

[0116] As an alternative to the procedure described with reference to **FIGS. 4-6**, ring **10** is installed using a slightly different installation tool that comprises anvil **30** and independently translatable sleeves **51** and **52** (as shown in **FIGS. 7, 8**, and **9**) at the site of an incision in the side wall of a blood vessel having exterior surface **40** and interior surface ("intima") **41**. Only the right half of the distal portion of each of elements **30, 51**, and **52**, and the right edge of the incision (whose axis of symmetry extends perpendicular to the plane of **FIG. 7**) are shown in **FIGS. 7, 8**, and **9**. **FIG. 7** shows ring **10** and the installation tool at an early stage of the installation process, **FIG. 8** shows them at a later stage, and **FIG. 9** shows them at a still later stage. When anvil **30** has retracted (upward) into the position shown in **FIG. 9**, ring **10** has been installed with ring portion **11** extending around the incision, tines **12** grabbing the tissue around the incision, and tines **12** having been deformed so as to evert the incised edges of the tissue to expose the intima **41** of the blood vessel as shown in **FIG. 9**.

[0117] More specifically, as shown in **FIG. 7**, anvil **30** is inserted into the incision. Then, sleeves **51** and **52** are advanced distally (relative to anvil **30**) to drive tines **12** of ring **10** between anvil **30** and the incised tissue edges until the tips of tines **12** engage the tine-forming surface **30**A of anvil **30**, and begin to curl radially outward (away from the central axis of anvil **30**) as they advance against anvil surface **30**A. Sleeves **51** and **52** continue to advance until they reach the position shown in **FIG. 8**, in which they have pressed ring **10**'s flat ring portion **11** in the distal direction against the vessel's exterior surface **40**, and caused the distal portion of each tine **12** to bend (against stationary surface **30**A of anvil **30**) relative to the rest of ring **10** until the tip of each tine has penetrated (and grabbed) the tissue around the incision. Then, as shown in **FIG. 9**, sleeve **51** and anvil **30** are retracted (in the proximal direction) while sleeve **52** remains extended in engagement with ring **10**. In response to the force exerted on tines **12** (and the incised tissue edges that have been grabbed by tines **12**) by retracting anvil **30**, each tine **12** folds or buckles at its hinge (or weak portion) radially outward (away from the central axis of anvil **30**) while continuing to grab the tissue, thereby everting the incised tissue edges as shown in **FIG. 9**. After such folding or buckling of tines **12**, sleeve **52** is retracted in the proximal direction or otherwise withdrawn, leaving ring **10** installed at the incision with tines **12** holding the incised tissue edges in the desired everted state (so that the everted tissue can be joined to tissue of another vessel or other organ). Optionally, a final step is performed in which an another element (not shown in **FIGS. 7-9**) of the installation tool is advanced into engagement with ring **10** (or the tissue that has been grabbed thereby), or in which anvil **30** is again advanced into the incision and sleeves **51** and **52** are then advanced against anvil **30**, to further bend the tines **12** relative to the rest of ring **10** and thereby further evert the incised tissue edges.

[0118] **FIGS. 10 and 13** are perspective views of anastomosis ring **60**, which is an embodiment of the inventive anastomosis ring. Ring **60** includes ten malleable tines **61** which extend out from cylindrical (tubular) ring portion **65**. **FIG. 10** shows tines **61** in their initial configuration (the configuration in which they would be when ring **60** is loaded onto an installation tool prior to installation at an incision in an organ). **FIG. 13** shows each of tines **61** in its final configuration (the configuration in which it would be following installation at an incision in an organ).

[0119] Each tine **61** of ring **60** has a flat cross-section, with two opposed faces and relatively small (narrow) edge surfaces between the faces. Each tine **61** has a relatively wide proximal end **64** (from which it extends out from ring portion **65**) and tapers to a sharp distal end **62**. Each tine **61** is preferably made from flat metal, and has a weak portion **63** which is defined by a hole formed (e.g., stamped or etched) therethrough (from one of the opposed faces to .the other) at a location between ends **62** and **64**. Prior to installation, each tine **61** is pre-formed into an S-shape as shown in **FIG. 10**, so that the tines' distal portions are oriented in a distal direction (so that the tines' distal portions are generally parallel to each other and to the axis of symmetry of ring **60**). During the installation process, a distal portion of each tine is curled radially outward (away from ring **60**'s axis of symmetry) so that it grasps tissue, and then the curled tines are folded (or buckled) radially outward about their weak portions to evert the tissue being grasped thereby, until each tine **61** reaches the final configuration shown in **FIG. 13**. As shown in **FIGS. 13 and 14**, when tines **61** are in their final configuration, the folded portion **67** of each tine that is farthest from the ring's tubular portion **65** is at (or very near to) the tine's weak portion **63**. Assuming that the central axis of tubular portion **65** is oriented vertically, the folded portion **67** is preferably slightly raised in the sense that it is slightly above the tine's lowest portion (**66**). When ring **60** has been installed around an incision in a vessel **68** (with tines **61** in the configuration shown in **FIG. 14** so as to evert the incised tissue edges), and vessel **68** is to be joined (at an anastomosis site) to a second vessel **69** that has been prepared for anastomosis by installation of an anastomosis ring (similar or identical to ring **60**) around an incision in the second vessel, the folded, raised portions **67** of tines **61** (of ring **60**) desirably shape the everted, incised tissue edges of vessel **68**. Specifically, the fact that portions **67** are raised (relative to portions **66**) causes ring **60** to present the intima of vessel **68** to the intima of vessel **69** in an orientation that promotes healing together of, and formation of a fluid tight seal between, the joined tissue of vessels **68** and **69**.

[**0120**] A variation on ring **60** will be described with reference to **FIG. 15**. This ring, identified by reference numeral **60'**, has a tubular central ring portion **65'** and ten malleable tines **61'** which extend out from the tubular ring portion. **FIG. 15** shows one of tines **61'** in its initial configuration (the configuration in which it would be when ring **60'** is loaded onto an installation tool prior to installation at an incision in an organ). The other tines **61'** of ring **60**,' are omitted from **FIG. 15** for clarity. Each tine **61'** has a flat cross-section, with two opposed faces and relatively small (narrow) edge surfaces between the faces. Each tine **61'** has a pair of notches **63'** in the edge surfaces at a first distance from ring portion **65'**. These notches define a weak portion of tine **61'** at said first distance from ring portion **65'**.

[**0121**] Ring **260** (shown in phantom view in **FIGS. 11 and 12**) differs from ring **60** (of **FIGS. 10, 11**, and **12**) in the following respects. In ring **60**'s pre-installation configuration, each of its tines **61** (which extend out from ring **60**'s cylindrical portion **65**) has a distal portion **61**A that is oriented vertically (when ring **60** is viewed as in **FIG. 11**) and terminates at a sharp tip **62**, a straight proximal portion **61**B oriented at a forty-five degree angle relative to distal portion **61**A, and a horizontally oriented straight portion **61**C between portions **61**A and **61**B. Ring **260** (shown in phantom view in **FIGS. 11 and 12**) has a central cylindrical portion which is identical to cylindrical portion **65** of ring **60**. However, each tine **261** of ring **260** in its pre-installation configuration extends out from ring **260**'s cylindrical portion with a distal portion that is oriented vertically (when ring **260** is viewed as in **FIG. 11**), a curved proximal portion R, and a horizontally oriented third portion between the distal portion and the curved proximal portion. An important difference between the curved tines **261** of ring **260** and the piecewise linear tines **61** of ring **60** is that, in the ring installation step to be described with reference to **FIG. 22**, tine **261** will bend and rotate farther than tine **61** due to the cam action of surface **76** of sleeve **75** on the smoothly curved tine **261**. This additional bending and rotation of tines **261** (to move them from a configuration corresponding to that shown in **FIG. 21** to a configuration corresponding to that shown in **FIG. 22**) allows sleeves **72, 73**, and **74** to more easily form the final bend in each tine **261** as sleeves **72, 73**, and **74** advance to press tines **261** against surface **76** (during the installation step to be described with reference to **FIG. 24**).

[**0122**] Next, with reference to **FIGS. 16-25**, we describe a tool **79** for installing ring **80** (partially shown in each of **FIGS. 16-25**), in tissue around an opening in an organ (e.g., an incision in a blood vessel). With respect to all embodiments of tools for installing the inventive rings disclosed herein, it is contemplated that the multiple movements of the various sleeves can be automated and synchronized to some degree such that the installation process requires a minimal number of operator manipulations of the installation tool. Ring **80** can be identical to ring **60** of **FIG. 14**. In ring **80**'s pre-installation configuration, each of its tines **80**A (which extend out from ring **80**'s cylindrical portion **85**) has a distal portion **81** that is oriented vertically (when ring **80** is viewed as in **FIG. 17**) and terminates at a sharp tip **82**, a proximal portion **83** oriented at a forty-five degree angle relative to distal portion **81**, and a horizontally oriented third portion **84** between portions **81** and **83**.

[**0123**] Each tine **80**A of ring **80** will preferentially fold at the junction between angled portion **83** and portion **84** (e.g., in response to forces exerted on ring **80** by retracting anvil **70** during the installation step shown in **FIG. 20**, and forces exerted on ring **80** by anvil **70** and sleeves **74** and **75** during the installation step shown in **FIG. 24**). Each tine **80**A preferably also has a weak portion (e.g., a hinge) at a location near to (but spaced from) the junction between portions **83** and **84**, so that each tine **80**A preferentially bends at both this junction and the weak portion during the steps described with reference to **FIGS. 20 and 24**. **FIG. 25** is a simplified perspective view of the distal end of tool **79** with ring **80** (in its initial configuration) mounted thereon, showing some of tines **80**A of ring **80**. Each tine **80**A has a hole **86** extending through it (at a location along tine portion **84**), each hole **86** defining a weak portion of the tine.

[**0124**] **FIG. 25A** is a perspective view of ring **80** around a fluted implementation of anvil **70**. Anvil **70** of **FIG. 25A** has grooves along its sides, and concave, tine-forming portions **70**S of its surface **70**A. Each concave portion **70**B is dimensioned and positioned to receive and form one of the tines of ring **80**.

[**0125**] With reference to **FIGS. 16-24** we next describe operation of installation tool **79** which comprises anvil **70** and independently translatable sleeves **71, 72, 73, 74**, and **75**, during installation of an anastomosis ring **80** in an organ (the organ is not shown). Only the right half of the distal portion of each of elements **71, 72, 73, 74**, and **75**, the distal portion of anvil **70**, and the right half of ring **80**, are shown in **FIGS. 16-24**. Tool **79** also comprises control assembly **79**A (shown only in **FIG. 16**) which is coupled to anvil **70** and sleeve elements **71-75** and configured to independently advance and retract appropriate ones of elements **70-75** at appropriate times. It is contemplated that some implementations of assembly **79**A are manually operated in the sense that a user must manually manipulate at least one element of **79**A to accomplish each advancing or retracting movement of each desired one of elements **70-75**, and that other implementations of assembly **79**A are automatically operated in the sense that they include a trigger, and hardware for implementing a timed sequence of advancing and retracting movements of elements **70-75** in response to a single actuation of the trigger. Other embodiments of the inventive installation tool (including those described with reference to **FIGS. 4-9** and **41-57**) have control assemblies coupled to the tool's anvil and sleeve elements and configured to advance and retract appropriate ones of the anvil and sleeve elements at appropriate times.

[**0126**] Initially, ring **80** is loaded onto tool **79** with tubular portion **85** in circular slot **74**A of sleeve **74** (shown in **FIGS. 16 and 17**), and tines **80**A of ring **80** held between sleeves **71**, **72**, **73**, **74**, and end portion **76** of sleeve **75** as shown in **FIG. 16**. Then, anvil **70** is inserted into the incision (or other opening) in the organ, and sleeves **71**, **72**, **73**, **74**, and **75** are then advanced (distally) together as a unit to drive tines **80**A between anvil **70** and the tissue edges until the tips of tines **80**A engage the tine-forming surface **70**A of anvil **70**, and begin to curl radially outward (away from the central axis of anvil **70**) as they advance against anvil surface **70**A. Sleeves **71**, **72**, **73**, **74**, and **75** continue to advance until they reach the position shown in **FIG. 17**, in which they have pressed portion **84** of each tine **80**A against the organ's exterior surface and caused distal portion **81** of each tine **80**A to bend (against stationary surface **70**A of anvil **70**) relative to the rest of ring **80** until the tip **82** of each tine has penetrated (and grabbed) the tissue around the opening. The distal end of sleeve **73** is angled to match the slope of each of tine portions **83** of ring **80** in its **FIG. 16** configuration. **FIG. 16** shows one tine **80**A whose tip has been advanced into engagement with surface **70**A (but which has not yet begun to curl), and **FIG. 17** shows the same tine after it has been advanced further (by sleeves **71**, **72**, **73**, **74**, and **75**) and begun to curl radially outward.

[**0127**] Then, while sleeves **71-75** remain stationary, anvil **70** is retracted (toward the top of **FIG. 18**) to further curl the curled distal portion **81** of each tine **80**A relative to the rest of ring **80** into the configuration shown in **FIG. 18**, thereby causing portion **81** of each tine to further penetrate and more securely grab the tissue around the opening.

[**0128**] Then, as shown in **FIG. 19**, sleeves **71** and **72** are retracted in the proximal direction (toward the top of **FIG. 19**) while sleeves **73**, **74**, and **75** and anvil **70** remain stationary in engagement with ring **80**.

[**0129**] Then, as shown in **FIG. 20**, anvil **70** is retracted (in the proximal direction) relative to sleeves **73**, **74**, and **75**. In response to the force exerted by anvil **70** on tines **80**A (and the tissue edges that have been grabbed by tines **80**A), each tine **80**A folds or buckles at both its weak portion and at the junction (identified by reference numeral **83**A in **FIGS. 17 and 25**) between portions **83** and **84**, so that its curled distal portion **81** moves radially outward (away from the central axis of anvil **70**) while it continues to grab the tissue, thereby everting the tissue edges. As noted, each tine **80**A preferably has a weak portion (e.g., a hinge) at a location spaced from the junction (**83**A) between portions **83** and **84**. In one implementation, this weak portion is determined by a hole **86** (shown in and described above with reference to **FIG. 25**) in each tine. Each hole **86** is preferably located along the tine such that, when tines **80**A are in their final configuration (shown in **FIG. 24**), the portion (**87**) of each tine that is farthest (radially) from the ring's tubular portion **85** does not coincide with the junction **83**A, and such portion **87** coincides with (or is very near to) hole **86**. In this implementation, hole **86** extends through portion **84** of each tine **80**A at a location near to, but spaced from junction **83** A between portions **83** and **84**. Such separation between hole **86** and junction **83**A (and greater distance between portion **85** and hole **86** than between portion **85** and junction **83**A) reduces trauma to tissue in the following sense during installation of ring **80** in the tissue. When ring **80** has been installed in the tissue in its final configuration (shown in **FIG. 24**), the installation procedure has not stretched the tissue along portion **83** of each tine (which is not shown in **FIG. 24**, but which would be between portion **83** and sleeve portion **76**). In contrast, the tissue in immediate contact with tip **82** of each tine has undergone significant stretching. The degree of stretching which the tissue has undergone is roughly proportional to the tissue's distance (along each tine from tip **82** to portion **87**) from tip **82**, with tissue nearer to portion **87** (along the tine's axis) having undergone less stretching than tissue farther from portion **87** along the tine's axis. Thus, since the location of the tine's weak portion effectively moves portion **87** closer (along the tine's axis) to tip **82** than it would be if the weak portion were not present (or if the weak portion had coincided with junction **83**A), the weak portion effectively reduces the amount of stretching undergone by the tissue during ring installation.

[**0130**] Each tine **80**A preferentially bends at both junction **83**A and at the weak portion (the location of hole **86**) during the steps described with reference to **FIGS. 20 and 24**.

[**0131**] After the folding or buckling of tines **80**A described with reference to **FIG. 20**, sleeve **73** is retracted in the proximal direction (as shown in **FIG. 21**), leaving ring **80** (and the tissue gripped thereby) between anvil **70** and sleeves **71**, **72**, **74**, and **75**, with sleeve **74** in a retracted position relative to sleeve **75**.

[**0132**] Then, sleeve **74** is advanced distally relative to sleeve **75** (into the position shown in **FIG. 22**) to bend and rotate each tine **80**A (relative to the rest of ring **80**) from the configuration shown in **FIG. 21** to that shown in **FIG. 22** as a result of force exertion on ring **80** by stationary sleeve **75** and the distal end of advancing sleeve **74**. This bending and rotation further everts the tissue edges around the organ opening, causes the tines **80**A to penetrate farther into the tissue, and allows sleeves **72**, **73**, and **74** to more easily form a final bend in each tine **80**A (in the step to be described with reference to **FIG. 24**). When ring **80** has been formed into the configuration shown in **FIG. 22**, portion **85** is at least substantially perpendicular to portion **83** of each tine **80**A, and portions **83** and **85** are supported by sleeve **75**.

[**0133**] After ring **80** has been placed in the configuration shown in **FIG. 22**, sleeve **74** is retracted in the proximal direction relative to portion **76** of sleeve **75**, into the position shown in **FIG. 23**. Then, sleeves **72**, **73**, and **74** are advanced distally relative to portion **76** of sleeve **75** to press tines **80**A and portion **85** against portion **76**, thereby forming a final bend in each of tines **80**A relative to portion **85** and moving the ring **80** into the final, installed configuration shown in **FIG. 24**. Specifically, portions **81**, **82**, and **84** of each tine **80**A are bent radially outward relative to portion **83** and then pushed distally against portion **83** to put ring **80** in the final configuration. In this final configuration, ring **80** is installed at the opening in the organ with tines **80**A holding the tissue edges in the desired everted state (so that the everted tissue can be joined to tissue of another vessel or other organ).

[**0134**] After installation of ring **80**, sleeve **75** is (e.g., portions comprising the distal end of sleeve **75** are) spread or dilated (radially outward away from anvil **70**'s central axis of symmetry) to decouple tool **79** from the installed ring, and tool **79** is removed from the installed ring.

[**0135**] In tool **79** (described with reference to **FIGS. 16-24**), flat portion **84** of each tine **80**A conforms with the flat upper surface of portion **76** of sleeve **75** during the step described with reference to **FIG. 23**, so that sleeves **72**, **73**, and **74** can efficiently form the final bend in each tine **80**A as sleeves **72**, **73**, and **74** advance to press tines **80**A against surface **76** (during the step described with reference to **FIG. 24**). Variations on installation tool **79** (e.g., those used to install rings having curved tines, such as ring **60**) can include a sleeve that corresponds functionally to sleeve **75** but has a tine-receiving surface (corresponding to the upper, tine-receiving surface of portion **76**) that is not flat, but is instead curved to match the curvature of tines of rings to be installed by such tool.

[**0136**] In variations on the described embodiments of the inventive tined anastomosis ring, the weak point of each tine is determined other than by a hole through the tine. For example, the weak point can be determined by notches cut into the tine (to reduce the tine's width), a tine portion having reduced thickness, or perforations cut into the tine.

[**0137**] In variations on the described embodiments of the inventive tined ring, the ring portion (from which the tines, and optionally also docking features, protrude) is not malleable. For example, the ring portion can be rigid or elastic. The ring portion is preferably integrally formed from metal, but can alternatively have another structure. For example, the ring portion can be assembled from component parts (e.g., metal parts) which are connected together (e.g., by welding), or can be made (entirely or partially) of material other than metal but which has the required mechanical properties (e.g., flexibility and/or moldability).

[**0138**] Next, with reference to **FIGS. 26-28**, we describe installation tool **90** which is another embodiment of the inventive tool for installing ring **80** (or variations on this embodiment of the inventive tined ring) around an opening of an organ (e.g., an incision in a blood vessel). Installation tool **90** includes anvil **70** and independently translatable sleeves **71**, **72**, **73**, and **74** which are identical to the corresponding, identically numbered, elements of tool **79** described above with reference to **FIGS. 16-25**. Tool **90** also includes sleeve **95** and annular disk **96** (which together replace sleeve **75** of above-described tool **79**), and hardware (not shown) for advancing and retracting elements **70**, **71**, **72**, **73**, **74**, and **95** at desired times. The inner radius of annular disk **96** is equal to the inner radius of portion **76** of sleeve **75** of tool **79**, and the width of disk **96** (from its inner to outer radius) is such that the overall distance from the inner radius of disk **96** to the outer radius of the distal portion of sleeve **95** is equal to the overall distance from the inner radius of portion **76** of sleeve **75** to the outer radius of sleeve **75**'s distal portion.

[**0139**] Tool **90** can be used to install ring **80** at the site of an incision in the side wall of a blood vessel (shown in **FIG. 28** but not **FIG. 26**) having exterior surface **40** and interior surface (inside lining or "intima") **41**. **FIG. 26** is a cross-sectional view of the right half only of the distal portion of each of elements **71**, **72**, **73**, **74**, and **95**, and the right half of ring **80** and disk **96**. Disk **96** is oblong (with an open center) or annular.

[**0140**] **FIG. 26** shows ring **80** and tool **90** at an early stage of the installation process. To load ring **80** and disk **96** at tool **90**'s distal end, ring portion **85** is inserted into slot (or groove) **74**A of sleeve **74**, and disk **96** is inserted in groove **95**A in sleeve **95**'s inner sidewall. Each of slot **74**A and groove **95**A is circular or oblong (e.g., each is circular when the tubular central portion of ring **80** is circular and disk **96** is annular). Sleeve **95** (or the distal end of sleeve **95**) can comprise multiple portions which can be moved radially toward each other (to grip the disk **96**) or radially away from each other (to release the disk **96**). The portions comprising sleeve **95**'s distal end are spread or dilated radially outward (away from each other and away from the central axis of symmetry of anvil **70**) to allow insertion of disk **96** in (or removal of disk **96** from) groove **95**A, or contracted radially inward (toward the central axis of anvil **70**) so that disk **96** is gripped between sleeve **95** and tines **80**A of ring **80**. In alternative embodiments of the invention, sleeve **95** includes an element which releasably holds disk **96** in groove **95**A. In other alternative embodiments, disk **96** (or a variation thereon) is removably mounted to a sleeve (sleeve **95** or a variation thereon) by a joining feature other than a groove or notch in the sleeve.

[**0141**] When ring **80** and disk **96** have been loaded onto the distal end of tool **90**, tool **90** is operated to install ring **80** at an incision or other opening in an organ. To accomplish this, tool **90** operates in essentially the same manner as above-described tool **79** would operate to install the same ring, with elements **95** and **96** of tool **90** together corresponding functionally to sleeve **75** of tool **79**, except in that disk **96** remains at the anastomosis site (with the fully installed ring) after sleeve **95** and the other elements of installation tool **90** are removed from the anastomosis site.

[**0142**] For the following reason, tool **90** can have a simpler design than that of tool **79**, and removal and release of tool **90** following installation of a ring can be easier than removal and release of tool **79** following ring installation. The radial distance over which the distal end of sleeve **95** must move (distance "A" in **FIG. 27**) to release disk **96** and to release portion **85** of ring **80** from between sleeves **74** and **95** is much less than the radial distance over which the distal end of sleeve **95** would need to move (distance "B" in **FIG. 27**) to release portion **85** from elements **74**, **95**, and **96** if disk **96** were integrally formed with (or permanently attached to) sleeve **95**, assuming that the overall distance from the inner radius of disk **96** to the outer radius of sleeve **95** is equal to the overall distance from the inner radius of portion **76** of sleeve **75** to the outer radius of the distal end of sleeve **75**.

[**0143**] Also, sleeve **95** of tool **90** (and sleeve **75** of tool **79**) are typically made of plastic, but it is practical to implement disk **96** as a metal disk. A metal implementation of disk **96** would typically be stronger than a typical plastic implementation of portion **76** of sleeve **75**.

[**0144**] When tool **90** has completed the installation of ring **80** at an incision in a blood vessel (as shown in **FIG. 28**), ring portion **85** extends around the incision, tines **80**A have grabbed the tissue around the incision and then been deformed so as to evert the incised edges of the tissue to expose the intima **41** of the blood vessel, and disk **96** is trapped between the vessel's exterior surface **40** and tines **80**A. Ring **80** can be implemented with docking features (and optionally also fasteners) that extend out from ring portion **85**. Alternatively, disk **96** can be implemented with docking features (and optionally also fasteners) that extend out from disk **96**'s outer periphery (for use in aligning ring **80** with, and optionally also attaching ring **80** to, another anastomosis ring). In the latter case, ring **80** is preferably implemented without docking features or fasteners to simplify its design.

[**0145**] When only the inventive tined anastomosis ring (and not also an additional element such as annular disk **96** of **FIG. 28**) is to be installed, the ring is preferably implemented to have one or more fasteners extending out from its central ring portion (the ring portion from which its tines extend). Various implementations of such fasteners will next be described with reference to **FIGS. 29-40**. Each fastener will be described as a feature of an embodiment of a tined anastomosis ring having a tubular central ring portion, although each fastener can be implemented as a feature of an anastomosis ring having a flat central ring portion, or as a feature of an annular ring (e.g., ring **96** of **FIG. 28**) to be installed with any embodiment of the inventive tined anastomosis ring.

[**0146**] **FIG. 29** is a perspective view of portions of two of the inventive anastomosis rings (ring **100** and ring **110**) which have been aligned together, and respectively include fasteners **101** and **111** which are tabs. Each of rings **100** and **110** has a tubular central portion (having the same shape as portion **65** of ring **60** of **FIG. 10**), with tines (not shown) that extend out from such tubular central portion. Ring **100** has tabs **101** that extend up from its tubular central portion at locations evenly spaced around the tubular central portion. Only one tab **101** is shown in **FIG. 29**. Each tab **101** has notches **102** at the junction between tab **101** and ring **100**'s tubular central portion.

[**0147**] Ring **110** has one slotted tab **111** for each tab **101** of ring **100**. Each tab **111** has a proximal portion **112** at the junction between tab **111** and ring **110**'s tubular central portion, and a distal end defining a slot **113**. Each tab **111** is bent into the shape shown in **FIG. 29**, so that tab **101** of ring **100** can be advanced upward through slot **113** to align the rings **100** and **110** together. When rings **100** and **110** have been aligned as shown, they are fastened together by bending each tab **101** radially outward and downward relative to table **111** so that tab **100** folds into an orientation that locks ring **101** together with ring **100**. The notches **102** in each tab **101** define a weak point at which tab **101** preferentially folds when it is bent as described.

[**0148**] Tab **121** (of anastomosis ring **120**) of **FIG. 30** is a variation on tab **101** of **FIG. 29**. Anastomosis ring **120** has tabs **121** which extend up from its tubular central portion at locations evenly spaced around the tubular central portion, and tines (not shown) that extend down from its tubular central portion. Only one tab **121** is shown in **FIG. 30**. Tab **121** differs from tab **101** only in that its weak portion (at the junction between tab **121** and ring **120**'s tubular central portion) is defined by a slot **122** extending through tab **121**, rather than by notches (e.g., notches **102** of **FIG. 29**) in the tab's sides.

[**0149**] Tab **131** (of anastomosis ring **130**) of **FIG. 31** is another variation on tab **101** of **FIG. 29**. Anastomosis ring **130** has tabs **131** which extend up from its tubular central portion at locations evenly spaced around the tubular central portion, and tines (not shown) that extend down from its tubular central portion. Only one tab **131** is shown in **FIG. 31**. Tab **131** differs from tab **101** in that its weak portion **131**A (which can be a thin portion of tab **131**) is oriented vertically, and in that it has a notch **132** at the junction between tab **131** and ring **130**'s tubular central portion. To fasten ring **130** to ring **110**, each tab **131** is bent or folded at its weak portion **131**A. In contrast, the weak portion of tab **101** is defined by a set of notches (e.g., notches **102** of **FIG. 29**) in the tab's sides.

[**0150**] **FIGS. 32 and 33** are perspective views of portions of two aligned anastomosis rings (rings **140** and **150**) having a different type of tab fasteners for fastening the rings together. Ring **140** has tabs **141** which extend out from around its tubular central portion, and ring **150** has tabs **151** which extend out from around its tubular central portion. Only one tab **141** and one tab **151** are shown in each of **FIGS. 32 and 33**. When rings **140** and **150** are aligned, each tab **141** has a flange **142** that circumferentially overlaps an edge **152** of one of tabs **151**. Tabs **141** and preferably also tabs **151** are made of spring metal (or are otherwise biased to remain in their originally manufactured orientations relative to the rest of the ring from which they protrude). To fasten ring **140** to ring **150**, each tab **141** is bent below the adjacent tab **151** (assuming that the rings are oriented with tabs **141** initially above tabs **151**), with flange **142** bending relative to the rest of tab **141** to allow it to pass edge **152** of tab **151**. After such relative movement, tabs **141** and **151** have the relative positions shown in **FIG. 33**, with spring force exerted by each tab **141** on tab **151** holding the rings together and tabs **151** preventing tabs **141** from springing back into their original position (i.e., the original position shown in **FIG. 32**).

[**0151**] Next, with reference to **FIGS. 34 and 35**, we describe another type of fastener which can be included as part of the inventive anastomosis ring. **FIG. 34** is a side cross-sectional view of portions of two aligned anastomosis rings (rings **160** and **180**) having spring fasteners for fastening the rings together. Each spring fastener comprises elements **163** and **181**. Fastener elements **163** are made of spring metal, are generally U-shaped, and each has a body which extends out at an acute angle from an edge (the bottom edge in **FIG. 34**) of ring **160**'s tubular central portion, with the body of each element **163** being attached at a proximal end portion **162** to the tubular central portion of ring **160**. Each element **163** has two tabs **161**, which extend out at an obtuse angle with respect to the body of element **163** (as shown in **FIG. 34**). When element **163** (in its **FIG. 34** configuration) is rotated (counterclockwise in **FIG. 34**) about end portion **162** relative to ring **160**'s tubular central portion, element **163** will spring back to the configuration shown in **FIG. 34**. Each fastener element **181** is made from malleable material, and has two wings **182**. Each wing **182** is pre-formed to extend in a plane oriented at a ninety-degree angle relative to the rest of the element **181** of which it is a part. When ring **180** is oriented with a vertical axis of symmetry, each element **181** extends vertically (or substantially vertically) upward away from ring **180**'s tubular central portion (as shown in **FIG. 34**).

[0152] To fasten ring **160** to ring **180**, a surgeon (or a surgeon-operated instrument) aligns ring **180** with ring **160** by positioning the tubular central portion of ring **180** (which has a slightly larger diameter than does the tubular central portion of ring **160**) around the tubular central portion of ring **160** so that the rings have a common axis of symmetry (which we shall refer to as being "vertical" to simplify the description) and so that an element **181** of ring **180** extends between the tabs **161** of each element **163** of ring **160** (in the relative orientation shown in **FIG. 35**). In some implementations of the rings, as the rings are aligned, tabs **161** of one element **163** (on one side of ring **160**'s tubular central portion) are temporarily displaced toward the tabs **161** of another element **163** (on another side, typically the opposite side, of ring **160**'s tubular central portion), thus bending each of the elements **163** about its end portion **162** toward the ring **160**'s tubular central portion, and then the opposed tabs **161** spring back (relax) away from each until each element **163** exerts spring force radially outward against the tubular central portion of ring **180**. In other implementations of the rings, elements **163** are not elastic. After the rings are aligned, wings **182** of each element **181** are spread apart by folding each wing **182** (outward in the directions of arrows A in **FIG. 35**, about a vertical axis) over an adjacent one of horizontally oriented tabs **161**. When this has been accomplished, the forces between fastener element **163** (including tabs **161**) and wings **182** fasten together the aligned rings **160** and **180**. In the final configuration, the tabs **161** on both sides of element **181** provide circumferential support to prevent rotation of ring **160** relative to ring **180** about their common axis.

[0153] A variation on fastener element **181** of **FIG. 35** will next be described with reference to **FIG. 36**. The fastener elements of **FIG. 36** implement an embodiment of the inventive tined anastomosis ring fastener. In **FIG. 36**, ring **160** is identical to ring **160** of **FIGS. 34 and 35**, but ring **170** differs from ring **180** (of **FIGS. 34 and 35**) in that it has fastener elements **171** which are shaped differently than fastener elements **181** of **FIG. 35**. Each fastener element **171** has a spring portion **173**, and a body **172** which ends at free edge **174**. When ring **170** is oriented with a vertical axis of symmetry, the spring portion **173** of each element **171** extends at least substantially vertically upward away from the upper edge of ring **170**'s tubular central portion (as shown in **FIG. 36**). At least the spring portion **173** of each element **171** is made of spring metal (or portion **173** is otherwise biased so that element **171** tends to remain in its originally manufactured orientation). To fasten ring **160** to ring **170**, a surgeon (or a surgeon-operated instrument) aligns ring **170** coaxially with ring **160** by positioning the tubular central portion of ring **170** (which has diameter slightly larger than does the tubular central portion of ring **160**) around the tubular central portion of ring **160** so that the rings have a common axis of symmetry (which we shall refer to as being "vertical" to simplify the description) and so that an element **171** of ring **170** extends between the tabs **161** of each element **163** of ring **160** (in the relative orientation shown in **FIG. 36**). Then, as ring **170** is moved vertically upward into horizontal alignment with ring **160**, the central sloping portion of body **172** (between wings **176**, of body **172**) slides over element **163** and/or the tubular central portion of ring **160**, while spring portion **173** is displaced radially outward relative to ring **170**'s tubular central portion to allow the thickest portion of element **171** to pass over ring **160**'s tubular central portion. In some implementations of the rings, when the rings are aligned, tabs **161** of one element **163** (on one side of ring **160**'s tubular central portion) are temporarily displaced toward tabs **161** of another element **163** (on another side, typically the opposite side, of ring **160**'s tubular central portion), thus bending each of the elements **163** about its end portion **162** toward the ring **160**'s tubular central portion, and then the opposed tabs **161** spring back (relax) away from each other until each element **163** exerts spring force radially outward against the tubular central portion of ring **170**. In other implementations of the rings, elements **163** are not elastic. When edge **174** has moved vertically above the upper edge of ring **160**'s tubular central portion, spring portion **173** springs back (radially inward) into its at least substantially vertical orientation (as shown in **FIG. 36**). When this has been accomplished, the forces between edge **174** and ring **160**'s tubular central portion and between fastener element **163** (including tabs **161**) and ring **170** fasten together the aligned rings **160** and **170**.

[0154] Variations on the **FIG. 36** embodiment employ fastener elements which are differently shaped than elements **163** and **173** of **FIG. 36**. For example, **FIG. 37** is a perspective view of a portion of tined anastomosis rings **170'** and **160'**, each embodying the invention. Ring **170'** has a tubular central portion and a number of spring fastener elements **171'**. Each element **171'** is made of spring metal (or is otherwise biased to remain in its originally manufactured orientation relative to the rest of ring **170'**) and has a shape which is a variation on that of above-described spring fastener element **171**. Preferably, elements **171'** are integrally formed with the rest of ring **170'**. Each fastener element **171'** has a spring portion **173'** (which corresponds functionally to spring portion **173** of element **171**), and a body having two tabs **174'**. Ring **160'** (of **FIG. 37**) is identical to ring **160** (of **FIG. 36**) except in that its fastener elements **163'** have straight circumferential support tabs **161'** that are oriented vertically; not bent circumferential support tabs with vertical portions and horizontally extending ends (e.g., bent circumferential support tabs **161** of ring **160**). When ring **170'** has been aligned with ring **160'**, elements **163'** and elements **171'** spring into a locked configuration in which they fasten together the aligned rings **160** and **170'**. When rings **160'** and **170'** are aligned and fastened together, tabs **174'** of each element **171'** are between the tabs **161'** of the corresponding one of elements **163'**, with the bottom surfaces of tabs **174'** exerting downward force on the upper edge of the portion of element **163'** between tabs **161'** and on the upper edge of the tubular central portion of ring **170'**.

[0155] Another type of fastener that can be used to hold together a pair of aligned anastomosis rings will be described with reference to **FIG. 38**. **FIG. 38** is a perspective view of portions of two aligned anastomosis rings (rings **190** and **200**). Each of rings **190** and **200** is a tined ring having a tubular central portion and fastener elements for fastening the rings together. The fastener elements of ring **190** are tabs **191** which extend out from ring **190**'s tubular central portion. Each tab **191** has a proximal end portion **192** at ring **190**'s tubular central portion and a distal end portion **193** that extends radially outside of ring **190**'s tubular central portion as shown in **FIG. 38**. The fastener elements of ring **200** are tabs **201** which extend radially outward from ring **200**'s tubular central portion. Each tab **201** has two parallel wings **202** which extend vertically from tab **201**'s central portion (when tab **201**'s central portion is oriented in a horizontal plane), and each wing **202** has a malleable end portion **203** as shown in **FIG. 38**.

[**0156**] To fasten ring **190** to ring **200**, a surgeon (or a surgeon-operated instrument) lowers ring **190** into alignment with ring **200** by positioning the tubular central portion of ring **190** (which has a slightly smaller diameter than does the tubular central portion of ring **200**) within the tubular central portion of ring **200** so that the rings have a common axis of symmetry and each tab **191** fits between the wings **202** of a different one of tabs **201**. When the rings have been so aligned with each other, each fastener is moved into its locking configuration (to fasten together the aligned rings **190** and **200**) by bending together the end portions **203** of wings **202** so that each tab **191** is held between a pair of bent-together end portions **203** and the rest of tab **201**.

[**0157**] Another type of fastener that can be used to hold together a pair of aligned anastomosis rings will be described with reference to **FIGS. 39 and 40**. The embodiments of **FIGS. 39 and 40** are variations on the snap fit fastener embodiment of **FIG. 36**. In each of **FIGS. 39 and 40**, ring **210** is a tined anastomosis ring having a tubular central portion and fastener elements for fastening ring **210** together with ring **190**. Ring **190** (of **FIGS. 39 and 40**) is identical to ring **190** of **FIG. 38**, except in that tabs **191** of **FIGS. 39 and 40** have their distal portions **193** extending vertically upward (rather than radially outward as in **FIG. 38**) prior to locking of ring **190** to another ring (i.e., ring **210**), and tabs **191** of **FIGS. 39 and 40** are malleable while tabs **191** of **FIG. 38** can but need not be malleable. Note that the folded-over geometry of each tab **191** (with a proximal end portion **192** extending in a first vertical direction away from a first one of the top or bottom edge of ring **190**'s tubular central portion to a folded portion, and extending in the opposite vertical direction beyond the fold) is needed where there is no room to add features to other one of the top or bottom edge of the tubular central portion (such as where the ring's tines extend out from said other one of the top or bottom edge of the tubular central portion). The fastener elements of ring **210** are slotted tabs **211** which extend generally vertically upward from the upper edge of ring **210**'s tubular central portion as shown in **FIG. 39**. Each tab **211** has a slot **212** extending therethrough. One edge **213** of each slot **212** is formed so that it extends radially inward (relative to the opposite edge of slot **212**) such that slot **212** is shaped to receive the distal end **193** of tab **191** when tab **191** is advanced vertically upward to bring ring **190** into alignment with ring **210** (as shown in **FIG. 39**). Tabs **191** and **211** (of the embodiment of **FIGS. 39 and 40**) are malleable. It is desirable to design tabs **211** to have the minimum possible vertical length, since if they are too long they may get in the way of one of the blood vessels joined at the anastomosis site. It is typically preferable to use fastener elements of the type to be described with reference to **FIGS. 58-61** (rather than those of **FIG. 39**) since the fasteners of **FIG. 58-61** have lower vertical profile (than do those of **FIG. 39**) after two aligned rings are fastened together by folding the tabs **383**, and since the **FIG. 39** fasteners may provide less circumferential positioning support (especially where the rings' central portions are circular rather than oblong) than do the fasteners of **FIGS. 58-61**.

[**0158**] To fasten ring **190** to ring **210**, a surgeon (or a surgeon-operated instrument) raises ring **190** into alignment with ring **210** by positioning the tubular central portion of ring **190** (which has a slightly smaller diameter than does the tubular central portion of ring **210**) within the tubular central portion of ring **210** so that the rings have a common axis of symmetry and each tab **191** fits into slot **212** of a different one of tabs **211** as shown in **FIG. 39**. When the rings have been so aligned with each other, each fastener is moved into its locking configuration (to fasten together the aligned rings **190** and **210**) by bending each pair of aligned tabs **211** and **191** radially outward (into the position shown in **FIG. 40**).

[**0159**] Next, an alternative embodiment of a tool for installing the anastomosis ring of the invention will be described with reference to **FIGS. 41-48**. Installation tool **230** of **FIGS. 41-48** comprises anvil **70** (which is identical to anvil **70** of **FIGS. 16-24**) and independently translatable sleeves **231**, **232**, **233**, **234**, and **235** (whose distal surfaces are shaped slightly differently than sleeves **71**, **72**, **73**, **74**, and **75** of **FIGS. 16-24**, as shown). **FIGS. 41-48** show the configuration of tool **230** during each of eight different steps of installing tined anastomosis ring **220** in an organ (the organ is not shown). Ring **220** is identical to ring **80** of **FIGS. 16-24**, except in that its tines are longer relative to the height of its tubular central portion **221** than are the tines of ring **80** relative to the height of tubular central portion **85** of ring **80**. Only the right half of the distal portion of each of elements **231**, **232**, **233**, 2ˆ4, and **235**, and the right half of ring **220** are shown in **FIGS. 41-48**.

[**0160**] To install ring **220**, the ring **220** is initially loaded onto tool **230** with tubular portion **221** in slot **234**A of sleeve **234** (as shown in **FIG. 41**), and the tines of ring **220** held between sleeves **231**, **232**, and **234**, and the end portion **236** of sleeve **235** (as shown in **FIG. 41**). Then, anvil **70** is inserted into the incision (or other opening) in the organ. Sleeve **234** of tool **230** differs from sleeve **74** of tool **79** in that sleeve **234** has two concentric slots **234**A and **234**B, each of which is circular or oblong, for receiving a tubular central portion (of a tined anastomosis ring) having a different diameter (largest radial dimension). Sleeve **74** has only one slot **74**A. Thus, an anastomosis ring whose tubular central portion has a larger diameter than that of ring **220** can be loaded onto and installed by tool **230**.

[**0161**] After ring **220** has been loaded and anvil **70** has been inserted into the opening in the organ, sleeves **231**, **232**, **233**, **234**, and **235** are advanced distally together as a unit to drive the tines of ring **220** between anvil **70** and the tissue edges, until the tines' tips engage the tine-forming surface **70**A of anvil **70** and begin to curl radially outward (away from the central axis of anvil **70**) as they advance against anvil surface **70**A. Sleeves **231**, **232**, **233**, **234**, and **235** continue to advance until they reach the position shown in **FIG. 42**, in which they have pressed a horizontal portion of each tine (assuming that ring **220** is oriented with a vertical axis of symmetry as shown in **FIG. 42**) against the organ's exterior surface and caused the distal portion of each tine to bend (against stationary surface **70**A of anvil **70**) relative to the rest of ring **220** until the tip of each tine has penetrated (and grabbed) the tissue around the opening. The distal end of sleeve **233** is angled to match the slope of the angled proximal portion of each tine (of ring **220** in its **FIG. 41** configuration). **FIG. 42** shows one tine in the position it would have after its tip has penetrated the tissue and its distal portion has curled radially outward to grab the tissue. Then, as shown in **FIG. 43**, sleeves **231** and **232** are retracted in the proximal direction (toward the top of **FIG. 43**) while sleeves **233,234**, and **235** and anvil **70** remain stationary in engagement with ring **220**.

[**0162**] Then, as shown in **FIG. 44**, anvil **70** is retracted (in the proximal direction) relative to sleeves **233, 234**, and **235**. In response to the force exerted by anvil **70** on the tines of ring **220** (and the tissue edges that have been grabbed by the tines), each tine folds or buckles at both its weak portion (at location **223** shown in **FIG. 44**) and at the junction (identified by reference numeral **222** in **FIGS. 43 and 44**) between its horizontal and angled portions, so that its curled distal portion **224** moves radially outward (away from the central axis of anvil **70**) while it continues to grab the tissue, thereby everting the tissue edges. Each tine preferably has a weak portion (e.g., a hinge) at a location spaced from the junction (**222**) between the tine's horizontal and angled portions. In one implementation, this weak portion is determined by a hole in each tine. Each hole is preferably located along the tine such that, when the tines are in their final configuration (shown in **FIG. 48**), the portion of each tine that is farthest (radially) from the ring's tubular portion **221** does not coincide with the junction **222**, and such portion coincides with (or is very near to) the hole.

[**0163**] Each tine preferentially bends at both junction **222** and at its weak portion during the steps described with reference to **FIGS. 44, 47**, an4 **48**.

[**0164**] After the folding or buckling of the tines described with reference to **FIG. 44**, sleeve **233** is retracted in the proximal direction (as shown in **FIG. 45**), leaving ring **220** (and the tissue gripped thereby) between anvil **70** and sleeves **234** and **235**, with sleeve **234** in a retracted position relative to sleeve **235**.

[**0165**] Then, sleeve **234** is advanced distally relative to sleeve **235** (into the position shown in **FIG. 46**) to bend and rotate each tine (relative the rest of ring **220**) from the configuration shown in **FIG. 45** to that shown in **FIG. 46** as a result of force exertion on ring **220** by stationary sleeve **235** and the distal end of advancing sleeve **234**. This bending and rotation further everts the tissue edges around the organ opening, causes the tines to penetrate farther into the tissue, and allows sleeves **232** and **233** to more easily form a final bend in each tine (in the step to be described with reference to **FIGS. 47 and 48**).

[**0166**] After ring **220** has been placed in the configuration shown in **FIG. 46**, sleeves **232** and **233** are advanced distally relative to portion **236** of sleeve **235** (as shown in **FIG. 47**) to press the tines against portion **236** (while sleeve **234** holds tubular portion **221** against portion **236**), thereby further bending the tines relative to tubular portion **221**. Sleeve **233** then continues to advance until a final bend has been formed in each tine relative to portion **221**, and the ring **220** has been bent into the final, installed configuration shown in **FIG. 48**. Specifically, the curled distal portion of each tine is bent radially outward relative to the proximal portion of each tine (by sleeves **232** and **233**, as shown in **FIG. 47**) and then pushed (by sleeve **233**, as shown in **FIG. 48**) distally against the proximal portion to put ring **220** in the final configuration, hi this final configuration, ring **220** is installed at the opening in the organ with its tines holding the tissue edges in the desired everted state (so that the everted tissue can be joined to tissue of another vessel or other organ).

[**0167**] After installation of ring **220**, sleeve **235** is (e.g., portions comprising the distal end of sleeve **235** are) spread or dilated (radially outward away from anvil **70**'s central axis of symmetry) to decouple tool **230** from the installed ring, and tool **230** is removed from the installed ring.

[**0168**] Another alternative embodiment of a tool for installing one of the inventive anastomosis rings will next be described with reference to **FIGS. 49-57**. Installation tool **330** of **FIGS. 49-57** comprises anvil **70** (which is identical to anvil **70** of **FIGS. 16-24**) and four independently translatable sleeves **331, 332, 333**, and **334** (which are shaped slightly differently than the five sleeves **231, 232, 233, 234**, and **235** of **FIGS. 41-48**, as shown). **FIGS. 49-57** illustrate the configuration of tool **330** during each of nine different steps of installing tined anastomosis ring **320** in incision **341** of blood vessel **340**. Tool **330** of **FIGS. 49-57** implements (during operation) a method for installing an anastomosis ring in an incision in a blood vessel (or another orifice of another type of organ).

[**0169**] Ring **320** is similar to ring **80** of **FIGS. 16-24**, but its tines (each comprising a distal portion **323** and a proximal portion **322**) are formed so that when ring **320** is loaded onto tool **330** with its tubular central portion **321** oriented with a vertical axis of symmetry, proximal portions **322** are horizontal and distal portions **323** are vertical. Only the right half of the distal portion of each of elements **331, 332, 333**, and **334**, and the-right half of ring **320** are shown in **FIGS. 49-57**.

[**0170**] To install ring **320**, the ring **320** is first loaded onto tool **330** with tubular portion **321** in slot **333**B of sleeve **333** (as shown in **FIG. 49**), and the tines of ring **320** held between sleeves **332** and **333** and the end portion **335** of sleeve **334** (as shown in **FIG. 49**). Then, anvil **70** is inserted into the incision **341**. Sleeve **333** of tool **330** differs from sleeve **74** of tool **79** in that sleeve **333** has two concentric slots **333**A and **333**B, each of which is circular or oblong, for receiving a tubular central portion (of a tined anastomosis ring) having a different diameter. Thus, an anastomosis ring having a smaller diameter tubular central portion (a tubular central portion having smaller diameter than that of tubular portion **321**) can be loaded onto tool **330** with its smaller diameter tubular central portion in slot **333**A.

[**0171**] After ring **320** has been loaded and anvil **70** has been inserted into incision **341**, sleeves **331, 332, 333**, and **334** are advanced distally together as a unit to drive the tines of ring **320** between anvil **70** and the incised tissue edges, until the tines' tips engage the tine-forming surface **70**A of anvil **70** and begin to curl radially outward (away from the central axis of anvil **70**) as they advance against anvil surface **70**A. Sleeves **331, 332, 333**, and **334** continue to advance until they reach the position shown in **FIG. 50**, in which they have pressed part of the horizontal portion **322** of each tine against the exterior surface of vessel **340** and caused the distal portion **323** of each tine to curl (against stationary surface **70**A of anvil **70**) relative to the rest of ring **220** until the tip of each tine has penetrated (and grabbed) the tissue around the incision **341**.

[**0172**] Then, as shown in **FIG. 51**, sleeve **331** is retracted in the proximal direction (toward the top of **FIG. 51**) while sleeves **332, 333**, and **334** and anvil **70** remain stationary in engagement with ring **320**.

[**0173**] Then, anvil **70** is retracted (in the proximal direction) relative to sleeves **332, 333**, and **334** into the position shown in **FIG. 52**. In response to the force exerted by anvil **70** on ring **320**'s tines (and the edges of tissue **340** that have been grabbed by the tines), each tine folds or buckles at both its weak portion (at location **327** shown in **FIG. 52**) and at the location along its length (identified by reference numeral **326** in **FIG. 52**) adjacent to the radially inner edge of sleeve **332**'s distal end portion, so that the curled distal portion **323** moves radially outward (away from anvil **70**'s central longitudinal axis) while it continues to grab the tissue, thereby everting the tissue edges. The radially inner surface of sleeve **332** has a recessed portion **332A** to provide clearance for distal portion **323** as distal portion **323** moves radially outward. Each tine preferably has a weak portion (e.g., a hinge) at a location spaced from location **326**. In one implementation, this weak portion is determined by a hole in each tine. Each hole is preferably located along the tine such that, when the tines are in their final configuration (shown in **FIG. 57**), the portion of each tine that is farthest (radially) from the ring's tubular portion **321** coincides with (or is .very near to) the hole; not with location **326**.

[**0174**] Each tine preferentially bends at both location **326** and at its weak portion **327** during the steps described with reference to **FIGS. 52 and 54-57**.

[**0175**] After the folding or buckling of the tines described with reference to **FIG. 52**, sleeve **332** is retracted in the proximal direction (into the position shown in **FIG. 53**), leaving ring **320** held between sleeves **333** and **334**.

[**0176**] Then, sleeve **331** and anvil **70** are advanced distally relative to sleeve **332** until curved distal end surface **331A** of sleeve **331** engages the tines of ring **320** (as shown in **FIG. 54**). Sleeve **331** then continues to advance so that the tines ride along surface **331A** so as to rotate the curled distal portion **323** of each tine radially outward into the configuration shown in **FIG. 54**. This moves the everted tissue adjacent to the tines radially outward, and further everts the everted tissue.

[**0177**] Then, sleeve **332** is advanced distally relative to sleeves **331** and **333** (and anvil **70**) until sleeve **332**'s distal end engages the curled distal portion **323** of each tine. Sleeve **332** then continues to advance so as to rotate each curled distal portion **323** further radially outward into the configuration shown in **FIG. 55**, while surface **331A** engages the intima of the everted tissue (to prevent radially inward movement of the everted tissue). This further everts the everted tissue and allows sleeve **332** to more easily form a final bend in each tine (in the step to be described with reference to **FIG. 57**).

[**0178**] Then, anvil **70** and sleeve **331** are retracted in the proximal direction into the position shown in **FIG. 56**, without exerting force on ring **320** or the everted tissue.

[**0179**] Then, sleeve **332** is advanced in the distal direction (relative to sleeves **333** and **334**) to bend and rotate each tine (relative the rest of ring **320**) from the configuration shown "in **FIG. 56** to that shown in **FIG. 57**, by pressing curled distal portion **323** of each tine (and the tissue adjacent thereto) against portion **335** of sleeve **334**. This final bending and rotation further everts the tissue edges around incision **341**. With ring **320** so installed in the incision **341** in its final configuration, its tines hold the incised tissue edges in the desired everted state (so that the everted tissue can be joined to tissue of another vessel or other organ).

[**0180**] After installation of ring **320**, sleeve **334** is (e.g., portions comprising the distal end of sleeve **334** are) spread or dilated (radially outward away from anvil **70**'s central axis of symmetry) to decouple tool **330** from the installed ring, and tool **330** is removed from the installed ring.

[**0181**] Tool **330** is simpler than above-described tool **230** in that it has only four advanceable and retractable sleeves (**331**, **332**, **333**, and **334**), whereas tool **230** has five such sleeves (sleeves **231**, **232**, **233**, **234**, and **235**).

[**0182**] Anastomosis ring **380** of **FIGS. 58-61** is installed around an incision in the side wall of blood vessel **378**, with curled tines **381** of ring **380** holding the incised tissue edges of vessel **380** with their intima **378A** exposed for anastomosis with vessel **379**. Four docking tabs (or "fingers") **383** extend out from ring **380**'s tubular central portion (parallel to the central longitudinal axis of ring **380**, which is generally vertical in **FIG. 58**). There is a hole **384** at the base of each tab **383**, defining a weak portion at which tab **383** will preferentially bend in response to exertion of radially outward bending force on its distal end **383A**.

[**0183**] **FIG. 61** shows ring **380** in its pre-installation configuration. Note that each tine **381** of ring **380** in the pre-installation configuration has a proximal portion which extends radially inward (perpendicular to ring **380**'s central axis of symmetry) toward the center of ring **380**'s tubular portion, and a distal (tip) portion extending perpendicular to such proximal portion. The "flat" tine geometry of ring **380** of **FIG. 61** (the term "flat" denotes that the proximal portions of tines **381** are all coplanar, in a plane perpendicular to the ring's central axis of symmetry) is preferred over the "angled" tine geometry of ring **60** of **FIG. 10** (in which the tines have proximal portions which extend at a 45 degree angle relative to the ring's central axis of symmetry, e.g., ring **60**'s central axis of symmetry).

[**0184**] Anastomosis ring **400** is installed around an incision in the side wall of blood vessel **379**, with curled tines **401** of ring **400** holding the incised tissue edges of vessel **379** with their intima (not visible in **FIG. 58**) exposed for anastomosis with vessel **378**. In order to align the tubular central portion of ring **380** with the tubular central portion of ring **400**, vessel **379** is gripped by flat end forceps (or "graspers") **420**, and moved toward tabs **383** of ring **380** so that tabs **383** enter the space **403** between the everted tissue of vessel **379** and the tubular central portion of ring **400**.

[**0185**] **FIG. 59** shows ring **400** being aligned with ring **380**, with tabs **383** of ring **380** extending upward through ring **400**'s tubular central portion. Forceps **420** are lowering vessel **379** and ring **400** along tabs **383** toward the tubular central portion of ring **380**, which in turn rests on vessel **378** and the tissue **377** which surrounds vessel **378**. In **FIG. 59**, two arms of forceps **420** are squeezing together opposite side walls of vessel **379**. As apparent from **FIG. 59**, the tubular central portion of ring **400** has greater diameter than that of ring **380**, so that the two rings can be aligned together with their tubular central portions aligned vertically (as shown in **FIG. 60**, in which the tubular central portion r>f ring **380** is not visible since it is within that of ring **400**).

[**0186**] After rings **380** and **400** have been aligned as shown in **FIG. 60**, forceps **420** release vessel **379**. Two arms of forceps **420** (which can be the same arms as were used to align the rings, but which preferably are another pair of arms of an implementation of forceps **420** having two pairs of arms) are then moved into engagement with the tabs **383** (e.g., slightly separated arms of forceps **420** are moved into engagement with one pair of opposed tabs **383**, and then the other pair of opposed tabs **383**). The tab-manipulating arms of forceps **420** are moved downward (when viewed as in **FIG. 60**) to exert bending force on tabs **383** to bend them radially outward into the locking configuration shown in **FIG. 60**. In the locking configuration, tabs **383** extend generally horizontally outward, away from the common central axis of symmetry of rings **380** and **400**, to lock rings **380** and **400** firmly together against tissue **377** with the exposed intima of vessel **378** sealed against the exposed intima of vessel **379**.

[**0187**] **FIGS. 62-63** illustrate a modified procedure for installing an anastomosis device using tool **330**, which uses fewer steps or "configurations" to complete the installation process. Although ring **320** is shown being installed, tool **330** can also be used to install reinforced anastomosis devices which are described below.

[**0188**] After loading the device **320** onto tool **330**, inserting anvil **70** into incision **341** (**FIG. 49**), advancing sleeves **331**, **332**, **333**, and **334** distally together as a unit to drive the tines of device **320** between anvil **70** and the incised tissue edges, until the tines' tips engage the tine-forming surface **70**A of anvil **70** and begin to curl radially outward (away from the central axis of anvil **70**) as they advance against anvil surface **70**A (**FIG. 50**), retracting sleeve **331** in the proximal direction (**FIG. 51**) while sleeves **332**, **333**, and **334** and anvil **70** remain stationary in engagement with device **320**, and retracting anvil **70** in the proximal direction, relative to sleeves **332**, **333**, and **334** into the position shown in **FIG. 52**, sleeve **332** is next retracted in the proximal direction in **FIG. 62**, so that the distal surface thereof forms a substantially smooth and continuous surface with the distal surface of sleeve **331** (e.g., with a few thousands of an inch). In this way, the distal ends of sleeves **331** and **332** form a substantially continuous camming surface against which the tines can be guided to their final deformed positions. Thus, sleeves **331** and **332** can next be advanced together to maintain the substantially continuous camming surface, to abut the tines of device **320** with the curved distal end surface **331**A of sleeve **331**. Sleeves **331** and **332** are continually advanced together, forcing the tines to travel along the substantially continuous camming surface so as to rotate the curled distal portion **323** of each tine radially outward into the final configuration shown in **FIG. 63**. Thus, the coordinated advancement of sleeves **331** and **332** essentially replaces the more complicated manipulations described above with regard to **FIGS. 54-57** with a single, smooth continuous motion during which the sleeves travel from the position shown in **FIG. 62** to the position shown in **FIG. 63**. The sum of the tolerances existing between the top of the tine **323** (and the variations that occur from tine-to tine) and the distal end **331**A of the sleeve **331** are large, so that it is difficult, when using a tool having separately advanced sleeves, such as described with regard to **FIGS. 54-56**, for example, to know the correct extent of advancement of the sleeve **331** (**FIG. 54**) to ensure that the tine is bent over sufficiently to underlie sleeve **332**, but so the sleeve **331** has not also been advanced to the extent where the everted wall running between the camming surface (distal end) **331**A and the clip is squashed or damaged. The further the sleeve **331** is distally advanced, the smaller the gap between surface **331**A and the device **320** becomes, due to the camming surface shape of the distal end **331**A. By advancing both sleeves **331** and **332** together so at to provide a common datum or camming surface, as described with regard to **FIGS. 62 and 63**, the extent to which the sleeve **331** can be automatically determined by the advancement of sleeve **332**, as the endpoint for advancement of sleeve **332** is determined when the bent over tine makes metal to metal contact with the non-bent portion of the tine of device **320**, as shown in **FIG. 63**. The single sleeve arrangement **631** in **FIG. 71**, described below, provides the same end-pointing feature, as the portion of the sleeve **631** that is further radially distant from the member **70** (and which replaces the sleeve **332** in the examples having two sleeves **331** and **332**) also comes to an automatic stop when the tines make metal to metal contact.

[**0189**] **FIGS. 64A-64B** show various formation stages of an anastomosis device **520** having increased bending strength in the regions extending between the weakened portions **526** which are designed to bend first, and the ring or tubular main body portion **521** of the device **520**. The reasoning behind maintaining the sleeve **332** in abutment against the device **320** while initially bending the tines **323** back with the anvil **70** as shown in **FIG. 51** and described above, is to prevent the tendency of the tines to bend in the regions between the indicated bending regions **326**,**327** and the tubular portion **321**. Thus, the sleeve **332** is used to strengthen or support this region during bending by the anvil **70**.

[**0190**] The device **520** is initially formed similarly to previously described devices or rings, in that the initial pattern is cut (e.g., laser cut) from tubular stock (e.g., surgical stainless steel) and then cold-worked over a mandrel having an oval-shaped cross-section to produce the shape shown in **FIG. 64A**. Wing-like extensions **525** are formed to extend from the areas between weakened areas **526** and the tubular portion **521**. Upon further formation of the device, the tines are folded over along the fold lines **522** at the level of the extent of the ring or tubular portion **521**.

[**0191**] Upon folding, adjacent extensions **525** overlap one another, as shown in **FIG. 64B**. Reinforcement of the structure is achieved by joining the overlapped portions of extensions **525**, such as by spot welding, riveting, connecting tabs, adhesives, or other fasteners. By joining the overlapping extensions, the device **520** is reinforced in the lateral direction, i.e., the "x-y plane", which is the direction normal to the axis L (the "z axis") of the device shown in **FIG. 64B**. Alternatively, the finished state or shape of the device **520** can be formed without bending and welding or other attachment of overlapping regions. Specifically, device **520** can be formed by metal forming or shaping from a flat or tubular stock to form an integrated device as shown in **FIG. 65**. In this manner, the reinforced sections **525**' are continuous and integral with the remainder of the device, thereby providing the increased strength in the x-y plane, but at the same time, no overlapping or joining is required to form the finished device. Either of the aforementioned techniques (describing **FIGS. 64A-64B** and **FIG. 65**) increases the bending strength of the portions which extend substantially in the plane normal to axis L. In the case of an oblong device such as shown in **FIGS. 64A-66B**, the additional material provided by the extensions **525** along the straight long fold lines **522**, as well as the sharp radius of curvature and the ends of the device and the overlapping of material in the extensions **525** (or the continuous reinforcement area **525'** as shown in **FIG. 65**) provides for added strength to the base area of the tines **523** to stay relatively planar in the "x-y plane" during bending of the tines at the weakened locations **526**.

[0192] **FIGS. 66A and 66B** show a pair of reinforced devices **520** designed to mate with one another in performing an anastomosis. The technique for joining the devices is similar to that described above with regard to **FIGS. 58-60**, except that the devices of **FIGS. 66A and 66B** only have one pair of docking tabs **527** and mating docking slots **528**, respectively.

[0193] Due to the increased bending strength of the base portions of the tines in devices **520**, a delivery tool **630** can be further modified over the tools described earlier, to still further simplify the process of installing the devices. Tool **630** is simpler than above-described tools **230, 330** in that it has only three advanceable and retractable sleeves (**631**, **633**, and **634**). Only the right half of the distal portion of each of sleeves **631**, **633**, and **634**, and the-right half of device **520** are shown in **FIGS. 67-72**.

[0194] To install device **520** (either a "male device", such as shown in **FIG. 66A** or a "female device", such as shown in **FIG. 66B**), the device **520** is first loaded onto tool **630** with tubular portion **521** in slot **633***a* or **633***b*, depending upon whether the male or female device is being loaded. The tubular portion of the female device **520** has a larger perimeter so as to surround the perimeter of the tubular portion of the male device **520** when they are mated. For this reason, tool **630** is provided with a pair of replaceable sleeves **633**, one having slot **633***a* and the other having slot **633***b*. When loading a male device, the sleeve **633** having slot **633***a* is loaded into tool **630** to accommodate the smaller dimensions of the tubular portion **521** of the male device **520**. Conversely, when a female device **520** is to be loaded, tool **630** is loaded with a sleeve **633** having slot **633***b* to accommodate the relatively larger dimensions of the tubular portion **521** of female device **520**.B of sleeve **333**. In either case, the tines of the device **520** are held between the distal end of sleeve **633** and the end portion **635** of sleeve **634** (as shown in **FIG. 67**).

[0195] After installation of the device **520** as described, anvil **70** is inserted into the incision **341**. After insertion of anvil **70**, sleeves **631**, **333**, and **634** are advanced distally together as a unit to drive the tines of ring **520** between anvil **70** and the incised tissue edges, until the tines' tips engage the tine-forming surface **70**A of anvil **70** and begin to curl radially outward (away from the central axis of anvil **70**) as they advance against anvil surface **70**A. Sleeves **631, 633**, and **634** continue to advance until they reach the position shown in **FIG. 68**, in which they have pressed part of the horizontal portion of each tine against the exterior surface of vessel **340** and caused the distal portion of each tine to curl (against stationary surface **70**A of anvil **70**) relative to the rest of device **520** until the tip of each tine has penetrated (and grabbed) the tissue around the incision **341**.

[0196] Next, as shown in **FIG. 69**, sleeve **631** is retracted in the proximal direction (toward the top of **FIG. 69**) while sleeves **633** and **634** and anvil **70** remain stationary in engagement with device **520**.

[0197] **FIG. 70** shows that anvil **70** is next proximally retracted relative to sleeves **633** and **634**. In response to the force exerted by anvil **70** on the tines of the device **520** (and the edges of tissue **340** that have been grabbed by the tines), each tine folds or buckles at the weakened location **526** so that the curled distal portions of the tines move radially outward (away from anvil **70**'s central longitudinal axis) while it continues to grab the tissue, thereby everting the tissue edges. Because of the increased strength provided in the regions of the tines including extensions **525**, there is no need for a sleeve to reinforce these regions during the step shown in **FIG. 70**. Accordingly, sleeve **631** is effectively a combination of the sleeves **331** and **332** of the tool **330** described above, and is not needed during this step.

[0198] After the folding or buckling of the tines described with reference to **FIG. 70**, sleeve **631** and anvil **70** are advanced distally until curved distal end surface **631**A of sleeve **631** engages the tines of device **520** (as shown in **FIG. 71**). Continued advancement of sleeve **631** and anvil **70** cause the tines to be bent or curled over as they ride along the camming surface provided by distal end **631***a* so as to rotate the curled distal portions of the tines radially outward into the configuration shown in **FIG. 71**. This moves the everted tissue adjacent to the tines radially outward, and further everts the everted tissue.

[0199] Then, anvil **70** and sleeve **631** are retracted in the proximal direction and the distal end portions **635** of sleeve **634** are dilated or spread radially outward to release the fully installed device **520**. With device **520** so installed in the incision **341** in its final configuration, its tines hold the incised tissue edges in the desired everted state (so that the everted tissue can be joined to tissue of another vessel or other organ).

[0200] While the present invention has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

What is claimed is:

1. An anastomosis device for attachment around an orifice in a first tubular tissue or organ and for everting tissue around a perimeter of the orifice, in preparation for anastomosis with a second tubular tissue or organ, said device comprising:

a ring portion sized to extend around the orifice; and malleable tines extending radially inward from said ring portion and having tine tips bent at an angle with respect to said radially extending tines and adapted to extend into the orifice, adjacent the perimeter of the orifice, wherein said tine tips are deformable to grasp the perimeter of the orifice, from inside the tubular tissue or organ and said tines are further deformable to evert the tissue around the perimeter of the orifice.

2. The anastomosis device of claim 1, wherein said tines each comprise a weakened portion adjacent said tine tips, respectively, wherein each of said the tines preferentially folds at the weakened portion in response to being subjected to bending force.

3. The anastomosis device of claim 1, further comprising extensions extending from said tines adjacent said ring portion, wherein said extensions which are adjacent one another overlap.

4. The anastomosis device of claim 1, further comprising extensions integrally joining portions of said tines adjacent said ring portion, thereby reinforcing said tines to provide at least a portion of said tines with increased bending strength.

5. The anastomosis device of claim 3, wherein said extensions that overlap are fixed in an overlapping configuration, thereby reinforcing said tines to provide said at least a portion of said tines with increased bending strength.

6. The anastomosis device of claim 5, wherein said extensions that overlap are fixed by spot welding.

7. The anastomosis device of claim 5, wherein said extensions that overlap are fixed by riveting.

8. The anastomosis device of claim 2, wherein each said weakened portion comprises at least one hole extending therethrough.

9. The anastomosis device of claim 1, wherein said tines extend substantially perpendicularly from said ring portion.

10. The anastomosis device of claim 9, wherein said tine tips extend substantially perpendicularly from said tines.

11. The anastomosis device of claim 1, wherein said ring portion includes a pair of fastener elements adapted to mate with another device in performing the anastomosis.

12. The anastomosis device of claim 11, wherein said pair of fastener elements comprises a pair of malleable tabs extending from opposite sides of said ring portion.

13. The anastomosis device of claim 11, wherein said pair of fastener elements comprises a pair of docking slots formed in opposite sides of said ring portion.

14. A method of attaching an anastomosis device to a tubular structure to be joined by anastomosis, said method comprising the steps of:

inserting an anvil having a bend forming surface into an orifice formed through a wall of the tubular structure;

advancing an anastomosis device having a ring portion with tines extending radially inward therefrom over the anvil, wherein the tines further include tine tips extending therefrom, substantially perpendicularly to the anvil as the device is advanced over the anvil;

continuing to advance the device until the tine tips extend into the orifice and past the inner wall surface of the tubular structure;

driving the tine tips against the bend forming surface of the anvil by continuing to advance the device, wherein the tine tips are curled under the wall of the tubular structure, thereby gripping the wall between the tine tips and the tines which form a curled tine structure.

15. The method of claim 14, further comprising the step of retracting the anvil while holding an opposing force on the ring portion, wherein the anvil contacts the curled tine structure and bends the tines in an opposite direction to the direction of bending of the tine tips, thereby everting the wall of the tubular structure that peripherally surrounds the orifice.

16. The method of claim 15, further comprising the step of advancing at least one additional member having a bend forming surface, over the anvil, contacting the curled tine structure and further bending the tines in the opposite direction to further evert the wall of the tubular structure.

17. The method of claim 16, wherein said at least one additional member is a single sleeve and the bend forming surface comprises a single continuous camming surface.

18. The method of claim 16, wherein said at least one additional member comprises two concentrically arranged sleeves each having a bend forming surface, wherein said sleeves are advanced together such that send bend forming surfaces align to form a single, substantially continuous camming surface.

19. The method of claim 16, wherein said at least one additional member comprises two concentrically arranged sleeves each having a bend forming surface, wherein a second of said sleeves is held in abutment against a portion of the tines adjacent the ring portion when the anvil is retracted, after which the second sleeve is retracted and a first of said sleeves is advanced against the curled tine structure, followed by advancement of the second sleeve against the curled tine structure.

20. The method of claim 16, wherein said further bending of the tines everts the wall of the tubular structure to an extent that the inside surface of the wall is exposed to be contacted during the anastomosis.

21. A pair of anastomosis devices adapted to form an anastomosis between first and second tubular members having first and second orifices;

a first device of said pair being adapted for attachment around the orifice in the first tubular member and for everting the wall of the first tubular member at a perimeter of the orifice, and a second device of said pair being adapted for attachment around the orifice in the second tubular member and for everting the wall of the second tubular member at the perimeter of the orifice of the second tubular member;

said first device comprising a ring portion sized to extend around the orifice of the first tubular member; and malleable tines extending radially inward from said ring portion and having tine tips bent at an angle with respect to said radially extending tines and adapted to extend into the orifice, adjacent the perimeter of the orifice, wherein said tine tips are deformable to grasp the wall at the perimeter of the orifice, from inside the tubular member and said tines are further deformable to evert the tissue around the wall forming the perimeter of the orifice; and

said second device comprising a second ring portion sized to extend around the orifice of the second tubular member and sized to fit concentrically over said ring portion of said first device; and malleable second tines extending radially inward from said second ring portion and having second tine tips bent at an angle with respect to said radially extending second tines and adapted to extend into the orifice of the second tubular member, adjacent the perimeter of the orifice, wherein said second tine tips are deformable to grasp the wall at the perimeter of the orifice, from inside the tubular member and said second tines are further deformable to evert the wall forming the perimeter of the orifice.

22. The pair of anastomosis devices of claim 21, wherein after attaching said first and second devices to the first and second tubular members, said second device is joined with said first device so that said second ring portion concentrically surrounds said first ring portion thereby contacting the

everted inner wall surface of the first tubular member with the everted inner wall surface of the second tubular member.

23. The pair of anastomosis devices of claim 22, wherein one of said first and second devices comprises at least a pair of mounting tabs extending from said ring portion or second ring portion, and the other of said first and second devices comprises at least a pair of docking slots formed in the other of said ring portion or second ring portion; said docking slots being arranged to mate with said mounting tabs for locking said first and second devices to complete the anastomosis.

24. The pair of anastomosis devices of claim 21, wherein the first and second tubular members are vessels.

25. The pair of anastomosis devices of claim 21, wherein the first and second orifices are formed in side walls of the first and second tubular members, respectively, and wherein the anastomosis is a side-to-side anastomosis.

26. A method of performing an anastomosis, comprising the steps of:

inserting an anvil having a bend forming surface into an orifice formed through a wall of a first tubular member;

advancing a first anastomosis device having a ring portion with tines extending radially inward therefrom over the anvil, wherein the tines further include tine tips extending therefrom, substantially perpendicularly to the anvil as the device is advanced over the anvil;

continuing to advance the first device and driving the tine tips against the bend forming surface of the anvil by continuing to advance the device, wherein the tine tips are curled under the wall of the tubular member, thereby gripping the wall between the tine tips and the tines which form a curled tine structure;

everting the wall of the first tubular member along a perimeter of the orifice by bending the tines in an opposite direction to the direction of bending of the tine tips;

inserting an anvil having a bend forming surface into an orifice formed through a wall of a second tubular member;

advancing a second anastomosis device having a ring portion sized to fit concentrically over the first ring portion and having second tines extending radially inward therefrom, over the anvil, wherein the second tines further include second tine tips extending therefrom, substantially perpendicularly to the anvil as the second device is advanced over the anvil;

continuing to advance the second device and driving the second tine tips against the bend forming surface of the anvil by continuing to advance the second device, wherein the second tine tips are curled under the wall of the second tubular member, thereby gripping the wall of the second tubular member between the second tine tips and the second tines which form a second curled tine structure;

everting the wall of the second tubular member along a perimeter of the orifice by bending the tines in an opposite direction to the direction of bending of the second tine tips;

sliding the second ring portion concentrically over the first ring portion, thereby contacting the everted wall of the second tubular member with the everted wall of the first tubular member, so that the inner wall surfaces of the first and second tubular members make contact; and

fastening the first and second devices together to maintain contact between the everted wall surfaces and to maintain the second ring portion in a position concentrically surrounding the first ring portion.

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