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ANASTOMOSIS DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is based upon and claims the benefit of the filing dates of co-pending, commonly owned U.S. Provisional Patent Application Serial No. 61/346,733, filed May 20, 2010 and co-pending, commonly owned U.S. Provisional Patent Application Serial No. 61/347,929, filed May 25, 2010, each of which is incorporated herein in its entirety.

FIELD

[0002] This application discloses a novel anastomosis device. More particularly, this application discloses an anastomosis system comprising vessel holding members and a stapler, which is particularly useful in end-to-end anastomosis of the portal vein in deceased donor liver organ transplant surgery.

BACKGROUND

[0003] Organ transplant surgery, such as a liver transplant, is reasonably common in the United States and throughout the world. Time is critical in organ transplant surgery, where there are many blood vessels from the transplant organ that must be attached to the patient's blood vessels. For blood to reach the organ with oxygen and nutrients and to preserve the function of the transplant, blood vessels must be attached quickly and effectively.

[0004] Over the years, different stapling and/or suturing type anastomosis devices have been proposed. However, none of the known stapler or suture technologies has yet been recognized as being sufficiently quick and effective for widespread adoption. Currently transplant surgeons attach the free ends of blood vessels manually by sewing them together, which may take up to 15 minutes each. However, this method is operator dependent, and the results can vary from surgeon to surgeon.

SUMMARY

[0005] According to an embodiment of the invention, a system for anastomosis comprises two vessel holding members and a stapling device that can attach blood vessels in a reproducible, almost automated manner. The vessel holding members each hold the respective ends of two blood vessels, and then the stapler staples the ends to one another. The results of this procedure are consistent and reproducible regardless of the operator. This technology is useful in any surgical procedure where the ends of two blood vessels or two tubular organs must be joined together.

[0006] The vessel holding members each comprise a tubular vessel holding member having a radially extending flange-like structure at one end. The flange-like structures are regular or irregular in shape, preferably with projections that will secure a vessel.

[0007] The stapling device comprises a tool capable of stapling in a circular or semi-circular pattern, to provide a leak-proof joint or connection between two vessels or tubular organs. In a preferred embodiment of the invention, the stapler is based upon a forceps structure where the proximal end of the forceps structure comprises a handle or grip and the distal end of the forceps structure comprises facing surfaces that can be positioned around vessel segments, such as opposing semi-circular members that clamp or close together. The semi-circular members have two parallel sections so that each pair of semi-circular or circular members can fit on either side of two flange members.

[0008] In a preferred embodiment of the invention, one or both of the facing surfaces of the distal end of the forceps comprise arcuate blade segments that form circular or semi-circular blades. These blades cut excess vessel tissue and, optionally, flange material, to provide a smooth surface.

[0009] According to an embodiment of the invention, the end of a vessel from an organ or the end of a tubular organ is inserted into the open end of a first vessel

holding member through the first vessel holding member and out the other end having a first flange member. The open end of the vessel or tubular organ is then stretched or everted so that the exterior surface and wall of the vessel or tubular organ are stretched over and engage the first flange member of the first vessel holding member. Similarly, the corresponding vessel or tubular organ from the patient is threaded through a second vessel holding member and the open end of that vessel or tubular organ is stretched or everted over the flange of that vessel holding member. The two flange members then are abutted together, and a stapling device operates to staple the flanges together. If one or both of the facing surfaces of the distal end of the stapling device have blades, then excess vessel or tubular organ tissue will be removed at the same time that the flange members are stapled together.

[00010] The flanges can be circular or irregular, preferably with points to hold the everted vessel tissue. Optionally, the outer surface of the flanges may comprise one or more barbs to engage vessel tissue.

[00011] The stapling device has a mechanism so that the semi-circular stapling sections come together to form essentially a complete circle and the staples are propelled from one or both sides of the semi-circular stapler members to engage the flanges and tissue. Preferably, the staples form almost all or all of a ring to prevent fluid leakage.

[00012] In a preferred embodiment of the invention, the distal end of the stapling device will be removable so that the distal end can be replaced with another distal end for stapling another vessel.

[00013] In another embodiment of the invention, the flange members could be fastened together with chemical, mechanical, or electrothermal means that is quick and efficient.

[00014] In another embodiment of a system of the invention, a system for anastomosis of two vessels or tubular organs comprises:

a first vessel holding member capable of holding an end of a first vessel or tubular organ;

a second vessel holding member capable of holding an end of a second vessel or tubular organ; and

a stapling device or tool for stapling together the ends of the first and second vessels or tubular organs.

[00015] In another embodiment of a system of the invention, each vessel holding member is tubular.

[00016] In another embodiment of a system of the invention, each vessel holding member has a radially extending flange-like structure at one end.

[00017] In another embodiment of a system of the invention, the flange-like structure is regular or irregular.

[00018] In another embodiment of a system of the invention, the flange-like structure has points to secure tissue.

[00019] In another embodiment of a system of the invention, the points are barbs.

[00020] In another embodiment of a system of the invention, the stapling device or tool has one or more stapling sections that form essentially a complete circle.

[00021] In another embodiment of a system of the invention, the stapling device or tool comprises arcuate blade segments.

[00022] In another embodiment of a system of the invention, the system comprises:

two tubular vessel holding members, each tubular vessel holding member having a proximal end, a distal end having a radially extending flange structure, and a lumen; and

a stapling device or tool having a proximal end and a distal end, wherein the distal end comprises a circular or semi-circular structure capable of stapling in a circular or semi-circular pattern.

[00023] In another embodiment of the invention, a method for anastomosis of two vessels or tubular organs comprises:

advancing a distal portion of a first vessel or tubular organ through the lumen of a first tubular vessel holding member having a proximal end, a distal end having a radially extending flange member, and a lumen;

everting the distal portion of the first vessel or tubular organ over the distal flange member of the first tubular vessel holding member;

advancing a distal portion of a second vessel or tubular organ through the lumen of a second tubular vessel holding member having a proximal end, a distal end having a radially extending flange member, and a lumen;

everting the distal portion of the second vessel or tubular organ over the distal flange member of the second tubular vessel holding member;

positioning the distal flange member of the first tubular vessel holding member adjacent to the distal flange member of the second tubular vessel holding member; and

stapling the distal flange members together,

wherein the first and second vessels or tubular organs will be securely affixed to each other.

BRIEF DESCRIPTION OF THE DRAWINGS

[00024] Figure 1 is a lateral view of an embodiment of a vessel holding member according to the invention;

[00025] Figure 2 is a head-on view of the embodiment of the invention shown in Figure 1;

[00026] Figure 3 is a cross-sectional view of the vessel holding member shown in Figures 1 and 2;

[00027] Figure 4 is an oblique view of an embodiment of a stapling device according to the invention;

[00028] Figure 5 is a partly cross-sectional view of the distal section of the stapling device shown in Figure 4;

[00029] Figures 6 and 7 are each a partial cross-sectional view of a segment of the distal section shown in Figure 5; and

[00030] Figure 8 is an oblique view of a stapling system according to the invention.

DETAILED DESCRIPTION

[00031] The application can perhaps be better understood by making reference to the drawings. In Figures 1 and 2, a vessel holding member 2 comprises a tubular structure 4 with a proximal opening 6 and a distal opening 8 and having a lumen 10 therethrough. A flange member 12 is integral with or attached to vessel holding member 2. Flange member 12 can be regular or irregular in shape, preferably having two or more projections or barbs 14. In Figure 2, flange member 12 is attached to structure 4 at attachment points 16.

[00032] A cross-sectional view of the vessel holding member 2 in Figures 1 and 2 is shown in Figure 3. The distal portion 18 of a vessel 20 has been advanced into proximal opening 6 and through lumen 10 and everted over flange member 12.

[00033] A stapler tool or device 22 shown in Figure 4 comprises a proximal portion 24, a fulcrum 26, and a distal portion 28. Proximal portion 24 comprises two

proximal members 30, each of which has a finger grip 32. A releasable locking mechanism 36 can lock proximal members 30 together. Distal portion 28 comprises a distal stapling system 38 attached to distal members 42.

[00034] A more detailed drawing of distal members 42 and distal stapling system 38 is shown in Figure 5. Distal stapling system 38 comprises two members 44, each having a rigid bottom piece 46 and a movable upper piece 48. Each upper piece 48 is in communication with, and is controlled by, a control member 50 at proximal portion 24. Preferably movable upper piece 48 is hinged to distal member 42 at hinge 62.

[00035] Rigid bottom piece 46 and upper piece 48 comprise staples 56 that are arranged closely together in circular or substantially circular fashion. The release of staples 56 is controlled by a trigger mechanism 52 at proximal portion 24. Staples 56 are fired into flange members 12 to secure the vessel ends together.

[00036] Optionally stapler system 38 may comprise two or more arcuate blade members to form circularly arranged blades 60 in addition to the staples 56. Blades 60 are intended to trim excess vessel tissue and any portion of the flange members 12 that might be pointed or jagged.

[00037] Rigid bottom piece 46 and upper piece 48 engage each other at points 64 and 66. The engaging surfaces are preferably reciprocally shaped to have a tight fit at points 64 and 66. Examples of reciprocally shaped surfaces 68 and 70, and 72 and 74, are set forth in the sections shown in Figures 6 and 7, respectively. Other examples of reciprocal shapes include curved or saw-tooth configurations.

[00038] In the oblique view of a system of the invention shown in Figure 8, portal vein segments 80 and 82 are positioned within vessel holding members 86 and 88, respectively. The respective distal ends 90 and 92 of portal vein segments 80 and 82 have been everted over flange members 94 and 96, respectively. The stapling device 100 comprises distal sections 102 and 104 that have facing stapling surfaces 108 and 110,

respectively. Stapling surfaces 108 and 110 have arcuate blades or blade segments (not shown).

[00039] When the proximal grips 114 and 116 of stapling device 100 are squeezed together by the operator (not shown), distal sections 102 and 104 move toward each other in the direction of arrows 120 and 122, respectively, so that portal vein segment distal ends 90 and 92 abut. Activation of button or switch 124 by the operator causes stapling surfaces 108 and 110 to propel staples (not shown) to staple flange members 94 and 96 together and to trim portal vein segment tissue to form a smooth surface.

[00040] The components of the disclosed anastomosis devices comprise materials known to those skilled in the art and have dimensions that would be known by, or readily discernible by, those skilled in the art. For example, vessel connector members 2 comprise physiologically acceptable materials such as nitinol or stainless steel. The tubular portion of each vessel holding member could comprise a solid or perforated material, such as a stent. Flange members are preferably solid or rigid surfaces that withstand the stress of the material everted thereover. The flanges must be designed to maintain shape but still accept staples or other securing devices.

[00041] Vessel holding members 2 could be from about 0.5 mm to about 3.0 mm in wall thickness and from about 1.0 cm to about 10.0 cm in length, with an inner diameter of from about 3.0 mm to about 30 mm. Flange members 12 could have a thickness of from about 0.8 mm to about 1.6 mm and a length, that is, the distance from the distal opening of the vessel holding member to the outer edge or a point of the flange, of from about 0.5 cm to about 2.0 cm.

[00042] Preferably the vessel holding members will be about the same size in a given application. However, it is within the scope of the invention that the length and/or inner diameter of two opposing vessel holding members could differ dependent upon the

vessels being mated, although the respective flange members must be identical or substantially similar in shape and/or size so that the surfaces will mate and that the secured interlocking junction will be secure.

[00043] To practice the invention, particularly in the case of an organ transplant, a method for anastomosis of two vessels comprises:

advancing a distal portion of a first vessel through the lumen of a first tubular vessel holding member having a proximal end, a distal end having a radially extending flange member, and a lumen;

everting the distal portion of the first vessel over the distal flange member of the first tubular vessel holding member;

advancing a distal portion of a second vessel through the lumen of a second tubular vessel holding member having a proximal end, a distal end having a radially extending flange member, and a lumen;

everting the distal portion of the second vessel over the distal flange member of the second tubular vessel holding member;

positioning the distal flange member of the first tubular vessel holding member adjacent to the distal flange member of the second tubular vessel holding member; and

stapling the distal flange members together,

wherein the first and second vessels will be securely affixed to each other.

[00044] It is within the scope of the invention that the stapling device can be configured so that distal portions of the device bring the vessel holding members together immediately prior to the stapling step. Also, it is within the scope of the invention that simultaneous with, or immediately thereafter, the stapling step, the stapling tool will trim excess vessel tissue and cut off or smooth out any sharp or jagged portions of the flange members.

[00045] It is also within the scope of the invention that the distal portion or portions of the stapling tool can be replaced. More particularly, when a surgeon, for example, has used the stapling tool to perform a first anastomosis by shooting the staples, the distal portion of the stapling tool can be quickly replaced with a new staple pack so that the surgeon can perform another anastomosis. This can be repeated for each subsequent anastomosis performed. The salient point is that rest of the stapling tool can be re-used for this patient, thus minimizing expenses. Optionally the rest of the stapling tool could be sterilized for use in another patient.

[00046] The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, and will be further apparent to one skilled in the art, that the improvements provided for in the present invention, while described with relation to certain specific physical embodiments, also lend themselves to being applied in other physical arrangements or combinations not specifically provided for herein, which are nonetheless within the spirit and scope of the invention taught here.

I CLAIM:

1. A system for anastomosis of two vessels or tubular organs, comprising:
a first vessel holding member capable of holding an end of a first vessel or tubular organ;
a second vessel holding member capable of holding an end of a second vessel or tubular organ; and
a stapling device for stapling together the ends of the first and second vessels or tubular organs.
2. The system of claim 1, wherein each vessel holding member is tubular.
3. The system of claim 1, wherein each vessel holding member has a radially extending flange-like structure at one end.
4. The system of claim 3, wherein the flange-like structure is regular or irregular.
5. The system of claim 3, wherein the flange-like structure has points to secure tissue.
6. The system of claim 5, wherein the points are barbs.
7. The system of claim 1, wherein the stapling device has one or more stapling sections that form essentially a complete circle.
8. The system of claim 1, wherein the stapling device comprises arcuate blade segments.
9. An anastomosis system comprising:
two tubular vessel holding members, each tubular vessel holding member having a proximal end, a distal end having a radially extending flange structure, and a lumen; and

a stapling tool having a proximal end and a distal end, wherein the distal end comprises a circular or semi-circular structure capable of stapling in a circular or semi-circular pattern.

10. A method for anastomosis of two vessels or tubular organs, the method comprising:

advancing a distal portion of a first vessel or tubular organ through the lumen of a first tubular vessel holding member having a proximal end, a distal end having a radially extending flange member, and a lumen;

everting the distal portion of the first vessel or tubular organ over the distal flange member of the first tubular vessel holding member;

advancing a distal portion of a second vessel or tubular organ through the lumen of a second tubular vessel holding member having a proximal end, a distal end having a radially extending flange member, and a lumen;

everting the distal portion of the second vessel or tubular organ over the distal flange member of the second tubular vessel holding member;

positioning the distal flange member of the first tubular vessel holding member adjacent to the distal flange member of the second tubular vessel holding member; and

stapling the distal flange members together,

wherein the first and second vessels or tubular organs will be securely affixed to each other.

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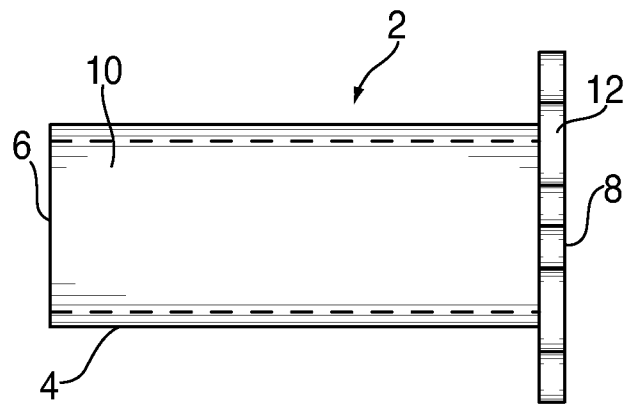


FIG. 1

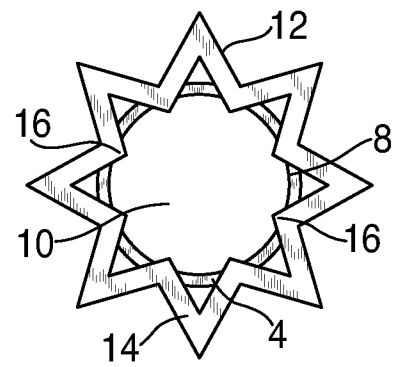


FIG. 2

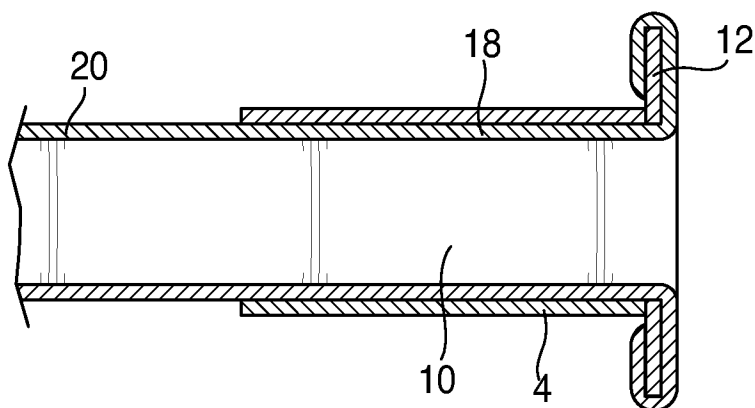
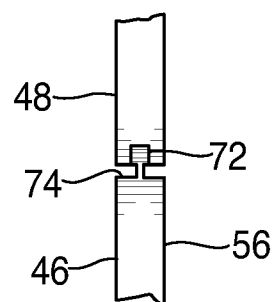
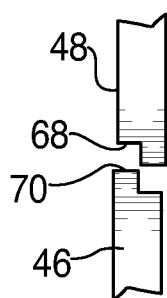
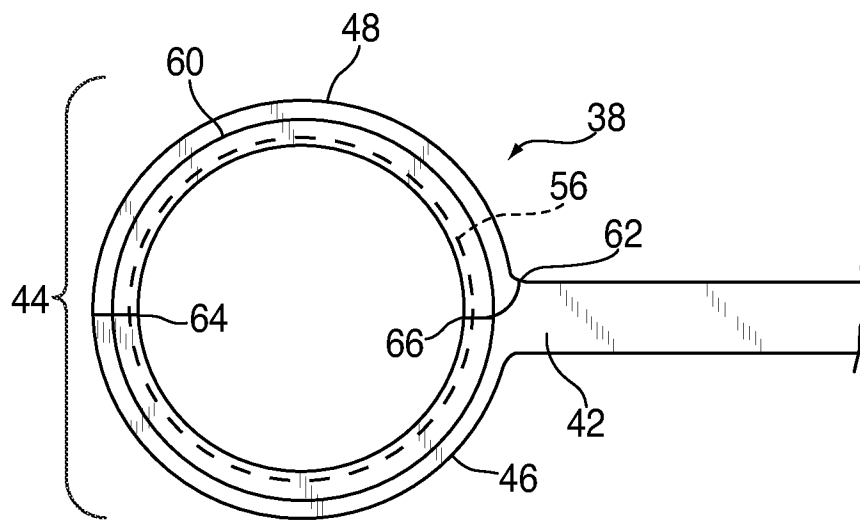
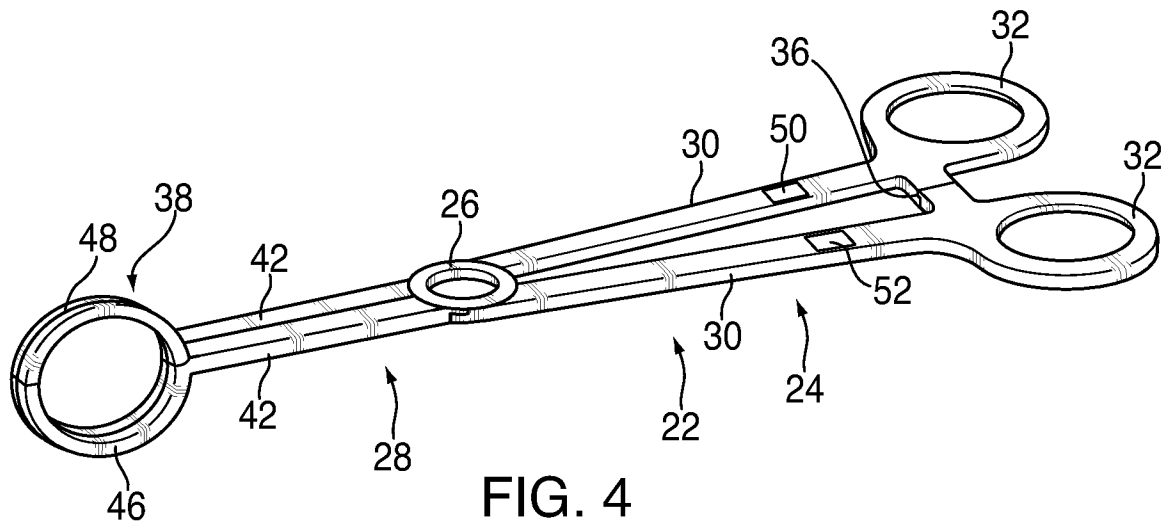


FIG. 3

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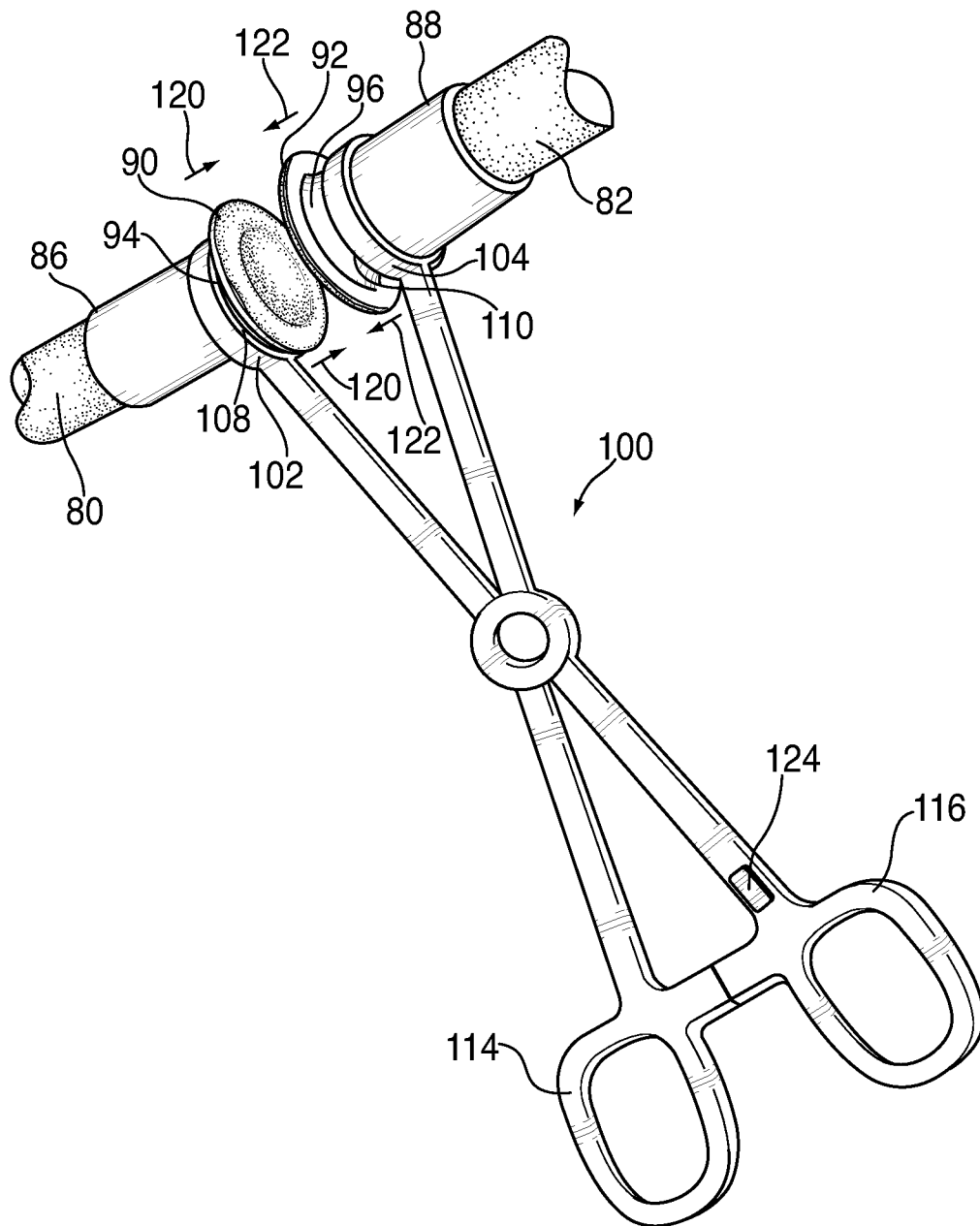


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/037304

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/04 (2011.01)

USPC - 227/179.1

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/00, 17/04, 17/10 (2011.01)

USPC - 227/19, 175.1, 176.1, 179.1

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

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

PatBase, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,752,024 A (GREEN et al) 21 June 1988 (21.06.1988) entire document	1-4, 7-9
Y		5-6, 10
Y	US 2003/0222117 A1 (ORBAN III) 04 December 2003 (04.12.2003) entire document	5-6, 10
A	US 2002/0185517 A1 (VRESH et al) 12 December 2002 (12.12.2002) entire document	1-10

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


* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

15 August 2011

Date of mailing of the international search report

19 AUG 2011

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