

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 March 2007 (15.03.2007)

PCT

(10) International Publication Number
WO 2007/029989 A1

(51) International Patent Classification:
A61F 2/06 (2006.01)

[KR/KR]; Daelim Gangbyeun Apt. 108-1601, Eungbong-dong, Sungdong-gu, Seoul 133-769 (KR).

(21) International Application Number:
PCT/KR2006/003599

(74) Agent: **PARK, Gil Leem**; 3rd Floor Yosam Bldg., 648-23 Yeoksam-dong, Gangnam-gu, Seoul 135-748 (KR).

(22) International Filing Date:
11 September 2006 (11.09.2006)

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(25) Filing Language: Korean

(26) Publication Language: English

(30) Priority Data:
10-2005-0084062
9 September 2005 (09.09.2005) KR
10-2006-0086581
8 September 2006 (08.09.2006) KR

(71) Applicant (for all designated States except US): **HBMEDICALS CO., LTD.** [KR/KR]; 3rd FL, PungSung Bldg., Banpo-dong, Seocho-gu, Seoul 137-802 (KR).

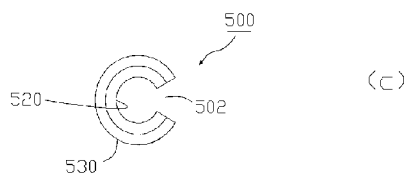
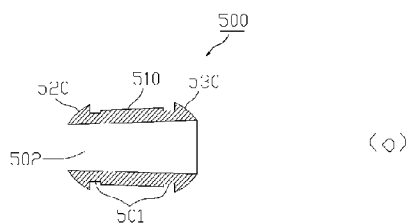
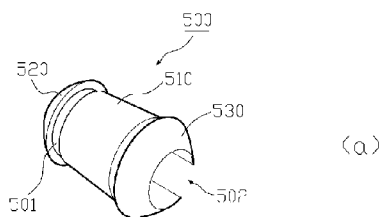
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,

(72) Inventor; and

(75) Inventor/Applicant (for US only): **LEE, Hoon Bum**

[Continued on next page]

(54) Title: TUBE-SHAPED VASCULAR ANASTOMOSIS DEVICES AND METHOD OF USING THEREOF



(57) Abstract: A vascular anastomosis device according to the present invention comprises a tube which is hollow. The tube can be cut in a longitudinal direction, and diameter of the tube may be formed to increase from one cut end to the other cut end. Two or more numbers of ring-shaped bumps or grooves are formed on the outer surface and/or on the inner surface of the tube according to the present invention. Further, the present invention provides a method of end-to-end anastomosis between two cut blood vessels or tubular vascular organs, and also provides an anastomosis method of the blood vessels which are closed or almost closed with no cutting thereof. Still further, the present invention provides a method and an anastomosis device of preventing an everted intima of the blood vessel after the surgery from coming back to the original state of condition.

WO 2007/029989 A1



RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

Description

TUBE-SHAPED VASCULAR ANASTOMOSIS DEVICES AND METHOD OF USING THEREOF

Technical Field

- [1] The present invention relates to a vascular anastomosis device and a method of anastomosis using thereof, and more particularly the present invention relates to the vascular anastomosis device which is hollow and of which a side is separated and the method of anastomosis using thereof.

[2]

Background Art

- [3] So called blood vessel diseases caused by obstruction have increased as blood vessels get narrowed or nearly closed due to the lack of physical exercise and western way of daily eating habits. Particularly, heart related diseases are mostly a cardiac muscle infraction and a stricture of the heart appeared by ischemia that closes the blood vessels providing nutrition and oxygen to the heart.
- [4] A surgery as a way of curing has often operated for the narrowed or nearly closed blood vessels. A technique of the surgery is a method of end-to-end anastomosis which cuts the part of blood vessels with the problem and thereafter anastomosing the blood vessels. At this time, a vein mainly from leg may be used as a substitute when a long blood vessel is needed in a case when the blood vessel which is cut is too long or in a case for bypassing the blood vessels with the problem is necessary.
- [5] Cut end of blood vessels consists of an intima, a media, and an adventitia, and the intima to intima anastomosis is necessary when anastomosing two blood vessels.
- [6] With regard to a curing of the disease of closed heart blood vessels, at a time of the operation of a reconstruction surgery by a flap transfer operation, specialized doctors in delicate surgery need to have enough view for the surgery with a microscope or high-powered microscope and a manual anastomosis method; as a result, this kind of surgery is executed by highly trained skillful doctors and it takes too much time and energy. Particularly, stitching and anastomosing heart blood vessels one by one is a very difficult thing to do in that the heart shrinks and expands consecutively on a regular basis. Accordingly, in a case of the heart surgery, there is a need of stopping the running of the heart during the time of an operation by causing to paralyzing the heart temporarily.
- [7] A number of methods of anastomosis have been developed to avoid the anastomosing blood vessels manually by a suture. Out of those, apparatuses which enable to carry out an easy end-to-end anastomosis of blood vessels are disclosed in

the U.S. Pat. No. 3,774,615, 4,214,586, and 4,917,087, and an example of customized commodity is a micro vascular anastomosis coupler of Synovis Micro Companies Alliance Co. of the U.S. Lim and two other inventors disclosed a device for anastomosis for anastomosing blood vessels with no surgery for the closed blood vessels have some weaknesses in that the blood vessels around the area where the blood vessels are anastomosed are not completely fixed, that it is not easy to connect with an adhesive all around the two cut blood vessels, and that blood might permeate out due to the fact that the area where cut ends meet is too small.

- [8] Robert W. Mericle in the U.S. Pat. No. 4,214,586 similar to the U.S. Pat. No. 3,774,615 in principle has developed an apparatus to fix the cut end of blood vessels more firmly. However, a weak point is in that anastomosis is not well executed due to the still too small area where the cut parts of blood vessels meet.
- [9] David J. Walsh and three other inventors proposed a tubular shaped vascular anastomosis device in the U.S. Pat. No. 4,917,087; it is used for an end-to-end or end-to-side anastomosis, but it can be used only when diameters of the two blood vessels are same in size and further it is not effective when there is a tendency for the blood vessels to come back to the original state of condition due to the weak fixing strength of the intima after an intima-to-intima anastomosis.
- [10] Further, in regard to an end-to-end anastomosis surgery, there are a lot more cases that diameters of blood vessels are not the same in size, so still the anastomosis surgery is done by specialized doctors who carry out anastomosis operations manually with the suture regardless of the history that there have been suggested many vascular anastomosis devices.
- [11] The present inventor responded to the needs and disclosed a tubular hollow organ anastomosis device in Korean Pat. 2001-30280 which enables an anastomosis of two cut tubular hollow organs like in a case of different blood vessels whose diameters are not the same in size. However, there is a disadvantage in that there is difficulty to produce the apparatus due to the complexity in its structure in a case when the diameter of a blood vessel is merely some millimeters in size. Further, the present inventor disclosed a tube-shaped vascular anastomosis device and a method of anastomosis in Korean Pat. No. 2005-84062, but it is not good enough to prevent the intima which is everted after an intima-to-intima vascular anastomosis surgery from coming back to the original state of condition.
- [12] Accordingly, the blood vessels of which diameters are same in size as well as the blood vessels of which diameters are different shall be easily end-to-end anastomosed through the improved tube-shaped vascular anastomosis device through the present invention along with the invention disclosed in the Korean Pat. No. 2005-84062. Further, it is advantageous to prevent the blood vessels from coming back to the

original state of condition after an anastomosis surgery, and the present invention provides a vascular anastomosis device that is easily produced due to its simple structure.

[13]

Disclosure of Invention

Technical Problem

[14] An objective of the present invention is to provide vascular anastomosis devices which may be used for an end-to-end anastomosis of blood vessels no matter the diameters are same or different in size.

[15] Another objective of the present invention is to provide the vascular anastomosis device which enables an easy anastomosis by widening the area where blood vessels are anastomosed as much as possible.

[16] A further objective of the present invention is to provide the vascular anastomosis device which solidifies anastomosis in anastomosing blood vessels by using thereof.

[17] Still a further objective of the present invention is to provide the vascular anastomosis device which prevents the blood vessels, between the intimas, subsequent to an anastomosis from coming back to the original state of condition by using thereof.

[18] Still a further objective of the present invention is to provide the vascular anastomosis device which can be easily produced.

[19] Still a further objective of the present invention is to provide a method of an easier anastomosis of blood vessels by using thereof.

[20] The objectives of the present invention shall be achieved in the detailed description of the present invention.

[21] The above and other objects, features, and advantages of the present invention will become more apparent from the following description in which a preferred embodiment of the invention is shown by way of illustrative example.

[22]

Technical Solution

[23] A vascular anastomosis device according to the present invention comprises a tube which is hollow. The tube is separated in a longitudinal direction, and the diameter of the tube may be formed to widen from one cut end to the other cut end little by little. One or more ring-shaped bumps or grooves are formed on the outer surface and/or the inner surface with regard to an anastomosis device according to the present invention.

[24] Further, the present invention provides a method of an end-to-end anastomosis of two cut blood vessels or two tubular vascular organs and a method of anastomosis of two blood vessels which becomes closed or nearly closed by using thereof. Further, the present invention provides an anastomosis device and a method which can prevent the

blood vessel intimas which are everted subsequent to an anastomosis surgery from coming back to the original state of condition.

[25]

Advantageous Effects

[26]

A vascular anastomosis device according to the present invention is used for anastomosing the blood vessels whose diameter is same or different in size. The vascular anastomosis device has effects in saving production costs due to its simple structure and shortening the time to be taken for an anastomosis surgery. Further, the vascular anastomosis device in its effects lessens significantly the time to be spent for an anastomosis surgery thanks to the fact that there is no need to cut the blood vessels of the problem. Further, a vascular anastomosis device according to the present invention has an effect in preventing the intima of blood vessels which was everted from coming back to the original state of condition and thereby prohibits the blood vessels from being closed.

[27]

Brief Description of the Drawings

[28]

Fig. 1 is a perspective view of an example of a tube-shaped vascular anastomosis device of which the side is separated according to the present invention.

[29]

Fig. 2 is a perspective view and a cross sectional view of two bumps and/or grooves which are formed on the outer and inner surface respectively.

[30]

Fig. 3 is a perspective view of another example of the tube-shaped vascular anastomosis device.

[31]

Fig. 4 is a cross sectional view of the two vascular anastomosis devices which are fixed by bumps and grooves.

[32]

Fig. 5 is a perspective view and a cross sectional view of an example of the vascular anastomosis device of which the side is separated, and of which the diameter in the middle and that of the both cut ends are different.

[33]

Fig. 6 is a perspective view and a cross sectional view of an example of the vascular anastomosis device of which the side is separated, and of which the diameter in the middle and that of the both cut ends are different, and which further comprises an anchoring needle.

[34]

Fig. 7 is a cross sectional view of a fixed state of condition of the two anastomosis devices shown in Fig 5 and 6.

[35]

Fig. 8 is a cross sectional view of a state of anastomosed condition of cut ends of blood vessels by using one vascular anastomosis device according to the present invention.

[36]

Fig. 9 is a cross sectional view of a state of anastomosed condition of cut ends of

blood vessels by using the two vascular anastomosis devices according to the present invention.

[37] Fig. 10 is a cross sectional view of a state of anastomosed condition of a folded blood vessel which is not cut by using two vascular anastomosis devices according to the present invention.

[38] Fig. 11 is a cross sectional view of a state of anastomosed condition of a folded blood vessel which is not cut by using a vascular anastomosis device according to the present invention.

[39]

Best Mode for Carrying Out the Invention

[40] A vascular anastomosis device and a method according to the present invention will be illustrated with reference to the drawings in the following. In regard to the same parts or corresponding parts, indicators will be omitted and the illustration of repetitive names will be omitted if not necessary.

[41] A tube-shaped vascular anastomosis device which is hollow and of which the side is separated according to the present invention is illustrated in Fig. 1. With reference to Fig. 1, the vascular anastomosis device 100 according to the present invention is hollow and tube-shaped, and the side is separated. The gap separated is relatively consistent. In other words, there seems to be no difference between the gap separated at the left part 114 and that at the right part 116. However, it is not a big deal whether the diameters at the left 104 and at the right 106 are same or different. (The vascular anastomosis device illustrated in Fig. 1 will be called "a first example type vascular anastomosis device" hereinafter.)

[42] In respect to a vascular anastomosis with two anastomosis devices, an anastomosis device is inserted into the other anastomosis device. Due to the gap separated 112, the diameter of the anastomosis device inserted can decrease and the diameter of the outer anastomosis device can increase so as that one anastomosis device is easily able to be inserted into the lumen of the other anastomosis device. At this time, the vascular tube shall not be pinched by differentiating relative locations of the gaps separated of the outer anastomosis device and the inner anastomosis device to be inserted.

[43] Further, when it is not easy for a vascular anastomosis device in the above to be inserted into the other vascular anastomosis device, it may be possible for the latter vascular anastomosis device to be enlarged for an easier insertion.

[44] Again in reference to Fig. 1, a ring-shaped external bump is formed on the outer surface in the middle of the first example type vascular anastomosis device 100, and the ring-shaped internal bump is also formed on the intima. The bump plays two roles; firstly in helping assembling of two vascular anastomosis devices when one is inserted

into the lumen of the other and secondly in preventing the two vascular anastomosis devices from slipping each other at the time when and after tying down the two by a suture. More than two bumps may be formed as illustrated in Fig. 2, and it is also possible to form a groove.

[45] A tube-shaped vascular anastomosis device according to the present invention is illustrated in Fig. 3. (The tube-shaped vascular anastomosis device illustrated in Fig. 3 will be called "a second example type vascular anastomosis device hereinafter") With reference to Fig. 3, the second example type vascular anastomosis device is tube-shaped and hollow; the diameters at the left end of the tube 304 and at the right end of the tube 306 are not prepared to be same in size. When anastomosing blood vessels by using the two vascular anastomosis devices (a first vascular anastomosis device and a second vascular anastomosis device hereinafter), the second vascular anastomosis device shall be produced to be bigger than the other first vascular anastomosis device and the diameter at one end shall be formed to be larger than the other diameter at the other end in order that the first vascular anastomosis device may be easily inserted into the lumen of the other second vascular anastomosis device. That is to say, the first vascular anastomosis device shall be produced to be bigger than the second vascular anastomosis device and the diameter at one tube-shaped end shall be prepared to be larger than the diameter at the other tube-shaped end in order for that the first vascular anastomosis device may be easily inserted into the second vascular anastomosis device.

[46] With regard to a different vascular anastomosis device according to the present invention as illustrated in Fig. 3, there is not formed a gap at its sides. Accordingly, the difference between the diameters at one end of the tube is relatively much larger than the vascular anastomosis device according to the present invention as illustrated in Fig. 1 in order for that a first vascular anastomosis device may be easily inserted into a second vascular anastomosis device even if there is no gap in a longitudinal direction.

[47] However, as a result, the first vascular anastomosis device may be alienated by being slipped away from the second vascular anastomosis device. For the prevention of the slippage like this, a bump or groove shall be formed as illustrated in Fig. 1 or 3. The bump or groove is also formed on the intima, that is, the inner surface as illustrated in Fig. 4, which prevents both the first and second vascular anastomosis devices from being slipped away when they are engaged subsequent to an insertion. Particularly, for the first and second vascular anastomosis devices to be engaged more solidly, it is preferred that a ring-shaped groove shall be formed on the outer surface of the first vascular anastomosis device as illustrated in Fig. 4(b), and that the corresponding bump shall be formed on the inner surface of the second vascular anastomosis device.

- [48] The vascular anastomosis device may be divided into a middle part 510 of the tube, a left part 520 of both cut ends, a right part 530 of both cut ends, and a groove 501. One of either diameter of the left side 520 or the right side 530 of the both cut ends may be larger than the other one. The anastomosis device is a form wherein the diameter increases in a round shape from either the left or right part of both cut ends. The inward side of the left part 520 and the right part 530 is located at the place where a diameter is maximized and, the groove 501 is formed on the left part 520 and right part 530 of the inward side. Further, the middle part 510 is located either at the left part 520 or the right part 530 of the groove 501 and the diameter of the middle part 510 is smaller than the diameters of the inward side of both ends 520, 530.
- [49] With regard to the vascular anastomosis device, when tying the flexible groove 501 of the anastomosis device, the diameters at both ends 520, 530 are larger than that at middle part 510, which prevents the anastomosis devices from slipping away afterwards.
- [50] Further, there is a difference in diameters at both left part end 520 and right part end 530. Accordingly, it is possible for any sizes of blood vessels to be inserted, of which the diameters are different respectively, to be anastomosed. In other words, any blood vessel whose diameter is various in sizes can be anastomosed in that both a left part-to-left part of both ends anastomosis and a left part-to-right part of both ends anastomosis is possible according to sizes of the diameter of a blood vessel. Further, an anastomosis device is firmly fixed not to be slipped away due to the differences in the diameters when a blood vessel is inserted. Accordingly, it is preferable for the diameters of both ends to be prepared to be slightly different. Further, blood vessels of different sizes therefore can be anastomosed, and one diameter either of left part end or right part end may be larger than the other.
- [51] Further, when the diameters of both left part end and the right part end are same, a vascular anastomosis in the case when the diameters of blood vessels are the same is applicable. Even if diameters of blood vessels are not same, the adjustment of the diameters of blood vessels through a gap separated 502; therefore the anastomosis device in the above can be used in an either case when both diameters are same or when both diameters are different.
- [52] There is not any bump or groove on the intima of the vascular anastomosis device. Accordingly, it is convenient to produce the anastomosis devices, and it is advantageous in that the fixation by the difference in diameters than the fixation by bumps is more solid when wearing-out and resistance of the bump are taken into consideration.
- [53] The vascular anastomosis device according to the present invention as illustrated in Fig. 6 is a type in which an anchoring needle 531 is sticking to the anastomosis device

illustrated in Fig. 5. (The anastomosis device illustrated in Fig. 6 will be called "a fourth example type vascular anastomosis device hereinafter."). With reference to Fig. 6(a), 6(b), and 6(c), in an intima-to-intima anastomosis subsequent to everting of blood vessels, the everted intima may come back to the original state of condition so as that the blood vessel may be possibly closed. The present invention is the vascular anastomosis device wherein the anchoring needle 531 is arranged at the rim of inward side of the both ends 520, 530 to fix the blood vessel of which the intima is exposed in order for the prevention of the problem mentioned in the above and thereby the structure of blood vessels is stabilized.

[54] With reference to Fig. 7, Fig. 7 (a) illustrates the fixed state of condition of two third example vascular anastomosis devices which are connected. One of the two anastomosis devices is inserted into the other anastomosis device according the present invention. Both the anastomosis devices have a separated gap 502. The advantages of the separated gap 502 are in that a diameter is adjustable according to sizes of vascular tubes when the sizes of both vascular tubes are different and in that it is easier for an anastomosis device to be inserted into the other anastomosis device. Further, when a blood vessel is inserted through the separated gap 502, the movement and everting of the blood vessel becomes easier.

[55]

[56] *Further, there are grooves 501 on both the anastomosis devices. The advantage of the formation of the groove is in that when a blood vessel is inserted into a vascular anastomosis device, the blood vessel is everted, the intima of the blood vessel which is everted is located over the groove 501, and the blood vessel comes into the groove 501 through the inward side of both ends, so the blood vessel is more firmly fixed and the structure of the blood vessel is stabilized. Further, there is an advantage in that anastomosis is adjustable depending on a diameter of the blood vessel through the groove 501.

[57]

Further, when the both anastomosis devices are connected, blood vessels are anastomosed by a suture or any other mechanical means applied to the groove 501. In this case, the groove 501 is flexible, so when this part is tied up the inward side of an outer vascular anastomosis device and the groove 501 of the outer surface of the inserted anastomosis device shall be compressed each other. Accordingly, the diameter at the middle part 510 of the inserted vascular anastomosis device is smaller than the diameters at the both ends, which makes the vascular anastomosis device firmly fixed and kept from being slipped away.

[58]

Fig. 7(b) illustrates a fixed state of condition of two forth example type vascular anastomosis devices which are connected. An anastomosis device is inserted into the other anastomosis device according to the present invention, and the gap 502 and

groove 501 in both the anastomosis devices have the same or similar roles in their functions.

[59] Further, in respect to the anastomosis of blood vessels, the intimas of the blood vessels are anastomosed, but there is a tendency for the everted intima to come back to the original state of condition. Accordingly, there a problem occurs that the blood vessels come to be narrowed when the everted intima is coming back to the original state of condition. For the prevention of this problem, the intima shall be fixed firmly on the vascular anastomosis device; and the vascular anastomosis device according to the present invention uses an anchoring needle 531 to solidify the fixation.

[60] The blood vessel prior to the engagement of both of the blood vessels according to the present invention, moves through the gap 502 and is everted until the intima is exposed to be seen. It is effective to prevent the blood vessels from coming back to the original state of condition by hooking up the end of the blood vessels with an anchoring needle and bending the anchoring needle thereafter. Further, it is preferable when the material of an anchoring needle is flexible in bending and the degree of its quality in softness is high.

[61] Further, when the anastomosis device to be inserted (a first vascular anastomosis device hereinafter), to which the bent anchoring needle 531 is connected, is inserted into an outer anastomosis device for both anastomosis devices to be connected, the blood vessels are anastomosed by applying a suture or any other mechanical means to the groove part 501. In this case, a fixing of the first vascular anastomosis device through the flexibility of the groove area is same or similar to that seen in Fig. 7(a).

[62] A method of anastomosing blood vessels according the present invention as described in the above will be illustrated with reference to Fig. 8 to Fig. 11.

[63] Fig. 8 is a cross sectional view of a state of the condition of a cut end of blood vessel which is anastomosed with one vascular anastomosis device according to the present invention. The vascular anastomosis device used at this time can be either one like a first, third, or forth example type vascular anastomosis device with a gap formed in a longitudinal direction as illustrated in Fig. 1, 5, and 6, or the other one like a second example type anastomosis device with no gap as illustrated in Fig. 3.

[64] With reference to Fig. 8, the end of cut end of a first vascular anastomosis device 850 is inserted into the lumen of a vascular anastomosis device 800 and wrap around the vascular anastomosis device 800 to cover completely, and the vascular anastomosis device 800 covered with the cut end of the first vascular anastomosis device is inserted into the cut end 860 of a second vascular anastomosis device so that the cut end 860 of the second vascular anastomosis device cover the vascular anatomosis device 800 completely. Then thereafter the intima of the second vascular anastomosis device 860 is compressed to the cut end 850 of the first vascular device. At a next step, one of the

three locations 810, 812, and 814 is selected to be tied-down by using a suture or to be fixed by using a mechanical means for healing. Further, an anchoring needle may be used to fix the blood vessel more firmly.

[65] The vascular anastomosis devices may remain for ever or may be absorbed into body depending on its constituting materials.

[66] Fig. 9 is a cross sectional view of a state of the condition the cut end of blood vessels which was anastomosed by using two vascular anastomosis devices. At this time, a vascular anastomosis device out of the first, third, and forth example type vascular anastomosis devices or the second example type vascular anastomosis device may be used, but it is a different situation from that of the vascular anastomosis device illustrated in Fig. 8 in that two anastomosis devices in a pair according to the present invention shall be used.

[67] With reference to Fig. 9, a cut end 950 of a first blood vessel and a cut end 960 of a second blood vessel are respectively inserted into two vascular anastomosis devices 901, 902 and are everted and wrap around each of the vascular anastomosis devices, and thereafter the first vascular anastomosis device covered with the blood vessel is completely inserted into the second vascular anastomosis device as illustrated in Fig. 9.

[68] At this moment, the vascular anastomosis devices of the first, third, and forth example type are used in a pair. In this case, when one of the vascular anastomosis devices 901 covered with blood vessels is inserted into the other vascular anastomosis device 902, diameter of the vascular anastomosis device 901 which is inserted through a gap of the vascular anastomosis device may decrease and diameter of the vascular anastomosis device 902 may increase, which is an advantage in that the insertion gets easier.

[69] A process of fixing those vascular anastomosis devices by a suture or any other mechanical means remains the same with that referred in Fig. 8. That is to say, one of the three marked locations 910, 912, and 914 is selected to be tied-down.

[70] If a vascular anastomosis device is used according to the present invention, an anastomosis surgery is possible without cutting blood vessels which was closed or nearly closed. The method is advantageous in that the anastomosis surgery is operated in a very simple way. In this case, "A first, third, or forth example type anastomosis device shall be used. In other words the blood vessel is inserted through the gap on a side of a vascular anastomosis device" without cutting the blood vessels which are closed. It is preferable to widen the gap of "the first, third, or forth example type anastomosis device as much as possible. Diameters of the tubes of the vascular anastomosis devices at this time shall be different each other when two vascular anastomosis devices are used as referred in Fig. 10, and the diameter of the tube of a vascular anastomosis device shall be preferred to be consistent when only one vascular

anastomosis device is used as referred in Fig. 11.

[71] With reference to Fig. 10, two of "the first, third or forth example type vascular anastomosis device" on which a gap is separated in a longitudinal direction as described in the above are used.

[72] In this case, first of all, a blood vessel 1050 is inserted into the separated gap separated of a first vascular anastomosis device 1001 and is folded over to the opposite direction as described in the examples above.

[73] At this time, the blood vessel 1050 shall be pulled and pushed for the closed part 1070 to be located away from the area of the first vascular anastomosis device 1001. When the blood vessel and the first vascular anastomosis device are arranged relatively in a secure location, the blood vessel gets stabilized as the same as the situation when inserting a first vascular anastomosis device 1001 into a second vascular anastomosis device 1002 at the location away from the place where the first vascular anastomosis device 1001 is inserted. In other words, the blood vessel 1050 is inserted through the separated gap on a side of the second vascular anastomosis device 1002, and the second vascular anastomosis device is slid and pushed to the direction of the first vascular anastomosis device to cover the first vascular device 1001 as illustrated in Fig. 10.

[74]

[75] *When the first vascular anastomosis device 701, the second vascular anastomosis device, and the blood vessel are arranged as illustrated in Fig. 10, the two anastomosis devices 701, 702 are fixed by a suture or any other mechanical means.

[76] Besides the method described above, if one out of a first, third, or forth example type vascular anastomosis devices is solely used and thereafter the blood vessel 1150 and the vascular anastomosis device 1100 are arranged as illustrated in Fig. 11, a closed part 1170 of the blood vessel 1150 can be isolated by fixing the vascular anastomosis device 1100 and the blood vessel 1150. At this time, it is preferable to maintain the diameter of the vascular anastomosis device consistent since only one vascular anastomosis device 1100 is used.

[77] If a vascular anastomosis surgery is executed by using the vascular anastomosis device according to the present invention as described in the above, the basic principle is met that an intima shall be in contact with another intima of blood vessel. Further, it is advantageous in that different blood vessels whose diameters are not same in their structures are easily anastomosed easily and naturally. At this time, the vascular anastomosis device according to the present invention is by and large completely surrounded by the intima of the vascular tube, and therefore the difference in diameters of the two blood vessels to be anastomosed depends on the limit of maximum stretch of the vascular tubes. On the other hand, this limit is twice in the case of a blood

vessel, it is not preferable that a diameter of both ends of a vascular anastomosis device according to the present invention is more than twice than the diameter of a blood vessel. It is because that it is likely for the blood vessel to be ruptured if the diameter of both ends is more than twice larger the diameter of the blood vessel.

[78] Further, a vascular anastomosis device according the present invention may be produced economically since its structure is very simple. Particularly, the vascular anastomosis device according to the present invention has an advantage in that a vascular anatomosis device is easily selected and produced which meets actually required necessary conditions in length of a tube, size and difference of both ends of tubes, width of separated gap in a longitudinal direction, and thickness of tubes.

[79] Further it is still advantageous in that a time required for a surgery can be saved and a time needed for the healing can be shortened since there is no need for specialized doctors who operate the surgery that requires stitching one by one by using a suture. Further, the time spent during the surgery shall be saved since there is no need to cut the vascular tube of the problem.

[80] Since a vascular anastomosis device according to the present invention is a small device to be embedded, the material that does not generate a negative reaction, for example, a stainless steel, a silicon, a titanium or a material such as PGLA (a polyglycolic acid and a mixture thereof) that can be decomposed naturally as time goes and adapted to body easily.

[81]

[82]

[83]

[84] *

Claims

- [1] A vascular anastomosis device which anastomoses one or two blood vessels or tubular vascular organs, comprising a tube-shaped body and one or more numbers of grooves or bumps formed along the outer surface and inner surface of the body.
- [2] The vascular anastomosis device which anastomoses one or two blood vessels or tubular vascular organs, comprising a tube-shaped body and one or more grooves formed along the outer surface of the body.
- [3] The vascular anastomosis device wherein the body as defined in Claim 2, comprising a left part of both cut ends of which the diameter increases in a curved line shape from the both cut ends and is maximized at the inward side of the left part of the both cut ends, a groove part which firms the fixation of blood vessels on the right part coming down vertically from the left part of the both cut ends, a middle part comprising a small straight line whose diameter is smaller than the inward side of the left part of the both cut ends coming up vertically from the groove part, a groove part which firms the fixation of blood vessels coming vertically down from the right part of the middle part, and a right part of the both cut ends in which diameter decreases in a curved line shape at the inward side of the right part of the both cut ends whose diameters, coming up vertically from the right part of the groove part, is maximized.
- [4] The vascular anastomosis device as defined in Claim 3, wherein an anchoring needle is joined at the rear of the inward side of left or right part.
- [5] The vascular anastomosis device wherein a diameter of the body is formed to increase from a cut end to the other cut end as defined in any one of Claims 1 to 4.
- [6] The vascular anastomosis device wherein the body is cut in a longitudinal direction as defined in any one of Claims 1 to 4.
- [7] The vascular anastomosis device wherein a diameter of the body is twice smaller than a diameter of the blood vessels anastomosed to the body.
- [8] The vascular anastomosis device wherein a material of the body is selected from the group consisting of a stainless steel, a silicon, a titanium, and a PGLA (a polyglycolic acid and a polylactic blend thereof) as defined in any one of Claims 1 to 4.
- [9] The vascular anastomosis device which anastomoses a cut end-to-cut end of one or two blood vessels or tubular vascular organs, comprising a first tube-shaped vascular anastomosis device to join to one blood vessel and a second tube-shaped vascular anastomosis device to join to another blood vessel and connecting two

- blood vessels by the first tube-shaped vascular anastomosis device being inserted into the second tube-shaped vascular anastomosis device to comprise one tube.
- [10] The tube-shaped vascular anastomosis device as defined in Claim 9 wherein one or more grooves or bumps are formed along the outer surface of the first vascular anastomosis device and the corresponding grooves or bumps are formed on the inner surface of the second vascular anastomosis device and wherein the union of the first anastomosis device and the second vascular anastomosis device is formed by the groove or bump of the first anastomosis device and second vascular anastomosis device when the first vascular anastomosis device is inserted into the second vascular anastomosis device to comprise one tube.
- [11] The vascular anastomosis device as defined in Claim 9 wherein one or more grooves are formed along the outer surface of the first anastomosis device or the second vascular anastomosis device and a flat face is formed with no groove along the inner surface, and wherein the union gets more secured by the difference of the diameters that the diameters of the both cut ends are larger than the diameter of the middle part in a case when the groove is compressed at the time while the first vascular anastomosis device is inserted into the second vascular anastomosis device to comprise one tube.
- [12] A method of anastomosis of cut blood vessels that a first blood vessel and a second blood vessel are in contact and thereafter are anastomosed, as a method of anastomosing two cut blood vessels by using the anastomosis device according to any one of Claims 1 to 8, comprising the following steps of a first step wherein a first blood vessel is inserted into the body until the intima of the blood vessel is everted and thereafter the body is completely covered by the first blood vessel and a second step wherein the body completely covered by the first blood vessel is covered by the second blood vessel completely.
- [13] The method of anastomosing cut blood vessels wherein the step of inserting end cut of the first blood vessel into the body and everting the end of the first blood vessel until the intima is exposed to cover the body completely as defined in Claim 12 comprising an additional step of fixing the everted blood vessel with an anchoring needle and bending the needle to fix the blood vessel and thereafter covering the body completely.
- [14] The method of anastomosis of cut blood vessels that a first blood vessel and a second blood vessel are in contact and thereafter are anastomosed, as a method of anastomosing two cut blood vessels by using the anastomosis device according to any one of Claims 1 to 8, comprising the following steps of a first step wherein the cut end of a first blood vessel is inserted into the body of a first vascular anastomosis device and everted until the intima is exposed to cover the

body of the first vascular anastomosis device completely, a second step wherein a cut end of a second blood vessel is inserted into the body of a second vascular anastomosis device and everted until the intima is everted until the intima is exposed to cover the body of the second vascular anastomosis device completely, and a third step of inserting the first vascular anastomosis device covered with the first blood vessel into the second vascular anastomosis device covered with the second blood vessel.

[15] The method of anastomosing cut blood vessels in which a step wherein a cut end of the first blood vessel is inserted into the body of the first vascular anastomosis device and everted until the intima is exposed to cover the body of the first vascular anastomosis device completely as defined in Claim 14, further comprising a step wherein the everted blood vessel is fixed with an anchoring needle and the needle is bent to fix the blood vessel and thereafter the blood vessel covers the body completely.

[16] The method of anastomosing cut blood vessels wherein a step that a cut end of the second blood vessel is inserted into the body of the second vascular anastomosis device and everted until the intima is exposed and the cut end of the blood vessel covers the body of the second vascular anastomosis device completely as defined in Claim 14, further comprises a step wherein the everted blood vessel is fixed with an anchoring needle and the needle is bent to fix the blood vessel and thereafter the blood vessel covers the body completely.

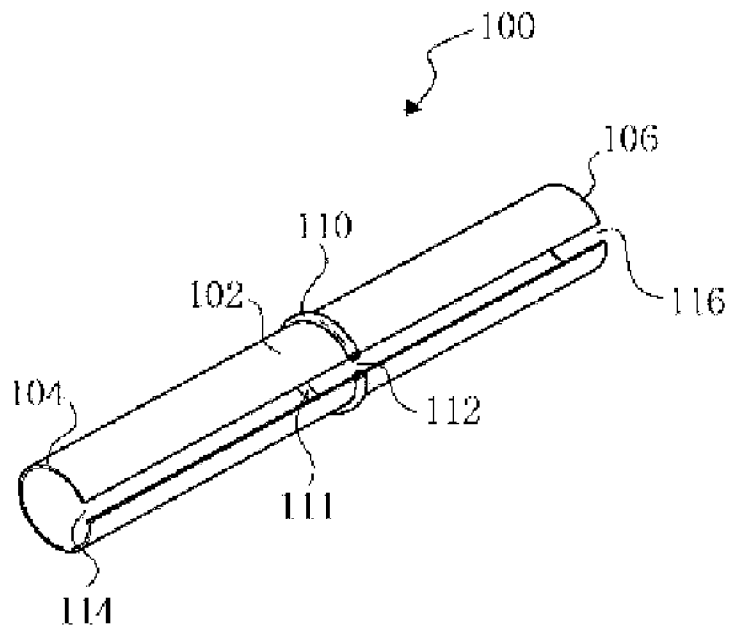
[17] The method of anastomosing cut blood vessels as defined in Claim 9 or 11 further comprising a step of fixing the outer surface of the second blood vessel joined to the first blood vessel by a suture or any other mechanical means.

[18] The method of anastomosing a blood vessel with no cutting, as the method of anastomosing blood vessels which is not cut by using a vascular anastomosis device according to Claim 6, comprising the following steps of a first step of inserting a blood vessel into the vascular anastomosis device completely through a gap separated on the body of the vascular anastomosis device, a second step of covering the body with a part of the blood vessel for the part of the blood vessel which is closed to be isolated, and a third step of fixing the blood vessel on the body with a suture or any other mechanical means.

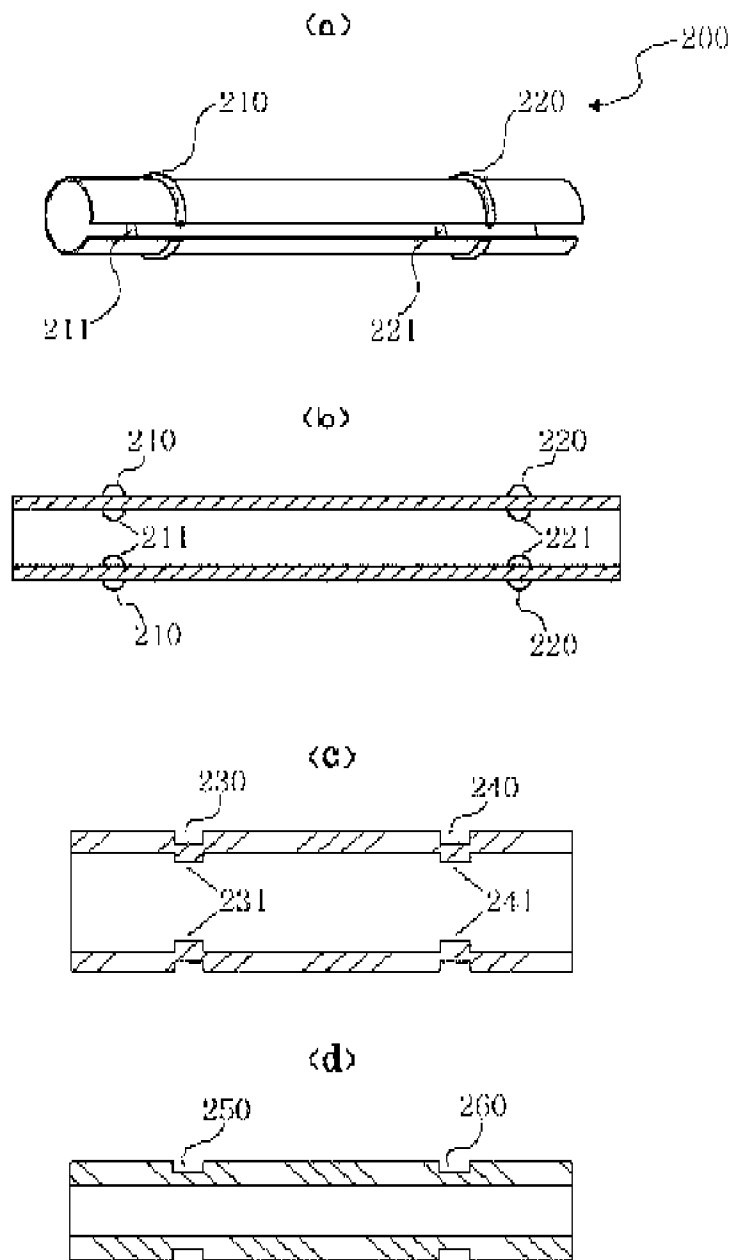
[19] The method of anastomosing a blood vessel with no cutting, as the method of anastomosing a blood vessel which is not cut by using two vascular anastomosis devices according to Claim 6, comprising the following steps of a first step of inserting a blood vessel into the vascular anastomosis device through a gap separated on the body of the first vascular anastomosis device, a second step of covering the body of the vascular anastomosis device with a part of the blood

vessel for the part of the blood vessel which is closed to be isolated, a third step of inserting the blood vessel which is in the opposite side to the part of the blood vessel which is closed through a gap separated on the body of the vascular anastomosis device, a forth step of inserting the first vascular anastomosis device covered with the blood vessel into the second vascular anastomosis device and a fifth step of fixing the first vascular anastomosis device and the second vascular anastomosis device by a suture or any other mechanical means.

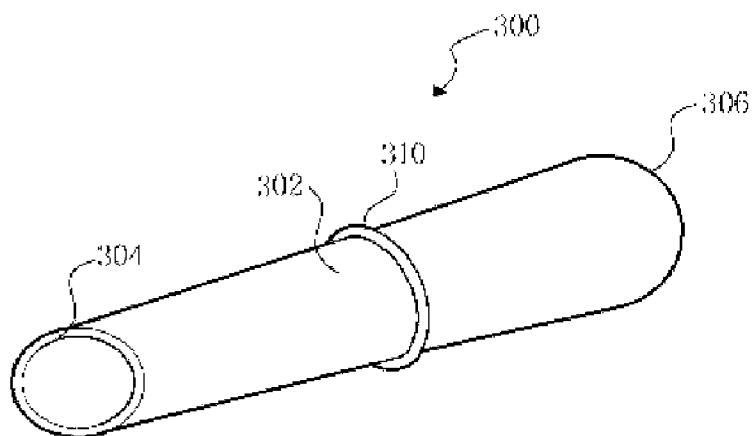
[Fig. 1]



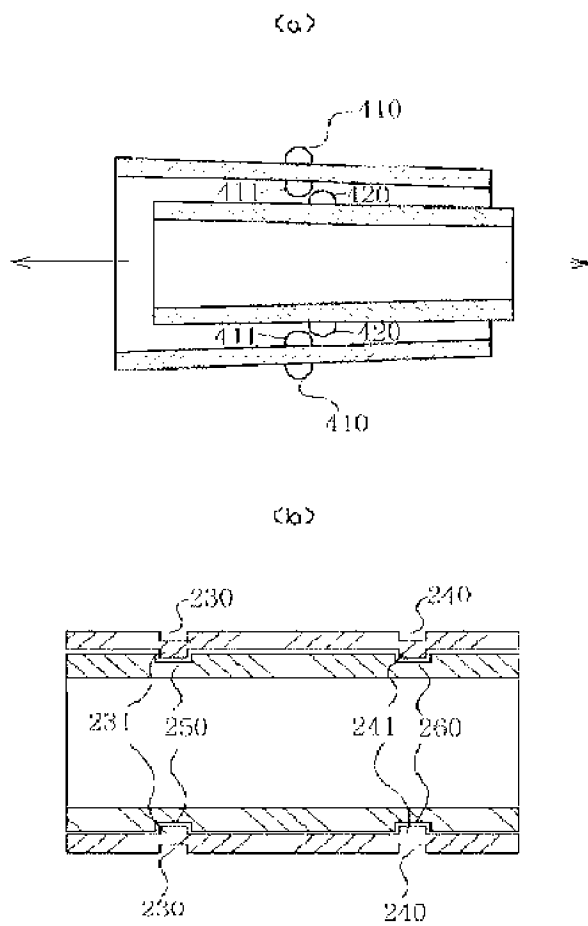
[Fig. 2]



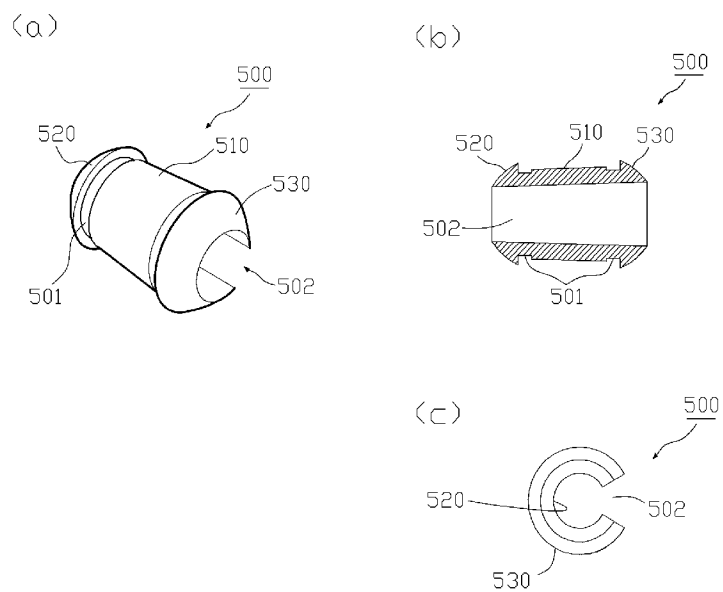
[Fig. 3]



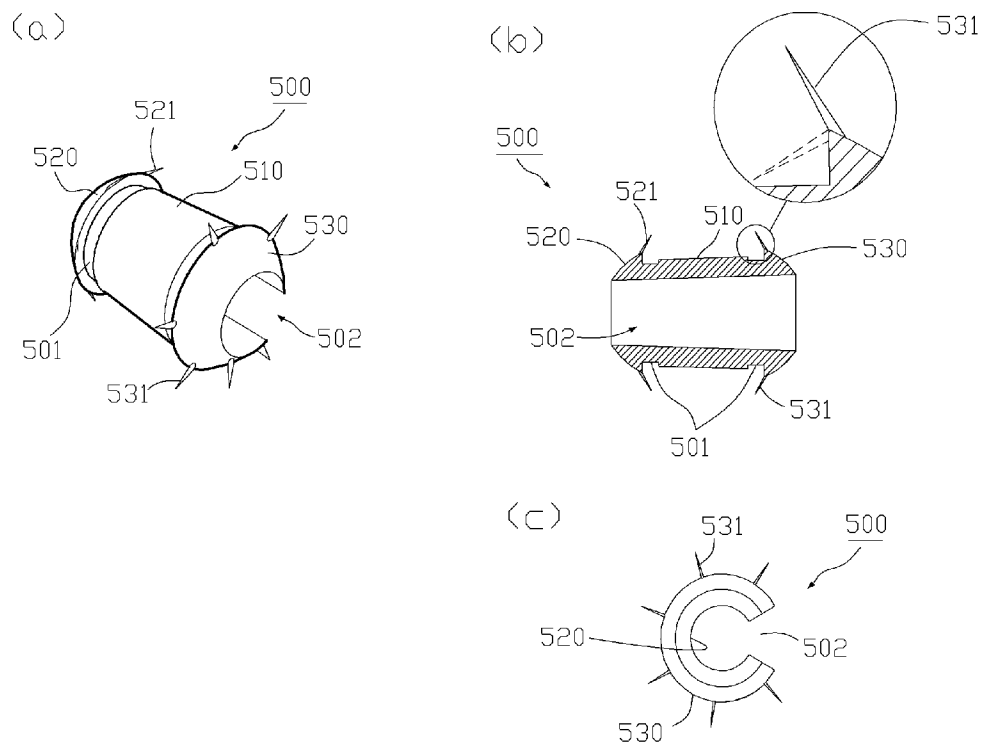
[Fig. 4]



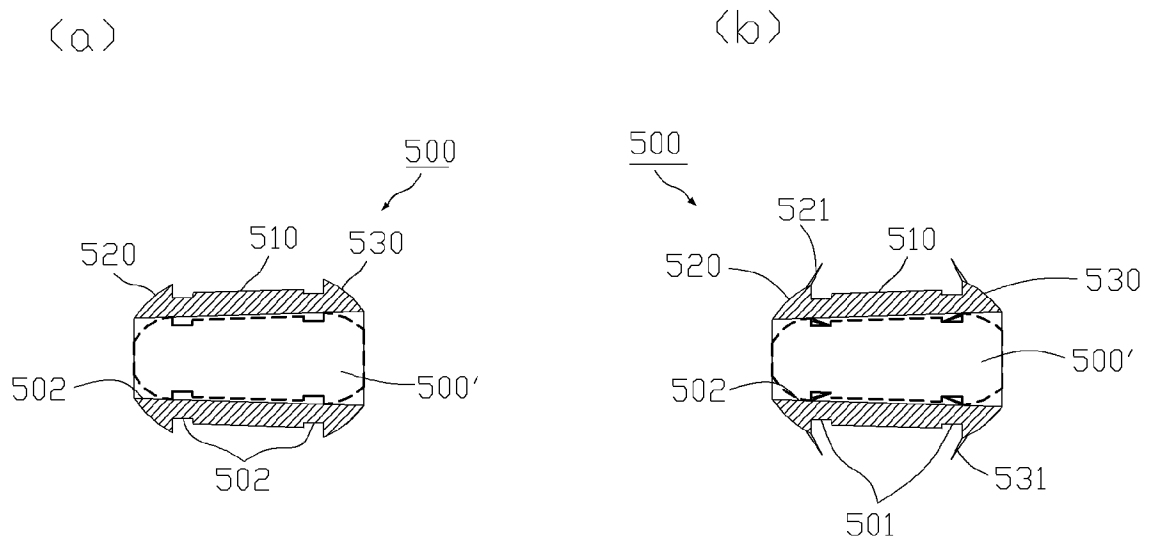
[Fig. 5]



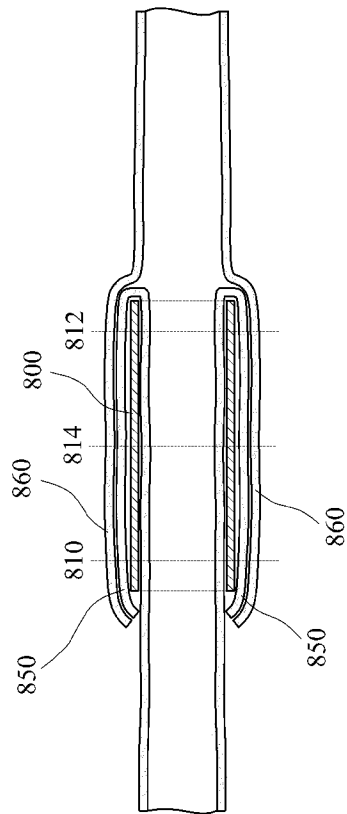
[Fig. 6]



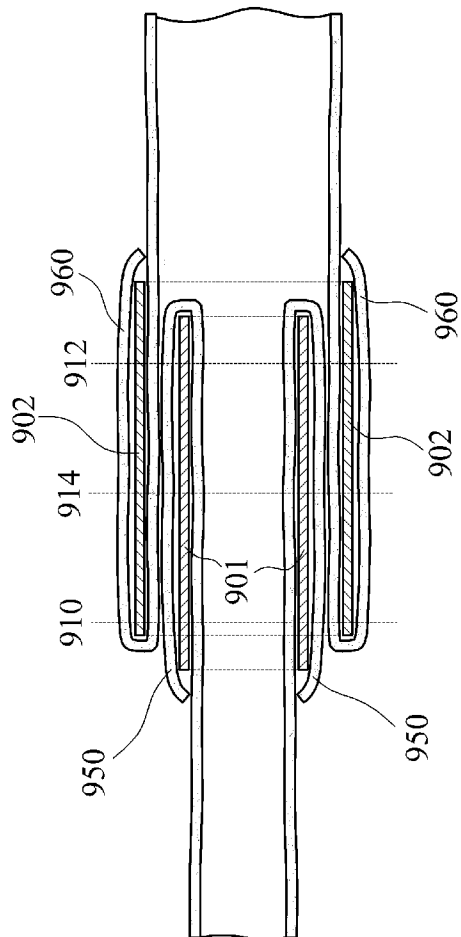
[Fig. 7]



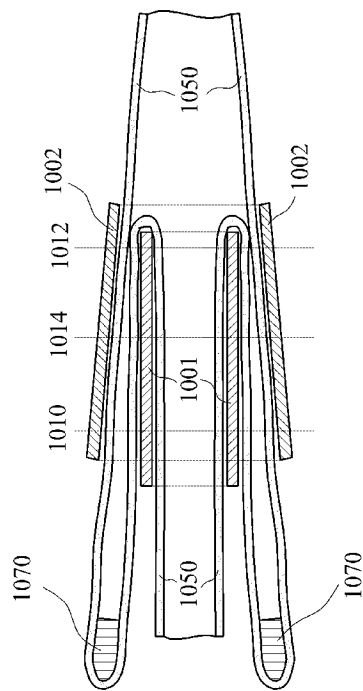
[Fig. 8]



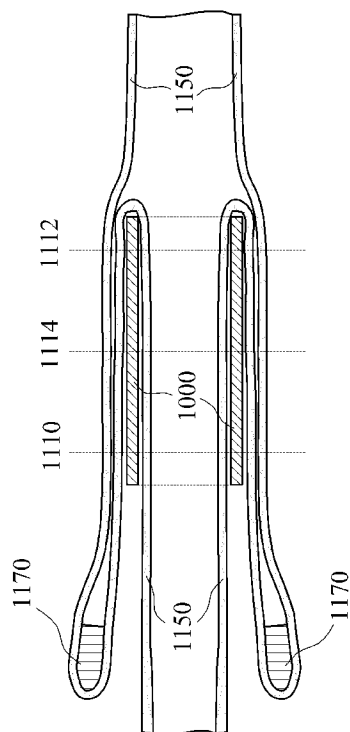
[Fig. 9]



[Fig. 10]



[Fig. 11]



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2006/003599**A. CLASSIFICATION OF SUBJECT MATTER***A61F 2/06(2006.01)i*

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)

A61F 2/06

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)

eKIPASS "anastom*", vascular, tube", Delphion

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,214,586(Mericle, R.W.) 29 July 1980 See abstract and figures 1-6	1-11
A	US 4,917,087(Walsh, D.J. et al.) 17 April 1990 See abstract and figures 1-3	1-11
A	US 6,176,864 B1(Chapman, T.) 23 January 2001 See abstract and figures 1-16	1-11



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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

11 DECEMBER 2006 (11.12.2006)

Date of mailing of the international search report

12 DECEMBER 2006 (12.12.2006)

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

PARK, JEONG UNG

Telephone No. 82-42-481-8159



INTERNATIONAL SEARCH REPORT

International application No.

PCT/KR2006/003599

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

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

1. ☒ Claims Nos.: 12-19
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 12 to 19 pertain to methods for treatment of the human or animal body by therapy and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/KR2006/003599

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4214586	29.01.80	FR 2442621 B1 GB 2039652 A1 JP 55076649	30.12.83 13.08.80 09.06.80
US 4917087	17.04.90	US 4873975 A US 4771775 A EP 158316 A3	17.10.89 20.09.88 26.02.86
US 6176864 B1	23.01.01	US 2001001827 A1 EP 1061859 A2 WO 9945852 A3	24.05.01 27.12.00 23.12.99