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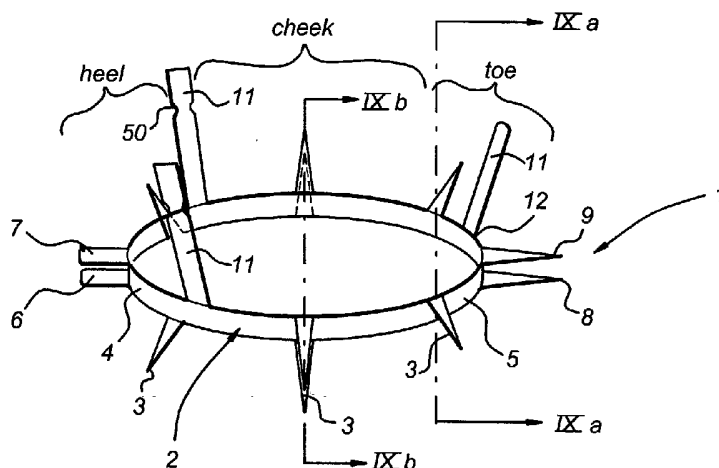
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(54) Title: VASCULAR ANASTOMOTIC BONDING DEVICE



(57) Abstract: The present invention relates to a vascular anastomotic device (1) comprising a single oval frame (2) for constructing an anastomosis between two blood vessels, the oval frame having a heel region frame part, a toe region frame part and two cheek region frame parts, wherein the heel region frame part (4) comprises two blunt heel lips (6, 7); the cheek region frame parts each comprises a plurality of cheek pins (3), and the toe region frame part (5) comprises two extensions (8, 9, 13, 14), wherein the two heel lips (6, 7) are axially spaced apart and extend radially outward from the frame (2), wherein the two toe extensions (8, 9, 13, 14) are axially spaced apart and extend radially outward from the frame (2), and wherein the cheek pins (3) are sharp pointed and extend radially outward from the frame (2). The vascular anastomotic device can be applied using simple instruments. Furthermore the arterial tissue does not have to be displaced to large extent, so that tearing of the blood vessels can be avoided.



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Vascular Anastomotic Bonding Device

Technical field of the invention

5 The invention relates to a vascular anastomotic device comprising a single oval frame for constructing an anastomosis between two blood vessels, the oval frame having a heel region frame part, a toe region frame part and two cheek region frame parts.

10 Background of the invention

Coronary Artery Bypass Grafting (CABG) procedures may be carried out using minimally invasive techniques in which blood vessels are joined via special tools through a small hole in the thorax.

15 A bypass is made by connecting a bypass graft artery or vein through a side-to-end, side-to-side or end-to-end anastomosis to the obstructed coronary artery, distally from the obstruction. The connection between the graft vessel and the arteriotomy edges in the coronary artery is conventionally carried out by suturing. It is a disadvantage that a proper apposition of the individual sutures requires great surgical
20 skills. Using steel clips or staples instead of a running suture or individual sutures results in a proper fixation, but the regularity of the anastomosis is still greatly dependent on the skills of the surgeon.

 In order to apply all staples or clips around the anastomotic line in one action, end-to-side staplers are known comprising an anvil with pots to guide the plastic
25 deformation of the staples, a cartridge holding the staples before application, and a driver pushing the staples out of the cartridge against the anvil. The known application tools are complex. Although the apposition problem is solved using so-called one-shot devices the visibility of the anastomotic line is poor due to the bulky application tool. It also requires a large amount of force to deform the staples in a way that maintains a
30 proper apposition. It is also possible to misplace one or more staples, thus resulting in a poor connection and a potential leakage along the anastomotic line.

Objects of the invention

It is an object of the present invention to provide a vascular anastomotic device that can be applied using simple instruments, preferably conventional instruments.

It is a further object of the present invention that arterial tissue does not have to
5 be displaced to large extent, so that tearing of the blood vessels can be avoided.

It is a further object of the present invention to provide a vascular anastomotic device that does not block the view on the anastomotic line.

Summary of the invention

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The above objects are achieved by a vascular anastomotic device which is characterised in that

- the heel region frame part comprises two blunt heel lips,
 - the cheek region frame parts each comprising a plurality of cheek pins,
 - 15 • the toe region frame part comprises two extensions
- wherein the two heel lips are axially spaced apart and extend radially outward from the frame,
- wherein the two toe extensions are axially spaced apart and extend radially outward from the frame, and
- 20 wherein the cheek pins are sharp pointed and extend radially outward from the frame.

When an anastomosis between two blood vessels is constructed, the two blood vessels are being connected. One of the blood vessels is a graft, the other is the recipient artery. Sharp cheek pins are mounted on the cheek region frame part for impaling both the graft and the recipient artery in order to prevent the connection
25 between the two blood vessels from loosening and/or leaking. In the heel region frame part the frame comprises two blunt heel lips for on the one hand positioning the frame in an incision in the recipient artery and for on the other hand clamping in-between vascular wall tissue of the graft and the recipient artery. The toe region frame part comprises two toe extensions for positioning the graft and the recipient blood vessel
30 together and to provide a leak-free connection between the graft and the recipient blood vessel.

The frame can be applied using conventional equipment, such as a pair of pincers. At first, the frame is mounted on an endpart of a graft. The endpart of the graft

can be inserted into an opening in the frame using conventional equipment. The graft wall is then everted and is being impaled by the cheek pins. The arterial tissue of the graft does not have to be displaced to a large extent. By hitching the lower blunt heel lip into an incision of the recipient artery, the frame, together with the graft mounted
5 onto that frame, can be attached to the recipient artery. In the cheek region the cheek pins impale the wall of the recipient artery, thus creating a connection between both the graft and the recipient artery. In a mounted state, the frame is hidden in an everted part of the graft thus not blocking the view on the anastomotic line.

A further embodiment of the present invention is characterised in that the cheek
10 region frame part comprises at least two cheek pins, preferably at least three cheek pins, more preferably at least four cheek pins. The cheek region frame part comprises at least two cheek pins to prevent the graft being released from the recipient blood vessel. When constructing an anastomosis, both the graft and the recipient blood vessel are being impaled by the sharp cheek pins. Two cheek pins are needed to ensure a tight
15 fitting between the graft and the recipient blood vessel. In order to ensure a tight fitting between the graft and the recipient blood vessel, cheek pins are to be placed radially spaced along the cheek region frame part.

Preferably the present invention is characterised in that at least two of the cheek pins are spaced in an axial direction. Two cheek pins are spaced in an axial direction to
20 enable a wire to be lead between the two cheek pins in the axial space between them. This wire is used to ensure a tight apposition. The graft wall and the wall of the recipient artery can be clamped together by a wire. In order to keep the wire in place and prevent the wire from being moved, the wire can be placed between at least two cheek pins that are spaced in an axial direction. To obtain a leak-free apposition the
25 wire clamping both the graft and the recipient artery together, should be placed along the anastomotic line.

In an embodiment the present invention is characterised in that at least one of the toe extensions is a blunt toe lip. One outer end of the graft is inserted through the frame and the wall of the graft can be everted around the frame and around the blunt toe lip,
30 thus constructing an intima-intima apposition in which the inner side of the graft wall is adjacent to the inner wall of the recipient artery.

In another embodiment the present invention is characterised in that both toe extensions are blunt toe lips. By using two blunt toe lips, the frame can be positioned

accurately in an incision made in the recipient artery, without the risk of tearing the recipient artery. Between both blunt toe lips, a part of the graft wall and a part of the recipient artery wall can be placed so that the graft wall and the recipient artery wall are being held together.

5 In a further embodiment the present invention is characterised in that at least one of the toe extensions is a sharp toe pin. When everting the endpart of the graft wall around the frame, the endpart of the graft wall is impaled by a sharp toe pin, thus preventing the endpart of the graft wall from being released from the frame. One endpart of the graft can be inserted into the opening in the frame. The wall of the
10 endpart can be everted around one blunt lip and will be impaled by a sharp toe pin from the outside of the graft wall to the inside of the graft wall. When constructing an anastomosis an intima-intima apposition is achieved. This ensures a tight connection between both blood vessels.

 In another embodiment the present invention is characterised in that both toe
15 extensions are sharp toe pins. These pins impale the walls of both the graft and the recipient artery when constructing an anastomosis.

 In a further embodiment the present invention is characterised in that the oval frame comprises at least one gripper lip for holding the frame using conventional equipment, the gripper lip extending in axial direction of the frame. When placing the
20 frame using conventional equipment, it is necessary to allign the assembly of the frame and the graft mounted on the frame on the right spot on the recipient vessel. When the endparts of the graft are everted around the frame, it is difficult to hold the frame using conventional equipment. The gripper part extends from between the everted endpart of the graft to outside said everted parts and can be held using a conventional pair of
25 pincers. After placing the frame on the right spot and having constructed the anastomosis, the gripper lip can optionally be removed, for example by breaking a weakened part. The frame then remains hidden between the everted endparts of the graft.

 In a further embodiment the present invention is characterised in that the device
30 comprises a wire of a length such that it can circumscribe the periphery of the frame to clamp walls of a target blood vessel as well as the recipient blood vessel between the wire and the frame. Preferably the wire forms a closed loop around the frame, such that the walls of the blood vessel are clamped between the wire and the frame, around the

entire perimeter of the frame. The wire prevents the connected blood vessels from moving apart and slipping off the frame. Furthermore, using a wire prevents the constructed anastomosis from leaking.

In a mounted condition the wire can pass between the axially spaced cheek pins, toe extensions and heel lips. Preferably the wire is an elastic wire, the perimeter of which is smaller than the perimeter of the frame in an unwound state and of which the perimeter in a stretched state is bigger than the perimeter of the frame.

In a further embodiment the present invention is characterised in that the frame comprises at least one frame part of which the radial thickness of the frame exceeds the axial height of the frame. In case the radial thickness exceeds the axial height, said part is so to say ring section shaped, whilst in case the axial height exceeds the radial thickness said part is so to say cylindrical shaped. Providing the frame with a ring section shaped part improves the radial stiffness and reduces locally axial height. Further it is of especial advantage if the 'ring section shaped' part is provided in the heel region. This because at this place the anastomosis will have a sharp angle between the connected vessels, resulting in relatively little space available. Further it provides an easy way of arranging the blunt heel lips close together by forming one of them by folding back over the ring shaped section.

Further the invention relates to a packaging comprising a device according to the present invention, wherein on the one hand the frame is aseptically packed and on the other hand the wire are aseptically packed in said packaging. By packing the frame and the wire aseptically, it is ready to be used in an operation room.

Further the invention relates to an assembly of a vascular anastomotic device according to this invention and a graft, characterised in that the vascular anastomotic device is mounted on one end of the graft, that said end of the graft is everted and that the pins impale the everted part in outward direction, from the outside of the everted part of the graft wall to the inside of the everted part of the graft wall. The assembly can be characterised in that the cheek region frame part is enclosed by everted endparts of the frame. The graft and the frame can be assembled before surgery takes place and before a patient enters the operation room. The time a patient spends in surgery can therefore be minimised.

The assembly can further be characterised in that an incision is made into the said end of the graft, the incision extending from the said end into the longitudinal direction

of the graft, and in that the eversion axis of the everted end extends along a line between the longitudinal end of the incision on the one hand and a point lying axially shifted diametrically opposite said longitudinal end of the incision. On the line, a part of the graft is everted around the frame, the inner side of the graft wall facing outwards.

- 5 The cheek pins can impale the everted part of the graft wall from the outside of the graft wall to the inside of the graft wall.

It is noted that whenever the word 'axial' in this application is meant to be essentially axial while the word 'radial' is meant to be essentially radial. The pins and lips that are extending radially outward can also extend under an angle up to a
10 maximum of 45 degrees, or as far as the function of the extending parts is fulfilled.

Brief description of the drawings

Some embodiments of the vascular anastomotic bonding device according to the
15 present invention will be described in detail with reference to the non-limiting drawings. In the drawings:

Fig. 1 shows a first embodiment of the vascular anastomotic bonding device according to the present invention;

Fig. 2 shows the embodiment of fig. 1, having a different toe region;

20 Fig. 3 shows the embodiment of fig. 1, having another different toe region;

Fig. 4 shows a second embodiment of the vascular anastomotic bonding device according to the present invention;

Fig. 5 shows the embodiment of fig. 4, having a different toe region;

Fig. 6 shows the embodiment of fig. 4, having another different toe region;

25 Fig. 7 shows a third embodiment of the vascular anastomotic bonding device according to the present invention;

Fig. 8 shows the embodiment of fig. 7, having another different toe region;

Fig. 9a shows a transversal cross-section of the embodiment of fig. 1 mounted on a graft and a recipient artery;

30 Fig. 9b shows another transversal cross-section of the embodiment of fig. 1 mounted on a graft and a recipient artery;

Fig 10a shows a longitudinal cross-section of the embodiment of fig. 8, mounted on a graft and a recipient artery;

Fig. 10b shows the same as fig. 10a for the embodiment of fig. 7;

Fig. 11 shows a transversal cross-section of a vascular anastomotic bonding device mounted on a graft;

Fig. 12a shows a step in the process of attaching a vascular anastomotic bonding device to a graft;

Fig. 12b shows a further step in the process of attaching a vascular anastomotic bonding device to a graft; and

Fig. 12c shows another step in the process of attaching a vascular anastomotic bonding device to a graft;

Fig. 12d-e shows three steps in attaching the prepared graft of fig. 12c to a recipient vessel.

Detailed description of the drawings

Fig. 1 shows a first embodiment of the vascular anastomotic bonding device according to the present invention. This embodiment comprises a single, oval shaped frame 2 having a plurality of sharp cheek pins 3 extending outwardly from the cheek region of the frame 2. The frame is divided into a heel region frame part 4, a toe region frame part 5 and two cheek region frame parts that are located between the heel region frame part 4 and the toe region frame part 5. The heel region frame part 4 and the toe region frame part 5 are the two sharply bent areas of the oval frame, as the cheek region frame parts comprise the two slighter bent areas of the oval frame 2. The frame 2 itself is constructed of a sheet-like material. When constructing the frame, the frame can be constructed from one plane of plate-like material. By bending the plate-like material into the desired shape, the frame 2 is obtained. To obtain an oval shaped frame 2, a connection has to be made on one spot, for example by spot welding. The frame 2 has an axial height exceeding the radial thickness of the frame 2.

In the heel region frame part 4 of this embodiment, two blunt heel lips 6, 7 are mounted onto the oval frame 2, extending radially outward from said frame 2. The two blunt heel lips 6, 7 are axially spaced apart over a distance that is equal to the height of the oval frame 2. When in use, between both blunt heel lips 6, 7, one endpart of a graft wall, as well as one wall of a recipient artery is placed (see figure 10b). The axial distance between both blunt heel lips is therefore approximately two times the thickness of an artery wall. In the toe region frame part 5, the frame comprises two

sharp toe pins 8, 9, extending radially outward from the frame 2. Both sharp toe pins 8, 9 are axially spaced apart over a distance that is approximately equal to the height of the oval frame 2.

5 The cheek region frame parts comprise a plurality of sharp cheek pins 3, extending radially outward from the frame 2. The sharp cheek pins 3 are radially spaced apart. In the axial direction, the sharp cheek pins 3 are axially spaced apart over a distance that is approximately equal to the height of the oval frame 2.

10 The frame 2 of fig. 1 comprises three gripper lips 11 that are mounted on the frame 2. These gripper lips 11 are made of the same material as the frame 2, the sharp pins 3 and the blunt lips 6, 7. The gripper lips 11 extend from the frame 2 in an essentially axial direction. When fixating the oval frame 2 to a graft, a surgeon can hold the frame 2 with a pair of pincers. In order not to damage the oval frame 2 and the sharp pins 3 and blunt lips 6, 7 that are extending therefrom, the surgeon will use the gripper lips 11 to get hold of the frame 2. After mounting the frame 2 on the graft and
15 putting the frame in place on the recipient artery, the gripper lips 11 are no longer necessary on the frame 2. Therefore the gripper lips 11 can be removed from the oval frame 2 by breaking at the connecting line 12 to the frame 2 or by breaking at the indentations 50.

Fig. 2 shows the embodiment of fig. 1, having a different toe region. On the
20 upper side of the frame 2 a sharp toe pin 9 is mounted. This sharp toe pin 9 is meant to impale the wall of a blood vessel. On the lower side of the frame 2 a blunt toe lip 13 is mounted. As can be seen in fig. 10a, the blunt toe lip 13, 29 causes that an everted end part of the graft is pressed with inner side tissue of the wall of the graft against inner side tissue of the wall of the recipient artery 31. Contact of the toe extensions with
25 blood is thus prevented and mutual growing together of the wall tissues is promoted.

Fig. 3 shows the embodiment of fig. 1, having another different toe region. In this embodiment the toe region frame part 5 comprises two blunt toe lips 13, 14. When constructing an anastomosis, one of the two blunt toe lips 13, 14 will be placed on the inside wall of the recipient blood vessel, while the other one of the two blunt toe lips
30 13, 14 will be placed adjacent to the inside wall of the graft. The two blunt toe lips secure the toe region frame part into place without impaling the graft and the recipient artery.

Fig. 4 shows a second embodiment of the vascular anastomotic bonding device 1 according to the present invention. This embodiment has a frame 2 of which the height in axial direction is much smaller than the radial thickness of the frame 2 in radial direction. In this embodiment, the heel region frame part 4 comprises two blunt heel lips 16, 17, which have been formed from a plate-like material. The upper blunt heel lip 17 has been formed by bending the produced part of the lower blunt heel lip 16. Both blunt heel lips 16, 17 are axially spaced from each other. The distance between both blunt heel lips 16, 17 in the axial direction is approximately equal to two times the thickness of the wall of the blood vessel.

The toe region frame part 5 of the embodiment of fig. 4 comprises two sharp toe pins 18, 19 that extend in a radially outward direction. Both sharp toe pins 18, 19 have been formed from the plate-like material. The upper sharp toe pin 19 has been formed by bending the producing part of the lower sharp toe pin 18. The sharp ends of both sharp toe pins 18, 19 are axially spaced over a small distance to accomodate a wire or elastic band placed in that space.

The cheek region frame parts comprise sharp cheek pins 20, extending outwardly from the oval frame 2. The oval frame 2, as well as the sharp cheek pins 20 extending from the cheek region frame parts are situated in the same plane.

Fig. 5 shows the embodiment of fig. 4, having a different toe region. Instead of a sharp toe pin 18, a blunt toe lip 21 extends from the toe region frame part 5 in a radially outward direction. A sharp toe pin 19 which starts from the produced part of the blunt toe lip 21, is bent to form an axial distance between the sharp toe pin 19 and the blunt toe lip 21.

Fig. 6 shows the embodiment of fig. 4, having another different toe region. The toe region frame part 5 comprises two blunt toe lips 21, 22. The upper blunt toe lip 22 is formed from the plane by bending the upper blunt toe lip 22 towards the lower blunt toe lip 21, thus creating a distance between the upper 22 and lower blunt toe lip 21 in an axial direction.

Fig. 7 shows a third embodiment of the vascular anastomotic bonding device 1 according to the present invention. This embodiment shows an oval shaped frame 2 comprising a heel region frame part 4, a toe region frame part 5 and two cheek region frame parts located between the heel region frame part 4 and the toe region frame part 5. The heel region frame part 4 comprises two blunt heel lips 24, 25, that extend from

the heel region 4 frame part in a radially outward direction. Both blunt heel lips are axially spaced to each other. In the heel region the frame comprises a sheet-like material of which the axial height is smaller than the radial thickness. In both cheek region frame parts and the toe region frame part 5, the frame 2 comprises a sheet-like material of which the radial thickness is smaller than the axial height. On the edge 28 between the heel region frame part 4 and the both cheek region frame parts, the frame parts are linked together.

Fig. 8 shows the embodiment of fig. 7, having another different toe region. In the toe region, the toe region frame part comprises one blunt toe lip 29 and a sharp toe pin 27, extending radially outward from the toe region frame part 5. On the upper side of the toe region frame part 5, the sharp toe pin 27 is mounted. In a state of use, the sharp toe pin 27 impales the graft wall from the outside to the inside thereof. On the lower side of the toe region frame part 5, the blunt toe lip 29 is mounted. In a state of use, the outer graft wall is everted around the blunt toe lip 29.

The embodiments according to figures 3 and 6 are especially intended for a side - to - side anastomosis. The embodiments according to figures 1, 2, 4, 5, 7 and 8 are especially intended for an end - to - side anastomosis. However use of the embodiments of figures 1, 2, 4, 5, 7 and 8 for a side - to - side anastomosis or use of the embodiments of figures 3 and 6 for an end - to - end anastomosis is also possible.

Fig. 9a shows a transversel cross-section along line IXa of the embodiment of fig. 1 mounted on a graft 30 and a recipient artery 31. One end of the graft 30 is everted around the frame 2. The graft 30 has been inserted through the opening 32 in the frame 2, the outer wall 33 of the graft 30 being adjacent to the inner wall of the frame 2. The inserted end of the graft 30 is then everted around the frame 2, the outer wall of the graft being adjacent to the outer wall of the frame 2. The sharp cheek pins 3 extending from the cheek region frame parts impale the graft wall 30 from the outside of the graft wall 30 to the inside of the graft wall 30. The cross-section of Fig. 9a has been made near the toe region frame part 5, on a line through both sharp pins 3 extending from the upper side of the frame 2. The inner wall of the recipient blood vessel is adjacent to the inner wall of the graft, thus establishing an intima-intima apposition. The wall of the recipient blood vessel 31 is impaled by the sharp pins from the inside 34 of the wall 31 to the outside of the wall 31.

To secure the constructed anastomosis, a wire 35 or an elastic band has been placed around the anastomosis surface. The wire 35 or elastic band is held in place by the sharp pins 3 extending from the frame. Therefore the wire 35 or elastic band cannot slide off from between the sharp pins 3. An elastic band also ensures a certain pressure on the frame 2, thus clamping both the graft 30 and the recipient blood vessel 31 together. It is therefore for the graft 30 and the recipient blood vessel 31 difficult to slide off the sharp pins 3 and a leak-free apposition between the graft and the recipient artery is obtained.

Fig. 9b shows another transversel cross-section along line IXb of the embodiment of fig. 1 mounted on a graft 30 and a recipient artery 31. The cross-section has been made in the cheek region frame part, on the line through the sharp cheek pins 3 that are axially spaced from one another. In fig. 9b, both axially spaced sharp cheek pins 3 are shown, impaling the graft 30 and the recipient blood vessel 31.

Fig 10 shows a longitudinal cross-section of the embodiment of fig. 8, mounted on a graft 30 and a recipient artery 31. The embodiment of the fig. 8 is shown in a state of use, while connected to a graft 30 and a recipient artery 31. The heel region frame part 4 of the vascular anastomotic device 1 comprises two blunt heel lips 24, 25. One end 36 of the graft 30 is placed between the two blunt heel lips 24, 25, the inner side of the graft wall being adjacent to the upper blunt heel lip 25. In the toe region the graft is everted around the lower blunt toe lip 29 extending from the toe region frame part. The outer end of the graft 30 is impaled by the sharp toe pin 27 extending from the toe region frame part. The graft is impaled from the outside of the graft wall to the inside of the graft wall.

Fig 10b shows in longitudinal cross section an end to side anastomosis like the one of fig 10a, however in this case the vascular anastomotic device of fig 7 is used. The difference thus essentially lies in the sharp lower toe pin 26 of fig 10b versus the blunt toe lip 29 of fig 10a. As the sharp lower pin 26 and sharp upper toe pin 27 both impale through the everted part 99 of the graft vessel, the cross section X can have a larger surface than in the situation of figure 10a.

For both figures 10a and 10b applies that before mounting of the graft 30 to the artery 31 (recipient vessel), the artery 31 must be provided with an opening 98 if this is not already present. For this purpose, an incision is made in the longitudinal direction of the recipient artery 31 from a first end to a second end. The upper side of the lower

blunt heel lip 24 extending from the heel region frame part lies against the inner side of the wall of the recipient artery 31 in the first end of the incision. The outer wall of the recipient artery 31 in the first end of the incision is adjacent to the outer wall of the graft 30. Both blunt heel lips are placed on the inside of the graft 30 and the recipient artery 31 respectively. Because both blunt heel lips lie against the wall of the graft or the recipient artery, they will not obstruct the bloodflow in the respective arteries.

According to fig 10a, in the toe region, the second incision end of the recipient artery 31 is placed between the everted wall part of the graft 30 and the sharp pin 27 that is extending from the toe region frame part. Between the lower blunt lip 29 and the sharp pin 27, the inner wall of the graft 30 is adjacent to the inner wall of the recipient artery 31, thus forming an intima-intima apposition.

According to fig 10b, in the toe region, the second incision end of the recipient artery 31 abuts against the everted part 99 of the graft 30. The sharp toe pin 26 lies against the inside of the wall of the recipient vessel 31. However, it is possible to impale the lower, sharp toe pin through the zone 97 of the recipient artery from inside the wall tissue of artery 31. This will result in an intima - intima contact of graft wall and recipient artery wall, as is also the case in figure 10a. This reduces the occurrence of thrombosis formation.

In both fig 10a and 10b, the graft 30 and the recipient artery 31 are secured by a wire 35 or an elastic band, which is placed around the frame. The wire 35 or elastic band prevents both the graft 30 and the recipient artery 31 from being released. In the heel region 4 the wire 35 or elastic band is placed between the axially spaced blunt heel lips 24, 25, thus preventing the graft 30 and the recipient artery 31 from being released. In the toe region, the wire 35 or elastic band is placed between the upper sharp toe pin 27 and the outer wall of the recipient artery 31, thus preventing the recipient artery 31 from being released. The wire 35 is placed between the upper sharp toe pin 27 and the lower blunt lip 29 to prevent the wire 35 from sliding away from the frame.

Fig. 11 shows a transversal cross-section of a vascular anastomotic bonding device mounted on a graft 30. The vascular anastomotic device 1 can be mounted on a graft 30 before surgery. This minimises the time that is needed for surgery. Fig. 11 shows a combination of a graft 30 and a vascular anastomotic bonding frame 2. The graft 30 has been inserted through the opening 32 in the frame 2 and has been everted around the frame 2. The frame 2 is located adjacent to the outer wall 37 of the graft.

The sharp pins 3 that extend from the frame 2 impale the graft 30 from the outside 37 of the wall to the inside 38 of the wall.

Referring to fig 12a - 12c and fig 12d - 12f, a method for preparing a graft for an anastomosis, respectively, a method of establishing an anastomosis will be elucidated.

A first step a) is that one provides or obtains a graft. The graft can be an artificial one or can originate from an animal or human donor. In general the graft will originate from the patient himself, for example from his arm, leg or chest. In this last case one will in general obtain the graft by a surgical procedure shortly before establishing the anastomosis.

After step a) or before step a) there will be a step b) of providing a vascular anastomotic device according to the invention.

After step a) and b), there follows step c), d) and e) (see also claim 16) which can be performed in arbitrary order.

With reference to fig 12b, one makes in a step c) an incision 95 in an end part 96 of the graft 30. This can be done by using a pair of scissors 40 or another suitable surgical instrument. The graft 30 can be supported in the meantime by means of pincers 39. The incision 95 is made in essentially the longitudinal direction.

With reference to fig 12a, one inserts in a step d) the end part 96 through the central opening of the frame 2 of the anastomotic device according to the invention. While inserting the graft 30 through the frame 2, the frame 2 can be held by a person using conventional equipment, such as a pair of pincers 39. Gripper lips 11 have been provided for easy gripping and handling of the frame 2. Also one outer end of the graft 30 can be held by using conventional equipment, such as a pair of pincers 39. Step d) can take place before or after step c).

In a subsequent step e), which in case step c) is done before step d), can take place before, after or simultaneously with step d), one inserts one of the blunt heel lips, called the upper heel lip, through the incision into the graft, and arrange the frame such that both the blunt heel lips extend in longitudinal direction of the graft away end part 96. The zone of the wall of graft lying in the extension of the incision will thus lie between the heel lips 6,7.

Fig. 12c shows final steps in the process of attaching a vascular anastomotic bonding device 1 to a graft 30. While holding the vascular anastomotic bonding frame 2 with a pair of pincers 39, the end of the graft 30 is everted and placed over the sharp pins 3, 8, 9 that extend from the frame 2. Only the part of the graft 30 that is inserted into the opening into the frame is everted. The eversion axis of the everted end extends along a line between the longitudinal end of the incision on the one hand and a point lying axially shifted diametrically opposite the longitudinal end of the incision. The wall of the graft 30 is being impaled from the outside to the inside by these sharp pins 3. As the everted inside of the wall of the graft is facing outward, the graft 30 can be attached to a recipient artery (not shown) during a surgery. In this respect one can recognise a step f) in which the sharp toe extensions 8, 9 (one or two, which might be the case) are impaled through the everted part 99, and a step g) in which the cheek pins 3 are impaled through the everted part 99. Step g) can be carried out before step f) but preferably step f) is carried out before step g). With respect to step g) it is preferred to start with the cheek pins close to the heel region and to end with the cheek pins in the middle of the respective cheek.

After having prepared the graft or having obtained a prepared graft one can start establishing the anastomosis itself. This is illustrated with reference to figures 12d - 12e.

A first step in establishing the anastomosis itself is making an opening 98 in the recipient wall of the recipient artery 31. It is to be noted that this opening 98 can be made before, after or simultaneously with preparing the graft (figures 12a - c). The opening 98 is preferably an incision or cut extending in longitudinal direction of the artery 31, see figure 12d.

In a next step, one hitches the blunt heel lip lying outside the graft, called the lower heel lip, through the opening 98 into the recipient vessel artery 31, behind the wall tissue of this artery 31 (see for example figures 10a and 10b).

Subsequently, one hitches the lower toe extension through the opening 94, into the recipient vessel 31. In case this lower toe extension is a sharp toe pin, one can also choose for impaling this toe pin from inside the wall tissue through outside the wall tissue.

Next subsequently, one will impale the cheek pins from inside the recipient vessel through its wall tissue to outside the recipient vessel. The now resulting condition is shown in fig. 12e.

Preferably the cheek pins near the heel region are first impaled and the cheek
5 pins in the middle of the cheeks are impaled last. Further, preferably one impales first the cheek pins of one cheek side and than the cheek pin of the other cheek side.

Referring to fig 12f, one clamps the wall tissue of the graft 30 and artery 31 onto each other by providing a tensioning wire 35 around the frame with the clamped wall tissue between the wire 35 and frame 2.

10 Each of the anastomosis devices described above are preferably single piece devices, which are formed by spark erosion or laser cutting from a sheet of material, and bend to the final shape. Material is preferably stainless steel, Phynox or nickel titanium alloy, and the like. The size of the device may vary to comply with different sized vessels.

15 Hemostasis in the anastomosis constructed using the anastomosis devices is preferably obtained by applying the wire 35 described above, other methods, like the application of glue or sealant may be used instead. The wire 35 can be a silicon band.

Although the invention principally concerned coronary bypass surgery, the anastomosis device can also be used in other type of anastomosis construction
20 procedures. For example, the construction of a femoral-femoral bypass, subclavian-carotid bypass, for organ transplants in plastic surgery, gastro-intestinal, bowel surgery, and the like. The graft used on the anastomosis device may be natural, for example the internal mammary artery, the radial artery, the gastro-epiploic artery, the saphenous vein, and synthetic.

25 The anastomosis device can be used in all possible coronary artery bypass procedures, like open chest procedures on the arrested heart, open chest procedures on the beating heart, closed chest procedures on beating or arrested heart. As only conventional instruments, like forceps and needle-holders, are used to apply the anastomotic device, the anastomotic device can especially be used in closed chest
30 bypass surgery using master-slave systems in which the movements of the surgeon's hand in the master are copied to the pincers of the slave-system that is located in the chest.

While the invention has been explained using the preferred embodiments, it will be apparent to one skilled in the art that various changes and modifications can be performed, without departing from the present invention.

Claims

1. Vascular anastomotic device (1) comprising a single oval frame (2) for constructing an anastomosis between two blood vessels, the oval frame having a heel region frame part, a toe region frame part and two cheek region frame parts,
5 region frame part, a toe region frame part and two cheek region frame parts,
characterised in that
- the heel region frame part (4) comprises two blunt heel lips (6, 7),
 - the cheek region frame parts each comprises a plurality of cheek pins (3),
 - the toe region frame part (5) comprises two toe extensions (8, 9, 13, 14)
- 10 wherein the two heel lips (6, 7) are axially spaced apart and extend radially outward from the frame (2), wherein the two toe extensions (8, 9, 13, 14) are axially spaced apart and extend radially outward from the frame (2), and wherein the cheek pins (3) are sharp pointed and extend radially outward from the frame (2).
- 15
2. Vascular anastomotic device 1) according to claim 1, **characterised in that** the cheek region frame part comprises at least two cheek pins (3), preferably at least three cheek pins (3), more preferably at least four cheek pins (3).
- 20
3. Vascular anastomotic device (1) according to claim 1 or 2, **characterised in that** at least two of the cheek pins (3) are spaced in an axial direction.
4. Vascular anastomotic device (1) according to one of the preceeding claims, **characterised in that** at least one of the toe extensions is a blunt toe lip (13),
25 preferably both toe extensions being blunt toe lips.
5. Vascular anastomotic device (1) according to one of the claims 1 - 4, **characterised in that** at least one of the toe extensions is a sharp toe pin (9), preferably both toe extensions being sharp toe pins (8, 9).
- 30
6. Vascular anastomotic device (1) according to one of the preceeding claims, **characterised in that** the oval frame (2) comprises at least one gripper lip (11) for

holding the frame (2) using conventional equipment, the gripper lip (11) extending in axial direction of the frame (2).

7. Vascular anastomotic device (1) according to one of the preceeding claims,
5 **characterised in that** the device comprises a wire (35) of a length such that it can circumscribe the periphery of the frame (2) to clamp walls of a blood vessel between the wire (35) and the frame (2).
8. Vascular anastomotic device (1) according to one of the preceeding claims,
10 **characterised in that** the device comprises a wire (35) of a length such that it can circumscribe the periphery of the frame (2) in closed loop to clamp walls of a blood vessel between the wire (35) and the frame (2).
9. Vascular anastomotic device (1) according to claim 7 or 8, wherein in mounted
15 condition the wire (35) passes between the axially spaced cheek pins (3), toe extensions (8, 9) and heel lips (6, 7).
10. Vascular anastomotic device according to claim 7, 8 or 9, **characterised in that**
20 the wire is an elastic wire (35), the perimeter of which is smaller than the perimeter of the frame (2) in an unstretched state and of which the perimeter in a stretched state is bigger than the perimeter of the frame.
11. Vascular anastomotic device according to one of the preceeding claims,
25 **characterised in that** the frame (2) comprises at least one framepart of which the radial thickness of the frame (2) exceeds the axial height of the frame (2).
12. Packaging comprising a device according to one of the claims 7 - 11, wherein on
the one hand the frame (2) is aseptically packed and on the other hand the wire (35) are
aseptically packed in said packaging.
30
13. Assembly of a vascular anastomotic device according to one of the claims 1 - 6
and a graft (30), **characterised in that** the vascular anastomotic device (1) is mounted
on one end of the graft (30), that said end of the graft (30) is everted and that the pins

impale the everted part in outward direction, from the outside of the everted part of the graft wall to the inside of the everted part of the graft wall.

14. Assembly according to claim 13, **characterised in that** the cheek region frame
5 part is enclosed by everted endparts of the graft (30).

15. Assembly according to claim 13 or 14, **characterised in that** an incision is made
into the said end of the graft, the incision extending from the said end into the
longitudinal direction of the graft, and in that the eversion axis of the everted end
10 extends along a line between the longitudinal end of the incision on the one hand and a
point lying axially shifted diametrically opposite said longitudinal end of the incision.

16. Method of preparing a graft (30) for an anastomosis, the method comprising the
steps:

15 a) providing or obtaining a graft (30)
b) providing a vascular anastomotic device according to one of the claims 1-11
c) making an incision in an end part of the graft, the incision extending from the end
in longitudinal direction of the graft
d) inserting the end part of the graft through the central opening of the frame of the
20 anastomotic device
e) inserting one of the blunt heel lips through the incision into the graft and
arranging the frame such that the blunt heel lips extend in longitudinal direction
of the graft and that a part of the wall of the graft, that lies in the prolongation of
the incision, lies in between the blunt lips.
25 f) impaling the at least one toe extension through said everted part.
g) impaling the cheek pins through said everted part.

17. Method of preparing a graft according to claim 16, wherein step f) is carried out
before step g).
30

18. Method of preparing a graft according to one of the claims 16-17, wherein, for
each cheek region, one impales the cheek pins near the heel region through said everted
part before impaling the other cheek pins of the respective cheek region.

19. Method of preparing a graft according to one of the claims 16-18, wherein, for each cheek region, the cheek pins, lying in about the middle between the toe region and cheek region, are impaled after the other cheek pins of the respective cheek region.

5

20. Method of making an anastomosis, the method comprising:

- the method of preparing a graft according to one of claims 16-19 or providing a graft prepared with an anastomotic device according to one of claims 1 - 11;
- making an opening into the wall of a recipient artery, the opening preferably being a cut extending in longitudinal direction of the recipient artery,
- hitching the blunt heel lip lying outside the graft through the opening into the recipient vessel behind wall tissue of the recipient vessel,
- hitching the lower toe extension through the opening into the recipient vessel behind wall tissue of the recipient vessel, or possibly impaling this lower toe extension through the wall tissue from inside to outside,
- impaling the cheek pins from inside the recipient vessel through its wall tissue to outside the recipient vessel.

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21. Method of making an anastomosis according to claim 20, wherein, for each cheek region, one impales the cheek pins near the heel region through the wall of the recipient artery before impaling the other cheek pins of the respective cheek region.

25

22. Method of making an anastomosis according to claim 20 or 21, wherein, for each cheek region, the cheek pins, lying in about the middle between the toe region and cheek region, are impaled after the other cheek pins of the respective cheek region.

30

23. Method of making an anastomosis according to one of the claims 20-22, wherein one impales first the cheek pins of one cheek region and then the cheek pins of the other cheek region.

24. Method of making an anastomosis according to one of the claims 20-23, wherein

one clamps the everted part of the wall of the graft and the wall part of the recipient artery circumscribing the opening onto each other and onto the frame by means of a wire enclosing the periphery of the frame.

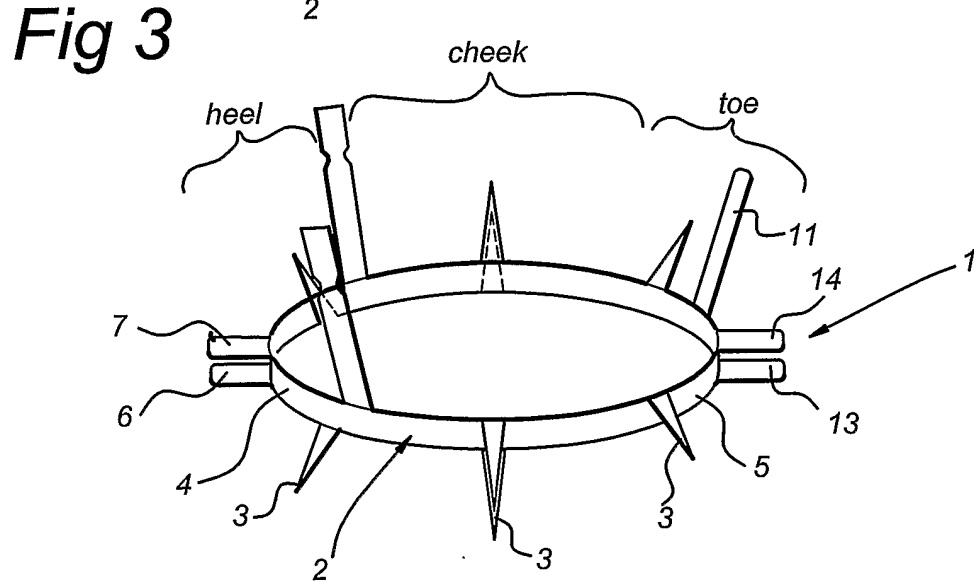
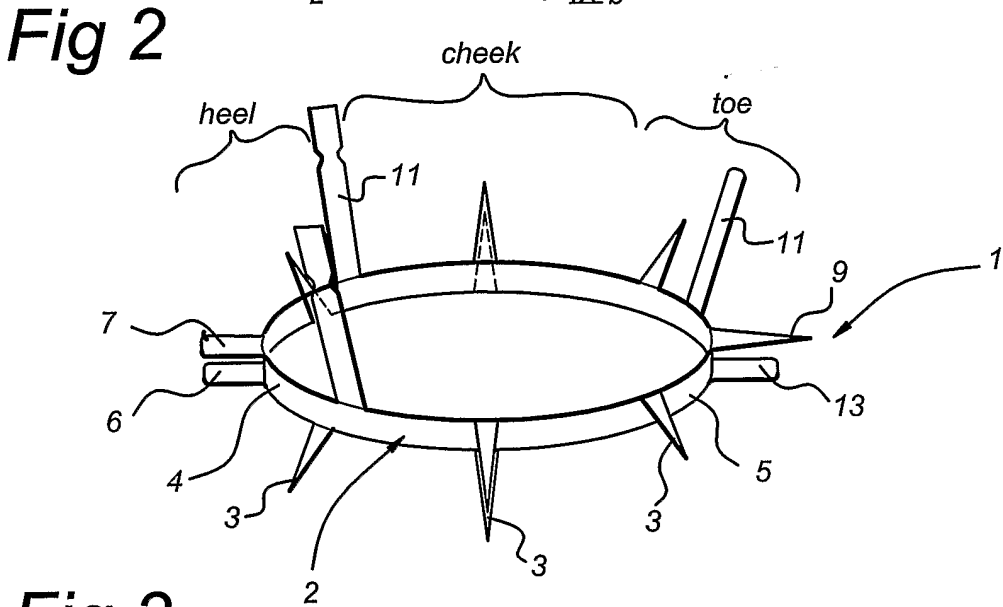
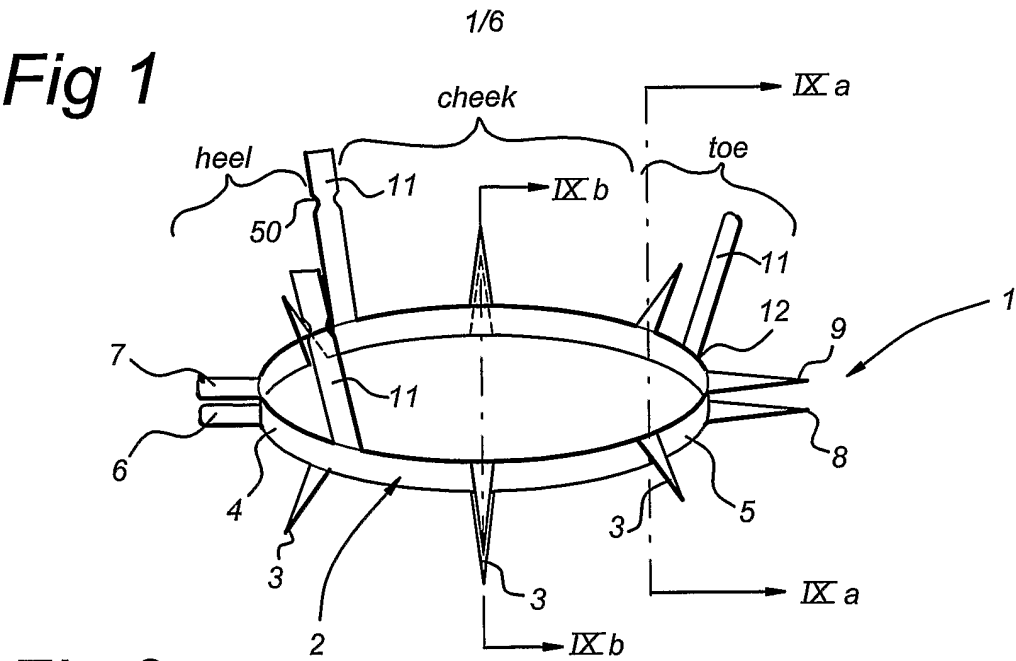


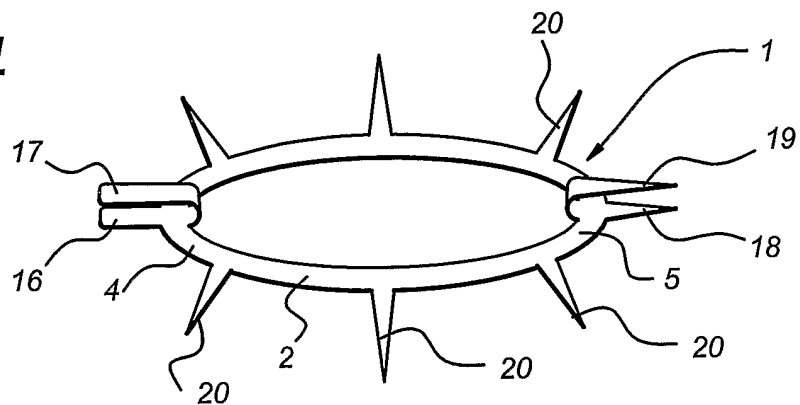
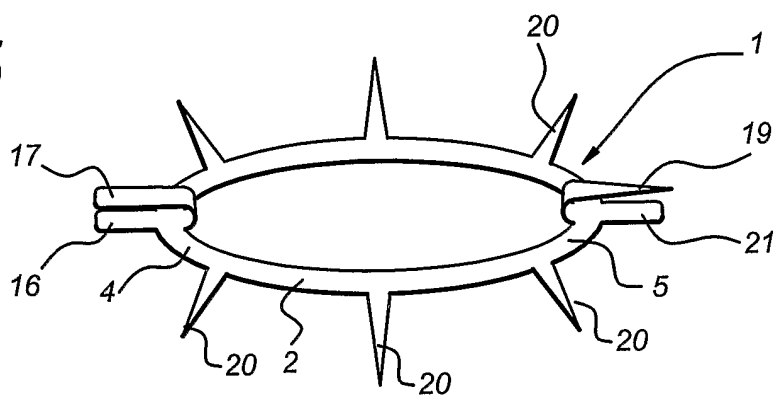
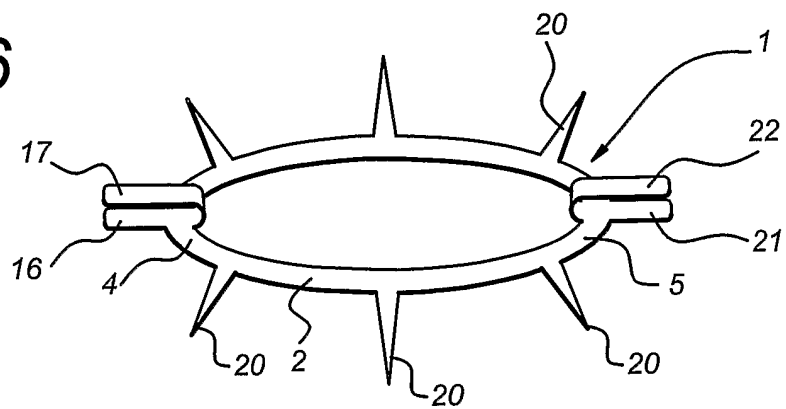
Fig 4**Fig 5****Fig 6**

Fig 7

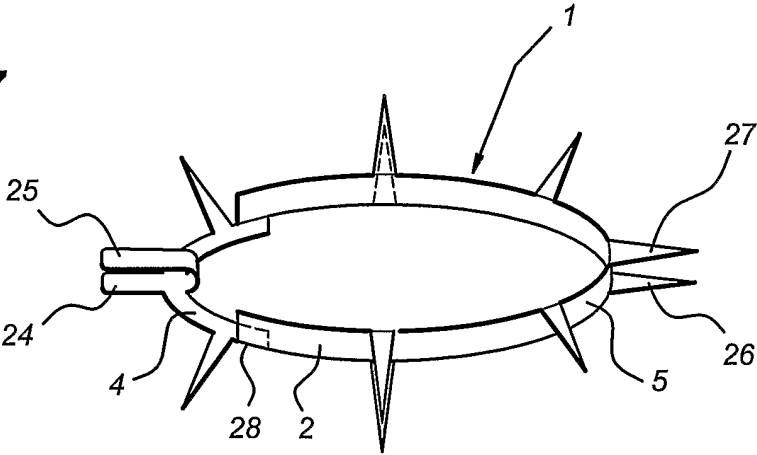


Fig 8

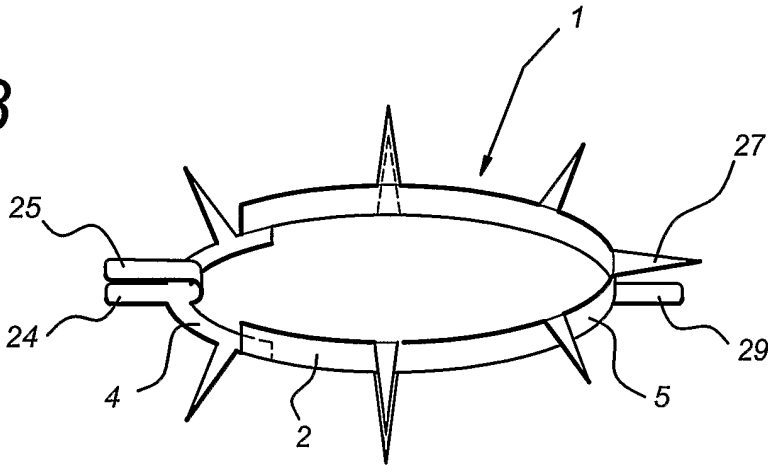


Fig 9a

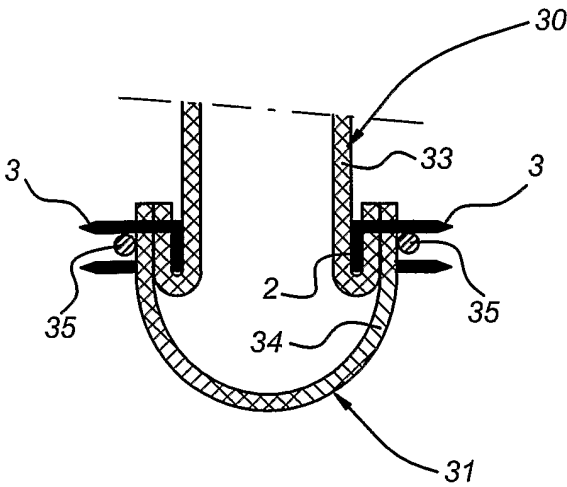


Fig 9b

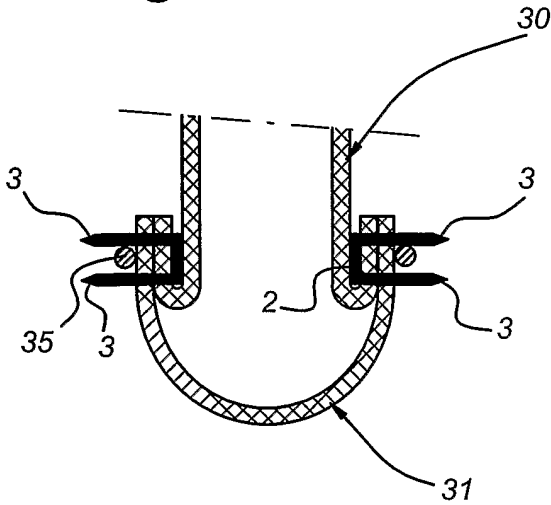


Fig 10a

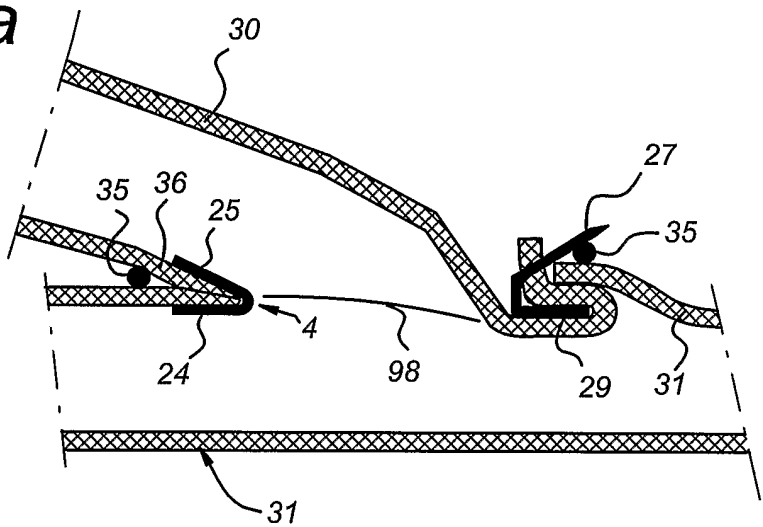


Fig 10b

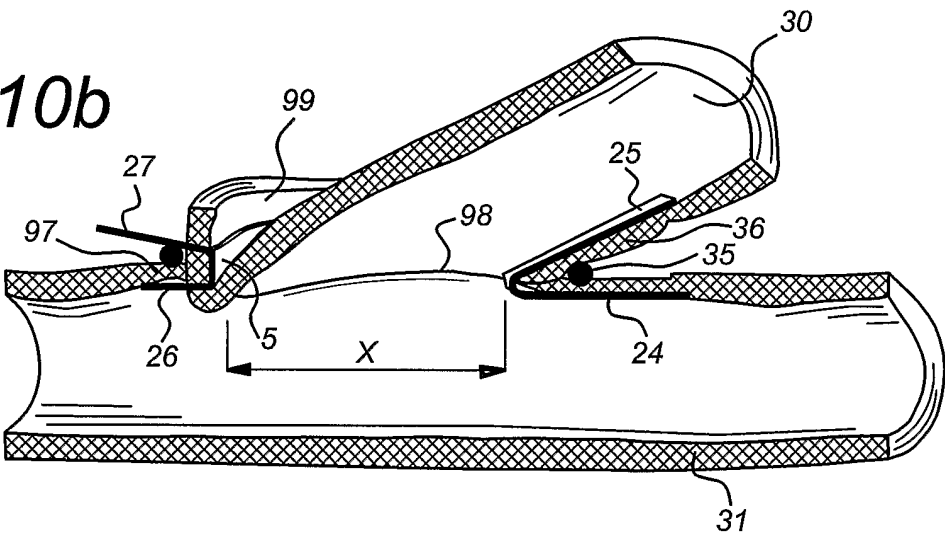


Fig 11

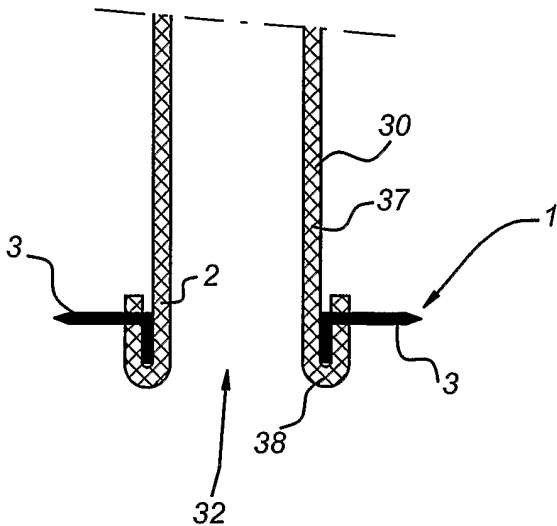
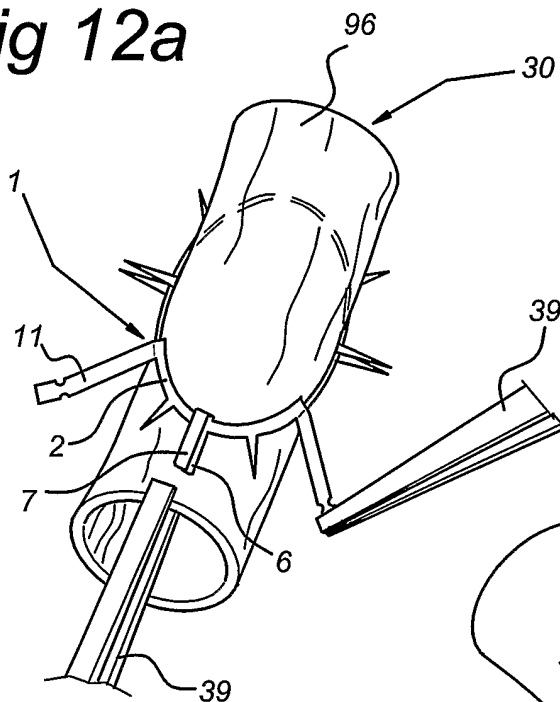
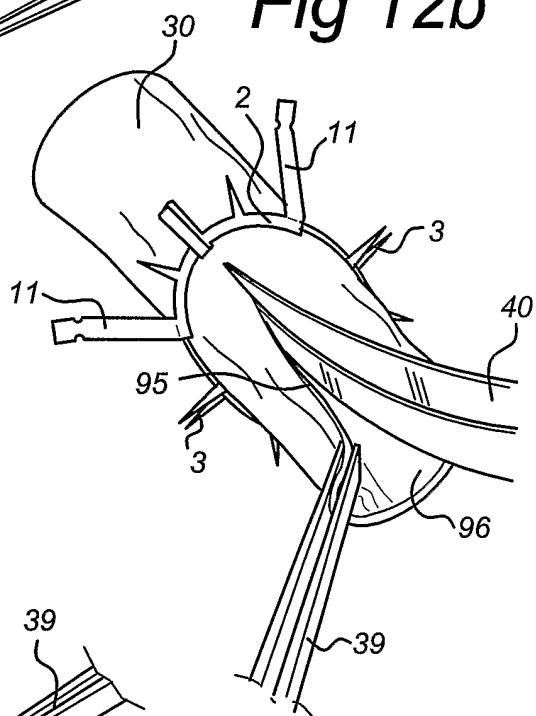
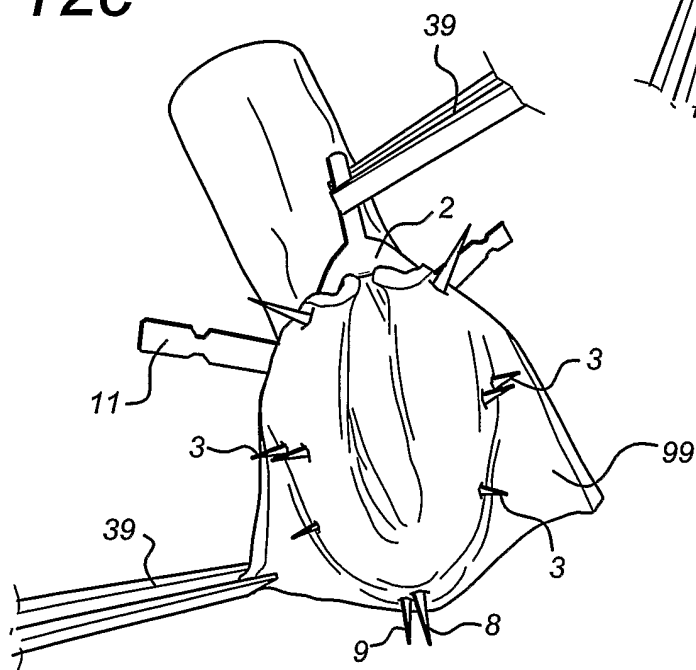
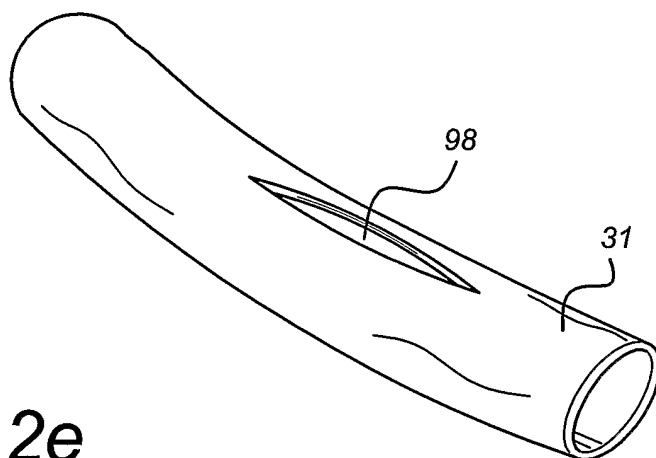
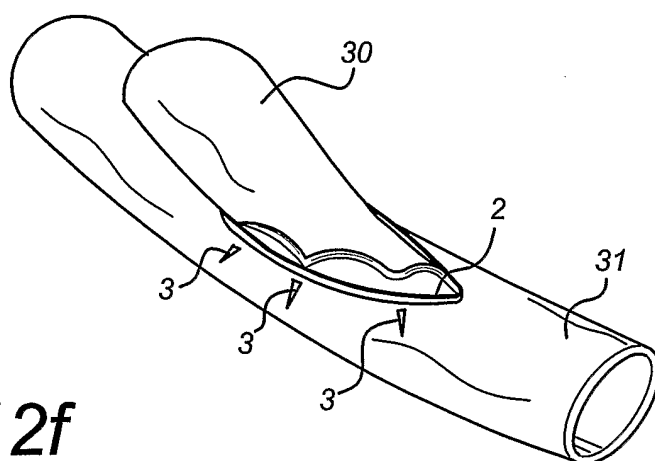
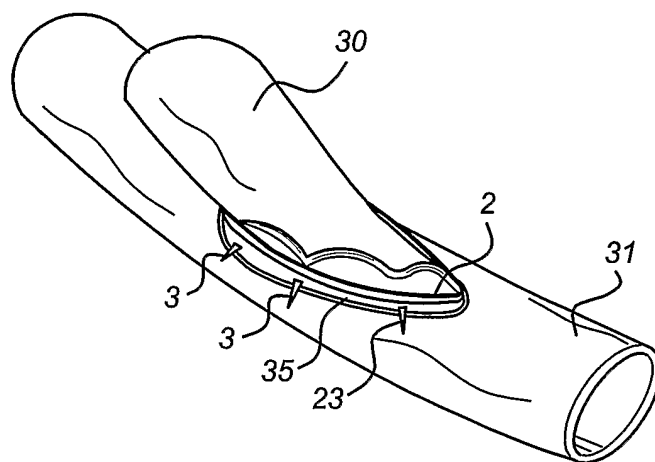


Fig 12a**Fig 12b****Fig 12c**

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Fig 12d*Fig 12e**Fig 12f*

INTERNATIONAL SEARCH REPORT

PCT/NL 03/00041

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/11

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 7 A61B

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 179 849 B1 (HENDRICKSEN MICHAEL ET AL) 30 January 2001 (2001-01-30) column 6, line 31 - line 67 column 7, line 1 - line 35 figures 14,15	1
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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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.

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Date of the actual completion of the international search

7 March 2003

Date of mailing of the international search report

14/03/2003

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PCT/NL 03/00041

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

PCT/NL 03/00041

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 13-24
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 II Observations where unity of invention is lacking (Continuation of item 2 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.
- ☐ No protest accompanied the payment of additional search fees.

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