(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 May 2002 (10.05.2002)

PCT

(10) International Publication Number
WO 02/36193 A1

(51) International Patent Classification[7]: A61M 25/00, 27/00

(21) International Application Number: PCT/SE01/02362

(22) International Filing Date: 26 October 2001 (26.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2000 5469 30 October 2000 (30.10.2000) NO

(71) Applicant and
(72) Inventor: NILSSON, Per, Erik [SE/SE]; Östra Lärkvägen 2, S-236 42 Höllviken (SE).

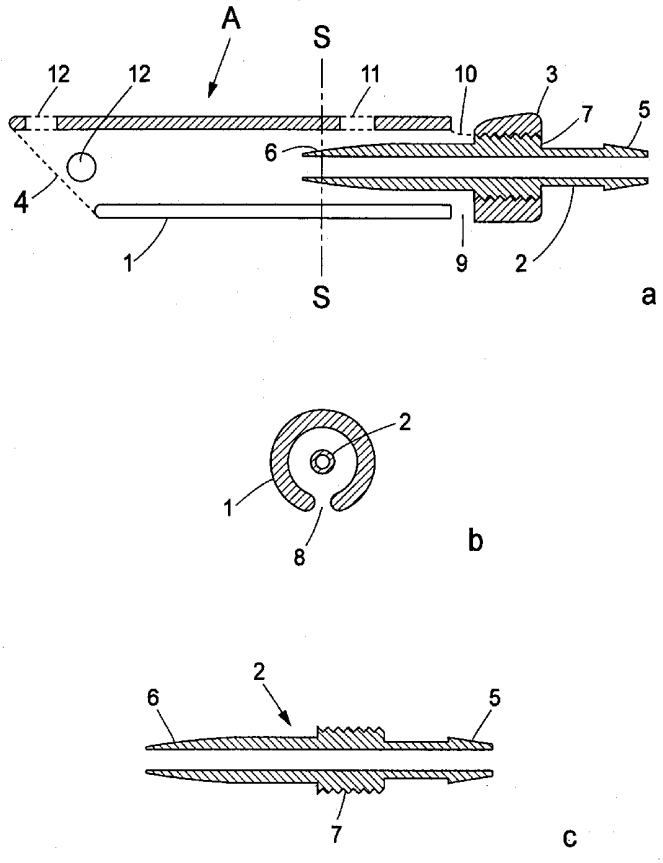
(74) Agent: ALBIHNS MALMÖ AB; P.O. Box 4289, S-203 14 Malmö (SE).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EC, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR PHYSIOLOGICAL DRAINAGE



(57) Abstract: The invention concerns a device (A) that can be used to create a new channel to conduct fluid from a fluid-conducting catheter to a blood vessel without contact between the device (A) or the catheter and the blood flow in the blood vessel. The device (A) comprises of an outer essentially tube-like part (1) with a first (3) and a second (4) end, and an inner essentially tube-like part (2) with a first (5) and a second (6) end. The tube-like parts are joined with essentially parallel axes and connected to each other close to the first end (3) of the outer tube-like part (1) and at the intermediate part (7) of the inner tube-like part (2). The outer tube-like part (1) has a lengthwise slit along part of its length from the second end (4) to let part of the blood vessel enter. The first end (5) of the inner tube-like part (2) is arranged to be conncted to the catheter and teh second end (6) of teh inner tube-like part (2) is wholly or partly surrounded by the outer tube-like part (1). The invention also concerns the use of such a device to connect a CSF conducting catheter to the deep neck vein of a human and applicator device and a support instrument facilitating the surgical procedure of applying the device (A).

WO 02/36193 A1

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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.

SYSTEM AND METHOD FOR PHYSIOLOGICAL DRAINAGE

Field of invention

This invention concerns a device to be applied on a blood vessel in such a way that it creates a new channel together with the vessel. The new channel runs essentially parallel with the vessel and conducts fluid from a fluid-conducting catheter to the blood vessel without contact between the device or the fluid conducting catheter and the blood flow in the vessel. The invention also comprises an instrument for the application of the device and a support instrument for the vessel during an operation connected to the application. Such a device is of particular use when treating (shunting) hydrocephalus, where it is desirable to create a channel to conduct CSF (cerebrospinal fluid) from the fluid conducting catheter to the deep neck vein without contact between the device, the catheter or any foreign body and the blood flow in the vessel.

The invention also comprises the use of such an invention to connect the CSF conducting catheter to the human deep neck vein and a way to apply the device.

Background

In individual patients the natural resorption of CSF is blocked or reduced because of malformation or following bleeding or infection. If the missing natural resorption is not compensated for the patient will develop hydrocephalus (increased intracranial pressure with brain damage). To avoid this the patient usually needs a lifelong drainage of CSF to the venous system or the abdomen.

When the infusion of fluid in the venous system is long-lasting as when shunting hydrocephalus there is an increased risk of thrombosis or infection caused by the foreign material of the catheter. Thrombosis lead to stop in the blood flow and infection makes it necessary to remove the catheter and treat with antibiotics before putting in a new catheter. The problem with thrombosis is reduced by letting the fluid conducting catheter end in the right atrium of the heart where the fast blood flow reduces the risk of thrombosis, but the risk for infection is still the same.

In the end of the 50's, when useful materials for catheters and pressure regulating valves became available, the most common method became draining CSF to the heart. When draining to the heart the catheter runs from the ventricular system of the brain under the skin and via a pressure or flow regulating valve that prevents backflow and further down under the skin into the deep neck vein and into the right atrium of the heart. Trials have been done where the catheter has been connected to a narrow branch of the neck vein in the hope that the fluid from the brain would prevent contact between the catheter and the blood. However, this did not function well.

To be able to regulate the blood flow from the brain and the pressure in the brain the veins in the neck are soft and have a variable volume. This results in back flow of blood, thrombosis and stop of the flow when the catheter ends in the blood in such a vein.

Today the usual method is draining to the abdomen. This removes the risk of thrombosis and is of great advantage when shunting children, as a long catheter in the abdomen can compensate for growth. In adult patients, draining to the abdomen has an important disadvantage with overdrainage and siphon effect caused by the increased pressure gradient in upright position compared with lying down. This problem is not fully solved by using antsiphon valves or other types of pressure and flow regulating valves. Another disadvantage in shunting to the abdomen is that abdominal disease, especially infection, may hinder the use of the shunt.

Obviously there exists a need to improve the methods now in use for shunting hydrocephalus. The ideal method would be to drain CSF to the sagittal sinus, the stiff vein in the middle inside the skull bone, and trials with this are in progress. However, with the conventional shunt systems of today it should be easier and less risky to find a way to drain to the deep neck vein and from there to the heart, but then without contact between the blood and any foreign material. In this way a catheter in the heart would be avoided as well as the use of X-ray, ECG or other means for this positioning.

Prior art includes a number of patent documents.

US 3,894,541 (El-Shafei et al.) discloses a method of treating hydrocephaulus preventing the contact between a shunting catheter and the circulating blood by inserting a venous end of a venous catheter into the proximal segment of the ligated neck vein against the direction of blood flow.

US 3,738,365 (Schulte) discloses an extensible catheter comprising a flexible metallic helical spring and slidable conduit sections.

US 3,769,982 (Schulte) discloses a physiological drainage system with closure means responsive to downstream suction comprising a flexible diaphragm extending across a control cavity.

Summary of the invention

Therefore an object of the present invention is to provide a device for conducting fluid from a fluid-conducting catheter to a blood vessel without contact between the device or the catheter and the blood flow in the vessel and to provide instrumentation for the application and a method for applying the device. When there is no contact between the blood and the foreign material the risk of thrombosis is diminished and infection is reduced.

In accordance with the invention this object is obtained by the means of the features of the device that are evident in the independent claim 1, of the applicator in claim 12, of the support instrument in claim 15, and of the method of applying in claim 13. Additional objectives and advantages are provided by means of the features in the dependent claims.

The invention concerns a device that can be used to conduct fluid, preferentially CSF, from a fluid-conducting catheter to a blood vessel without contact between the device or the catheter and the blood flow in the blood vessel. This can be obtained by applying the device on a blood vessel in such a way that a part of this blood vessel, in cross section, creates a new, narrow channel with invariable volume and essentially running in parallel with the length of the blood vessel and the blood flow. CSF flows into this channel via a fluid-conducting catheter that is connected to the device and out of this channel via its opening into the vein. Because the channel has a constant volume and is filled with CSF the blood flowing in the blood vessel is prevented from passing into the new channel and come in contact with the device.

Part of the inventive concept is also an integral support instrument for capturing and compressing a vessel during the operation, comprising a handle member that has an elongated handle member connected to a fork-like vessel-capturing element having a first and a second prong; wherein the first prong is essentially U-shaped, and the second prong is shorter than said first prong and being essentially L-shaped, and wherein a vessel-capturing slit is formed between said prongs.

Brief description of the drawings

The following section describes preferred embodiments of the invention in detail, with reference to the accompanying drawings.

Figure 1a shows a midline section of the preferred design of the device according to the invention, seen from the side;

Figure 1b shows a cross section of the device in figure 1a, along the line S-S in figure 1a;

Figure 2 shows a midline section of the inner tube-like part of the device, seen from the side;

Figure 3 shows the outer tube of the device, a) from the side, b) seen from below, c) seen from above;

Figure 4 illustrates the resulting blood vessel channel after applying the device, a) midline section, b) cross section;

Figure 5 shows the applicator system seen from the side, and

Figure 6 – 9 illustrate four steps in the procedure.

Figure 10 a show in perspective a support instrument for keeping a vessel in place during an operation.

Figure 10 b shows in a view from above a detail of a fork-like element of the instrument in fig 10a.

Figure 10c shows in a side view, the instrument of fig. 10a.

Detailed description of preferred embodiments

Figure 1 a shows a midline section of a preferred design of device A according to the invention.

The device A is composed of two parts: one outer tube-like part 1 with a first 3 and a second 4 end and one inner tube-like part 2 with a first 5 and a second 6 end. The two tube-like parts are essentially concentric and parallel. The two tube-like parts 1 and 2 are joined near the end 3 of the outer part 1 and at an intermediate part 7 of the inner part 2.

Figure 1b shows a cross section of the device along the line S – S in figure 1a. Here it is obvious that the two tube-like parts 1 and 2 are concentric. It is also obvious that the outer part 1 has a slit 8, which will be mentioned later on.

Figure 2 shows in closer detail a midline section of an embodiment of the inner part 2. Part 2 is essentially axially symmetric with exception for the thread of screw on the intermediate part 7.

The first end 5 of the inner part 2 is arranged to be connected to a fluid-conducting catheter. In the shown design, this is achieved by shaping end 5 as an external nipple.

The other end 6 of the inner part 2 is designed to facilitate its passing through an opening in the vessel wall and at the same time give a close connection between the blood vessel wall and said part 2. This is achieved by making this part slightly conical, pointing to the end 6.

The outer part 1 and the inner part 2 are in the illustrated embodiment joined with threads. The inner part 2 is supplied with external threads along the outer intermediate part 7, and the outer part 1 is supplied with corresponding internal threads at an internal part close to the first end 3.

Alternatively, the outer part 1 and the inner part 2 can be joined by conical surfaces. In this case the inner part 2 has a slightly conical form pointing either to the first end 5 or the second end 6, while the outer part 1 at its first end 3 has a corresponding internal conical form.

The two parts can if desired also be joined by glue.

As yet an alternative, the outer part 1 and the inner part 2 can be solidly joined from the beginning, instead of being two parts meant to join later on. The device has been designed to be possible to manufacture in one piece by injection moulding.

However, there are some advantages to make the device A in two separate parts, as it may allow simple manufacturing and combination of different materials and designs.

Figure 3a) – c) shows in closer detail the outer tube-like part 1 of the device seen from a) the side, b) from below, c) from above.

The outer tube-like part 1 has along a part of its length from the second end 4 a lengthwise slit 8 for entrance of a corresponding length of the blood vessel.

When the outer and inner part 1 and 2 are joined, as illustrated in figure 1, the second end 6 of the inner tube-like part 2 is wholly or partly surrounded by the split equipped part of the outer part 1.

The lengthwise slit 8 has essentially a width corresponding to the double thickness of the blood vessel wall. The intention with the slit 8 is to limit, in the cross section, the part of the blood vessel that enters the lengthwise slit 8. This part of the blood vessel will, before it enters the lengthwise slit 8, be punctured in such a way (see procedure figure 6) that the end 6 of the inner part 2 can pass the vessel wall in this part of the vessel when the vessel enters the slit 8. After this, the inner part 2 from the end 6 to the intermediate part 7 will be inside the part of the vessel that has entered the slit 8. In this way, as well as by the moulding effect of the infusion needle 24 when the glue is injected (see procedure figure 6 - 8) a new narrow and stiff channel will be created along the blood vessel, constituting a channel of living tissue from the end 6 of the inner tube-like part 2 to the end 4 of the outer tube-like part 1. Figure 4a shows the appearance of the new channel 401 when the device A has been applied on a blood vessel. The outer part 1 has been removed in the drawing for reasons of clarity. Figure 4b shows the same situation in cross section.

After the device A has been applied on a blood vessel there is thus a double blood vessel wall in slit 8, part of the circumference as well as part of the length (corresponding to the length of the slit 8) of the blood vessel is situated inside the outer part 1. The end 6 of the inner tube-like part 2 passes the blood vessel wall that is inside the outer tube-like part 1. The width of slit 8 is enough for nutrition of the vessel wall inside part 1, but does not allow fluid to pass through i.e. between, the compressed vessel walls in the slit 8. Too narrow a slit will prevent nutrition and too wide a slit will allow blood to pass through and come into contact with foreign material (the end 6 of the inner part 2).

The second end 4 of the outer tube-like part 1 is cut oblique in such a way that the side running alongside slit 8 is the shortest. This facilitates passing of the device onto the vessel and gives a better anatomy for passage of the new channel into the blood vessel (the deep neck vein). The outer tube-like part 1 has two cross openings 9 and 10 near the end 3. The opening 9 is joined with and crosses the lengthwise slit

8, and the other opening 10 is arranged opposite the opening 9. The crossing opening 10 is featured in the same way. All edges and corners are rounded to adjust to the anatomy of the tissue.

The openings 9 and 10 give opportunity to fix the vessel wall to the device with one or more sutures. The opening 10 can also, if desirable, serve as an opening for a suture thread tied to the vessel. This makes it possible to pull the vessel wall in between the inner part 2 and the outer part 1 of the device. Said opening 10 can also be used to check that the blood vessel wall is in the proper position and that the glue flows out as intended. The glue used is preferably Tisseel®, a two-component glue. The fibrinogen and the thrombin of such a glue give a rubberlike tissue that is later organised as the surrounding tissue.

The end 4 of the outer tube-like part 1 has at least one hole 12 to allow fixing the vessel wall to the outer part 1 with suture. The glue will also fix the vessel wall to the inside of the outer part 1 partly by adhering directly to the inside of the outer part 1, partly by filling the openings 9 - 12 of the part 1, thereby mechanically fixing the vessel to said part 1.

The outer tube-like part 1 has an additional hole 11 to fix the device A to the applicator (at the end of a glue conducting tube 27) and to apply glue. As the glue is injected from the syringe on the applicator it passes hole 11 and fills the space between the inside of the outer part 1 and the vessel wall.

Preferably, the whole device A is made out of firm tissue-compatible materials like plastics, nylon, ceramics or metals. A suitable plastic is polyetheretherketone (PEEK). The various parts can be made out of different materials that are firm and compatible. It is an advantage if the material used is resistant and stable to allow repeated sterilization procedures, e.g. to withstand steam and air at 140°C, to allow sterilization by heat and/or to resist ethylene oxide at 50 degrees Celsius as this is another procedure of sterilization.

Figure 5 a) shows in a side view, an applicator 20 for applying the device A. The Applicator 20 facilitates the procedure when applying the device A in accordance with the invention on a blood vessel and especially when applying the device A on the deep neck vein when shunting a patient with hydrocephalus.

The applicator 20 consists of a frame 21made of anodised (eloxidized) aluminium or other suitable material. The frame 21 carries the puncture needle 23, a blunt infusion needle 24 that is connected to a tube 25, a glue conducting tube 27 and the glue syringe 26.

The glue conducting tube 27 is at its lower end arranged for solid and dense connection to the hole 11of the device, but the device A may still easily be removed. The device A is kept in place on the frame 21 also by help of the force created from the infusion needle 24 and from that said needle is guided by a hook-shaped guide

51. Said guide 51 is advantageously arranged to apply a little force on said needle 24 towards the frame 21 creating a force helping to keep the device A in place at the frame 21. The upper end of the tube 27 is arranged to be connected to the glue syringe 26 via its angled needle 58 that has a piece of catheter to prevent leakage.

The puncture needle 23 is fixed to the frame 21 by means of a lock 41. The lock 41consists of a long, narrow part that has a hook 42 and two small projections 43, 44, each with a hole fitting the puncture needle 23. This lock is arranged to keep the puncture needle 23 in the correct position and yet be easy to remove.

When using the applicator 20 a piece 28 of a silicon catheter is connected to the end 5 of the inner part 2 of the device A to prevent leakage. This catheter 28 will later on in the procedure be connected to the catheter from the shunt valve via a connector or be removed to allow the catheter from the shunt valve to be connected directly to the nipple of the device A.

The infusion needle 24 passes through the catheter 28 and through the inner 2 and outer 1 parts of the device A to a point where it meats the puncture needle 23, that is applied in such a way that the two needles form a sharp angle and the opening of the puncture needle covers the end of the infusion needle. This arrangement allows the infusion needle 24 to be blunt to avoid undue puncturing. The tube 25 that is connected to the other end of the infusion needle is used to check the function of the new channel when the device A is applied on the deep neck vein and the new channel 401 has been created. The infusion needle is withdrawn to a reference point 29 to allow for this check. In this position, the infusion needle ends inside the inner tube-like part 2 close to its end 6 and the new channel is empty and ready to check for free passage. When the needle is fully retracted, the device A will be released from the applicator 20 and the catheter 28 should then be held with forceps to prevent air embolism or backflow. It is advantageous to provide a mark 60 on the applicator 20 that indicates remaining length of catheter on the infusion needle 24.

The following section will describe how a device according to the invention can be used to connect a CSF conducting catheter to the deep neck vein in a human.

The device A and the applicator 20 are symmetric and their use is independent of whether the person who uses them is right- or left-handed.

Figure 5 b) shows the applicator likewise from the side and also showing a number of cross sections. The figure emphasises on the cross sections of the frame at positions AA to D and G as seen from the left referring to the side view of figure 5b. In cross section AA is shown a docking site 54 of the frame 21 for the device A. In cross section B is shown how the tube 27 extend into the docking site 54. In C is shown how the hook-shaped guide 51 is arranged for guiding the infusion needle 24 as described above. In D is shown a guide opening 56. The views E and F shows a

locking wheel for the (double) syringe seen from two views orthogonal to the side view, i.e., from behind and from above. In G is shown a cross section of the frame at position G having a profile looking like an inverted T.

Figure 6 illustrates the first part of an application procedure. An appropriate length of the deep neck vein is dissected free, lifted and fixed by a support structure 31. The device A can be applied in a direction parallel or anti-parallel to the blood stream. A double suture 33 is placed proximally and distally relatively to the intended puncture site. The puncture will be facilitated by lifting the vessel wall of the vein with the suture needle. After the puncture, the puncture needle 23 is removed

Figure 7 illustrates how the infusion needle 24 with the device A is brought further onto the vein by stretching the suture threads via the slit 8 through the opening 9 in the opposite direction relatively to the direction of the infusion needle 24. In this way, the inner tube 2 of the device A is passed more easily through the vessel wall of the vein.

The proper position of the vein in the device A can be checked in three ways:

A. The vessel wall of the vein can be seen in the upper opening 10.

B. The suture threads should be situated clearly opposite to the upper opening 10.

C. The slit 8 should to its whole extent be filled with vessel wall.

Figure 8 illustrates that the double suture 33 is tied around the inner tube and by an extra suture incision also around the outer tube. Figure 8 also shows a suture 32 that attaches the wall of the vein vessel to the device A near the hole 12.

When the vein wall is in proper position in the device A and fixed with sutures, glue is injected with force. Glue from the syringe 26 is injected via the tube 27 through the hole 11 in the outer part of the device in such a way that the space between the inside of the outer part and the vessel wall and all openings are filled with glue. The infusion needle functions as a mould for the new channel that will get the same length as slit 8.

Figure 9 illustrates the fourth part of the procedure.

When after a few minutes the glue has settled, the glue syringe is removed and the infusion needle is withdrawn to a position where the needle ends inside the inner part 2 of the device A. Infusion via the infusion needle will now wash out blood from the new channel and its function can be checked. After this, the infusion needle is fully withdrawn and the device A is released from the applicator 20 and can be connected to the catheter coming from the shunt valve.

After possibly adding additional glue on the outside of the device, the wound is sutured to give additional support to the device A.

By means of the device A corresponding to the invention a part of the deep neck vein is now transformed into a narrow, stiff channel with invariable volume.

The walls of this channel are living vein walls with good nutrition and the channel is filled with CSF. Backflow of blood in this channel is prevented by the stiff blood vessel walls and by the tightness in the slit and by the shunt valve. The new channel has to be narrow (about 1 millimetre in diameter) to allow the small volume of CSF (less than 500 millilitre per 24 h) to remove the blood that mixes with the CSF in the opening into the vein.

Accordingly, this invention makes it possible to drain CSF to the deep neck vein and further to the heart without contact between the fluid-conducting catheter or any foreign material and the blood flow in the vein and at the same time avoid the use of X-ray, ECG or other means to secure the proper position of the catheter in the heart.

The invention also excludes the risk of thrombosis and decreases the risk of infection since neither the device corresponding to the invention, the fluid-conducting catheter or any other foreign material comes in contact with the blood flow in the vein. Draining to the deep neck vein gives a natural antisiphon effect.

Figure 10 a) shows a view of a support, or a support instrument 1000, for supporting fixing and shutting off of a vessel. The support instrument 1000 is especially advantageous for supporting and fixing a neck vein when connecting a hydrocephalus shunt according to an embodiment of the invention to the vein, and the above mentioned support structure 31 in fig. 6 could advantageously be equal to this support instrument 1000.

An embodiment of the support comprises a handle 1001, a bend 1003, an extending common part 1004, a bifurcation 1005 and two elongated members, one concave or U-shaped 1010, 1012, 1015 and one L-shaped 1020, 1025. The support is preferably devised with essentially flat parts, i.e., at least the common part 1004 and a distal part 1015 of the U-shaped member 1010, 1012, 1015 are devised having essentially rectangular cross sections, with a thickness substantially smaller than a corresponding width. In a typical embodiment the thickness is approximately 0.5 to 2.5 mm and the width of the common part is approximately 5 to 15 mm.

The support is devised for capturing a blood vessel between the U-shaped member 1015 and the L-shaped member 1025, in the opening 1030 that is formed between said members, said opening 1030 continues as a lengthwise slit 1031 between said members 1012, 1025. Said lengthwise slit 1031 between these members has essentially a width corresponding to the double thickness of the blood vessel wall for the vessel in question, i.e., embodiments of the support instrument provides different sizes of said slit, and of course also of the instrument itself. The reason for having a slit of that dimensions is that when a vessel is captured in the slit, the vessel is flattened and compressed so that the blood-flow is reduced. Typical widths include 1 to 1.5 mm. The reduction is in most cases complete so that the

blood flow is shut off. The U-shaped and the L-shaped members preferably have a rectangular or quadratic cross section, and are so arranged that said opening 1030 and slit formed between the portions 1012 and 1025 is wide enough to let the vessel slide gently into place when the support is twisted a bit. The members have rounded edges, so that the risk of hurting the vessel or other tissues during proper use of the support instrument is reduced or eliminated. The opening 1030 is preferrably arranged so that a free end 1026 of the member 1025 are placed opposite a bend 1014 between the distal parts of the U-shaped member 1012, 1015. Said free end 1026 is triangularly shaped so that the opening 1030 is wide at start and narrows as it transitions to the slit 1031.

The support is devised to lock itself into place at the operating wound as the distal part of the U-shaped member and the common part 1004 or the part of the U-shaped and L-shaped members 1010, 1020 immediately following the bifurcation 1005 are arranged to make contact to the wound edges, and because the cross section of said members and part is flat or rectangular. Because the vessel itself, when caught in the slit between the members 1025, 1012 or just resting above both members, will exert a certain force on the support instrument 1000 directed downwards to the bottom of the operating wound, the instrument will come neatly into place.

CLAIMS

1. A device (A) for conducting fluid from a fluid-conducting catheter to a blood vessel, **characterised** in that the device together with the blood vessel forms a channel in a part of the length of the blood vessel, which channel runs essentially parallel with the vessel, and in that neither the device (A) nor the fluid-conducting catheter are in contact with the blood flow in the blood vessel.

2. The device according to claim 1, **characterised** in that it comprises an outer essentially tube-like part (1) with a first (3) and a second (4) end portion, and an inner essentially tube-like part (2) with a first (5) and a second (6) end portion, which tube-like parts are arranged with essentially parallel axes and joined with each other at or close to the first end portion (3) of the outer tube-like part (1) and at a portion (7) of the inner tube-like part (2), and where the other tube-like part (1), along a part of its length, extending from its second end portion (4) is provided with a longitudinal slit (8) for reception of a part of the blood vessel; the first end portion (5) of the inner tube-like part (2) is arranged to be connected to the catheter and the second end portion (6) of the inner tube-like part (2) is wholly or partly enclosed by said outer tube-like part (1), and is arranged to cross the vein wall.

3. The device according to claim 2, **characterised** in that the longitudinal slit (8) has a width that essentially corresponds to the double thickness of the vessel wall of a vessel for which the device is adapted.

4. The device according to any of the claims 2-3, **characterised** in that the outer part (1) and the inner part (2) are joined by means of threads.

5. The device according to any of the claims 2-3, **characterised** in that the outer part (1) and the inner part (2) are joined by means of conical contact surfaces.

6. The device according to any of the claims 2-3, **characterised** in that the outer (1) and the inner (2) tube-like parts are integrated.

7. The device according to any of the claims 2-6, **characterised** in that the second end (4) of the outer tube-like part (1) is cut at an angle in such a way that the side with the lengthwise slit (8) of the outer tube-like part (1) is the shortest.

8. The device according to any of the claims 2-7, **characterised** in that the outer tube-like part (1) is devised with a first (9) and a second (10) opening close to its

first end portion (3) wherein the first opening (9) is joined with and is transversal to the longitudinal slit (8), and where the second opening (10) is situated essentially diametrically opposite the first opening (9).

9. The device according to any of the claims 2-8, **characterised** in that the tube-like part (1) at its second end portion (4) is devised with at least one hole (12) for suturing the device to the blood vessel.

10. The device according to any of the claims 2-9, **characterised** in that the outer tube-like part (1) is provided with a hole (11) for entry of glue and/or for temporary fixation of the device to an applicator instrument.

11. The device according to any of the claims 2-10, **characterised** in that the device is made of a solid tissue compatible material e.g. polyetheretherketone (PEEK).

12. Applicator for the application of the device according to any of the claims 2-11 on a blood vessel, **characterised** in that the applicator (20) comprises a frame part (21) arranged for holding an infusion needle (24), a puncture needle (23) preferably attached to the applicator (20) with a lock part (41) and a tube (25), and a glue conducting tube (27) preferably connected to a glue syringe (26).

13. Method for applying the device according to any of the claims 9-11 with the aid of the applicator (20) according to claim 12, **characterised** in that:
- the device is attached to the applicator (20) by means of the glue conducting tube (27) and the infusion needle (24);
- a part of the neck vein of a patient is dissected free, lifted and fixed, and a double suture (33) using suture threads is placed around the intended puncture site;
the vessel wall of the vein is lifted by means of the suture needle to facilitate the puncture;
the puncture needle (23) is removed and the infusion needle (24) is moved into the vein simultaneously as the suture threads are pulled in the opposite direction of the infusion needle (24) to facilitate the sliding of the device into place;
Tying the suture (33);
Attaching an additional suture (32) to said hole (12) for suturing, for attaching the vessel wall to the device near said hole (12) for suturing;
- biological glue is injected via said glue syringe while the infusion needle still is in;
- when the glue has settled the infusion needle is withdrawn;
the infusion needle (24) is fully retracted to release the device A from the applicator (20); and

- the device A is connected to the catheter from the shunt valve.

14. The use of a device according to any of the claims 1-11 to connect a CSF conducting catheter to the deep neck vein in a human.

15. An integral support instrument (1000) for capturing and compressing a vessel comprising a handle member (1001), having an elongated handle member connected to a fork-like vessel-capturing element having a first and a second prong; wherein the first prong (1010, 1012, 1015) is essentially U-shaped, and the second prong (1020, 1025) is shorter than said first prong and being essentially L-shaped, and wherein a vessel-capturing slit (1031) is formed between said prongs.

16. The instrument of claim 15, **characterised** in that said fork-like vessel-capturing element is connected to the elongated handle member by means of an angled connection (1003)

17. The instrument of claim 15, **characterised** in that said prongs are arranged so that said slit allows a vessel to slide into place in between the prongs, compressing the vessel sufficiently to shut off the blood flow in said vessel.

18. The support instrument according to claim 15, **characterised** in that a free end (1026) of the second prong (1025) is arranged essentially opposite a bend (1014) provided between two distal parts of the first prong (1012, 1015).

19. The support instrument according to claim 15, **characterised** in that a free end (1026) of the second prong (1025) has an essentially triangular shape.

20. The support instrument according to claim 15, **characterised** in that said prongs are arranged and have such a shape that said instrument, when placed in an operating wound, assumes a self-locking position when placed so that at least one of said prongs assumes a position beneath a vessel.

21. The support instrument according to claim 15, **characterised** in that one of said prongs have an approximately rectangular cross section.

22. The support instrument according to claim 15, **characterised** in that the most distal part (1025) of the second prong is devised below the first prong (1010, 1012, 1015) when the instrument is held in a horizontal position such that said U-shape is essentially vertical.

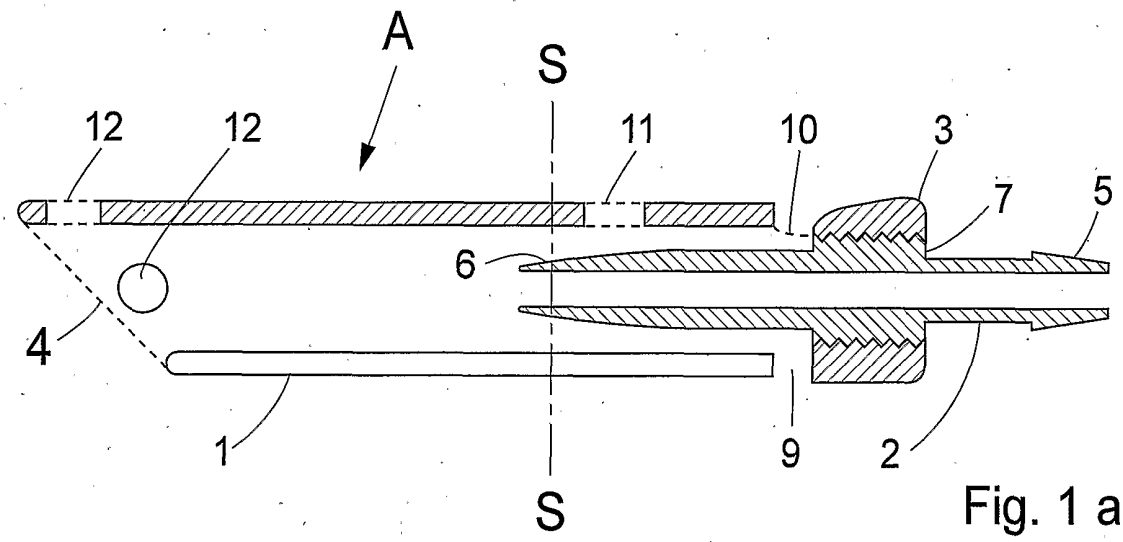


Fig. 1 a

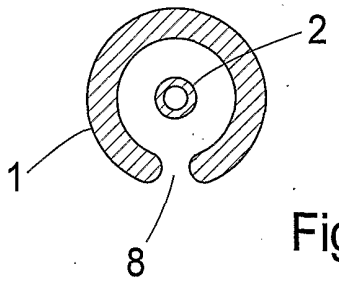


Fig. 1 b

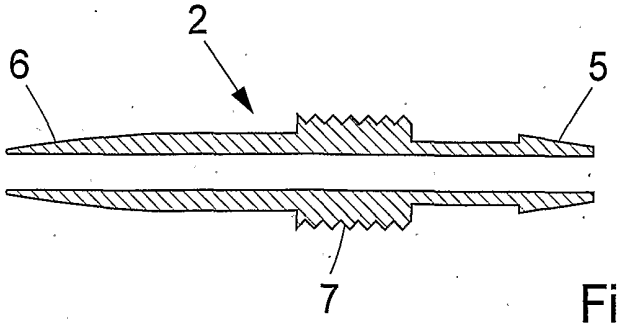


Fig. 1 c

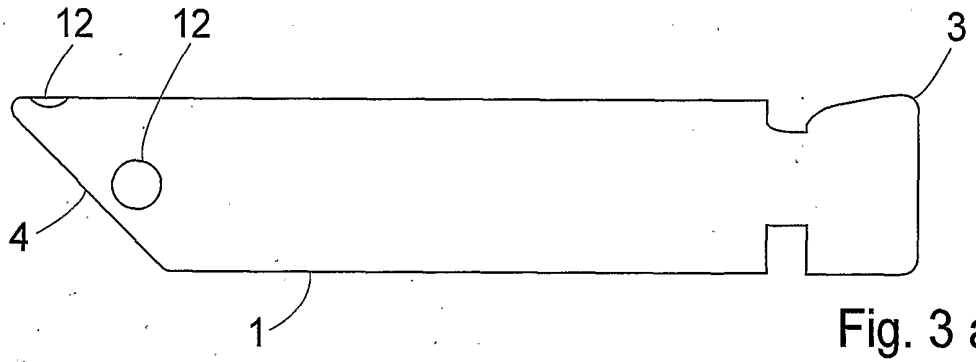


Fig. 3 a

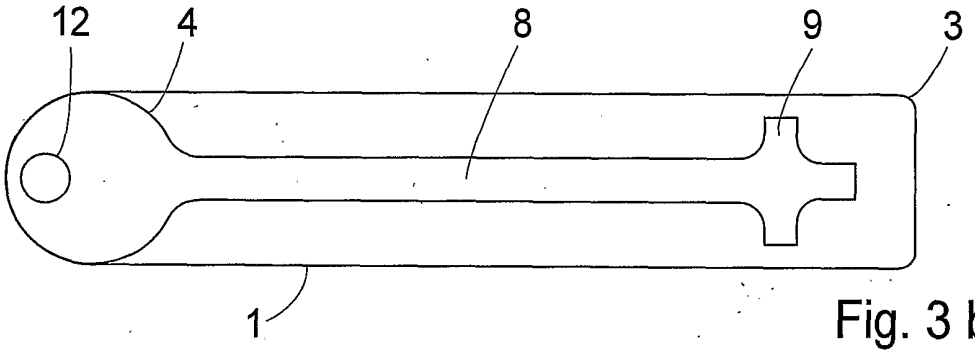


Fig. 3 b

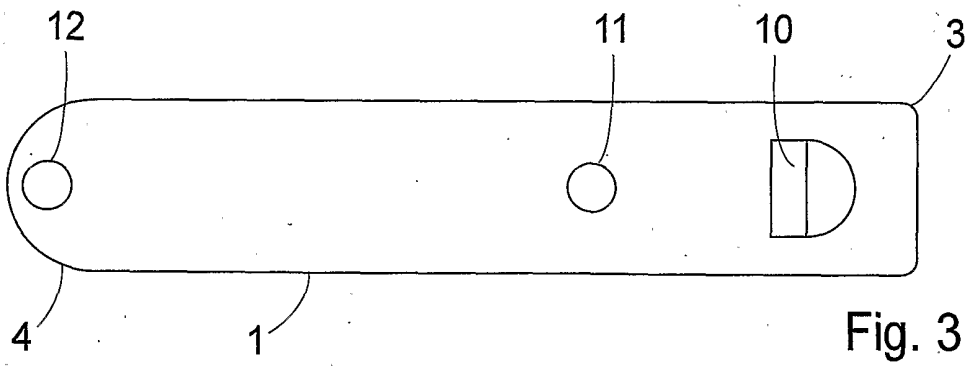


Fig. 3 c

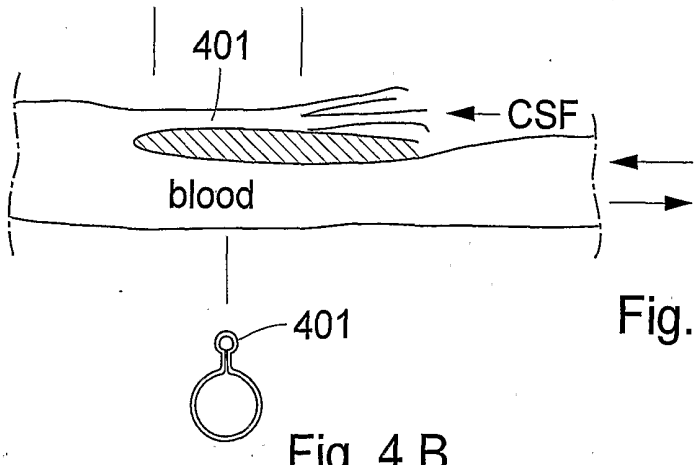


Fig. 4 a

Fig. 4 B

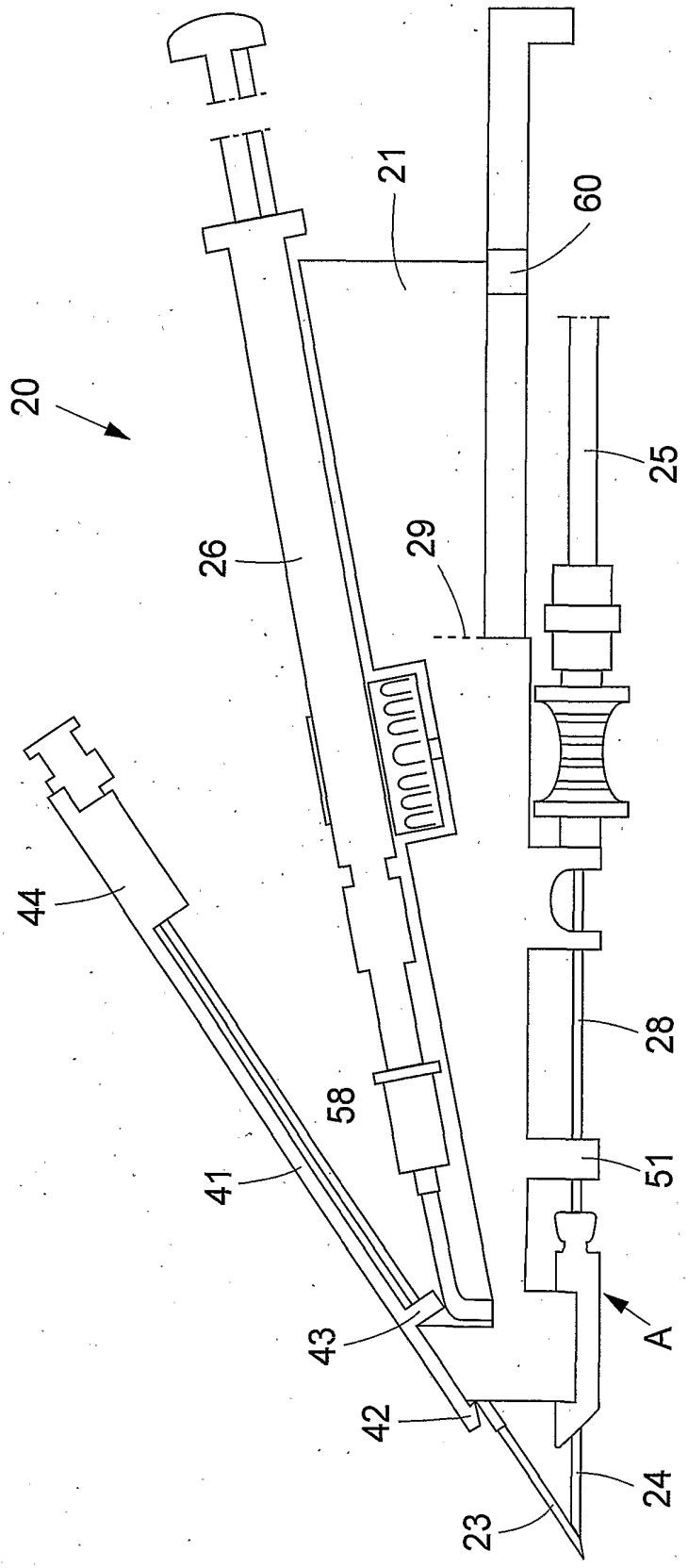


Fig. 5 a

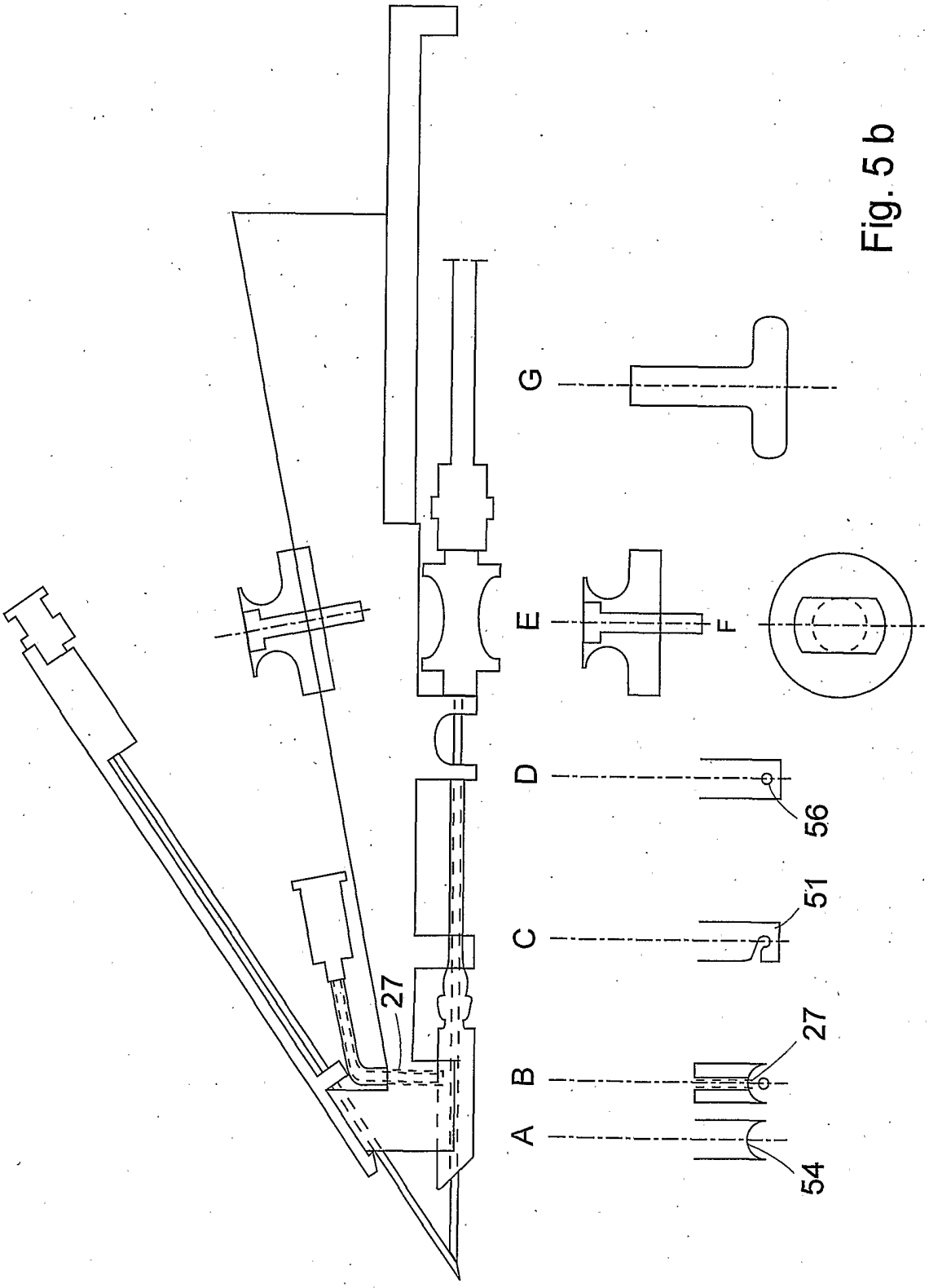


Fig. 5 b

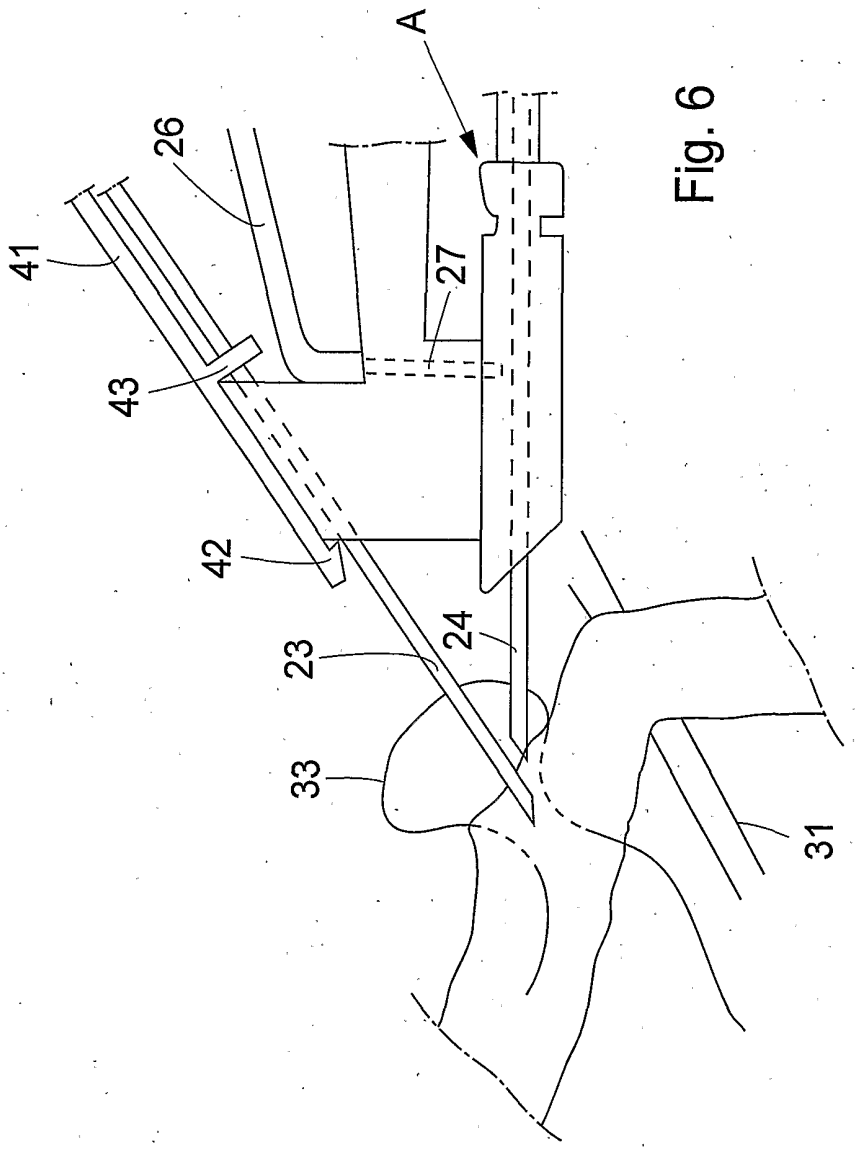


Fig. 6

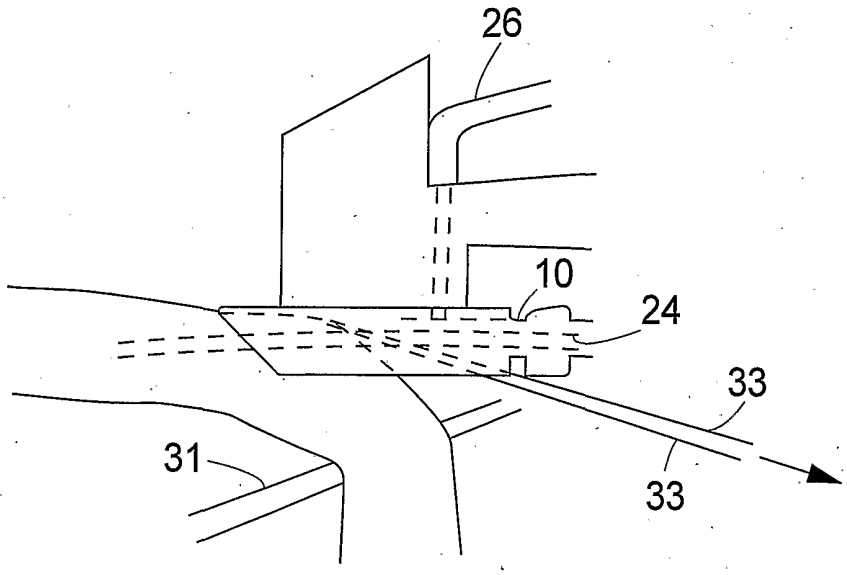


Fig. 7

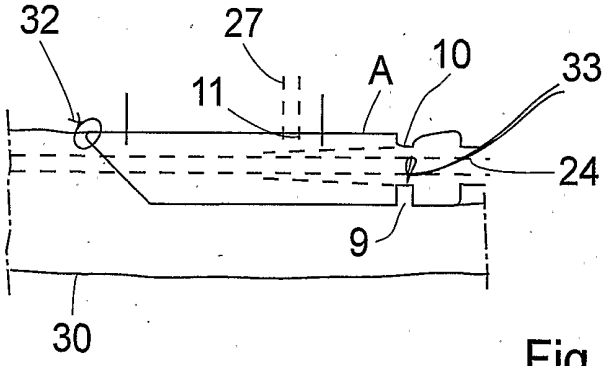


Fig. 8

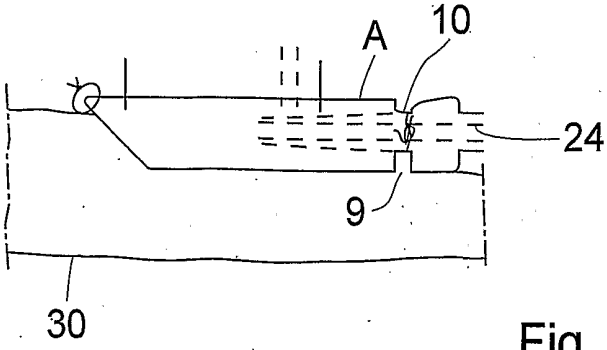


Fig. 9

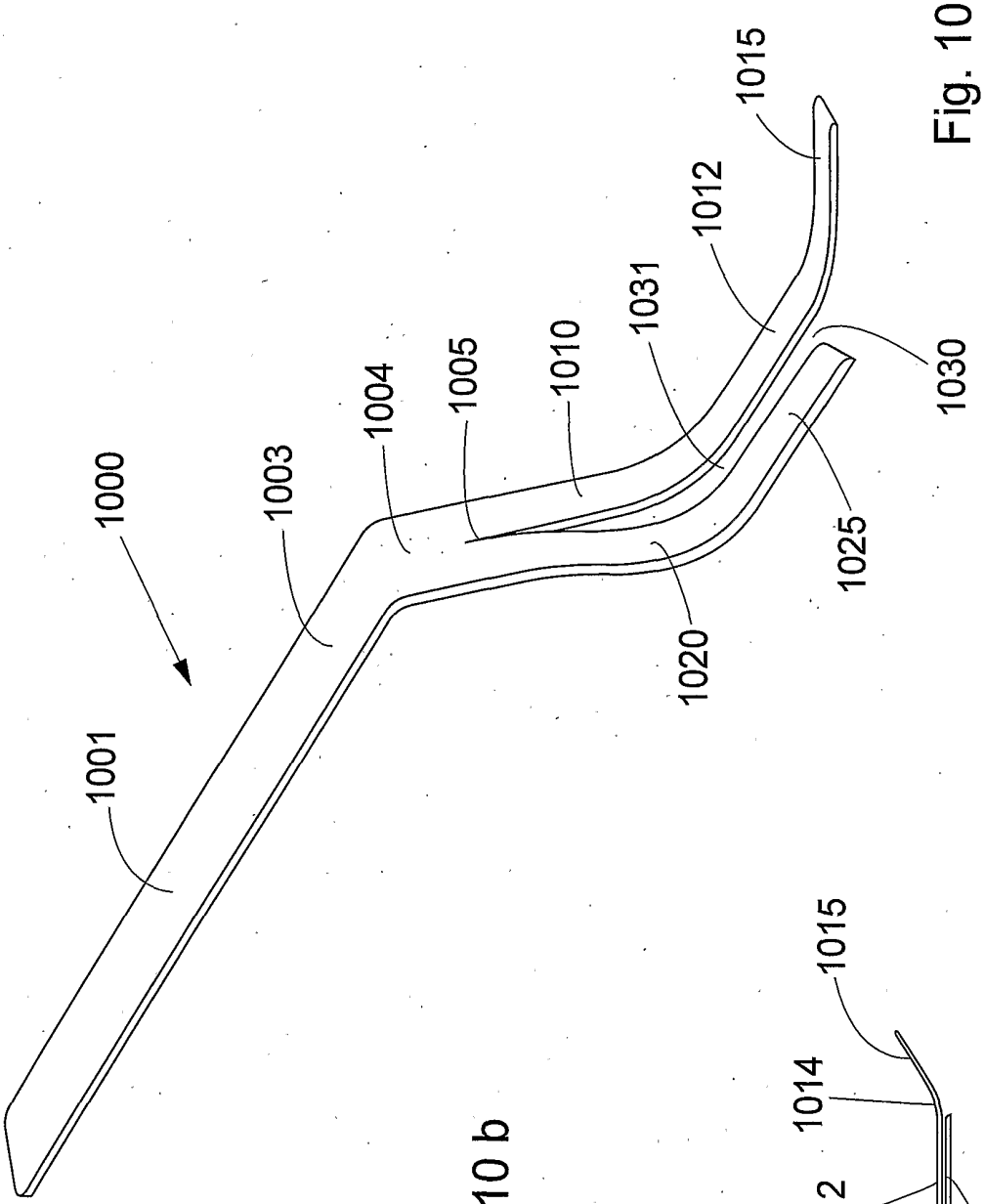


Fig. 10 a

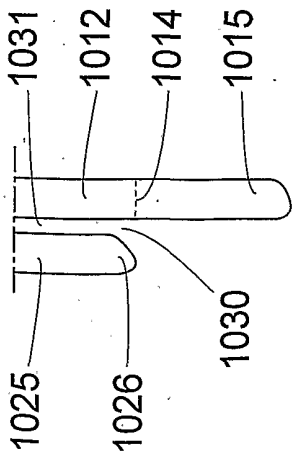


Fig. 10 b

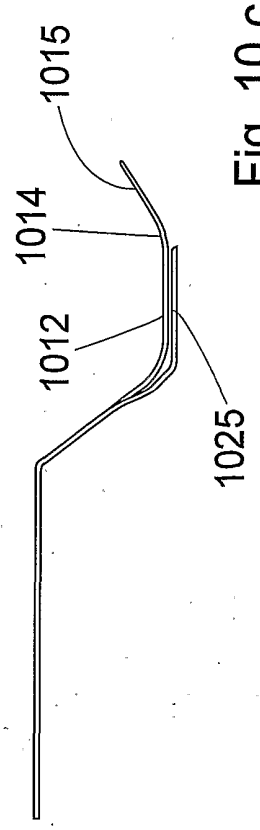


Fig. 10 c

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/02362

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 25/00, A61M 27/00
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)

IPC7: A61M

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3738365 A (RUDOLF R SCHULTE), 12 June 1973 (12.06.73), figures 1-28, claims 1-30 --	1-12,13,14
A	US 3769982 A (RUDOLF R SCHULTE), 6 November 1973 (06.11.73), figures 1-3, claims 1-10 --	1-12,13,14
A	US 3894541 A (ISMAIL LOFTY EL-SHAFEI), 15 July 1975 (15.07.75), figures 1-3, claim 1 --	1-12,13,14

☐ 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 another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 April 2002	11-04-2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Agneta Änggård/EK Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/02362

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.:
because they relate to subject matter not required to be searched by this Authority, namely:

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:

Invention 1:
The invention according to claims 1-14 relates to a device and method for conducting fluid from a fluid-conducting catheter to a blood vessel.

Invention 2:
The invention according to claims 15-22 relates to an instrument for capturing and compressing a vessel.

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.: **1-14**

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/01/02

International application No.
PCT/SE 01/02362

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 3738365 A	12/06/73	US 3623484 A	30/11/71
US 3769982 A	06/11/73	JP 48041588 A	18/06/73
US 3894541 A	15/07/75	NONE	