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Device for visually indicating a blood pressure

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ABSTRACT:

The invention relates to an indicator device for visually indicating a pressure of blood inside a blood vessel (8). It comprises a body (3, 10) in which a duct (14; 14') extends. The duct (14; 14') has a sealed proximal end, and the distal end
5 portion of the body (3, 10) is adapted to be positioned inside the blood vessel (8). There is provided at the distal end of the body (3, 10), a liquid inlet opening (11) in fluid communication (6) with the duct (14; 14'). A window in the form of an at least semi-transparent section (20) is provided in the body, for enabling
10 visual observation of blood (23) entering into the duct (14; 14') via the inlet opening (11), when the inlet opening (11) is located inside the blood vessel.

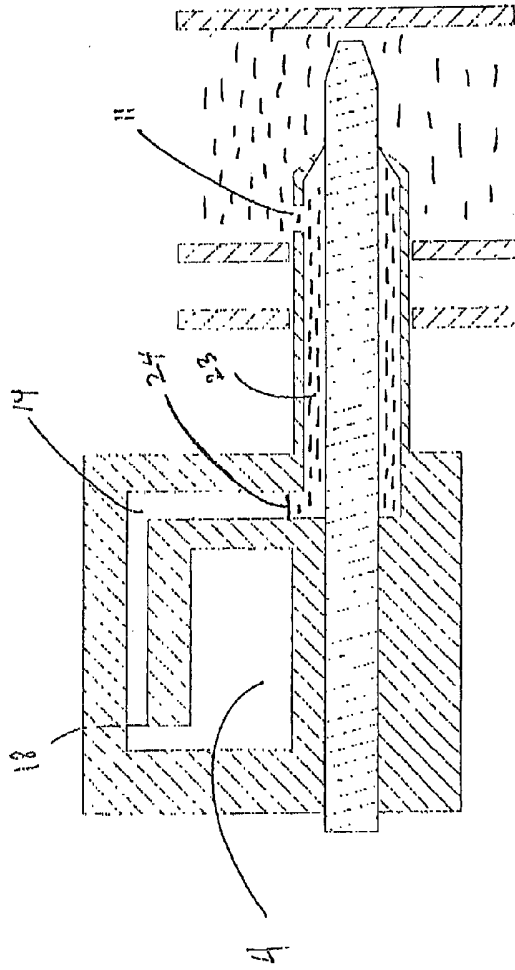


Fig. 2

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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title: **DEVICE FOR VISUALLY INDICATING A BLOOD PRESSURE**

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

File: 41457AUP00

DEVICE FOR VISUALLY INDICATING A BLOOD PRESSURE

The present invention relates to an indicator device for visually indicating a pulsating pressure of blood flowing inside a blood vessel, and a method, the device and method being usable for verifying correct positioning of a an insertion
5 tube for a wound closure element and of the wound closure element itself inside a blood vessel, in the process of closing a puncture in a blood vessel.

Background of the invention and prior art

10 A system for sealing a percutaneous puncture in a vessel can comprise an inner seal, which is adapted to be positioned against an inner surface of the vessel wall, and a locking member, which is connected to the inner seal by, for example, a filament or a suture and which is adapted to be positioned against an
15 outer surface of the vessel wall, such that the percutaneous puncture is sealed there between. During the phase of inserting the inner seal, the inner seal is folded inside an insertion tube, resting in the puncture to provide access to the inner of the blood vessel. Deployment of the inner seal inside the vessel takes place by pushing the inner seal through the insertion tube, and out from its
20 distal end opening. To ensure proper unfolding of the inner seal inside the vessel, the inner seal has to be deployed some distance away from the puncture hole in the vessel wall before the inner seal is retracted to be securely seated against the inner surface of the vessel wall. When the inner seal has been deployed inside the blood vessel, the insertion tube is retracted out from the
25 puncture, and in the same movement the inner seal is retracted and seated against the inner wall of the blood vessel. When the inner seal has been correctly positioned against the inner surface of the vessel wall, the locking member is pushed forward through the insertion tube until the locking member is in contact with the outer surface of the vessel wall. To effectuate the different actions described above, insertion tools have been proposed, which also accommodate the inner seal and the locking member before the sealing procedure.
30

As indicated, a critical moment in the above procedure is to ascertain a correct positioning of the insertion tube before deployment of the inner seal. To achieve this there are various methods disclosed in the prior art. One method (see e.g. US-5,306,254) comprises making available a channel for blood to flow in
5 through a distal opening in a dilator, inserted in an introducer sheath, via an opening or port located at a point on said introducer. There is also provided a proximal opening through which blood can flow out, whereby the occurrence or non-occurrence of outflow of blood indicates correct or incorrect position. Thereby, said port is located on the introducer sheath such that blood enters
10 said port only when the tip of the introducer sheath is at a correct position. This method although being relatively efficient, entails spillage of blood, which is inconvenient and may soil the environment around the patient to an undesirable extent.

15 In US-5,295,969 there is disclosed a means for accessing blood vessels for the insertion of a guide wire while preventing the free release of blood. Specifically, a hollow, thin-walled metal tube typically having a sharp point at its distal end is joined at its proximal end to a transparent viewing section. The viewing section has a distal narrow lumen and a proximal chamber which has a cap at its
20 proximal end. The cap encloses a pressure sealing means through which a guide wire can be passed. After the distal end of the metal tube is placed in an artery, blood will rush through the metal tube and into the viewing section. The air in the air-tight proximal chamber will alternatively be compressed between diastolic and systolic blood pressure. Feedback to the operator that the distal
25 end of the metal tube is properly placed within an artery can be achieved by observing the reciprocating pulsatile motion of the blood column within the distal narrow lumen of the viewing section. When the proper pulsatile motion is observed, a guide wire can be passed through the sealing means in the cap, through the viewing section, through the metal tube and finally the guide wire
30 will enter the lumen of the artery.

However, a disadvantage with this device is that it will not be usable for all possible pressures that may be encountered. Namely, if blood enters the chamber

the meniscus of blood will be located inside the chamber, and fluctuations may not readily be observed, either because the difference in levels between fluctuations is too small, or because the chamber simply cannot be observed.

5 Thus, these known insertion tools can be improved.

Summary of the invention

10 The object of the present invention is therefore to provide a means for visual indication that an insertion tube for a wound closure has been correctly positioned inside a blood vessel (i.e. verification of correct position), such that the closure element can be deployed safely and correctly, and whereby less blood flows from the puncture wound than compared to prior art procedures.

15 This object is achieved by an indicator device/a display device for visually indicating a pulsating pressure of blood flowing inside a blood vessel as claimed in claim 1.

20 The device is usable together with a system for deploying and attaching a wound closure member, said device being connectable to an insertion tube of such a system, such that blood from a blood vessel in which the insertion tube is inserted can flow into the display device, for visually displaying the pulsation of the blood flowing into the device, thereby providing the desired verification.

Brief Description of the Drawings

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The invention will now be further illustrated with reference to the attached drawings described below:

30 **Figure 1.** schematically shows a system for deploying a wound closure including an indicator device according to the invention in an initial stage of the procedure;

Figure 2. shows the system of Fig. 1 in a situation wherein the indicator detects a diastolic pressure;

Figure 3. shows the system of Fig. 1 in a situation wherein the indicator detects a systolic pressure;

Figure 4. shows the system of Fig. 1 in a situation wherein the indicator detects a high systolic pressure;

Figure 5. shows the system of Fig. 1 in a situation wherein the indicator detects a diastolic pressure after calibration;

Figure 6. shows the system of Fig. 1 in a situation wherein the indicator detects a systolic pressure after calibration;

Figure 7. schematically shows one embodiment of a duct with varying cross-section;

Figure 8. schematically shows another embodiment of a duct with varying cross-section;

Figure 9. schematically shows a further embodiment of a duct with varying cross-section; and

Figure 10. schematically shows a further embodiment of a device according to the invention.

Detailed description of the invention

An indicator device for visually indicating a pressure of blood flowing inside a blood vessel according the present invention in its most general aspect, comprises a structure, that, as an example, can be provided in the form of a body or handle to be gripped by a user of the device, inside which a duct ex-

tends. The duct has a distal end and a proximal end. A liquid inlet opening is provided at the distal end of the overall structure in fluid communication with the duct. The duct can extend all the way up to the distal end of said structure. The proximal end is sealed, such that no gas or liquid can escape from the duct at the proximal end. The distal end portion of the structure is adapted to be positioned inside said blood vessel. The inlet opening can be provided at the very distal tip of the distal end portion of the structure, or at a preferably known distance from said tip. The distal portion of the structure can be shaped as a tube which can have a suitable diameter for being inserted into the blood vessel, which will be described more in detail below. By shaping the structure as a tube in this region, and by providing said inlet opening on said tube in the distal region thereof, also said inlet opening can be positioned inside the blood vessel. The tube can be provided as a separate part that is attachable to the body, or it could be integrated with the body to form a unitary structure. The structure has an at least semi-transparent section, forming a wall or a window in said duct, for enabling visual observation of liquid entering into said duct via said inlet opening, when said inlet opening is located inside said blood vessel.

Due to the over-pressure in a blood vessel, i.e. higher than the atmospheric pressure, blood entering the duct when the device is properly deployed inside the blood vessel, will flow into the duct, via the inlet opening, until the gas pressure inside the sealed system counterbalances the blood pressure, and when the blood goes through the pulsation cycle with diastolic and systolic pressures, the meniscus in the duct will oscillate correspondingly between two levels or positions in the duct.

One embodiment of the invention comprises a relatively long, say up to 1 meter, or at least a few decimetres long narrow diameter tubing, the diameter of which suitably is 0,5 – 2 mm, more preferably 1 – 1,5 mm. In this embodiment the tubing itself constitutes the “structure”, according to the general concept, mentioned above, and the lumen inside the tubing constitutes said duct. Suitably there is provided a support member for gripping the device as a whole, on which support member a support element can be attached. The tubing suitably

is wound around said support element to form a helical structure, in order to reduce the length/size of the "window" for visual inspection of the pulsating blood. Due to the narrow dimension of the tubing, blood flowing inside the tubing from a blood vessel in which the pressure is slightly higher than atmospheric, will be easily perceptible as it fluctuates or oscillates between two levels in the helix, similar to what was described above.

In a particularly preferred embodiment, schematically illustrated in Fig. 1 (which shows a device according to the invention integrated in a system for deployment of a wound closure element, in an initial state before being inserted into a blood vessel), the device according to the invention, generally designated 2, comprises a main body 3 in which there is a gas-filled container or chamber/cavity 4 coupled via a fluid communication pathway 6 to the blood vessel 8. The body has a protruding member in the form of a tube 10 having a diameter rendering it suitable for insertion through a percutaneous wound 12 in the blood vessel 8. The tube 10 is provided with a side opening 11 for enabling blood to flow into the fluid communication pathway 6, when the insertion tube 10 is located inside the blood vessel 8. In the fluid communication pathway 6 there is provided a narrow duct 14, entering via an aperture 16 into said chamber at a level above the lowest level, i.e. the bottom 17, of said chamber 4, thereby creating a spill-over edge 18 for blood exiting through said aperture 16. In the shown embodiment the duct 14 extends essentially horizontally and is located above the chamber 4, whereby gravity will cause the excess blood to drop down into the chamber.

In Fig. 1 there is also inserted a guide rod 5 in the pathway 6, the function of which is to make insertion of the device into the blood vessel easier. This guide rod is subsequently removed when the correct position of the deployment device has been attained and verified using the present invention. After removal the wound closure can be inserted, deployed and attached.

In a preferred embodiment the duct 14' extends preferably essentially horizontally in the upper region of the main structure (indicated by broken lines in Fig.

1; shown with solid lines in Figs. 2-8) to an opening 16' and a spill-over edge 18'. A window 20 (shown by cross-hatching) formed by making the structure at least semi-transparent in this essentially horizontal region enables visual observation of blood flowing in the duct.

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The gas-filled chamber 4 is normally, i.e. in non-operative condition, at atmospheric pressure, and the gas will normally be air, although other gases are possible.

- 10 In particular the device according to the invention is usable together with a system for the safe and correct deployment and positioning of an inner seal of a sealing unit for closing a percutaneous puncture in a blood vessel, whereby the device according to the invention will be used for verification of correct positioning of parts of the system before the inner seal of a wound closure device is deployed inside the vessel.
- 15

A blood vessel sealing unit can comprise an inner seal, which is adapted to be positioned against an inner surface of the blood vessel wall, and a locking member, which is connected to the inner seal by, for example, a filament or a suture and which is adapted to be positioned against an outer surface of the blood vessel wall, such that the percutaneous puncture is sealed there between.

20

In order that the inner seal shall be capable of covering the puncture, it must have an extension that is larger than the hole. Therefore it must be folded together during passage of the hole, and it must be deployed at a minimum distance from the vessel wall inside the vessel. The inner seal is passed through the hole via an insertion tube (corresponding to the tube 10 in fig. 1, however the guide rod 5 shown in Fig. 1 must of course have been removed in order that this be possible), and when it exits the insertion tube at the distal end thereof, it unfolds. A preferred distance for deployment, although not limited thereto, is about 10 - 20 mm from the vessel wall. In order to enable deployment at this preferred position, the inventors have devised the position indicator means ac-

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ording to the present invention, which thus can be coupled to the insertion system/device.

5 A system/device for the insertion/deployment of an inner seal of a wound closure unit, together with which the invention can be used, generally comprises a body (corresponding to the body 3 shown in fig. 1) provided with at least one passage/lumen/channel 22 for passing devices such as a guide wire (not shown), a guide rod 5 or a dilator (not shown) in and out of the blood vessel 8 (only one of these devices are shown in Fig. 1, namely a guide rod 5). An insertion tube 10 can be a separate member coupled to the body such that it attaches to an outlet of said passage/lumen/channel (although in Fig. 1 it is shown as an integrated part of the body 3). The indicator device according to the invention is preferably integrated in the body 3. It comprises a cavity or chamber 4 inside the body for the accommodation of blood. The chamber is in fluid communication with the blood vessel via the insertion tube 10. Thus, 15 when the insertion tube 10 is located inside the blood vessel 8, the pressure difference will force blood to flow into the insertion tube 10, via the duct 14, 14' and enter into the cavity 4 in the body 3. However if the blood pressure is low, the blood might not reach all the way to the chamber 4, but will only extend in the duct 14, 14' to some position where it may be observed through the window 20.

The function of an indicator device according to the invention will now be described with reference to the embodiment shown in Figs. 1-6.

25 Thus, the embodiment of the indicator device according to the invention shown in Figs. 1-7 is integrated with a system for insertion/deployment of an inner seal of a wound closure unit, schematically illustrated in Fig. 1, which shows an initial state just before the distal end of the insertion tube 10 is inserted into the blood vessel 8. The guide rod 5 is inserted and extends out from the insertion tube so as to provide for easy entry into the blood vessel 8 through the wound 12. In this stage no blood flows into the side opening 11 in the insertion tube 10.

- In Fig. 2 the insertion tube has been inserted into the blood vessel 8 to a point where blood 23 can enter the side opening 11. The situation in fig. 2 corresponds to a situation in the heart (pulse) cycle where diastolic pressure prevails. In this case, the air inside the chamber 4 is slightly compressed but the blood pressure is not high enough to enable the blood to flow all the way into the chamber 4. Instead the meniscus 24 is positioned at a distance from the spill-over edge 18.
- Next in Fig. 3, a situation corresponding to systolic pressure is illustrated. Here, the blood has flown in the duct 14 all the way up to the spill-over edge 18', but has not actually flown into the chamber 4. Thus, the meniscus 25 is located near the edge 18'.
- In Fig. 4 on the other hand, the systolic pressure is high enough that the blood has flown over the spill-over edge 18', and dropped down into the chamber 4, where a pool 24 of blood collects. Blood will continue to flow over the edge 18' until the pressure inside the chamber 4 counterbalances the blood pressure. Then, when the pressure returns to diastolic, the meniscus 26 will withdraw to a position that could resemble the one shown at 27 in Fig. 5.

By providing the spill-over edge such that it always will be located over the level of blood collecting in the blood accommodating chamber return flow back into the duct 14 will be prevented.

In the next cycle, when the pressure returns to systolic again, as shown in Fig. 6, the meniscus 28 will again attain the same position as shown in Fig. 3.

In an optimized configuration, the chamber volume is adapted to the expected pressure ranges (systolic pressure ranges approximately between 100 – 200 mm Hg, and diastolic pressure ranges approximately between 60 – 100 mm Hg), such that the lowest possible (or imaginable) systolic pressure (i.e. about 100 mm Hg) would render the meniscus of the blood in the duct visible in the win-

dow 20 of the device. Preferably it would extend up to or close to the spill-over edge 18, 18'.

5 Similarly, the highest diastolic pressure (i.e. about 100 mm Hg) should not extend too far into the window 20, and could even be invisible through the window. In the latter case, however, the lowest possible systolic pressures would not either be visible in the window, and thus a balance between these two situation must be ascertained.

10 Set up in this way, all pressures that may be encountered during a detection procedure, would be visually detectable. High systolic pressures would lead to the blood flowing over the spill-over edge 18, 18' until a counter pressure inside the blood accommodating chamber 4 will prevent further flow. Again, it should be emphasized that the arrangement of the spill-over edge relative to the chamber will prevent return flow into the duct.

The key to achieving proper function is therefore to dimension the duct and chamber appropriately. This would be a matter of experimentation that is within the ability of the skilled man without inventive work.

20 One operable embodiment that has been tested has a chamber volume of about 620 mm³, and a volume of the duct of about 80 mm³, as measured from the exit into the chamber (near the spill-over edge) and to a point corresponding to the location of the blood meniscus as shown in Fig. 5. These values are of course only exemplary, and are not to be construed as limiting on the invention, which can be varied in many ways.

30 The cycle described above that the system goes through is in effect a self-calibration of the device to set itself up for displaying the meniscus through the window 20 in the body 3, in a state of systolic pressure, and to at least partially withdraw from sight in the window 20 during diastolic pressure. The self-calibration is an effect of the relative arrangement of the spill-over edge and the chamber, respectively.

For the intended use together with a system for deployment of an inner seal of a wound closure unit, it is preferable if the inner seal can be deployed at a distance of at least about 10 mm from the vessel wall, in order that the seal be able to unfold properly, before it is retracted to rest against wall.

To this end, the inlet opening 11 is positioned at a distance of 10 mm from the tip of the insertion tube 10. Thereby, the operator will immediately recognize when the correct position has been reached because he will immediately be able to observe a fluctuating meniscus through the window 20. Should the device inadvertently be retracted such that the tip of the insertion tube 10 no longer is at the desired distance, this will also immediately be registered by the terminated fluctuations of blood in the window.

In a particularly preferred embodiment of the invention, the duct 14 can have a varying cross-section over its length. The reason for this is that it will be possible to amplify small pressure variations in the beginning of a heart cycle. Namely, by making the duct narrower in the first part, say corresponding to the vertical portion of the duct 14 seen in Fig. 1, or say half of the horizontally extending portion of the duct 14 in Fig. 1, it will be possible to more easily detect a very slight pressure increase. The cross-section can be changed stepwise along the duct or continuously changed. The detailed design of the profile of the changing cross-section for a desired purpose can be arrived at with routine experimentation.

Alternatively, the duct can be made to continuously become narrower towards the spill-over edge, whereby the sensitivity in the detection of pulsation is reduced. Also, by shaping the duct suitably, i.e. to account for the varying pressure during a cycle, a linear displacement of blood within the window can be achieved. This can be of advantage if the fluctuations are large in or near the systolic pressure region and smaller in other pressure ranges. These alternative designs are shown schematically in Figs. 8-10.

Another option is to let the duct widen in the direction towards the spill-over edge.

Widening can be more forgiving, in the sense that it can accommodate a wider pressure range.

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In fact, it would also be possible to arrange parallel ducts having inverted variations of the cross-section, so as to ascertain detection in both cases mentioned. In another embodiment the duct could be made to widen in a first region, and then become narrower in a second region.

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A further preferred embodiment comprises a duct having such dimensions that the meniscus of the blood flowing in the duct always will be essentially perpendicular to the direction of flow. This would be achieved by making the duct thin enough, such that capillary forces will maintain the desired perpendicularity of the meniscus. Suitably the duct is 2-3 mm thick or less, more preferably the
15 the duct is 1 mm thick or less, most suitably 0,5 mm or less. A suitable width of the duct in the window region could be about 1-5 mm, preferably 2-4 mm, although other dimensions could equally well be suitable for specific purposes.

20 In an alternative embodiment of the device according to the invention, schematically shown in Fig. 10, the prior art device shown in US-5,295,969 can be modified according to the present invention, by extending the lumen 30, by providing a piece of tubing 32 extending into the blood accommodating chamber 34. The proximal opening of the tube 32 will form a spill-over edge 36. In this
25 way, the device will be rotationally symmetric, and the orientation during insertion of the needle into a blood vessel is unimportant.

In actual practice of using a system for wound closure, together with which the invention is primarily intended to be used, the insertion tube is normally in-
30 serted into the blood vessel at an angle of say 30 – 45° with respect to the extension of the blood vessel in question. In a situation like that, it can be advantageous if there is provided two oppositely located inlet openings on the insertion tube. The two openings will then be located at different distances from the

tip of the insertion tube. The difference is such as to render the position of both openings essentially the same, with respect to the inner vessel wall, when the insertion tube is inserted into the blood vessel at the mentioned angle. The two openings are provided as a measure to ascertain that at least one of them will
5 be exposed to the blood inside the vessel.

10

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. An indicator device for visually indicating a pressure of blood inside a blood vessel, comprising a body in which a duct extends, the duct having a
5 sealed proximal end; wherein the distal end portion of the body is adapted to be positioned inside the blood vessel; and wherein there is provided at the distal end of the body, a liquid inlet opening in fluid communication with the duct; the body having a window in the form of an at least semi-transparent section for enabling visual observation of blood entering into the duct via the inlet
10 opening, when the inlet opening is located inside the blood vessel.
2. The device as claimed in claim 1, wherein the sealed proximal end of the duct comprises a blood accommodating chamber.
- 15 3. The device as claimed in claim 1 or 2, wherein the duct opens into the chamber via an aperture having a spill-over edge, the aperture being located at a level above the bottom of the blood accommodating chamber, whereby return flow of blood back into the duct is prevented.
- 20 4. The device as claimed in any of claims 1-3, wherein the blood accommodating chamber is located in the body, and wherein there is provided an insertion tube extending distally of the body.
5. The device as claimed in claim 4, wherein the inlet opening is located on
25 the insertion tube.
6. The device as claimed in any preceding claim, wherein the duct extends vertically to an aperture opening into the blood accommodating chamber.
- 30 7. The device as claimed in any of claims 1-5, wherein the duct extends horizontally above the chamber to an aperture opening into the blood accommodating chamber.

8. The device as claimed in any preceding claim, wherein the duct exhibits a varying cross-section over its length
9. The device as claimed in claim 8, wherein the duct becomes narrower in the direction towards the blood accommodating chamber.
10. The device as claimed in claim 8, wherein the duct widens in the direction towards the blood accommodating chamber.
11. The device as claimed in claim 8, wherein the duct first becomes narrow and then widens.
12. The device as claimed in any of claims 8-11, wherein the cross-section varies within the window formed by said at least semi-transparent section.
13. The device as claimed in any preceding claim, wherein the duct is helically shaped.
14. The device as claimed in any preceding claim, wherein the blood accommodating chamber and of the duct, respectively, are dimensioned such that the counter-pressure therein when blood enters, will cause the blood meniscus at the lowest possible systolic pressure to be located within the window, and preferably near the spill-over edge.
15. The device as claimed in claim 14, wherein the meniscus is essentially perpendicular with respect to the direction of flow in the duct.
16. A system for sealing a percutaneous wound in a blood vessel, comprising an inner seal adapted to be positioned against an inner surface of the vessel wall and a locking member which is connected to the inner seal and which is adapted to be positioned against an outer surface of the vessel wall, such that the percutaneous puncture is sealed there between;

a body portion having at least one duct for insertion and extraction of devices to and from the inner of said blood vessel;

an insertion tube coupled to said body portion, and adapted to be inserted into the blood vessel through said wound, and through which the inner seal can be passed for deployment inside the blood vessel;

characterized in that

the system comprises an indicator device as claimed in any of claims 1-12.

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17. The system as claimed in claim 16, wherein the indicator device is integrated in said body portion.

18. The system as claimed in claim 16 or 17, wherein a window through which blood can be visually observed is provided in said body portion.

19. An indicator device for visually indicating a pressure of blood inside a blood vessel, said device being substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

20

20. A system for sealing a percutaneous wound in a blood vessel, said system being substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings and/or examples.

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DATED this 13th Day of January 2004
BALDWIN SHELSTON WATERS
Attorneys for: RADI Medical Systems AB

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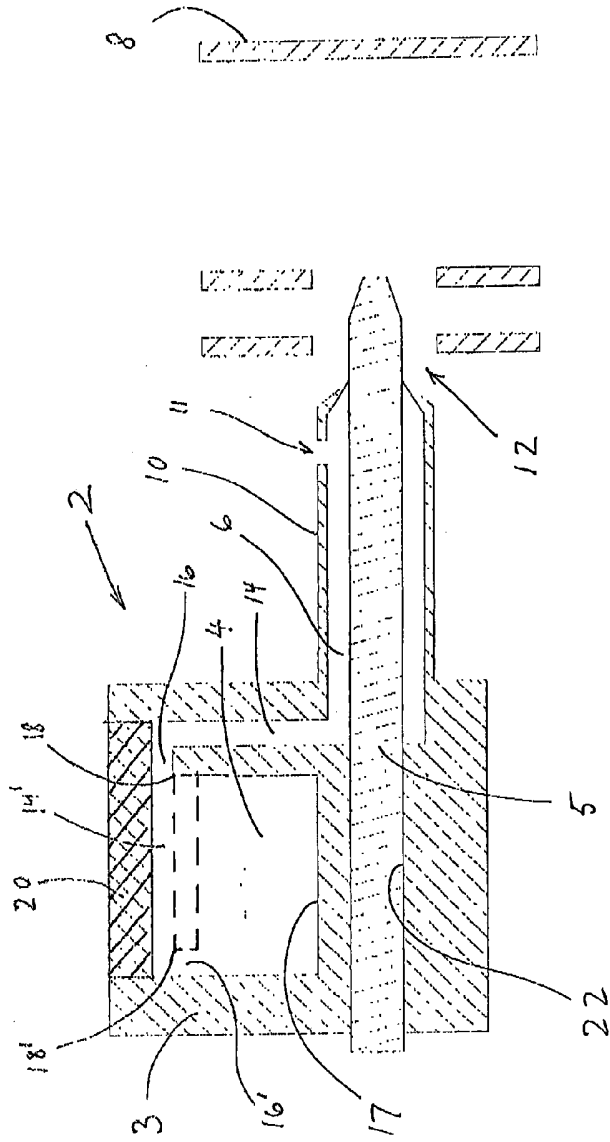


Fig. 1

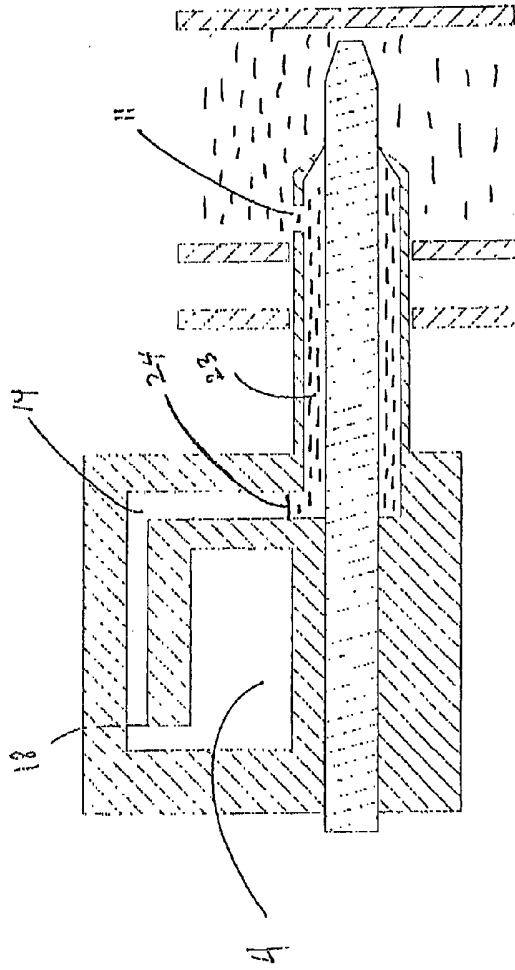


Fig. 2

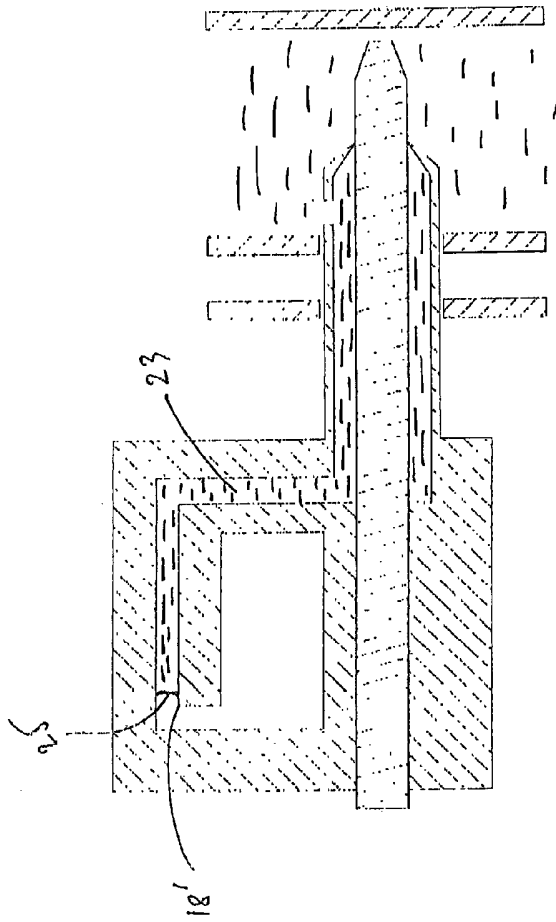


Fig. 3

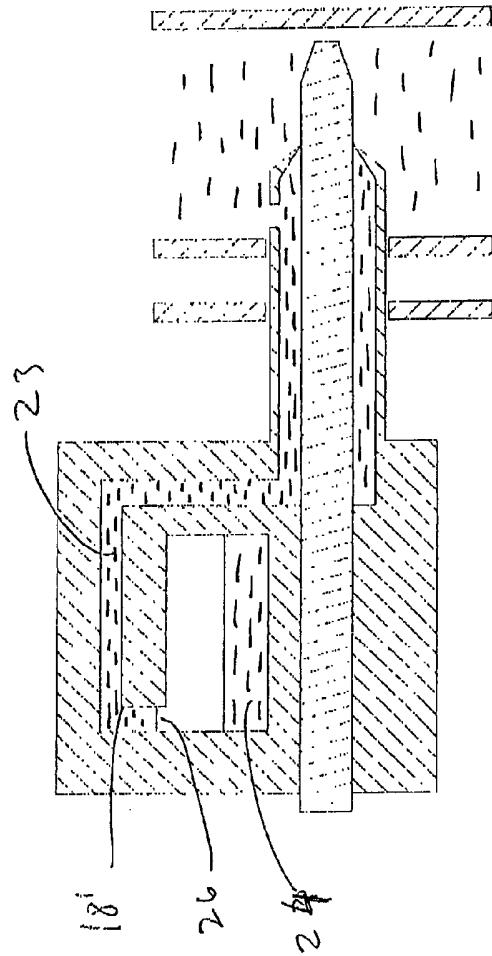


Fig. 4

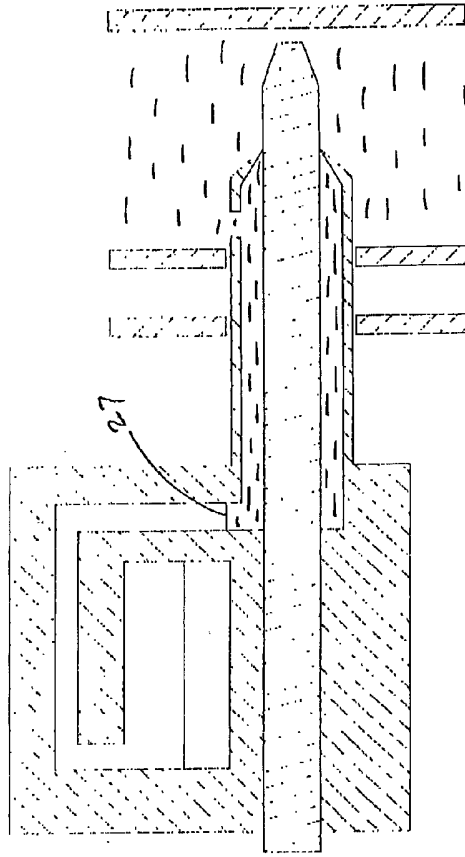


Fig. 5

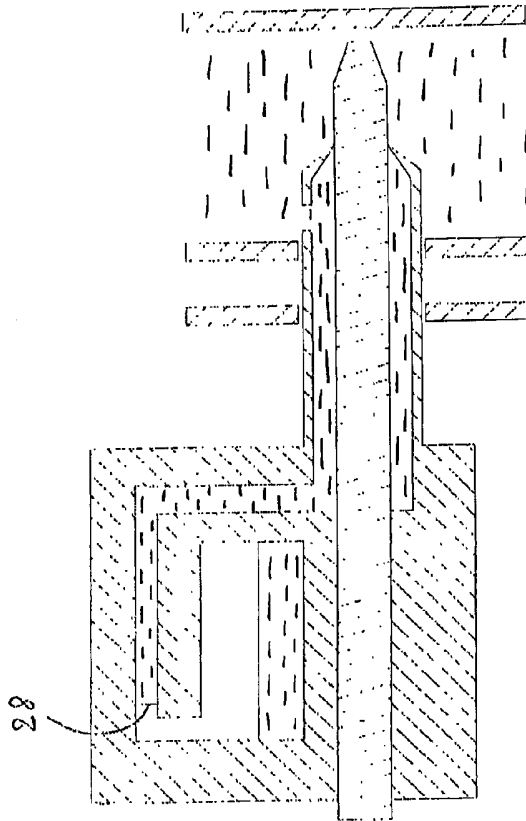


Fig. 6

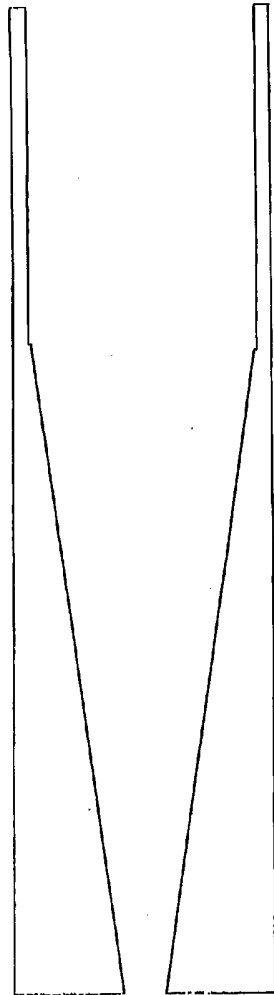


Fig. 7

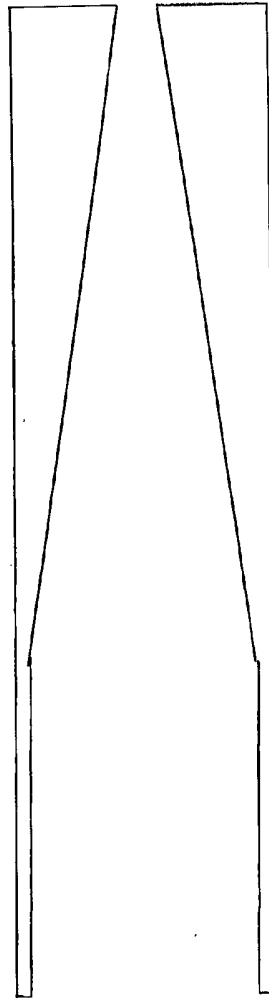


Fig. 8

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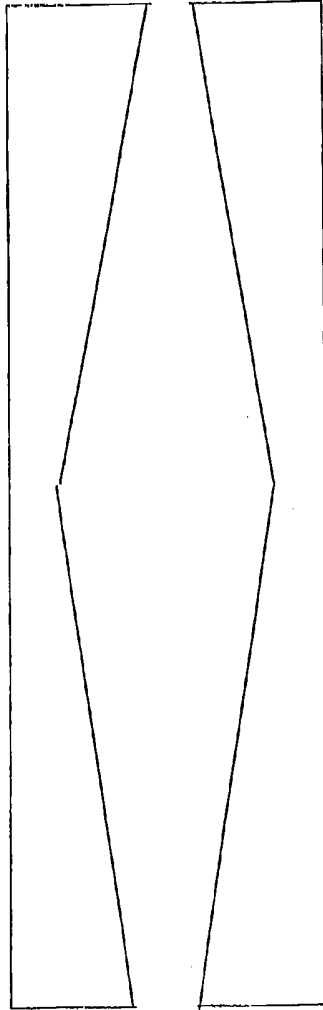


Fig. 9

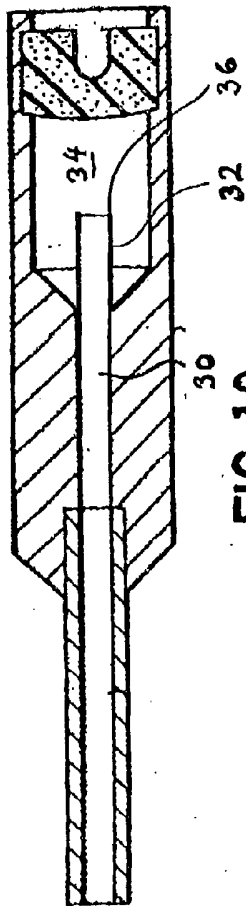


FIG. 10