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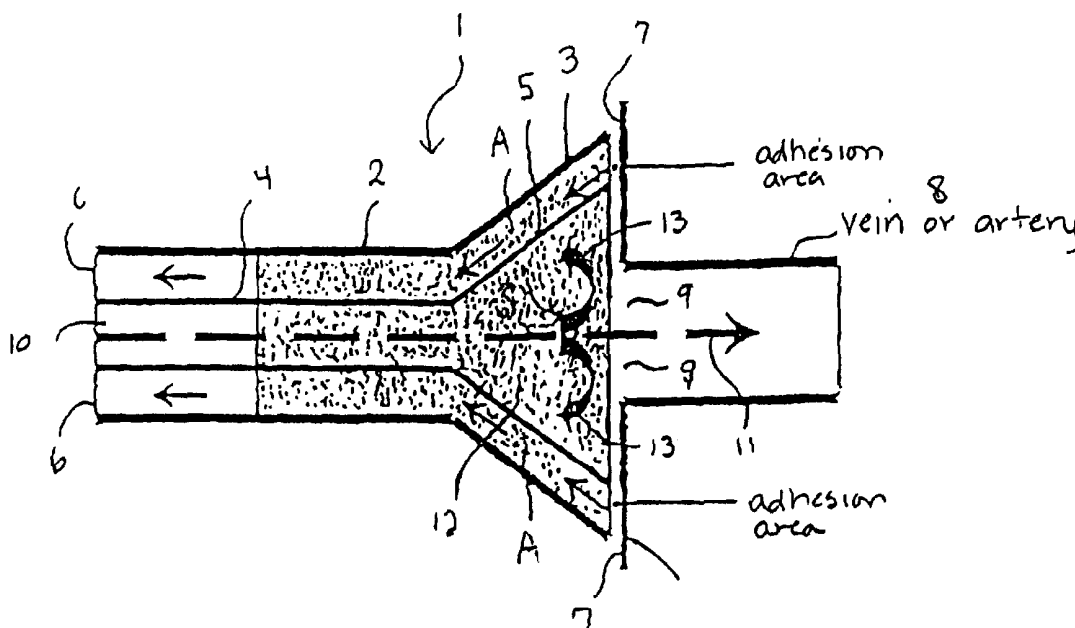
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(54) Title: INSTRUMENT FOR EXTRALUMINAL PERFUSION OF A VENOUS AND/OR ARTERIAL VESSEL



(57) Abstract: This invention provides a surgical instrument that allows artificial perfusion of one or more arteries and/or veins, and that is capable of being anchored to biological structures using negative pressure, which also determines the sealing action of a paraostial seal through the center of which the perfusion fluid is conveyed into the cannula. This invention further provides for methods of using the surgical instrument for the extraluminal perfusion of a venous and/or arterial vessel.



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**INSTRUMENT FOR EXTRALUMINAL PERFUSION OF A VENOUS AND/OR
ARTERIAL VESSEL**

CROSS-REFERENCE TO RELATED APPLICATION(S)

The present application claims priority to Italian Application Number B02000A 000534, filed on September 15, 2000 in the name of PRO.BIO.SPE. s.r.l, inventor Giorgio Arpesella, entitled Strumento per la Perfusione Extraluminale di un Vaso Venoso e/o Arterioso a Posizione Paraostiale (Instrument for Extraluminal Perfusion of a Venous and/or Arterial Vessel in Paraostial Position), hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

15 The present invention relates generally to a surgical instrument that allows artificial perfusion of one or more arteries and/or veins, and specifically to a surgical instrument for artificial perfusion that is capable of being anchored to biological structures using negative pressure.

BACKGROUND OF THE INVENTION

Artificial perfusion of a vessel with blood or other nutritional fluids, continuous or intermittent, is used to protect tributary tissues from ischemia during a surgical procedure performed on or near that vessel and/or surrounding tissue. Artificial perfusion is particularly important during cardiovascular surgery, such as coronary bypass surgery.

At present, existing perfusion catheters and/or cannulae require the introduction of some portion of the cannula body into the lumen of the vessel. In addition, conventional perfusion devices sometimes introduce an anchoring means, such as an expandable balloon, into the lumen of the vessel to secure the cannula. There are, however, several problems, both anatomical and functional, inherent to such conventional perfusion devices.

For example, the external diameter of the cannula must be smaller than the internal diameter of the vessel, limiting the usefulness of conventional perfusion cannulae in very small vessels such as the intercostal arteries. Calcification, fibrosis, and other such pathologies of the vessels can also prevent the introduction of the cannula. Another possible complication is coronary main stem stenosis, which can preclude introduction of the conventional perfusion cannula. In addition, damage to the vessel can occur during insertion of the cannula. Finally, early collateral vessels starting near the point of introduction into the vessel can be obstructed by the conventional perfusion cannula, limiting the perfusion in some downstream territories, as, for example, in the great cardiac vein (cardiaca magna) in the coronary sinus.

1 Conventional perfusion cannulae also have a number of functional limitations. For
example, in small diameter cannulae, the high velocity of fluid emerging from the cannulae can
damage the vessel wall, producing jet lesions inside the vessel. Also, in order to hold the cannula
5 in place during perfusion, and to avoid leakage of blood or perfusate, many conventional
perfusion devices use, for example, a self-inflating balloon or snares from outside of the vessel,
increasing the invasiveness of conventional cannulation and the potential for damage to the
vessel and/or surrounding tissue.

What is needed, therefore, is an instrument that can perfuse a vessel with minimal
10 intrusion into the lumen of the vessel, thereby avoiding one or more of the above-mentioned
limitations of conventional perfusion cannulae.

Such an instrument would greatly extend the applications and the indications of
intraoperative vessel perfusion. For example, such a perfusion instrument would have direct
applicability to retrograde coronary perfusion. Retrograde perfusion or retroperfusion refers to
the administration of nutritive and other solutions through the venous system. Previous studies
15 have, at least indirectly, demonstrated the efficacy of venous coronary retroperfusion. For
example, Hochberg et al., (1979) *J. Thoracic Cardiovasc. Surg.* **77**: 1-12, performed an in vivo
revascularization of the satellite vein of the anterior descending artery, which had previously been
occluded. After some months, Hochberg demonstrated, first with an angiography and later
histologically, the normal perfusion of every layer of the myocardium, including the
20 subendocardial one, with no evidence of edema, parenchymal hemorrhage or venous thrombosis.
Earlier, Chiu and Mulder, (1975) *J. Thoracic Cardiovasc. Surg.* **70**: 177-182 showed that
maximum protection of an ischemic myocardium by venous perfusion occurs when the venous
anastomosis is performed on the satellite vein of the occluded artery.

25 However, two problems with conventional coronary retroperfusion have limited its
applicability: the limitation of retroperfusion in protecting the right ventricle and the presence of
veno-venous shunts (through the Thebesian system), which increase the non-nutritive flow of the
perfusing fluid.

For example, Allen et al. (1995) *J. Thoracic Cardiovascular Surgery* **109**: 1116-1126 has
30 noted that retrograde cardioplegia provides poor right ventricular myocardial perfusion as
assessed by contrast echocardiography and coronary ostial drainage, concluding that this poor
perfusion is inadequate to meet myocardial demands as demonstrated by the right ventricular
extraction after a prolonged retrograde infusion and that, therefore, surgeons must not rely solely
on retrograde cardioplegia for right ventricular myocardial protection, particularly if continuous
warm blood cardioplegia is used.

35 The reduced perfusion of the right ventricle is a consequence of the fact that the major
cardiac venous tributaries of right ventricle flow near the ostium of the coronary sinus. Using

1 conventional intraluminal cannulation, these veins are excluded from retrograde perfusion because of the necessity to cannulate the sinus well deeper than the ostium level and the occlusion of the right ventricle veins by the self-inflating balloon of the intraluminal catheter.

5 This problem has limited the application and the extent of retrograde perfusion of coronary circulation. If this problem could be solved, it is likely that retrograde perfusion would be used more often, as in "beating heart" surgery.

10 Beating heart surgery, i.e., surgery performed without arresting the heart, involves the use of retrograde perfusion while performing valve surgery, with different techniques used for aortic and mitral surgery. The main advantages of beating heart surgery, as described by B. Gersak (2000) *Heart Surgery Forum* 3: 232-237, are: 1) the myocardial muscle continues to be perfused, 2) no reperfusion injury, 3) reduced possibility of atrial fibrillation, and 4) testing of the mitral valve repair can be performed in real physiologic conditions.

15 Beating heart techniques are particularly useful, and sometimes unavoidable, in patients with low ejection fraction, where a cardioplegic arrest could damage a variable amount of myocardium. When only antegrade perfusion is used to perform the same surgery, the techniques are more complex and require a more complex perfusion apparatus, as shown in Miyari, et al. (1996) *Ann. Thorac. Surg.* 61: 743-745, and Alfonso-Tadaomi, (1996) *Ann. Thorac. Surg.* 61: 1265-1266, both incorporated by reference in their entireties.

20 What is also needed, therefore, is a perfusion device that solves one or more of the above-mentioned limitations of conventional perfusion devices in coronary retrograde perfusion.

25 Surgical procedures on the cardiovascular system require the interruption of blood flow in different arterial and venous segments, resulting in the interruption of nutritive flow to various organs and tissues. Aortic surgery, in every segment (ascending, arch, thoracic, abdominal), requires the interruption of flow to vital organs, such as brain, spinal cord, liver, and kidneys, and to wide regions of the body, such as the limbs and abdomen. In both acute (aortic dissection, aortic aneurism rupture, trauma) and chronic (atherosclerotic aneurism) pathological states, paralysis, due to the interruption of blood supply to spinal cord, can be a complication of such surgery.

30 The spinal cord is not supplied by a single artery, but by a series of lower intercostal arteries, with unpredictable differences in each patient. Attempts to identify a single artery (Adamkiewicz artery) have previously failed; see R. Griepp and M. Ergin, (1996) *J. Thorac. Cardiovasc. Surg.* 112: 1202-1215. Anatomical studies show a mean number of the Adamkiewicz arteries (1.3 ± 0.65 per cadaver) originating from the intercostal and/or lumbar arteries on the left side, frequently at the T8-L1 vertebral level, and no statistically significant correlation between the diameter of the spinal cord arteries and that of intercostal and lumbar arteries, suggesting that "during operations on the thoracoabdominal aorta, the intercostal and/or

35

1 lumbar arteries should be preserved, regardless of their diameter, to prevent postoperative paraplegia." T. Koshino, et al. (1999) *J. Thorac. Cardiovasc. Surg.* 117: 898-905.

5 Clinically, "an aggressive approach to maintain intercostal patency during clamp-and-sew repair of thoracoabdominal aneurism may effectively lower the incidence of spinal cord injury without prolonging aortic cross-clamp time." S. Ross, et al., (1999) *J. Thorac. Cardiovasc. Surg.* 118: 17-25.

10 The incidence of paralysis varies from 4% to 38%, depending of the presence of dissection, extensive thoracoabdominal disease and prolonged cross-clamp time. Chronic situations are less correlated to the incidence of paralysis, due to chronic ischemia of the spinal cord and to the presence of collateral vessels, stressing the importance of continuing perfusion during the surgical treatment. Other studies demonstrate that the perfusion pressure distal to the cross-clamp site must be greater than 55 mm Hg to reduce the incidence of paralysis, e.g. in the surgical treatment of descending aorta aneurism with the aid of centrifugal pump partial bypass, showing that a discrete pressure is necessary to assure physiologic perfusion.

15 Nevertheless, even when important segmental arteries are reattached, spinal ischemia may also occur during anastomosis, particularly when clamping time is prolonged. The usefulness of an intraluminal shunt in preventing paraplegia *in vivo* had been described. See S. Van Voorst, et al. (1997) *Ann. Thorac. Surg.* 63: 419-424, hereby incorporated by reference in its entirety.

20 Recent studies performed to evaluate the efficacy of retrograde perfusion of the spinal cord during aortic surgery to reduce or prevent neurological complications concluded that retrograde perfusion does not protect the spinal cord from ischemic injury, as the collateral network between the azygos and caval systems prevents the oxygenated blood from reaching the cord. See F. Follis, et al., (1999) *J. Thorac. Cardiovasc. Surg.* 118: 597-603, hereby incorporated by reference in its entirety. These results, confirmed by other studies, stress the importance of finding a way to provide antegrade perfusion of the supra-aortic vessels during aortic arch surgery. According to the Kazui technique, the protection of brain in these cases is achieved by cannulating the common brachiocephalic artery to provide flow to the brain during deep hypothermia and circulatory arrest. See Kazui, et al. (1994) *Ann. Thorac. Surg.* 57: 904-911; Kazui, et al., (1995) *Eur. J. Cardiothorac. Surg.* 9: 491-495; Kazui, et al., (2000) *Ann. Thorac. Surg.* 70: 3-8; Kazui, et al., (2001) *J. Thorac. Cardiovasc. Surg.* 121: 491-499, all hereby incorporated by reference in their entireties.

25 Thus, what is also needed is a perfusion device that can perfuse multiple vessels, such as the intercostal arteries and/or supra-aortic vessels, during surgery.

30 During partial (left-heart bypass, femoro-femoral bypass) or total cardiopulmonary bypass, cannulation of the common femoral artery is used when the aortic site of cannulation is

1 unavailable or undesirable. Conventional cannulation of the common femoral artery results in
the exclusion of distal perfusion to the superficial and deep femoral arteries, causing ischemia to
the limb. This ischemia causes metabolic changes in the limb, such as high lactate
5 concentrations, creatine phosphokinase release, and acidosis, and may be clinically significant,
particularly during prolonged cannulation.

Thus, what is further needed is a perfusion device that can perfuse proximally and distally
in a vessel, avoiding ischemia of distal portions of the body.

10 SUMMARY OF THE INVENTION

The present invention is embodied in a surgical instrument for the perfusion of a venous
and/or arterial vessel. The surgical instrument is anchored to or adjacent to the artery or vein,
forming a seal through the center of which a cannula for delivery of the perfusion fluid is
introduced.

15 The instrument is anchored by applying a vacuum inside a gripping cup. The gripping cup
is positioned so as to engage the surface of the vessel at or near an opening into the vessel, as, for
example, at or near an ostium to a vessel in the heart or a surgical incision in the wall of a vessel.
The gripping cup is connected via lines to a vacuum pump or any other source of negative
pressure. A vacuum is provided to the interior of the gripping cup, thereby sealing the gripping
20 cup in place. A perfusion cup, associated with the gripping cup, is also thereby sealed in place,
around the opening or entry into the vessel.

The instrument includes: a perfusion cup having an interior space in fluid communication
with an end; a cannula attached to the perfusion cup to supply perfusate to the interior of the
perfusion cup from a perfusate source; a gripping cup having an interior and an end, the gripping
25 cup positioned outside of the perfusion cup; and a vacuum line in fluid communication with the
gripping cup to provide a vacuum to the interior of the gripping cup from a vacuum source. The
end of the perfusion cup and the end of the gripping cup are usually preferably coplanar, but this
can vary depending on the application.

30 The perfusion cup is to be sealed around an opening in or to the artery or vein, which can
be a surgical incision, an ostium at the beginning of a vessel, or the like, and has a diameter
suitable for use in vessels of any lumen size, including those presenting calcified plaques near the
edges of the opening. A relatively large diameter perfusion cup may also be used to act as a
decelerating element for the perfusion cannula by reducing the flow speed of the perfusion fluid
inside the cup prior to entering the vessel.

35 The major characteristics and advantages of the present invention of a perfusion
instrument include one or more of the following:

1. The use of negative pressure to adhere the instrument to the external rim of a vessel ostium or to the vessel tissue adjacent an incision in the vessel.
2. The ability to perfuse the vessel at the physiologic fluid pressure by means of a chamber that reduces the flow and kinetic energy of the perfusate.
3. The ability to perfuse collateral vessels, immediately adjacent the ostium or incision of the vessel.
4. The ability to perfuse at the entrance of a vascular ostium.
5. Ease of removal of the instrument at the end of a surgical procedure.
6. The ability to perfuse arterial or venous vessels of various sizes with a standard cannula.
7. The ability to perfuse a vessel despite calcifications, fibrosis, or other such irregularities of biological tissue at or near the opening into the vessel.
8. The ability to collect fluids leaking from the opening into the vessel.

Other features and advantages of the present invention will become apparent from the following description of the preferred embodiments, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of the suction cup portion of the perfusion instrument attached to the surface of a vessel.

FIG. 2 is a schematic diagram of a conventional intraluminal cannula inserted through the ostium or into the lumen of a vessel, as is known in the art.

FIG. 3 is a schematic diagram of the front view of the suction cup portion of the perfusion instrument.

FIG. 4 is a schematic diagram of the bottom view of the suction cup portion of the perfusion instrument.

FIG. 5 is a schematic diagram of the top view of the suction cup portion of the perfusion instrument.

FIG. 6 is a schematic diagram of a perfusion system including the perfusion instrument.

FIG. 7 is a schematic diagram showing two embodiments of the perfusion instrument.

FIG. 8 is a schematic diagram showing an alternative embodiment of the perfusion instrument, comprising separate attachment and perfusion elements, attached to the interior

1 surface of a vessel and arranged to perfuse the ostium of an adjacent vessel.

FIG. 9 shows an alternative embodiment of the perfusion instrument, suitable for use in perfusing a vessel through a surgical incision in the vessel wall.

5 FIG. 10 a is a diagram of a traditional prior art intraluminal cannula within the coronary sinus, while FIG. 10 b illustrates the use of the perfusion instrument of the present invention at the coronary sinus.

DETAILED DESCRIPTION OF THE INVENTION

10 The present invention relates to an instrument that attaches at or near one or more openings to blood vessels such as arteries or veins, allowing unobstructed artificial perfusion of the vessel(s). The opening to the vessel may be a natural ostium, or entry, from a larger vessel or organ, such as the heart or aorta, in which case the instrument is preferably attached to the interior surface of the larger vessel or organ at or near the ostium. Alternatively, the opening to the vessel may be a surgical incision or the like in the surface of the vessel wall, in which case the
15 instrument is preferably attached to the exterior surface of the vessel, at or near the incision. In a preferred embodiment, artificial perfusion is achieved without the need for significant intraluminal incannulation. The perfusion instrument can have different geometrical shapes and dimensions, depending on the vascular-anatomical structures to be perfused. However, the common denominator is a characteristic and innovative method of anchoring it to biological
20 structures, obtained by applying a negative pressure which determines the sealing action around a center portion through which the perfusion liquid is conveyed.

With particular reference to medical-surgical procedures entailing organ ischemia (interruptions of blood flow) of various durations, several known methods of organ protection are employed in order to prevent irreversible damage. These protective methods generally consist of
25 supplying, continuously or intermittently, a perfusion of crystalloid or hematic solution through arterial and/or venous vessels using catheters or cannulae of different shapes. The typical drawback of all such devices is that they must be introduced a substantial distance into the interior lumens of host vessels. More advanced cannulae are held in place by means of an inflated balloon that provides both a stabilizing function (i.e. preventing the cannula from
30 slipping out of the vessel by adhering to it) and a sealing function (i.e. preventing the perfusion fluid, or perfusate, from flowing back outside the vessel in question).

The cannulae and catheters with inflated balloons currently in use have additional limitations of an anatomical nature, such as the small lumen of a vessel and/or the presence of small calcifications in the proximity of the point of entry into the vessel (e.g. the edge of the
35 ostium). In addition, damage to the vessel wall can result from the high kinetic energy of the

1 perfusate flowing from the cannula into the vessel.

2 The purpose of the present invention is to eliminate such drawbacks by providing a device
3 that allows a cannula equipped with a sealing element to remain attached to an opening in an
4 artery or vein, through the use of a suction cup that is activated by a vacuum source, and to
5 introduce the perfusate into the artery or vein with little or no intrusion into the lumen of the
6 vessel.

7 These and other characteristics will become more apparent with reference to a simple
8 embodiment of the invention, shown here as a mere example which is not in any way restrictive
9 of the scope of the present application.

10 Several embodiments of the present invention are illustrated in FIGs. 1 and 3-10. FIGs. 1,
11 3-8 and 10 depict a perfusion instrument used for extraluminal perfusion of a vessel at the
12 ostium, the point at which the vessel branches off from a parent vessel or organ. In these
13 embodiments, the instrument is attached to the interior surface of the parent vessel or organ, at
14 (FIGs. 1, 3-7, 10) or near (FIG. 8) the ostium, with no intrusion of the cannula into the lumen of
15 the perfused vessel. FIG. 9 depicts an embodiment of the present instrument in which the
16 instrument is attached to the external surface of the perfused vessel at an incision site, with
17 minimal intrusion of the cannula into the lumen of the perfused vessel.

18 As shown in FIG. 1, the perfusion instrument 1 includes an outer cylindrical body or stem
19 2 terminating in a frustoconical outer cup 3 ("gripping cup"). Disposed within the stem 2 is a
20 cannula 4, terminating in a frustoconical inner cup 5 ("perfusion cup"), the perfusion cup
21 disposed within the gripping cup 3. Also disposed within the stem are one or more vacuum lines
22 6, connected to a vacuum or other source of negative pressure (shown in FIG. 6) that produces a
23 vacuum over the interspace formed between the gripping cup 3 and the perfusion cup 5.

24 In use, the end of the perfusion instrument 1 is placed against the paraostial area 7 of a
25 vein or artery 8, with the ostium 9 covered by the perfusion cup 5. The cannula 4 contains a
26 lumen 10, forming the physiological flow line through which blood, nutrients, drugs, or other
27 fluids are introduced into the vein or artery 8 through the ostium 9, as indicated by the broken
28 arrow 11. When a vacuum is applied, the negative pressure in the interspace A causes the
29 gripping cup 3 to adhere to the paraostial area 7 of the vein or artery 8, forming a paraostial seal
30 around the ostium 9. Fluids introduced into the cannula 4 flow through the lumen 10 of the
31 cannula and into the interior 12 of the perfusion cup 5, where the flow of the fluid is decelerated
32 prior to entry into the ostium 9, as indicated by arrows 13. This fluid deceleration is a result of
33 the relatively large diameter perfusion cup 5 in relation to the cannula lumen 10.

34 As shown in FIG. 1, the end of the gripping cup 3 and the end of the perfusion cup 5
35 preferably are substantially coplanar. As used herein, "substantially coplanar" means that the

1 edge of the perfusion cup lies in or slightly above or below the same plane as the edge of the
gripping cup, thus allowing a good seal with the perfusion cup upon application of a negative
pressure or vacuum to the gripping cup. However, other configurations are within the scope of
5 the present invention, depending on the geometry of the biological tissue at or near the opening in
the perfused vessel.

Also as shown in FIG. 1, the gripping cup is positioned concentrically outside of the
perfusion cup. Alternatively, the gripping cup may be positioned separately from the perfusion
cup, as shown in FIG. 8, so long as it is not within the perfusion cup.

10 By way of comparison, a prior art intraluminal catheter used in an ostial position is shown
in FIG. 2. Here, the catheter 14 is introduced a substantial distance into the lumen 15 of the vein
or artery 8. The intraluminal catheter of this common device is stabilized by a balloon 16, which
is inflated to secure and seal the catheter within the lumen of the blood vessel. As a
physiological fluid is introduced into the vessel through the lumen of the catheter, indicated by
15 the broken arrow 17, the fluid emerges from the end of the catheter, decelerating only after
entering the lumen 15 of the vessel, as indicated by arrows 19, potentially resulting in lesions
caused by the jet of fluid against the vessel wall, as indicated by arrows 20.

A front view of the perfusion instrument is shown in FIG. 3. As shown, the two vacuum
lines 6 are positioned on either side of the cannula 4. When vacuum is applied, the resulting
negative pressure area A forms between the perfusion cup 5 and gripping cup 3. Top and bottom
20 views of the perfusion instrument are shown in FIGs. 4 (bottom) and 5 (top).

FIG. 6 shows the perfusion instrument connected to a vacuum pump 21, a roller pump 22
for delivering the physiological fluid to the vein or artery, a gauge 23 for measuring the pressure
of the physiological fluid being administered, and a chamber 24 for the collection of any fluids
that may leak from the seal formed by the perfusion cup. The gauge 23 is connected to the
25 cannula 4 by a line 25. Preferably, two vacuum lines 6 are joined by a Y-connector 26 to a single
confluence line 27 that connects to chamber 24. The chamber, in turn, is connected to vacuum
pump 21. Note that a single vacuum line can be used but two are preferable in the event that one
becomes blocked by tissue or the like.

30 In use, the vacuum pump produces a relative negative pressure area in the interspace A,
causing the end of the perfusion instrument to adhere to the surface of the vein or artery, with the
ostium surrounded by the perfusion cup, as shown in FIG. 1. The roller pump delivers the
physiological fluid from a container (not shown) through the cannula 4 to the vein or artery. Any
fluids leaking through the seal formed by the perfusion cup around the ostium of the vein or
artery are removed via the vacuum lines 6 and collected in the chamber 24.

35 FIG. 7 shows an ascending aorta 28 and a thoracic aorta 29 with two embodiments of the

1 present invention. The coronary sinus adjacent the base of the ascending aorta has been
surgically opened to reveal two separate ostia of coronary arteries, to which are applied two
devices 1 according to the present invention. An alternative embodiment of the instant invention,
5 a perfusion patch 30, different in shape and size, but not basic in functional operation, from those
previously described, acts simultaneously through several ostia 31 located over a relatively wide
area of the surgically opened thoracic aorta.

For example, in this embodiment, multiple ostia 31 are all incorporated into a single inner
perfusion cup 32, disposed within a single outer gripping cup 33. As in the embodiment
10 described in detail above, vacuum lines (not individually shown), disposed within tube 34, are in
fluid communication with the interior of the gripping cup 33 to form a negative pressure area A
in the interspace between the gripping cup and the perfusion cup when a vacuum is applied, to
thereby form a seal between the inner surface wall of the vessel and the gripping cup and
perfusion cup, around all of the ostia 31. Also disposed within tube 34 is a cannula, through
15 which physiological fluids are delivered through the perfusion cup, and ultimately through the
ostia sealed within the perfusion cup to the various vessels connected to the thoracic aorta 29.

Although shown with reference to the thoracic aorta in FIG. 7, the perfusion patch can be
used at any location in the body where it is useful to simultaneously perfuse more than one
opening. Vessels for which the perfusion patch can be used include, but are not limited to, the
20 intercostal arteries, providing blood to the spinal cord, the coronary arteries, which can be
perfused individually, as shown in FIG. 7, or by a single perfusion patch, and the supra-aortic
branches, arteries to the limbs and brain.

Another embodiment of the instant device is shown in FIG. 8. Here, the perfusion
instrument 35 includes a cylindrical body 36 terminating at one end in three separate cups 37, 38
25 and 39. Cannula 40, partially disposed within the cylindrical body 36, terminates in the central,
or perfusion, cup 37, which acts here only as a paraostial seal, not as a gripping element. Two
vacuum lines 41 and 42, partially disposed within cylindrical body 36 on either side of cannula
40, are each connected at one end to rigid stems 43 and 44, as shown in FIG. 8. Rigid stems 43
and 44 terminate in gripping cups 38 and 39, respectively, which here act only as gripping
30 elements to secure the perfusion instrument to the vessel.

In use, the perfusion instrument is positioned with the perfusion cup 37 on the surface 45
adjacent the ostium 47 of a vessel 46. The ostium 47 of the vessel is within the circumference of
the inner lumen of the cup 37. While at rest, that is, when no vacuum is applied, the two gripping
cups 38 and 39 are positioned on either side of the ostium, with the edges of the gripping cups
slightly higher than the edge of perfusion cup 37, relative to the surface of the vessel. When a
35 vacuum pump (not shown) connected to the two vacuum lines 41 and 42 is turned on, the

1 resulting negative pressure area A' causes the two gripping cups 38 and 39 to adhere to the
paraostial surface, slightly compressing perfusion cup 37 onto the surface to thereby achieve a
seal around the ostium. Physiological fluids can then be administered through cannula 40 into
5 perfusion cup 37, as indicated by broken arrow 48, where the fluid decelerates, as indicated by
arrows 49, prior to entering the vessel 46 via the ostium 47.

An embodiment of the present invention suitable for use at a surgical incision in the wall
of a vessel is shown in FIG. 9. In this embodiment, a hollow perfusion cannula 50, preferably
with a bend near its end 51 to form a short, tubular extension 52, is disposed within an outer
10 sheathe 53. The outer sheathe also includes a bend near its end 54 to form an outer tubular
extension. The end 51 of the cannula 50 preferably extends slightly beyond the end 54 of the
sheathe 53, but can be flush with the sheath 53. A space 55 is thus provided between the cannula
50 and the outer sheathe 53.

Through a small incision, the tip 51 of the cannula is inserted into the vessel 55.
15 Importantly, the cannula is only inserted a short distance, on the order of a few millimeters,
preferably 4 to 5 millimeters, into the vessel, so as not to impede the flow of blood and perfusate
in the vessel. Preferably, the incision is made sufficiently small so that the tip 51 of the cannula
50, when inserted into the incision, fits sufficiently tightly to prevent excessive leaking from the
vessel. A vacuum is then applied to the space 55 between the outer sheathe and the cannula,
20 causing the end 54 of the outer sheathe to adhere to the outer surface of the vessel, thereby
holding the cannula in place in the incision. The perfusate is then administered to the vessel
through the cannula 50 and into the vessel 55. Optionally, a "safety purse string" suture can be
added, using it for the closure of incision around the end of the cannula 50 during perfusion, to
thereby reduce leakage around the tip of the cannula.

25 Alternatively, the incision can be made smaller than the diameter of the cannula, so that
the incision is contained within the lumen of the cannula and the edges of the cannula rest against
the outer surface of the vessel without any intrusion into the interior of the vessel.

Although FIG. 9 shows a near right angle bend in the end of the cannula and outer sheathe,
it is apparent that other configurations, including straight cannulae, are within the scope of this
30 invention, depending on the site of intended use.

As described above, the present invention provides for a perfusion instrument that is
anchored via a suction device at or near an opening in a vessel, to thereby perfuse the vessel with
little or no intrusion into the lumen of the perfused vessel itself. This makes the invention
suitable for a wide range of applications, including many that are not practical using conventional
35 perfusion catheters.

For example, the perfusion instrument of the present invention can be applied to the

1 coronary sinus during retrograde coronary perfusion, avoiding the limitations of existing
intraluminal cannulae and assuring complete perfusion of the entire cardiac venous system,
including the right ventricle. As shown in FIG. 10a, conventional intraluminal cannulation
5 bypasses the major cardiac venous tributaries of the right ventricle, resulting in reduced perfusion
of the right ventricle. The perfusion instrument of the present invention, however, may be
secured to the ostium, as shown in FIG. 10b, providing complete perfusion of the entire cardiac
venous system, including the right ventricle.

10 The resulting safety and efficacy of the global perfusion of venous cardiac system using
the present invention would almost certainly widen the use of this retrograde perfusion technique.
For example, it is believed that the present invention can be used with new applications of
“beating heart techniques” and by all the attempts to be “less invasive,” i.e. “more physiologic,”
in treating the heart.

15 With the appropriate configuration, the present invention will allow the surgeon to closely
regulate the retrograde flow of a potassium infusion in the heart, switching the flow on and off, to
thereby vary the heart’s beating and steady state according to surgical necessity.

20 Another advantage of a method of assuring a complete perfusion of the heart using only
one cannula, steadily kept in position with the aid of vacuum, is the continuity of the operation.
The surgical procedure is never interrupted, driving the cardioplegic and/or blood infusion
according to the requirements of different surgical steps.

25 In addition to its usefulness in coronary retrograde perfusion, it is also believed that the
present invention can be used as a “perfusion patch” for intercostal arteries and/or supra-aortic
vessels during aortic surgery. Such a perfusion patch, as shown in FIG. 7, could assure the
perfusion of a large number of intercostal arteries in the thoraco-lumbar segment during the distal
and proximal anastomosis of descending tract of the aorta, in the surgical treatment of acute and
chronic pathology. The “no-flow time” would be limited only to the few minutes of opening the
aneurysm and positioning the described “patch.”

30 In acute dissection, this method ensures the perfusion of the true lumen, as the vacuum
fixes the patch to the intima of the aorta. In case of a re-entry flap at the level of thoraco-lumbar
arteries, the “patch” could be attached following the rim of the flap to perfuse only the true lumen
or could be remodeled to perfuse only the arteries not dissected. The described embodiment can
alternatively have numerous vacuum holes along its perimeter and can follow a desired adhesion
line.

35 In chronic pathology, once the inner thrombus has been removed, the application of
“patch” guarantees the perfusion of those arteries that still show a reflux from the periphery. At

1 the end of the anastomosis is possible to switch off the vacuum to the “perfusion patch” and pull
it out like an intravascular shunt, re-starting the physiologic circulation.

5 The present invention can also be used to provide antegrade perfusion of the supra-aortic
vessels during aortic arch surgery. Using the device of the present invention, modified to
conform to an appropriate shape and size as required by vessels to be perfused, the perfusion of
one or more supra-aortic vessels could be achieved without the trauma of cannulation of an
artery.

10 The present invention can also be used for perfusion through an incision in the side of a
vessel. For example, the perfusion instrument can be used at a surgical incision in the femoral
artery during cardiopulmonary bypass surgery, ensuring both proximal and distal perfusion
through the femoral artery.

Other uses of the perfusion instrument of the present invention are apparent, as will be
appreciated by those of ordinary skill in the art.

15 Although the invention has been described in detail with reference to only a few preferred
embodiments, those having ordinary skill in the art will appreciate that various modifications can
be made without departing from the spirit of the invention. For example, it should be understood
that the inner and outer cups of the present invention can be modified to produce a wide range of
shapes and contours for use in various locations in the body. As designed, the device allows for
numerous modifications and variations that are within the scope of the invention’s concept. In
20 addition, all elements may be substituted for technically equivalent ones.

With such possibilities in mind, the invention is defined with reference to the following
claims.

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1 WHAT IS CLAIMED IS:

5 1. A perfusion instrument that utilizes vacuum from a vacuum source to remain secured to a host vessel and that provides perfusate from a perfusate source to the host vessel, the instrument comprising:

a perfusion cup having an interior and an end;

a cannula in fluid communication with the perfusion cup such that perfusate can flow from the perfusate source to the interior of the perfusion cup;

10 a gripping cup having an interior space and an end, the gripping cup positioned outside of the perfusion cup; and

a vacuum line in fluid communication with the gripping cup such that vacuum from the vacuum source can be provided to the interior of the gripping cup.

15 2. The instrument of claim 1, wherein the end of the perfusion cup and the end of the gripping cup are substantially coplanar.

3. The instrument of claim 1, wherein the perfusion cup is disposed concentrically within the interior of the gripping cup.

20 4. The instrument of claim 1, further comprising a collection chamber, wherein the collection chamber is in communication with the vacuum line between the gripping cup and the the vacuum source.

5. The instrument of claim 1, further comprising a pressure gauge in communication with the cannula.

25 6. The instrument of claim 1, wherein the diameter of the perfusion cup is sufficiently large relative to the diameter of the cannula to act as a decelerating element for the cannula, reducing the flow speed of the perfusate inside the perfusion cup.

30 7. The instrument of claim 1, wherein the diameter of the perfusion cup is sufficiently large to enclose at least one ostium.

8. The instrument of claim 1, further comprising a hollow rigid tube with a first end and a second end, wherein the first end of the tube is in communication with the interior of the gripping cup and the second end is in communication with the vacuum line.

35 9. The instrument of claim 8, wherein at least two gripping cups are positioned outside of the perfusion cup.

- 1 10. The instrument of claim 9, wherein the ends of the gripping cups are higher
relative to the end of the perfusion cup.
- 5 11. A method for perfusing an artery or vein, comprising the steps of:
- providing a perfusion instrument, the instrument comprising a perfusion cup having an
interior and an end, a cannula in fluid communication with the perfusion cup such that perfusate
can flow from a perfusate source to the interior of the perfusion cup, a gripping cup having an
interior space and an end, the gripping cup positioned outside of the perfusion cup, and a vacuum
10 line in fluid communication with the gripping cup such that vacuum from a vacuum source can
be provided to the interior of the gripping cup;
- placing the perfusion cup in fluid communication with an opening in an artery or vein;
- placing the gripping cup adjacent to the opening in the artery or vein;
- 15 applying vacuum to the interior of the gripping cup, to thereby anchor the gripping cup
adjacent to the opening in the artery or vein; and
- passing the perfusate through the cannula, into the interior of the perfusion cup and
through the opening in the artery or vein.
- 20 12. The method of claim 11, wherein the perfusion cup is enclosed within the interior
of the gripping cup.
13. The method of claim 11, further comprising providing a collection chamber,
wherein the collection chamber is in communication with the vacuum line between the gripping
cup and the the vacuum source.
- 25 14. The method of claim 11, further comprising a pressure gauge in communication
with the cannula.
15. The method of claim 11, wherein the diameter of the perfusion cup is sufficiently
large relative to the diameter of the cannula to act as a decelerating element for the cannula,
30 reducing the flow speed of the perfusate inside the perfusion cup.
16. The method of claim 11, further comprising providing a pump, wherein the pump
engages the cannula to thereby pump the perfusate from the perfusate source through the cannula
into the interior of the perfusate cup.
- 35 17. The method of claim 11, wherein the perfusion cup is placed over a surgical
incision in the artery or vein.

1 18. The method of claim 11, wherein the perfusion cup is placed over an ostium of the
artery or vein.

5 19. The method of claim 18, wherein the perfusion cup is placed over more than one
ostium, such that each ostia is contained within the interior of the perfusion cup.

10 20. The method of claim 11, wherein the end of the gripping cup is positioned slightly
higher than the end of the perfusion cup when the perfusion cup is placed over the opening in the
artery or vein, such that applying the vacuum to the interior of the gripping cup causes the
perfusion cup to compress against the surface of the artery or vein around the opening, thereby
preventing substantial leakage of perfusate from the perfusion cup.

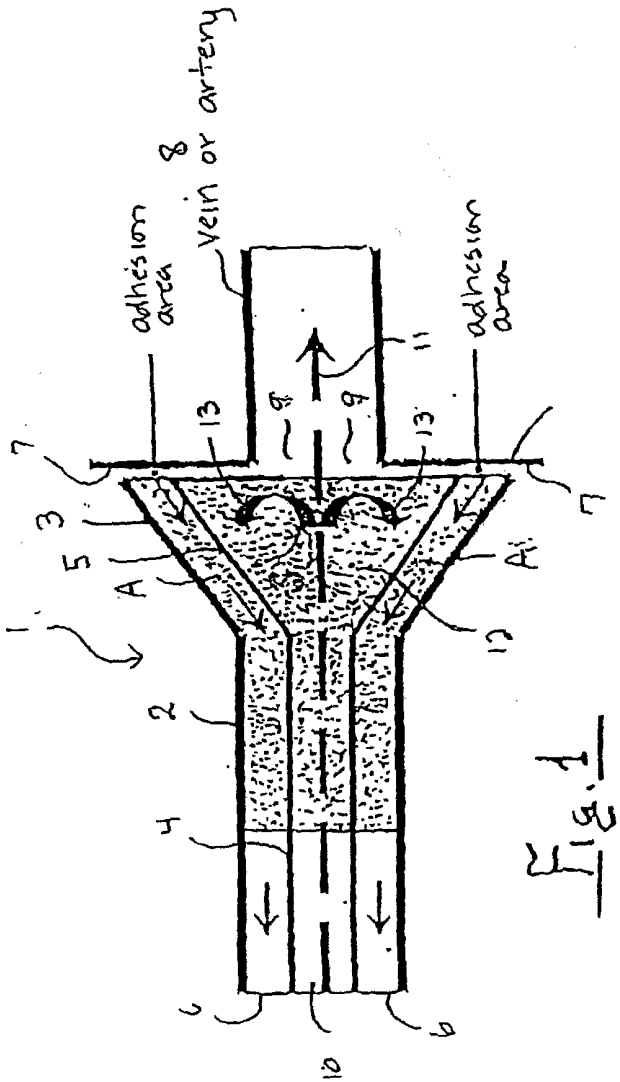


Fig. 1

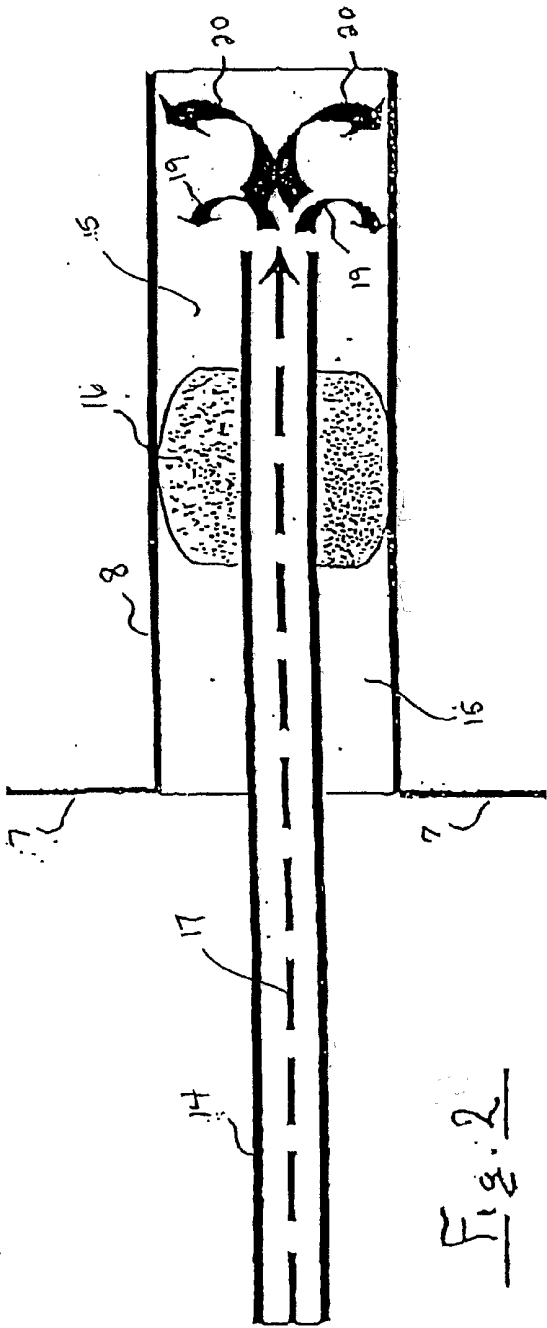
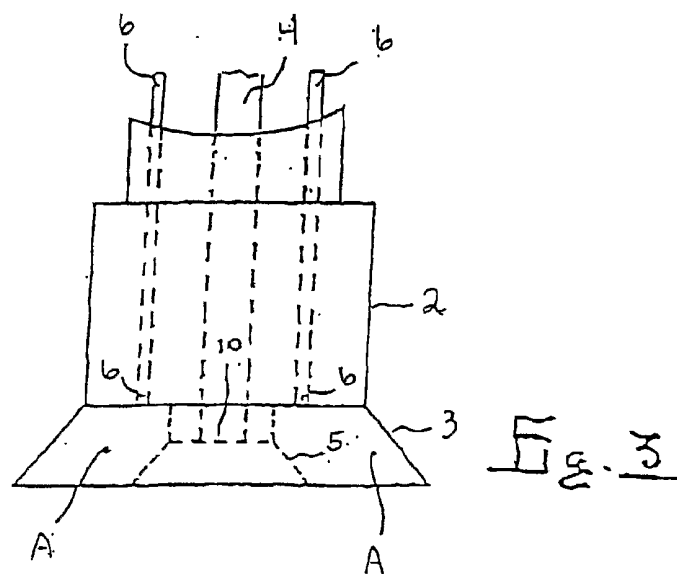


Fig. 2

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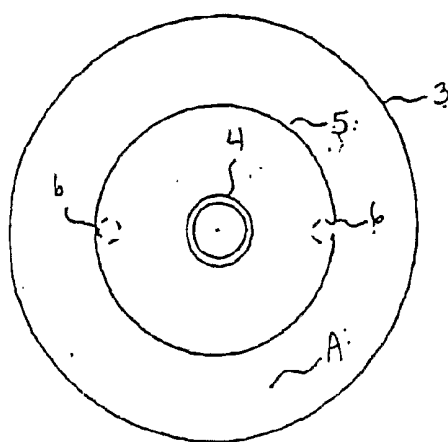


Fig. 4

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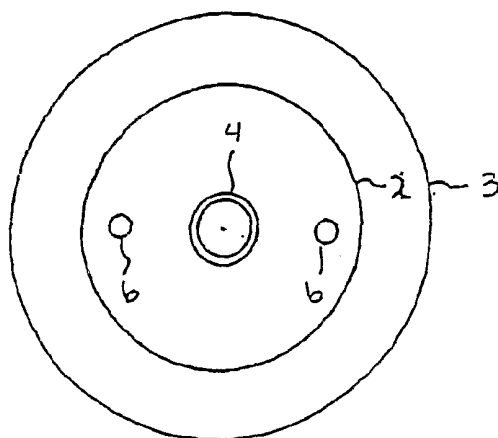
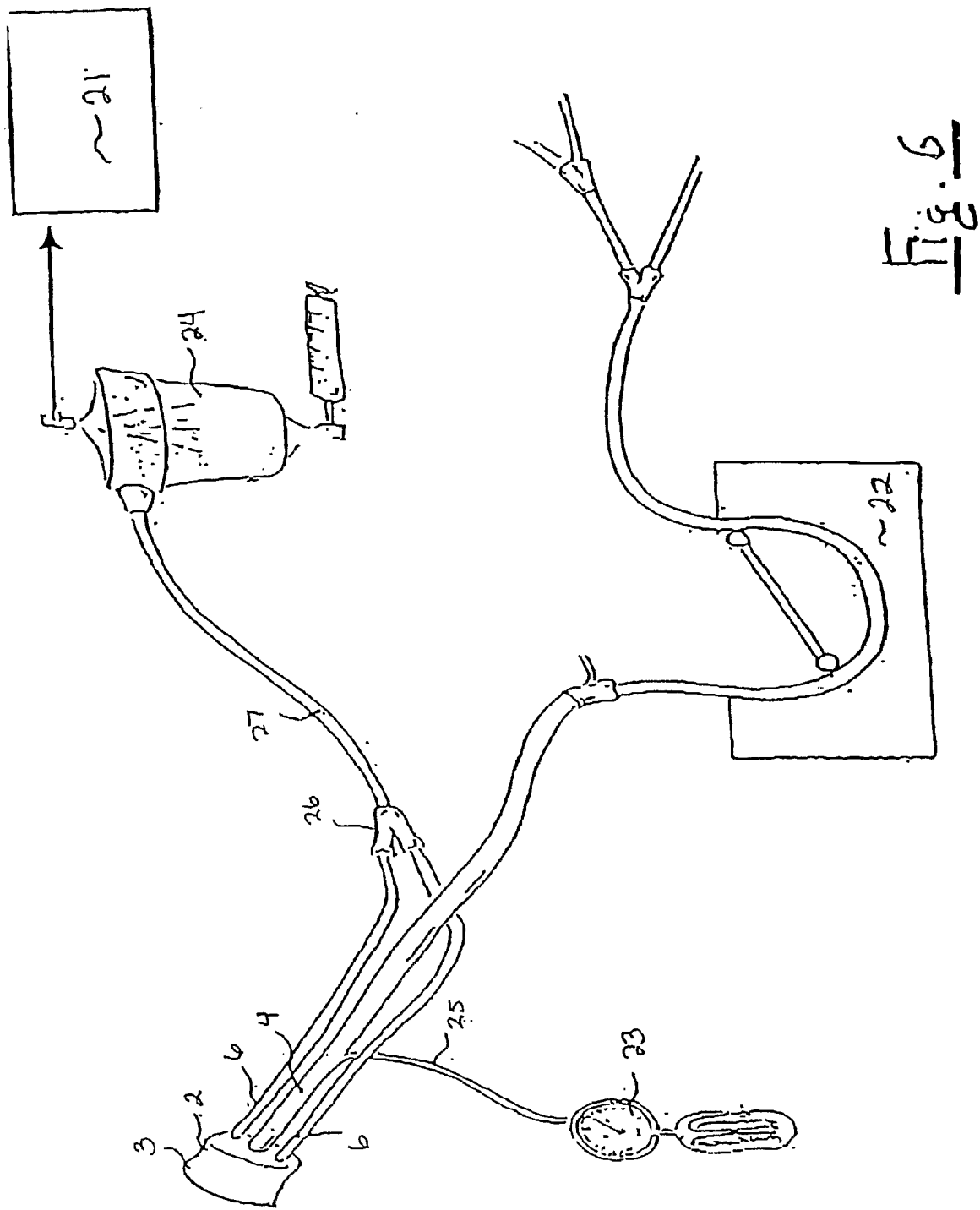


Fig. 5



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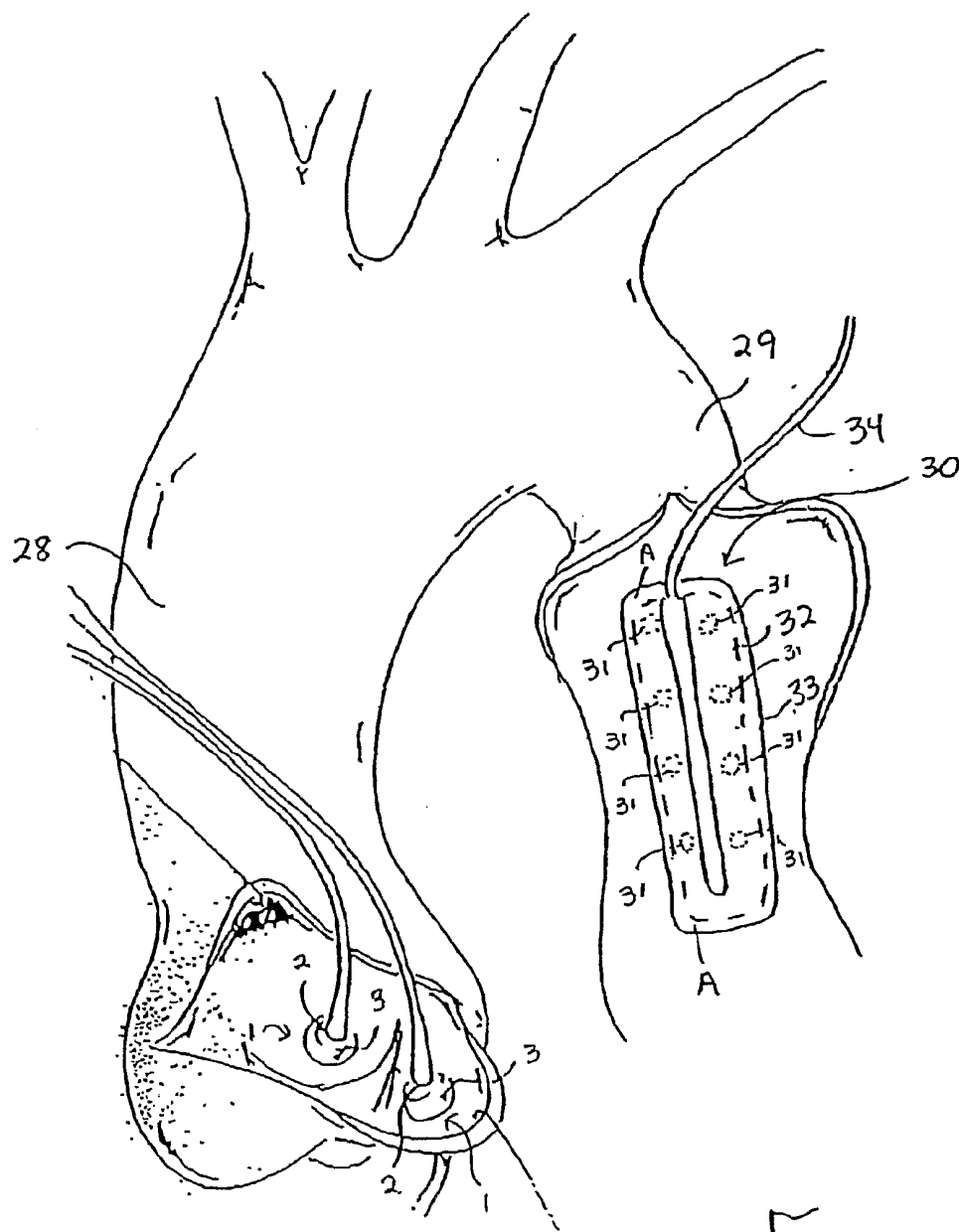


Fig. 7

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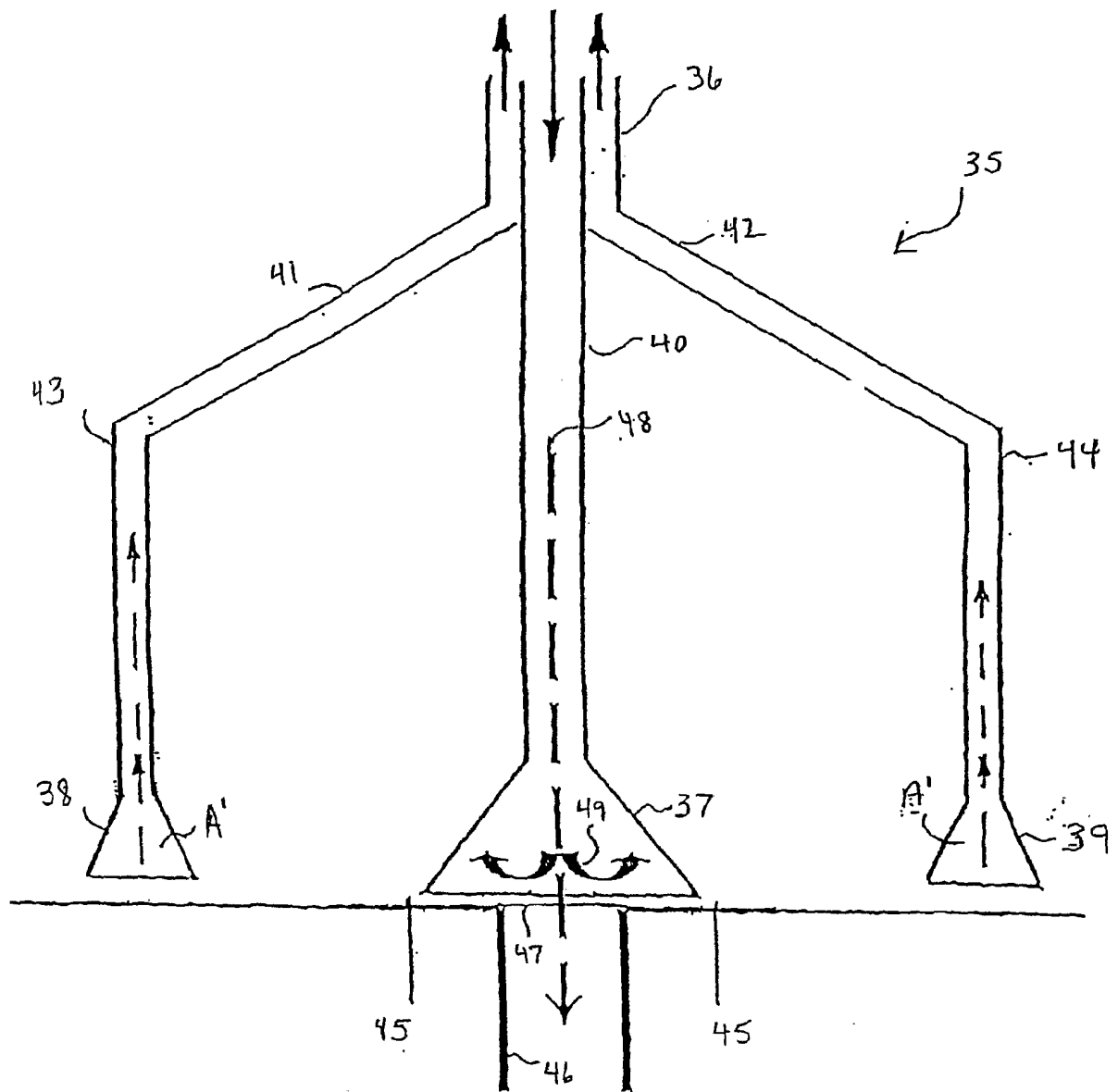


Fig. 8

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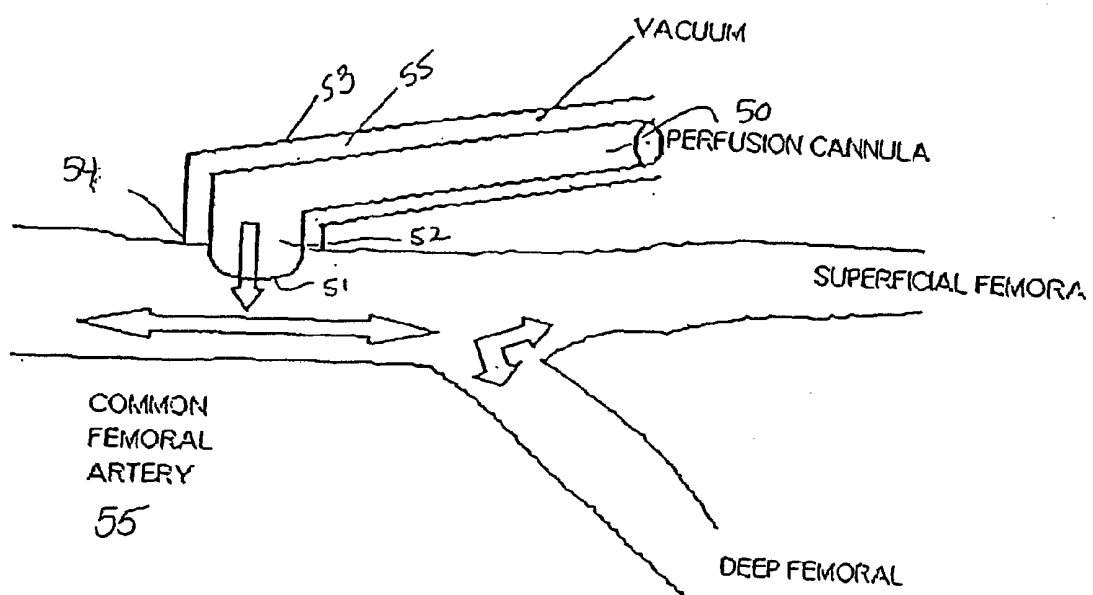


FIG 9

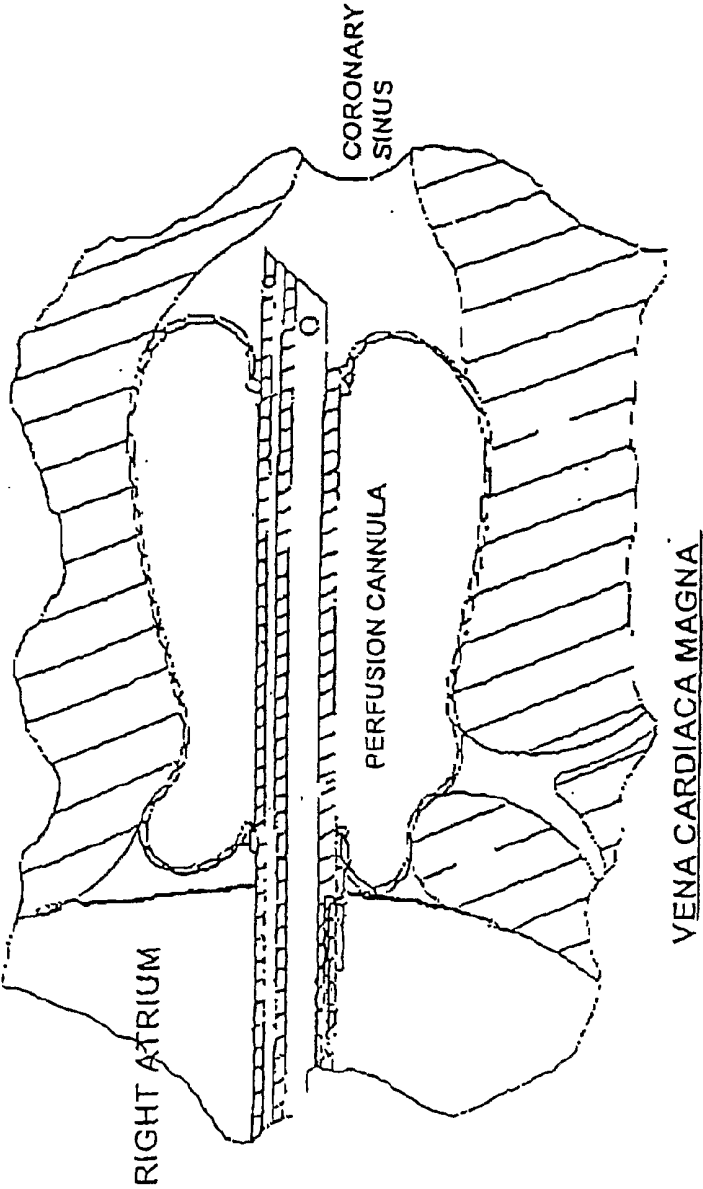


FIG. 10a

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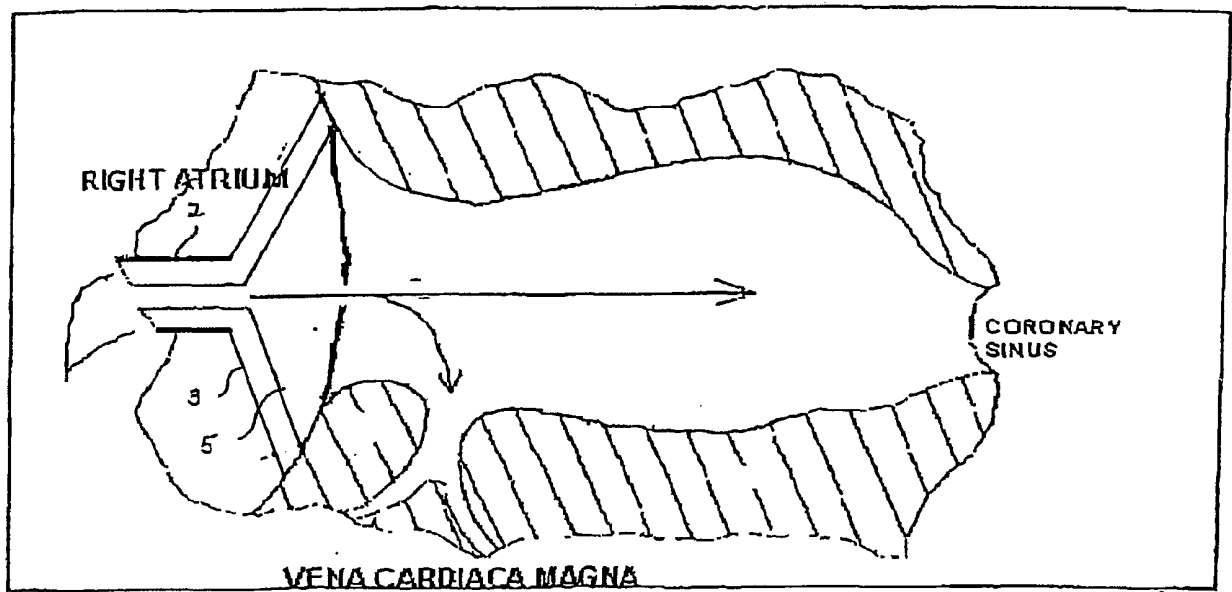


Fig. 10b