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Pevsner

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[54] **MINIATURE BALLOON CATHETER METHOD AND APPARATUS**

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Issued: **Apr. 25, 1978**
Appl. No.: **681,676**
Filed: **Apr. 29, 1976**

[51] **Int. Cl.**[4] **A61M 25/00**

[52] **U.S. Cl.** **128/325**; 604/99; 604/103

[58] **Field of Search** 128/325, 344, 129; 604/96–103

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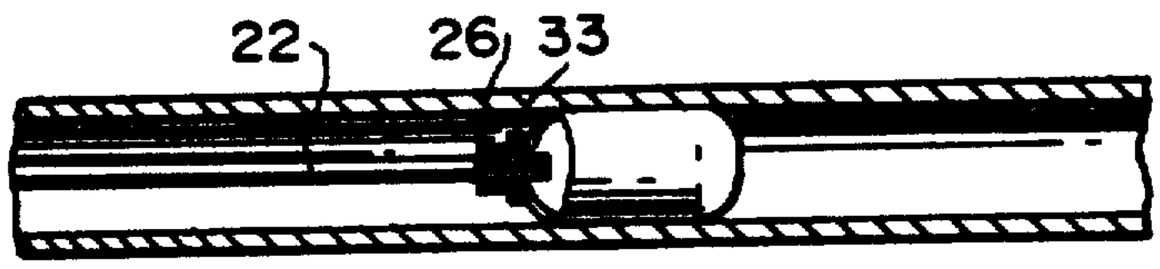
Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Griffin, Branigan & Butler

[57] **ABSTRACT**

A miniaturized balloon catheter assembly includes a cannula and an inflatable tubular balloon constructed of a silastic tubing detachably mounted on the cannula for performing a surgical procedure in a human vessel in response to pressure therein. In one embodiment, the balloon is detachable mounted with the detachability being responsive to pressure. For example, the balloon elastically grips the cannula and there is a small metallic C-shaped spring mounted about the balloon and cannula. In another embodiment, a valve, such as a pinhole in the silastic material for example, is included in the balloon which opens only after the pressure within the balloon exceeds a predetermined amount. According to a method of the invention, the cannula and the attached balloon are inserted into a small vessel and the balloon is pressurized therethrough. The balloon is partially inflated to allow fluid flow in the vessel to position the balloon at a desired location. The balloon is further inflated to fix the balloon in position against the walls of the vessel. Pressure is thereafter increased in the balloon to activate a desired procedure within the vessel. In the first embodiment the desired procedure is to withdraw the cannula from the affixed balloon as the increased pressure lubricates the connection between the balloon and the cannula. The C-spring and the silastic balloon cooperate to close off the opening into the balloon left by the retracted cannula and thereby leave the balloon in position in the vessel. In the second embodiment, the desired procedure is for the increased pressure to open the pin-hole and disperse a fluid into the vessel from the balloon. There are alternate embodiments for performing the above methods and the methods can be combined.

14 Claims, 13 Drawing Figures



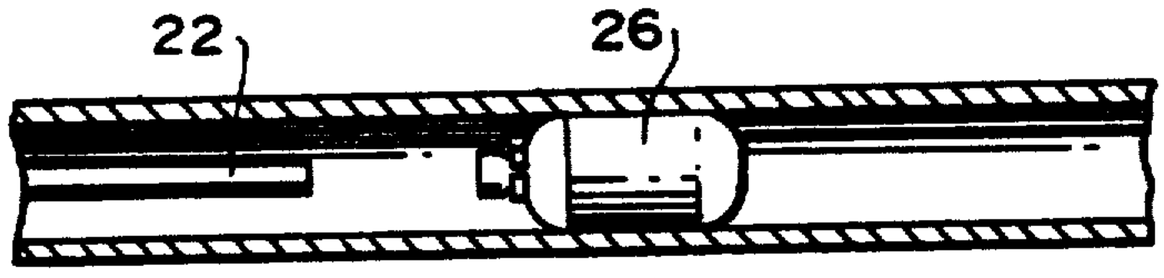
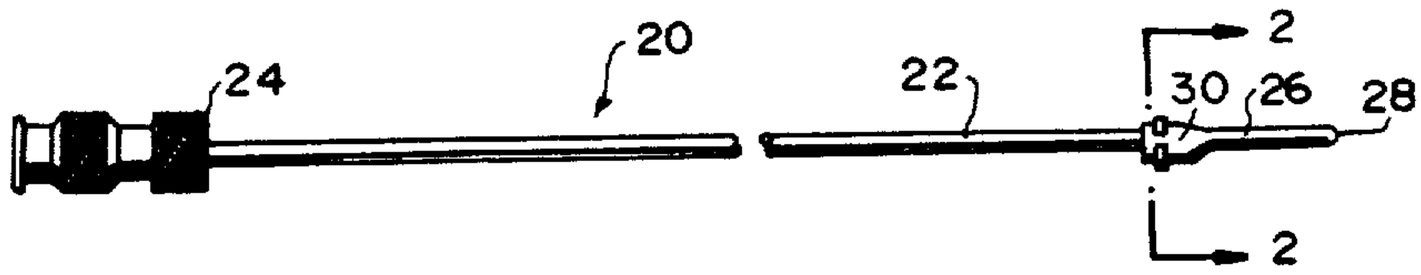


FIG. 1



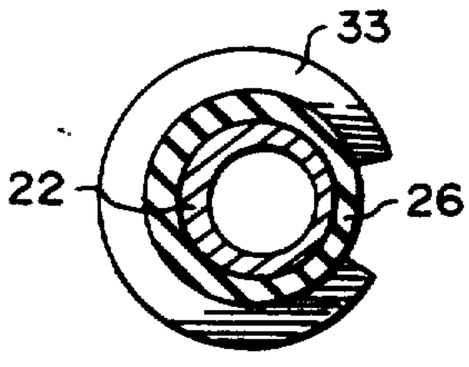


FIG. 2

FIG. 3

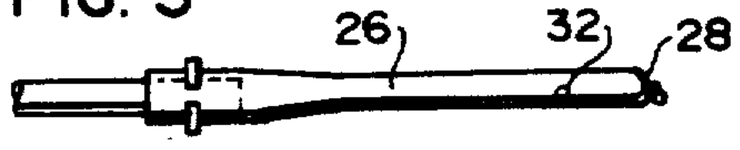
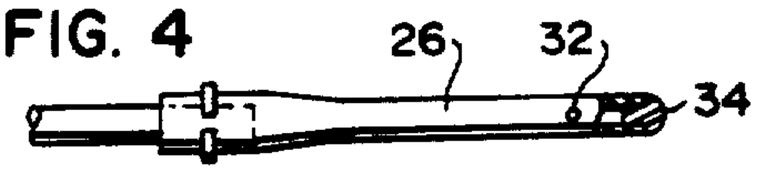


FIG. 4



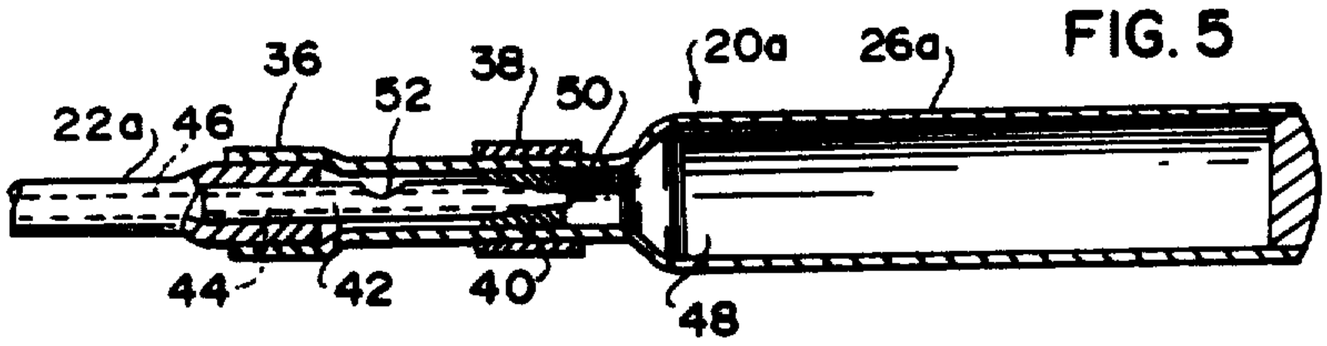


FIG. 5

FIG. 6

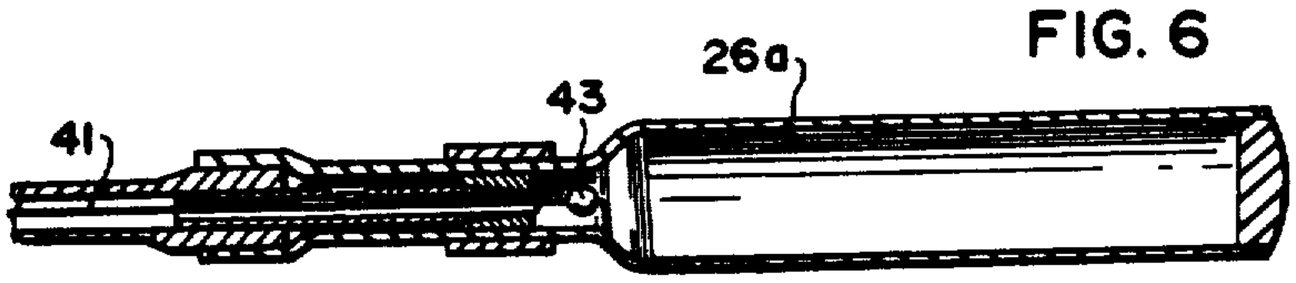


FIG. 7

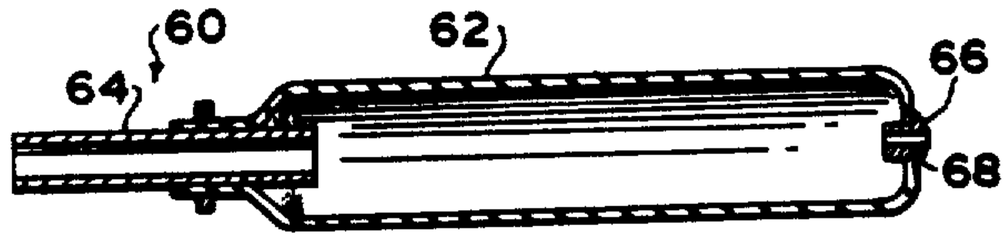


FIG. 8

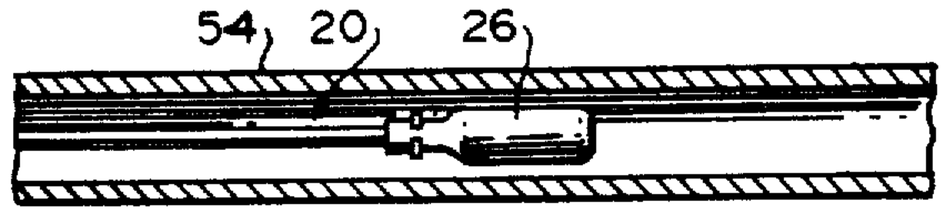


FIG. 9

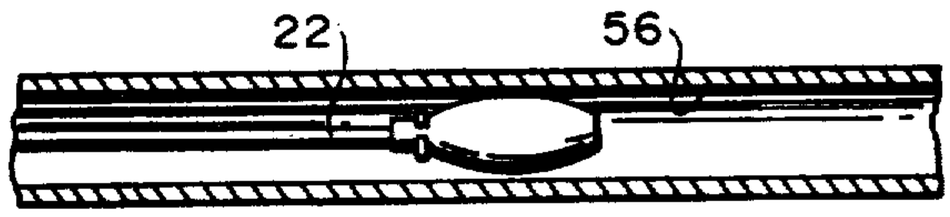


FIG. 10

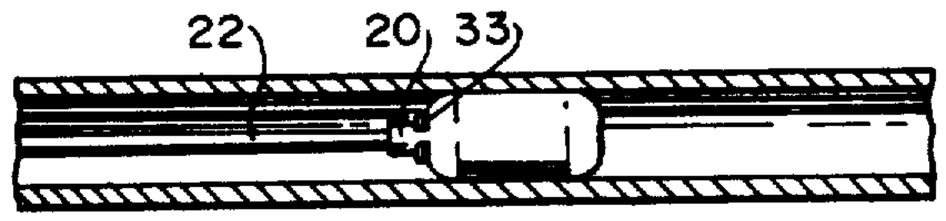


FIG. 11

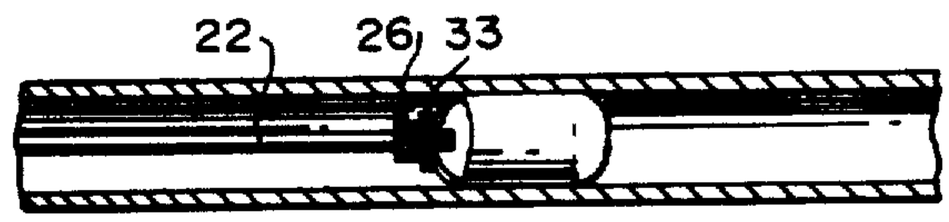


FIG. 12

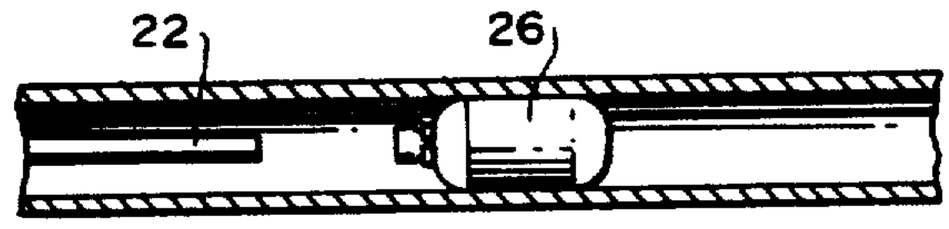
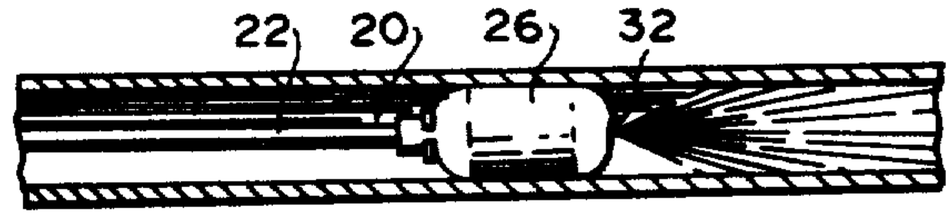


FIG. 13



MINIATURE BALLOON CATHETER METHOD AND APPARATUS

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

This invention relates broadly to the art of balloon catheters, and more particularly to the art of miniaturized balloon catheters generally for use in blood vessels and the like.

A significant publication disclosing prior art developments in the area of this invention is Serbinenko, Balloon Catheterization and Occlusion of Major Cerebral Vessels, Journal of Neurosurgery, Volume 41, August 1974, pages 125–145. This article describes the work of Dr. Serbinenko with miniaturized balloon catheters. Dr. Serbinenko has employed balloon catheters to occlude vessels in cardiovascular surgery as well as for other purposes, and his article is incorporated by reference here.

Dr. Serbinenko employs a latex balloon that is held onto a cannula by means of an elastic string for achieving permanent occlusion of vessels. The balloon is inserted into a vessel and allowed to move to a proper position by fluid circulation within the vessel. The balloon is then inflated by means of a solidifying filler until it is fixed against the walls of the vessel. After the solidifying filler has solidified the cannula is pulled from the balloon and the balloon is left in the vessel.

A difficulty with Dr. Serbinenko's arrangement is that the balloon sometimes comes off of the cannula prematurely because the elastic string does not tightly hold the balloon to the cannula. Still another difficulty with Dr. Serbinenko's arrangement is that the solidifying filler is somewhat difficult and awkward to work with. Thus, it is an object of this invention to provide a miniaturized balloon catheter which can be used for permanent occlusion of a vessel but which is not prematurely detached from the cannula and which can be inflated by a nonsolidifying fluid.

Dr. Serbinenko has also employed a miniaturized balloon catheter to achieve profusion. That is, Dr. Serbinenko has made a small pin-hole in his latex balloon from which a dye or the like is discharged from the balloon into the vessel. However, in Dr. Serbinenko's arrangement, the fluid to be profused passes through the pin-hole as soon as the fluid enters the balloon. It is sometimes desirable that the fluid not pass through the hole until the balloon has accomplished occlusion of the vessel. Thus, it is another object of this invention to provide a miniaturized balloon catheter which does not initiate profusion of fluid until the balloon has achieved occlusion of the vessel.

It is a further object of this invention to provide a miniaturized ballon catheter, and a method for using the miniaturized balloon catheter which is efficient in operation, and relatively easy and inexpensive to manufacture.

SUMMARY

According to principles of one aspect of this invention, a miniaturized balloon catheter is inflated within a vessel until it is fixed against the walls of the vessels, and thereafter released from its attached cannula and sealed

off against deflation. In this respect, the mechanism for attaching the balloon catheter to the cannula responds to increased pressure within the balloon once the balloon is fixed to release the balloon from the cannula so that the cannula can be pulled from the balloon and thereafter closes the opening in the balloon left by the extracted cannula. In one embodiment, the balloon is of a self-sealing silastic material and its diameter is approximately the same as the cannula. The balloon is fitted onto the cannula and a C-spring is mounted over the balloon and cannula to hold the balloon to the cannula. Pressure within the balloon beyond a predetermined degree opens the C-spring to allow the cannula to be removed.

Also in accordance with principles of another aspect of this invention, additional pressure within the balloon after the balloon is fixed against the walls of the vessel opens a valve in the balloon to disperse fluid from the balloon into the vessel for perfusion. This valve, in one embodiment, comprises a pin-hole in the self-sealing silastic balloon.

Additional arrangements for performing the above functions are also described herein.

To summarize, in general, the method and device of this invention deals with a miniaturized balloon catheter assembly adapted for use in diagnosis in therapy procedures in connection with small human vessels. The device includes a cannula having a small outer diameter for insertion into small human vessels. An inflatable tubular balloon is mounted on the end of the cannula that is inserted into the vessel. The cannula and balloon are adapted to be carried by fluid in the vessel to a desired location therein. The force of pressure operates at the other end of the cannula to inflate the balloon. The balloon includes elements for responding to increased pressure therein once the balloon is fixed to the walls of the vessel to initiate desired diagnostic and/or therapy procedures within the vessel at the desired location.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention in a clear manner.

FIG. 1 is a plan view of a balloon catheter assembly of the invention;

FIG. 2 is a sectional view taken on line 2—2 of FIG. 1;

FIG. 3 is an enlarged fragmentary plan view thereof showing the inflatable balloon portion attached to the end of a cannula;

FIG. 4 is an enlarged fragmentary view thereof showing a form of inflatable balloon portion attached to the end of the cannula;

FIG. 5 is a partial sectional view of an alternate form of the balloon catheter assembly of the invention showing only the end portion of the cannula which is attached to the balloon portion;

FIG. 6 is a partial sectional view of the alternate arrangement of the balloon catheter with a wire by which detachment at any balloon size may be achieved;

FIG. 7 is a sectional view of a further alternative form of the balloon catheter of the invention;

FIGS. 8–12 are sequential schematic representations of the use of the types of devices depicted *in* FIGS. 1–4;

FIG. 13 is a schematic representation of the use of a balloon catheter of this invention for achieving profusion.

DESCRIPTION OF PREFERRED EMBODIMENTS

FIGS. 1 and 2 show a catheter assembly 20 which includes a hollow cannula 22, open at both ends, with a connector 24 at one end which is adapted for connection to a conventional source of pressurized fluid. Mounted on the other open end of the cannula 22 is an inflatable balloon portion or inflatable tube 26 as a self-sealing material described further below. The distal end 28 of the balloon portion is closed by knotting the end. The proximal end 30 is expanded to cover and frictionally engage the adjacent end of the cannula 22. In this respect, in a preferred embodiment the interior diamters of both the balloon or tube portion 26 and the hollow cannula 22 are approximately 0.011 inch and the outer diameters thereof are 0.024 inch. Thus, the balloon or tube portion 26 contracts onto the hollow cannula 22. This brings the passageway in the cannula 22 in communication with the interior passage of the inflatable balloon portion or tube 26. As shown in FIG. 2, the inflatable *tube* 26 has a pin-hole 32 adajcent to the distal end 28 which is normally closed when the balloon portion 26 is in the relaxed, uninflated condition since the material of the balloon is self-sealing. This hole could also be in the distal end 28. Again this is accomplished by forming the balloon portion 26 of an elastomeric self-sealing material such as silastic tubing.

FIG. 4 shows an alternative means for forming the distal end of the balloon portion 26. In place of the knot at the end 28, a plug 34 attached by an adhesive is employed. It is also contemplated that in place of a pin-hole 32, an opening can be positioned through the knot or the plug 34. The pin-hole 32 forms a passageway for fluid to pass from the distal end of the balloon portion 26 once the pressure within the balloon portion exceeds a predetermined amount.

Materials which can be used for the components of catheter 20 are, for cannula 22, a plastic such as polyethylene or any conventional substitute therefor; and, for the expandable balloon portion 26, silastic tubing.

In addition to balloon portion 26 contracting onto the hollow cannula 22, a C-shaped spring 33 is mounted on the outside of the balloon portion to positively hold the balloon portion 26 and the hollow cannula 22 together. The C-shaped spring is constructed of a watch-spring metal and, in a preferred embodiment, this spring has a contracted internal diameter of 0.018 inch and an outside diameter of 0.020 inch. When the spring has expanded, it has an inside diameter of 0.028 inch and an outside diameter of 0.033 inch. These dimensions of the C-spring cooperate with those of the balloon portion 26 such that when the cannula 22 is not positioned within the C-spring 33 then the opening to the balloon portion 26, which the cannula 22 held open, is closed by the C-spring.

FIG. 5 depicts an alternate device which is used as a detachable implant device for permanent vessel occlusion, for example. The materials used for *cannula* 22a and inflatable balloon portion 26a are the same as in the previously discussed embodiments and the difference in

structure resides in the interconnection between portion 26a and cannula 22a. In place of the expanded frictional interengagement, a combination type structure is employed. In this regard, a proximal end 36 of inflatable portion 26a is expanded in the same manner and coupled with the outer surface of cannula 22a. Spaced from end 36 on portion 26a is an expandable ring 38 which is concentrically aligned with an inner plug 40. The plug is of an expandable elastomeric self-sealing material and is provided with a small pin-hole that may be formed by a wire or it may be pierced by a hollow pin 42 located within inflatable portion 26a. Pin 42 has a through passageway 44 which communicates at one end with the through passageway 46 of cannula 22a and at the other communicates with the chamber 48 in the main body portion of inflatable balloon 26a. This communication is accomplished by passing the pointed tip 50 of pin 42 through plug 40 so that its open tip is in communication from cannula 22 to the chamber 48 in balloon 26a.

An additional element of structure on pin 42 is a side opening 52 located between lug 40 and the end of cannula 22a. This side opening is utilized for activating the detachment between inflatable portion 26a and cannula 22a as will be described in detail below in connection with FIGS. 8–12. The through passageway is provided so that the fluid from the pressure source can pass into the inflatable portion and inflate balloon 26a. The FIG. 5 embodiment is perhaps cheaper to manufacture than the FIGS. 1–4 embodiments.

The embodiment of FIG. 6 is the same as the FIG. 5 embodiment with the exception of an additional wire 41 which passes through the through-passageway and terminates in a stop at the end in the form of a sphere 43. Naturally other configurations for the stop can be readily contemplated. The wire is of smaller character than the passageway so that fluid can bypass the wire and inflation can occur to the desired degree. Then the wire can be withdrawn to block the open end of tip 50 by engagement with stop 43 which closes the opening. Thereafter, further pressure will only be able to exit through the side opening 52 to accomplish detachment. In this manner, no further expansion of the balloon occurs during the detachment procedure. All fluid passes through the side opening.

The embodiments of FIGS. 5 and 6 do not have the pin-hole at the distal end of portion 26a for perfusion of material contained therein. However, it is contemplated that a passageway can be provided as is present in the embodiments of FIGS. 1–4 so that the combination of detachable means and perfusion means is present in the same device.

Turning to operation of the embodiments of FIGS. 1–6, reference is made to FIGS. 8–12. It should be noted at the outset that it is possible for the device to be initially introduced into a human vessel 54 by first passing a catheter of larger diameter into the vessel and then passing the cannula 20 or 20a through the larger catheter into the vessel 54. The larger catheter can then be removed or retained in position during the remainder of the operable procedures. It is contemplated that the larger catheter through which the device can be passed can be used with all of the discussed embodiments.

Naturally the dimensions of the balloon catheter assembly are a matter of choice depending upon the particular human vessel to which it is to be applied, keeping in mind, that the device is to be used in very small human vessels. In any event, the length and lateral dimensions are determined by use. In addition to expand-

ing the balloon portion to engage the outer surface of the end of the cannula, it is also possible to shrink the end of the balloon portion on the end of the cannula to produce the same result.

Turning to operation of cannula **20**, FIG. **8** shows the cannula **20** in position in the small human vessel **54** prior to introduction of pressured fluid to expand portion **26**. A first amount of pressurized fluid is then introduced as shown in FIG. **9** so as to partially expand balloon portion **26**. This increases the lateral dimension of the assembly and gains the assistance of blood flowing through the vessel to push the assembly along through the vessel until it reaches the desired operable location. At that point, as shown in FIG. **10**, further pressurized fluid is passed into the assembly so as to expand balloon **26** until it engages with the inner wall **56** of the vessel **54** and becomes fixed in position.

Thereafter, as shown in FIG. **11**, a third stage of further pressurized fluid is passed through cannula **22**. Since further expansion of balloon **26** is retarded the further fluid tries to pass between the balloon portion **26** and the cannula **22** under the C-spring **33**. The passage of this fluid lubricates the connection between balloon **26** and the cannula **22** so that the cannula **22** can be relatively easily withdrawn from the balloon **26**.

A similar procedure is followed for the embodiment of FIGS. **5** and **6** wherein once the balloon is fixed within the vessel so that further expansion of the balloon **26** is retarded, fluid passes through side opening **52** in the pin **42** and expands the proximal end portion of balloon **26a** which is between band **38a** and the proximal tip including portion **36**. This expansion of portion **36** frees it from engagement with cannula **22a** and permits cannula **22a** and pin **42** to be withdrawn from inflatable portion **26a**. There is minimal resistance between tip **50** and plug **40** due to the nature of the material of plug **40** or the prepositioned hole therein and the tapered tip **50** of the pin **42**. The cannula **22a** and pin **42** can thus be removed from the assembly and from the vessel **54** leaving the inflatable portion **26a** in position as an implant.

Once pin **42** has been removed from plug **40** the self-sealing nature of plug **40** or the resilience of outer band **38** or both cause the plug **40** to close the open therethrough thereby forming a valve means to seal the inflated balloon portion **26a** and retain it in expanded position in proper location in the vessel.

Operation of the perfusion embodiment is depicted in FIG. **13**. Introduction and positioning of assembly **20** is accomplished in the same manner depicted in FIGS. **8–10**. Thereafter the third stage is reached at which additional fluid is introduced through cannula **22** from the fluid source and, since inflatable portion **26** is retarded from further expansion, the fluid forces a medicament or radiopaque dye, contained within the balloon portion **26**, out through opening **32** in the end of body **26**. Since body **26** seals the vessel at the point of its location the dye is not diluted by blood at the upstream end of the vessel and accordingly is fully effective in use at the point of perfusion.

As discussed above, the device can be a combination of the one depicted in use in FIGS. **8–12** and the one depicted in use in FIG. **13** so that perfusion can be produced and detachment achieved with perfusion continuing after the implant is made for a length of time.

FIG. **7** of the drawings shows a further embodiment of the present invention wherein a balloon catheter **60** is designed for non-detachable use and, in particular, for perfusion. The balloon portion **62** is friction fit over the open end of the cannula **64** for introduction of fluid. The friction fit can be accomplished as in previous embodiments by a shrink fit between the parts or expanding the elastomeric balloon portion until it frictionally engages with the outer surface of catheter **64**. The opposite end of the balloon portion has a plug **66** of self-sealing elastomeric material such as silastic with a passageway **68** therethrough normally closed in view of the nature of the material of plug **66**. Sufficient introduction of fluid into balloon portion **62** will expand the balloon portion and eventually provide sufficient pressure to cause the elastomeric plug **66** to open passageway **68** and permit perfusion of the material contained within the balloon portion to be expelled downstream. It is possible to put the opening in the balloon portion at the end as shown in FIG. **5** or in the side as shown in FIGS. **1–3** or even in the rear end portion for introduction of material from the balloon portion upstream of its location.

It is also contemplated that the introduction catheter for the embodiment shown can be of the double lumen type. That is, one lumen is directed into the balloon portion of the catheter assembly for introduction of fluid and expansion of the balloon portion; and, the other lumen is for introduction of fluid into the area of attachment between the balloon portion of the catheter. In this manner the connection portion is expanded and detachment of the components is accomplished so that the balloon portion remain as an implant. With the double lumen design, it is possible to retain a predetermined expansion level of the balloon portion since further expansion will not occur when fluid is passed only through the second lumen which opens into the area for detachment only and not into the balloon portion.

Thus the several aforenoted objects and advantages are most effectively attained. Although several somewhat preferred embodiments have been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby and its scope is to be determined by that of the appended claims.

I claim:

1. A miniaturized balloon catheter assembly for use in small vessels comprising:

a cannula having proximal and distal ends including an attaching means at the proximal end thereof for attaching to a source of pressurized fluid and having a small outer diameter for insertion into small vessels;

an inflatable balloon including a means forming a mouth at a proximal end thereof mounted on an external surface of the cannula at the distal end of the cannula to be in fluid communication therewith, the cannula and balloon together adapted to be carried by the fluid in a vessel to desired locations therein, whereupon attachment of the cannula fluid source of pressurized fluid and introduction of amounts of pressurized fluid flow inflate the balloon to fix it in position against the wall of said vessel at a desired location; and,

a balloon-retaining means responsive to a predetermined further amount of pressure to initiate a desired procedure within the small vessels, said balloon-retaining means including a resilient contracting member surrounding said means forming said mouth for holding said means forming said mouth on said external surface of said cannula, said resilient contracting member being constructed to have

a specific predetermined internal size when in a contracted state for: contracting with a uniform predetermined tension about said means forming said mouth when said means forming said mouth is mounted on said cannula to hold said balloon on said cannula upon said balloon being inflated to fix it in position against the wall of said vessel at said desired location, expanding in response to said predetermined further amount of pressure in said balloon to release said cannula from said mouth, and thereafter contracting toward said specific predetermined internal size to close said balloon mouth and thereby retain said inflated balloon fixed in position against said wall.

2. A miniaturized balloon catheter as in claim 1 wherein said balloon is of an elastomeric silastic material.

3. A miniaturized balloon catheter assembly as in claim 1 wherein said cannula and said balloon are normally of approximately the same diamter and attachment of the inflatable portion of the cannula is achieved by expanding the means forming a mouth, and extending it over the adjacent end of the cannula.

4. A minaturized balloon catheter as in claim 3 wherein said resilient contracting member is a C-shaped spring.

5. A miniaturized balloon catheter as in claim 4 wherein the inner diameter of said balloon is approximately 0.011 inch and its outer diameter is approximately 0.024 inch while said C-shaped spring has an inner diameter of approximately 0.018 inch when it is in a non-expanded condition.

6. A miniaturized balloon catheter as in claim 1 wherein said resilient contracting member does not wrap about said means forming said mouth more than once.

7. A diagnostic and therapeutic method for carrying out procedures in small vessels by utilizing a miniaturized balloon catheter assembly including a resilient cannula adapted for attachment to a source of pressurized fluid and having a small outer diameter for insertion into small vessels and an inflatable balloon having a mouth at the proximal end thereof mounted on the end of the cannula in fluid communication therewith comprising the steps of:

inserting the distal end of said cannula into the mouth of said inflatable balloon;

attaching said inflatable balloon to said resilient cannula with a resilient contracting member by surrounding a portion of said inflatable balloon near said mouth with said resilient contracting member and thereby contracting said balloon onto said resilient cannula, said resilient contracting member having a predetermined internal size when in a fully contracted state for: contracting about said balloon portion to hold said balloon on said cannula with a uniform tension when said balloon is mounted on said cannula and for contracting toward said predetermined internal size to close said balloon mouth when said balloon is not mounted on said cannula;

inserting the balloon catheter assembly into a small vessel;

attaching the cannula to a source of pressurized fluid and pressurizing the balloon portion to partially inflate the balloon portion to permit the balloon portion and attached cannula to be directed by the fluid flow within the vessel to the desired location;

further inflating the balloon portion to fix the balloon portion in position;

increasing the fluid pressure inside the balloon portion to expand said resilient contracting member; and

withdrawing said cannula from said mouth to allow said resilient contracting member to contract and thereby close said balloon mouth to retain said inflated balloon fixed in position.

8. The invention in accordance with claim 7 wherein said resilient contracting member is a C-shaped spring.

9. A miniaturized balloon catheter as in claim 8 wherein the inner diameter of said balloon is approximately 0.011 inch and its outer diameter is approximately 0.024 inch while said C-spring has an inner diameter of approximately 0.018 inch when it is in a non-expanded condition.

10. The invention in accordance with claim 7 wherein the balloon includes an opening in it distal end and expels fluid therethrough downstream of the balloon portion during and after said cannula is withdrawn from said mouth.

11. In a miniaturized balloon catheter assembly adapted for use in diagnostic and therapeutic procedures in connection with small vessels comprising: a cannula having means at a proximal end for attachment to a source of pressurized fluid and having a small outer diameter for insertion into small vessels, an inflatable tubular balloon having a mouth portion and mounted at the distal end of the cannula in fluid communication therewith, the cannula and balloon adapted to be carried by the fluid in the vessel to a desired location therein, whereupon introduction of an amount of pressurized fluid flow from the source of pressurized fluid will inflate the balloon to fix it in position, activation means responsive to a further amount of pressure to initiate a desired procedure within the small vessel at the desired location, said balloon being detachably mounted at the distal end of said cannula;

the subassembly of a sealing means which, when the cannula and balloon are positioned at the desired location in the human vessel, seals the mouth portion of the balloon, said sealing means including elastomeric self-sealing plug material positioned in the mouth of the inflatable balloon adjacent to the end of the cannula, an expandable circumferential band on the outer surface of the inflatable balloon in concentric position with respect to the plug material therein, said subassembly further comprising a pin having a passageway therethrough and one end mounted at the distal end of the cannula with the passageway therein in communication with the passageway through the cannula and the other end of the pin positioned through a small opening in the self-sealing plug material into fluid communication with the inflatable balloon on the side of the plug material distal from the cannula and when in that position expanding the circumferential band, so that when the balloon is detached from the distal end of the cannula the pin is removed from the plug material, whereupon the elastomeric self-sealing plug material and the expandable circumferential band will close the opening in the plug material and the mouth portion of the balloon to retain the balloon in inflated condition.

12. The subassembly of claim 11 wherein said expandable circumferential band comprises a single strand element which does not extend about said plug material a plurality of times.

13. A miniaturized balloon catheter assembly adapted for use in diagnostic and therapeutic procedures in connection with small vessels comprising; a cannula having means at a proximal end for attachment to a source of pressurized fluid and having a small outer diameter for insertion into small vessels, an inflatable tubular balloon having a mounth means constructed of self-sealing material for forming an opening into said balloon through which said balloon can be inflated, but which can be closed to maintain said balloon in an inflated state, said balloon being mounted at the distal end of the cannula in fluid communication therewith, said cannula extending into the mouth means of said balloon so that said balloon can be inflated and deflated via said cannula, the cannula and balloon adapted to be carried by the fluid in the vessel to a desired location therein, whereupon introduction of an amount of pressurized fluid flow from the source of pressurized fluid will inflate the balloon to fix it in position and a further amount of pressure will initiate a desired procedure within the small vessel at the desired location, said balloon having a sealing means thereon so that when the cannula and balloon are positioned in the desired location in the human vessel the cannula can be detached from the balloon whereupon the sealing means will seal the mouth portion of the balloon, said sealing means including a circumferential expandable-band means on the outer surface of the mouth means of said inflatable balloon tending to hold the balloon mouth means onto said cannula, said expandable-band means comprising a single strand element which does not extend about said mouth means a plurality of times, said expandable-band means and said mouth means having the joint function of responding to a sufficient amount of pressurized fluid passing through the cannula into the inflatable balloon to inflate the balloon to a desired amount by detaching the cannula from the balloon for removal of the cannula from the balloon mouth means, and responding to a decreased pressure in said balloon after said cannula has been removed by closing the opening in said mouth means of the balloon to retain the balloon in an inflated condition.

14. A diagnostic and therapeutic method for carrying out procedures in small vessels by utilizing a miniaturized balloon catheter assembly including a resilient cannula adapted for attachment to a source of pressurized fluid and having a small outer diameter for insertion into small vessels and an inflatable balloon having a mouth means constructed of self-sealing material for forming an opening into said balloon, through which said balloon can be inflated, but which can be closed to maintain said balloon in an inflated state, said balloon being mounted on the end of the cannula in fluid communication therewith, said method comprising the steps of:

inserting the distal end of said cannula into the mouth means of said inflatable balloon so that said balloon can be inflated and deflated via said cannula;

attaching said inflatable balloon to said resilient cannula with a resilient contracting member by surrounding said mouth means with said resilient contracting member and thereby contracting said balloon onto said resilient cannula, said resilient contracting member comprising a single strand element which does not extend about said mouth means a plurality of times, said contracting member contracting about said balloon portion to hold said balloon on said cannula with a uniform tension when said balloon is mounted on said cannula to close said opening when said balloon is not mounted on said cannula;

inserting the balloon catheter assembly into a small vessel;

attaching the cannula to a source of pressurized fluid and pressurizing the balloon portion to partially inflate the balloon portion to permit the balloon portion and attached cannula to be directed by the fluid flow within the vessel to the desired location;

further inflating the balloon portion to fix the balloon portion in position;

increasing the fluid pressure inside the balloon portion to expand said resilient contracting member; and

withdrawing said cannula from said mouth means to allow said resilient contracting member to contract and thereby close said balloon mouth means to retain said inflated balloon fixed in position.

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