

[54] **CATHETER**

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128/343, 240, 2 M, 2.05 M, DIG. 9, 2.05 R

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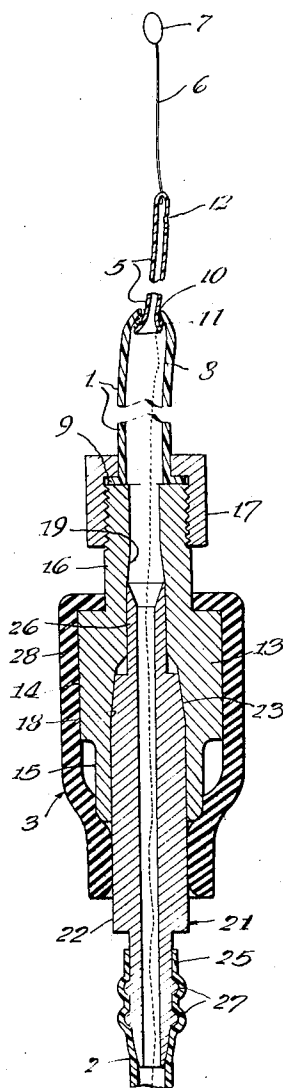
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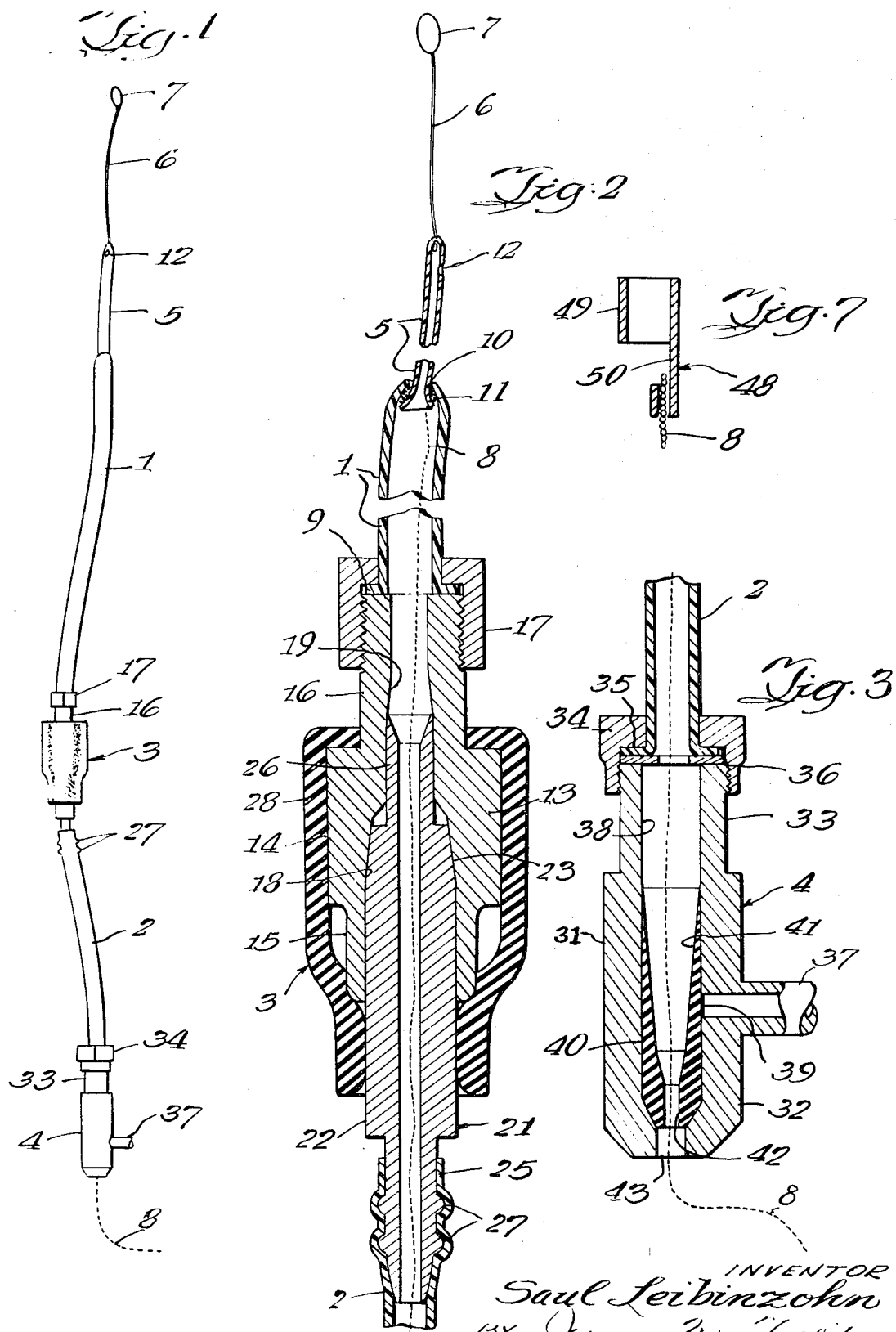
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[57] **ABSTRACT**

A catheter adapted for introduction into difficulty accessible regions of the human body comprising a catheter tube and a flexible tube adapted for displacement within the catheter tube and for protrusion from the distal end of the catheter tube. A radio-opaque embolus is attached to the distal end of the flexible tube by means of a flexible thread. When the catheter is inserted into the body in the vicinity of the required region, the embolus is directed into the required region by the flow of bloodstream together with gravity forces, carrying with it the flexible tube. Suitable fluid can then be injected into the required region through the catheter and apertures formed in the flexible tube.

16 Claims, 9 Drawing Figures





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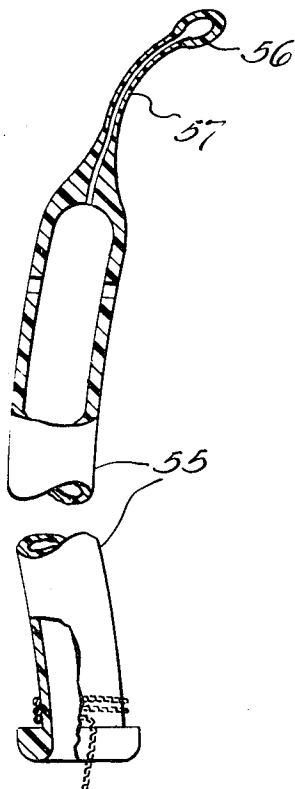


Fig. 9

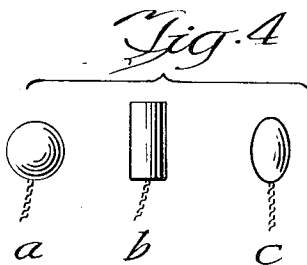


Fig. 4

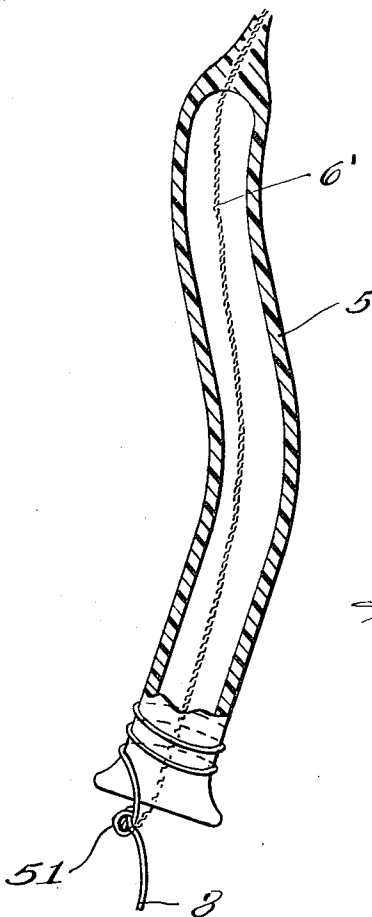


Fig. 8

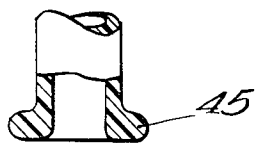


Fig. 5

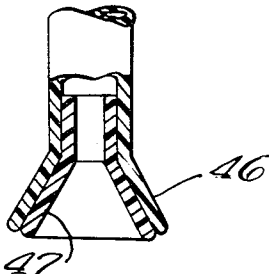


Fig. 6

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CATHETER

This invention relates to a catheter.

According to the present invention there is provided a catheter comprising a catheter tube, a flexible tube adapted for displacement in the catheter tube and for protrusion therefrom, an at least partially radio-opaque embolus attached by means of a highly flexible thread to that end of the flexible tube adapted to protrude from the catheter tube and displacing means coupled to the opposite end of the flexible tube for displacing it through the catheter tube so as to free the embolus and flexible tube for limited motion with respect to the catheter tube.

As used in this specification, the term "embolus" refers to an artificially constructed body adapted to be introduced into and to circulate in the blood stream.

The construction and use of the catheter in accordance with the invention arises out of the discovery that the flow of the bloodstream itself together with gravity considerations can, under appropriate circumstances, result in the direction of an embolus, located in the bloodstream, into a tract in which it will progress taking with it the flexible tube. Once the flexible tube is located in the required tract it can be advanced or withdrawn by means of the displacing means. With the flexible tube located in the required position the catheter can be employed, for example, for the introduction of a suitable fluid into the tract, the fluid being injected through the catheter and being ejected from suitable apertures formed in the flexible tube. Such a fluid can, for example, be a contrast fluid for use in radiological examination of the region. In all cases, the movement of the catheter into the required tract can be monitored in view of the provision of the radio-opaque embolus and the precise moment when the embolus enters the required duct can be determined.

If the embolus has a specific gravity greater than that of the blood and the tract to be catheterized is directed downwardly, the combined effect of the bloodstream flow and gravity will result in the direction of the embolus into this tract. On the other hand, if the overall specific gravity of the embolus is less than that of the blood the tendency of the embolus will be to rise and this tendency together with the blood flow will aid in directing the embolus into an upwardly directed tract.

The construction and mode of use of a catheter in accordance with the present invention will be clarified by recourse to the following description and with reference to the accompanying drawings in which:

FIG. 1 is a schematic side elevation of the catheter when fully extended;

FIG. 2 is a longitudinal sectional view on an enlarged scale of a first detail of the catheter shown in FIG. 1;

FIG. 3 is a longitudinal sectional view on an enlarged scale of a second detail of the catheter shown in FIG. 1;

FIGS. 4a, 4b and 4c are respective elevational views of three differing forms of emboli;

FIGS. 5 and 6 are respective views of differing forms of flexible tube endings;

FIG. 7 is a cross-sectional view of a stylet coupling collar;

FIGS. 8 and 9 are longitudinal sectional views of modified forms of flexible tubes.

As seen in the drawings, the catheter comprises a pair of standard catheter tubes 1 and 2, the two tubes being joined together by a connecting piece 3. The free

end of the catheter tube 2 is fitted with an inlet valve 4, while, as shown in FIG. 1 of the drawings, there projects from the free end of the catheter tube 1 a flexible tube 5 which is connected at its projecting end by means of a highly flexible thread 6 to a radio-opaque embolus 7. A stylet wire 8, shown projecting out of the valve means 4 extends through the whole length of the catheter and is secured to the inner end of the flexible tube 5 in a manner to be described below.

Reference will now be made to FIG. 2 of the drawings in which is shown in detail the mode of connection of the two catheter tubes 1 and 2 and the construction of the flexible tube 5.

As seen in FIG. 2, the catheter tube 1 is provided, at one end, with an externally directed flange 9 and tapers at its other end to define an aperture 10. The flexible tube 5 which has a much narrower diameter than the catheter tube 1 is provided with a flared end 11 and is secured at its opposite closed end to the end of the highly flexible thread 6. One or more ejecting apertures 12 are formed in the flexible tube adjacent to its closed end. The stylet wire 8 is secured to the flared end 11 of the flexible tube 5 by being spiralled therearound, the spiralled end being adapted to bear against the tapered end of the tube 1 so as to seal it.

The connecting piece 3 comprises a first steel coupling element 13 constituted by a central broad portion 14 and two terminal portions of smaller diameter 15 and 16. The terminal portion 16 is externally threaded so as to receive a locking nut 17 which is provided with an inwardly directed flange arranged to clamp in position the flange 9 of the catheter tube 1. The coupling element 13 is internally bored, the diameter of the bore being at its maximum adjacent to the terminal end 15 and at its minimum adjacent to the terminal end 16. The bore is provided with two tapering wall portions 18 and 19.

The connecting piece 3 furthermore comprises a second steel coupling element 21 which consists of a main tubular portion 22 having a tapering conical portion 23 adapted to fit closely within the tapering bore 18 of the coupling element 13. The main tubular portion 22 is provided at either end with tubular extensions 25 and 26 of narrower diameter than the main tubular portion 22, with a uniform bore extending through the entire coupling element 21. The tubular extension 26 fits within the tubular bore formed in the coupling element 13 while the other tubular extension 25 is provided with a couple of ribs 27 on which is fitted the end of the catheter tube 2. A rubber sleeve 28 surrounds the elements 13 and 21.

Reference will now be made to FIG. 3 of the drawings for a description of the inlet valve means 4 of the catheter. This inlet valve means 4 comprises a steel tubular T-piece 31 having a main body portion 32 and a tubular extension thereof 33 whose extremity is externally threaded so as to receive a locking nut 34 which locks in position via a washer 36 an outwardly extending flange 35 of the catheter tube 2 against the outer edge of the tubular extension 33. The tubular T-piece 31 is furthermore provided with an inlet duct 37 which communicates with the main bore 38 of the valve via an inlet port 39. A rubber sleeve 40 whose internal wall 41 tapers is inserted in the main bore 38 so as to seal the port 39. The construction of the sleeve 40 is such that

when a fluid pressure is built up in the catheter and, in consequence, in the tubular bore 38, this pressure presses the tapering walls of the sleeve against the port 39 sealing it but when on the other hand fluid is injected through the duct 37 this fluid is forced into the bore 38 and therefore into the catheter by pressing away the sleeve 40.

As can be seen in the drawings the stylet wire 8 extends through the entire catheter and emerges through the bore 42 formed in the terminal portion of the sleeve 40 and the outlet port 43 of the T-piece 31.

FIGS. 4a, 4b and 4c show different constructions of emboli. Thus in FIG. 4a the embolus is completely spherical, in FIG. 4b the embolus is right cylindrical while in FIG. 4c the embolus is substantially discoid in shape. While the particular shape of the embolus is not critical, the discoid construction has been found in practice to be preferable, it being less likely to become undesirably lodged during catheterization in the tract. Furthermore with a flat discoid shape the embolus in movement offers a relatively large area for radiological detection with minimal risk of blocking the tract.

As seen in the drawings, the end of the stylet wire 8 is coupled to the end of the flexible tube by being wound therearound. In order to ensure that the coupling is effective the end of the flexible tube should be appropriately formed. As seen in FIG. 5 the end of the flexible tube is provided with an outwardly extended flange 45. This flange 45 is of thickened construction thereby strengthening the end of the flexible tube. As seen in FIG. 6 of the drawings, the end 46 of the flexible tube is flared and is provided with a correspondingly flared stiffening portion 47.

FIG. 7 illustrates an alternative mode of coupling the stylet wire 8 to the flexible tube 5. In accordance with this construction a two-piece collar construction 48 is employed; the first collar portion 49 is firmly clamped around the end of the flexible tube while the second collar portion which is connected to the first by the common wall strip 50 is firmly crimped around the end of the stylet wire 8.

FIG. 8 illustrates a slightly modified construction in which the thread 6' does not terminate at the end portion of the flexible tube 5 but extends through the flexible tube 5 and out thereof so as to be secured to a looped portion 51 of the stylet wire 8 adjacent to its place of coupling to the flexible tube 5. The purpose of this modification is to ensure that, in the event that the flexible tube breaks in use the parts thereof will remain attached to the thread 6' which is of considerable tensile strength. In this way there is avoided the danger of parts of the catheter remaining in the tract.

FIG. 9 shows a still further modified form of a flexible tube 55 which is formed integrally with the embolus 56 and connecting thread 57. In this case the embolus is formed as a hollow structure into which is introduced, via a very narrow bore formed in the thread 57 a contrast liquid thereby rendering the embolus radio-opaque. In other respects the flexible tube 55 is constructed similarly to the flexible tube 5 previously described.

As previously indicated, the embolus is formed of a radio-opaque material. Suitable material can, for example, be heavy non-corrosive metals such as platinum, stainless steel or the like. Alternatively, the embolus

can be constituted by a soluble material, e.g., gelatine mixed with a suitable contrast material. In this case the embolus remains in the tract for the period necessary for catheterization after which period solution takes place.

A still further alternative is to form the embolus of a deformable material, for example a rubber balloon, which contains the liquid contrast material. Such a possibility is envisaged in connection with the embodiment shown in FIG. 9 where the embolus is formed integrally with the flexible tube. A still further possibility is forming the embolus of lead oxide, which has been bonded together by means of a suitable bonding material.

Where the embolus is to enter a downwardly directed tract the specific gravity of the embolus must be greater than that of the blood and no problem is encountered when such an embolus is radio-opaque. Where however, the embolus is to enter an upwardly directed tract, the embolus must be capable of floating in the bloodstream and for this purpose the overall specific gravity of embolus must be less than that of the blood. This requirement must be reconciled with that of radio-opacity and this is achieved by distributing throughout the embolus radio-opaque material.

The thread used to attach the embolus to the flexible tube can, for example, be formed of silk. A still better possibility is the use of a nylon thread in view of its invariant physical characteristics, especially in liquid. The length of the thread can vary from 1 to 4 centimeters.

The stylet is preferably formed of steel having a diameter of between 0.2 to 0.6 mm.

The flexible tube is made of a highly flexible material, which is resistant to the media into which it is introduced. The tube in addition to its high flexibility must have a very thin wall and a high tensile strength. Suitable materials may include, latex, silicon rubber or a suitable plastic material. The internal diameter of the tube can vary from about 0.6 to 2 mm while the wall thickness thereof can vary from 0.05 to 0.5 mm. Different lengths of flexible tubes can be employed ranging from 5 to 15 cm.

In accordance with a specific modification the flexible tube is so shaped as to be capable of flexing in a preferred direction. This can be achieved e.g., by shaping the tube so that over the major portion of its length it is of relatively flat cross-section, it becoming circular only in the region of its mouth. Such a construction ensures a preferred direction of flexing of the tube and therefore facilitating its entry into a tract located in that preferred direction.

While, as indicated above, the fluid is ejected from the flexible tube through apertures, slits can equally well be formed in the flexible tube for the ejection of the fluid.

The mode of assembly and use of the catheter described above will now be explained:

The catheter tube 1 secured to the coupling element 13 is arterially introduced by any known standard method into the region of the tract to be catheterized. After introduction, the catheter tube is closed against outflow of blood by clipping the skirt portion of the rubber sleeve 28. When catheterization is proceeded with the second catheter tube 2, which is connected to second coupling element 21 and which is loaded with

the flexible tube and embolus, is coupled to the first tube by the insertion of the second coupling element within the first coupling element, the skirt of the rubber tube then embracing the second coupling element. With the catheter tube 1 suitably inserted and connected to the catheter tube 2, the flexible tube 5 and the embolus 7 attached to the tube by the flexible thread 6 is pushed forward from the catheter tube 2 in which it was contained by means of the stylet 8 which projects out of the valve means 4. As can be seen in FIG. 2 of the drawings when the flexible tube has been fully projected out of the catheter tube, the spiralled end of the stylet effectively seals the mouth 10 of the catheter tube and fluid injected through the catheter passes through the flexible tube and out of the apertures 12.

The directing of the catheter into a particular tract will now be described.

With the catheter tube 1 positioned in the vicinity of the tract to be catheterized the flexible tube is advanced so that the embolus 7 is located upstream of the tract. The position of the embolus at all times is monitored by means of X-rays. With the catheter in this position and with the patient disposed with the tract to be catheterized directed downwardly, the catheter or the stylet is very slowly and gradually withdrawn, the embolus at all times moving freely in rhythm with the pulsating bloodstream. When sufficient withdrawal has taken place for the embolus to be disposed directly above the tract, the embolus tends to enter the tract (as a result of the combined effects of gravity and blood flow) and is caught in the mouth thereof. The fact that the embolus has been so caught is evident on the X-ray screen by virtue of the fact that the previous pulsating movement of the embolus ceases and it is therefore assumed that the embolus is lodged in the mouth of the tract. In this position the stylet is pressed forward and the embolus is freed to flow into the tract followed by the flexible tube. The advancement of the stylet and/or the catheter is continued until the catheter is in the required position whereupon the fluid that is to be injected into the tract is introduced through the valve injecting means 4. In the case that this fluid is a contrast medium the injection of the fluid is rapidly followed by the full representation of the region on the X-ray screen.

While in the construction just described it is desirable that when the flexible tube has been directed to the desired position the tube 1 is sealed by the spiralled end of the stylet, in a modified construction this spiralled end can be dimensioned so that all positions in the catheter tube 1, sealing thereof is effected.

It will be appreciated that while a particular technique has been described above for using the catheter in accordance with the invention, other techniques can equally well be used, all of which depend, inter alia, on the flow guidance of the catheter by the radio-opaque embolus.

After catheterization has been completed, the flexible tube and the embolus are withdrawn into the catheter tube 2 which is detached from the tube 1, and the latter tube is withdrawn entirely.

It will be appreciated that the novel catheter construction described above allows for the introduction of the catheter into regions which were hitherto accessi-

ble with the greatest difficulty. The introduction of this catheter can furthermore be effected very quickly with minimum traumatic risk for the patient and with the use of standard catheter tubes. The introduction of the novel catheter and its correct positioning does not require any special skills as even with a relatively inexperienced operator minimum risk of perforation exists.

I claim:

1. A catheter comprising a catheter tube having first and second ends with a lumen interconnecting said ends, a flexible tube carried for longitudinal displacement within the catheter tube and for protrusion from the first end thereof, an at least partially radio-opaque embolus, a highly flexible thread interconnecting said embolus and the end of the flexible tube adapted to protrude from the catheter tube, said embolus being fixedly attached to said thread, said catheter tube and said flexible tube being provided with means for preventing separation of the flexible tube from the first end of the catheter tube, and displacing means coupled to the opposite end of the flexible tube for moving it through the catheter tube so as to free the embolus and flexible tube for limited longitudinal motion with respect to the catheter tube.

2. A catheter according to claim 1, wherein said displacing means comprises a stylet wire which extends through the catheter and is coupled to the inner end of the flexible tube.

3. A catheter according to claim 2, wherein said stylet wire is spiralled about the inner end of the flexible tube.

4. A catheter according to claim 2, wherein said stylet wire is coupled to the flexible tube by means of a double collar structure one component of which is clamped to the end of the flexible tube and the other component of which is crimped to the end of the stylet wire.

5. A catheter according to claim 2, wherein said thread extends through the flexible tube and is secured to the stylet wire.

6. A catheter according to claim 1, wherein said embolus is of spherical, discoid or cylindrical shape.

7. A catheter according to claim 1, wherein said embolus is formed of stainless steel.

8. A catheter according to claim 1, wherein said embolus is formed of platinum.

9. A catheter according to claim 1, wherein said embolus is formed of a radio-opaque soluble material.

10. A catheter according to claim 1, wherein said embolus is formed of a deformable hollow material adapted to contain a contrast medium.

11. A catheter according to claim 1, wherein said flexible tube, embolus and thread are formed as an integral whole, the embolus being hollow and being adapted to have a contrast medium introduced therein via a bore formed in the connecting thread.

12. A catheter according to claim 1, wherein outlet apertures or slits are formed in the flexible tube.

13. A catheter according to claim 1, wherein said catheter tube is formed of two parts, said flexible tube being adapted to project from a first part, and the second part being provided with a valve inlet means, connecting means being provided for connecting said two parts together.

14. A catheter according to claim 13, wherein said connecting means comprises a pair of tubular metal coupling elements having respectively tapering outer and inner walls adapted to fit one within the other and to be respectively coupled to said tube parts.

15. A catheter tube according to claim 13, wherein said connecting means is provided with a flexible sleeve having a skirt portion adapted to be clipped so as tem-

porarily to close said one catheter tube part.
16. A catheter according to claim 13, wherein said valve inlet means is constituted as a tubular T-piece, having an inlet limb which communicates via an inlet port with a limb coupled to the second catheter tube part, means being provided for unidirectionally closing said inlet port.

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