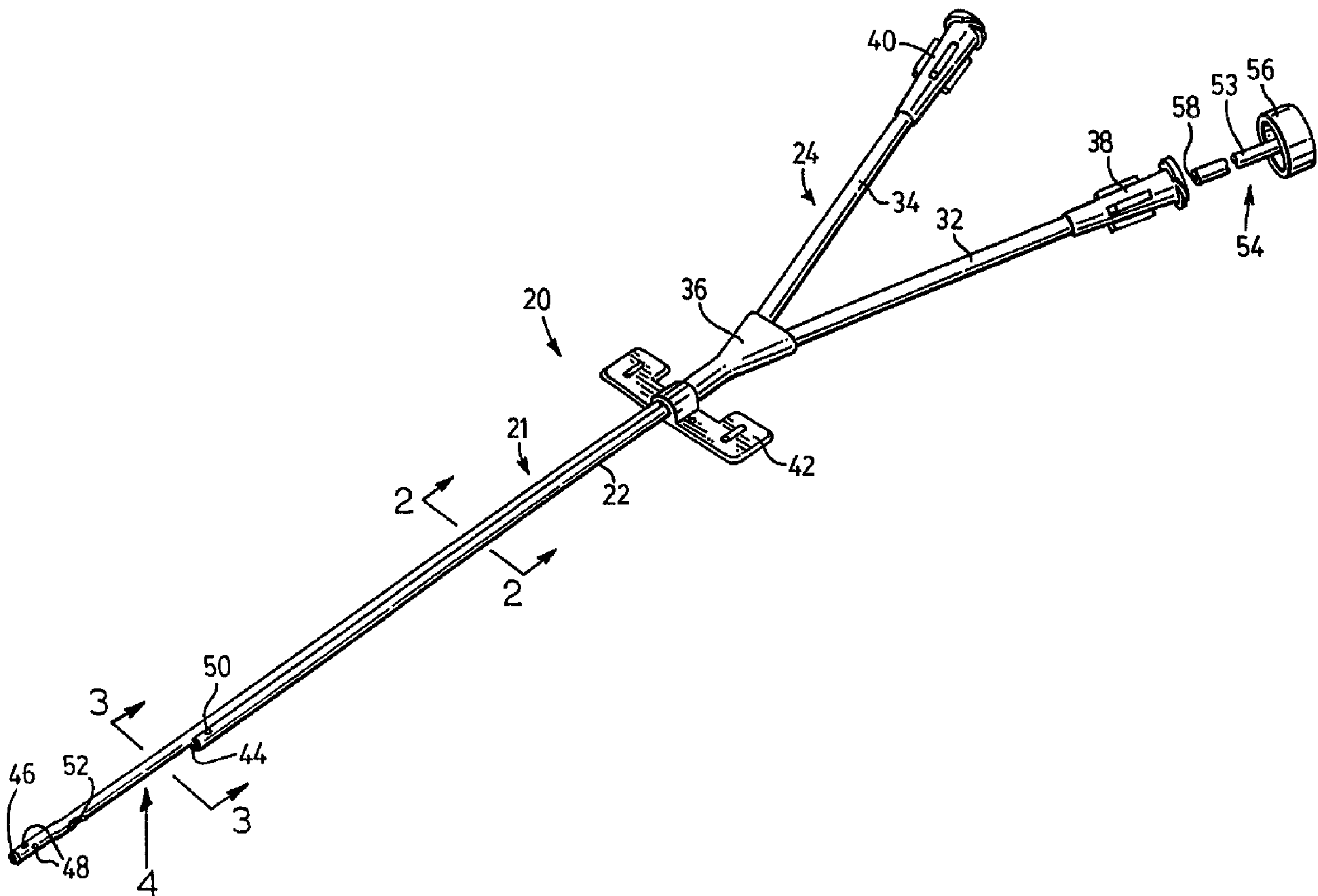




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(54) Titre : CATHETER A CANAUX MULTIPLES  
 (54) Title: CATHETER WITH MULTIPLE LUMENS



(57) Abrégé/Abstract:

The invention provides a catheter assembly (20) including a catheter (21) having an elongate main body (22) extending longitudinally between proximal and distal ends. A tip structure (26) is attached to the distal end of the main body and also extends

(57) **Abrégé(suite)/Abstract(continued):**

longitudinally. The main body and tip structure combine to define side-by-side intake (28) and return (30, 51) lumens and the intake lumen terminates at a transverse intake opening (44) at the distal end of the main body. The return lumen terminates at the distal end of the tip structure at a transverse return opening (46) and a side opening (52) is provided adjacent the return opening. The assembly also includes a tubular applicator (54) which passes through the intake lumen, through the side opening and into the return lumen. This permits the assembly to be passed over a guide wire (55) by engaging the guide wire inside the tubular applicator and sliding the assembly over the guide wire.



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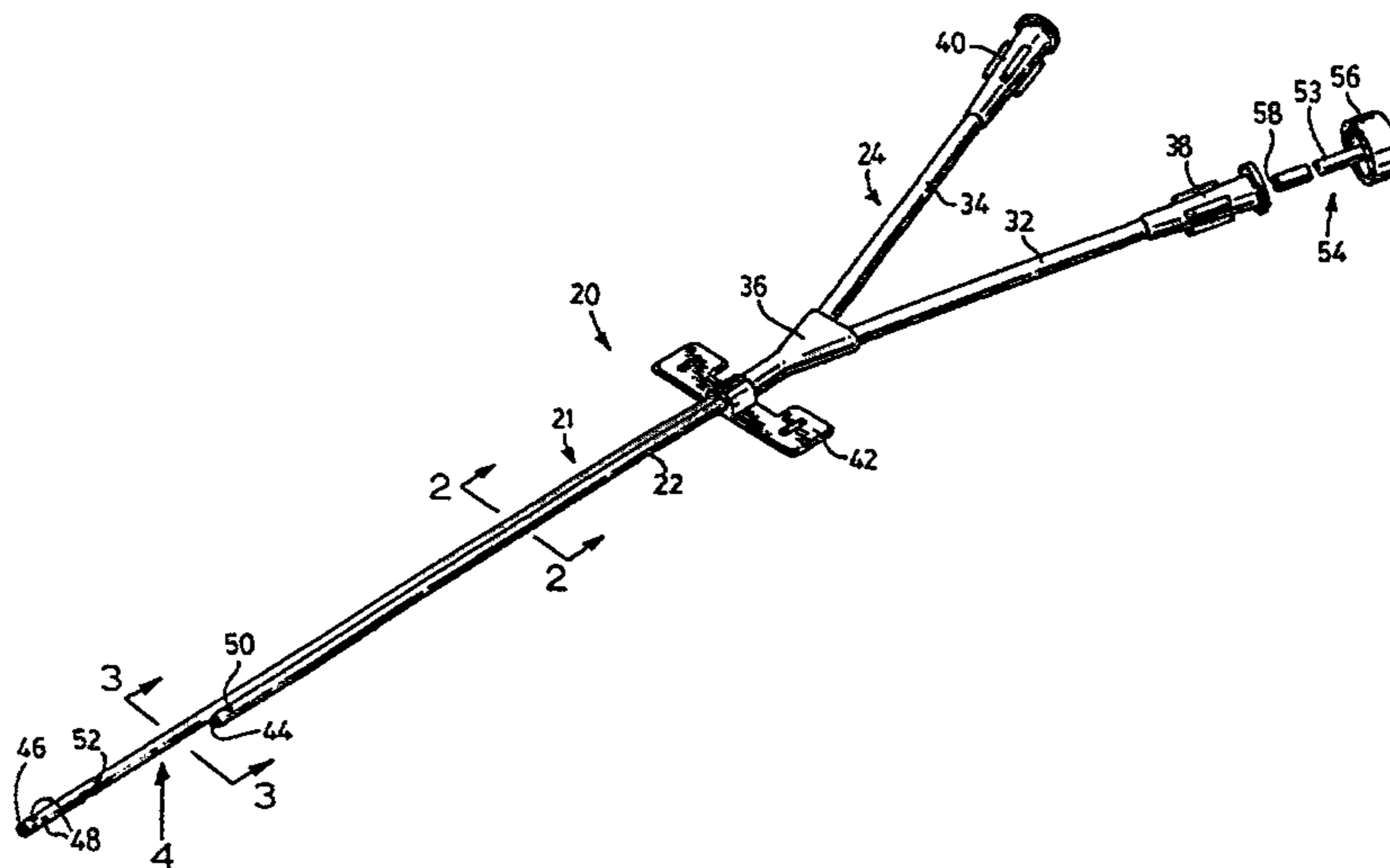
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(54) Title: CATHETER WITH MULTIPLE LUMENS



(57) Abstract

The invention provides a catheter assembly (20) including a catheter (21) having an elongate main body (22) extending longitudinally between proximal and distal ends. A tip structure (26) is attached to the distal end of the main body and also extends longitudinally. The main body and tip structure combine to define side-by-side intake (28) and return (30, 51) lumens and the intake lumen terminates at a transverse intake opening (44) at the distal end of the main body. The return lumen terminates at the distal end of the tip structure at a transverse return opening (46) and a side opening (52) is provided adjacent the return opening. The assembly also includes a tubular applicator (54) which passes through the intake lumen, through the side opening and into the return lumen. This permits the assembly to be passed over a guide wire (55) by engaging the guide wire inside the tubular applicator and sliding the assembly over the guide wire.

DESCRIPTIONCATHETER WITH MULTIPLE LUMENSTECHNICAL FIELD

5           This invention relates to a dual lumen catheter and more particularly to such a catheter which is to be engaged into body tissue over a guide wire of the Seldinger type. The catheter is particularly useful in haemodialysis treatments.

BACKGROUND ART

10           Although this invention will be described with reference to use in haemodialysis, it will be appreciated that the various forms of the invention can be used wherever dual flow is required.

          Haemodialysis can be defined as the temporary removal of blood from a patient for the purpose of extracting or separating  
15 toxins from the blood and returning the cleansed blood to the same patient. Haemodialysis is indicated in patients where renal impairment or failure exists, that is in cases where the blood is not being cleansed naturally by the kidneys.

          In the case of chronic renal impairment or failure,  
20 haemodialysis is carried out on a repetitive basis. For example, in end stage kidney disease where transplantation of kidneys is not possible or for medical reasons is contra-indicated, the patient will have to be dialysed about 100 to 150 times per year. This can result in several accesses to the bloodstream to enable the act of  
25 haemodialysis to be performed over the remaining life of the patient. The fact that dual flow is required to conduct haemodialysis means that there must be two distinct channels, one to remove the blood from the patient, and the other to return it. This was achieved in one approach by two insertions, each insertion  
30 carrying a single lumen catheter. Subsequently, dual lumen

catheters which require only one insertion site have been inserted both by surgical cut-down techniques and also by engagement over a Seldinger wire using a technique developed by Dr. S. I. Seldinger which was presented at the Congress of the Northern Association of Medical Radiology at Helsinki in June of 1952. The technique  
5 remains current and is used widely.

It is clear that if a dual lumen catheter is to be inserted over a wire, the leading end of the catheter must be arranged to permit this engagement through tissue without tearing or snagging the  
10 tissue. An earlier approach to solving this problem was to make the dual lumen catheter of a co-axial construction which allowed the tip to be tapered for engagement through the tissue over the existing wire. Other catheters were developed where the lumens are arranged in side-by-side configuration and a tip formed especially to  
15 close off one lumen at a point spaced from the tip so that a tip could be formed around the return lumen to facilitate engagement over the wire. Structures of this kind can be found in U.S. Patents 4,619,643; 4,583,968; 4,568,329; 4,543,087; 4,692,141 and 4,568,329. One of the disadvantages of this arrangement is that the structures  
20 result in stiff tips which although facilitating dilation of body tissue as the catheter is moved over the wire, they tend to result in relatively stiff structures inside the blood vessel after placement. As a result such catheters are useful only for temporary access.

If a catheter is to be used for extended placement, it must be  
25 extremely flexible to avoid stress in the blood vessel, and as much as possible, permit the catheter to move in the blood flow to minimize the possibility of the catheter remaining in pressure contact with the wall of the blood vessel at one spot for prolonged periods. It is also true, that if a catheter is designed for prolonged placement, then the  
30 very flexibility that is desirable for prolonged placement creates

limitations for engagement over the Seldinger wire because the catheter lacks sufficient strength to dilate the tissue during insertion.

In summary, although there have been significant developments in the structures of dual lumen catheters with the lumens arranged in side-by-side configuration, these structures have been limited in their usefulness primarily because of the difficulties of meeting both the design criteria required for placement by the Seldinger technique and the somewhat conflicting criteria which must be met for prolonged placement.

A further consideration in the design of dual lumen catheters is the positioning of the intake and return openings. In catheters of the type where the tip has been formed to dilate tissue as the catheter slides over a Seldinger wire, the intake openings are generally on the side of the catheter. This can result in the catheter being drawn by suction forces towards the blood vessel wall and blood flow will then be cut off. It is therefore desirable to arrange the intake opening to be at the end of the intake lumen with the opening extending generally transversely with respect to the longitudinal extent of the catheter. It is very unlikely that the blood vessel will occlude such an opening so that there is a better likelihood of continuous intake flow. On the other hand, this results in a catheter contour which is less than desirable for sliding over a Seldinger wire.

It is one of the objects of the present invention to provide a catheter having side-by-side dual lumens with the intake opening arranged generally transversely with respect to the longitudinal extent of the catheter and which can be engaged over a Seldinger wire.

It is a further object of the invention to provide a catheter for prolonged placement which has the necessary flexibility

characteristics and which can be engaged over a Seldinger wire.

### DISCLOSURE OF THE INVENTION

In one of its aspects the invention provides a catheter assembly for engagement over a guide wire to enter the catheter assembly by sliding the catheter assembly along the guide wire, the  
5 assembly having a catheter and a tubular applicator the catheter comprising:

a main body extending longitudinally and defining intake and return passages, the intake passage terminating at a distal end of the  
10 body at an intake opening extending generally transversely with respect to the main body and forming an intake lumen;

a proximal end coupling structure having a connection attached to the main body and a pair of tubes including connectors at their respective proximal ends and the tubes being connected at  
15 their distal ends to the connection such that selected ones of the tubes are coupled for fluid flow to respective ones of the passages;

tip structure extending longitudinally from the distal end of the main body and forming a continuation of the return passage to form with this passage a return lumen, the tip structure defining a  
20 distal end return opening and a side opening on a side of the tip structure closest to the intake lumen; and

the tubular applicator extending through the one of said tubes, through the connector and the intake lumen, through said side opening, and through a portion of the tip structure between the  
25 side opening and the return opening whereby the catheter assembly can be slid over the guide wire by containing the wire in the applicator with the applicator exposed between the side opening and the intake opening to present a smoother exterior for insertion through body tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

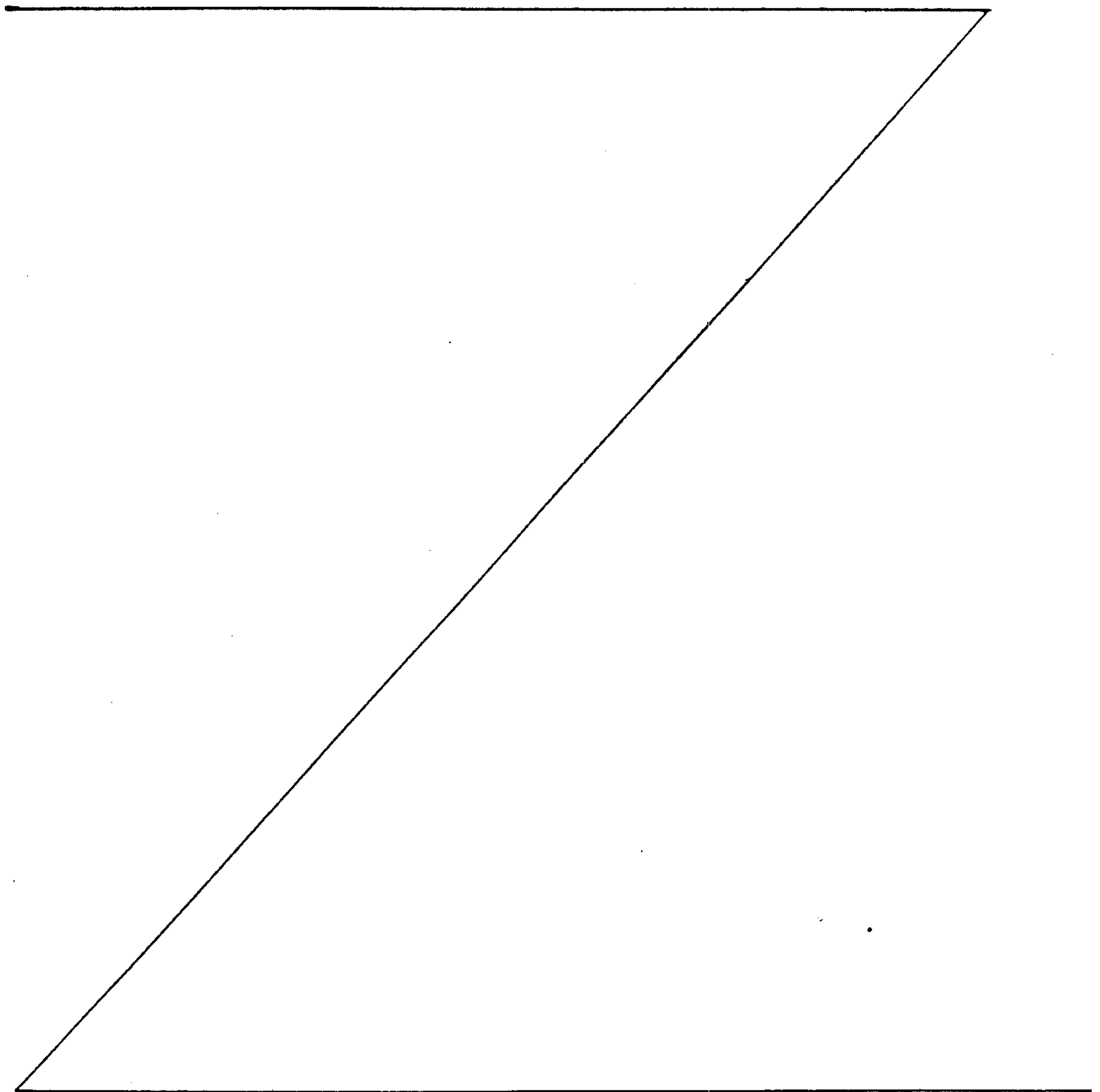
Fig. 1 is a diagrammatic isometric view of a catheter looking from the proximal end towards the distal end and incorporating a preferred embodiment of the invention;

5 Fig. 2 is a sectional view on line 2-2 and drawn to a larger scale;

Fig. 3 is a view similar to Fig. 2 and drawn on line 3-3 of Fig. 1;

10 Fig. 4 is a side view in the direction of the arrow 4 shown in Fig. 1 and drawn to a larger scale;

Fig. 5 is a view similar to Fig. 4 and showing an applicator





and wire, and a rod engaged in the catheter;

Fig. 6 is a view similar to Fig. 5 and showing an alternative embodiment of the catheter assembly; and

Fig. 7 is a further view of the catheter shown in Fig. 4 after  
5 insertion and containing mandrels.

### BEST MODE FOR CARRYING OUT THE INVENTION

Reference is made to Fig. 1 which illustrates a preferred embodiment of catheter assembly according to the invention and identified generally by the numeral 20. A catheter 21 has a main  
10 body 22 which terminates at its proximal end in a coupling structure indicated generally by the numeral 24 and at its other end, (i.e. at its distal end) in a tip structure indicated generally by the numeral 26.

As seen in Fig. 2, the cross-section of the main body 22 is  
15 generally kidney shaped and includes a first or intake passage 28 and a second or return passage 30. These passages lead from the coupling structure 24 which includes an intake tube 32, return tube 34, and a connection 36 providing fluid communication between the respective passages 28, 30 (Fig. 2) and the tubes 32, 34. The tubes  
20 32, 34 are very flexible and have at their proximal ends respective luer connectors 38,40 as is conventional in the art. Commonly the tubes 32, 34 would also include pinch clamps and these have been omitted to simplify the drawing.

The main body also carries a suture wing structure 42 located  
25 against the connector 36 and at its other end, the main body terminates at a transversely extending intake opening 44 providing access to the passage 28. The tip structure 26 forms a continuation of the passage 30 and ends at a return opening 46 at the distal end of the catheter. As is conventional in catheter structures for use in

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haemodialysis, a number of side holes 48 are provided adjacent the return opening 46 and similarly holes 50 are provided adjacent the intake opening 44.

Reference is next made to Figs. 3 and 4 to better describe the tip structure 26. It will be seen in Fig. 3 that the cross-section is round and defines a third passage 51. The exact shape of the tip structure is the result of some post-forming after the blank for the main body has been modified by cutting back the material defining the passage 28 so that only the tip structure projects beyond the intake opening 44. The second passage 30 (Fig. 2) and the third passage are aligned to combine to form a return lumen and the passage 28 defines an intake lumen.

As seen in Fig. 4, the tip structure includes a side opening 52 on the side of the tip structure nearest the intake opening 44. The opening 52 is preferably in the form of a slit or slot but for the purposes of drawing, the opening is shown formed by cutting away material. The slit is preferred, particularly if the material of the catheter is sufficiently flexible as will be the case in most instances.

The purpose of the opening 52 is to facilitate use of a tubular applicator 54 shown generally in Fig. 1.

Reference is now made to Figs. 1 and 5. The applicator 54 has a cap 56 which fits on the luer connector 38 and when in that position, a main portion 53 of the applicator will then project through the return opening 46 in the tip structure 26 as seen in Fig. 5. The applicator is entered through the intake tube 32, connector 36, and through the intake passage 28 in the main body 22, so that it will project from the intake opening 44 at the end of the passage 28. The applicator then extends from opening 44, through side opening 52 and through part of the third passage 51 (Fig. 3) from the side opening 52 to the return opening 46 ready to engage the

catheter assembly so formed over a guide wire 55 seen in Fig. 5 for purposes of illustration.

As seen in Fig. 5, the flexibility of the tip structure 26 is such that the applicator 54 has the main portion 53 of the applicator 54 entered through the side opening 52 and continues within the return lumen exiting at the return opening 46. The length of the applicator main portion 53 is chosen so that with the cap 56 (Fig. 1) engaged with the luer connector 38, the distal end of portion 53 just projects beyond the return opening 46 to present a stepped profile for dilating tissue. It will be evident that the cap 56 and luer connector combine to act as a locator which positions the applicator in the catheter 21.

Reference is next made to Fig. 6 which illustrates a second embodiment of tip structure. As seen in this Fig., a tip structure 126 is provided having an intake or first passage 128 and second or return passage 130 which meets a third passage 151 in the tip structure to complete the intake lumen. An opening or slit 152 is provided in the tip structure so that an applicator 154 can pass through this opening into the return lumen. The passage 151 in the tip structure includes a part extending from the side opening 152 to the return opening 146. This part is shaped externally to define a slight taper 160 about a part of the passage of reduced diameter to fit around a guide wire 162. This part of reduced diameter meets the remainder of the passage 151 at a socket 164 where the change in diameter provides a shoulder for engagement by the distal end of the applicator 154. As a result the applicator can be used to push the very flexible catheter guided by the wire 162.

#### INDUSTRIAL APPLICABILITY

In use the catheter and the applicator will be preassembled.

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The assembly will be completed in the case of catheter 21 (Fig.1) by including a flexible rod 60 (Fig. 5) used to stiffen the tip structure 26. This rod will be pushed until it meets resistance and then held there. The whole assembly is then slipped along guide wire 55  
5 which has been pre-positioned in a blood vessel for the purpose. As the catheter assembly engages tissue the outer surfaces will dilate the tissue and eventually the smooth main body will be resident in the resulting tunnel through the tissue. The rod 60, applicator 54 and lastly, guide wire 55 will be removed leaving the catheter 21 (Fig. 1)  
10 for use in conventional fashion.

The catheter also has advantages which come into play when the catheter is in place between treatments. It is common to use an anti-coagulant (commonly heparin) and to fill the catheter with this material to minimize the risk of stagnant blood clotting inside the  
15 catheter. In practice, the heparin does tend to migrate into the bloodstream to some extent and is of course displaced by blood. For this and other reasons, an alternative to the use of an anti-coagulant would be preferred.

Reference is now made to Fig. 7 which shows catheter 20  
20 containing a pair of fitted occlusion mandrels 170, 172. These are positioned in the lumens to project slightly and to occlude the lumens entirely. There is then no need to use an anti-coagulant.

Catheter assembly 120 shown in Fig. 6 will be used in similar fashion. However because the applicator 154 meets a socket  
25 in the tip structure, the applicator can be used to push the catheter and it may be possible to do this without the need for a rod such as rod 60 (Fig. 5).

It will be evident from the foregoing description that variations can be made to the catheter, and in particular to the tip  
30 structure. Two examples are given and others are possible. In

practice, because both the applicator and the tip structure will have some flexibility, the actual appearance may not be exactly as drawn. For simplicity, Fig. 5 shows all the flexibility in the tip structure whereas Fig. 6 shows all the flexibility in the applicator. It will be  
5 evident that this makes for a simplified drawing but does not accurately represent the shape. Nevertheless, it will be clear that the applicator performs the purpose of closing off the intake openings 44, 144 and combines with the tip structure to provide a smooth surface suitable for dilating and passing through tissue. Of course  
10 the tip structure will pass entirely through the tissue leaving the main body 22 (Fig. 1) extending through the tissue and into the blood vessel. The smooth shape of the main body will permit the tissue to close around the main body and essentially seal the tissue to the main body as is conventional in the art.

15 The material of choice for vascular access catheters made according to the invention is polyurethane. The catheters would use such a material having a 60-65D durometer and the insertion applicator would be of a stiffer form of polyurethane sufficient to perform the designed function.

20 These and other variations are within the scope of the invention as described and claimed.

INDEX OF REFERENCE SIGNS

20	Catheter assembly	21	Catheter
22	Main body	24	Coupling structure
26	Tip structure	28	Intake passage
5	30 Return passage	32	Intake tube
	34 Return Tube	36	Connection
	38 Luer connector	40	Luer connector
	42 Suture wing structure	44	Intake opening
	46 Return opening	48	Side opening
10	50 Holes	51	Third passage
	52 Side opening	53	Main portion
	54 Tubular applicator	55	Guide wire
	56 Cap	60	Rod
	120 Catheter assembly	126	Tip structure
15	128 Intake passage	130	Return passage
	144 Intake opening	146	Return opening
	151 Third passage	152	Opening or slit
	154 Applicator	160	Taper
	162 Guide wire	164	Socket
20	170 Occlusion mandrel	172	Occlusion mandrel

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CLAIMS

1. A catheter assembly (20, 120) for engagement over a guide wire (55, 162) to enter the catheter assembly by sliding the catheter assembly along the guide wire, the assembly having a catheter (21) and a tubular applicator (54) the catheter comprising:

a main body (22) extending longitudinally and defining intake (28, 128) and return (30, 130) passages, the intake passage terminating at a distal end of the body at an intake opening (44, 144) extending generally transversely with respect to the main body and forming an intake lumen;

a proximal end coupling structure (24) having a connection (36) attached to the main body (22) and a pair of tubes (32, 34) including connectors (38, 40) at their respective proximal ends and the tubes being connected at their distal ends to the connection such that selected ones of the tubes are coupled for fluid flow to respective ones of the passages;

a tip structure (26, 126) extending longitudinally from the distal end of the main body and forming a continuation of the return passage to form with this passage a return lumen, the tip structure defining a distal end return opening (46, 146) and a side opening (52, 152) on a side of the tip structure closest to the intake lumen; and

the tubular applicator (54) extending through the one of said tubes, through the connector and the intake lumen, through said side opening, and through a portion of the tip structure between the side opening and the return opening whereby the catheter assembly (20, 120) can be slid over the guide wire by containing the wire in the applicator with the applicator exposed between the side opening and the intake opening to present a smoother exterior for insertion through body tissue.

2. A catheter assembly as claimed in claim 1 in which the passages are substantially round in cross-section.

3. A catheter as claimed in claim 1 in which the applicator includes a cap 56 in engagement with a corresponding one of said connectors (38, 40) when the applicator reaches to or slightly outside the return opening.

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4. A catheter as claimed in claim 1 in which the side opening is a slit.
5. A catheter assembly as claimed in claim 1 in which the tip structure (26, 126) defines a socket inside the continuation of the return passage and between the end return opening (46, 146) and the side opening (52, 152) the socket being proportioned to receive the end of the applicator so that the applicator can be used to push the catheter assembly with the force applied to the applicator being transferred at the socket to the catheter.
6. A catheter assembly as claimed in claim 5 in which the passages are substantially round in cross-section.
7. A catheter as claimed in claim 5 in which the side opening is a slit.
8. A catheter assembly (20, 120) for engagement over a guide wire (55, 162) to guide the catheter assembly through body tissue, the catheter assembly having a catheter (21) and a tubular applicator (54), the catheter comprising:
  - an intake lumen (28) terminating at a distal end in an intake opening (44) extending transversely with respect to the intake lumen;
  - a return lumen (30, 51) extending side-by-side with the intake lumen and extending beyond said intake opening to terminate at a return opening (46) extending transversely with respect to the return lumen, a tip structure (26) extending between the intake opening and the return opening and containing a portion (51) of the return lumen, a tip structure defining a side opening (52) adjacent the return opening, and a coupling structure (24) at a proximal end of each of the intake and return lumens to make connection to the catheter assembly; and
  - a tubular applicator (54) extending through the intake lumen, through said side opening and into the portion 51 of the second lumen whereby the catheter assembly can be slid over the guide wire engaged through the tubular applicator.
9. A catheter assembly as claimed in claim 8 in which the assembly further includes a flexible rod (60) engaged in the return lumen (30).



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10. A catheter assembly as claimed in claim 8 in which the return lumen includes a section of reduced cross-section between the side opening and the return opening to form a socket (164) so that the end of the applicator will engage this section to facilitate pushing the catheter assembly over the guide wire.

11. A catheter as claimed in claim 8 in which the intake and return lumens are substantially round in cross-section.

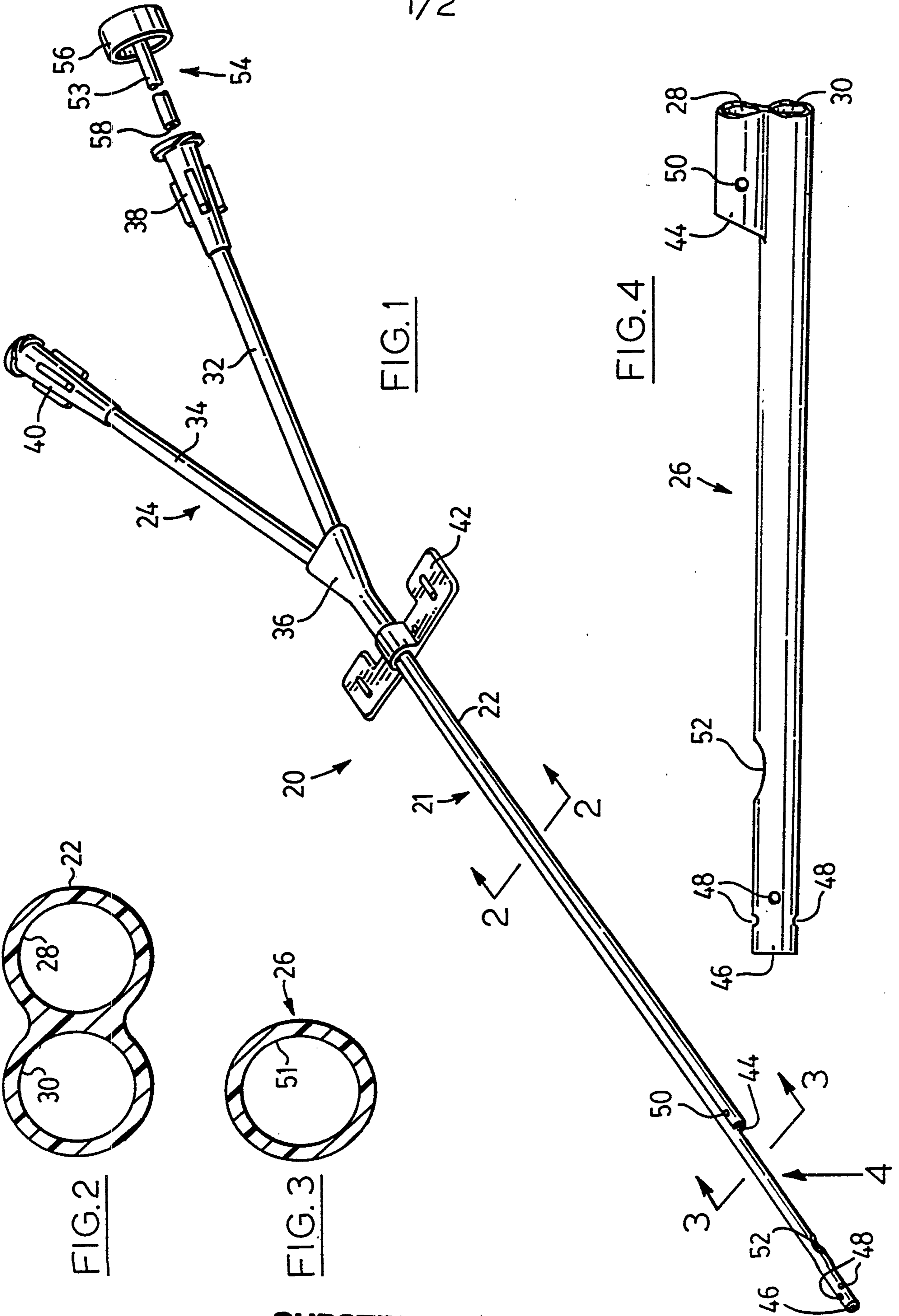


FIG. 2

FIG. 3

FIG. 1

FIG. 4

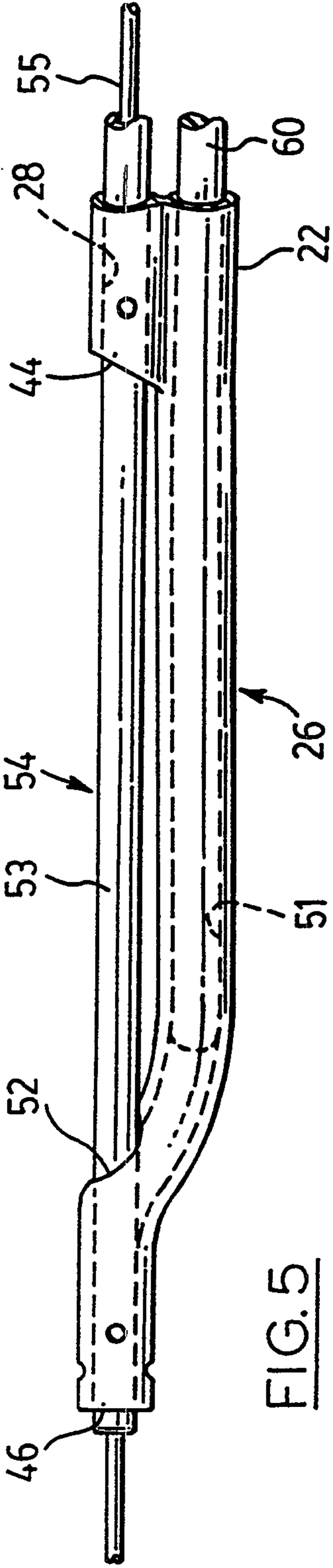


FIG. 5

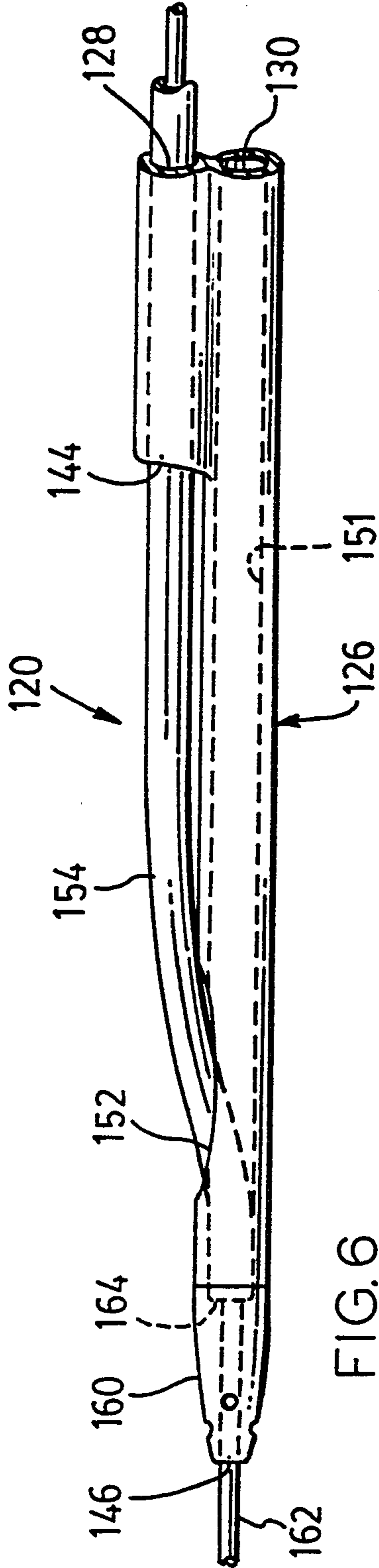


FIG. 6

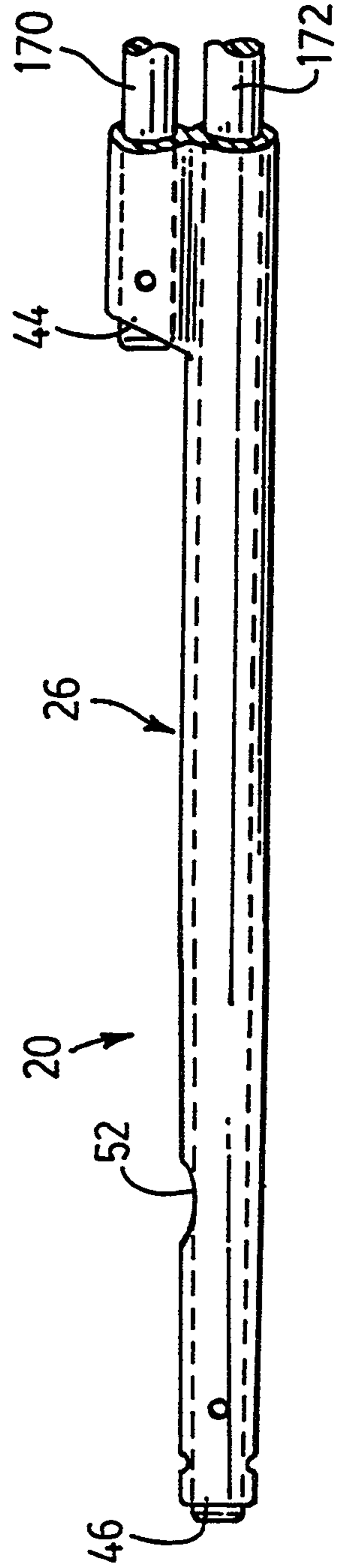


FIG. 7

