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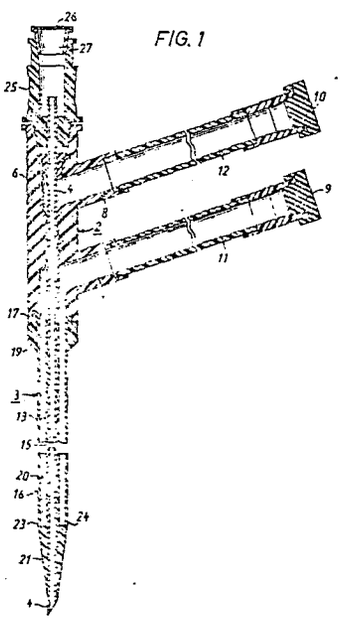
(54) An intravascular catheter.

(57) An intravascular catheter, comprising a hub (2) having a pair of axially spaced branched tubes (7,8) mounted thereto, a flexible double-walled tube (3) having an inwardly tapered tip portion (21) and consisting of coaxial inner (13) and outer tubes (16) and a needle (4) removably inserted into said inner tube. The base edge of the inner tube (13) is located intermediately between the positions from which said two branched tubes (7,8) extend outward so that the inner passageway (15) of tube (13) after removing of needle (4) communicates with the branched tube (8). The base edge of the outer tube (16) is fixed to the tip of the hub (2) so that the annular passageway (20) formed between said outer and inner tubes (13,16) communicates with the other branched tube (7). The inner passageway (15) has an opening at the tapered tip (21) of the double-walled tube (3) and the forward end portion of the outer tube (16) is provided with bores (23,24) at its connection with the tapered tip portion (21).

FIG. 1



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An intravascular catheter

This invention relates to an intravascular catheter useful for extracorporeal blood circulation through an artificial kidney, an artificial lung, or the like.

In a conventional blood dialyzing operation using an artificial kidney, a couple of needles are kept inserted respectively to each of the vein and artery of a patient for the suction and recovery of blood through the artificial kidney. In this case, the patient suffers from pain because two needles are inserted into his blood vessels. In addition, the life of the shunt serving to connect directly the artery and the vein tends to be shortened.

To overcome the above-noted drawbacks, a so-called "single needle system" has been proposed in which withdrawing from and returning to the body of the blood are effected by using a single needle. In this case, the opening-closing of a valve is performed electrically so as to enable the single needle to withdraw and return the blood alternately. The alternate operation naturally leads to a longer dialyzing time than for the case of using two needles, because shortening of the dialyzing time will cause sharp and enlarged fluctuations in the internal pressure of the dialyzing circuit, giving bad influences to the patient. It should also be noted that the single needle system necessitates a

particular machine for operating the circulation.

The invention aims at eliminating these drawbacks by providing an intravascular catheter of a double-walled structure. The invention as characterized in the claims solves the object of providing an intravascular catheter wherein a single needle need be inserted only once into a blood vessel of a patient for achieving extracorporeal blood circulation, thereby alleviating the pain of the patient. Further, the catheter of the invention will enable an effective blood circulation equivalent to the conventional device using two needles. Still further, the catheter of this invention can be operated very easily.

Below, the invention is explained in greater detail by referring to the drawings illustrating preferred embodiments, and wherein:

Figure 1 is a longitudinal sectional view of an intravascular catheter according to one embodiment of this invention;

Figure 2 is a longitudinal sectional view of the hub included in the catheter of Figure 1;

Figure 3 is a view with parts broken away and in section of a vascular channel with catheter embodying the invention being inserted therein;

Figure 4 is a longitudinal sectional view showing a modification of a sealing member to be mounted to the base portion of the hub; and

Figure 5 is a longitudinal sectional view of an intravascular catheter according to another embodiment of this invention.

As shown in Figure 1, an intravascular catheter according to one embodiment of this invention comprises a hub 2, a double-walled tube 3 mounted to the tip portion of the hub 2 and having a tapered tip portion, and a needle 4 removably inserted into the double-walled tube 3. The hub 2, which is made of, for example, polycarbonate or polypropylene, is provided with an axial passageway 5 as shown in Figure 2. The base end portion of the hub is sealed with a sealing member 6 formed of, for example, synthetic rubber so as to close the axial passageway 5, with the tip end of the axial passageway left open. Further, the hub 2 is provided with first and second auxiliary passageways 7 and 8 branched from the axial passageway 5. In general, first and second auxiliary tubes 11 and 12 formed of a transparent flexible plastic material and having caps 9 and 10 (see Figure 1) removably mounted to the tips thereof are connected to the first and second auxiliary passageways 7 and 8, respectively.

The hub 2 may be formed by integral molding. Alternatively, it is possible to separate the hub into two sections, one section comprising the first auxiliary passageway 7 and the other section including the second auxiliary passageway 8. Namely, these two sections are molded separately and joined to each other later. The separate molding method is preferred because the subsequent work of fixing an inner tube 13 to the hub can be facilitated.

A double-walled tube 3 consisting of the inner tube 13 and an outer tube is mounted to the forward end portion of the hub 2. Specifically, the base portion of the inner tube 13 is inserted into the axial passageway 5 of the hub to reach, for example, a stepped portion 14 provided between the first and second auxiliary blood passageway 7 and 8, and is bonded to the inner wall of the hub defining axial

passageway 5 by using an adhesive or the like. Thus, the second auxiliary passageway 8 of the hub is allowed to communicate with a central passageway 15 formed in the inner tube 13. On the other hand, the base edge of the outer tube 16 is fixed to the forward end of the hub such that a flange 17 formed at the base edge of the outer tube is engaged with a stepped portion 18 of the hub, with a reinforcing member 19 disposed to ensure stable engagement between the flange 17 and the stepped portion 18. Naturally, the particular construction mentioned permits a sufficiently strong fixing of the outer tube to the hub.

The outer tube 16 completely surrounds that portion of the inner tube 13 which extends from the forward end of the hub 2 so as to have an annular passageway 20 formed between the outer wall of the inner tube and the inner wall of the outer tube. As shown in the drawing, the annular passageway 20 communicates with the first auxiliary passageway 7 of the hub. In other words, the axial passageway 5 formed in the hub 2 is divided by the presence of the inner tube 13 into two independent passageways communicating respectively with the first and second auxiliary passageways 7 and 8.

The inner and outer tubes 13 and 16 are bonded to each other at the forward end portions by fusion or the like. Further, the double-walled tube 3 consisting of these tubes 13 and 16 has a tapered tip portion 21. When a needle 4 is inserted through the central passageway formed in the inner tube 13, the shape of beveled tip of the double-walled tube 3 nearly conforms with the shape of the tip of the needle 4, thereby substantially avoiding the formation of a stepped portion therebetween for ease in passage through the skin and vascular wall.

At least one bore, for example, a pair of mutually facing bores 23, 24 as shown in Figure 1, is formed in the tip portion of the outer tube 16 so as to enable the annular passageway to communicate with a blood vessel when the tip portion of the double-walled tube has been inserted into the blood vessel. It is preferred to provide the bores 23, 24 in a manner to communicate with the tip of the annular passageway 20 as shown in Figure 1. Otherwise, the blood introduced into the tip portion of the annular passageway would stagnate, leading to coagulation of the blood.

Incidentally, it is preferred to use a highly flexible plastic material such as TFE (tetrafluoroethylene) resin or FEP (fluorinated ethylene propylene) resin for forming each of the inner and outer tubes of the double-walled tube 3.

The needle 4 provided by, for example, a stainless steel tube is removably inserted through the elastic sealing member 6 into the central passageway formed in the inner tube. As shown in Figure 1, the tip of the needle is sharpened so as to facilitate insertion into a blood vessel, and the base of the needle is provided with a head 25. Further, a cap 27 equipped with a water-repelling filter 26 serving to withdraw the air from the needle is mounted to the head 25. When the needle 4, which is hollow, has been inserted into a blood vessel of the patient, the blood flows into the head 25 of the needle. Thus, it is preferred to use a transparent material for forming each of the head 25 and the cap 27, so that blood flow introduced into the head can be observed through the transparent material, rendering it possible to confirm the insertion of the tip of the needle into a blood vessel.

Figure 3 illustrates the use of the intravascular catheter having the construction described above. Specifically, the

sharpened tip of the needle 4 is inserted into a blood vessel 28 and, then, the needle 4 alone is withdrawn with the tip portions of the inner and outer tubes 13 and 16 kept fully inserted within the blood vessel 28. As described above, the blood flows into the head 25 of the needle soon after the tip of the needle has penetrated the blood vessel 28. Since the head 25 is formed of a transparent material, the blood introduced therein is readily visible, rendering it possible to confirm that the tip of the needle has been properly inserted into the blood vessel 28.

It should be noted that the tapered tip portion of the double-walled tube 3 well conforms with the sharpened tip of the needle 4 as described previously. This construction is very effective for facilitating the insertion of the tip portion of the double-walled tube into the blood vessel 28. Specifically, the outer diameter of the tip of the double-walled tube is substantially equal to that of the tip of the needle such that the resistance to insertion is negligible, resulting in smooth inserting.

As soon as the needle 4 has been withdrawn, the puncture made by the needle insertion in the sealing member 6 closes under the elasticity of the sealing material, thereby preventing the blood from leaking to the outside through the sealing member. The sealing effect can be enhanced if an auxiliary cap 29 is mounted to the base portion of the hub upon withdrawal of the needle 4.

After the intravascular catheter has been set as shown in Figure 3, the air within the catheter is vented. Namely, the caps 9 and 10 mounted to the first and second auxiliary tubes 11 and 12, which are connected to the first and second auxiliary passageways of the hub, are removed for the air withdrawing operation. Finally, a blood dialysis circuit 30 is connected to the auxiliary tubes 11 and 12 via connecting means. It is seen that the second auxiliary tube 12 con-

stitutes a part of the passageway of blood flowing into the dialysis circuit 30. On the other hand, the first auxiliary tube 11 constitutes a part of the returning blood passageway. It is important to note that the bores 23, 24 provided at the tip of the outer tube 16 are suitably spaced from a port 31 leading to the center passageway formed in the inner tube 13. It follows that the blood returned to the blood vessel through the bores 23, 24 is prevented from entering again the dialysis circuit 30 through the port 31, as shown in Figure 3. Incidentally, Figure 3 shows that the double-walled tube inserted into the blood vessel 28 extends in the direction opposite to the flow direction of the blood; however, it is possible to reverse the inserting direction of the double-walled tube.

In the latter case, the blood circulation should also be reversed, i.e., the blood should be introduced into the catheter from the bores 23, 24, and returned to the blood vessel 28 through the port 31.

As described in detail, the intravascular catheter of this invention comprises a double-walled tube provided with two separate blood passageways through which the blood is introduced into an artificial kidney or the like and returned to the patient, respectively. It is important to note that the blood-treating circuit outside the body of the patient is rendered operable upon withdrawal of the needle inserted into a blood vessel of the patient. In other words, it suffices to insert the needle into a blood vessel only once for rendering the catheter of this invention operable. Naturally, trauma to the patient caused by the insertion of the needle can be markedly alleviated, and the life of the shunt can be increased, as compared with the conventional construction. Further, the intravascular catheter of this invention can be used in the blood dialysis system utilizing the conventional catheter comprising two needles.

The sealing member 6 mounted to the base end portion of the hub should naturally be formed of a highly flexible material. For enhancing the sealing effect, however, it is possible to employ various valve mechanisms. For example, Figure 4 shows a flexible sheet 32 mounted to the inner edge of the sealing member 6. Naturally, the sheet 32 acts as a valve so as to prevent the blood from leaking out through the sealing member 6.

Although the foregoing has been primarily described with respect to an intravascular catheter having a pair of auxiliary passages branched from the axial passage of the hub, it is also possible to omit the second auxiliary passageway 8 and to utilize the axial passage per se as the second auxiliary passage. Figure 5 shows an embodiment of such a construction wherein only the second auxiliary passageway 8 and the sealing member 6 are omitted. Accordingly, the intravascular catheter shown in Figure 5 comprises a hub 33 having an axial passage 34 opening at both ends, an auxiliary passageway 7 branched from the axial passageway 34, a flexible double-walled tube 3 having an inwardly tapered tip portion 21 and consisting of an inner tube 13 extending into the axial passageway 34 formed in the hub 33 and providing a central passageway 15 and an outer tube 16 disposed coaxially with the inner tube 13, thereby forming an annular passageway 22 between the outer wall of the inner tube 13 and the inner wall of the outer tube 16, the base edge of the inner tube being secured at an intermediate inner wall of the axial passageway 34 between the auxiliary passageway 7 and the forward end of the axial passage 34, the base edge of the outer tube 16 being fixed to the forward end of the hub 33 so as to enable the annular passageway 22 to communicate with the auxiliary passageway 7, and the central passageway 15 having an opening at the tapered tip 21 of the double-walled tube 3

and the forward end of the annular passageway 20 communicates with a pair of bores 23, 24 provided in the forward end portion of the outer tube 16, and a needle 4 removably inserted into the central passageway 15 formed in the inner tube 13 such that the tip of the needle 4 extends beyond the tapered tip 21 of the double-walled tube 3.

As described above, the catheter shown in Figure 5 makes use of part of axial passage 5 as the second auxiliary passageway 8. Accordingly, in the employment of this type of catheter, upon withdrawal of the needle 4 from a vascular channel, leaving the tip of the double-walled tube kept within the channel, one end of a blood circulating tube is connected to a recessed end portion 35 of the hub 2, thereby obtaining a blood circulation equivalent to that provided by the intravascular catheter shown in Figure 1. It is also possible to preliminarily provide the recessed end portion of the hub with an elastic reseal plug.

Patent Claims:

1. An intravascular catheter,
characterizid by
a hub (2) having an axial passage (5) which is open at the forward end and sealed with a sealing member (6) at the base end opposite to said forward end, a first auxiliary passageway (7) branched from the axial passageway (5) near the forward end of the hub (2), and a second auxiliary passageway (8) communicating with the axial passageway (5) at the sealed end thereof;
a flexible double-walled tube (3) having an inwardly tapered tip portion (21) and consisting of an inner tube (13) extending into the axial passageway (5) formed in the hub (2) and providing a central passageway (15) and an outer tube (16) disposed in coaxial relation to the inner tube (13), thereby forming an annular passageway (20) between the outer wall of the inner tube (13) and the inner wall of the outer tube (16), the base edge of the inner tube being secured at an intermediate portion between the positions from which the first and second auxiliary passageways (7, 8) extend outward so as to enable the central passageway (15) formed in the inner tube (13) to communicate with the second auxiliary passageway (8), the base edge of the outer tube (16) being fixed to the forward end of the hub (2) so as to enable the annular passageway (20) to communicate with the first auxiliary passageway (7), and the central passageway (15) having an opening at the tapered tip of the double-walled tube (3) and the forward end of the annular passageway (20) communicating with at least one bore provided at the forward end portion of the outer tube (16); and
a needle (4) removably inserted into the central passageway (15) formed in the inner tube (13) through the sealing member (6) provided at the base portion of the hub (2) such

that the tip of the needle (4) extends beyond the tapered tip (21) of the double-walled tube (3).

2. The intravascular catheter according to claim 1, wherein a flexible sheet acting as a valve to prevent the blood from leaking out is mounted to the inner edge of the sealing member (6).

3. The intravascular catheter according to claim 1, wherein a cap (27) provided with a water repelling filter (26) serving to withdraw the air is mounted to the head of the needle (4).

4. An intravascular catheter,
characterized by
a hub (33) having an axial passage (34) opening at both ends and an auxiliary passageway (7) branched from the axial passageway (34);
a flexible double-walled tube (3) having an inwardly tapered tip portion (21) and consisting of an inner tube (13) extending into the axial passageway (34) formed in the hub (33) and providing a central passageway (15), and an outer tube (16) disposed in coaxial relation to the inner tube (13), thereby forming an annular passageway (22) between the outer wall of the inner tube (13) and the inner wall of the outer tube (16), the base edge of the inner tube (13) being secured at an intermediate inner wall of the axial passageway (34) between the auxiliary passageway (7) and the forward end of the axial passageway (34), the base edge of the outer tube (16) being fixed to the forward end of the hub (33) so as to enable the annular passageway (22) to communicate with the auxiliary passageway (7), and the central passageway (15) having an opening at the tapered tip (21) of the double-walled tube (3), with the forward

end of the annular passageway (20) communicating with at least one bore (23, 24) provided in the forward end portion of the outer tube (16); and

a needle (4) removably inserted into the central passageway (15) formed in the inner tube (13) such that the tip of the needle (4) extends beyond the tapered tip (21) of the double-walled tube (3).

FIG. 1

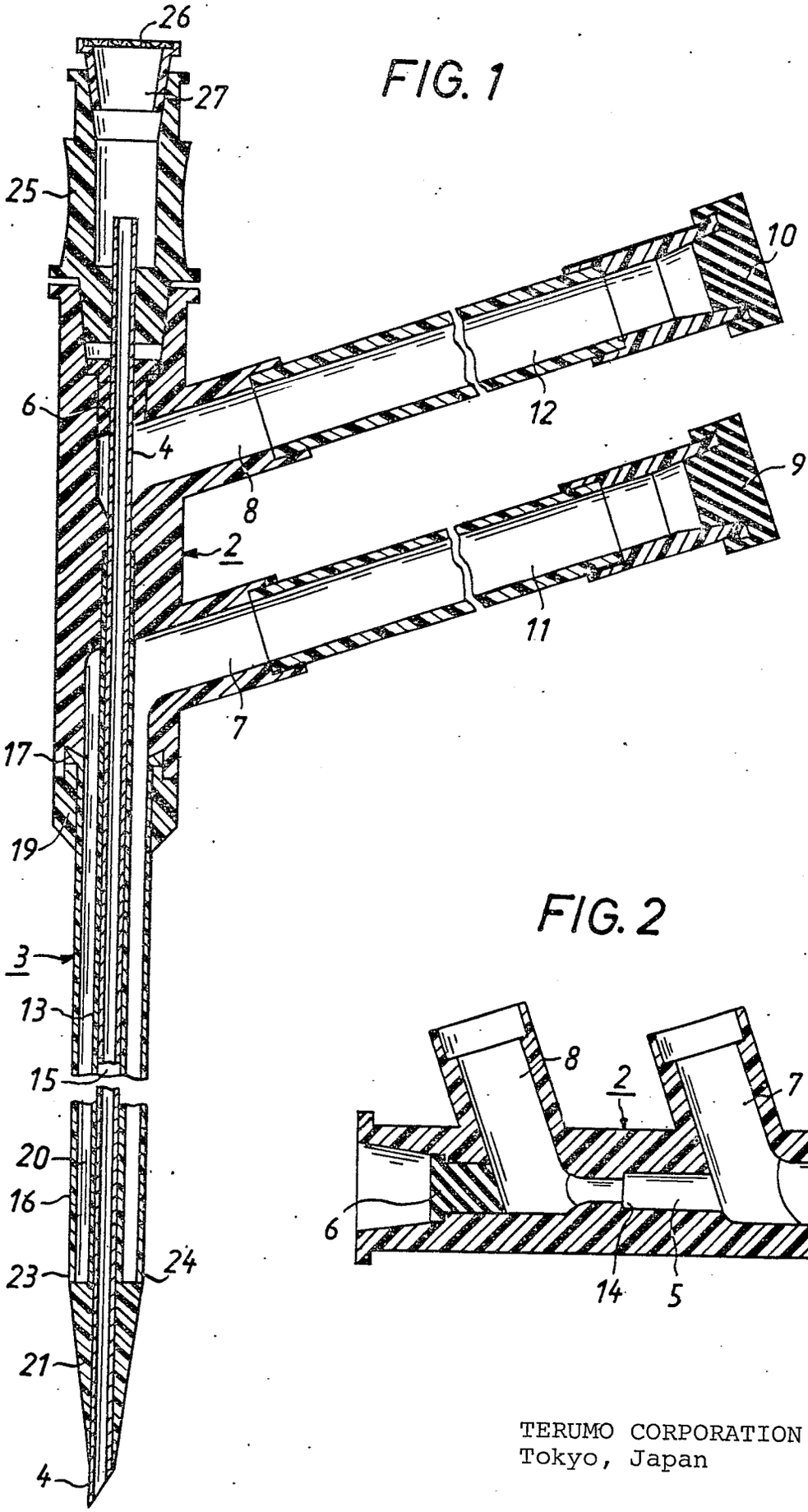

FIG. 2

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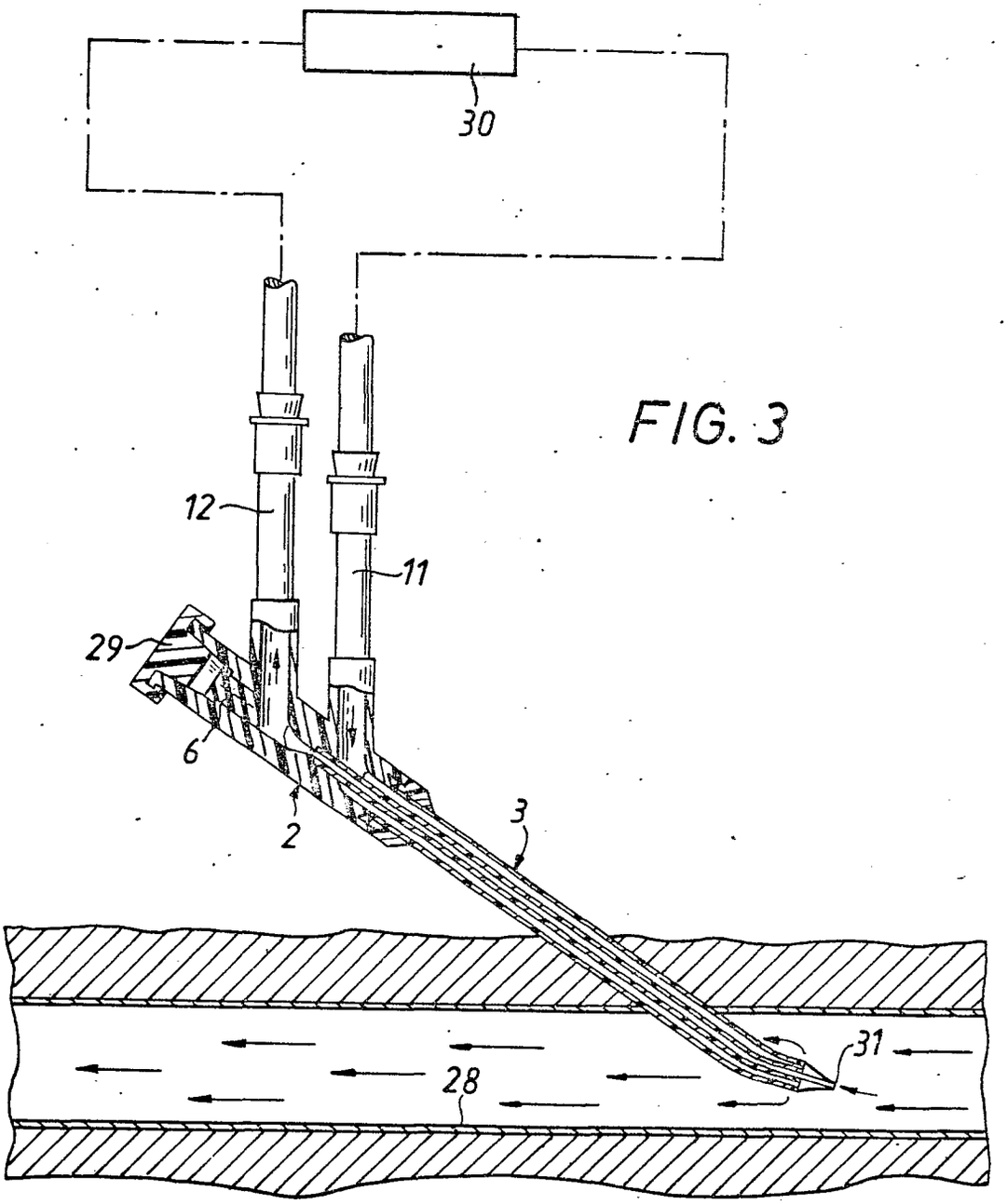
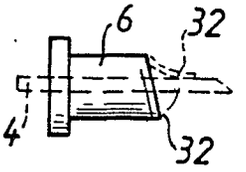


FIG. 3

FIG. 4



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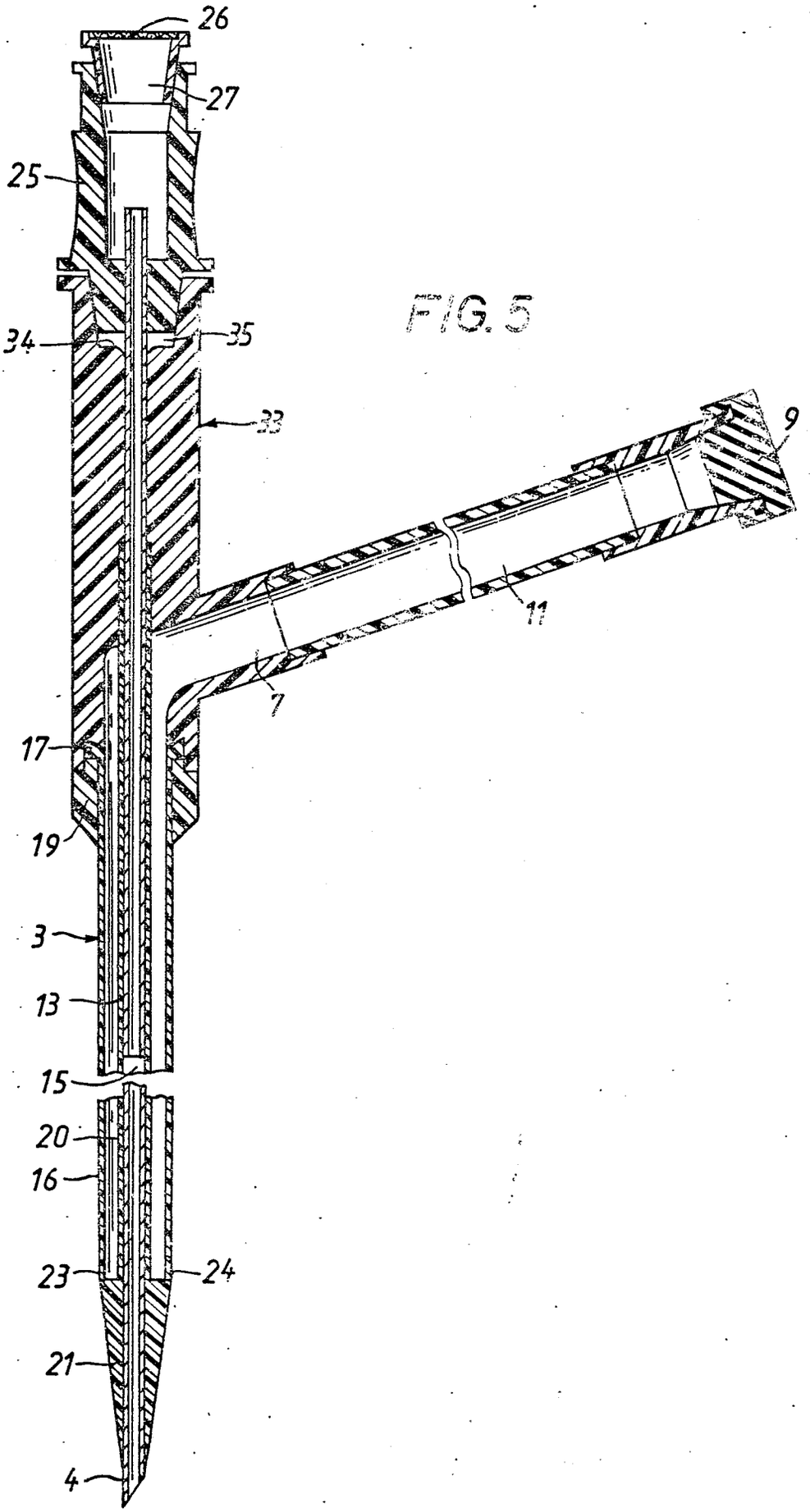

FIG. 5

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European Patent Office

EUROPEAN SEARCH REPORT

Application number

EP 78 10 0066

0000041

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
	DE - A - 2 645 520 (McLAUGHLIN) 14-4-1977 * Figure 3; pages 13-15 * --	1,2,4
	BE - A - 851 299 (HOSPAL) 31-5-1977 * Figures 1,2; page 5, line 33 - page 8, line 35 * --	1,4
E,P	DE - A - 2 613 281 (TERSTEEGEN) 6-10-1977 * Figure; claims 1,2 * & FR - A - 2 355 517 20-1-1978 ----	1,4

CLASSIFICATION OF THE APPLICATION (Int. Cl.²)

A 61 M 25/00

TECHNICAL FIELDS SEARCHED (Int.Cl.²)

A 61 M 1/03
A 61 M 25/00
A 61 M 5/14
A 61 M 5/32

CATEGORY OF CITED DOCUMENTS

X: particularly relevant
A: technological background
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X The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	14-09-1978	NOESEN