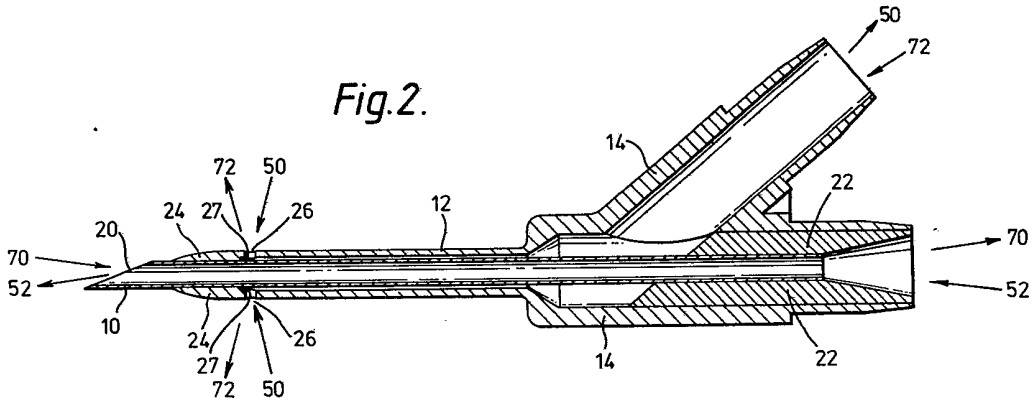
(12) UK Patent Application (19) GB (11) 2 032 778 A

(21) Application No **7934116**
(22) Date of filing **2 Oct 1979**
(23) Claims filed **2 Oct 1979**
(30) Priority data
(31) **78/40222**
(32) **12 Oct 1978**
(33) **United Kingdom (GB)**
(43) Application published **14 May 1980**
(51) **INT CL³ A61M 5/14**
(52) Domestic classification **A5R GN**
(56) Documents cited **None**
(58) Field of search **A5R**
(71) Applicants **Avon Medicals Limited, 1649 Pershore Road, Birmingham**
(72) Inventors **Christopher Harris, John Martin Scruton**
(74) Agents **Mewburn Ellis & Co.**

(54) **Fistula needle**

(57) A fistula needle for use in haemodialysis has a cylindrical metal inner portion 10 fitting coaxially within a cylindrical plastics outer portion 12. An end part 24 of the outer portion 12 merges smoothly onto the outer surface of the inner portion 10 to fit snugly around it, the inner diameter of the remainder of the outer portion 12 being greater than the outer diameter of the inner portion 10. In order to minimise any space in which blood might collect and stagnate, blood inflow/outflow holes 26 are positioned almost immediately adjacent the contact between inner and outer portion 10 and 12. At the end of the outer portion 12 remote from the holes 26 there is a body 14 having two branches for the attachment of tubes leading to and away from the needle. The body 14 is formed in one piece with the outer portion 12.

Fig.2.




GB 2 032 778 A

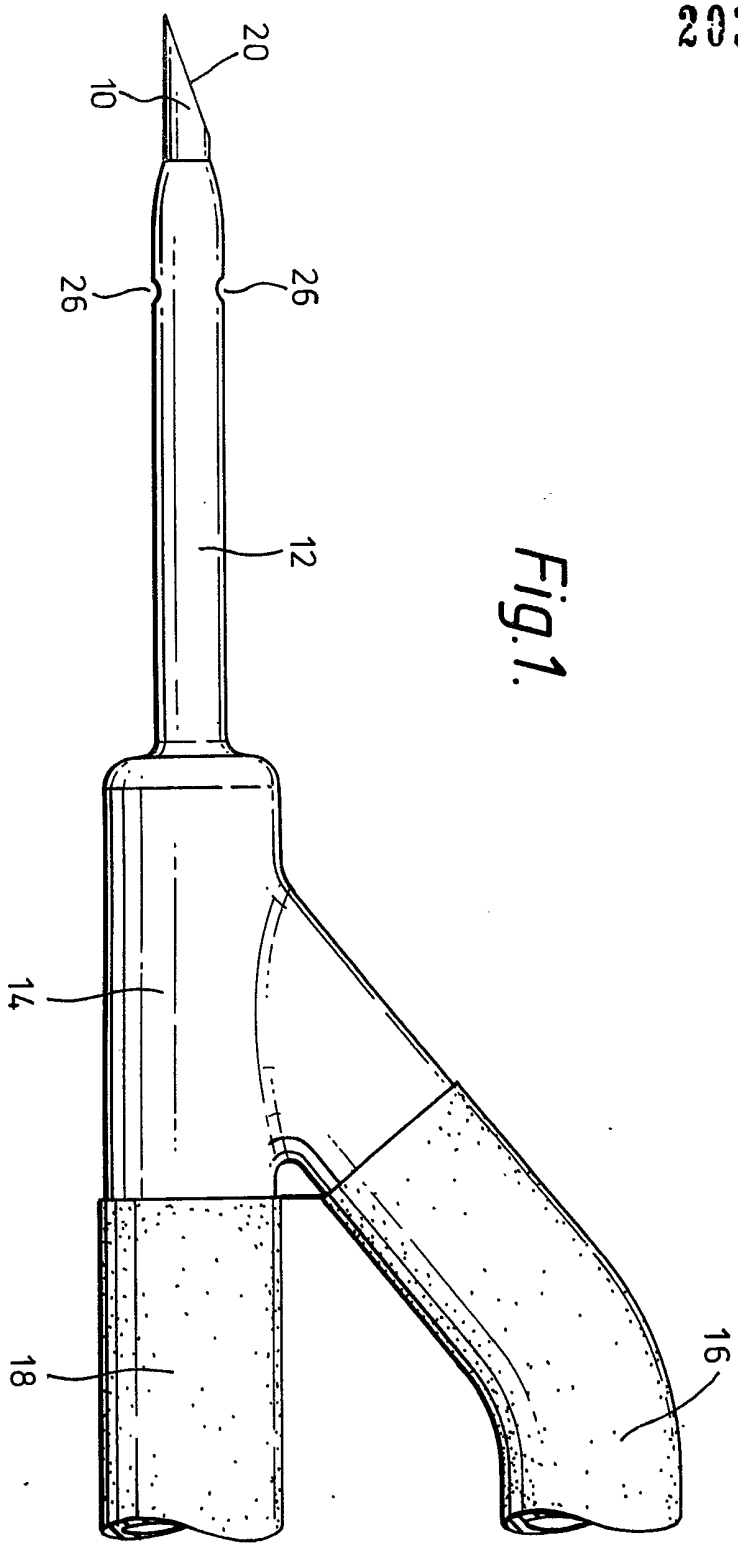



Fig.1.

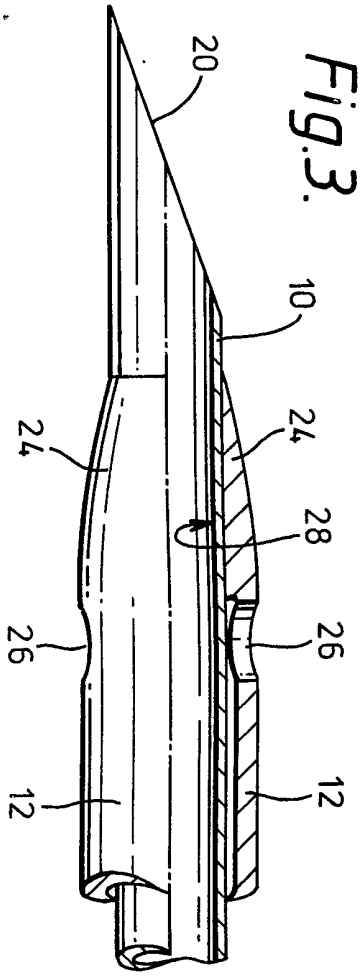



Fig.3.

Fig.2.




Fig.4.

SPECIFICATION

**Fistula needle**

This invention relates to fistula needles such as are used in haemodialysis where a needle or needles are inserted in a vein so that blood may be withdrawn from, treated, and returned to the body.

Every puncture damages a blood vessel and long-term patients may undergo dialysis for periods of years so that it is essential to minimise the frequency of insertion of the needles. This can be done by using a single fistula needle for both the inflow and the outflow of blood.

The simplest method of single-needle dialysis employs an ordinary fistula needle attached to a Y-piece; inflow and outflow blood is pumped alternately, that is, while outflow blood is pumped from the vein, the inflow line is clamped off and vice-versa. However, the pumps required are expensive, complicated and noisy, the alternative action means pumping is necessary for either twice as long or at twice the flow rate during each half cycle, and there is a "dead-space" which allows a certain volume of blood within the needle and Y-piece to be re-withdrawn before it returns to the vein thus reducing efficiency. Several more complicated needles work on the same principle but have relatively moving parts which add to expense and difficulty of production.

Alternatively, double-lumen needles with concentric tubes are used. Typical examples consist of concentric steel tubes in which the outer tube is swaged onto the inner tube at some distance from the needle tip and, even further from the tip, there are holes in the outer tube to permit outflow of blood from the vein. Such needles have the advantages that the "dead-space" is eliminated, there are no moving parts and blood can be withdrawn and returned simultaneously, thus being faster and using simple pumps. However there are disadvantages in that there is always a conical space between the swage and the outer tube holes in which blood can clot, and they are expensive and difficult to make with the required precision.

The benefits of using double lumen needles are nevertheless most attractive so that any improvement in design which leads to a reduction in the disadvantages is highly welcome. We have now found that an improved double-lumen needle results if the outer needle is of a moulded plastics material which fits snugly, at the appropriate region, round the inner metal needle. With a moulded plastics outer needle it is easy, and therefore inexpensive, to make an accurate and tight fit of the end of the outer needle about the inner needle, and the blood inflow/outflow holes can be positioned almost immediately adjacent the portion where inner and outer needles join so that any space in which blood might collect and stagnate is made extremely small. Furthermore when the outer needle is of moulded plastics, its inner surface can be contoured so as to reduce turbulence and encourage a streamlined flow of blood through the needle.

According to the present invention there is provided a fistula needle having a cylindrical metal inner portion fitting coaxially within a cylindrical plastics outer portion, the inner diameter of the outer portion being greater than the outer diameter of the inner portion, said outer portion being adapted at one end to fit snugly around said inner portion, and a hole or holes through the outer portion at that end, adjacent the area of contact between inner and outer portions.

Preferably the outer portion is branched for the attachment of tubes leading to and away from the needle and preferably the inner portion is held, at the end remote from the holes through the outer portion, in a tube within one of the branches which limits its movement relative to the outer portion or alternatively is shaped to fit snugly within the appropriate branch of the outer portion.

Two embodiments of the invention will now be described with reference to the accompanying drawings wherein:–

Fig. 1 shows a needle according to the invention in side elevation,

Fig. 2 shows a cross-section on the centreline of the needle of Fig. 1,

Fig. 3 shows the distal end of the needle of Fig. 1, partly in cross section and

Fig. 4 shows an alternative embodiment in cross-section.

For clarity, in each of the drawings both the needle point and the blood entry exit holes are shown in a convenient orientation with respect to the needle axis. The exact orientation of needle bevel and blood holes may vary according to individual preference of medical personnel and facility of use of the needle in particular conditions.

As seen in Figs. 1 and 2, the needle has a cylindrical metal inner portion 10, and a cylindrical plastics outer portion 12, which is in one with the branched plastics body moulding 14. Attached to the branched ends of the body 14, are tubes 16 and 18 for the blood withdrawn from the vein and the blood returning to the vein. The inner portion 10, is cut obliquely at one end 20, to provide a cutting bevel, and the other end is held within a plastics tube 22. The shape of this tube 22, allows the inner portion 10 to be seated within the outer portion 12 and body 14, preventing relative movement between the outer portion and the inner portion. As shown most clearly in Fig. 3, the outer portion 12, has a smaller internal diameter and a tapering exterior surface at the end 24, so as snugly to fit around and coaxially with the inner portion 10.

There are holes 26, on opposite sides of the outer portion 12 situated almost immediately adjacent the surface of contact 28 between outer and inner portions. There may alternatively be one hole or several holes arranged equidistantly around the outer portion 12.

Because the outer portion 12 is of a plastics material, it is easily moulded at the end, 24, to give both a snug fit around the inner portion 10 and an increased thickness of the outer portion at that end 24, so that the holes 26 can be positioned almost immediately adjacent the surface of contact 28, leaving a minimal space 27 having a width measured in the direction of

the needle axis of the order of ten thousandths of an inch. Furthermore, the streamlined surfaces which are achieved by using moulded plastics for the outer portion 12 and body 14 promote laminar flow of the blood through the needle with minimal turbulence.

In use, the whole needle end is inserted into a vein, that is so that both the inner end 20, and the holes 26, in the outer portion are in the vein. Blood is then pumped from the vein through the outer portion 12, in the direction shown by the arrows 50, treated and returned to the body through the inner portion 10 in the direction shown by the arrows 52.

Alternatively the blood may be pumped in the reverse direction i.e. from the vein through the inner portion 10 in the direction of the arrows 70 and returned through the outer portion 12 in the direction of the arrows 72.

An alternative embodiment is shown in Fig. 4 in which reference numbers correspond with those of Figs. 1 to 3. In this case the inner portion 10 has an end portion 60 which is of greater diameter so that all of the plastics outer portion 12, and body 14, are moulded in one piece and the inner portion 10 is inserted so that in its final position, the larger end 60, itself completes the Y-piece. This construction produces a reduction in the resistance to blood flow through the needle assembly.

Thus the invention provides a needle which has few parts, viz. one steel part and two plastics mouldings in the embodiment of Figs. 1 to 3, one steel part and one moulding in the embodiment of Fig. 4, these parts being easily and therefore cheaply made. There are no moving parts, so that the danger is eliminated of pieces coming adrift in the blood stream, and the moulding of the outer portion is designed to eliminate any clotting space or turbulence-producing points.

CLAIMS

1. A fistula needle having a cylindrical metal inner portion fitting coaxially within a cylindrical plastics outer portion, an end part of which fits snugly around the inner portion, the inner diameter of the next adjacent part of the outer portion being greater than the outer diameter of the inner portion whereby concentric flow passages are defined, and a hole or holes through the outer portion adjacent the contact between inner and outer portions.

2. A fistula needle according to claim 1, wherein at the end of the outer portion remote from the hole or holes there is a body having two branches, into one of which the other end part of the inner portion extends.

3. A fistula needle according to claim 2, wherein the inner diameter of the branch into which the other end part of the inner portion extends is greater than the outer diameter of the latter.

4. A fistula needle according to claim 2 or claim 3, wherein the branch into which the other end part of the inner portion extends has a tube within it for holding that end part of the inner portion in position, the outer surface of the tube being a snug fit with the inner surface of the branch and the outer surface of that end part of the inner portion being a snug fit with the inner surface of the tube.

5. A fistula needle according to claim 4 wherein the tube is made of plastics material.

6. A fistula needle according to claim 2, wherein the outer diameter of at least part of the other end part of the inner portion is greater than the outer diameter of the main part of the inner portion, and the outer surface of the end part of the inner portion having an increased diameter is a snug fit with the inner surface of the branch.

7. A fistula needle according to any one of claims 2 to 6, wherein the branched body is made of plastics material and is formed in one with the outer portion.

8. A fistula needle according to any one of the preceding claims wherein at the said one end surface of the outer portion merges smoothly into the outer surface of the inner portion.

9. Fistula needles substantially as herein described, with reference to and as illustrated in Figs. 1 to 3 and Fig. 4 of the accompanying drawings.

Printed for Her Majesty's Stationery Office by The Tweeddale Press Ltd., Berwick-upon-Tweed, 1980.
Published at the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.