

FORM 1

613234
SPRUSON & FERGUSON

COMMONWEALTH OF AUSTRALIA
PATENTS ACT 1952
APPLICATION FOR A STANDARD PATENT

Shiley Incorporated, of 17600 Gillette, Irvine, California, UNITED STATES OF AMERICA, hereby apply for the grant of a standard patent for an invention entitled:

Femoral Arterial Cannula

which is described in the accompanying complete specification.

Details of basic application(s):-

<u>Basic Applic. No:</u>	<u>Country:</u>	<u>Application Date:</u>
238,154	US	29 August 1988

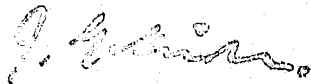
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DATED this TWENTY FIFTH day of AUGUST 1989

Shiley Incorporated

By:



Registered Patent Attorney

TO: THE COMMISSIONER OF PATENTS
OUR REF: 104678
S&F CODE: 60030

REPRINT OF RECEIPT
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AUSTRALIA
CONVENTION
STANDARD
& PETTY PATENT
DECLARATION

~~PC 7484~~

FEMORAL ARTERIAL CANNULA

I/~~WA~~ Allen J. Spiegel on behalf of Shiley, Inc.

of 235 East 42nd Street, New York, State of New York,
United States of America

do solemnly and sincerely declare as follows:—

X. X and Wx are the approximations for the patient

(or, in the case of an application by a body corporate)

1. I am/~~WAX~~ ~~the~~ authorised by

Shiley, Inc.

the applicant(s) for the patent to make this declaration on its/their behalf.

2. The basic application(s) as defined by Section 141 of the Act was/were made

in United States of America

on August 29, 1988

by Gerald D. Buckberg, James V. Maloney, Jr., Kenneth A. Jones and Weldon D. West

8. X xññXxə xřə XlxəxcXuxX XñWəñDə(X)XəFtKə XñWəñtXohXřə WəXřəX
Xə WñtXə WəS(XəpXñXəXñXñS)

(or where a person other than the inventor is the applicant)

3. Gerald D. Buckberg, James V. Maloney, Jr., Kenneth, A. Jones and Weldon D. West of respectively 13238 Riviera Ranch Road, Los Angeles; 139 North Saltair Avenue, Los Angeles; 135 N. Pennsylvania, Lake Elsinore; and 26682 Las Tunas, Mission Viejo; State of California, United States of America; (Citizens: United States of America; Occupations: First two are Surgeons and the Second two are Engineers.)

(respectively)

is/are the actual inventor(s) of the invention and the facts upon which the applicant(s) is/are entitled to make the application are as follows:

The Applicant Company is the Assignee of the said invention from the actual inventors by virtue of an Assignment dated August 26, 1988 and August 29, 1988.

4. The basic application(s) referred to in paragraph 2 of this Declaration was/~~were~~ the first application(s) made in a Convention country in respect of the invention (s) the subject of the application.

Declared at New York, this 8th day of August 1989
New York Shiley, Inc.

Allegre

Signature of Declarant(s)

To: The Commissioner of Patents

ALLEN J. SPIEGEL
DIRECTOR OF FOREIGN PATENTS

1/81

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(54) Title
FEMORAL ARTERIAL CANNULA

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(56) Prior Art Documents
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AU 93919/82 A61M 25/00

(57) Claim

1. A cannula, comprising an elongated tube having a tip section which is adapted to be inserted into a vascular conduit, the elongated tube further having an intermediate section adjacent to said tip section, wherein said intermediate section has a diameter larger than that of the tip section such that a shoulder is formed at the juncture of the two sections, said shoulder being sufficiently larger than the diameter of the conduit such that it engages the exterior of the conduit and limits the insertion of the tip section into the conduit, the surface of said shoulder for engaging the conduit substantially conforming to the exterior of the conduit and being consistent with the angle of insertion of the tip section into the conduit such that a seal is formed by the shoulder with respect to the exterior of the conduit.

3. The cannula of Claim 2, including an orientation indicator on the exterior of said cannula to indicate the desired rotational orientation of the cannula about its axis when being inserted into the conduit.

5. A cannula assembly, comprising the cannula of any one of the preceding claims, and a stylet slidably positioned within the body, wherein said stylet includes a stop on its outer periphery which slides within the interior of the body so that if the tip of the body is in a vascular conduit, the stop limits withdrawal of the stylet when engaging a seal in the end of the cannula.

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FORM 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

COMPLETE SPECIFICATION

(ORIGINAL)

FOR OFFICE USE:

Class Int Class

Complete Specification Lodged:
Accepted:
Published:

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Related Art:

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Complete Specification for the invention entitled:

Femoral Arterial Cannula

The following statement is a full description of this invention, including the best method of performing it known to me/us

FEMORAL ARTERIAL CANNULA

This invention relates to an improved cannula or catheter assembly particularly useful in medical procedures.

In recent years, there has been developed a femoral-to-femoral
5 cardiopulmonary bypass system wherein it is not necessary to open the patient's chest. Such a system has many obvious advantages and is useful in situations where medical treatment can be administered to the heart without having open-chest surgery. To accomplish this, it is necessary to employ large diameter cannulas and catheters in order to maximize blood
10 flow. It is also, of course, important that the necessary connections to the cannulas be made with a minimum of blood loss, in a minimum of time, and with a minimum of trauma and risk to the patient. Cannulating a femoral artery is particularly difficult because of the pressure involved as well as the large flow through the artery.

15 There is disclosed herein a cannula, comprising an elongated tube having a tip section which is adapted to be inserted into a vascular conduit, the elongated tube further having an intermediate section adjacent to said tip section, wherein said intermediate section has a diameter larger than that of the tip section such that a shoulder is formed at the
20 juncture of the two sections, said shoulder being sufficiently larger than the diameter of the conduit such that it engages the exterior of the conduit and limits the insertion of the tip section into the conduit, the surface of said shoulder for engaging the conduit substantially conforming to the exterior of the conduit and being consistent with the angle of
25 insertion of the tip section into the conduit such that a seal is formed by the shoulder with respect to the exterior of the conduit.



- 2 -

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings, wherein:

Figure 1 is a schematic perspective view of an arterial cannula inserted in a femoral artery;

5 Figure 2 is a view similar to Figure 1, but with the stylet of the cannula assembly partially withdrawn;

Figure 3 is a perspective view of the cannula assembly of Figures 1 and 2;

10 Figure 4 is a perspective view of the stylet of the assembly of Figure 3;

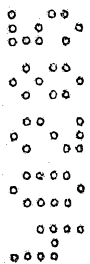


Figure 5 is a perspective view of an anti-backflow ring of the cannula assembly;

Figure 6 is an enlarged perspective schematic view of the cannula assembly inserted in a femoral artery;

5 Figure 7 is a side elevational, partially sectionalized view of the assembly of Figure 3;

Figure 8 is a cross-sectional view of the cannula assembly with the stylet partially withdrawn and with the cannula clamped to prevent flow therethrough;

10 Figure 9 is a cross-sectional view on line 9-9 of Figure 7.

A femoral arterial cannula assembly 65 is shown in Figure 3. The assembly includes a cannula 64, a stylet 66 which is slidably received within the cannula, a fitting 68 secured to the proximal end of the cannula, a stopcock 70 on the fitting, and a clamp 71.

15 The cannula 64 comprises an elongated tubular body 72 preferably made from a medical-grade polyvinyl chloride, or silicone rubber. The body 72 has three primary sections including a distal tip section 72a for insertion into the femoral artery, an intermediate section 72b adapted to extend from the artery to a raised suture stabilizing ring 72c to be located near the exterior skin of the leg, and an exterior section 72d extending from the suture ring 72c to the fitting 68.

20 The tip of section 72a is tapered to facilitate insertion into an artery. In a preproduction version of the cannula, the exterior diameter of the tip section 72a is 6.68 mm or 20 French, and the interior diameter is 5.08 mm. The intravascular length of the tip section 72a in a preproduction version is 5.88 cm, which is a desirable length to ensure adequate seating within the artery.

25 The intermediate section 72b has a length of about 5 cm, with an interior diameter that tapers to about 9.27 mm, and with an exterior diameter which tapers from the tip end of about 8.4 mm and increases to about 12-13 cm. Thus, it can be seen that there is a significant exterior

diameter change from the tip section 72a to the tip end of the intermediate section 72b. This diameter change forms an annular shoulder 72e adapted to engage the exterior of an artery. That shoulder is formed at an angle of approximately 45° with respect to a diametrical plane through the cannula. It has been found that this angle is particularly desirable for sealing with the exterior of the femoral artery when the cannula is inserted in the direction towards the heart.

Due to the angled shoulder and the angle at which the cannula tip is inserted in the femoral artery, it is important the cannula be rotationally oriented properly. Thus, for orientation purposes, there is formed an elongated orientation rib 72g on the exterior of sections 72b and 72d extending from the suture ring 72c to the proximal end of the body which mates with the fitting 68. The section 72d is about 19 cm in length, making the overall length of the cannula about 33 cm. The interior and exterior diameters are constant with the end of section 72b.

A pair of suture wings or flaps 74 are formed integral with and extend outwardly from the cannula exterior section 72d. The flaps form a lower surface which is approximately tangent with the exterior of the section 72d. The suture wings in a prototype are positioned about 5 cm from the suture ring 72c.

Referring to Figures 3 and 4, the stylet 66 is an elongated flexible tubular element preferably made of medical-grade polyvinyl chloride or silicone rubber. The stylet 66 is slightly longer than the cannula 12 having a tapered tip 66a on one end which extends beyond the tip of the cannula when the stylet is fully inserted therein. The overall length is about 42 cm. A knob 76 on the other end of the stylet extends beyond the fitting 68 and is useful for installing and removing the stylet from the cannula. The diameter of the stylet is slightly smaller than the inner diameter of the tip of the cannula. A small diameter lumen 77 is formed throughout the length of the catheter

and is adapted to receive a small diameter guidewire. Included on the stylet 66 is an elongated cylindrical stop 66b having an exterior diameter which is sized to slide relatively easily within the cannula, but nevertheless there is resistance to movement caused by the stop 76b engaging the interior of the cannula. The stop 76b is spaced from the tip end of the stylet about 15 cm and has a length of about 4 cm. This means that the end of the stop 76b closest to the tip 66a of the stylet is located at the suture ring of the cannula when the stylet is fully inserted in the cannula, as seen in Figure 7.

Also included in the cannula assembly is an anti-backflow ring 80 preferably made of medical-grade silicone rubber. The ring has a short barrel-like tubular shape with two axially spaced outwardly extending annular ribs 80a. The ribs are dimensioned such that the backflow ring fits fairly tightly within the interior of the fitting 68 or the cannula end; and in that position, fits snugly on the stylet 66.

Mounted on the exterior of the cannula between the suture wings and the fitting 68 is the adjustable medical clamp 71. The clamp is of standard construction, adapted to be manually set to pinch the cannula closed when the stylet is removed.

In use, the guidewire is inserted into the femoral artery followed by the cannula with the stylet fully inserted, as shown in Figures 1, 3 and 6. The cannula is preferably introduced by use of the Seldinger technique, or a cutdown procedure along with vessel dilation. The assembly, guided by the guidewire, is inserted to the point where the cannula angled shoulder 72e engages the exterior of an artery 82 with the cannula tip section 72a extending into the artery, together with the tip of the stylet, as illustrated in Figure 6. It can be seen from that figure that the angled shoulder 72e seal engages the artery in a manner such that the artery substantially conforms to the shoulder with the exterior of the artery, and limits

insertion. With the cannula so positioned, it is sutured to the leg by means of the wings, and the raised suture ridge, as shown in Figure 6.

5 With the cannula so positioned, there is little blood leakage through the hole in the artery as a result of the seal with the shoulder 72e. Also, the ring 80 prevents leakage through the annular passage between the stylet and the cannula, as seen in Figure 7. With the forward portion of the cannula relatively firmly positioned on the patient's
10 leg, the proximal end of the cannula is free to be raised or manipulated, as may be appreciated from Figure 2.

When it is desirable to connect the cannula to an extracorporeal circuit, the stylet 66 is partially withdrawn by pulling on the knob 76 to the position shown in Figure 8,
15 wherein the stops 66b on the stylet engages anti-backflow ring 80 in the fitting. Note that there is firm resistance by the ring to withdrawing the ring 80 out of the cannula so that an operator recognizes the stopping point. The tip 66a of the stylet is spaced considerably from the suture ring
20 since the length of the stylet from the plug 66b to its tip 66a is somewhat less than the length of the cannula from its fitting end to the suture ring 72c. With the stylet 66 so positioned, the clamp 71 is squeezed onto the cannula section 72d at a location between the tip 66a of the stylet
25 and the suture ring 72c, as seen in Figure 8. By locating the clamp close to the tip 66a of the stylet, there is only a small quantity of blood between the clamp and the ring 80. Once the clamp has been positioned and closed, the stylet can be withdrawn completely with a pulling force greater
30 than that to move the stop, such that the ring 80 in the end of the fitting is also withdrawn, captured on the stylet 66. At this stage, there is only a small quantity of blood in the open end of the cannula, and it is not under pressure. Because of this and the suture wings, the proximal end of
35 the cannula can be easily handled for making connections to a pump and priming the cannula without loss of blood.

The claims defining the invention are as follows:

1. A cannula, comprising an elongated tube having a tip section which is adapted to be inserted into a vascular conduit, the elongated tube further having an intermediate section adjacent to said tip section, wherein said intermediate section has a diameter larger than that of the tip section such that a shoulder is formed at the juncture of the two sections, said shoulder being sufficiently larger than the diameter of the conduit such that it engages the exterior of the conduit and limits the insertion of the tip section into the conduit, the surface of said shoulder for engaging the conduit substantially conforming to the exterior of the conduit and being consistent with the angle of insertion of the tip section into the conduit such that a seal is formed by the shoulder with respect to the exterior of the conduit.

2. The cannula of Claim 1, wherein the surface of said shoulder which engages the conduit is formed at an angle of approximately 45° with respect to the diameter of the cannula.

3. The cannula of Claim 2, including an orientation indicator on the exterior of said cannula to indicate the desired rotational orientation of the cannula about its axis when being inserted into the conduit.

4. The cannula of Claim 1, including a pair of suture wings extending outwardly from the exterior of the cannula adapted to be sutured to a patient's skin so as to maintain the cannula tip section properly in the conduit while leaving the proximal end of the cannula outwardly from the wings to be easily manipulated.

5. A cannula assembly, comprising the cannula of any one of the preceding claims, and a stylet slidably positioned within the body, wherein said stylet includes a stop on its outer periphery which slides within the interior of the body so that if the tip of the body is in a vascular conduit, the stop limits withdrawal of the stylet when engaging a seal in the end of the cannula.

6. The cannula assembly of Claim 5, including an anti-backflow ring positioned in the end of the body remote from the tip forming a seal to prevent leakage out of said cannula and forming a temporary limit for said stop when said stylet is in the process of being withdrawn from the cannula.

7. The cannula assembly of Claim 6, wherein said stylet stop is spaced from the stylet tip and is spaced from said tip section when the stylet is fully inserted into the cannula body, whereby said stylet can be



withdrawn to the point where the stop engages said ring a temporary limiting withdrawal of the stylet, and including means at a location between the tip of the partially withdrawn stylet and the tip of the cannula for limiting fluid flow into the cannula said stylet being adapted to be fully withdrawn from the cannula including forcing said ring out of the cannula body.

8. A method of making a connection to a vascular conduit, comprising the following steps:

inserting the tip of a cannula assembly of any one of claims 5 to 7 into the conduit;

partially withdrawing from the cannula, the stylet, while keeping the stop on the stylet exterior within the cannula; and

blocking flow through the cannula at a location between the cannula tip and the tip of the partially withdrawn stylet.

9. The method of Claim 8, further including the steps of: completely withdrawing the stylet from the cannula; and making connections to the end of the cannula before opening the cannula.

10. A method of installing a flexible femoral arterial cannula, comprising the following steps:

inserting the cannula of any one of claims 1 to 4 into a patient's femoral artery; and

attaching the cannula to the patient's leg with a pair of flap-like wings on the cannula close to the entry of the cannula to the patient's leg so as to firmly maintain the cannula tip in the artery while permitting the proximal end of the cannula outwardly from said wings to be movable.

11. A cannula substantially as hereinbefore described with reference to the accompanying drawings.

12. A method of making a connection to a vascular conduit substantially as hereinbefore described with reference to the accompanying drawings.

DATED this TWENTY-SIXTH day of APRIL 1991

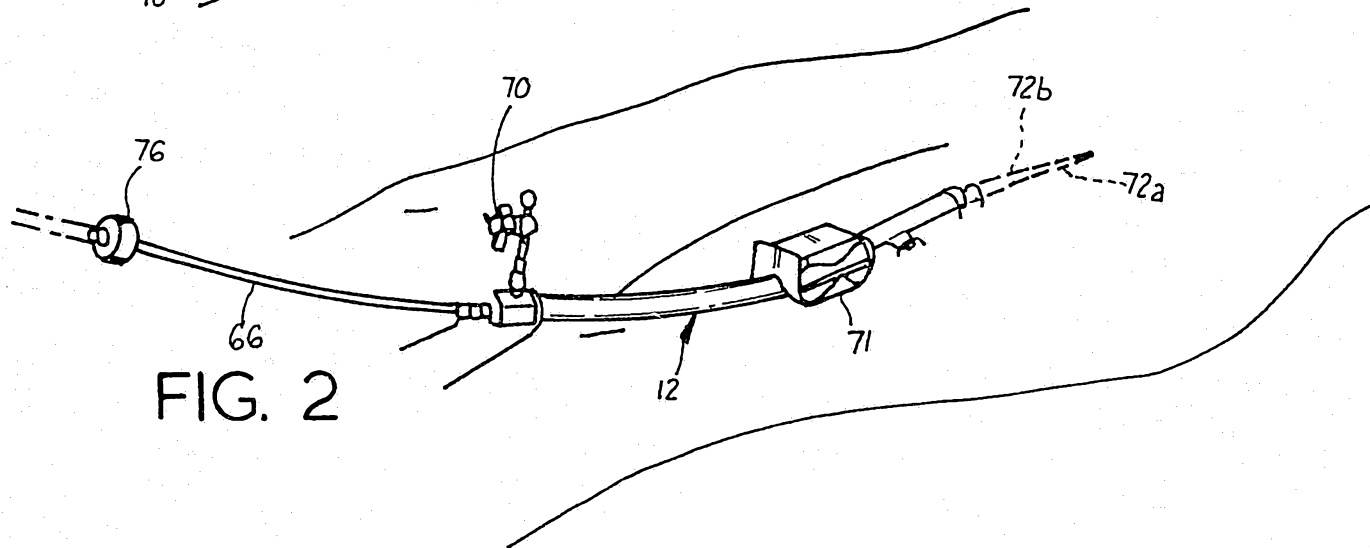
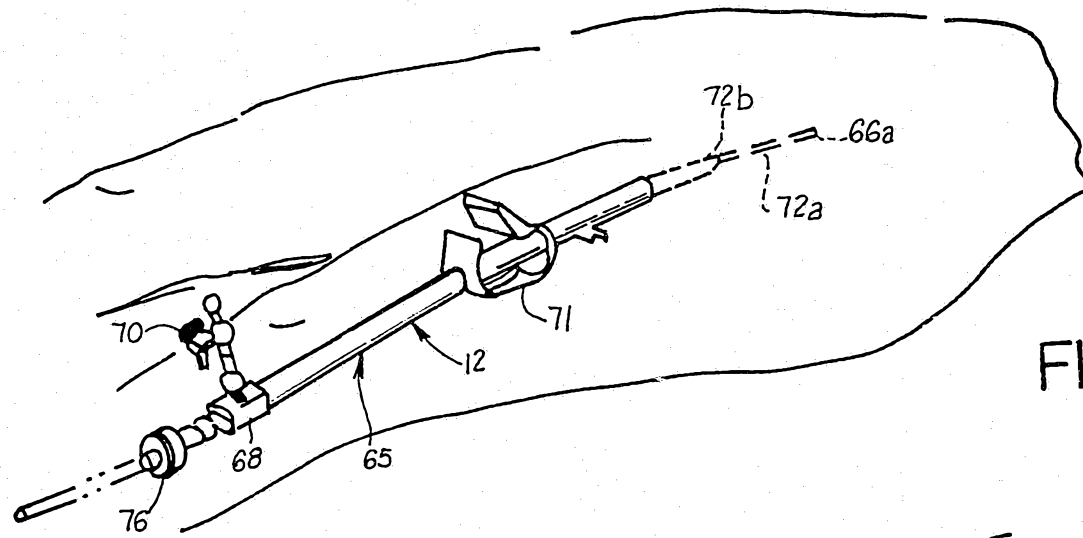
Shiley Incorporated

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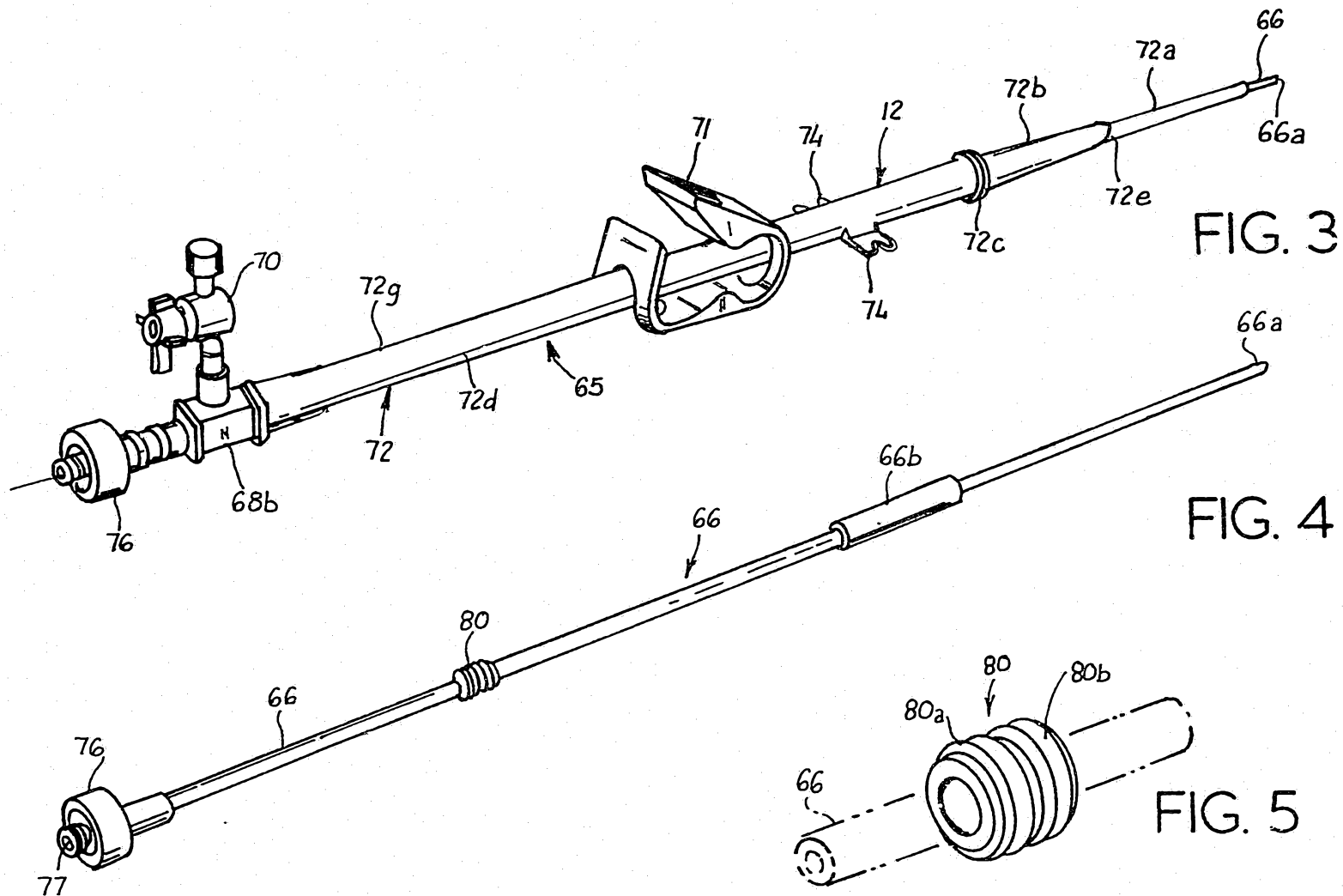


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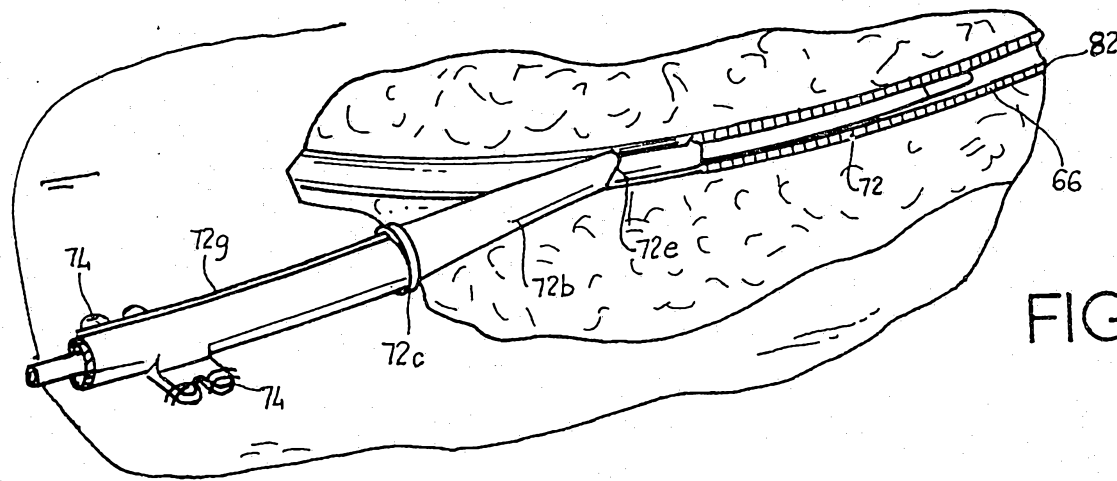
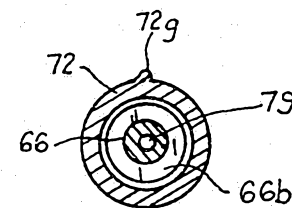


FIG. 6

FIG. 9



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FIG. 7

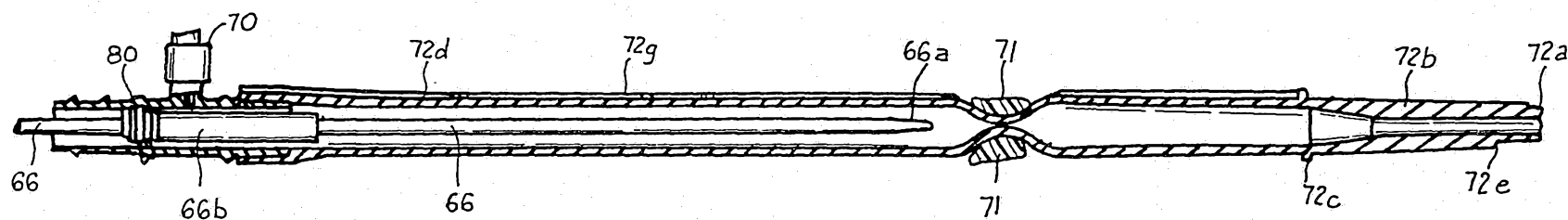
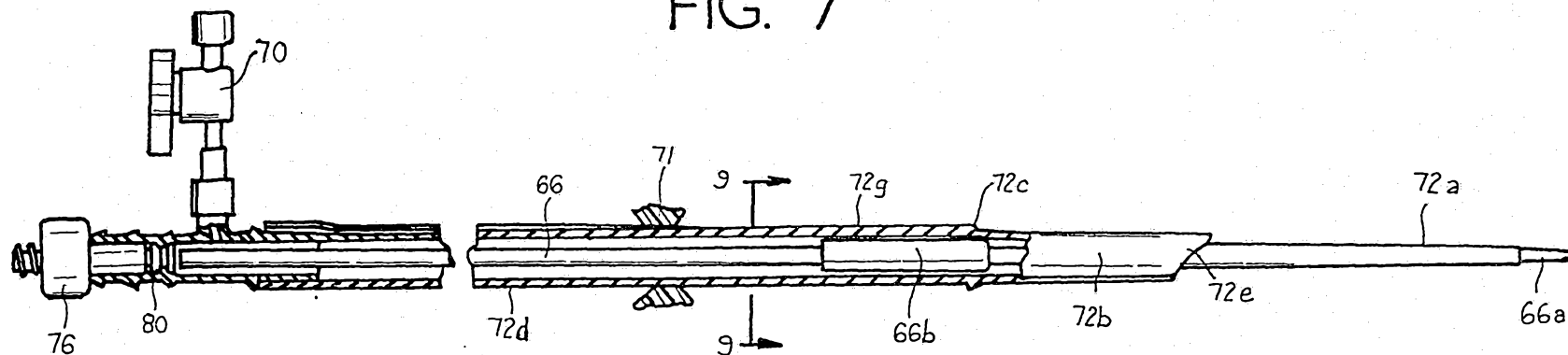


FIG. 8