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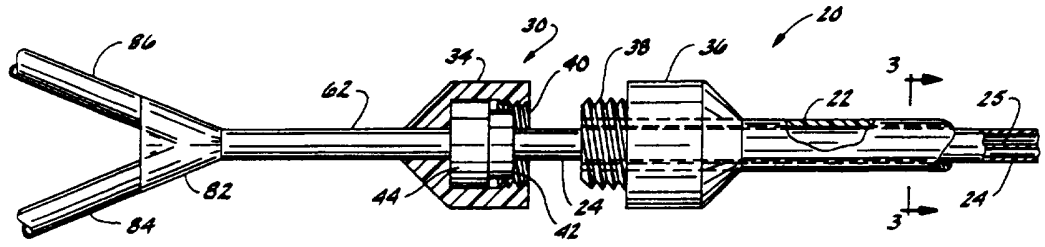

(57) Abstract

A hemodialysis catheter (20) for removal of unfiltered blood from a vein of a dialysis patient and for infusion of the blood back into the vein after the blood has been filtered by the hemodialysis machine. The catheter comprises inner (24) and outer (22) elongate tubes each having a distal end and a proximal end. The inner tube (24) is sized for being inserted through the outer tube (22). The distal end of the outer tube is insertable into the vein of the patient. The inner and outer tube are configured for withdrawal of the inner tube form the outer tube while maintaining the distal end of the outer tube in the vein of the patient to provide for facilitated removal of the inner tube when the inner tube becomes occluded so as to deter blood flow.

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HEMODIALYSIS CATHETER

Background of the Invention

This invention relates to venous dialysis catheter assemblies of the type used with hemodialysis machines for transporting blood from the patient to the machine and back to the patient, and in particular, to such an assembly which provides for a relatively permanent placement of a venous dialysis catheter, yet allows for ease of replacement of its blood transport unit.

Hemodialysis, the removal of waste material from the blood, can be achieved through a variety of vascular access devices. For many patients, particularly where clinical circumstances preclude access via arteriovenous fistula construction, vascular access is provided through venous catheter devices. Temporary access may be gained by using a percutaneous catheter device. However, such percutaneous catheters generally have a functional duration of only a few weeks. Such devices are usually inserted at the bedside and allow immediate dialysis use. With such temporary percutaneous devices, the two main limitations are infection and catheter thrombosis (occlusion due to clotting). Either complication will generally require catheter removal and the insertion of a new catheter device. Thus, as a result of the need for frequent replacement, the use of such devices is often associated with venous site injury and, ultimately, loss of the access site. Once all access sites are lost due to multiple cannulations, the patient is left without a viable means for continuing hemodialysis.

As a step toward addressing this situation, surgically implanted subcutaneous venous catheter devices have been developed which provide some patients with access for hemodialysis for intermediate to long-term use of months to sometimes years. These longer term venous catheter devices are usually associated with longer term patency and reduced incidence of infection. The infection risk is reduced somewhat compared to temporary percutaneous devices because of the subcutaneous position of the catheter prior to skin exit and the use of, e.g., a Dacron cuff attached to the catheter in the subcutaneous tunnel to induce a fibrotic barrier to bacterial migration. However, the incidence of catheter thrombosis, either partial or complete, remains a critical limitation to long-term use of such venous catheters. Catheter thrombosis causes blockage of the blood flow during hemodialysis and disrupts the dialysis regimen. Attempts at fibrolytic therapy with urokinase or streptokinase has met with only limited success in salvaging occluded devices. Further, such therapy increases the risk of infection due to catheter manipulation during attempts to lyse catheter clots. Additionally, increased clotting has been reported to be associated with thrombolytic therapy. Thus, presently, the only satisfactory option for catheter thrombosis is catheter replacement, which presents the same problems associated with temporary catheters discussed above.

Thus, a need exists in hemodialysis therapy for an improved catheter assembly which addresses the above problems associated with catheter thrombosis and catheter replacement.

Summary of the Invention

Among the several objects of this invention may be noted the provision of an improved catheter assembly for conveying blood between a hemodialysis machine and a patient; the provision of such a device which includes a blood transport unit which is easily replaceable at the bedside without the need for surgery; and the provision of such a device which is of relatively simple and inexpensive construction.

Generally, a hemodialysis catheter of the present invention comprises an inner and an outer tube. The outer tube has a distal end, a proximal end, and a tube receiving passageway extending from the proximal end to the distal end for passage therethrough of the inner tube. The distal end is insertable into a vein of the patient. The inner tube has a distal end, a proximal end, and first and second blood transporting passageways extending from the proximal end to the distal end. The inner tube is sized and configured for being inserted, distal end first, through the proximal end of the outer tube and for being inserted into the tube receiving passageway of the outer tube to an inserted position in which a distal portion of the inner tube extends out of the distal end of the outer tube. The inner and outer tubes are further configured for withdrawal of the inner tube from the outer tube while maintaining the distal end of the outer tube in the vein of the patient to provide for facilitated removal of the inner tube when the inner tube becomes occluded so as to deter blood flow. The first and second blood transporting passageways are in fluid communication with the vein of the patient when the distal end of the outer tube is in the vein of the patient and the inner tube is in its inserted position. The first blood transporting passageway is configured for withdrawal of unfiltered blood from the vein of the

patient and the second blood transporting passageway is configured for infusion of filtered blood back into the vein of the patient.

A method for filtering the blood of a patient using the hemodialysis catheter assembly of this invention is also provided. The method includes the following steps: transferring unfiltered blood from the patient through the first blood transporting passageway and into a hemodialysis machine where the blood is filtered; and transferring filtered blood from the hemodialysis machine through the second blood transporting passageway into the vein of the patient.

A method for replacing an inner tube of the hemodialysis catheter assembly of this invention includes the following steps: removing the inner tube via the proximal end of the outer tube while the outer tube remains in the vein of the patient; inserting the distal end of a new sterile inner tube into the proximal end of the outer tube; pushing the inner tube through the outer tube until the distal end of the inner tube protrudes beyond the distal end of the outer tube in the vein of the patient; and locking the connector to secure the tubes in place.

Other objects and features will be in part apparent and in part pointed out hereinafter.

Brief Description of the Drawings

Fig. 1 is an elevational view of a venous dialysis catheter of the present invention;

Fig. 2 is an enlarged fragmented elevational view of the catheter of Fig. 1 showing the connector in an unlocked position and with portions broken away to show detail;

Fig. 3 is a cross-sectional view taken along the plane of line 3-3 of Fig. 2;

Fig. 4 is a cross-sectional view of a second embodiment of a catheter of the present invention.

Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

Detailed Description of the Preferred Embodiment

Referring now to the drawings, and first to Fig. 1, there is generally indicated at 20 a hemodialysis catheter assembly for transferring blood from the vein of a patient to a dialysis machine for filtration and back to the vein of the patient. The catheter 20 comprises an outer tube 22, a removable inner tube 24, a connector 30, and an annular cuff 32 which allows fibrous in-growth to anchor the catheter 20 and provides a fibrous barrier to bacterial migration.

The outer tube 22 has a proximal end 56, an elongate body portion 58, and a distal end 60. The distal end 60 of the outer tube 22 is constructed to remain in the vein of the patient at all times during use. The outer tube 22 further comprises a tube-receiving passageway 54 that extends from the proximal end 56 of the outer tube 22 to the distal end 60 of the outer tube 22.

The inner tube 24 has a proximal end 62, an elongate body portion 64, and a distal end 66 which is inserted within the vein of the patient. The inner tube 24 is comprised of first and second blood transporting passageways 26 and 28. As shown in Fig. 3, the blood transporting passageways 26 and 28 are positioned side-by-side (Fig. 3). Both of the blood transporting passageways 26, 28 are in fluid communication with the vein of the patient when the distal end 60 of the outer tube 22 is in the vein of the patient and the inner tube 24 is in its inserted position. First blood transporting

passageway 28 carries the unfiltered blood from the vein of the patient to the hemodialysis machine where the blood is filtered. Second blood transporting passageway 26 brings the blood back from the hemodialysis machine for infusion of filtered blood back into the vein of the patient. It is to be understood that the first and second blood transporting passageways 28, 26 as shown in Fig. 1, may be switched (i.e., passageway 26 carries unfiltered blood from the vein of a patient to the hemodialysis machine and passageway 28 brings the blood back from the hemodialysis machine) without departing from the scope of this invention. The inner tube 24 is sized and configured for insertion, distal end 66 first, through the proximal end 56 of the outer tube 22 and for being inserted into the tube receiving passageway 54 of the outer tube to an inserted position in which a distal portion 74 of the inner tube 24 extends out of the distal end 60 of the outer tube. The outer and inner tubes 22, 24 are further configured for withdrawal of the inner tube from the outer tube while maintaining the distal end 60 of the outer tube in the vein of the patient to provide facilitated removal of the inner tube when the inner tube becomes occluded so as to deter blood flow. Both the outer and inner tubes 22, 24 are preferably made from silicon rubber, polyurethane, polyethylene or any other suitable venous catheter material. The outer tube 22 may, for example, have an inner diameter of 4.5 mm to accommodate an inner tube 24 having an outer diameter of 4 mm. It is to be understood that other diameter tubing may be used without departing from the scope of the invention.

The distal portion 74 of the inner tube 24 extends beyond the distal end 60 of the outer tube 22 further into the vein of the patient. Preferably, the first blood transporting passageway 26 extends out further beyond the distal end 60 of the outer tube 22

than does the second blood transporting passageway 28. Opening 94 is provided on both sides of blood transporting passageway 26 to allow flow into and out of the inner tube 24 and provides alternative flow passages in case the inner tube is positioned such that some of the openings are occluded by engagement with a wall of the vein. Blood transporting passageway 28 includes a tapered end 66 to facilitate insertion of the inner tube into the vein.

The catheter assembly 20 further comprises a connector for locking the inner tube 24 into a fixed position within outer tube 22 when the inner tube is in its inserted position. As shown in Fig. 2, the connector 30 comprises a first threaded connection 36 attached to the proximal end 56 of the outer tube 22 and a second threaded connection 34 attached to the inner tube 24. As shown in Fig. 2, a female screw 40 is on the inner tube 24 and a male screw 38 is on the outer tube 22, however, these may be reversed. It is to be understood that other types of releasable connectors may be used without departing from the scope of this invention. For example a snap type connector or luer type fitting may also be used. The threaded connections 34, 36 may be integrally formed with the tubes 22, 24, may be swaged onto the tubes or connected by any other suitable means. The threaded connectors may be made from metal or any suitable polyurethane material. Included within the second threaded connection 34 is a hub 44 which may be integrally formed with the inner tube 24 or formed as a separate piece and attached to the inner tube. The hub 44 is provided to position the inner tube 24 in the outer tube 22 with the distal portion 74 protruding beyond the outer tube a predetermined distance. For example, a hub having a 12 mm diameter and width of 1 cm may be used for an inner tube that extends 5 cm beyond the outer tube. It is to be understood that hubs of different sizes and

shapes or other devices which longitudinally position the inner tube 24 within the outer tube 22 may be used without departing from the scope of this invention.

Preferably, the second threaded connector 34 further includes an antiseptic impregnated sponge disk 42. The disk 42 is positioned between the two threaded connections 34, 36 to reduce the possibility of infection by particulates introduced at the interface between the inner tube 24 and outer tube 22. The disk 42 is impregnated with an antiseptic such as "BETADINE" (polyvinylpyrollidone/iodine solution) or any other suitable antiseptic. The disk 42 is located adjacent to the hub 44 and upon screwing closed the connector 30, the sponge disk is compressed between the face of the male connector 38 and the hub.

In a preferred embodiment, an annular cuff 32 is attached to the outer tube 22 and positioned between the connector 30 and the distal end 60 of the outer tube. The cuff 32 is formed of fibrous material compatible with the ingrowth of human tissue when inserted within the patient to provide a fibrous barrier to bacterial migration. The cuff 32 may be formed of any material capable of permitting the ingrowth of tissue such as polymer wool, PTFE, ceramic material or any other suitable material. The cuff 32 is positioned in the subcutaneous tunnel to allow fibrous ingrowth to anchor the catheter as well as provide a fibrous barrier to bacterial migration.

The hemodialysis catheter assembly 20 includes an inlet tube 84 and an outlet tube 86 for connection with the hemodialysis machine. The inlet and outlet tubes 84, 86 each include a luer fitting 90 for attachment with the hemodialysis machine. The outlet tube 86 transfers the unfiltered blood from the patient to the hemodialysis machine and the inlet tube 84 transfers the filtered blood from the hemodialysis

machine back to the patient. The inlet and outlet tubes 84, 86 are connected to a first side 102 of a junction 82 which has a second side 104 connected with the proximal end 62 of the inner tube 24. The junction 82 is designed to allow fluid communication between the outlet tube 86 and the first blood transporting passageway 26 and the inlet tube and the second blood transporting passageway 28. The junction 82 may be integrally formed with the inner tube 24, inlet tube 84 and outlet tube 86 or may be formed separately and have openings for receiving the individual tubes or any combination thereof. The junction 82 is preferably formed of rubber or any other material compatible with the material of the tubes 24, 84, 86. Removable caps 92 are provided at the ends of the inlet and outlet tubes 84, 86 for protecting the catheter assembly 20 from contamination when it is not hooked up with the hemodialysis machine. A pair of clamps 98 are attached to the inlet and outlet tubes 84, 86 for independently occluding blood flow through the inlet and outlet tubes during attachment and detachment of the tubes to the hemodialysis machine.

A second embodiment of this invention is shown in Fig. 4. The catheter assembly includes an inner tube 48 having a first blood transporting passageway 126 located within a second blood transporting passageway 128. A portion of the tube 46 containing the first blood transporting passageway 126 is tangential with tube 48 containing the second blood transporting passageway 128. The first blood transporting passageway 126 is defined by an inner surface 68 of a first tube portion 46 of the inner tube and the second blood transporting passageway 128 is defined by an outer surface 70 of the first tube portion 46 and by an inner surface 72 of a second tube portion 48 of the inner tube. It is to be understood that the first and second fluid passageways may be

switched or may be in the shape of other configurations without departing from the scope of this invention.

To use the hemodialysis catheter assembly 20, the distal end 60 of the outer tube 22 is surgically implanted by, for example, direct surgical cut-down and venotomy in the internal jugular vein. The outer tube 22 may also be placed in other suitable locations and by other appropriate procedures. Following insertion of the outer tube 22, the tube is flushed with an appropriate saline and the inner tube 24 is introduced into the outer tube as far as possible with the total entry distance being limited by the position of the hub 44. This will allow the inner tube 24 to protrude beyond the distal end 60 of the outer tube 22 so that the distal portion 74 of the inner tube 24 is within the superior vena cava. Once the inner tube is in place the patient may undergo dialysis by attachment of the inlet and outlet tubes 84, 86 to the dialysis machine. Following dialysis, each luer fitting 90 is flushed with a suitable saline to reduce the chance of catheter lumen thrombosis. The same inner tube 24 is used for each dialysis session as long as adequate flow can be maintained. It is intended that the inner tube 24 will remain inserted until such time as removal is required due to thrombosis or other complications. The inner tube 24 is removed by extracting the tube from the proximal end 56 of the outer tube 22 while the distal end 60 of the outer tube remains in the vein of the patient. During removal of the inner tube 24, the outer tube 22 is temporally occluded with a clamping device (not shown) to prevent back bleeding through the outer tube or air embolism occurring. The inner tube 24 is discarded and a new sterile inner tube is introduced into the existing outer tube 22 and located as described above according to the position of the hub 44. A new antiseptic impregnated sponge disk 44 is positioned between the two connections 34, 36 and the

screw connector 30 is tightened to secure the positioning of the inner tube such that the distal portion 74 of the inner tube extends beyond the outer tube 22 in the vein of the patient. The inlet and outlet tubes 84, 86 of the new inner tube 24 can then be aspirated to confirm free flow of blood and then flushed with saline solution. The hemodialysis machine can then be connected and dialysis resumed. If blood flow once again declines, the inner tube can be repeatedly replaced as described above.

During operation of the catheter assembly when it is hooked up to the hemodialysis machine, blood from the vein of a patient enters the distal end 66 the first blood transporting passageway 26 of the inner tube 24 and travels the elongate body portion 64 of the inner tube 24. It exits the proximal end 62 and travels through the dialysis machine (not shown) where it is filtered. The filtered blood enters the proximal end 62 of the second blood transporting passageway 28 and travels the elongate portion 64 until it reaches the distal end 66 of the blood transporting passageways 26 and 28, where it is returned to the vein of the patient.

In a method of this invention, a hemodialysis catheter 20 as described above is used to filter the blood of a patient by transferring unfiltered blood from the patient through the first blood transporting passageway 26 and into a hemodialysis machine where the blood is filtered; and transferring filtered blood from the hemodialysis machine into the second blood transporting passageway 28 into the vein of the patient.

In a second method of this invention, the inner tube 24 of a hemodialysis catheter 20 as described above is replaced by removing the inner tube via the proximal end of the outer tube 22 while the outer tube remains in the vein of the patient; inserting the distal end 66 of a new sterile inner tube into the proximal end 56 of the outer tube; pushing the inner tube through the outer tube

until the distal end of the inner tube protrudes beyond the distal end of the outer tube in the vein of the patient; and locking the connector 30 to secure the tubes in place.

The above described hemodialysis catheter assembly 20 provides for easy replacement of the inner tube 24 while leaving the outer tube 22 in place in the patient, thus allowing long-term utilization of venous catheter dialysis to minimize disruption of the dialysis regimen, as well as reduced medical costs for thrombolytic therapy and surgical replacement of the entire catheter. The unique catheter design ensures proper positioning of the inner tube 24 and reduction of the risk of incapacitating thrombus formation.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

As various changes could be made in the above constructions and methods without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

CLAIMS

WHAT IS CLAIMED IS:

1. A hemodialysis catheter assembly for removal of unfiltered blood from a vein of a dialysis patient and for infusion of the blood back into the vein after the blood has been filtered by a hemodialysis machine, the hemodialysis catheter comprising inner and outer elongate tubes, the outer tube having a distal end, a proximal end, and a tube-receiving passageway extending from the proximal end to the distal end for passage therethrough of the inner tube, the distal end being insertable into the vein of the patient, the inner tube having a distal end, a proximal end, and first and second blood-transporting passageways extending from the proximal end to the distal end, the inner tube being sized and configured for being inserted, distal end first, through the proximal end of the outer tube and for being inserted into the tube-receiving passageway of the outer tube to an inserted position in which a distal portion of the inner tube extends out of the distal end of the outer tube, the inner and outer tubes further being configured for withdrawal of the inner tube from the outer tube while maintaining the distal end of the outer tube in the vein of the patient to provide for facilitated removal of the inner tube when the inner tube becomes occluded so as to deter blood flow, the first and second blood transporting passageways being in fluid communication with the vein of the patient when the distal end of the outer tube is in the vein of the patient and the inner tube is in its inserted position, the first blood transporting passageway being configured for withdrawal of unfiltered blood from the vein of the patient and the second blood transporting passageway

being configured for infusion of filtered blood back into the vein of the patient.

2. A catheter assembly as set forth in claim 1 wherein the blood transporting passageways are side-by-side.

3. A catheter assembly as set forth in claim 1 wherein the inner tube comprises first and second blood transporting passageways, the first blood transporting passageway is within and coaxial with the second blood transporting passageway, and wherein the first blood transporting passageway is defined by an inner surface of a first tube portion of the inner tube and the second blood transporting passageway is defined by an outer surface of the first tube portion and by an inner surface of a second tube portion of the inner tube.

4. A catheter assembly as set forth in claim 1 further comprising a connector for locking the inner tube to the outer tube in a fixed position when the inner tube is in its inserted position.

5. A catheter assembly as set forth in claim 4 wherein said connector comprises a first threaded connection attached to the proximal end of the outer tube and a second threaded connection attached to the inner tube.

6. A catheter assembly as set forth in claim 5 further comprising a hub connected to the inner tube for longitudinally positioning the inner tube within said outer tube relative to said first threaded connection.

7. A catheter assembly as set forth in claim 6 further comprising an antiseptic impregnated sponge disk

interposed between said first threaded connection and said second threaded connection.

8. A catheter assembly as set forth in claim 4 further comprising a cuff attached to the outer tube and positioned between the connector and the distal end of the outer tube, said cuff being formed of fibrous material compatible with the ingrowth of human tissue when inserted within the patient to provide a fibrous barier to bacterial migration.

9. A catheter assembly as set forth in claim 1 further comprising an inlet tube and an outlet tube, both of said inlet and outlet tubes being adapted for connection with the hemodialysis machine, a junction having a first side attached to said inlet and outlet tubes and a second side attached to the proximal end of the inner tube, said outlet tube being in fluid communication with the first blood transporting passageway and said inlet tube being in fluid communication with the second blood transporting passageway.

10. A catheter assembly as set forth in claim 9 further comprising a pair of clamps attached to the inlet and outlet tubes for independently occluding blood flow through the inlet and outlet tubes.

11. A method of filtering the blood of a patient, said method comprising the following steps:

providing a hemodialysis catheter assembly comprising inner and outer elongate tubes, the inner and outer tubes each having a distal end and a proximate end, the inner tube being located within the outer tube and being configured for withdrawal from the outer tube while

maintaining the distal end of the outer tube in a vein of the patient, the inner tube having a first blood transporting passageway and a second blood transporting passageway;

transferring unfiltered blood from the patient through the first blood transporting passageway and into a hemodialysis machine where the blood is filtered; and

transferring filtered blood from the hemodialysis machine through the second blood transporting passageway into the vein of the patient.

12. A method for replacing an inner tube of a catheter assembly when the catheter assembly becomes occluded so as to impede the adequate flow of blood needed to maintain efficient hemodialysis, the catheter assembly comprising inner and outer elongate tubes, the inner and outer tubes each having a distal end and a proximate end, the inner tube being located within the outer tube and being configured for withdrawal from the outer tube while maintaining the distal end of the outer tube in a vein of the patient, said method comprising the following steps:

removing the inner tube via the proximal end of the outer tube while the outer tube remains in the vein of the patient;

inserting a new sterile inner tube, the distal end of the inner tube entering the proximal end of the outer tube; and

inserting the inner tube into the outer tube until the distal end of the inner tube protrudes beyond the distal end of the outer tube in the vein of the patient.

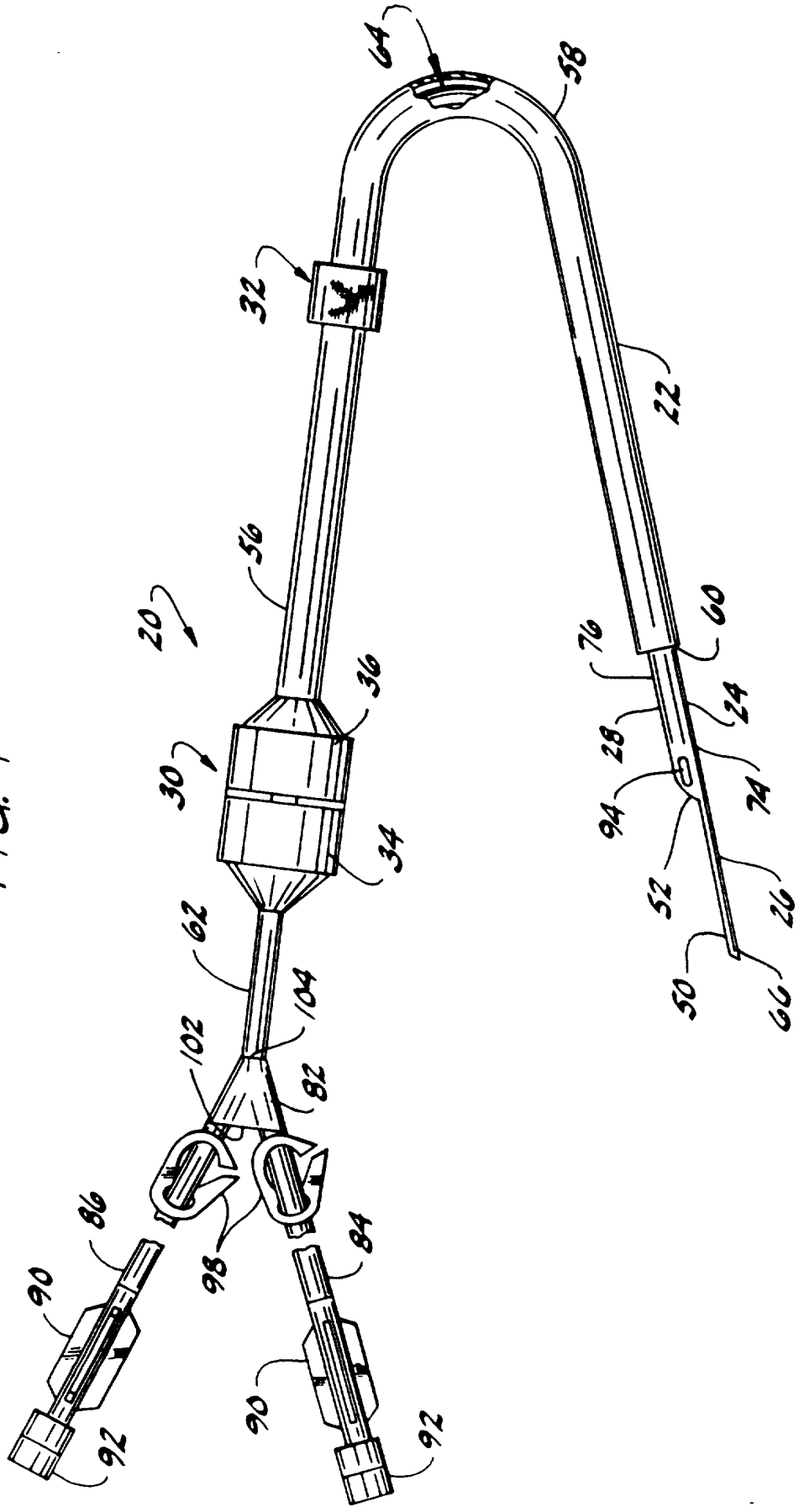
13. A method for replacing an inner tube of a catheter assembly as set forth in claim 12 further comprising the steps of providing a connector for connecting the inner tube to the outer tube in a fixed position and locking the connector to secure the tubes in place.

14. A method for replacing an inner tube of a catheter assembly as set forth in claim 13 further comprising the step of providing an antiseptic mpregnated sponge disk within the connector.

15. A method for replacing an inner tube of a catheter assembly as set forth in claim 13 further comprising the step of providing a hub within the connector to longitudinally position the inner tube relative to the outer tube.

16. A method for replacing an inner tube of a catheter assembly as set forth in claim 12 further comprising the step of providing a cuff formed of fibrous material compatible with the ingrowth of human tissue when inserted within the patient to provide a fibrous arrier to bacterial migration.

FIG. 1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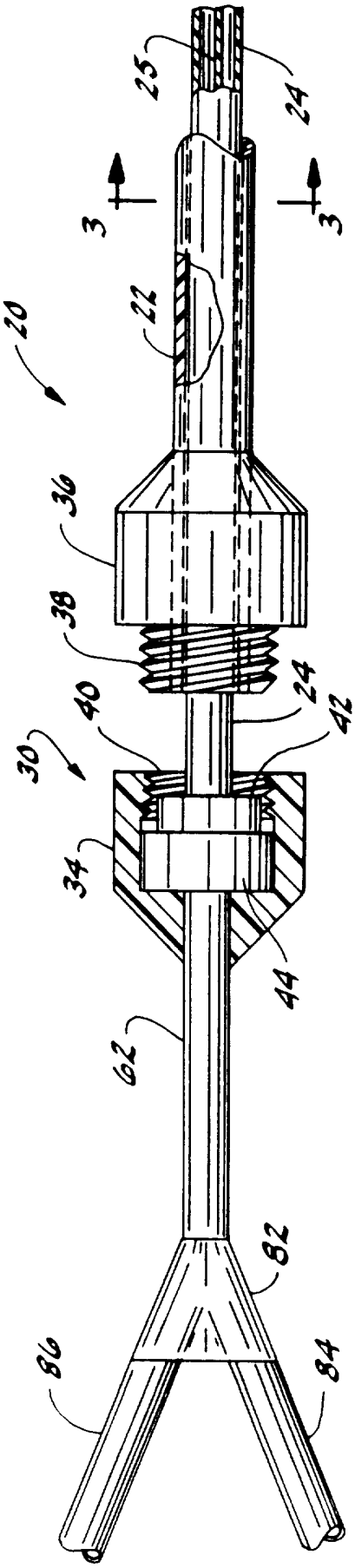

FIG. 2

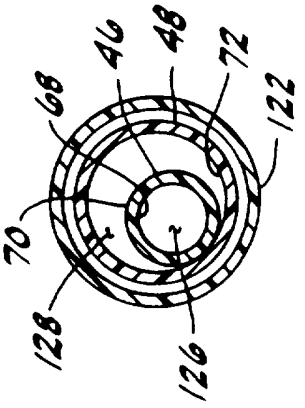

FIG. 4

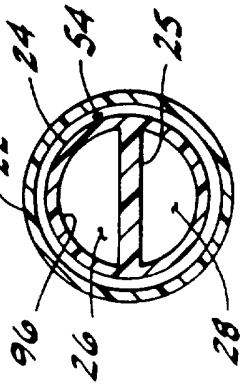

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/12592

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 37/00
US CL : 604/4
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/4-6, 27- 28, 43, 264, 280

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A 5,156,592 (MARTIN ET AL.) 20 October 1992.	1-16
A	US, A, 5,167,623 (CIANCI ET AL.) 01 December 1992.	1-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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