

Spire Biomedical, Inc. does business throughout Pennsylvania, including using, selling, or offering for sale products made by a method that infringes the '211 Patent.

3. Defendant Spire Corporation is a Massachusetts corporation with its principal place of business at One Patriots Park, Bedford, MA. On information and belief, Spire Corporation does business throughout Pennsylvania, including using, selling, or offering for sale products made by a method that infringes the '211 Patent.

4. Jurisdiction is proper in this Court under 28 U.S.C. §§ 1331 and 1338(a) as this case arises under the patent laws of the United States, 35 U.S.C. §§ 271 and 281.

5. Venue is proper in this Court under 28 U.S.C. § 1400(b).

COUNT I
PATENT INFRINGEMENT

6. Medcomp incorporates by reference the allegations of paragraphs 1 through 5 as though fully set forth herein.

7. On April 19, 2005, the '211 Patent was duly and legally issued and assigned to Medcomp and Twincath, LLC. A true and correct copy of the '211 Patent is appended hereto as Exhibit "A".

8. The claims of the '211 Patent are directed toward methods of making a multilumen catheter assembly.

9. Medcomp is the owner by assignment of the '211 Patent, its subject matter, and the rights of recovery flowing therefrom.

10. On information and belief, Defendants have manufactured, and continue to manufacture, multilumen catheters in the United States.

11. On information and belief, Defendants have sold or offered for sale, and continue to sell or offer for sale, multilumen catheters throughout the United States, including in this judicial district.

12. On information and belief, Defendants manufacture multilumen catheters according to a method that infringes one or more valid and enforceable claims of the '211 Patent.

13. Defendants have infringed, and continue infringe, directly or indirectly, the '211 Patent by, *inter alia*, themselves practicing, or by inducing others or contributing to others practicing one or more valid and enforceable claims of the '211 Patent.

14. As a direct and proximate result of Defendants' acts of infringement of the '211 Patent, Medcomp has suffered injury and damages for which it is entitled to relief, including, but not limited to, monetary damages including lost profits and a reasonable royalty.

15. On information and belief, Defendants have knowingly, willfully, and deliberately infringed the '211 Patent in conscious disregard of Medcomp's rights, making this case exceptional within the meaning of 35 U.S.C. § 285 and justifying treble damages pursuant to 35 U.S.C. § 284.

16. On information and belief, Defendants will continue to infringe the '211 Patent, causing immediate and irreparable harm unless this Court enjoins and restrains their activities.

17. On information and belief, the infringement by Defendants has deprived, and will further deprive, Medcomp of profits, royalties, and other related revenue which

Medcomp would have made or would enjoy in the future; has injured Medcomp in other respects; and will cause Medcomp added injury and damage, including loss of profits, royalties, and other related revenue in the future unless Defendants are enjoined from infringing Medcomp's '211 Patent.

WHEREFORE, Medcomp prays that judgment be entered in its favor and against Defendants Spire Biomedical, Inc. and Spire Corporation as follows:

(a) Enter judgment for Medcomp that the '211 Patent was duly and legally issued, is valid and enforceable, and has been infringed by Defendants;

(b) Enter judgment for Medcomp that Defendants have willfully infringed, and are willfully infringing, one or more claims of the '211 Patent;

(c) Issue a permanent injunction restraining Defendants, their directors, officers, agents, employees, successors, subsidiaries, assigns, and affiliates, and all persons acting in privity or in concert or participation with any of them from the continued infringement, direct or contributory, or active inducement of infringement by others of the '211 Patent;

(d) Direct Defendants to file with this Court, and serve on Medcomp, a written report under oath setting forth in detail the manner and form in which Defendants have complied with the injunction;

(e) Order defendants to account for in written form and to pay to Medcomp actual damages suffered by reason of Defendants' infringement of the '211 Patent, including, but not limited to, monetary damages including lost profits and a reasonable royalty, and further order that such damages be trebled due to Defendants' deliberate, willful, and knowing conduct;

(f) Order Defendants to pay to Medcomp its costs, expenses, and fees, including reasonable attorneys' fees pursuant to 35 U.S.C. § 285, and pre-judgment and post-judgment interest at the maximum rate allowed by law; and

(g) Grant Medcomp such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff Medical Components, Inc. demands a jury trial on all issues so triable.

Respectfully Submitted,

BLANK ROME LLP

BY: /s/ Alfred W. Zaher
ALFRED W. ZAHER P.A. 73,814
BRUCE D. GEORGE, P.A. 84,320
JOEL L. DION [JLD6264], P.A. 200,477
One Logan Square
Philadelphia, PA 19103-6998
(215) 569-5500

Attorneys for Plaintiff Medical Components, Inc.

Dated: July 11, 2007

EXHIBIT A



US006881211B2

(12) **United States Patent**
Schweikert et al.

(10) **Patent No.:** **US 6,881,211 B2**
(45) **Date of Patent:** **Apr. 19, 2005**

(54) **MULTILUMEN CATHETER ASSEMBLY AND METHODS FOR MAKING AND INSERTING THE SAME**

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(75) **Inventors:** **Timothy M. Schweikert**, Levittown, PA (US); **Anthony Madison**, Lansdale, PA (US); **Donald Schon**, Paradise Valley, AZ (US)

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(73) **Assignees:** **Medical Components, Inc.**, Harleysville, PA (US); **Twincath, LLC**, Phoenix, AZ (US)

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(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

Tesio, F., et al. "Double Catheterization of the Internal Jugular Vein for Hemodialysis: Indications, Techniques and Results"; Artificial Organs, 1994; 18(4): pp 301-304.

(Continued)

(21) **Appl. No.:** **10/681,394**

Primary Examiner—Daniel Robinson

(22) **Filed:** **Oct. 8, 2003**

(74) *Attorney, Agent, or Firm*—Joseph E. Maenner; Monte & McGraw, P.C.

(65) **Prior Publication Data**

(57) **ABSTRACT**

US 2004/0075198 A1 Apr. 22, 2004

Related U.S. Application Data

(62) Division of application No. 09/585,149, filed on Jun. 1, 2000, now Pat. No. 6,719,749.

(51) **Int. Cl.⁷** **A61M 27/00**

(52) **U.S. Cl.** **604/544**

(58) **Field of Search** 604/544, 43, 28, 604/34, 35, 284, 96.01, 536

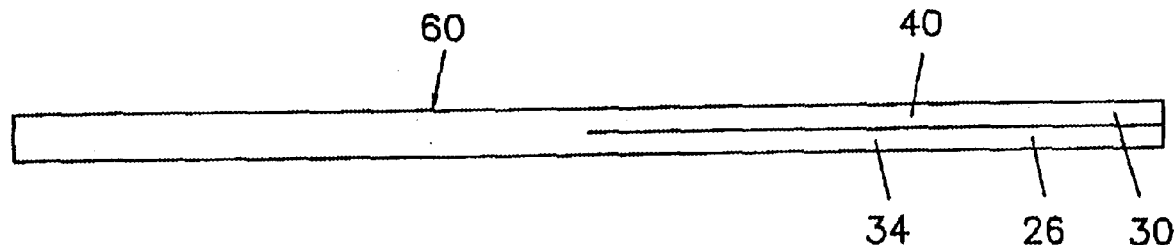
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A multilumen catheter assembly and methods for making and inserting the same are provided. The catheter assembly includes a unitary catheter and at least two distal end tubes which extend distally from the unitary catheter. The at least two lumens in the unitary catheter are in fluid communication with passageways through the distal end tubes. The catheter assembly may be made by extruding a unitary catheter tube having internal longitudinally extending lumens, then splitting the tube on its distal end portion to form distal end tubes. The tubes are then ground and polished to form a smooth surface on the exterior of the tubes. The catheter assembly may also be made by forming an outer layer on at least two longitudinally extending catheters while leaving two distally extending portions of the tubes outside the outer layer to form the distal end tubes. The multilumen catheter assembly may be inserted in a patient for acute and chronic catheterization and subcutaneously tunneled and inserted using a single insertion procedure while leaving the distal end tubes within the vessel capable of free movement and sealing the insertion site into an area to be catheterized.

19 Claims, 7 Drawing Sheets



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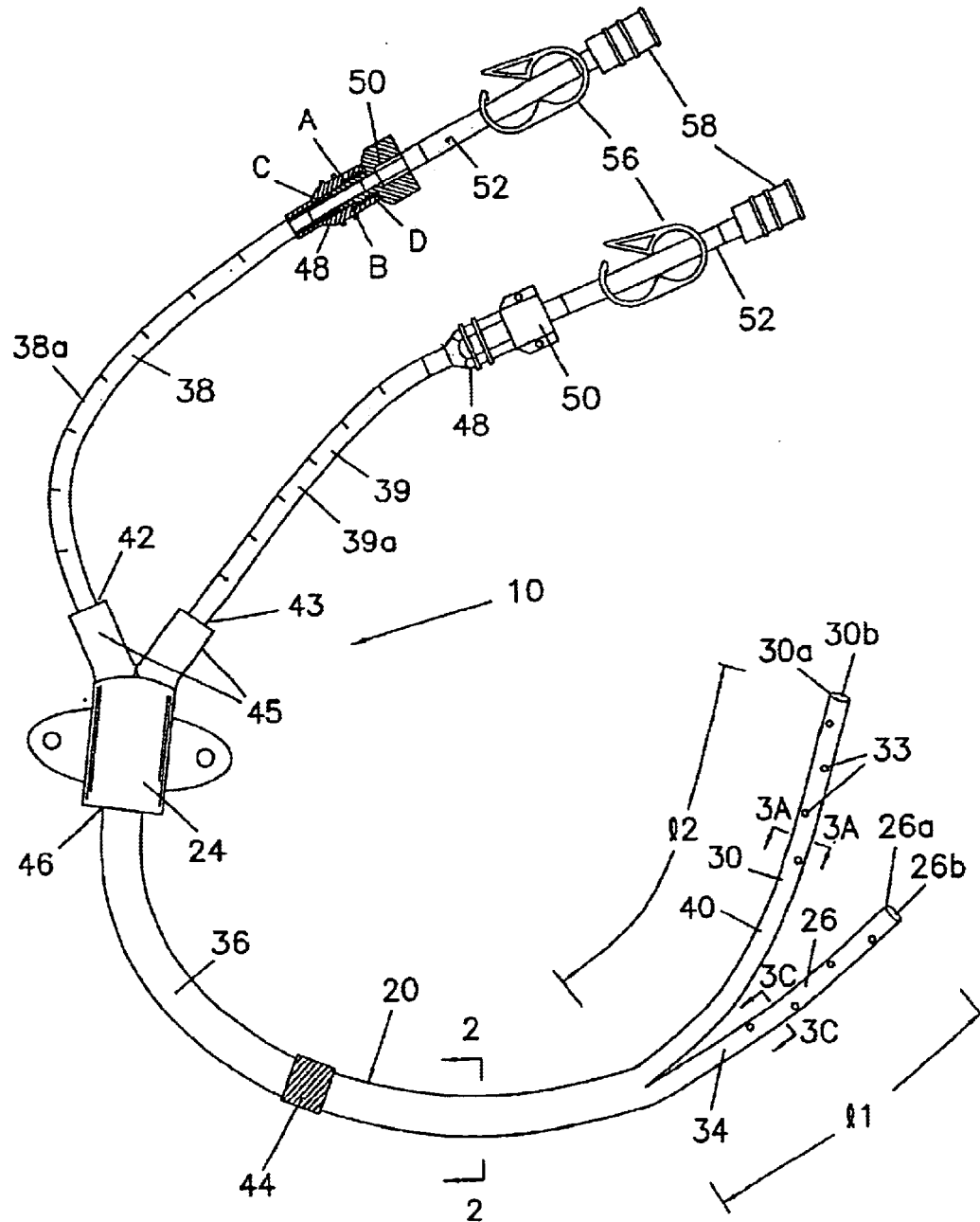


FIG. 1

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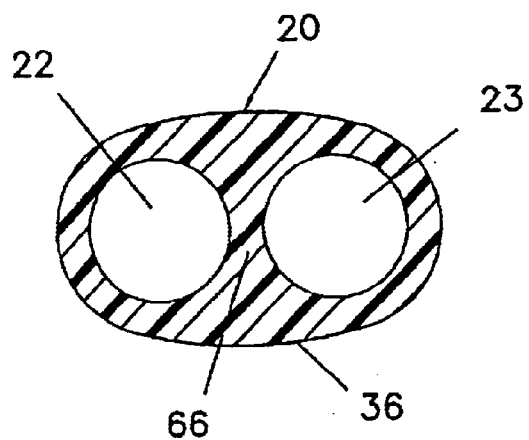


FIG. 2

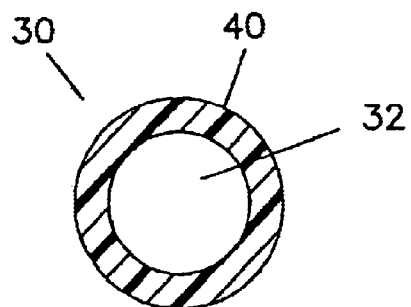


FIG. 3A

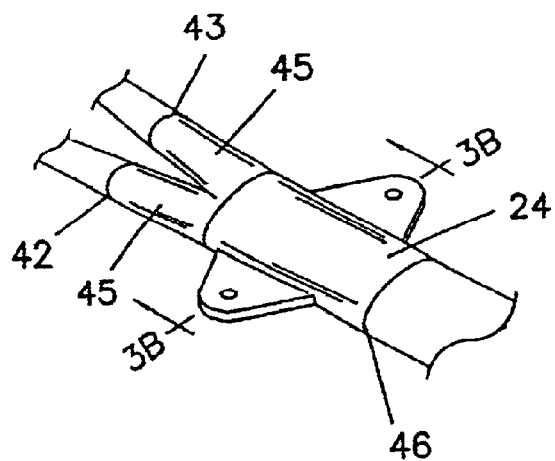


FIG. 3

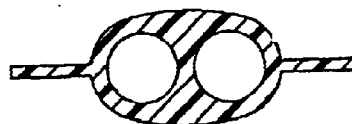


FIG. 3B

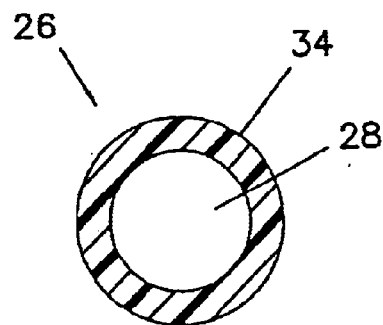


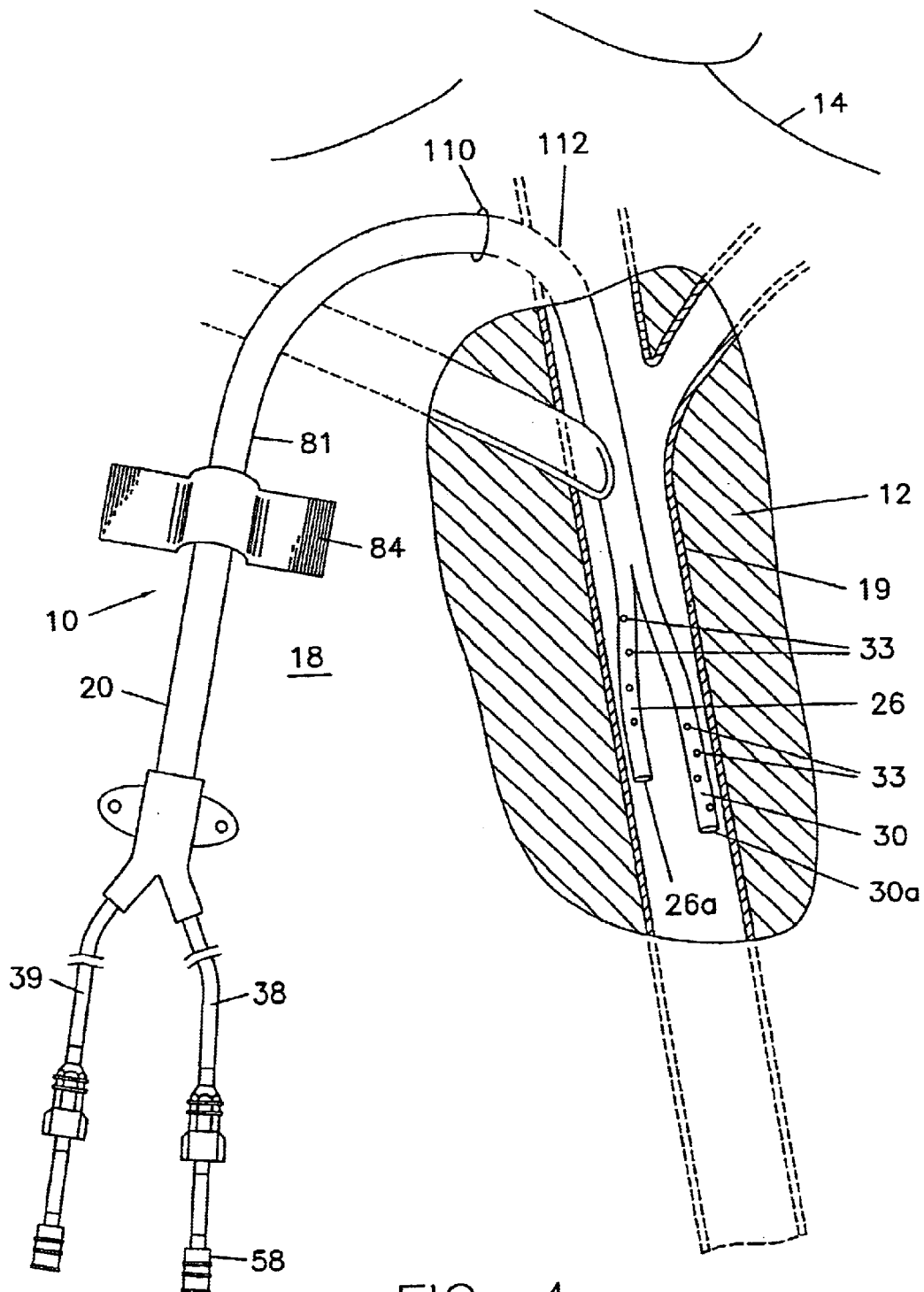
FIG. 3C

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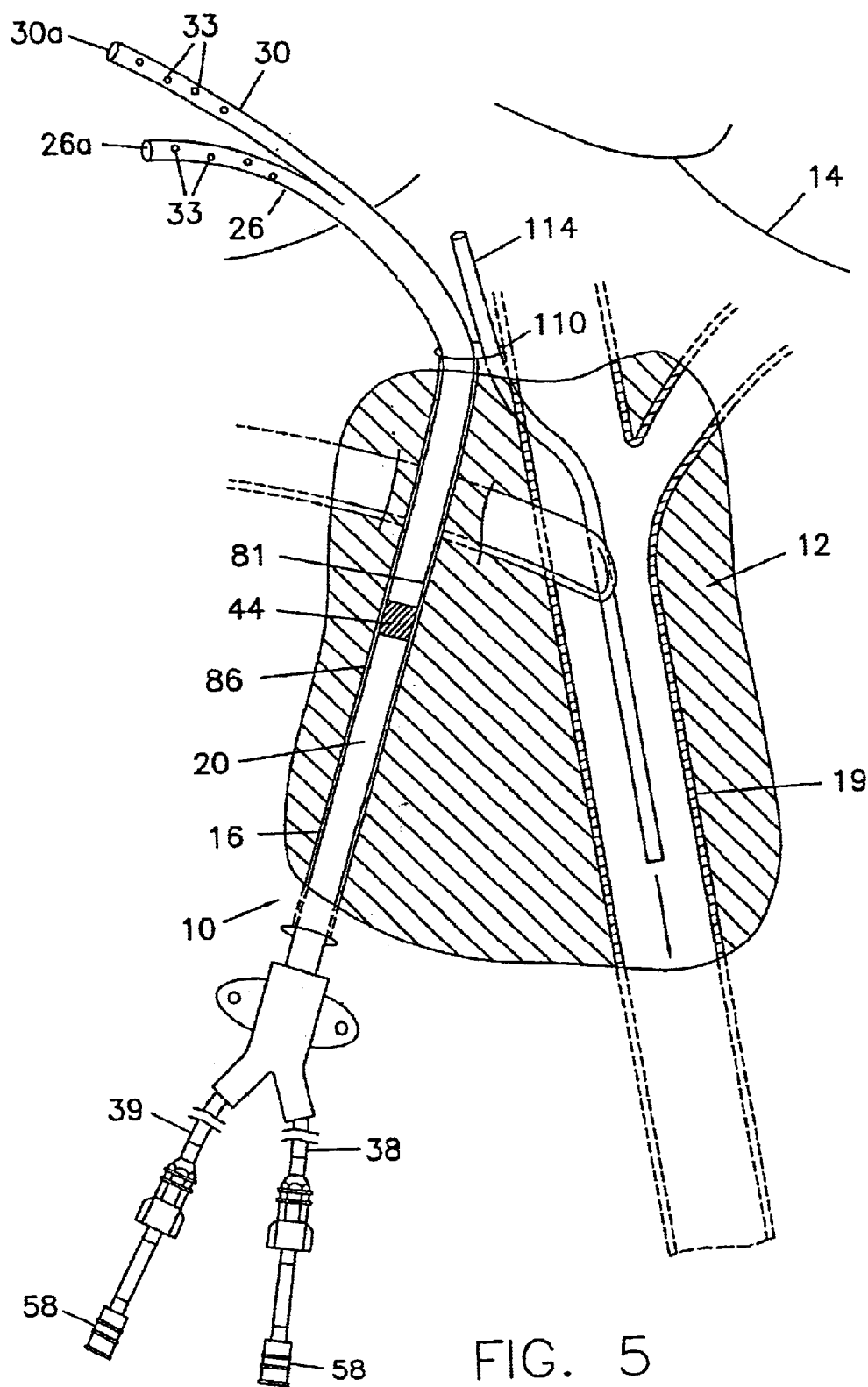


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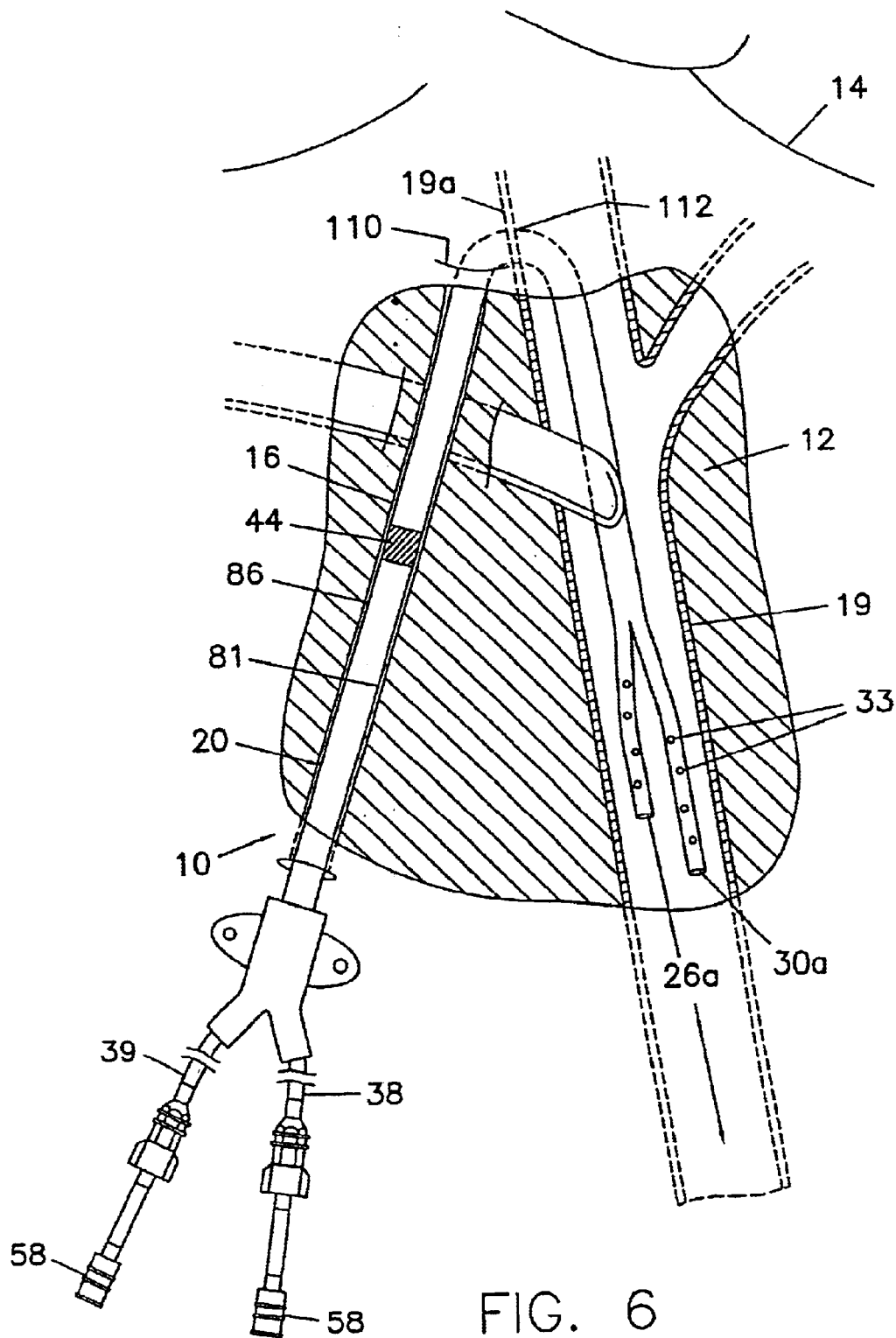


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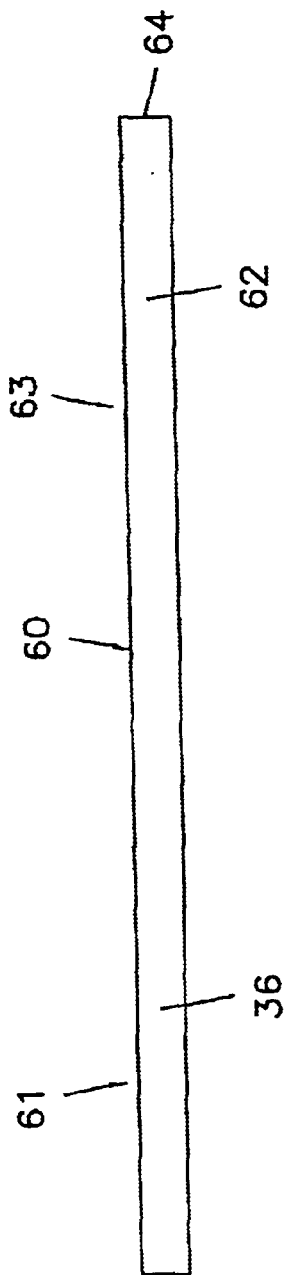


FIG. 7A

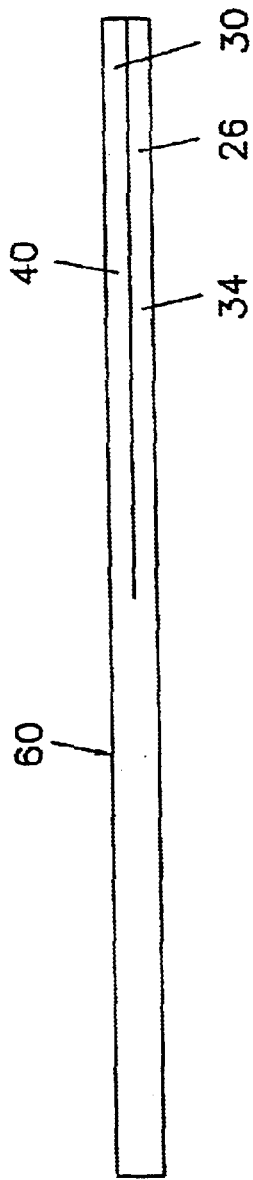


FIG. 7B

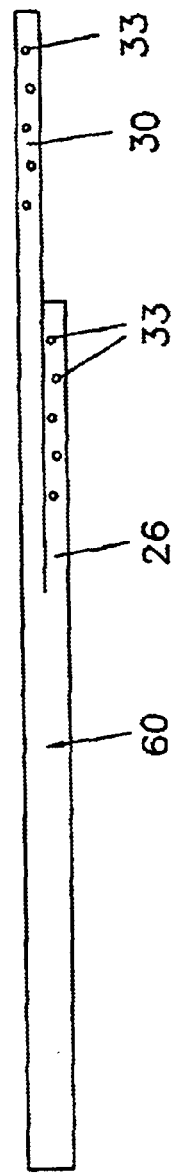


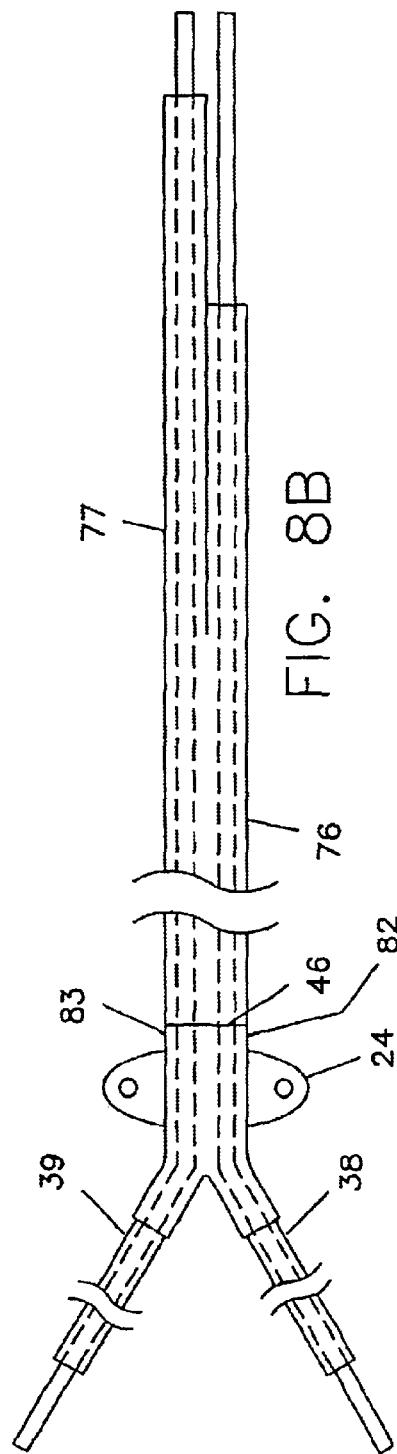
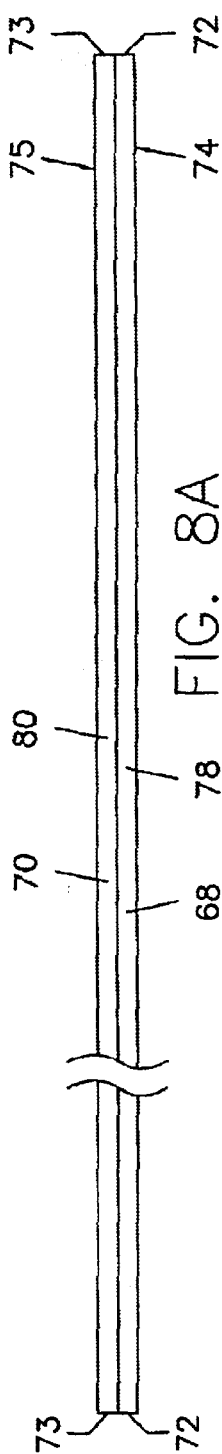
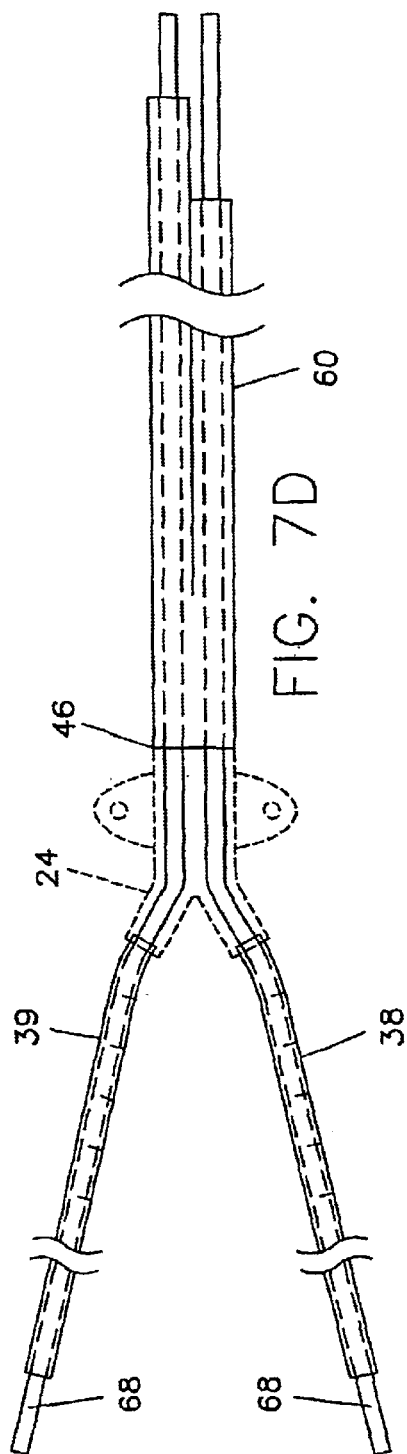
FIG. 7C

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MULTILUMEN CATHETER ASSEMBLY AND METHODS FOR MAKING AND INSERTING THE SAME

CROSS REFERENCE TO RELATED APPLICATION

This application is a divisional application of and claims the benefit of U.S. patent application Ser. No. 09/585,149, now allowed, filed Jun. 1, 2000, which is incorporated herein by reference now U.S. Pat. No. 6,719,749.

BACKGROUND OF THE INVENTION

Catheters for the introduction or removal of fluids may be located in various venous locations and cavities throughout the body for the introduction or removal of fluids. Such catheterization may be performed by using a single catheter having multiple lumens. A typical example of a multiple lumen catheter is a dual lumen catheter in which one lumen introduces fluids and one lumen removes fluids. Catheterization may also be performed by using separate, single lumen catheters inserted through two different incisions into an area to be catheterized. Such multiple catheter assemblies are known as Tesio catheters. Procedures are also known as described in U.S. Pat. No. 5,624,413 for inserting two wholly independent single lumen catheters into a vessel through a single insertion site.

Generally, to insert any catheter in a blood vessel, the vessel is identified by aspiration with a long hollow needle in accordance with the Seldinger technique. When blood enters a syringe attached to the needle, indicating that the vessel has been found, a thin guide wire is then introduced, typically through a syringe needle or other introducer device, into the interior of the vessel. The introducer device is then removed leaving the guide wire within the vessel. The guide wire projects beyond the surface of the skin.

At this point, several options are available to a physician for catheter placement. The simplest is to pass a catheter into the vessel directly over the guide wire. The guide wire is then removed leaving the catheter in position within the vessel. However, this technique is only possible in cases where the catheter is of a relatively small diameter, made of a stiff material and not significantly larger than the guide wire, for example, for insertion of small diameter dual lumen catheters. If the catheter to be inserted is significantly larger than the guide wire, a dilator device is first passed over the guide wire to enlarge the hole. The catheter is then passed over the guide wire, and the guide wire and dilator are removed.

In the case of an individual, single-lumen catheter typically used in multiple catheter assemblies (e.g., a Tesio catheter), a physician may use an introducer sheath. If a Tesio is used for hemodialysis, for example, each catheter is inserted in two separate veins, such as the femoral vein. Alternatively, each catheter may be inserted in two different locations of the same vein, such as the internal jugular vein as noted above. The introducer sheath is simply a large, stiff thin-walled tube, which serves as a temporary conduit for the permanent catheter which is being placed. Tearaway sheaths are also available which split apart for easier removal. The introducer sheath is positioned by placing a dilator device inside of the introducer and passing both the dilator and the introducer together into the vessel over a guide wire. The guide wire, left in the vessel after insertion as described above, and the dilator are then removed, leaving the thin-walled introducer sheath in place. The catheter is placed through the introducer sheath. Each of the

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catheters in the assembly is typically subcutaneously secured within the patient's body by a cuff located in a subcutaneous tunnel, or by otherwise externally affixing the catheter to the body.

The Tesio catheter may also be inserted, in accordance with the technique described in U.S. Pat. No. 5,624,413 as noted above, through a single insertion point using a sheath into the vessel. The Tesio, once inserted in the vessel, is then tunneled separately through the patient in two subcutaneous tunnels for securement of the external, proximal portions of the catheter.

The Tesio double catheter assembly, while comfortable for the patient, due to its soft durometer, and very effective for hemodialysis, typically requires multiple procedures and incisions for insertion and/or for tunneling, which increase the attendant risks of the catheterization procedure. Further, in the case of side-by-side placement of two catheter tubes through a single insertion site in a vessel, while minimizing the number of procedures, can present a potential for leakage between the catheter tubes at the point where the catheter tubes pass into the vessel.

However, Tesio catheter assemblies provide catheters which are capable of independent movement within the vessel. Such catheters present several advantages over unitary multi-lumen catheters formed of a single internally divided tube when in the vessel. Because the individual tubes of a Tesio double catheter assembly are independently movable at their fluid outlets, it is possible to provide fluid intake and/or return flow around the entire circumference of the distal ends of the catheter tubes. In addition, if one tube becomes blocked, or otherwise requires replacement, it can be removed independently of the other tube. Further, the softer durometer of such catheters, which are typically made of a silicone or a similar material, reduces the risk of vessel wall damage. The 360° circumferential flow provides a more stable tube within the vessel, which is less likely to be suctioned against the vessel wall due to a pressure differential, as occasionally occurs in the use of some side-by-side multi-lumen catheters.

U.S. Pat. No. 5,718,692, issued to Schon, et al., ("the Schon catheter") describes a self-retaining double catheter system in which each catheter can be subcutaneously secured without the use of fabric tissue ingrowth cuffs or external suturing as a result of the placement of a retaining sleeve surrounding both individual catheters in a multiple catheter assembly to hold the catheters together at the location of the sleeve. The individual catheters are permanently linked in one portion by a hub for self-anchoring under the skin, as an alternative to requiring a fabric stabilizing cuff, such that such cuffs are optional. The distal ends are longitudinally prespaced by an appropriate distance to avoid recirculation. While this device requires only one incision, it requires two subcutaneous tunnels in order to facilitate the self-retaining feature. This catheter provides independently movable distal ends within the vessel and 360° circumferential flow in the manner of a standard Tesio. Further, since the retaining sleeve is located outside the vessel when in place to provide the self-retaining feature, at the point of entry into the vessel, the catheters are side-by-side in the manner of a standard Tesio catheter, and there still remains the potential risk of blood leakage between the catheters at the vessel site.

U.S. Pat. No. 5,947,953 discloses a splittable multiple catheter assembly that has a hub and at least two fully independent catheter tubes which are initially releasably joined together, for example, by a breakable membrane. A

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single subcutaneous tunnel may be used in inserting the catheter, and the catheter tubes are at least partially separated by splitting the catheter tubes prior to insertion into a vessel. As a result, the portions of the catheter within the vessel are capable of independently moving and having 360° circumferential flow from the distal portion of each tube. The catheter may be secured using standard securement means such as suturing, ingrowth or other available securement devices.

A further multiple catheter assembly is described in U.S. Pat. No. 5,776,111 for use in acute Tesio catheterizations. The assembly includes two independent single lumen catheters joined at a location by a generally flat disc that may be attached to the surface of a patient's skin to secure the assembly in an acute procedure. The distal ends are prespaced to avoid recirculation.

There is a need in the art for a multiple catheter assembly and a need for making such a catheter assembly which can provide the advantages of the above-mentioned multi-lumen catheters with respect to easy insertion through a single tunneling procedure and which prevents the potential risk of leakage at the site of vessel entry, but which can still provide the advantage of multiple catheter assemblies with respect to independent movement within a vessel and good flow properties.

SUMMARY OF THE INVENTION

The present invention provides a method of making a multilumen catheter assembly, comprising forming a unitary catheter tube to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen and a second lumen, each of the first lumen and the second lumen extending longitudinally through the unitary catheter tube; and splitting the unitary catheter tube longitudinally along the distal end portion of the unitary catheter tube to form a first distal end tube and a second distal end tube.

The invention further includes a method of making a multilumen catheter assembly, comprising arranging a first catheter having a distal end, a distal end portion and at least one first lumen extending longitudinally therethrough and a second catheter having a distal end, a distal end portion and at least one second lumen extending longitudinally therethrough such that the first catheter and the second catheter are substantially longitudinally parallel; and forming an outer layer around at least a portion of an exterior surface of the first catheter proximal to the distal end portion of the first catheter and around at least a portion of an exterior surface of the second catheter proximal to the distal end portion of the second catheter such that first catheter and the second catheter are fixed within the outer layer, the first lumen and the second lumen are generally parallel within the outer layer and the distal end portions of the first and second catheters extend outwardly and distally from the portions of the exterior surfaces of the first and second catheters which are within the outer layer and the distal end portions are capable of independent movement.

The invention also includes, in one embodiment, a method of making a multilumen catheter assembly which comprises forming a unitary catheter tube to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen and a second lumen, each of the first lumen and the second lumen extending longitudinally through the unitary catheter tube; forming a first distal end tube having a first passageway extending longitudinally therethrough and a

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second distal end tube having a second passageway extending longitudinally therethrough; and attaching the first and second distal end tubes to the distal end of the unitary catheter tube such that the first passageway in the first distal end tube is in communication with the first lumen of the unitary catheter tube and the second passageway in the second distal end tube is in communication with the second lumen in the unitary catheter tube.

A multilumen catheter assembly is included in the invention which comprises a unitary catheter having an exterior surface and a first lumen and a second lumen extending longitudinally therethrough, a distal end and a proximal end; and a first distal end tube defining a first longitudinally extending passageway and a second distal end tube defining a second longitudinally extending passageway, wherein the first and second distal end tubes extend distally from the distal end of the unitary catheter, the first passageway in the first distal end tube is in fluid communication with the first lumen, the second passageway in the second distal end tube is in fluid communication with the second lumen and the first and second distal end tubes are capable of independent movement with respect to each other.

The invention also encompasses a method for inserting a multilumen catheter assembly into an area of a body to be catheterized. The multilumen catheter assembly comprises a unitary catheter having an exterior surface and at least a first lumen and a second lumen extending longitudinally therethrough, a distal end and a proximal end; and at least a first distal end tube defining a first longitudinally extending passageway and a second distal end tube defining a second longitudinally extending passageway, wherein the first and second distal end tubes extend distally from the distal end of the unitary catheter, the first passageway in the first distal end tube is in fluid communication with the first lumen, the second passageway in the second distal end tube is in fluid communication with the second lumen and the first and second distal end tubes are capable of independent movement with respect to each other. The method comprises making an incision near the area to be catheterized; inserting the first and second distal end tubes through the incision and into the area to be catheterized until the first and second distal end tubes are fully within the area to be catheterized and a portion of the unitary catheter extends into the area to be catheterized; and securing the proximal end of the unitary catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of preferred embodiments of the invention, will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings embodiments which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown. In the drawings, the same reference numerals are employed for designating the same elements throughout the several figures. In the drawings:

FIG. 1 is a perspective view of a multilumen catheter assembly in accordance with an embodiment of the present invention;

FIG. 2 is an enlarged cross-sectional view of the multilumen catheter assembly of FIG. 1, taken along line 2—2;

FIG. 3 is an enlarged perspective view of the hub in the catheter assembly of FIG. 1;

FIG. 3A is a cross sectional view of a distal end tube of the multilumen catheter assembly of FIG. 1 taken along line 3A—3A;

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FIG. 3B is a cross sectional view of the hub of the multilumen catheter assembly of FIG. 3 taken along line 3B—3B;

FIG. 4 is a partially broken-away diagrammatic view of a multilumen catheter assembly which has been inserted into an area to be catheterized, in accordance with a method of inserting a multilumen catheter assembly according to the present invention;

FIG. 5 is a partially broken-away diagrammatic view of a multilumen catheter assembly subcutaneously tunneled in a body before insertion into an area to be catheterized, in accordance with one embodiment of a method for inserting a multiple catheter assembly in accordance with the invention;

FIG. 6 is a partially broken-away diagrammatic view of a multiple catheter assembly of FIG. 5 in which the distal end tubes of the assembly are inserted into the area to be catheterized;

FIG. 7A is a partially broken away plan view of a unitary catheter tube for use in making a multilumen catheter according to one embodiment of the invention;

FIG. 7B is a partially broken away plan view of the unitary catheter tube of FIG. 7A which has been split at the distal end to form distal end tubes;

FIG. 7C is a partially broken away plan view of the unitary catheter tube of FIG. 7B after shortening the first distal end tube and forming a plurality of holes in the distal end tubes;

FIG. 7D is a partially broken away plan view of the unitary catheter tube of FIG. 7C on metal rods which are also inserted into first and second extension tubes prior to molding a hub in accordance with the invention;

FIG. 8A is a partially broken away plan view of a first and second catheter for use in making a multilumen catheter assembly according to a further embodiment of the invention;

FIG. 8B is a partially broken away plan view of the first and second catheters of FIG. 8A having an outer layer formed over a portion of the catheters, metal rods inserted within the catheters for placing the catheters in rigid position while molding a hub around the catheters at the proximal end of the outer layer.

DETAILED DESCRIPTION OF THE INVENTION

Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention. The words "right," "left," "outwardly" and "inwardly" designate directions in the drawings to which reference is made. The words "proximal" and "distal" refer to directions away from and closer to, respectively, the insertion tips of the first and second catheters in the multiple catheter assembly according to the present invention. The terminology includes the words above specifically mentioned, derivatives thereof, and words of similar import.

The following describes preferred embodiments of the invention. However, it should be understood, based on this disclosure, that the invention is not limited by the preferred embodiments described herein. Referring now to the drawings in detail, there are shown in FIG. 1, a preferred embodiment of a multilumen catheter assembly generally indicated as 10, according to the invention. The multilumen catheter assembly 10 shown in FIG. 1 is a double catheter assembly, although assemblies having three or more lumens and distal end tubes are within the scope of the invention.

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Further, the methods for making such catheters are described in detail below are also applicable to making assemblies having more than two lumens and distal end tubes. The present description, however, for convenience purposes describes the assembly based on a two lumen embodiment.

Referring to FIGS. 4–6, and as described in further detail below, a multilumen catheter assembly according to the present invention is inserted into a patient and into an area 12 of a body 14 to be catheterized for removing and introducing fluids to the area 12. The catheter assembly 10 is secured to a fixed location in or on the body 14, such as a subcutaneous area 16, as shown in FIGS. 5 and 6, in the body 14 before it is properly inserted and positioned in the catheterization area 12. This method is particularly preferred for chronic catheterization. Alternatively, in an acute catheterization, the catheter assembly 10 may be secured to an external surface 18 of the body 14, as shown in FIG. 4, before or after it is properly inserted and positioned in the catheterization area 12.

The multilumen catheter assembly 10 of the present invention can be adapted for use in various applications in which bodily fluids, medicaments or other solutions are introduced into and removed from the body such as perfusion, infusion, plasmapheresis, hemodialysis, chemotherapy, and the like. The catheter assembly 10 is particularly suitable for chronic hemodialysis and apheresis. The area to be catheterized is preferably a blood vessel such as an internal jugular vein, but may be any suitable area within the body. Other areas in which the catheter assembly may be used include, for example, other blood vessels, including the femoral and subclavian veins, any abscess cavity, post-operative cavity, the peritoneal cavity, and other areas of the body including intra-abdominal, sub-diaphragmatic and sub-hepatic areas. It should be understood by one of ordinary skill in the art from this disclosure that these areas are exemplary, and that the catheter assembly may be used to remove or introduce fluids in various areas to be catheterized.

The embodiment of the invention shown in FIG. 1 is particularly useful for intake, or removal, of blood to be purified from a blood vessel, such as the internal jugular vein, and introduction of purified blood into the same vessel. The blood can be purified by any suitable hemodialysis apparatus (not shown) attached in communication with the lumens of the catheter assembly of the invention 10. The catheter assembly 10 may also be used to introduce medication or other fluids including glucose or saline solutions into the body.

For the purposes of describing the preferred embodiment of the present invention, the device will be described with respect to the preferred application of hemodialysis, more specifically, for purifying blood flowing through the internal jugular vein 19. However, it will be understood by one skilled in the art based on this disclosure, that the assembly can be configured and adapted, by increasing or decreasing the size (diameter or length) and/or number of distal end tubes and/or lumens in the assembly, such that the assembly can be beneficially used for other medical applications in which fluids are introduced into and/or removed from the body.

Referring now to the embodiment of FIG. 1 and FIGS. 3A and 3C, the multilumen catheter assembly 10 includes a unitary catheter 20, and an optional hub 24, as described in more detail below. The assembly 10 further includes a first distal end tube 26 which has an outer surface 34 defining a first passageway 28 extending longitudinally through the

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distal end tube **26**. A second distal end tube **30** has an outer surface **40** defining a second longitudinally extending passageway **32**. The first and second passageways **28, 32** are in fluid communication with, respectively, a first lumen **22** and second lumen **23** which extend through the full length of the unitary catheter **20** as shown in FIGS. 1 and 2. The distal end tubes **26, 30** are preferably have outer surfaces which are continuous with the outer surface of the unitary catheter on the outer portion and extend distally from the distal end **31** of the unitary catheter. The distal end tubes **26, 30** are capable of independent movement and are not attached to each other, but only to the unitary catheter **20**.

Preferably, the first and second distal end tubes **26, 30** and/or the passageways **28, 32** through the end tubes and the first and second lumens **22, 23** have a generally circular cross section as shown in FIGS. 1, 3A and 3C since it is most conducive to fluid flow properties. However other shapes such as D-shaped passageways and/or lumens, oval passageways and/or lumens, triangular, square, kidney-shaped or other configurations are also within the scope of the invention. Further, while the distal end tubes **26, 30** and the lumens **22, 23** are preferably identical in cross section, it is within the scope of the invention to vary the size, shape or configuration of the distal end tubes and lumens in cross section such that smaller tubes and/or lumens or varying types of lumens and distal end tubes may be used for other applications, such as addition of a third, smaller lumen and corresponding distal end tube for introduction of medication.

It is further within the scope of the invention that the distal end tubes have varying diameters or distal end shapes as are known in the art or to be developed. For example, the distal end tubes may have a larger diameter proximate to the unitary catheter which transitions abruptly or gradually to a smaller diameter proximate to the distal ends of the tubes. Alternatively, a more tapered, conical or angled distal end may be provided for varying applications. However, blunt ends, preferably formed of soft durometer material are preferred for the catheter and distal ends to provide comfort to the patient and avoid vessel wall trauma and stenosis.

The first and second distal end tubes **26, 30** have respective first and second distal ends **26a** and **30a**. Preferably, as shown in FIG. 1 the first distal end tube **26** has a length l_1 which is less than a length l_2 of the second distal end tube **30** when measured in a longitudinal direction along each of the distal end tubes **26, 30**. As shown in FIG. 1, the catheter assembly **10** is curved to show that the catheter assembly including the distal end tubes **26, 30** are flexible, however, the catheter assembly **10** may be elongated to be fully extended in the longitudinal direction for the purposes of measuring l_1 and l_2 in a straight line along the distal end tubes. The distal end tubes preferably also have a plurality of holes **33** extending through the exterior surfaces **34, 40** of the distal end tubes **26, 30** to provide for additional or alternative flow paths for fluids flowing from between the area outside the tubes to the area inside the tubes and vice versa. Such holes **33** are preferably arranged in a circumferentially and helically around the tubes to provide optimal flow properties and avoid suctioning of the distal tubes against the area to be catheterized such as a vessel wall. Further, such holes minimize vibratory movement of the distal end tubes **26, 30** by equalizing the disturbances of intake and return flow through the apertures **33**. Minimizing the vibratory movement helps prevent stenosis. The apertures **33** also provide alternative openings in the distal end tubes **26, 30** such that if flow becomes blocked at an opening **26b** or **30b**, dialysis can continue while a replacement catheter assembly is being provided.

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FIG. 2 shows a cross-section of the unitary catheter **20**, which shows that the unitary catheter **20** has first and second lumens **22, 23** which are co-extensive with the passageways **28, 32** in the first and second distal end tubes **26, 30**, respectively. The unitary catheter **20** has a preferably smooth exterior surface **36**, which is illustrated in the embodiment shown in FIGS. 1 and 2. Preferably the unitary catheter **20** has a transverse cross section which is generally oval in shape, although any transverse cross sectional shape may be used. Preferably, shapes which are curved and smooth are used, such as circular or kidney-shaped to provide for smooth insertion through a vessel wall or other body area. Further, by providing the unitary catheter **20** with a smooth, preferably curved outer surface as shown, when the catheter assembly is inserted into an area to be catheterized, such as a vessel, the area to be catheterized can seal around the unitary catheter **20** while the distal end tubes **26, 30** are preferably fully within the area to be catheterized and independently moveable.

A fabric tissue ingrowth cuff **44** or other similar subcutaneous securement device is preferably provided on the unitary catheter **20**, which can be used to allow subcutaneous tissue or other body tissue depending upon the application of the catheter assembly to grow into the cuff **44** to thereby secure the catheter, preferably in chronic catheterizations. However, it will be understood based on this disclosure that other securement methods and devices known or to be developed may be used with the assembly and in methods according to the present invention.

With reference to FIG. 1, the catheter assembly preferably has extension tubes **38, 39** which are in fluid communication with the first and second lumens **22, 23** and the first and second passageways **28, 32** through the distal end tubes **26, 30**, respectively of the unitary catheter **20** preferably through the hub **24**. FIG. 3 shows the hub **24**, which is formed around the exterior surfaces **38a, 39a** of the distal ends **42, 43** respectively of the extension tubes **38, 39** and around a proximal end **46** of the unitary catheter **20**. When forming the hub around the distal ends **42, 43** of the extension tubes **38, 39**, it is preferred that the hub have projecting portions **45** configured to divert the extension tubes **38, 39** away from each other to facilitate keeping the lines from tangling or catching on each other. The extension tubes **38, 39** and the unitary catheter **20** are sealed within the hub **24** in a watertight seal.

The hub **24** is sealed, such as by bonding, adhering, heat molding or otherwise attaching the hub **24** to the distal ends **42, 43** of the extension tubes **38, 39** and proximal end **46** of the unitary catheter **20**. In one embodiment of the invention, described in further detail below, the extension tubes **38, 39** are proximal portions of two separate catheters which are then coated with an outer layer, preferably by heat molding, to form the unitary catheter portion of the assembly. As such, the extension tubes **38, 39** are continuous with the unitary catheter **20** and the hub **24** can be simply molded or otherwise adhered around the end of the unitary catheter and around the proximally extending portions of the catheters within the outer layer.

The catheter assembly further preferably comprises connection devices for connecting the extension tubes **38, 39** to a hemodialysis unit. Any suitable connector may be used. Preferably, a detachable quick connect device is used such as that shown in FIG. 1. Such connector devices are known in the art and are commercially available on catheters available from Medical Components, Inc., Harleysville, Pa. As such they are described herein for convenience purposes, however, since other connectors may be used, while preferred, the connectors shown in FIG. 1 are optional.

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The connectors in FIG. 1, described herein to have identical parts, have a first detachable fitting **48** which may be slidable along the extension tubes **38, 39**, but quick connects, either by a snap-fit, screw threads or other suitable closure, preferably screw threads as shown in lines A in the partial cross sectional view of the connector in FIG. 1 to the end piece **50**. Mating screw threads D may also be provided to the bottom of end piece **50** as shown in FIG. 1. The fitting and the end piece preferably include a tight fit, and may have a gasket or other seal device B as shown in FIG. 1 which is merely a silicone rubber cylindrically shaped gasket to ensure a tight fit. Other suitable sealing mechanisms to avoid detachment or slippage or leakage through the connectors and extension tubes are acceptable. The end pieces **50** are configured to have extending portions C shown in phantom in FIG. 1 which fit snugly into the proximal end openings of extension tubes thereby preferably a tight fit with the interior surfaces of the tubes **38, 39**. When the end pieces **50** and fittings **48** are locked together, they hold the tubes securely.

The connector may have a further, replaceable and detachable connection section including detachable tubes **52** which are preferably made of a more resilient and easily replaceable material than extension tubes **38, 39**. While this is not necessary, it enables the use of softer durometer materials to be used for the extension tubes, but avoids possible damage to them from clamps or quick changes to connect to hemodialysis equipment. Clamps **56** may also be provided to stop flow or seal off tubes when not in use. Standard luer locks **58** or similar connectors may be provided on the proximal ends of the tubes **52** to connect to dialysis equipment.

The distal end tubes **26** and **30** extend from the unitary catheter **20** and are formed by splitting an initially formed unitary catheter tube and by grinding and polishing to yield smooth, round tubes as described below. The hub **24** attaches the extension tubes **38, 39** to the unitary catheter **20**.

The first distal end tube **26** and the second distal end tube **30**, the unitary catheter tube **20**, the extension tubes **38, 39** and the hub are all preferably made of biocompatible plastics or elastomers, most preferably biocompatible elastomers.

Suitable biocompatible plastics may be selected from materials such as, for example, polyurethane, polyethylene, homopolymers and copolymers of vinyl acetate such as ethylene vinyl acetate copolymer, polyvinylchlorides, homopolymers and copolymers of acrylates such as polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate and hydroxymethyl methacrylate, polyurethanes, polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, polycarbonates, polyamides, fluoropolymers such as homopolymers and copolymers of polytetrafluoroethylene and polyvinyl fluoride, polystyrenes, homopolymers and copolymers of styrene acrylonitrile, cellulose acetate, homopolymers and copolymers of acrylonitrile butadiene styrene, polymethylpentene, polysulfones, polyesters, polyimides, polyisobutylene, polymethylstyrene and other similar compounds known to those skilled in the art. It should be understood that these possible biocompatible polymers are included above for exemplary purposes and should not be construed as limiting. If a biocompatible polymeric material is used to form the unitary catheter **20**, distal end tubes **26, 30** and preferably the extension tubes **38, 39** it is most preferred that the polymeric material includes a polyurethane polymer or a polyolefin polymeric material having a preferably soft durometer, as specified below.

The extension tubes **38, 39** may be made separately from the unitary catheter and distal end tubes and formed of a

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material such as a polyurethane or a polyvinyl chloride polymer or elastomer. However, it is preferred that the extension tubes **38, 39** are formed of the same material as the unitary catheter and distal end tubes.

It is most preferred to use a biocompatible elastomer to form the unitary catheter, distal end tubes, hub and extension tubes. Suitable, preferred, biocompatible elastomers for use in forming the unitary catheter **20**, distal end tubes **26, 30** and preferably the extension tubes **38, 39** include biocompatible elastomers such as medical grade silicone rubbers, polyvinyl chloride elastomers, polyolefin homopolymeric and copolymeric elastomers, urethane-based elastomers, and natural rubber or other synthetic rubbers. Preferably, the unitary catheter, distal end tubes and extension tubes are made of the elastomeric material such that they are flexible, durable, soft, and with respect to those portions inserted in the patient or tunneled, they are easily conformable to the shape of the area to be catheterized **12** and/or the subcutaneous area **16**. Further, these materials help to minimize risk of harm to vessel walls.

If the catheter assembly **10** is used for hemodialysis applications, the unitary catheter **20**, distal end tubes **26, 30** and preferably the extension tubes are most preferably formed of a soft silicone elastomer which has a hardness of from about 75-A to about 85-A on a Shore durometer scale. Suitable, preferred elastomers include silicone or polyurethane elastomers, and most preferably polyurethane elastomers, such as, for example, Pelletane® from Dow Corning, or as Tecothane®, Carbothane® or Tecoflex® available from Thermetics. The distal end tubes **26, 30** may also optionally be made such that they include 20% barium sulfate in the elastomer to provide radiopacity if desired. While it is preferred to have a Shore-A durometer hardness in the above Shore-A durometer range and a somewhat soft material, if a biocompatible elastomer is used, particularly for hemodialysis, it is also possible to make a device from an elastomer having a lower Shore-A durometer hardness outside this range, particularly one which is more rigid material if a particular application so requires, without departing from the spirit of the invention. It is also preferred that the hub is formed of an elastomeric material, and most preferably the same material as the remaining components of the assembly **10**. However, the hub while preferably somewhat flexible, may also preferably be somewhat harder and more rigid, by about 5–10 points on the Shore-A durometer scale, than the unitary catheter, distal end tubes and extension tubes. It will be understood based on this disclosure that the softness or rigidity may be varied for different applications.

Most preferably, the unitary catheter **20** and distal end tubes **26, 30** are formed of Carbothane® of durometer of about 75-A, extension tubes **38, 39** of Carbothane® 75-A or 85-A and a Carbothane® hub of about 85-A durometer. Alternatively, a preferred combination may be formed of a Tecoflex® of durometer of about 80-A for the unitary catheter **20** and distal end tubes **26, 30**, and a Pelletane® of durometer of about 80-A for the hub and/or extension tubes **38, 39**. The additional components for attaching to dialysis or similar equipment including luers, connectors and the like are preferably formed of a polymeric and/or elastomeric material such as acetal, silicone 80-A or polyvinyl chloride. However, such connectors may be formed from any suitable material known or to be developed in the art for forming such connectors and/or adapters.

The invention further includes methods for making a multilumen catheter assembly such as the assembly of FIG. 1. The method will be illustrated with respect to FIG. 1 and

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FIGS. 7A–7D. The method includes forming a unitary catheter tube **60**, which has a proximal portion **61**, a distal portion **63** and a distal end portion **62** which terminates in a distal end **64**. The unitary catheter tube **60**, as shown in FIG. 7A, may be formed using any suitable heat molding process including injection molding, expansion/compression molding and extrusion. Preferably the unitary catheter tube **60** is formed by extrusion through a die to form internal lumens such as those shown for the device of FIG. 1 in FIG. 2. The lumens are preferably substantially the same and more preferably substantially identical in size and configuration. The tube **60** with internal longitudinally extending lumens may also be formed by injection molding the tube around metal rods which have the shape of the internal lumens. However, extrusion is most preferred.

As shown in FIG. 7B, the tube **60** is then split longitudinally along the distal portion **62** of the tube using a sharp edge such as a hot knife or razor blade (not shown) for a preferred distance, depending upon the particular size of the catheter. Preferably, the tube **60** is split a distance of from about 4 cm to about 6 cm, and most preferably about 9 cm extending to the distal end **64** of the unitary tube. The tube is preferably split as evenly as possible between the two lumens along the internal septum **66** (shown in FIG. 2). If more than one lumen were present, the unitary tube would be split equally along each internal septum with preferably a substantially equal amount of tubing material surrounding each of the split portions of the tube. Splitting the unitary catheter tube **60** forms a first distal end tube **26** and a second distal end tube **36**. The first distal end tube is then cut to size such that it is shorter in length than the second distal end tube as shown in FIG. 1 for avoiding recirculation of fluids entering and leaving the tubes within the area to be catheterized **12**.

After the unitary catheter tube and distal tubes are formed, the exterior surface **36** of the unitary catheter tube and the exterior surfaces **34**, **40** of the distal end tubes are then ground and polished by radio frequency (RF) tipping to provide a smooth surface. This process involves using RF energy to re-heat the outer surface until there is some melting and to polish the surface. Further, the distal end tubes **26**, **30** preferably undergo this procedure on a mandrel such that they may be re-shaped to have a generally circular transverse cross section both in the interior passageways **28**, **32** and on the exterior surfaces **34**, **40** as shown in FIGS. 1, 2, 3A and 3B. Once the surfaces are shaped and smoothed, as shown in FIG. 7C, a plurality of holes **33** are then formed in the distal end tubes using techniques well known in the art such that the catheter tube **60** is now formed into a unitary catheter such as the unitary catheter **20** of FIG. 1.

As an alternative to splitting the unitary catheter, after forming the unitary catheter tube **60**, distal end tubing of lengths l_1 , l_2 (which may be previously extruded or heat molded) may then be fused onto the unitary catheter tube **60**. The two distal end tubes are formed such that they have respectively longitudinal passageways **28**, **32** extending therethrough, and may also be formed to include a plurality of holes **33** either prior to attaching to the distal end of the unitary catheter tube or such holes may be formed after attaching to the unitary catheter tube **60**. The formed distal end tubes are then attached by a suitable heat molding or other form of attachment such as an adhesive, ultrasonic welding or other methods known in the art, to the distal end of the unitary catheter tube such that the first passageway in the first distal end tube is in communication with the first lumen of the unitary catheter tube and the second passageway in the second distal end tube is in communication with

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the second lumen in the unitary catheter tube. Preferably heat fusing is used to attach the distal end tubes, and the fusing may be carried out using heat applied to the unitary catheter tube and distal end tubing lengths in a female cavity mold to thereby create a smooth fused portion where the tube **60** and end tube lengths meet. The resulting structure would be of the same basic appearance of the device of FIG. 7B but formed differently. From there on, the structure may be formed as set forth with respect to unitary split catheter tube **60** in FIGS. 7A–7D, however, the resulting distal end tubes will preferably already have a smooth surface from the heat fusing and prior extrusion to shape such that further polishing and grinding as described herein would not be necessary. However, it will be understood that the present invention does not exclude such further shaping and/or polishing.

The extension tubes **38**, **39** may be provided either by extruding or molding them initially when forming the unitary catheter tube **60** using techniques similar to those used to form the distal end tubes as described above. However, it is more preferred to attach the extension tubes to the proximal end **46** of the unitary catheter tube using the technique illustrated in FIG. 7D. Metal rods **68** are used which are bent to provide a desired angle of separation for the proximally extending projections **45** of the hub **24** once formed. The angle may be varied within the scope of the invention, preferably from about 25° to about 50°, and more preferably about 36°. The metal rods are inserted through the extension tubes **38**, **39** and through the lumens within the unitary catheter tube **60** as formed in the manner described above. The extension tubes are spaced from the proximal end **46** of the unitary catheter tube **60** a distance slightly less than the size of the hub mold such that when the hub is molded around the extension tubes and unitary catheter tube, the hub will overlap the tubes for a watertight seal. The assembled rods and tubes are then placed in a mold and the hub **24** molded around the tubes as shown in phantom lines in FIG. 7D. After forming the extension tubes **38**, **39** in connection by the hub to the unitary catheter tube **60**, the metal rods are removed, and the connector assembly shown in FIG. 1 or another suitable connector are preferably then connected, either permanently or detachably as in FIG. 1 to form a complete and preferred multilumen catheter assembly such as the assembly **10** of the invention.

In one embodiment of the method of the invention, as shown in FIGS. 8A and 8B, a multilumen catheter may be made by arranging a first catheter **68** and a second catheter **70** in a substantially longitudinally parallel arrangement, preferably such that they are juxtaposed to each other, however, a gap may be present between the catheters **68**, **70**. Further, more than one catheter may be used and similarly arranged. Each of the catheters is preferably a single lumen catheter, however, multilumen catheters may also be used for some applications. The first and second catheters **68**, **70** each have a respective distal end **72**, **73**, distal end portion **74**, **75** and at least one lumen in each catheter which extend longitudinally therethrough which are preferably the same as the lumens **22**, **23** formed in the unitary catheter tube **60** as shown in FIG. 2.

An outer layer **76** is formed around at least a portion **77** of the exterior surfaces **78**, **80** of the first and second catheters **68**, **70** which is proximal to the distal end portions **74**, **75** of the catheters. The outer layer is preferably extruded around the two catheters. However, the arrangement of catheters and formation of the outer layer **76** may also be formed by extruding the two catheters simultaneously through dies while coextruding the outer layer **76** around the

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catheters **68, 70**. However, the outer layer is coextruded only over a portion of the exterior surfaces of the catheters proximal to the distal end portions **74, 75**. Once the outer layer is formed, sufficient heat molding capability may be applied to heat mold the first and second catheters together. The lumens are generally longitudinally parallel and the catheters are heat molded together, preferably in juxtaposed relation and fixed within the outer layer. The distal end portions of the catheters extend outwardly and distally from the portions of the exterior surfaces of the first and second catheters which are within the outer layer. Since the distal end portions are not connected, they are capable of independent movement. It is also within the scope of the invention to heat mold a fill material between the first and second catheters to ensure that a smooth, oval exterior surface is formed around the catheters once the outer layer is formed.

As with the method discussed above, extension tubes may be provided to the ends of the catheters if the outer layer is formed to extend to the proximal ends of the catheter tubes in the manner shown in FIG. 7D for the previous method. Alternatively, the outer layer is formed over only a portion of the catheters leaving separate proximal ends extending from the area of the outer layer in the proximal direction to form extension tubes. In such case, as shown in FIG. 8B, the proximal end portions which serve as extension tubes **38, 39** in the manner shown in FIG. 1 extend proximally from the proximal end **46** of the outer layer formed around the catheters which provides a unitary catheter **20** as in FIG. 1. A hub is then molded around the proximal end of the outer layer and around the sections **82, 83** of the proximally extending proximal end portions adjacent the outer layer. Preferably, to maintain the unitary catheter tube and extension tubes in place, the mold either has cavities to receive the tubes or, more preferably, metal rods such as metal rods **68** are inserted through the extension tubes and lumens within the formed unitary catheter portion to retain the shape of the lumens and hold the tubes in place. A plurality of holes **33** may also be provided to the distal end portions. After forming the hub, the catheter assembly preferably includes connectors and the like as described above.

The multilumen catheter assembly is preferably used in hemodialysis and may be inserted as described below. Referring to again to FIGS. 1-6, the first distal end tube **26** and the second distal end tube **30** are configured to be placed, or inserted into, the area to be catheterized **12** which is preferably an internal jugular vein **19** as shown in FIG. 6. The unitary catheter **20** is configured to extend into the area to be catheterized **12** through the entry point **112** into the vein **19**. The unitary catheter **20** is also sufficiently long to be secured to the patient either by subcutaneously tunneling the unitary catheter **20** as shown in FIGS. 5 and 6 or by attaching to the outer skin of the patient as shown in FIG. 4.

In an embodiment of one method of inserting a catheter according to the present invention as shown in FIG. 4, described herein with respect to the embodiment of FIG. 1 for convenience purposes, the portion of the unitary catheter **20** which extends proximally out of the incision **110** formed in the patient for preferably acute catheterization may be secured to the skin **18** of the body **14** by a suitable fastening material **56**, such as adhesive tape, or an exterior securement device (not shown) as shown in U.S. Pat. No. 5,776,111. This method of securing and positioning the catheter assembly **10** is typically used in emergency or acute catheterization.

In another embodiment of the present invention method as shown in FIGS. 5-6, a proximal end **81** of the unitary

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catheter **20** may be secured in a subcutaneous area such as a subcutaneous tunnel **16** formed through the body **14** and typically extending between a subcutaneous area near the insertion site **112** into the vessel and a caudal exit site as shown in FIG. 6. Methods of tunneling are known to those of ordinary skill in the art. Tunneling may be used in either chronic or acute procedures.

Referring to FIGS. 1 and 4-6, each of the catheters **26, 30** is configured to have a suitable length and width useful for insertion into the internal jugular vein **19** as described. The distal end tubes **26, 30** are of different lengths as described above and their ends **26a** and **30a** are proximally and longitudinally spaced from each other by a sufficient distance which is the difference between l_1 and l_2 which substantially prevents recirculation of the purified blood and blood to be purified. The distance is preferably from about 3 to about 4 centimeters, however, it should be understood by one of ordinary skill in the art, based on this disclosure, that the ends can be flush with each other and the distance between the ends **26a, 30a** can be varied for different applications of the multilumen catheter assembly **10**. Since blood flows toward the atrium, the blood flow in the internal jugular vein **19** is in a downward direction in FIGS. 4-6 as shown by the directional arrow in the vein **19**. Thus, the distal end **30a** of the second distal end tube **30** is "downstream" from the distal end **26b** of the first distal end tube **26**.

During use of the multilumen catheter assembly **10** for hemodialysis, blood is preferably drawn out of the internal jugular vein **19** (i.e., the arterial flow) through the distal end **26a** of the first distal end tube **26** (upstream catheter) and returned (i.e., the venous flow) through the distal end **30a** of the second distal end tube **30** (downstream catheter). This flow direction may be reversed depending upon the desired flow rate and concerns associated with approaching the atrium during hemodialysis for the internal jugular vein. It should be understood by one of ordinary skill in the art, based on this disclosure, that either direction of flow may be used provided that flow in both lumens for hemodialysis applications is in opposite directions. If flow is reversed to draw from near the atrium, higher flow rates for high flow rate dialysis devices of flow rates of about 450 cc/min may be achieved. The ability to use higher flow rates without collapse of the lumens, as in multiple lumen catheters, decreases the time necessary for a patient to undergo conventional dialysis treatments, a significant patient benefit.

Referring now to the acute catheterization procedure of FIG. 4 an incision **110** is initially made near an insertion site **112** which is to be aspirated with a syringe or other introducer apparatus near or proximate the area to be catheterized **12**. If the multilumen catheter assembly **10** is used for hemodialysis and the area to be catheterized **12** is the internal jugular vein **19**, the incision **110** is made in the clavicular triangle region, as shown for example, in FIG. 4. The exact location of the incision **110** can be varied by the physician. In accordance with the Seldinger technique, a narrow needle is inserted through the incision **110** and into the vein **19**, and the vein aspirated. A guide wire is then passed through the needle, or other introducer, and the needle is removed. A dilator (not shown) and a tearable sheath are introduced over the guide wire and partially into the vein **19**. While the sheath is not shown in FIG. 4, the sheath as used in the acute method is the same as the sheath **114** as shown in FIG. 6 with respect to the following description of the subcutaneous tunneling method. Once the sheath is in place, the guide wire is removed. The insertion site **112** is now ready to accept the catheter assembly **10**.

The distal end tubes **26, 30** are inserted into, and through, the sheath in juxtaposed relationship. The distal end tubes

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26, 30 are inserted until they are properly positioned within the area 12, as shown in FIG. 4 and the unitary catheter 20 extends through the vessel entry site 112. The sheath is then removed in the conventional manner, leaving the distal end tubes 26, 30 in the area 12. As shown in FIG. 4, the distal end tubes 26, 30 may freely move within the area 12.

Next, the incision 110 is closed and the proximal portion 81 of the unitary catheter 20 is secured to an external surface 18 of the body 14 by fastening material 84, such as adhesive tape. The incision 110 may also be closed after securement. While not necessary in acute catheterization, tunneling and subcutaneous securement can be effected by use of a trocar as discussed below with respect to chronic catheterization. The luer locks 58 are connected in fluid communication to respective fluid inlets and outlets of a hemodialysis unit, or other fluid transfer equipment (not shown) and dialysis may now begin.

The chronic catheterization procedure is now described with respect to FIGS. 5 and 6. Referring to FIG. 5, the unitary catheter 20 of the multilumen catheter assembly 10 may be located within a subcutaneous tunnel 86 in the subcutaneous area 16 of the body 14, using various tunneling techniques. In one technique, the distal end tubes 26, 30 are pulled through the tunnel 86 from the caudal end of the tunnel, while forming the tunnel using a trocar or other tunneling tool, leaving the proximal portion 81 of the unitary catheter 12 at least partially within the tunnel 86 and the distal end tubes 26, 30 extending outwardly from the opposite end of the tunnel 86 near the area to be catheterized 12. One technique for tunneling the distal end tubes 26, 30 through a subcutaneous area includes an elastomeric tube. A tunneling tool, e.g., a trocar, is generally already equipped with a 3 or 4 in (7.62 to 10.16 cm) elastomeric safety tube over its pointed, cutting end (not shown). If the trocar does not already have such a tube, any similar tube may be used in conjunction with the trocar. The safety tube may be slid down the trocar to capture the ends of the distal end tubes. Preferably, the gripping end of the trocar is first inserted into the lumen of the longer distal end tube. The tube may then be slid over the connected trocar and distal end tube to also capture the end of the shorter distal end tube. Using either technique, the connected trocar and distal end tubes 26, 30 are pulled through a subcutaneous tunnel made by the pointed end of the trocar. Once the catheters have been placed in the subcutaneous area, and prior to inserting the distal end tubes 26, 30 into the area to be catheterized 19, the tubes 26, 30 and portion of the unitary catheter 20 extending from the patient appear as shown in FIG. 5.

Referring now to FIGS. 5 and 6, an incision 110 is made at the insertion site 112, either before or after tunneling, and the distal end tubes 26, 30 are inserted into, and through, the sheath 114 in a juxtaposed manner, in the same manner as described above with respect to FIG. 4. The remaining catheter insertion and incision closure steps are the same as those described above with respect to FIG. 4. After the multilumen catheter assembly 10 is inserted as shown in FIG. 6, the incision is closed and the unitary catheter 20 of the assembly 10 is substantially below the skin of the patient. Lastly, the open ends of the luer locks 58, extending caudally from the tunnel, are attached in fluid communication with respective fluid inlets and outlets of a hemodialysis unit, or other fluid transfer equipment (not shown), and dialysis can begin.

To further ensure that the proximal portion 81 of the unitary catheter remains secured in the subcutaneous area 16 of the body 14, one or more anchoring members, such as a tissue ingrowth cuff 44 may be positioned around (i.e.,

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circumferentially disposed on) the proximal portion 81 of the unitary catheter 20, such that the anchoring members will be situated in the subcutaneous area 16 after tunneling, as is well-known in the prior art.

The present invention provides the advantages of a Tesio or Schon multiple catheter assembly, in that it has two freely movable distal tips, while also providing the advantages of a single insertion method, and the ability to easily manipulate the proximal portion of the unitary catheter 20 and tunnel with only one tunneling procedure. The unitary catheter 20 has a smooth, generally convex exterior surface, which passes through the insertion site 112. With reference to FIG. 6, vessel wall 19a can readily seal around the smooth curved surface of the unitary catheter 20. If the distal end tubes 26 and 30 were located at the insertion site 112, the vessel wall 19a would not be able to ensure as tight a seal, because there would still be a potential risk of leakage between the tubes which would form a figure-8 configuration.

By having the unitary catheter 20, which has the smooth, generally curved surface, the vessel wall 19a can seal quite well around the surface particularly well with a ligature. Since there is a good seal at the insertion site 112, the risk of blood loss around the unitary catheter 20 is minimized.

The smooth, round distal end tubes 26 and 30 do not have any protuberances on their surfaces that would promote clotting. A rough external surface provides protuberances, which can be points where clotting can begin. The distal end tubes 26 and 30 have smooth, round exterior surfaces that float freely within the vessel 19, which do not provide a source of clot formation. The free-floating distal end tubes 26 and 30 provide the many advantages of an individual catheter tube, such as provided by a Tesio catheter, including no tendency to suction against an inside surface of the vessel wall 19a, which minimizes the tendency of stenosis. The multilumen catheter assembly 10 further has little tendency to kink, since the unitary catheter 20 has a good deal of support due to the thickness of its walls and cross-section and due to the smoothness of the separate catheter tubes.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

We claim:

1. A method of making a multilumen catheter, comprising: forming a unitary catheter tube to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen and a second lumen, each of the first lumen and the second lumen extending longitudinally through the unitary catheter tube; and

splitting the unitary catheter tube longitudinally along the distal end portion of the unitary catheter tube to form a first distal end tube and a second distal end tube.

2. The method according to claim 1, further comprising grinding and polishing the first and second distal end tubes to provide a generally smooth exterior surface to each of the two distal end tubes.

3. The method according to claim 2, further comprising grinding and polishing the first and second distal end tubes on a mandrel to shape the first and second distal end tubes to have a generally circular transverse cross sectional configuration.

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4. The method according to claim 1, further comprising forming the unitary catheter tube by a heat molding process.

5. The method according to claim 4, wherein the heat molding process is extrusion.

6. The method according to claim 1, further comprising forming the unitary catheter tube such that the unitary catheter tube has a cross sectional configuration which is generally oval.

7. The method according to claim 1, further comprising forming the unitary catheter tube such that the first and second lumens of the unitary catheter tube are substantially identical in transverse cross section.

8. The method according to claim 7, wherein the first and second lumens have a generally circular transverse cross section.

9. The method according to claim 1, further comprising forming a plurality of holes through an exterior surface of the first distal end tube and through an exterior surface of the second distal end tube.

10. The method according to claim 1, wherein the first distal end tube has a length which is less than a length of the second distal end tube, the lengths being measured in a longitudinal direction.

11. The method according to claim 1, further comprising providing a first extension tube in fluid communication with a proximal end of the first lumen and a second extension tube in fluid communication with a proximal end of the second lumen.

12. The method according to claim 11, further comprising providing a hub having at least a first passageway and a second passageway extending therethrough which connects the proximal end of the unitary catheter tube to the first and second extension tubes such that the first passageway is in fluid communication with the first lumen and the first extension tube and the second passageway is in fluid communication with the second lumen and the second extension tube.

13. The method according to claim 12, wherein the hub is formed by heat molding and the method further comprises inserting a first rod in the first extension tube and in the first lumen such that the first lumen is spaced from the first extension tube, inserting a second rod in the second extension tube and in the second lumen such that the second lumen is spaced from the second extension tube, molding the hub around the rods such that the hub encloses the proximal end of the unitary catheter and connects the proximal end of the unitary catheter to the first and second extension tubes, and removing the first rod and the second rod after forming the hub.

14. The method according to claim 13, wherein the hub is molded to have proximally extending projections formed around distal ends of the first and second extension tubes to divert the first and second extension tubes away from each other.

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15. A method of making a multilumen catheter assembly, comprising:

arranging a first catheter having a distal end, a distal end portion and at least one first lumen extending longitudinally therethrough and a second catheter having a distal end, a distal end portion and at least one second lumen extending longitudinally therethrough such that the first catheter and the second catheter are substantially longitudinally parallel; and

forming an outer layer around at least a portion of an exterior surface of the first catheter proximal to the distal end portion of the first catheter and around at least a portion of an exterior surface of the second catheter proximal to the distal end portion of the second catheter such that the first catheter and the second catheter are fixed within the outer layer, the first lumen and the second lumen are generally parallel within the outer layer and the distal end portions of the first and second catheters extend outwardly and distally from the portions of the exterior surfaces of the first and second catheters which are within the outer layer and the distal end portions are capable of independent movement.

16. The method according to claim 15, wherein the outer layer is heat molded around at least a portion of the exterior surface of the first catheter and around at least a portion of the exterior surface of the second catheter.

17. The method according to claim 16, wherein the first and second catheter are in juxtaposed relation within the outer layer.

18. The method according to claim 15, wherein a proximal end portion of the first catheter and a proximal end portion of the second catheter extend proximally from a proximal end of the outer layer and a hub is provided around the proximal end of the outer layer and around a section of the proximal end portions of the first and second catheter adjacent the outer layer.

19. A method of making a multilumen catheter assembly, comprising:

forming a unitary catheter tube to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen and a second lumen, each of the first lumen and the second lumen extending longitudinally through the unitary catheter tube;

forming a first distal end tube having a first passageway extending longitudinally therethrough and a second distal end tube having a second passageway extending longitudinally therethrough; and

attaching the first and second distal end tubes to the distal end of the unitary catheter tube such that the first passageway in the first distal end tube is in communication with the first lumen of the unitary catheter tube and the second passageway in the second distal end tube is in communication with the second lumen in the unitary catheter tube.

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