EUROPEAN PATENT SPECIFICATION

Date of publication and mention of the grant of the patent:

Application number: 07852640.7
Date of filing: 09.10.2007

International application number:
PCT/US2007/021688
International publication number:
WO 2008/051375 (02.05.2008 Gazette 2008/18)

CATHETER TUNNELER ADAPTER AND METHOD OF ASSEMBLY TO A CATHETER
KATHETERTUNNELUNGSADAPTER UND VERFAHREN ZU DESSEN ANBRINGUNG AUF EINEM KATHETER
ADAPTATEUR POUR TUNNELISATION DE CATHÉTER ET PROCÉDÉ D'ASSEMBLAGE AVEC UN CATHÉTER

Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC MT NL PL PT RO SE SI SK TR

Priority: 19.10.2006 US 852847 P
Date of publication of application:
15.07.2009 Bulletin 2009/29

Proprietor: Medical Components, Inc.
Harleysville, PA 19438 (US)

Inventor: STEPHENS, John
Perkiomenville, PA 18074 (US)

Representative: Callies, Rainer Michael
Patentanwalt
Fronhof 1
37581 Bad Gandersheim (DE)

References cited:
WO-A-2005/009502
US-B1- 6 872 198

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
The present invention relates to medical devices and more particularly to an adapter for a vascular catheter to facilitate subcutaneous tunneling thereof.

DESCRIPTION

FIELD OF THE INVENTION

Catheters for the introduction or removal of fluids may be located in various venous locations and cavities throughout the body of a patient for introduction of fluids to the body or removal of fluids from the body. 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 fluid and the other lumen removes fluid. An example of such a multiple catheter is the SPLIT-CATH® catheter, sold by Medical Components, Inc. of Harleysville, Pennsylvania.

BACKGROUND OF THE INVENTION

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 fluid and the other lumen removes fluid. An example of such a multiple catheter is the SPLIT-CATH® catheter, sold by Medical Components, Inc. of Harleysville, Pennsylvania.

An alternative installation procedure is available for installing the catheter that better suits the patient’s needs and the surgeon’s skills. Such an alternative catheter assembly is the multi-lumen catheter disclosed in U.S. Patent Publication No. US 2004/0092863. In order to be able to perform the tunneling after the distal end of the catheter assembly is inserted into the patient (termed retrograde tunneling), the proximal ends of each catheter must be attached to a tunneler device adapted to pull the proximal end of each catheter through the tunnel. After tunneling, the proximal ends of the catheters must be disconnected from the tunneling device and then connected to a catheter hub.

United States Patent No. US 2004/0176739 is directed to a catheter tunneling adapter that allows for the simultaneous tunneling of the proximal ends of each catheter in a multi-lumen catheter assembly. The adapter is comprised of a generally elongated body having a distal end and a proximal end and a longitudinal axis extending therethrough between the distal end and the proximal end. The proximal end includes a connector for connecting a catheter tunneler thereto. The distal end comprises a connector for connecting a plurality of lumens thereto. The publication also provides a method of inserting a catheter having a plurality of lumens into a patient. The method is comprised of inserting a distal end of each of the plurality of lumens into a blood vessel in the patient; connecting a proximal end of each of the plurality of lumens to a tunneling device; forming a subcutaneous tunnel with the tunneling device; drawing the proximal ends of each of the plurality of lumens simultaneously through the tunnel; disconnecting the tunneling device from the proximal ends of each of the plurality of lumens; and connecting the proximal ends of each of the plurality of lumens to a catheter hub component. Such a catheter hub component is disclosed in U.S. Patent No. 7,261,708 that is mountable to a catheter’s proximal end after tunneling thereof has been performed.

It would be desirable to provide the practitioner the option of inserting the distal catheter portion into the vasculature using a stylet rather than an introducer sheath. It would be desirable to provide an adapter that releasably connects the stylet with the catheter for vascular insertion, after which the stylet is removable. It would further be desirable for such an adapter to also provide for subsequent connection thereto of a tunneler.

BRIEF SUMMARY OF THE INVENTION

The present invention comprises an adapter according to claim 1. At its distal end the adapter is securable onto the ends of two (or more) lumens of a catheter to facilitate implantation thereof in a patient’s vasculature, and is securable at its proximal end to, sequentially, a
tubes. The adapter may if desired have more than one proximal tubes of the catheter and then discarded; fur-
ther is affixed to the catheter. The adapter may be removed and is shipped with a stylet already in position releasably secured to the adapter. Even more preferably, the adapt-
er is assembled to the catheter during manufacturing, through the subcutaneous tunnel. Preferably, the adapt-
er is affixed to the catheter lumens by severing the ends of both proximal tubes of the catheter and then discarded; fur-
ther, the tunneler need not be separately removed from the adapter after tunneling since it will be discarded, as well. The adapter may if desired have more than one flexible arm for a catheter with more than two proximal tubes.

[0009] The adapter of the present invention may be generally tubular with a through passageway extending from an entrance for connection to the stylet and tunneler and an exit for connection to the catheter proximal end.

[0010] In a preferred embodiment, the adapter, which is adapted for use with a catheter whose proximal end has at least two separate lumens defined in proximal tubes that are separate from each other, has a generally tubular body with a through passageway as set forth hereinabove, and the body also includes a flexible arm of soft material that extends at a lateral offset distally of the distal end of the adapter body to a free end concluding in a plug that is disposed distally of the passageway entrance and is offset laterally of the longitudinal axis of the through passageway.

[0011] The present invention also comprises an assembly of the adapter embodiments hereinabove described affixed respectively to the multiple proximal tubes of a multiple-lumen catheter. The assembly may include a stylet removably connected to the proximal passageway entrance of the adapter and extending therethrough.

[0012] The present invention also comprises a method of assembling a tunneling adapter to a proximal end of a dual-lumen catheter, according to claim 15. Especially, the invention comprises a method of assembling a tun-
ner to a catheter, including the steps of providing a dual lumen catheter; providing a tunneler; providing an adapt-
er having a passageway extending therethrough from a proximal end to a distal end and also having a flexible arm extending distally therefrom and concluding in a distally extending plug spaced laterally from the longitudinal axis of the adapter; affixing the plug sealingly in and to a second lumen of a multiple lumen catheter; and affixing a trailing end of a tunneler to the proximal end of the adapter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The accompanying drawings, which are incor-
porated herein and constitute part of this specification, illustrate the presently preferred embodiment of the invention, and, together with the general description given above and the detailed description given below, serve to explain the features of the invention. In the drawings:

Fig. 1 is an isometric view of an adapter of the present invention;
Fig. 1A is an enlarged cross-sectional view taken along lines 1A-1A of Fig. 1;
Figs. 2 and 3 are longitudinal cross-sectional views of the adapter of Fig. 1, exploded from which are two lumens of a dual-lumen catheter in Fig. 2, and in Fig. 3 showing the adapter affixed to the two lumens;
Fig. 4 is a longitudinal cross-sectional view of the adapter of Figs. 1 to 3 exploded from a stylet to be releasably connected thereto and also shows a swivel lock affixed to the stylet's proximal hub;
Fig. 5 is a longitudinal cross-sectional view of the adapter of Figs. 1 to 3 affixed to the catheter with the stylet and a guide wire inserted through a passageway of the adapter and into a lumen of the catheter;
Fig. 6 is a cross-sectional view of the adapter of Figs. 1 to 3, exploded from which are two styles of tunnel-
ers that are releasably connectable to the adapter;
Fig. 7 is a longitudinal cross-sectional view of the adapter assembled to a tunneler of Fig. 6 with the adapter affixed to the two catheters and being pulled through a subcutaneous tunnel of a patient;
Fig. 8 is an isometric view of an alternate embodiment of adapter for a single-lumen catheter;
Fig. 9 is an isometric view of a third embodiment of adapter, wherein the adapter is modified at its distal end for use with a dual lumen catheter wherein the lumens have D-shaped cross-sections; and
Fig. 10 is a flow chart illustrating the steps of inserting a catheter assembly into a patient using the adapter of Figs. 1 to 3, according to the method of the present invention.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0014] In the drawings, like numerals indicate like ele-
ments throughout. Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention. The words "proximal" and "dis-
tal” refer to directions away from and closer to, respectively, the insertion tips of a catheter adapted to connect to the adapter of the present invention. The terminology includes the words above specifically mentioned, derivatives thereof, and words of similar import. The following describes a preferred embodiment of the invention. However, it should be understood based on this disclosure, that the invention is not limited by the preferred embodiment described herein.

A first embodiment of adapter 10 of the present invention is shown in Figures 1 to 7. Adapter 10 is shown in Fig. 1 to include body 12 having a proximal end 14, a distal end 16, a through passageway 18 extending through the body 12 from an entrance 20 at the proximal end 14 to an exit 22 at the distal end 16. The through passageway 18 also includes an intermediate, smaller diameter portion 24 and a transition portion 26 extending to the exit 22 and defining a distally facing ledge 28.

Adapter 10 also includes a flexible arm 30 having an elongated section, strut or tether 32 extending to a free end 34 having a frustoconical enlargement 36 defining a distally facing ledge 38 distally from which extends a somewhat elongated plug 40 having a rounded, blunt tip 42. Preferably, the strut or tether 32 has a flattened cross-section (see Fig. 1A) facilitating deflection of the flexible arm toward the longitudinal axis defined by the through passageway 18, as will be described hereinafter relating to subcutaneous tunneling of the catheter’s proximal end. The strut or tether 32 is disposed at an angle a (see Fig. 4) of between 3 and 15 degrees with respect to the longitudinal axis of the adapter, and preferably about 10 degrees, and has a length sufficient to space distally the frustoconical enlargement 36 and plug 40 from the distal end 16 of body 12 when the flexible arm is deflected during tunneling. As is seen in Fig. 4, the enlargement 36 and the plug 40 then extend from the strut 32 generally parallel to the longitudinal axis. It is preferable that adapter 10 be made of soft biocompatible material like polyurethane, such as, for example, PEL-LETHANE® polyurethane sold by Dow Chemical Co. of Midland, Michigan and having a durometer such as about 80A. Preferably, modest gripping features may be provided on the outer surfaces of adapter body 12, which preferably is smooth and essentially free of threads or other discontinuities and has rounded edges at least after being affixed to a catheter as hereinafter described.

In Figures 2 and 3, adapter 10 is shown with a catheter 50 having a proximal end where the first and second proximal tubes 52,54 of the catheter are shown separated near their first and second proximal ends 56,58, such as by having been split apart for a selected length as disclosed in U.S. Patent Publication No. US 2004/0176739, and defining first and second lumens 60,62. Preferably, the length of the second proximal tube is shortened such as by trimming, such that the affixing of the first and second proximal tubes to the adapter permits the first and second proximal tubes to remain adjacent to each other.

During assembly of the adapter 10 to the catheter 50, first proximal tube 52 is insertable into passageway exit 22 until first proximal end 56 abuts ledge 28; second proximal tube 54 is insertable over plug 40 of flexible arm 30 until proximal end 58 abuts ledge 38. Preferably, plug 40 is so sized and shaped to be in a tight fit within second lumen 62 to assuredly seal therewith; further, preferably, the catheter proximal tubes are bonded or welded to adapter 10. Adapter 10 will later be removed from the catheter 50 by severing end portions of first and second proximal tubes 52,54 and then discarded. The maximum diameter of the frustoconical enlargement 36 is at least as large and preferably greater than the outer diameter of second proximal tube 54.

In Figures 4 and 5, a stylet 70 is shown having a relatively stiff, elongate stylet section 72 sufficiently long to extend completely through first lumen 60 of catheter 50 and beyond its distal tip (not shown), so that a guide wire 68 is easily insertable through the stylet and thus through the adapter and the catheter, for use in vascular placement of the catheter’s distal portion, should the practitioner choose to use stylet in vascular placement rather than introducer sheath and dilator methods. Stylet 70 also has a proximal hub 74 distally of which is secured a freely rotatable swivel lock 76, with stylet hub 74 including a frustoconical distal projection 78. In Fig. 5, after stylet section 72 is inserted through adapter 10 from its proximal end, and extends into and through catheter first lumen 60, swivel lock 76 is adapted to be force fit over the outer surface of proximal end 14 of adapter 10, as the frustoconical distal projection 78 enters into the adapter’s entrance 24 for releasable connection with the adapter, with stylet 70 being rotatable with respect to the catheter/adapter assembly. In Fig. 5, a guide wire 68 is shown inserted into the stylet 70, adapter 10 and catheter first lumen 60. Although not shown in Fig. 5, the guide wire distal end preferably extends through first lumen 60 and distally from the distal tip opening thereof and threaded into the second lumen distal tip portion that is longer than the first lumen, to project from the second lumen distal tip opening, as disclosed in U.S. Patent No. 6,991,625.

After the distal portion of the catheter 50 has been placed into the vasculature by use of the stylet (or by an introducer sheath/dilator approach), the stylet is removed and discarded, and the proximal portion of the catheter assembly now is to be tunnelled. Referring now to Figs. 6 and 7, two styles of tunnelers are shown, either one of which is connectable to the proximal end 14 of adapter 10. More conventional is tunneler 90, having a rigid shaft 92 extending from a blunt tunneling tip 96 to a blunt connection tip 94 adjacent to which is a connection section 98 having a plurality of barbs or annular projections that could be used to connect to a catheter lumen directly, but are also useful in establishing a firm connection with adapter 10. Also shown is another style of tunneler 80, the Raulerson Ring Handled Y Adapter Tunneler sold by Medical Components, Inc. of Harleysville,
Referring now to Figure 7, tunneler 80 is shown after having been tunneled subcutaneously in patient 100 to define a tunnel 102 prior to connection to adapter 10. Then, tunneler 80 was inserted into proximal entrance 24 of adapter 10 forcibly connecting therewith via connection section 88. Tunneler 80 is shown after partially pulling adapter 10/catheter 50 proximal portion through tunnel 102.

It may be seen in Figure 7 that flexible arm 30 of adapter 10, affixed to second proximal tube 54, is easily deflected toward first proximal tube 52 while being drawn through tunnel 102, thus facilitating the subcutaneous tunneling procedure. Frustoconical enlargement 36 of flexible arm 30 has a maximum diameter just greater than the outer diameter of second proximal catheter tube 54 so that there is no friction or snagging or dragging caused by the proximal edge of second proximal tube 54 at proximal end 58, and the sealed nature of the connection of plug 40 with second lumen 62 prevents any fluid, debris or air from entering second lumen 62.

After tunneling is completed, the proximal ends of first and second proximal catheter tubes are severed adjacent to adapter 10, and the severed ends and the adapter are now discarded along with the tunneler. Now, the remaining portions of the catheter proximal tubes 52,54 enable placement thereonto of a hub such as is disclosed in U.S. Patent No. 7,261,708 that is mountable onto a proximal catheter end having two proximal tubes, after tunneling of the catheter. Then, conventional extension tube assemblies are securable onto the exposed ends of the proximal tubes that protrude beyond the hub such as with conventional luer fittings to define a complete, implanted catheter assembly.

Figure 8 illustrates another embodiment of adapter 200 that is useful with a single-lumen catheter. Adapter 200 has a body 202 with a through passageway 204 extending from an entrance 206 at proximal end 208 to an exit 210 at distal end 212. Unlike the adapter 10 of Figs. 1 to 7, adapter 200 does not have or need a flexible arm, since the catheter has only a single lumen which would be inserted into exit 210 of adapter 200 and bonded or welded thereto. Since passageway 204 is aligned with the lumen of the catheter, a stylet is easily insertable into entrance 206 and into and through the lumen of the catheter. Again, as with adapter 10 the stylet enables a guide wire to be easily inserted through the adapter and the catheter for placement of the catheter’s distal portion into the vasculature of a patient. Then the stylet is removed and a tunneler connected to the adapter at entrance 206 for tunneling of the adapter/catheter assembly.

A third embodiment of adapter 300 is depicted in Figure 9. Adapter 300 is modified at its distal end to accommodate a catheter 350 whose first and second lumens 360,362 have a D-shaped cross-section. Adapter passageway 318 has an exit 322 that is D-shaped in cross-section. Also, plug 340 on flexible arm 330 also has a D-shaped cross-section to be received sealingly into the second lumen’s proximal end, and a correspondingly shaped enlargement 336.

A flow chart is provided in Figure 10 to set forth the method of using the adapter of the present invention, based on the embodiment of adapter 10 shown in Figures 1 to 3, and following a retrograde tunneling procedure. It is expected that the adapter of the present invention will be affixed to the proximal tubes 52,54 of the catheter 50 when received by the practitioner, and a stylet 70 is in position in the assembly releasably connected to the adapter 10. When received as an assembly by the practitioner, the assembly may either be inserted in the vasculature through use of the stylet, a dilator and a guide wire, or through use of an introducer sheath and dilator and guide wire. If the stylet approach is not to be used, the practitioner will remove and discard the stylet 70. If irrigation of the catheter is desired, a syringe (not shown) is attachable to the adapter or to the stylet.

In the method using an introducer sheath, the incision is formed in the blood vessel and a guide wire 68 (Fig. 5) is inserted therethrough and into the vasculature to the desired location. The introducer sheath (not shown) is placed into position over the guide wire’s proximal end for the sheath’s distal tip to extend to the incision. If enlargement of the vessel’s incision is needed due to the diameter of the particular catheter to be implanted, a dilator (not shown) is placed onto the guide wire and is pressed through the sheath until the incision is dilated by the dilator’s distal tip. The dilator is then removed from the sheath and the distal portion of the catheter assembly is inserted over the guide wire proximal end so that the guide wire extends through the second lumen’s distal tip and then out of the second lumen and into and through the first lumen’s distal tip, and the catheter is then inserted into the sheath and through the sheath’s distal tip until the catheter’s distal portion is within the vasculature; the sheath is then removed and discarded as the distal portion of the catheter assembly is positioned at the desired location in the vasculature by pushing it over and along the guide wire.

Following the dilator/sheath procedures to insert the distal catheter portion into position in the vasculature, and while the proximal catheter portion with adapter remains outside the patient, the practitioner then attaches the tunneler 90 to the adapter 10 and forms a subcutaneous tunnel and pulls the adapter and catheter proximal end through the tunnel 102; or the tunneler 80 is used to form the subcutaneous tunnel 102, then is attached to the adapter 10 and then pulls the adapter and the catheter proximal end through the tunnel 102. Thereafter, the catheter lumens 60,62 are clamped and the proximal tubes 52,54 are severed adjacent the adapter, and the adapter 10 and tunneler 80 or 90 and severed...
ends are discarded. Then a hub (not shown) is secured to the remaining lengths of the proximal tubes, and the extension tube assemblies are affixed to the newly defined proximal tube ends, and the clamps are removed from the lumens since the extension tube assemblies include associated clamps thereon.

In an alternate method, if the stylet 70 and guide wire are to be used to insert the catheter assembly, tunneling and post-tunneling procedures would be the same as hereinabove described. Insertion of the catheter assembly distal portion into the vasculature prior to tunneling would be accomplished as follows: a guide wire 68 is inserted into the incision and through the blood vessel to the desired site; a dilator is placed onto the guide wire proximal end and moved to the incision, and the vein access is dilated; the proximal end of the guide wire is then inserted into the stylet distal tip which is distal to the catheter's second lumen distal tip, and through the stylet distal tip and thus through the remainder of the stylet which is located within the first lumen 60 of the catheter 50, and through the adapter 10 and proximally outwardly of the stylet hub 74; the guide wire is held while the catheter assembly is then advanced into the vein and placed in the vasculature to the desired location. While the lumens 60,62 of the catheter assembly are pinched or clamped, the stylet and guide wire and dilator would then be removed and discarded, and the tunneling procedures described above would then be followed.

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

Claims

1. A catheter tunneling adapter (10) for connection to a proximal end of a multiple lumen catheter (50), wherein the adapter includes a generally elongated body (12) having a distal end (16) and a proximal end (14) and a longitudinal axis extending therethrough between the distal end and the proximal end, and a passageway (18) extending generally longitudinally through the generally elongated body from an entrance (20) at the proximal end to an exit (22) at the distal end, wherein the entrance (20) is adapted to be removably connected to a distal end (84,94) of a catheter tunneler (80,90), and the exit (22) is adapted to be connected to a first proximal tube (52) of a catheter (50) through which extends a first lumen (60) of the catheter, characterized in that:

   the adapter includes a flexible arm (30) that protrudes distally of the distal adapter end (16), offset laterally from the distal end, and concludes in an elongate plug (40) adapted to fit sealingly in a proximal end of a second proximal tube (54) of the catheter (50) and thus occlude a second lumen (62) of the catheter.

2. The catheter tunneling adapter (300) according to claim 1, wherein the plug (340) has a D-shaped cross-section, for insertion into a correspondingly D-shaped cross-section of the second lumen (362) of the catheter (350), and the passageway exit (322) also has a D-shaped cross-section to receive thereinto the correspondingly D-shaped cross-section of the first proximal tube of the catheter.

3. The catheter tunneling adapter (10) according to claim 1, wherein the flexible arm (30) includes an elongate section (32) adapted to be easily deflectable toward the longitudinal axis of the passageway (18) and the first proximal tube (52) of the catheter during tunneling.

4. The catheter tunneling adapter (10) according to claim 3, wherein the elongate section (32) has a flattened cross-section oriented so that the flexible arm (30) is easily deflectable toward a longitudinal axis of the passageway (18).

5. The catheter tunneling adapter (10) according to claim 3, wherein at least the flexible arm (30) comprises a soft material facilitating flexing of the flexible arm.

6. The catheter tunneling adapter (10) according to claim 3, wherein the flexible arm (30) includes an enlargement (36) proximally of the plug (40) that has a maximum diameter at least as great as an outer diameter of the second proximal tube (54) and defines a distally facing abutment shoulder (38) for abutment with the proximal end (58) of the second proximal tube.

7. The catheter tunneling adapter (10) according to claim 6, wherein the enlargement (36) is frustoconical increasing in diameter proceeding distally to the plug (40).

8. The catheter tunneling adapter (10) according to claim 3, wherein the elongate section (32) of the flexible arm (30) extends from an outer surface of the adapter body (12) at an angle of between 3 and 15 degrees with respect to the longitudinal axis.

9. The catheter tunneling adapter (10) according to claim 8, wherein the elongate section (32) extends from the outer surface of the adapter body (12) at an angle of about 10 degrees with respect to the longitudinal axis.
10. The catheter tunneling adapter (10) according to claim 8, wherein the enlargement (36) and the plug (40) extend parallel to the longitudinal axis.

11. An assembly of the adapter (10) of any of claims 1 to 10 and a dual-lumen catheter (50) affixed thereto at the distal end (16) of the adapter.

12. The assembly of claim 11, further including a stylet (70) extending into the entrance (20) and through the assembly, and having a proximal hub (74) removably affixed to the adapter proximal end (14).

13. The catheter tunneling adapter (10) according to any of claims 1 to 10, wherein the adapter comprises polyurethane.

14. The assembly of either of claims 11 or 12, wherein the adapter comprises polyurethane.

15. A method of assembling a tunneling adapter (10) to a proximal end of a dual-lumen catheter (50), comprising the steps of:

- providing an adapter (10), the adapter having a proximal end (14) and a distal end (16) and a passageway (18) extending therethrough from an entrance (20) at the proximal end to an exit (22) at the distal end, the adapter entrance adapted to receive removably thereinto a distal end (84,94) of a tunneler (80,90);
- providing a dual-lumen catheter (50);
- characterized in that the adapter includes a flexible arm (30) extending distally beyond the distal end (16) and concluding in a distally extending plug (40) spaced laterally of the longitudinal axis of the adapter and that the method comprises the further steps of:

  - splitting a proximal portion of the dual-lumen catheter into first and second proximal tubes (52,54);
  - affixing a proximal end (56) of the first proximal tube (52) within the passageway exit (22) of the adapter, and
  - affixing a proximal end (58) of the second proximal tube (54) onto and around the plug (40), thereby occluding the second lumen (62).

16. The method of assembling a tunneling adapter (10) to a catheter (50) according to claim 15, further including the step of shortening the length of the second proximal tube (54) such that the affixing of the first and second proximal tubes (52,54) to the adapter permits the first and second proximal tubes to remain adjacent to each other.

17. The method of assembling a tunneling adapter (10) to a catheter (50) according to either of claims 15 or 16, further comprising the step of assembling a connection end (84,94) of a tunneler (80,90) to the passageway entrance (20) of the adapter.

Patentansprüche

1. Kathetertunnelungsadapter (10) zum Verbinden mit einem proximalen Endes eines Mehrfachlumenkatheters (50), wobei der Adapter einen allgemein länglichen Körper (12) mit einem distalen Ende (16) und einem proximalen Ende (14) und einer Längsachse, die sich durch ihn hindurch zwischen dem distalen Ende und dem proximalen Ende erstreckt, und einen Durchgang (18) aufweist, der sich allgemein in Längsrichtung durch den allgemein länglichen Körper von einem Eingang (20) an dem proximalen Ende zu einem Ausgang (22) an dem distalen Ende erstreckt, wobei der Eingang (20) angepasst ist, entfernbar mit einem distalen Ende (84,90) verbunden zu werden, und der Ausgang (22) angepasst ist, mit einem ersten proximalen Schlauch (52) eines Katheters (50), durch den sich ein erstes Lumen (60) des Katheters erstreckt, verbunden zu werden, dadurch gekennzeichnet, dass:

- der Adapter einen flexiblen Arm (30) aufweist, der distal von dem distalen Adapterende (16), seitlich von dem distalen Ende versetzt, vorsteht und in einem länglichen Stopfen (40) abschließt, der angepasst ist, dichtend in ein proximales Ende eines zweiten proximalen Schlauches (54) des Katheters (50) zu passen und so ein zweites Lumen (62) des Katheters zu verschließen.

2. Kathetertunnelungsadapter (300) gemäß Anspruch 1, wobei der Stopfen (340) einen D-förmigen Querschnitt hat, zum Einführen in einen entsprechend D-förmigen Querschnitt eines zweiten Lumens (362) des Katheters (350), und der Durchgangsausgang (322) ebenfalls einen D-förmigen Querschnitt hat, um darin den entsprechend D-förmigen Querschnitt des ersten proximalen Schlauches des Katheters aufzunehmen.

3. Der Kathetertunnelungsadapter (10) gemäß Anspruch 1, wobei die flexible Arm (30) einen länglichen Abschnitt (32) aufweist, der angepasst ist, leicht zu der Längsachse des Durchgangs (18) und dem ersten proximalen Schlauch (52) des Katheters hin während des Tunnelns biegbare zu sein.

4. Kathetertunnelungsadapter (10) gemäß Anspruch 3, wobei der lange Abschnitt (32) einen abgeflachten Querschnitt hat, der so orientiert ist, dass...
1. Adaptateur de tunnellisation de cathéter (10) destiné à être raccordé à une extrémité proximale d’un cathéter à lumières multiples (50), l’adaptateur comprenant un corps généralement allongé (12) présen-
l'adaptateur comprend un bras souple (30) qui fait saillie de manièr e distale vis-à-vis de l'extrémité distale de l'adaptateur (16), est décalé latéralement par rapport à l'extrémité distale, et se termine par un bouchon allongé (40) conçu pour se loger à étanchéité dans l'extrémité distale d'un deuxième tube proximal (54) du cathéter (50) et obstruer ainsi une deuxième lumière (62) du cathéter.

3. Adaptateur de tunnellisation de cathéter (10) selon la revendication 1, dans lequel le bras souple (30) comprend une section allongée (32) conçue pour pouvoir être aisément déviée en direction de l'axe longitudinal du passage (18) et du premier tube proximal (52) du cathéter lors de la tunnellisation.

4. Adaptateur de tunnellisation de cathéter (10) selon la revendication 3, dans lequel la section allongée (32) présente une section transversale aplatie orientée de telle sorte que le bras souple (30) puisse être aisément dévié en direction d'un axe longitudinal du passage (18).

5. Adaptateur de tunnellisation de cathéter (10) selon la revendication 3, dans lequel le bras souple (30) comprend un matériau mou facilitant la flexion du bras souple.

6. Adaptateur de tunnellisation de cathéter (10) selon la revendication 3, dans lequel le bras souple (30) comprend un élargissement (36) situé de manière proximale vis-à-vis du bouchon (40) présentant un diamètre maximal au moins aussi grand qu'un diamètre extérieur du deuxième tube proximal (54) et définissant un épauplement formant butée orienté de manière distale (38) destiné à venir en butée contre l'extrémité proximale (58) du deuxième tube proximal.

7. Adaptateur de tunnellisation de cathéter (10) selon la revendication 6, dans lequel l'élargissement (36) est tronconique, son diamètre augmentant en allant dans le sens distal vers le bouchon (40).

8. Adaptateur de tunnellisation de cathéter (10) selon la revendication 3, dans lequel la section allongée (32) du bras souple (30) s'étend à partir d'une surface externe du corps d'adaptateur (12) à un angle compris entre 3 et 15 degrés par rapport à l'axe longitudinal.

9. Ensemble composé de l'adaptateur (10) selon l'une quelconque des revendications 1 à 10 et d'un cathéter à double lumière (50) fixé à celui-ci au niveau de l'extrémité distale (16) de l'adaptateur.

10. Ensemble selon la revendication 11, comprenant en outre un stylet (70) s'étendant dans l'entrée (20) et à travers l'ensemble, et comportant une embase proximale (74) fixée de manière amovible à l'extrémité proximale (14) de l'adaptateur.

11. Ensemble selon la revendication 11, comprenant en outre un stylet (70) s'étendant dans l'entrée (20) et à travers l'ensemble, et comportant une embase proximale (74) fixée de manière amovible à l'extrémité proximale (14) de l'adaptateur.

12. Ensemble selon la revendication 11, comprenant en outre un stylet (70) s'étendant dans l'entrée (20) et à travers l'ensemble, et comportant une embase proximale (74) fixée de manière amovible à l'extrémité proximale (14) de l'adaptateur.

13. Ensemble selon la revendication 11, comprenant en outre un stylet (70) s'étendant dans l'entrée (20) et à travers l'ensemble, et comportant une embase proximale (74) fixée de manière amovible à l'extrémité proximale (14) de l'adaptateur.

14. Ensemble selon la revendication 11, comprenant en outre un stylet (70) s'étendant dans l'entrée (20) et à travers l'ensemble, et comportant une embase proximale (74) fixée de manière amovible à l'extrémité proximale (14) de l'adaptateur.

15. Procédé d'accouplement d'un adaptateur de tunnellisation (10) à une extrémité proximale d'un cathéter à double lumière (50), comprenant les étapes suivantes :
à travers lui depuis une entrée (20) au niveau de l'extrémité proximale jusqu'à une sortie (22) au niveau de l'extrémité distale, l'entrée de l'adaptateur étant conçue pour recevoir de manière amovible une extrémité distale (84, 94) d'un dispositif de tunnellisation (80, 90) ; fournir un cathéter à double lumière (50) ; caractérisé en ce que l'adaptateur comprend un bras souple (30) s'étendant de manière distale au-delà de l'extrémité distale (16) et se terminant par un bouchon (40) s'étendant de manière distale, espacé latéralement de l'axe longitudinal de l'adaptateur et en ce que le procédé comprend en outre les étapes suivantes :

16. Procédé d'accouplement d'un adaptateur de tunnellisation (10) à un cathéter (50) selon la revendication 15, comprenant en outre l'étape consistant à raccourcir la longueur du deuxième tube proximal (54) de telle sorte que la fixation des premier et deuxième tubes proximaux (52, 54) à l'adaptateur permette aux premier et deuxième tubes proximaux de rester en position adjacente l'un par rapport à l'autre.

17. Procédé d'accouplement d'un adaptateur de tunnellisation (10) à un cathéter (50) selon l'une quelconque des revendications 15 et 16, comprenant en outre l'étape consistant à accoupler une extrémité de raccordement (84, 94) d'un dispositif de tunnellisation (80, 90) à l'entrée (20) du passage de l'adaptateur.
FIG. 4

FIG. 5
FIGURE 10

PROVIDE CATHETER ASSEMBLY
WITH ADAPTER AND STYLET

[RETROGRADE TUNNELING --
WITH STYLET:]  

CREATE INCISION, INSERT
GUIDE WIRE DISTAL END INTO
INCISION; DILATE INCISION

INSERT GUIDE WIRE INTO
CATHETER BY THREADING PROX-
IMAL GUIDE WIRE END INTO
DISTAL TIP AND THROUGH
ADAPTER BEYOND STYLET HUB

HOLD GUIDE WIRE IN PLACE AND
ADVANCE CATHETER DISTAL
PORTION INTO VEIN

REMOVE GUIDE WIRE AND
STYLET TOGETHER WHILE
PINCHING THE OPEN LUMEN

[RETROGRADE TUNNELING --
WITHOUT STYLET:]  

REMOVE STYLET FROM CATHETER
/ADAPTER ASSEMBLY, DISCARD
STYLET; CLAMP THE OPEN LUMEN

CREATE INCISION; INSERT GUIDE
WIRE DISTAL END INTO INCISION;
DILATE INCISION; INSERT
SHEATH OVER GUIDE WIRE
PROXIMAL END UP TO INCISION

INSERT GUIDE WIRE INTO
CATHETER BY THREADING PROX-
IMAL END INTO DISTAL TIP AND
THROUGH AND BEYOND ADAPTER

INSERT THE CATHETER INTO AND
THROUGH SHEATH; REMOVE AND
DISCARD SHEATH; PUSH CATHE-
TER DISTAL PORTION INTO VEIN

[TUNNELING]

ATTACH TUNNELER TO ADAPTER  
FORM SUBCUTANEOUS TUNNEL

FORM SUBCUTANEOUS TUNNEL
WHILE PULLING ADAPTER
THROUGH TUNNEL

ATTACH TUNNELER TO ADAPTER  
PULL ADAPTER THROUGH TUNNEL

CLAMP BOTH PROXIMAL TUBES

SEVER PROXIMAL TUBES ADJACENT TO
ADAPTER; DISCARD ADAPTER AND TUNNELER

ATTACH EXTENSION ADAPTERS
TO LUMENS; REMOVE CLAMPS
REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader’s convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 20040092863 A [0005]
- US 20040176739 A [0006] [0017]
- US 7261708 B [0006] [0023]
- US 6991625 B [0019]