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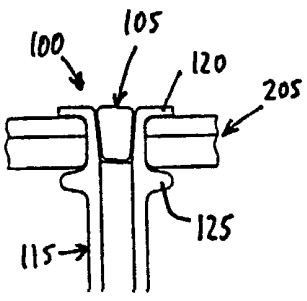
WO 01/52922 A1

(54) Title: TRANSDERMAL SPACER



(57) Abstract: Hemodialysis access device in the form of a transdermal spacer (100) comprising a transdermal cannula (115) having a flange (120) so as to prevent the transdermal cannula from moving too far into the body tissue and/or a second flange (125) for preventing the transdermal cannula from protruding too far out of the skin. The transdermal cannula also having a transdermal plug (105) which sits in and closes off access to the lumen of the transdermal cannula, but may be removed to permit insertion of a transcutaneous needle.

TRANSDERMAL SPACER

Field Of The Invention

This invention relates to hemodialysis in general, and more particularly to apparatus and methods for effecting the same.

Background Of The Invention

A healthy kidney removes toxic wastes and excess water from the blood. In End Stage Renal Disease ("ESRD"), or chronic kidney failure, the kidneys progressively stop performing these essential functions over a long period of time. When the kidneys fail, a patient dies within a short period of time unless that patient receives dialysis treatment for the rest of that patient's life or undergoes transplantation of a healthy, normal kidney. Because few kidneys are available for transplantation, the overwhelming majority of patients with ESRD receive dialysis treatment.

Hemodialysis therapy is an extracorporeal (i.e., outside the body) process which removes toxins and water from a patient's blood. A hemodialysis machine

pumps blood from the patient, through a dialyzer, and then back to the patient. The dialyzer removes the toxins and water from the blood by a membrane diffusion principle. Typically, a patient with chronic kidney disease required hemodialysis three time per week for 3-6 hours per session. Removing blood from the body requires a vascular access to the patient's blood system.

Hemodialysis access systems have been developed which comprise a subcutaneous port and catheter.

More particularly, and looking now at Figs. 1 and 2, such systems generally comprise a port 5 which is adapted to be positioned subcutaneously within the chest 10 of the patient, and a catheter 15 which is connected to port 5 and extends subcutaneously into the vascular system 20 of the patient. Port 5 includes an output bay 25 and an input bay 30. Catheter 15 includes a pair of lumens: a suction lumen 35 for connecting the port's output bay 25 to the vascular system of the patient, and a return lumen 40 for connecting the port's input bay 30 to the vascular system of the patient. The port also includes a valve (not shown in Figs. 1 and 2) disposed intermediate the

output bay 25 and the suction lumen 35, and a valve (not shown in Figs. 1 and 2) disposed intermediate the input bay 30 and the return lumen 40, such that blood will be prevented from flowing out of the port's output and input bays at inappropriate times.

By way of example but not limitation, hemodialysis access systems of the type comprising a subcutaneous port and catheter are described and illustrated in, or are otherwise referred to in, (1) U.S. Patent No. 5,989,206, issued 11/23/99 to Frank R. Prosl et al. for APPARATUS AND METHOD FOR THE DIALYSIS OF BLOOD (Attorney's Docket No. PROSL-1); (2) pending U.S. Patent Application Serial No. 09/251,572, filed 02/17/99 by Harold M. Martins et al. for APPARATUS AND METHOD FOR THE DIALYSIS OF BLOOD, METHOD FOR FABRICATING THE SAME, AND METHOD FOR THE DIALYSIS OF BLOOD (Attorney's Docket No. PROSL-3 CIP); and (3) pending U.S. Patent Application Serial No. 09/226,956, filed 01/08/99 by Brian K. Estabrook et al. for APPARATUS AND METHOD FOR SUBCUTANEOUS ACCESS TO THE VASCULAR SYSTEM OF A PATIENT (Attorney's Docket No. PROSL-4).

The aforementioned U.S. Patent No. 5,989,206, and the aforementioned U.S. Patent Applications Serial Nos. 09/251,572 and 09/226,956, are all hereby incorporated herein by reference.

When a patient is to undergo an active dialysis session, the subcutaneous port 5 is accessed by a pair of transcutaneous needles. More particularly, a first transcutaneous needle is passed through the skin of the patient so that the first transcutaneous needle's distal tip connects into the output bay 25 of the port, and a second transcutaneous needle is passed through the skin of the patient so that the second transcutaneous needle's distal tip connects into the input bay 30 of the port. As the first transcutaneous needle connects into the output bay of the port, the first transcutaneous needle opens the output bay's associated valve to fluid flow, and as the second transcutaneous needle connects into the input bay of the port, the second transcutaneous needle opens the input bay's associated valve to fluid flow. Then the proximal ends of the two transcutaneous needles are connected to the input and output bays of the dialysis machine (not shown) with appropriate tubing. Once this

has been done, dialysis may be undertaken in ways well known in the art, with "dirty" blood being withdrawn from the patient through the catheter's suction lumen 35, and with "clean" blood being returned to the patient through the catheter's return lumen 40. At the conclusion of the dialysis session, the tubing is removed from the proximal ends of the two transcutaneous needles, and the two needles are withdrawn from the port. It is to be appreciated that as the two transcutaneous needles are withdrawn from the port, the valves associated with the port's output and input bays automatically close, so as to prevent the patient from "bleeding out" through the port.

By way of example but not limitation, a transcutaneous needle is described and illustrated in the aforementioned U.S. Patent Application Serial No. 09/226,956, which application has already been incorporated herein by reference.

For convenience, Fig. 3 shows a transcutaneous needle 45 such as is disclosed in the above-identified U.S. Patent Application Serial No. 09/226,956. As is explained in more detail in the above-identified U.S. Patent Application Serial No. 09/226,956, such

transcutaneous needles preferably include an associated obturator 50 which is positioned within the bore of the needle while the needle is advanced through the skin of the patient so as to prevent the needle from coring tissue. Once the needle has been successfully docked with the port, obturator 50 is removed from the needle and then appropriate blood tubing is connected to the proximal end of the needle.

As noted above, a patient with chronic kidney disease typically requires hemodialysis three times per week. This means that with hemodialysis access systems of the sort utilizing ports, the patient must typically undergo six needle punctures per week (i.e., two needle punctures at each of three sessions). In practice, medical personnel try to alternate the locations of the needle punctures so as to prevent undue trauma to the patient's skin. However, it is impossible to eliminate tissue trauma altogether. In addition, patients typically suffer some discomfort as the transcutaneous needles are passed through the skin.

Objects Of The Invention

Accordingly, a primary object of the present invention is to provide a transdermal spacer for use with a subcutaneous hemodialysis port, whereby an opening through the skin of the patient may be maintained between active dialysis sessions.

Another object of the present invention is to provide an improved method for effecting hemodialysis, wherein a transdermal spacer is used to maintain an opening through the skin of the patient so as to provide ready access to a subcutaneous hemodialysis port.

Summary Of The Invention

In one form of the invention, there is provided a transdermal spacer for maintaining an opening through the skin of a patient between active dialysis sessions, the transdermal spacer comprising a plug having a proximal end and a distal end.

In another form of the invention, there is provided a transdermal spacer for maintaining an opening through the skin of a patient between active dialysis sessions, the transdermal spacer comprising: a

transdermal cannula having a proximal end and a distal end, and a lumen extending between the proximal end and the distal end; and a closure having a proximal end and a distal end, the closure being sized to close off the lumen.

In still another form of the invention, there is provided a method for performing dialysis on the blood of a patient, the method comprising: (a) installing a hemodialysis port subcutaneously in the body of the patient, and installing a transdermal spacer percutaneously in the body of the patient; (b) removing at least a portion of the transdermal spacer so as to provide percutaneous access to the hemodialysis port; (c) passing a percutaneous hemodialysis needle across the space previously occupied by the removed structure; and (d) performing dialysis on the blood of the patient.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is

to be considered together with the accompanying drawings wherein:

Fig. 1 is a schematic side view showing a subcutaneous port and catheter deployed in a patient's body;

Fig. 2 is an enlarged schematic side view of the hemodialysis port and catheter deployed in the body of the patient;

Fig. 3 is a side view, in section, of a typical transcutaneous needle which may be used in conjunction with a subcutaneous hemodialysis port;

Fig. 4 is a schematic side view of a transdermal spacer formed in accordance with the present invention;

Fig. 5 is a schematic side view of an alternative form of transdermal spacer formed in accordance with the present invention;

Fig. 6 is a schematic side view of the distal portion of another form of transdermal spacer formed in accordance with the present invention;

Fig. 7 is a schematic side view of the proximal portion of another form of transdermal spacer formed in accordance with the present invention;

Fig. 8 is a schematic side view of the proximal portion of still another form of transdermal spacer formed in accordance with the present invention;

Figs. 9 and 10 are schematic side views of the proximal portion of yet another form of transdermal spacer formed in accordance with the present invention;

Fig. 11 is a schematic side view of another embodiment of the present invention; and

Fig. 12 is a schematic side view of yet another embodiment of the present invention.

Detailed Description Of The Preferred Embodiments

Looking now at Fig. 4, there is shown a novel transdermal spacer 100 formed in accordance with the present invention. Transdermal spacer 100 comprises a plug 105 sized to fill an opening 200 formed in the skin 205 of a hemodialysis patient. More particularly, between active dialysis sessions, plug 105 sits in, and maintains, opening 200 in skin 205. However, at the start of an active dialysis session, plug 105 may be removed from opening 200 so as to permit a transcutaneous needle to pass through opening 200 and access the underlying port 5, and hence catheter 15.

If desired, the proximal end of plug 105 may include some sort of removal means (e.g., a recessed handle) to facilitate withdrawal of plug 105 from opening 200.

Plug 105 preferably has an antimicrobial agent associated with the plug. For example, plug 105 might be somewhat porous so that it can carry an antimicrobial agent. Alternatively, plug 105 could be formed out of non-porous material and have an antimicrobial coating applied thereto.

If desired, plug 105 may have a clotting promoter associated with the plug so as to stop bleeding. For example, plug 105 might be somewhat porous so that it can carry a clotting promoter. Alternatively, plug 105 could be formed out of a non-porous material and have an antimicrobial coating applied thereto. By way of example but not limitation, the clotting promoter might be vitamin K or collagen, etc.

If desired, and looking now at Fig. 5, plug 105 may include a proximal flange 110. Proximal flange 110 is adapted to engage the outer surface 210 of skin 205, so as to prevent excess insertion of plug 105. If desired, proximal flange 110 may include a layer of

self-adhesive material 111 on its underside to bind the flange to the patient's skin.

Looking next at Fig. 6 and 7, in another form of the invention, transdermal spacer 100 may comprise a transdermal cannula 115 in combination with plug 105. Transdermal cannula 115 is adapted to extend through opening 200 in skin 205 and at least part way toward port 5. In one preferred form of the invention, transdermal cannula 115 is configured, and disposed, so that its distal end engages the mouth of either an input bay or an output bay of port 5, but not to open the valve 55 (Fig. 6) of that bay. The proximal end of transdermal cannula 115 is adapted to sit in, and hold open, the opening 200 in skin 205, and to releasably receive plug 105. More particularly, between active dialysis sessions, transdermal cannula 115 sits in, and hold open, opening 200 in skin 205, and plug 105 sits in, and closes off, the interior lumen of transdermal cannula 115. However, at the start of an active dialysis session, plug 105 may be removed from the interior of transdermal cannula 115 so as to permit a transcutaneous needle to pass through the cannula to access port 5.

Transdermal cannula 115 preferably has an antimicrobial agent associated with the device. For example, transdermal cannula 115 might be somewhat porous so that it can carry an antimicrobial agent. Alternatively, transdermal cannula 115 could be formed out of a non-porous material and have an antimicrobial coating applied thereto. Or, where transdermal cannula 115 is configured, and disposed, so that its distal end engages the mouth of either an input bay or an output bay of port 5, transdermal cannula 115 may have its interior filled with an antimicrobial agent between access events and its side wall constructed to permit the antimicrobial agent to permeate through the side wall between access events.

If desired, transdermal cannula 115 may have a clotting promoter associated with the device so as to stop bleeding. For example, transdermal cannula 115 might be somewhat porous so that it can carry a clotting promoter. Alternatively, transdermal cannula 115 could be formed out of a non-porous material and have a clotting promoter applied thereto. By way of example but not limitation, the clotting promoter might be vitamin K or collagen, etc.

If desired, transdermal cannula 115 may be provided with a proximalmost flange 120 (Fig. 7) so as to prevent the transdermal cannula from moving too far into the body tissue, and/or a second flange 125 (Fig. 8) for preventing the transdermal cannula from protruding too far out of the skin. Again, if desired, proximalmost flange 120 may include a layer of self-adhesive material 121 on its underside to bind the flange to the patient's skin.

Furthermore, and looking now at Figs. 9 and 10, where the transdermal cannula 115 is adapted to have its distal end in engagement with port 5, the body of transdermal cannula 115 may be formed with a bellows section 130 which can permit some movement of skin 205 and port 5 toward and away from one another without unseating transdermal cannula 115.

As noted above, port 5 normally has two output/input bays 25, 30 (Fig. 2), and is normally accessed by two transcutaneous needles. Accordingly, a pair of plugs 105 will normally be used, either to close off skin opening 200 directly (Figs. 4 and 5) or to close off transdermal cannula 115 (Figs. 7 and 8). To that end, if desired, a pair of plugs 105 may be

connected together, e.g., by a single flange 110, in the manner shown in Fig. 11.

As noted above, transdermal cannula 115 is intended to be selectively closed off by plug 105 between active dialysis sessions. Alternatively, and looking now at Fig. 12, a top cap 130 may also be used to close off transdermal cannula 115. Furthermore, if desired, a pair of caps 130 may be joined to one another, in a manner analogous to that shown in Fig. 11, so as to close off a pair of transdermal cannulas 115.

It will be appreciated that various changes may be made to the preferred embodiments disclosed above without departing from the scope of the present invention.

By way of example but not limitation, in the foregoing description, the invention is discussed in the context of a port 5 having an output bay 25 and an input bay 30. However, the invention could also be used with a pair of ports, where one port contains the output bay 25 and the other port contains the input bay 30. And the invention can be used independently of hemodialysis ports, e.g., the invention can be used to

maintain an opening through the skin of a patient so as to provide access to some other internal structure.

By way of further example but not limitation, in the foregoing description, the invention is discussed in the context of a transcutaneous needle 45 of the sort having an associated obturator 50. However, the invention could also be used with a transcutaneous needle not having an associated obturator; indeed, the use of the transdermal spacer eliminates the need for an obturator in many cases.

Still other modifications will be apparent to those skilled in the art.

What Is Claimed Is:

1. A transdermal spacer for maintaining an opening through the skin of a patient between active dialysis sessions, said transdermal spacer comprising a plug having a proximal end and a distal end.

2. A transdermal spacer according to claim 1 wherein said plug is adapted for prolonged placement in the body of the patient.

3. A transdermal spacer according to claim 1 wherein said plug has a length which is substantially the same as the thickness of the patient's skin.

4. A transdermal spacer according to claim 1 wherein said plug has a diameter which is only slightly larger than the diameter of a percutaneous hemodialysis needle.

5. A transdermal spacer according to claim 1 wherein said plug comprises stabilization means for stabilizing the position of said plug relative to the opening in the patient's skin.

6. A transdermal spacer according to claim 5 wherein said stabilization means comprise a flange disposed about said proximal end of said plug.

7. A transdermal spacer according to claim 1 wherein said plug comprises removal means for facilitating removal of said plug in preparation for an active dialysis session.

8. A transdermal spacer according to claim 1 wherein said plug comprises antimicrobial material associated with said plug.

9. A transdermal spacer according to claim 8 wherein said antimicrobial material comprises a coating applied to said plug.

10. A transdermal spacer according to claim 8 wherein said antimicrobial material is incorporated into the body of said plug.

11. A transdermal spacer for maintaining an opening through the skin of a patient between active dialysis sessions, said transdermal spacer comprising:

a transdermal cannula having a proximal end and a distal end, and a lumen extending between said proximal end and said distal end; and

a closure having a proximal end and a distal end, said closure being sized to close off said lumen.

12. A transdermal spacer according to claim 11 wherein said transdermal cannula is adapted for prolonged placement in the body of the patient.

13. A transdermal spacer according to claim 11 wherein said transdermal cannula has a length which is substantially the same as the thickness of the patient's skin.

14. A transdermal spacer according to claim 11 wherein said lumen has a diameter which is only slightly larger than the diameter of a percutaneous hemodialysis needle.

15. A transdermal spacer according to claim 11 wherein said transdermal cannula comprises stabilization means for stabilizing the position of said transdermal cannula relative to the opening in the patient's skin.

16. A transdermal spacer according to claim 15 wherein said stabilization means comprise a flange disposed about said proximal end of said transdermal cannula.

17. A transdermal spacer according to claim 11 wherein said closure comprises removal means for facilitating removal of said closure in preparation for an active dialysis session.

18. A transdermal spacer according to claim 11 wherein said transdermal spacer comprises antimicrobial material associated with said transdermal spacer.

19. A transdermal spacer according to claim 18 wherein said antimicrobial material comprises a coating applied to said transdermal cannula.

20. A transdermal spacer according to claim 18 wherein said antimicrobial material is incorporated into the body of said transdermal cannula.

21. A transdermal spacer according to claim 18 wherein said antimicrobial material comprises a coating applied to said closure.

22. A transdermal spacer according to claim 18 wherein said antimicrobial material is incorporated into the body of said closure.

23. A transdermal spacer according to claim 18 wherein said closure comprises a relatively soft,

porous body, and further wherein said antimicrobial material is held by said body.

24. A transdermal spacer according to claim 11 wherein said closure comprises a plug having a proximal end and a distal end, said plug being sized to fit within said lumen.

25. A transdermal spacer according to claim 11 wherein said closure comprises a cap adapted to fit over the proximal end of said transdermal cannula.

26. A transdermal spacer according to claim 11 wherein said distal end of said transdermal cannula is adapted to mate with a hemodialysis port subcutaneously installed in said patient.

27. A transdermal spacer according to claim 26 wherein the body of said transdermal cannula comprises a bellows construction.

28. A method for performing dialysis on the blood of a patient, said method comprising:

(a) installing a hemodialysis port subcutaneously in the body of the patient, and installing a transdermal spacer percutaneously in the body of the patient;

(b) removing at least a portion of said transdermal spacer so as to provide percutaneous access to the hemodialysis port;

(c) passing a percutaneous hemodialysis needle across the space previously occupied by the removed structure; and

(d) performing dialysis on the blood of the patient.

29. A transdermal spacer according to claim 6 wherein a layer of self-adhesive material is attached to said flange.

30. A transdermal spacer according to claim 16 wherein a layer of self-adhesive material is attached to said flange.

31. A transdermal spacer according to claim 18 wherein said antimicrobial material fills the interior of said transdermal cannula.

32. A transdermal spacer according to claim 31 wherein the side wall of said transdermal cannula is constructed to permit said antimicrobial material to permeate through said side wall.

33. A transdermal spacer according to claim 1 wherein said plug comprises a clotting promoter associated with said plug.

34. A transdermal spacer according to claim 11 wherein said transdermal spacer comprises a clotting promoter associated with said transdermal spacer.

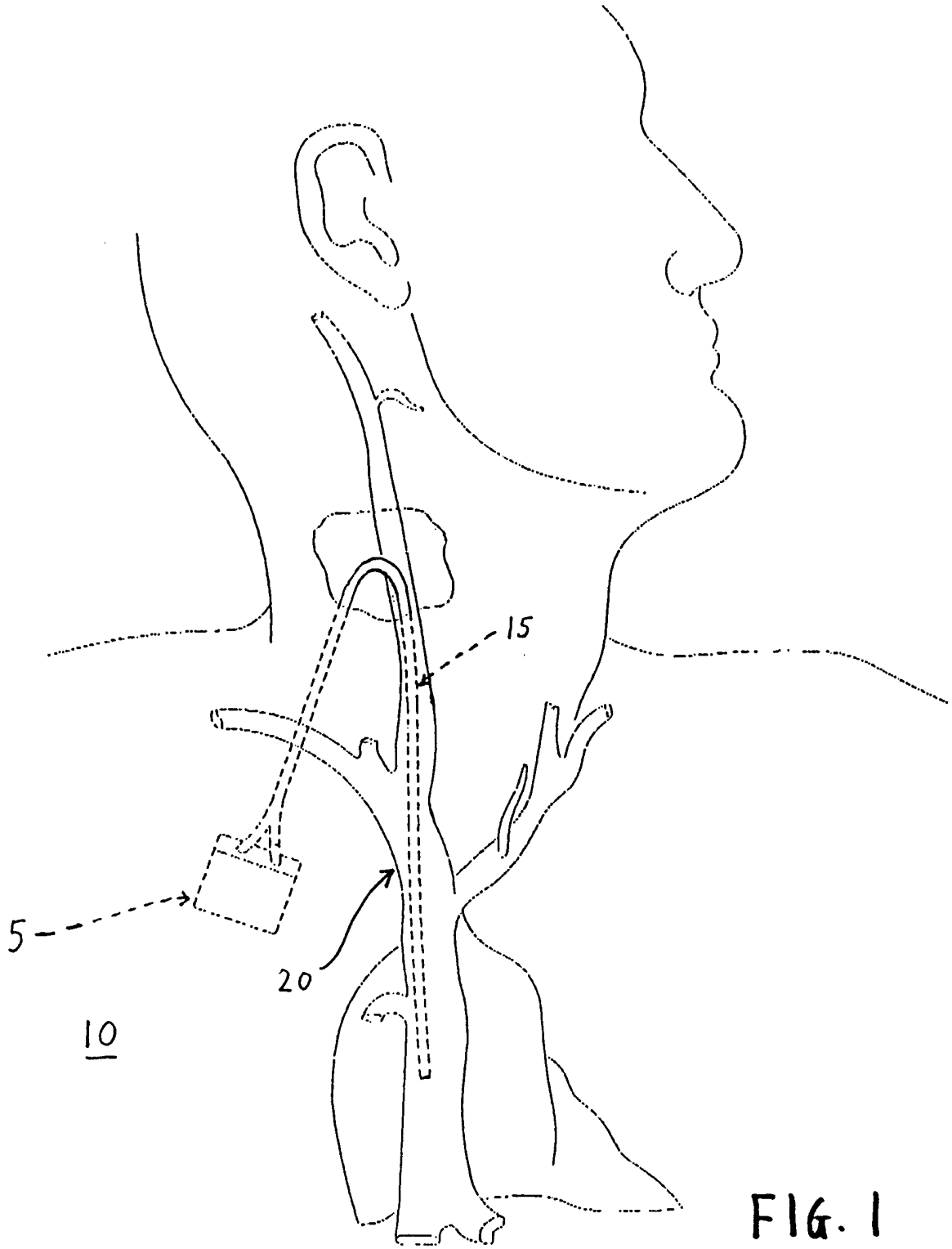


FIG. 1

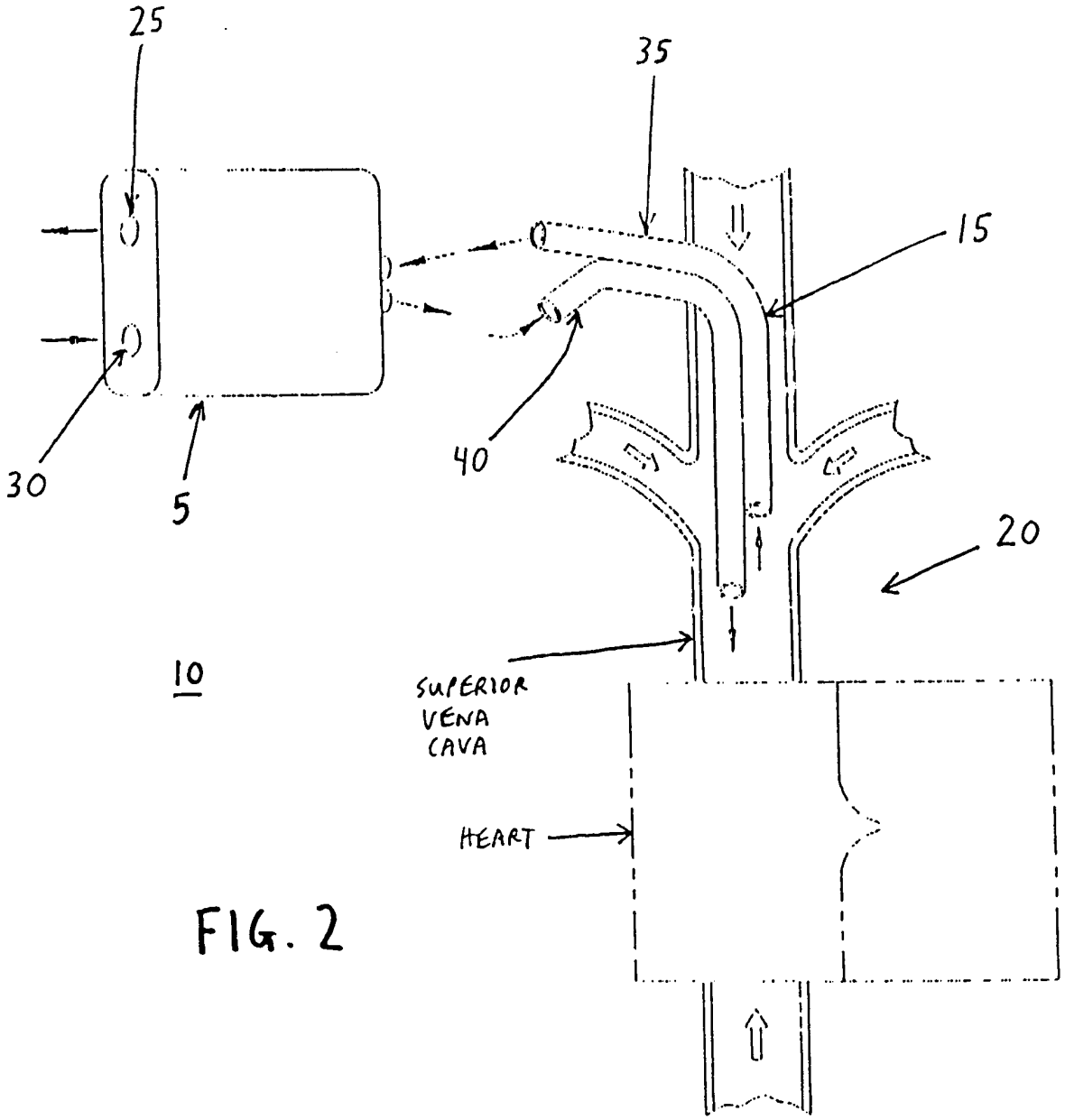


FIG. 2

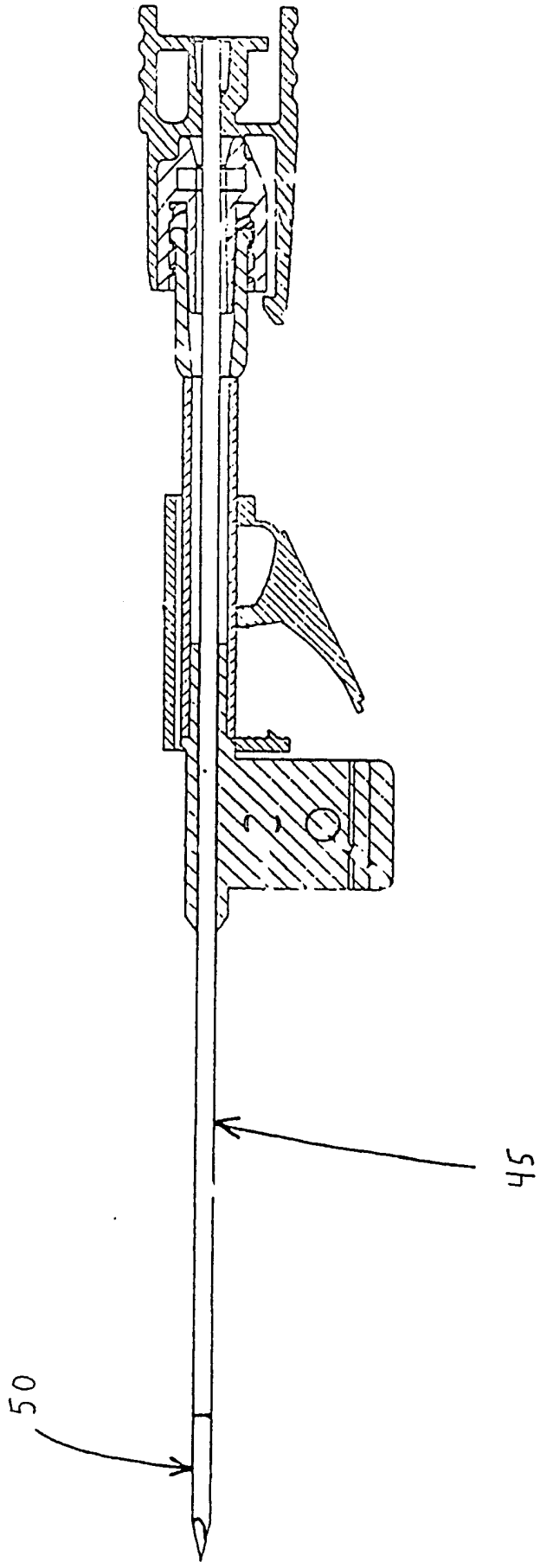


FIG. 3

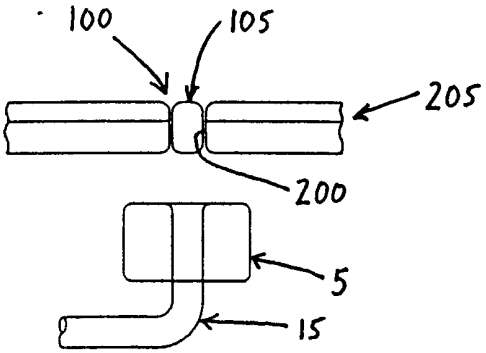


FIG. 4

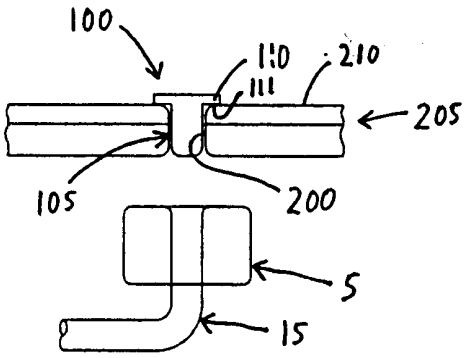


FIG. 5

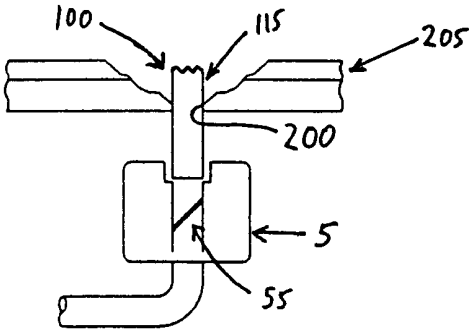


FIG. 6

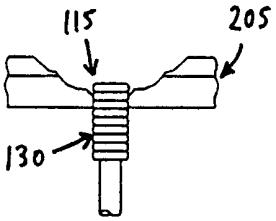


FIG. 9

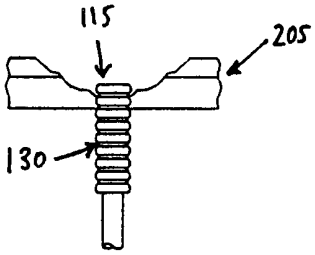


FIG. 10

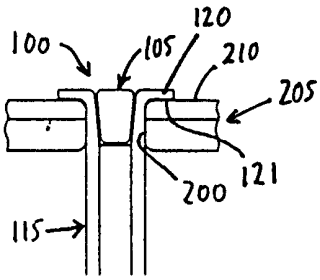


FIG. 7

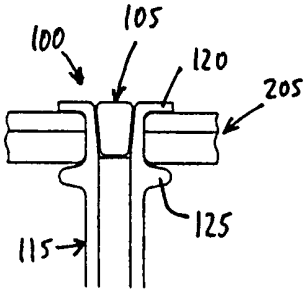


FIG. 8

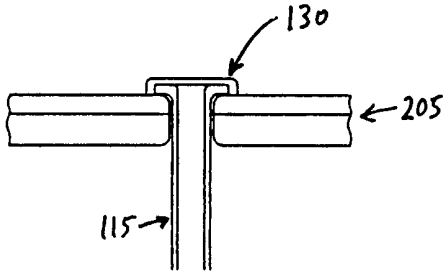


FIG. 12

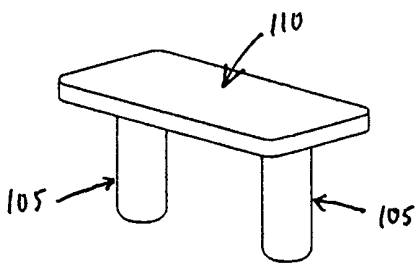


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/01872

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 5/00, 5/14
US CL :604/256

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/256, 8, 11, 13

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 5,116,357 A (EBERBACH) 26 MAY 1992, SEE FIGS. 16 & 21.	1-7,11-14, 17,24,26 ——— 8-10,18, 21-24,31, 33,34
X — Y	US 5,192,301 A (KAMIYA ET AL.) 09 MARCH 1993, SEE FIG. 4.	1-7 ——— 8-10,18,21, 22

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 25 APRIL 2001	Date of mailing of the international search report 02 MAY 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JENNIFER MAYNARD Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (July 1998)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/01872

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 5,571,181 A (LI) 05 NOVEMBER 1996, SEE FIGS. 2B & 3.	11,15,16, 25 ——— 19
X — Y	US 5,645,565 A (RUDD ET AL.) 08 JULY 1997, SEE FIG. 5.	1-7 ——— 8-10,33