

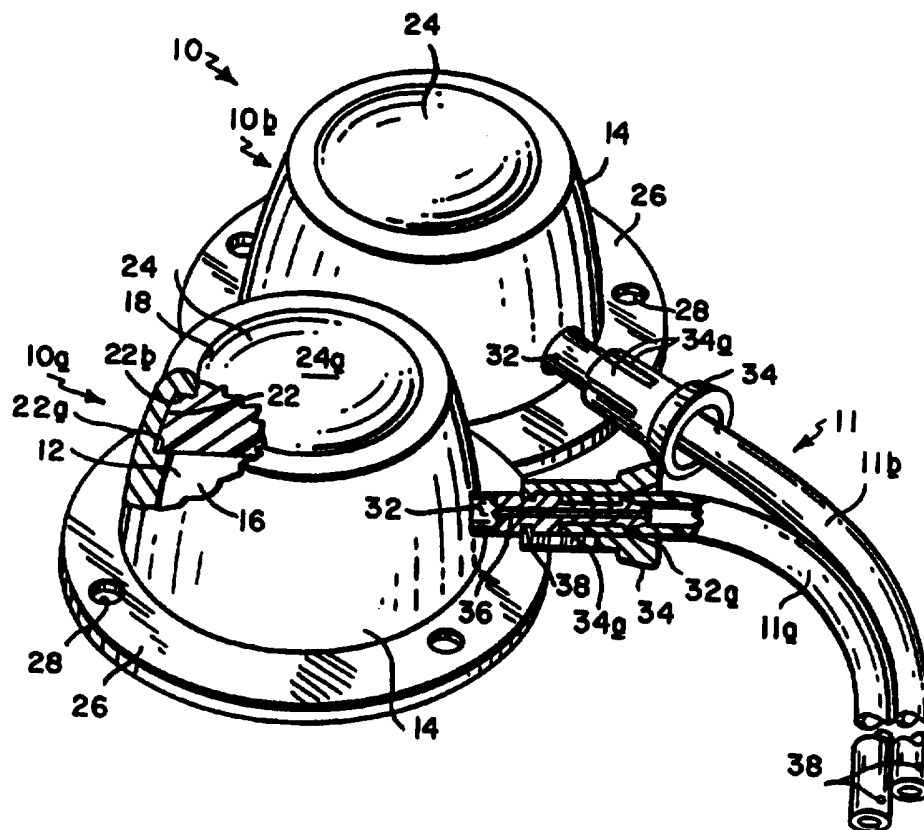


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(21) International Application Number: PCT/US96/03814 (22) International Filing Date: 21 March 1996 (21.03.96) (30) Priority Data: 08/407,166 21 March 1995 (21.03.95) US (71) Applicant: THEREX CORPORATION [US/US]; 1600 Providence Highway, Walpole, MA 02081 (US). (72) Inventor: MELSKY, Gerald, S.; 2 Dewey Road, Lexington, MA 02173 (US). (74) Agents: McKENNA, John, F. et al.; Cesari and McKenna, 30 Rowes Wharf, Boston, MA 02110 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: VASCULAR ACCESS SYSTEM**(57) Abstract**

A vascular access system has an implantable head which includes a pair of similar access ports, each port having an internal chamber with an open mouth, an outlet cannula extending from the port and being in fluid communication with the corresponding chamber and a domed septum closing the mouth of the corresponding chamber. A flexible dual-lumen catheter is connected to the head. The catheter has a pair of unitary closely spaced-apart parallel lumens which are separable so that the catheter proximal end can be connected to the head's outlet cannulas, with the outlet cannula of one port being received in one of the catheter lumens and the outlet cannula of the other port being received in the other catheter lumen. Locking sleeves are provided on the head for locking the outlet cannulas in their respective catheter lumens and a special access needle is provided for accessing the head to avoid coring of the head's septa.



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VASCULAR ACCESS SYSTEM

FIELD OF THE INVENTION

5 This invention relates to a vascular access system. It relates more particularly to a vascular access device and associated access needle which facilitate hemapheresis.

BACKGROUND OF THE INVENTION

10 For patients with certain chronic conditions, it is often necessary to remove blood from a patient's body in order to collect blood cells, remove a specific cell type or for plasma exchange and then to return blood to the body as quickly as possible. For example, during plasmapheresis, blood is withdrawn from the patient's vasculature using a needle attached to a tube leading to a centrifuge. The centrifuge separates the blood plasma from the
15 other blood components which are then mixed with fresh plasma and returned to the patient's body via a second tube and needle. In some cases, this procedure must be repeated as often as twelve times per month.

In order to obtain the requisite blood flow to and from the patient, e.g., 85 ml/min, an external catheter is often used as the principle hemapheresis
20 access. The catheter consists of a tube, generally of silicone rubber, having a round or oval crosssection and two lumens. The distal end of the catheter resides in the patient's vasculature. A common location for that end is the superior vena cava. The proximal end of the catheter lies outside the patient's skin so that it is accessible by medical personnel performing the
25 procedure. That end is usually fitted with Luer connectors for coupling the catheter to conduits leading to the external separating machine that processes the patient's blood.

The connectors at the proximal end of the catheter, while offering a "needle free" means of connecting the patient to the external machine, are
30 difficult to maintain in a sterile condition. Once these connectors become

contaminated, the organisms may be transmitted to the patient during the procedure. Also, even though these catheters are flushed with heparinized solutions after each use, their lumens frequently become occluded with thrombus. This is due, in part, to blood being drawn into the lumens in order to make up for the volume of fluid lost by the process of diffusion through the wall of that segment of the catheter which resides outside of the patient.

To avoid the problem of infection, implantable dual-chamber vascular access devices' have been developed which provide direct access to the vascular system of a patient receiving extracorporeal blood treatment. Such devices' are disclosed in patent 5,041,098. One embodiment comprises a head consisting of a pair of ports joined at their peripheries. Each port has an internal chamber and a self-sealing septum spanning the open face of the chamber to establish a closed reservoir within the port. A tubular cannula extends from the side wall of each port to establish fluid communication between the reservoir and an external catheter leading to the infusion site. The proximal end of each catheter is permanently connected to a coupling member which is releasably connected to the corresponding port's outlet cannula by means of a coupler. The distal ends of the two catheters are usually cut to length so that the two lumens terminate about one inch apart. Also, in some cases, there may be side openings adjacent the ends of the catheters.

In use, that prior device is surgically implanted within the patient's body so that the catheters access the vasculature through a major vessel such as the subclavian vein. The head is surgically implanted within the body, e.g., in a pocket in the musculature of the chest, and the proximal ends of the catheters are tunneled to this pocket and connected to the head using the couplers.

That known device is accessed by inserting hypodermic needles connected to the external machine through the septa into the internal chambers of the two ports. Blood is withdrawn from the vasculature through

one port and introduced or re-introduced into the vasculature through the other port.

Vascular access devices typified by the ones in the above patent are disadvantaged in that they allow only relatively low blood flow rates. This is because in order for the devices' septa to reseal, they must be penetrated by relatively small needles, i.e., 19 gauge or smaller diameter. Larger gauge needles result in coring of the septa and reduced puncture life. Such coring would require that the prior devices be replaced relatively often.

The prior devices of this general type are disadvantaged also because their outlet catheters have to be customized to the patient prior to implantation of the device. More particularly, the distance between the implantation site for the head, e.g., the subclavian pocket, and the infusion site, e.g., the superior vena cava, may vary from patient to patient depending upon the patient's size. Since the proximal end of the catheter is permanently fixed to the head itself or to a coupling member that is connected to the head, the critical distance for a given patient must be measured and the catheter cut to the proper length and permanently connected to the coupling member prior to implantation. The alternative is to utilize an access device having an unnecessarily long catheter and to accommodate the extra catheter length as a meandering or fold within the body. However, this results in an unwanted increase in the fluid flow resistance of the device.

Accordingly, it would be desirable to be able to provide a vascular access system especially suited for hemapheresis which allows a maximum amount of fluid flow to and from the infusion site and which can remain implanted in the body for a prolonged period.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the invention to provide an improved implantable vascular access device and system for hemapheresis.

Another object of the invention is to provide a device of this type which has a relatively long useful life.

A further object of the invention is to provide a vascular access device for hemapheresis which is relatively easy to implant.

5 Yet another object of the invention is to provide such a device which is no more expensive to make than prior comparable devices of this general type.

Other objects will in part, be obvious and will, in part, appear hereinafter.

10 The invention accordingly comprises the features of construction, combination of elements and arrangement of parts which will be exemplified in the following detailed description, and the scope of the invention will be indicated in the claims.

15 In general, the present system comprises an implantable vascular access device and associated needle for use in the extracorporeal treatment of blood or fractions thereof. The device includes dual access ports, each port having an internal chamber defined by the side and bottom walls of the port. A self-sealing, needle-penetrable septum closes the open top of each chamber. Each septum is quite thick, being dome shaped so it protrudes
20 from the top of the corresponding port. Consequently, when the device is implanted, the septa are relatively easy to locate. More importantly, the septa are not prone to leakage even after being penetrated a relatively large number of times by a relatively large diameter needle.

A separate outlet cannula extends from each port. The proximal end
25 of each cannula is in fluid communication with the chamber in the corresponding port. The opposite or distal end of each cannula is barbed so that the proximal end of a flexible resilient catheter can be engaged tightly over the barbed end. Preferably, the outlet cannula of each port carries a locking collar which can be slid over the proximal end of the catheter to hold
30 that end in place and to provide stress relief at that location.

In accordance with the invention, the two catheters associated with the two ports of the present access device are normally joined together along their lengths so that they form a unitary dual-lumen catheter. However, the two catheters sections, or at least their proximal end segments, are separable
5 much like the two insulated conductors of a standard lamp cord, so that the two catheter sections can be separated by pulling them apart.

When the device is implanted, the head is positioned in a sub-cutaneous pocket made by blunt dissection of tissue just below the clavicle. The distal end of the catheter is positioned at the junction of the superior
10 vena cava and the ventricular atrium by accessing the subclavian or jugular vein. The proximal end of the catheter is then tunneled to the pocket containing the head and trimmed so that it just reaches the head. Next, the proximal ends of the catheter sections are pulled apart and engaged over the outlet cannulas of the two ports comprising the head and locked in place with
15 the locking collars. Thus, at the time the device is implanted in a patient, its dual-lumen outlet catheter can be cut to exactly the right length to span the distance between the head and the infusion site for that particular patient. Thus, the catheter presents a minimum flow resistance to fluid flow for that
20 patient.

As we shall see, the system also includes an especially large needle, i.e., 16 gauge or less, to be described in more detail later for accessing the device. The needle has a hub and a stylet which occludes the lumen of the needle cannula during insertion of the needle through a septum of the access
25 device. With the stylet in place, the needle can penetrate the septum without coring the septum material. Once the needle is in place, the stylet may be removed and the hub of the needle cannula connected to a line leading to an external blood separation machine.

BRIEF DESCRIPTION OF THE DRAWING

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawing, in which:

- 5 FIG. 1 is an isometric view with parts broken away showing a vascular access device for hemapheresis incorporating the invention, and
- FIGS. 2A to 2C are diagrammatic views illustrating the operation of the overall vascular access system.

10 DESCRIPTION OF THE PREFERRED EMBODIMENT

- Referring to FIG. 1 of the drawing, our vascular access system comprises a head 10 connected to a catheter 11. The head includes a pair of substantially identical ports 10a and 10b joined at their peripheries. Each port has a bottom wall 12 and a generally cylindrical side wall 14 extending
- 15 up from the bottom wall so as to form an internal chamber 16 having an open mouth 18. A conical groove 22 is inscribed in the interior surface of wall 14 adjacent to mouth 18 for seating a needle-penetrable self-sealing septum 24. Septum 24 is "shoe-horned" into the mouth 18 so that its inner edge seats on the inner wall 22a of groove 22 and so that the outer edge of 22b of that
- 20 groove overhangs the septum, thereby retaining the septum 24 in place so that the septum spans mouth 18.

- Septum 24 has a rounded, raised central portion or dome 24a which protrudes from mouth 18. Thus, when the head 10 is implanted in the body, the raised portions 24a of septa 24 can be felt under the skin so that needles
- 25 can be aimed properly at the septa. Also, the extra thickness of the domed septa makes them less prone to leakage.

 Preferably, each port 10a, 10b is provided with a bottom flange 26 having suture holes 28 spaced around the flange so that when the head 10 is implanted in the body, it can be sutured to adjacent tissue.

An outlet cannula 32 extends from the side wall 14 of each port 10a, 10b. Each cannula 32 is in fluid communication with the internal chamber 16 of the corresponding port and the outer end of each cannula is barbed at 32a. Also, each cannula 32 carries a locking sleeve 34 which is slidable along that
5 cannula between an extended position shown in FIG. 1 wherein the sleeve is positioned over the barb 32a and a retracted position wherein the sleeve is spaced somewhat from that barb. The cylindrical body of each sleeve 34 is slitted to form a circular array of flexible, resilient tines 34a. The free ends of the tines have inwardly extending ribs 36 which are arranged to engage in a
10 circular groove 38 inscribed in the corresponding cannula 32 to releasably maintain sleeve 34 in its extended position shown in FIG. 1.

Outlet catheter 11 is composed of two sections 11a and 11b which are joined together along their lengths, but which are separable by pulling the two sections apart. To connect catheter 11 to the head 10, the proximal end of
15 the catheter is squared off and the two sections 11a and 11b are pulled apart a sufficient amount to enable the proximal end of catheter section 11a to be engaged over the outlet cannula 32 of port 10a and to enable the similar end of catheter section 11b to be slid onto the outlet cannula 32 of port 10b. Then, the two locking sleeves 34 are moved to their extended positions to
20 secure the proximal ends of the catheter sections to their respective ports and to provide stress relief for the catheter.

Preferably, the distal end of the catheter 11 is designed so that the exit points of the two catheter sections are spaced apart from one another by about 1 inch. This helps to reduce unwanted re-circulation of blood returning
25 to the patient's vasculature via one catheter section being drawn back immediately into the other catheter section. The distal ends of the two catheter sections 11a and 11b may also be provided with one or more side ports 38 to maximize blood flow through the device.

The other component of our system is a special access needle shown
30 generally at 42 in FIGS. 2A to 2C. Needle 42 includes a relatively large

diameter cannula 44, e.g., 12 to 16 gauge, having a stylet or obturator 46 which occludes the lumen of the cannula when the needle is inserted through septum 24 into port 10a or 10b. With the stylet in place, the needle cannula may penetrate septum 24 through the skin S as shown in FIG. 3A without
5 coring the septum.

Preferably, the stylet 46 is provided with a hub 52 at its proximal end which releasably engages to a connector or hub 54 at the proximal end of the cannula 44. Once needle 42 is inserted into the port 10a or 10b, the hub 52 may be de-coupled from connector 54 and the stylet 46 withdrawn from the
10 cannula as illustrated in FIG. 2B. Then, connector 54 may be coupled to a mating connector 56 attached to the end of a tube 58 connected to the external machine as shown in FIG. 2C.

Surgical placement of the illustrated device is similar to that of other conventional access devices. More particularly, the catheter 11 is implanted
15 under the skin S so that its distal end lies at the junction of the superior vena cava with the ventricular atrium. This may be accomplished by accessing the sub-clavean or jugular vein either by the Seldinger technique or by a direct cut-down. A kit containing a peel-away introducer/dilator, along with a guide wire and Seldinger needle, may be provided to facilitate the Seldinger
20 procedure. The head 10 may be implanted in a subcutaneous pocket made by blunt dissection of the tissue below the clavicle. Then, the proximal end of the catheter is tunneled to this pocket, trimmed and connected to the port head. As noted above, the catheter 11 is designed so that the end of the catheter proximal to the head may be cut to the correct length and bifurcated
25 by hand so that the two branches may be securely attached to the head's two outlet cannulas 32. In other words, the catheter 11 may be trimmed at the time of implant so that it has the shortest possible length consistent with proper head placement in the patient, thus minimizing flow resistance. Thus, it is no longer necessary to pre-fit the outlet catheter to the particular patient.

After the head 10 is implanted, it may be accessed as described above using needle 42 which, because of its relatively large diameter, also minimizes fluid flow resistance in the system. At the same time, because the needle cannula 44 contains the stylet 46 during the needle insertion process,
5 there is minimum coring of the head's septa 24. That and the thickness of septa 24 enable each port to be accessed many times without leaking. Therefore, the device should be able to remain implanted for a long period of time.

It will thus be seen that the objects set forth above, among those made
10 apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense. It is also to be understood that the
15 following claims are intended to cover all of the generic and specific features of the invention described herein.

CLAIMS

1 1. A vascular access system comprising an implantable head, said head
2 including
3 a pair of similar integral access ports, each port having
4 an internal chamber with an open mouth,
5 an outlet cannula extending from the port and being in fluid
6 communication with the corresponding chamber, and
7 a relatively thick septum spanning and closing the mouth of the
8 corresponding chamber, and
9 a flexible dual-lumen outlet catheter, said catheter having
10 proximal and distal ends, and
11 a pair of closely spaced-apart parallel lumens extending
12 between said ends, said lumens being separable at least at the proximal end
13 of the catheter so that said catheter can be cut to the proper length and
14 bifurcated during implantation of the head enabling said catheter proximal
15 end to be connected to said head with the cannula of one port being received
16 in one catheter lumen and the cannula of the other port being received in the
17 other catheter lumen.

1 2. The vascular access system defined in claim 1 wherein the septum of
2 each port is dome shaped so that it protrudes appreciably from the chamber
3 mouth of the associated port.

1 3. The vascular access system defined in claim 2 and further including a
2 perforate flange extending around the perimeter of the head.

1 4. The vascular access system defined in claim 1 wherein the catheter
2 distal end is stepped so that one of the catheter lumens is longer than the
3 other.

1 5. The vascular access system defined in claim 4 and further including
2 one or more side openings adjacent to the distal end of the catheter.

1 6. The vascular access system defined in claim 1 and further including a
2 catheter locking sleeve movably engaged on the outlet cannula of each port
3 for retaining said cannula in the corresponding catheter lumen.

1 7. The vascular access system defined in claim 1 and further including an
2 access needle for accessing each port by penetrating its associated septum,
3 each said needle including
4 a relatively large diameter access cannula;
5 a stylet slidably received in said access cannula, said stylet
6 having first and second ends and being co-extensive with the access
7 cannula, and
8 coacting first and second coupling means on said first ends of
9 said access cannula and stylet, respectively, for releasably mechanically
10 coupling the stylet to the cannula so that the second ends of the access
11 cannula and stylet are maintained more or less adjacent to one another while
12 the needle is penetrating said associated septum.

1 8. The vascular access system defined in claim 7 wherein the access
2 cannula of each needle is 16 gage or less.

1 9. A vascular access system comprising
2 an implantable head, said head including
3 a pair of similar integral access ports, each port having
4 an internal chamber with an open mouth,
5 an outlet cannula extending from the port and being in
6 fluid communication with the corresponding chamber, and

7 a relatively thick domed septum closing the mouth of the
8 corresponding chamber and projecting outwardly therefrom;

9 a flexible dual-lumen catheter having proximal and distal ends
10 and a pair of closely spaced-apart parallel lumens extending between said
11 ends, said lumens being separable at least at the proximal end of the
12 catheter so that said catheter proximal end may be defined during
13 implantation of the head and connected to said head with a cannula of one
14 port being received in one catheter lumen and the cannula of the other port
15 being received in the other catheter lumen;

16 means on the outlet cannula of each port for releasably
17 retaining said cannula in the corresponding catheter lumen, and

18 an access needle for accessing one of said ports by penetrating
19 the associated septum, said needle including,

20 a relatively large access cannula having first and second
21 ends,

22 a stylet slidably received in said access cannula, said
23 stylet having first and second ends and being co-extensive with the access
24 cannula, and

25 coacting coupling means on the first ends of said access
26 cannula and stylet, respectively, for releasably mechanically coupling the
27 stylet to the access cannula such that the second ends of the access cannula
28 and stylet are maintained adjacent to one another while said needle is
29 penetrating said associated septum.

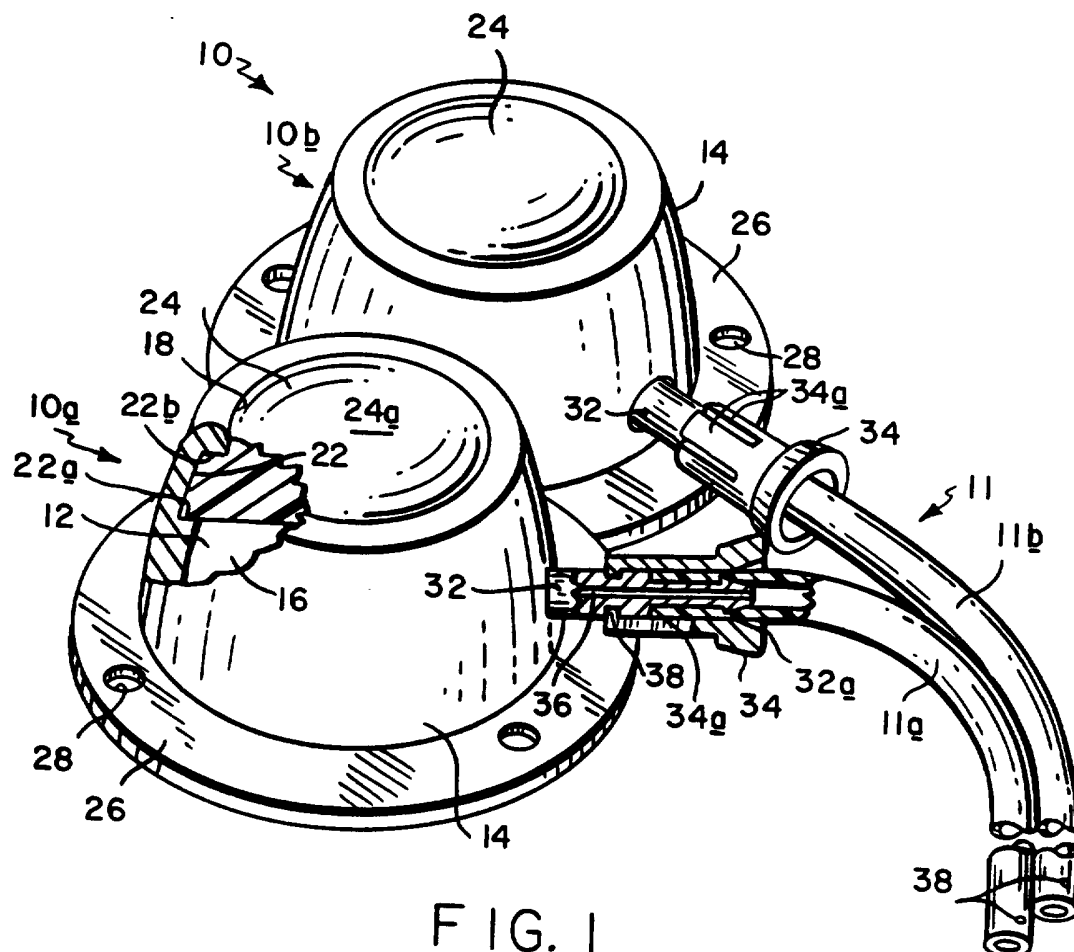


FIG. 1

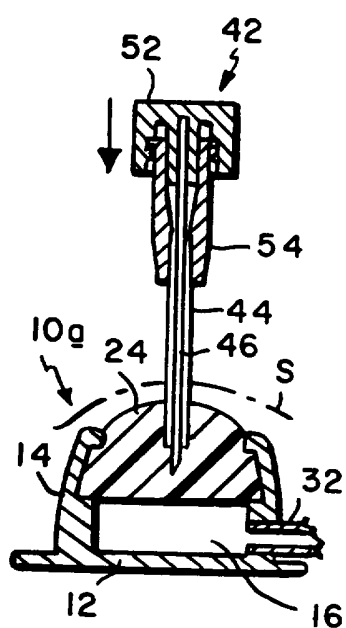


FIG. 2A

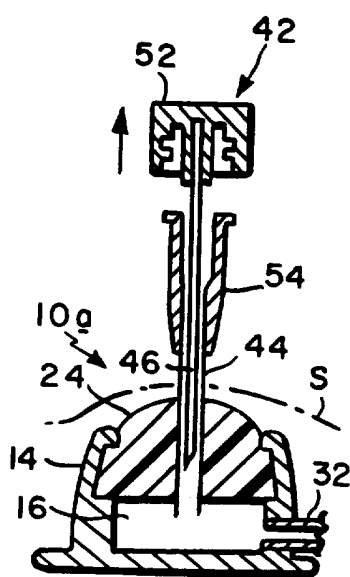


FIG. 2B

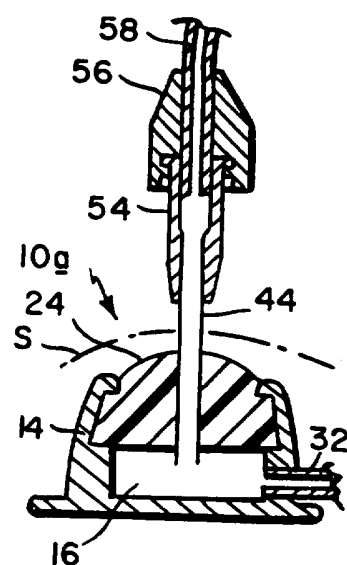


FIG. 2C

INTERNATIONAL SEARCH REPORT

Inter national Application No
PCT/US 96/03814

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/02

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)
IPC 6 A61M

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

5 July 1996

Date of mailing of the international search report

31.07.96

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INTERNATIONAL SEARCH REPORT

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Internal Application No

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