

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
13 February 2003 (13.02.2003)

PCT

(10) International Publication Number  
WO 03/011206 A1

(51) International Patent Classification<sup>7</sup>: A61J 15/00,  
A61M 39/20

Dimas, CA 91773 (US). HUTSON, Lonnie [—/—]; Suite 104, 301 E. Arrow Highway, San Dimas, CA 91773 (US). CLARK, Raymond, D. [—/—]; 5471 Elderberry Way, Oceanside, CA 92057 (US).

(21) International Application Number: PCT/US01/24100

(22) International Filing Date: 31 July 2001 (31.07.2001)

(74) Agent: STEINS, Karl, M.; Steins & Associates, 2333 Camino del Rio South #120, San Diego, CA 92108 (US).

(25) Filing Language: English

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(26) Publication Language: English

(71) Applicant (for all designated States except US): LH MEDICAL PRODUCTS, INC. [US/US]; 301 E. Arrow Highway, Suite 104, San Dimas, CA 91773 (US).

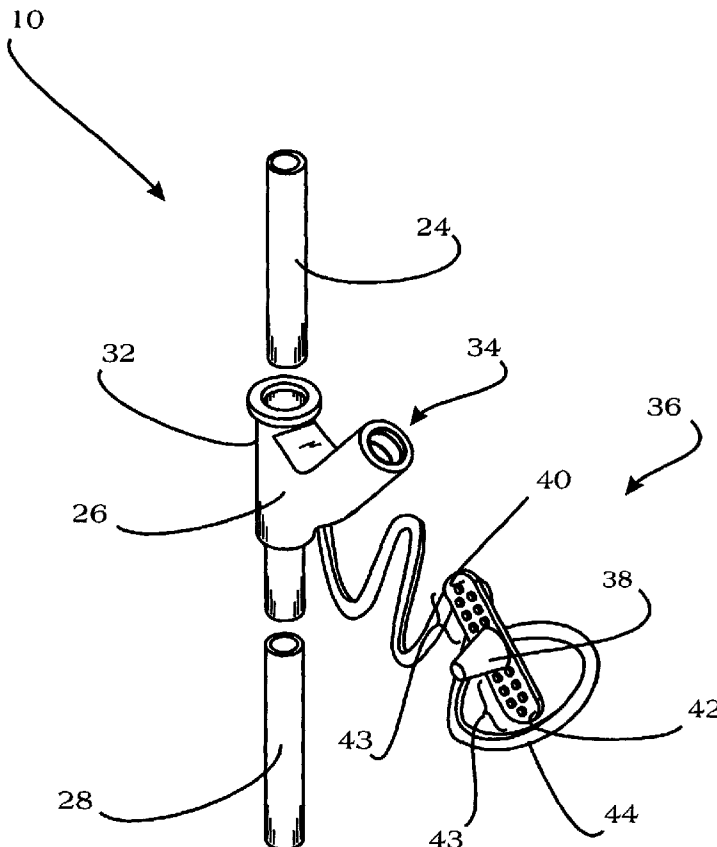
(72) Inventors; and

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

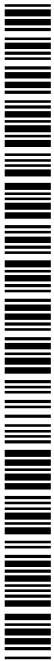
(75) Inventors/Applicants (for US only): HOFFSTETTER, Leonard [—/—]; Suite 104, 301 E. Arrow Highway, San

[Continued on next page]

(54) Title: FEEDING TUBE SPIKE SET WITH INTEGRATED Y-PORT



(57) Abstract: A feeding tube spike set with integrated Y-port is disclosed. The preferred spike set includes a spike, a drip chamber, a y-port fitting, a stepped connector, and tubing connecting these components to one another in series. The y-port fitting further includes a body, a plug assembly and an undulating retaining member connecting the plug assembly to the body. The plug assembly further includes a plug from which a pair of tabs extends. The body also includes a flushing port formed within it; the preferred flushing port includes a plurality of ridges formed along its bore to assist in retaining a secure seal between the inserted plug and the body.



WO 03/011206 A1



patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

— *with international search report*

## FEEDING TUBE SPIKE SET WITH INTEGRATED Y-PORT

BACKGROUND OF THE INVENTION1. Field of the Invention

This invention relates to products to permit the enteral feeding of patients, and in particular to an improved feeding tube spike set with integrated Y-port.

5

2. Description of Related Art

There are two problems associated with enteral patient feeding. The first problem is the inadvertent disconnection of the tubing leading to the feeding tube, the other involves the difficulty of administering water to the patient. The solution provided  
10 by previous inventors, namely Michels et al. US Patent No: 5,322,073 and D360,030, involved providing a y-tube connector that included an integrated retaining strap for the disconnectable tubing entering the connector from the nutrient container. The problem with this arrangement is that the user is required to unplug the entrance to the y-tube and then connect the hose into the y-tube through this cumbersome retaining strap. What  
15 would be better would be to simply provide an integrated system that includes all components necessary from the nutrient supply to the enteral connector.

The second problem involves the y-port fitting in the spike set. This y-port fitting is provided to enable health care personal to inject water to either flush the system or to hydrate the patient. The difficulty involves the fact that there are a variety of  
20 different means by which the water is introduced into the y-port connector. Many times a variety of different sizes of syringes might be used. In many cases however, the tip of the

syringe does not exactly match the configuration of the port in the y-port fitting. What would be very beneficial would be to provide a y-port fitting that permits a wide variety of syringe configurations to be inserted into the fitting, and sealing the syringe tip connection to prevent leakage of water or other material when the patients being hydrated.

SUMMARY OF THE INVENTION

In light of the aforementioned problems associated with the prior devices, it is an object of the present invention to provide a Feeding tube spike set with integrated Y-port. The preferred spike set will include a spike, a drip chamber, a y-port fitting, a stepped  
5 connector, and tubing connecting these components to one another in series. It is a further object that the y-port fitting include a body, a plug assembly and an undulating retaining member connecting the plug assembly to the body. It is yet another object that the plug assembly include a plug from which a pair of tabs extend. It is another object that the body include a flushing port formed within it; the preferred flushing port should include a  
10 plurality of ridges formed along it's bore to assist in retaining a secure seal between the inserted plug and the body.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and features of the present invention, which are believed to be novel, are set forth with particularity in the appended claims. The present invention, both as to its organization and manner of operation, together with further objects and advantages, may best be understood by reference to the following description, taken in connection with the accompanying drawings, of which:

Figure 1 depicts a preferred embodiment of the improved feeding tube spike set of the present invention;

Figure 2 is a perspective view of the y-port fitting of the spike set of Figure 1;

Figure 3 is a back view of the y-port fitting of Figures 1 and 2;

Figure 4 is a front view of the y-port of Figures 1 through 3;

Figure 5 is a top view of the y-port of Figures 1 through 4;

Figure 6 is a bottom view of the y-port of Figures 1 through 5;

Figure 7 is a left side view of the y-port of Figures 1 through 6;

Figure 8 is a right side view of the y-port of Figures 1 through 7;

Figure 9 is a partial cutaway side view of the y-port of Figures 1 through 8;

and

Figure 10 are partial cutaway side views of preferred ridge designs for the y-port of the present invention.

DETAILED DESCRIPTION  
OF THE PREFERRED EMBODIMENTS

The following description is provided to enable any person skilled in the art to make and use the invention and sets forth the best modes contemplated by the inventors of carrying out their invention. Various modifications, however, will remain readily apparent to those skilled in the art, since the generic principles of the present invention have been defined herein specifically to provide a Feeding tube spike set with integrated Y-port.

If we first turn to Figure 1, we can discuss the improved feeding spike set 10 of the present invention. Figure 1 depicts a preferred embodiment of the improved feeding tube spike set of the present invention. It should be understood that all components are integrated into a single system to prevent leakage and inadvertent disconnection. The same components as with a conventional system are provided, however, they are permanently attached in string. As such, the system 10 includes a spike 12 which is attached to a drip chamber 14 by a first tube section 16. In between the spike 12 and the drip chamber 14 is found a roller clamp 18 for regulating the flow of nutrients into the patient. The drip chamber 14 then may be attached to a coupling 20 by a second tube section 22. It should be understood that the coupling 20 may or may not be eliminated in other embodiments of spike set 10, depending upon the particular application for the set 10. A third tube section 24 then connects the coupling 20 to the improved y-port fitting 26. A fourth tube section 28 then connects the y-port fitting 26 to a stepped connector 30, which is configured attach to the enteral feeding tube. If we now turn to Figure 2, we can further examine the improved y-port fitting 26 of the present invention.

Figure 2 is a perspective view of the y-port fitting 26 of the spike set of Figure 1. As can be seen in Figure 2, the y-port fitting 26 comprises a body 32 preferably formed of a non reactive plastic material. Within the body 32 is formed a flushing port 34. Further detail with regard to flushing port 34 will be provided below in connection with other figures. A plug assembly 36 is integral to the fitting 26 in order to permit the port 34 to be sealed when not in use. The plug assembly 36 comprises of a plug 38 and a pair of tabs 40 and 42 to assist in the insertion and removal of a plug 38 to and from the flushing port 34. A plurality of nubs 43 are preferably formed on the surfaces of the tabs 40 and 42 in order to provide additional grip benefits to the user. The plug assembly 36 is attached to the body 32 by a flexible undulating plug retaining member 44. This elongate undulating design is provided to provide additional ease in inserting and removing the plug 38 from the flushing port 34. Furthermore, since the plug retaining member 44 is so long, it will permit healthcare personal to prevent the plug 38 from interfering with their work.

Figures 3 and 4 depict back and front views, respectively, of the body 32 and the flushing port 34.

Figures 5 and 6 depict top and bottom views, respectively, of the plug assembly 36 and the retaining member 44 in the preferred design.

Figures 7 and 8 depict right and left side views of the plug assembly 36, the body 32, and the retaining member 44.

Turning to Figure 9, we can examine yet another unique feature of the present invention. Figure 9 is a partial cutaway side view of the y-port 26 of Figures 1 through 8. As should be appreciated, the bore depth 46 of the flushing port 34 is longer than the conventional flushing port in order to provide the additional flexibility of using a



variety of different syringe tip profiles. Furthermore, along the bore of the flushing port 34 are a plurality of circular ridges 48. These ridges cooperate with the tip of a wide variety of syringes to prevent leakage when water is administered.

Figure 10 provides further detail regarding these ridges 48. Figure 10 are  
5 partial cutaway side views of preferred alternate designs for ridges of the present invention. As seen in Figure 10, the ridges 48, while being circular around the periphery of the flushing port, may have a unique aspect to their cross-section. In one preferred embodiment the ridges will have a non-smooth profile 48A in that the leading edge of the ridge will be smooth, however the trailing edge will be cut off possibly even at a 90-  
10 degree or greater angle. This cut-off edge has been seen to provide additional leak prevention in the design by preventing the inserted tip from being removed. In another preferred embodiment a smooth profile ridge 48B will be provided; this ridge, while not providing as substantial of a retaining force upon a syringe that's asserted therein, will likely provide easier engagement and disengagement of the syringe in the flushing port,  
15 while still providing substantial leak prevention.

Those skilled in the art will appreciate that various adaptations and modifications of the just-described preferred embodiment can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the appended claims, the invention may be practiced other than as  
20 specifically described herein.

CLAIMSWhat Is Claimed Is:

1. An improved spike set for enteral feeding, comprising:
  - a spike;
  - a drip chamber;
  - a y-port fitting, said y-port comprising a body defined by a flushing port formed therein, said flushing port defined by a bore having an outer surface, said outer surface including at least one ridge formed thereon;
  - a stepped connector; and
  - tubing connecting said spike to said drip chamber and said drip chamber to said y-port fitting and said y-port fitting to said stepped connector.
2. The spike set of Claim 1, wherein said y-port fitting comprises:
  - a retaining member extending from said body, said retaining member defining an undulating shape and having a distal end; and
  - a plug assembly at said distal end.
3. The spike set of Claim 2, wherein said plug assembly further comprises a plug and a pair of tabs extending therefrom.
4. The spike set of Claim 3, wherein said flushing port is configured to receive said plug.
5. The spike set of Claim 4, wherein each said ridge defines a semi-circular cross-section.
6. The spike set of Claim 4, wherein each said ridge defines a quarter-circular cross-section.
7. The spike set of Claim 4, wherein said tabs further include a plurality of nubs formed thereon to provide grip.

8. An improved y-port fitting for enteral feeding, comprising:
  - a body further defined by a flushing port, said flushing port comprising:
    - a bore formed in said body,
    - said bore further defined by a bore surface, and
  - said body further comprising at least one ridge protruding from said bore surface;
  - a retaining member extending from said body, said retaining member defining an undulating shape and having a distal end; and
  - a plug assembly at said distal end said plug assembly further defined by a plug, said plug configured to be cooperatively accepted in said bore.
9. The y-port fitting of Claim 8, wherein said plug assembly further comprises a plug and a pair of tabs extending therefrom.
10. The y-port fitting of Claim 9, wherein each said ridge defines a semi-circular cross-section.
11. The y-port fitting of Claim 9, wherein each said ridge defines a quarter-circular cross-section.
12. The y-port fitting of Claim 9, wherein said tabs further include a plurality of nubs formed thereon to provide grip.
13. An integrated y-port and spike set for enteral feeding, comprising:
  - a spike;
  - a drip chamber;
  - a y-port fitting, said y-port fitting comprising a body defined by:
    - a flushing port formed in said body, said flushing port defined by a bore having an outer surface, said outer surface including at least one ridge formed thereon;
    - a stepped connector; and

tubing connecting said spike to said drip chamber and said drip chamber to said y-port fitting and said y-port to said stepped connector.

**14.** The integrated y-port and spike set of Claim 13, wherein said outer surface of said bore consists of three said ridges formed thereon.

**15.** The integrated y-port and spike set of Claim 13, further comprising:

an undulating retaining member extending from said body; and

a plug attached to the distal end of said retaining member, said plug further including a pair of tabs extending from said plug, at least one surface of each said tab further comprising a plurality of nubs formed thereon.

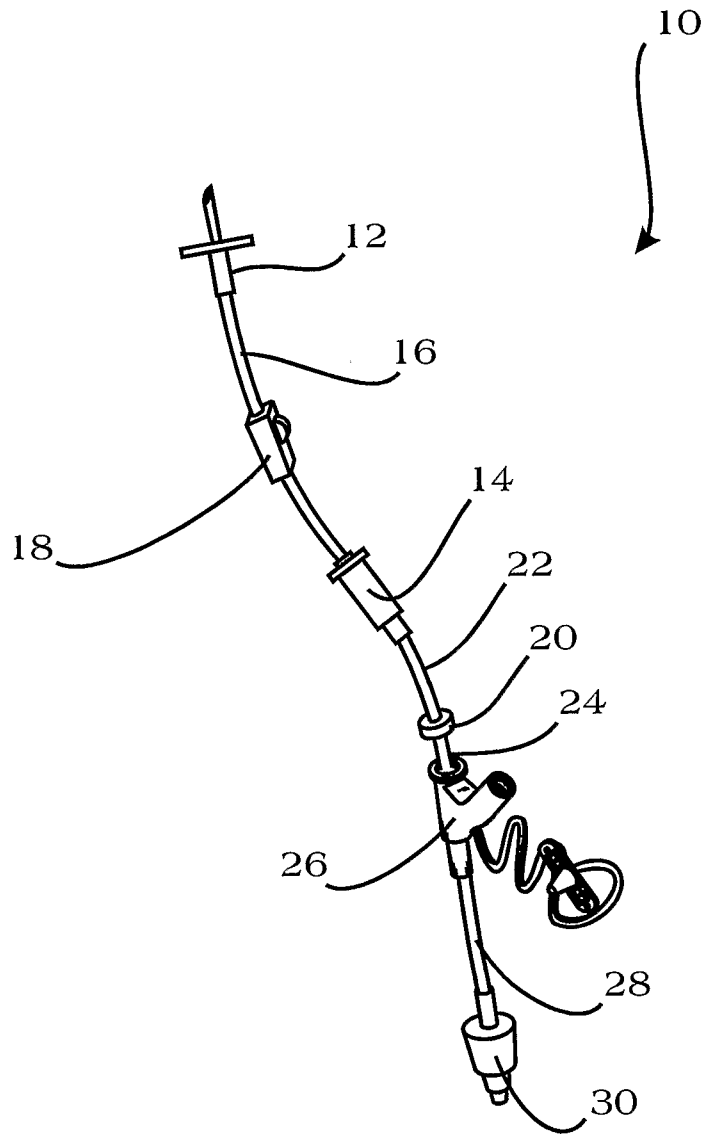


FIGURE 1

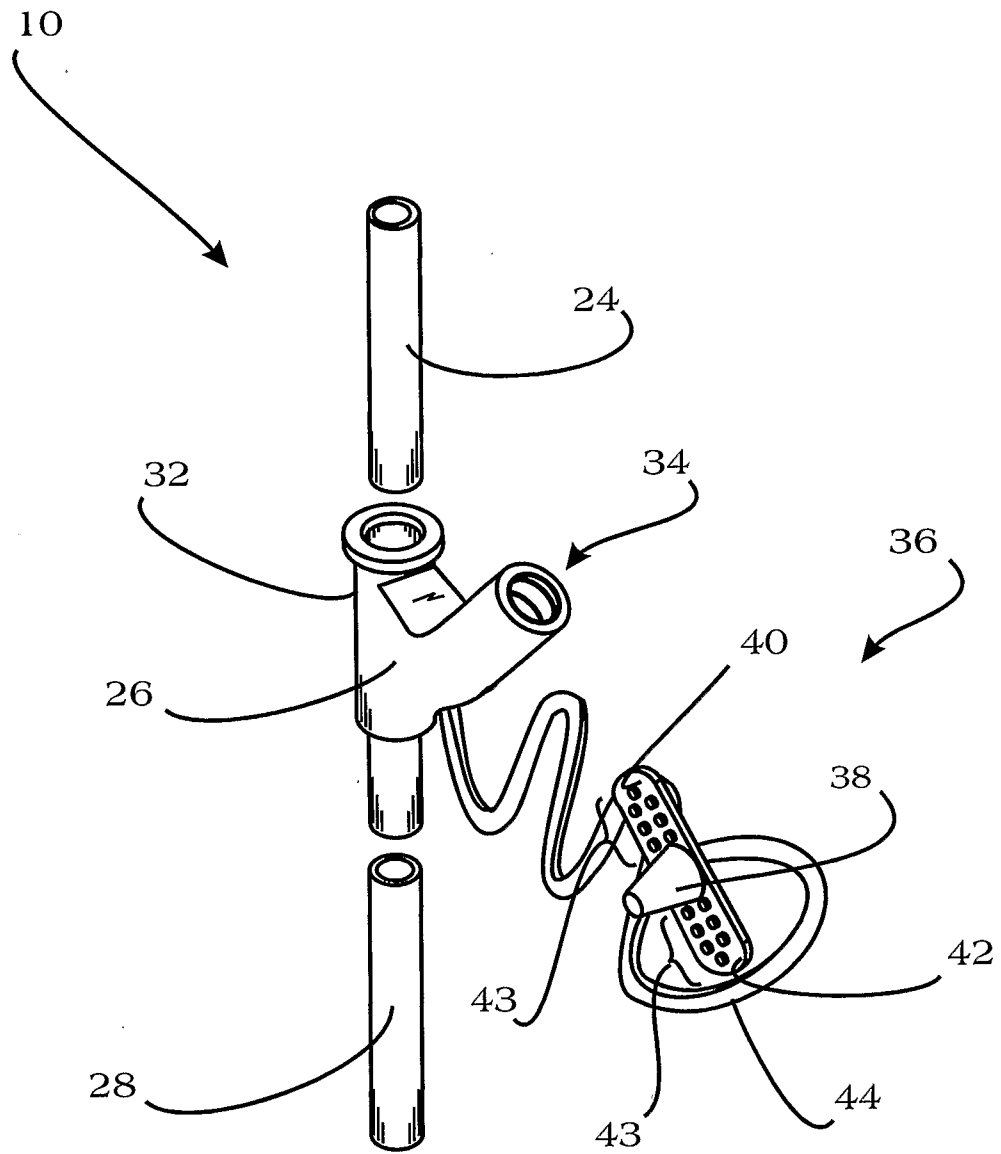


FIGURE 2

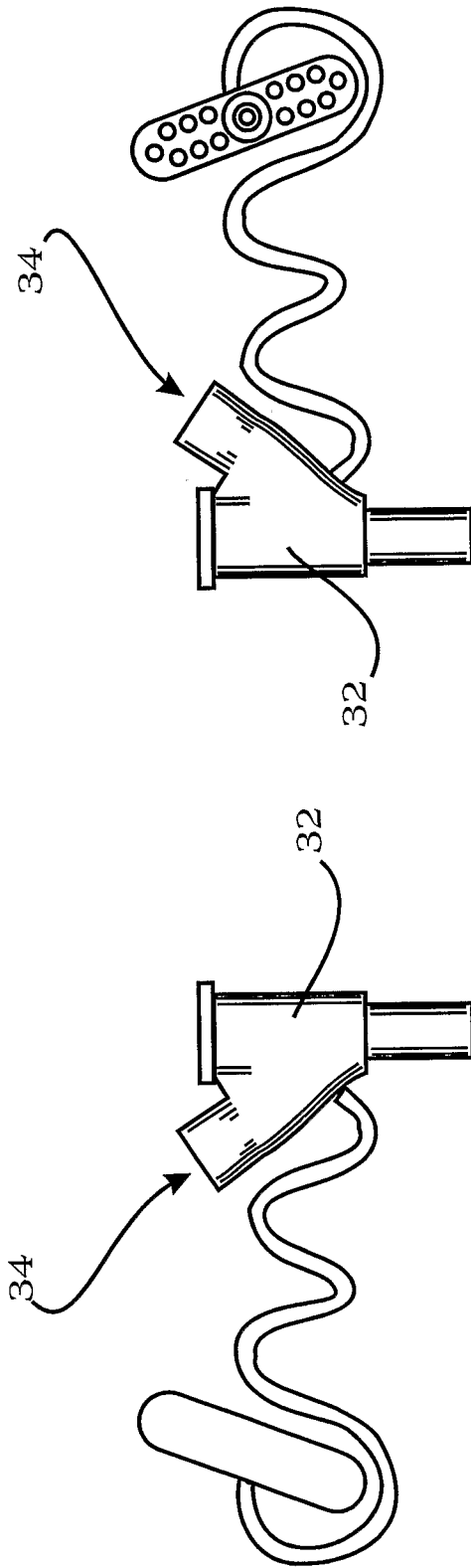


FIGURE 4

FIGURE 3

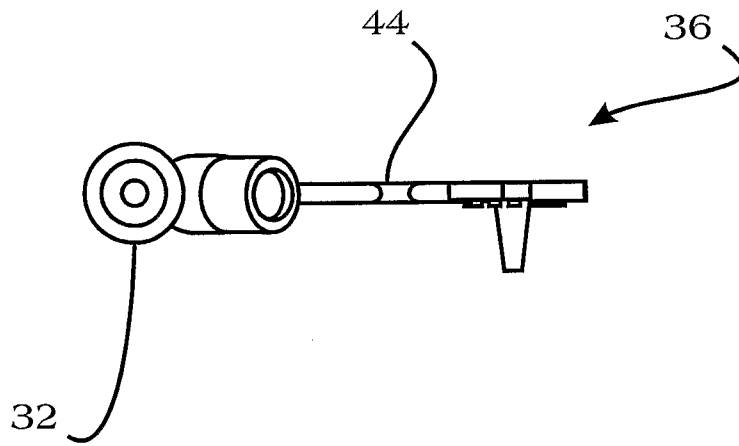


FIGURE 5

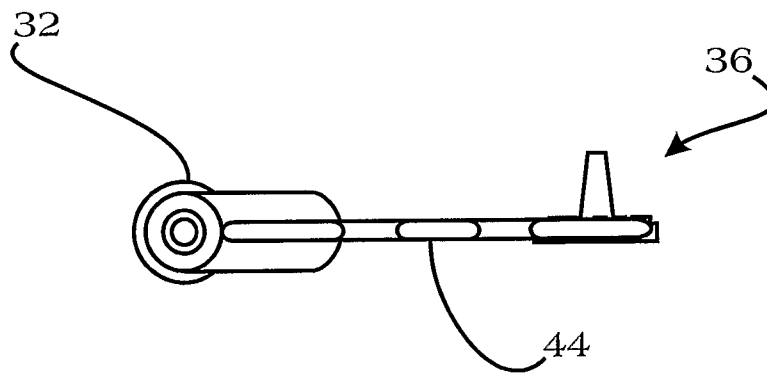


FIGURE 6



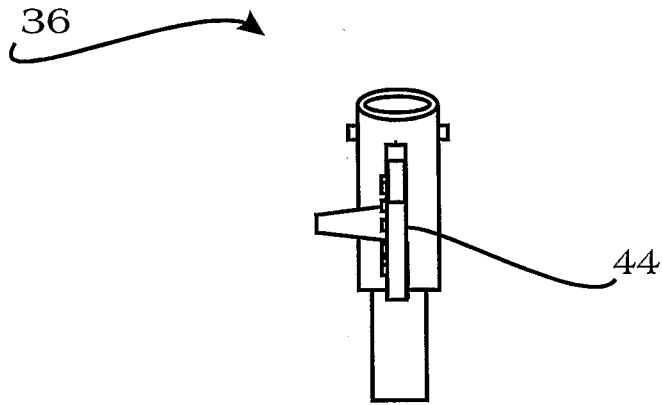


FIGURE 7

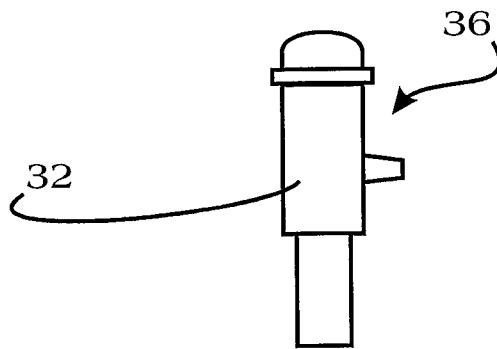


FIGURE 8

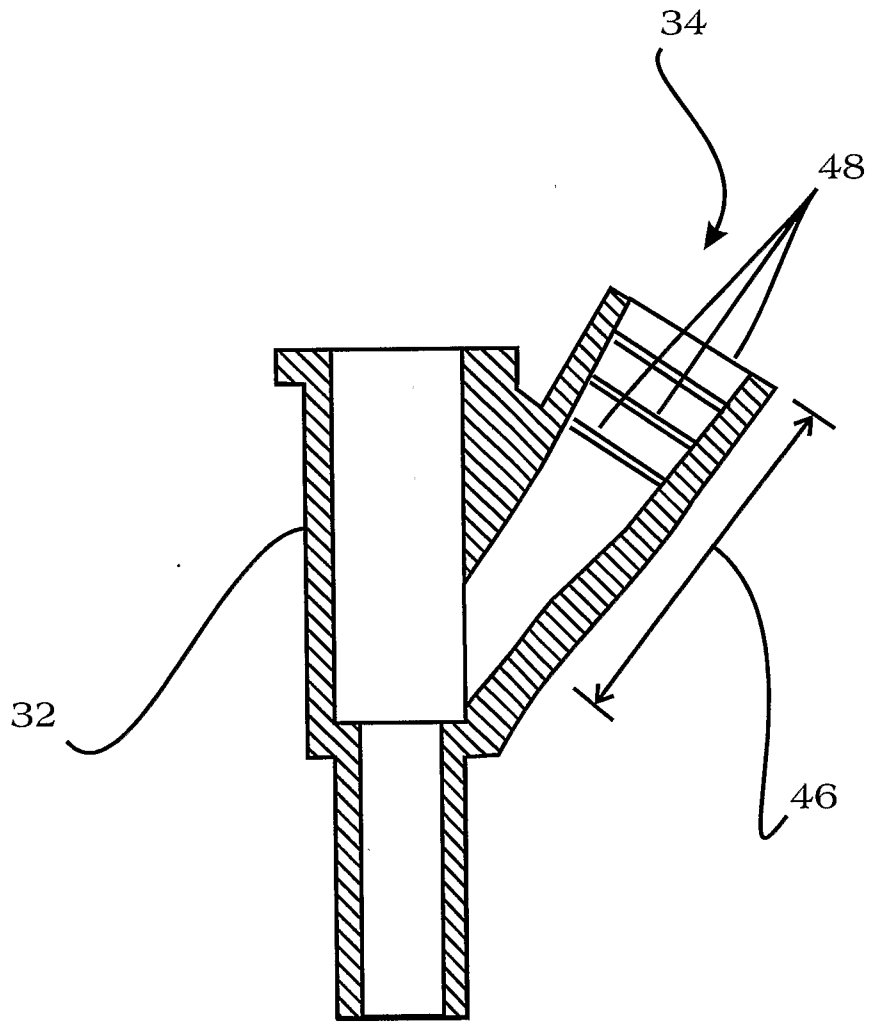


FIGURE 9

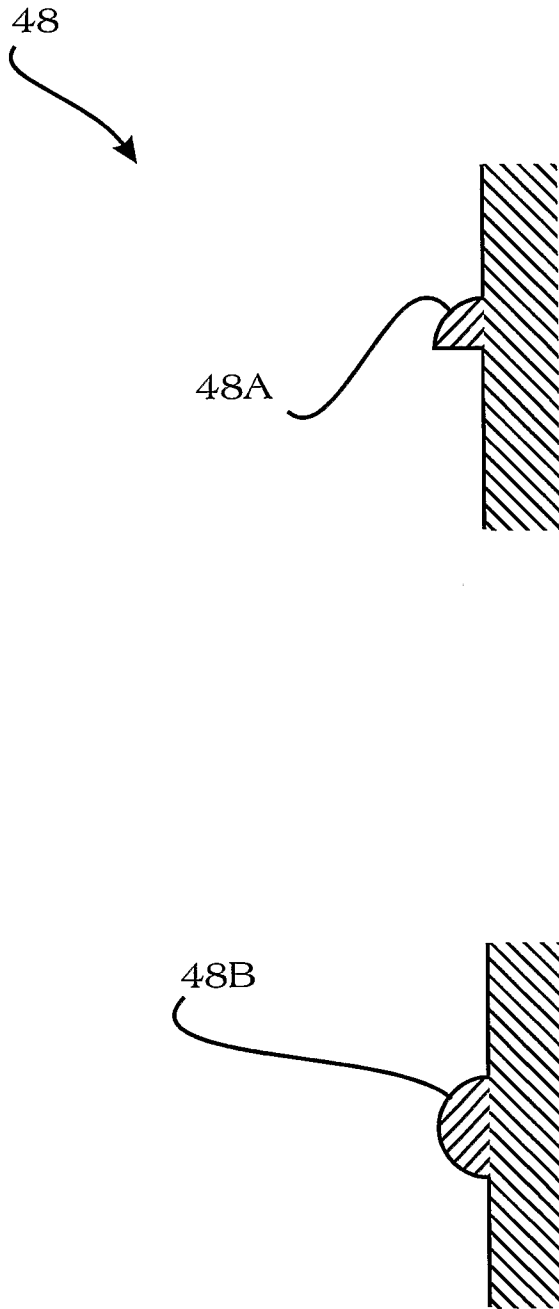


FIGURE 10

## INTERNATIONAL SEARCH REPORT

International Application No

PC 1/US 01/24100

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61J15/00 A61M39/20		
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 7 A61J 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) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 027 900 A (NESTLE SA) 16 August 2000 (2000-08-16)  column 3, line 21 -column 4, line 3; figure 1  ---	1-5, 7-10, 12-15
Y	US 5 322 073 A (MICHELS LESTER D ET AL) 21 June 1994 (1994-06-21)  figure 2  ---	1-5, 7-10, 12-15
A	EP 0 801 940 A (NIZELL PRODUKTE) 22 October 1997 (1997-10-22) figure 10  ---	5,10
A	US 4 561 110 A (HERBERT REINHOLD) 24 December 1985 (1985-12-24) figure 3  ---	5,10
	-/--	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
° Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *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) *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 *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 *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 *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. *&* document member of the same patent family		
Date of the actual completion of the international search  19 March 2002		Date of mailing of the international search report  25/03/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Godot, T

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/24100

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 250 040 A (PARKS STEPHEN K ET AL) 5 October 1993 (1993-10-05) column 6, line 45 - line 59 column 8, line 50 - line 53; figures 8,15 ---	7,12,14, 15
A	EP 0 088 056 A (ASTRA LAEKEMEDEL AB) 7 September 1983 (1983-09-07) figure 6 ---	7,12,14, 15
A	EP 0 416 580 A (ABBOTT LAB) 13 March 1991 (1991-03-13) the whole document ---	1,8,13
E	US 6 332 467 B1 (HOFFSTETTER LEONARD ET AL) 25 December 2001 (2001-12-25) the whole document -----	1-15

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/24100

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1027900	A	16-08-2000	EP 1027900 A1	16-08-2000
			AU 2802500 A	29-08-2000
			WO 0047250 A1	17-08-2000
US 5322073	A	21-06-1994	US 5554140 A	10-09-1996
EP 0801940	A	22-10-1997	EP 0801940 A2	22-10-1997
US 4561110	A	24-12-1985	AR 229630 A1	30-09-1983
			AT 30673 T	15-11-1987
			AU 555823 B2	09-10-1986
			AU 1022283 A	14-07-1983
			BR 8300049 A	20-09-1983
			CA 1189027 A1	18-06-1985
			DD 209389 A5	09-05-1984
			DE 3247294 A1	14-07-1983
			DE 3277609 D1	17-12-1987
			DK 2783 A ,B,	08-07-1983
			EP 0083778 A2	20-07-1983
			ES 518784 D0	16-02-1984
			ES 8402788 A1	16-05-1984
			FI 830046 A ,B,	08-07-1983
			HR 920398 B1	29-02-1996
			HU 187006 B	28-10-1985
			JP 1725251 C	19-01-1993
			JP 4009059 B	19-02-1992
			JP 58169466 A	05-10-1983
			NO 830022 A ,B,	08-07-1983
			PL 240077 A1	12-09-1983
			SI 8310019 A8	31-08-1995
			YU 1983 A1	30-04-1988
			ZA 8300069 A	30-11-1983
US 5250040	A	05-10-1993	US 5234417 A	10-08-1993
			WO 9109643 A1	11-07-1991
			US 5399173 A	21-03-1995
EP 0088056	A	07-09-1983	AT 73989 T	15-04-1992
			AU 556483 B2	06-11-1986
			AU 1114083 A	18-08-1983
			CA 1191483 A1	06-08-1985
			CY 1797 A	17-02-1995
			DE 3382534 D1	30-04-1992
			DE 88056 T1	01-03-1984
			DK 46483 A ,B,	09-08-1983
			EG 15513 A	30-12-1986
			EP 0088056 A1	07-09-1983
			FI 830420 A ,B,	09-08-1983
			HK 78394 A	12-08-1994
			JP 1843990 C	12-05-1994
			JP 3028221 B	18-04-1991
			JP 58146348 A	31-08-1983
			NO 830348 A ,B,	09-08-1983
			NZ 203183 A	31-07-1985
			PH 20936 A	05-06-1987
			SG 84794 G	14-10-1994
			US 4643309 A	17-02-1987

**INTERNATIONAL SEARCH REPORT**  
 Information on patent family members

International Application No  
 PCT/US 01/24100

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0416580	A	13-03-1991	US 5057093 A	15-10-1991
			AT 118344 T	15-03-1995
			AU 641678 B2	30-09-1993
			AU 6220090 A	14-03-1991
			CA 2024696 A1	08-03-1991
			DE 69016889 D1	23-03-1995
			DE 69016889 T2	31-08-1995
			EP 0416580 A2	13-03-1991
			ES 2072341 T3	16-07-1995
			JP 2958350 B2	06-10-1999
			JP 3106371 A	02-05-1991
			<hr/>	
US 6332467	B1	25-12-2001	NONE	
<hr/>				