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Section 29

AUSTRALIA

Patents Act, 1990

PATENT REQUEST: STANDARD PATENT/PATENT OF ADDITION

We, being the person(s) identified below as the Applicant, request the grant of a patent to the person identified below as the Nominated Person, for an invention described in the accompanying standard complete specification. Full application details follow.

[71]	APPLICANT: ADDRESS:	NB INTERNATIONAL TECHNOLOGIES 55 Avenue Nestle, 1800 Vevey, Switzerland
[70]	NOMINATED PERSON: ADDRESS:	NB INTERNATIONAL TECHNOLOGIES 55 Avenue Nestle, 1800 Vevey, Switzerland
[54]	INVENTION TITLE:	ENTERAL-SPECIFIC SPIKE/BAG PORT SYSTEM
[72]	NAME(S) OF ACTUAL INVENTORS:	ROBERT A. MILLER, MICHAEL BECKER, JERRE KACHMAR, ALGIRDAS J. BINDOKAS and RICHARD A. ROLLINS
[74]	ADDRESS FOR SERVICE IN AUSTRALIA: ATTORNEY CODE:	Peter Maxwell & Associates Blaxland House, Suite 10, 5 Ross Street, NORTH PARRAMATTA NSW 2151 MX

BASIC CONVENTION APPLICATION(S) DETAILS

[31] APPLN NO.	[33] COUNTRY	COUNTRY CODE	[32] DATE OF APPLN
07/585,818	U.S.A.	US	20/09/1990

SO24042 30/08/91

Drawing number recommended to accompany the abstract: Fig 1

DATED this 29th day of August 1991.

NB INTERNATIONAL TECHNOLOGIES
By their Patent Attorneys,
PETER MAXWELL & ASSOCIATES

T P Maxwell

NOTICE OF ENTITLEMENT

COMMONWEALTH OF AUSTRALIA

THE PATENTS ACT 1952

DECLARATION IN SUPPORT OF A CONVENTION APPLICATION FOR A PATENT

AUSTRALIA
CONVENTION
STANDARD
& PETTY PATENT
DECLARATION
SFP.1

In support of the Convention Application made for a patent for an invention entitled:

Title of Invention

"ENTERAL-SPECIFIC SPIKE/BAG PORT SYSTEM"

I/We ANDRZEJ LEDZION, President,

Full name(s) and address(es) of Declarant(s)

of NB International Technologies
55, Avenue Nestle
1800 Vevey, Switzerland

do solemnly and sincerely declare as follows:–

Full name(s) of Applicant(s)

1. ~~I am/We are the applicant(s) for the patent~~

(or, in the case of an application by a body corporate)

1. I am/We are authorised by

the applicant(s) for the patent to make this declaration on its/their behalf.

2. The basic application(s) as defined by Section 141 of the Act was/were made

Basic Country(ies) in United States of America

Priority Date(s) on 20 September 1990

Basic Applicant(s) by ROBERT A. MILLER, MICHAEL BECKER, JERRE KACHMAR, ALGIRDAS J. BINDOKAS and RICHARD A. ROLEINS

3. ~~I am/We are the actual inventor(s) of the invention referred to in the basic application(s)~~

Full name(s) and address(es) of Inventor(s)

(or where a person other than the inventor is the applicant)

3. ROBERT A. MILLER, MICHAEL BECKER, JERRE KACHMAR, ALGIRDAS J. BINDOKAS and RICHARD A. ROLLINS of 4111 White Ash Road, Crystal Lake, Illinois 60014, USA; 212 Stillwater Court, Palatine, Illinois 60067, USA; 126 South Lakestreet, Grayslake, Illinois, 60030, USA; 67 Waverly Avenue, of Clarendon Hills, Illinois, 60514, USA and 207 N. Rouse, Mundelein, Illinois 60060, U.S.A.

(respectively)

is/are the actual inventor(s) of the invention and the facts upon which the applicant(s) is/are entitled to make the application are as follows:

Set out how Applicant(s) derive title from actual inventor(s) e.g. The Applicant(s) is/are the assignee(s) of the invention from the inventor(s)

NB International Technologies, is the Assignee by virtue of Assignment dated 16 July 1991 and 17 September 1990, of the inventors ROBERT A. MILLER, MICHAEL BECKER, JERRE KACHMAR, ALGIRDAS J. BINDOKAS and RICHARD A. ROLLINS

4. The basic application(s) referred to in paragraph 2 of this Declaration was/were the first application(s) made in a Convention country in respect of the invention(s) the subject of the application.

Declared at Vevey this 21st day of August 19 91

NB International Technologies,

By: .....
Signature of Declarant(s)

Its: Andrzej Ledzion
President

SFP4 To: The Commissioner of Patents 11/81

AU9183501

(12) PATENT ABRIDGMENT (11) Document No. AU-B-83501/91
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 642525

(54) Title
ENTERAL-SPECIFIC SPIKE/BAG PORT SYSTEM

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585818	20.09.90	US UNITED STATES OF AMERICA

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(71) Applicant(s)
NB INTERNATIONAL TECHNOLOGIES

(72) Inventor(s)
ROBERT A. MILLER; MICHAEL BECKER; JERRE KACHMAR; ALGIRDAS J. BINDOKAS; RICHARD A. ROLLINS

(74) Attorney or Agent
PETER MAXWELL & ASSOCIATES , Patent & Trade Mark Attorneys, 5-7 Ross St, NORTH PARRAMATTA NSW 2151

(56) Prior Art Documents
US 4150673
US 4187893
EP 0200483

(57) Claim

1. A port/spike fluid connection assembly for the administration of an enteral product comprising:

an enteral set having a spike with a diameter substantially less than a diameter of a standard parenteral set spike;

a port including an elongated tube, with a frangible membrane disposed inside a bore of the tube and dividing the bore into an upper bore and a lower bore; and

means, in the upper bore, for permitting the enteral set spike to pierce the membrane and preventing the standard parenteral set spike from piercing the membrane, the means being slidably movable from a first position located at a top of the upper bore to a second position located near the frangible member.

.../2

13. An enteral set and container comprising:

an enteral set having a spike with a diameter substantially less than a diameter of a spike of a standard parenteral set;

an enteral container including a port including an elongated bore, with a frangible membrane disposed inside the elongated bore and dividing the bore into upper and lower bore sections; and

an annular ring, in the upper bore section, for permitting the spike of the enteral set to pierce the membrane and preventing the spike of the standard parenteral set from piercing the membrane.

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Regulation 3.2

AUSTRALIA

Patents Act, 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

Original

TO BE COMPLETED BY THE APPLICANT

NAME OF APPLICANT: NB INTERNATIONAL TECHNOLOGIES

ACTUAL INVENTOR(S): ROBERT A MILLER, MICHAEL BECKER, JERRE KACHMAR, ALGIRDAS J. BINDOKAS and RICHARD A. ROLLINS

ADDRESS FOR SERVICE: Peter Maxwell & Associates
Blaxland House,
Suite 10, 5 Ross Street,
NORTH PARRAMATTA NSW 2151

INVENTION TITLE: ENTERAL-SPECIFIC SPIKE/BAG PORT SYSTEM

The following statement is a full description of this invention, including the best method of performing it know to me:-

The present invention relates to a port assembly for an enteral feeding bag. In particular, the present invention relates to a port assembly that prevents the insertion of a spike of a parenteral set, while permitting insertion of a spike of an enteral set, into an enteral container.

Collapsible containers for the administration of medical solutions are well known. An example of such a container is the VIAFLEX® container marketed by Baxter Healthcare Corporation, Deerfield, Illinois. Typically, the containers, also known as "bags", include a port that provides access to the material packaged within the bag. The port includes a tubular structure defining an inner bore. Located within the inner bore is a frangible membrane that provides a barrier between the material (usually a fluid) contained within the bag and the outside environment.

Spikes are used to pierce the frangible membrane and gain access to the fluid within the bag. The spikes are typically part of a set that allows the infusion of the product within the container to a patient.

Such collapsible containers or bags are typically used, in the medical field, for administering parenteral solution, peritoneal dialysis solutions, and enteral feeding compositions. "Parenteral" refers to the infusion of a product intravenously, while "enteral" refers to infusion of the product into the gut, typically through a tube inserted through the

nose and into a patient's stomach. Although it is not uncommon that the bags used in enteral and parenteral systems are similar, the functions of the fluids employed in the respective systems are not. Indeed, in many instances, if a solution intended for enteral infusion was mistakenly introduced into a patient parenterally, serious harm to the patient could result.

SUMMARY OF THE INVENTION

According to the invention, there is provided a port/spike fluid connection assembly for the administration of an enteral product comprising:

an enteral set having a spike with a diameter substantially less than a diameter of a standard parenteral set spike;

a port including an elongated tube, with a frangible membrane disposed inside a bore of the tube and dividing the bore into an upper bore and a lower bore; and

means, in the upper bore, for permitting the enteral set spike to pierce the membrane and preventing the standard parenteral set spike from piercing the membrane, the means being slidably movable from a first position located at a top of the upper bore to a second position located near the frangible member.

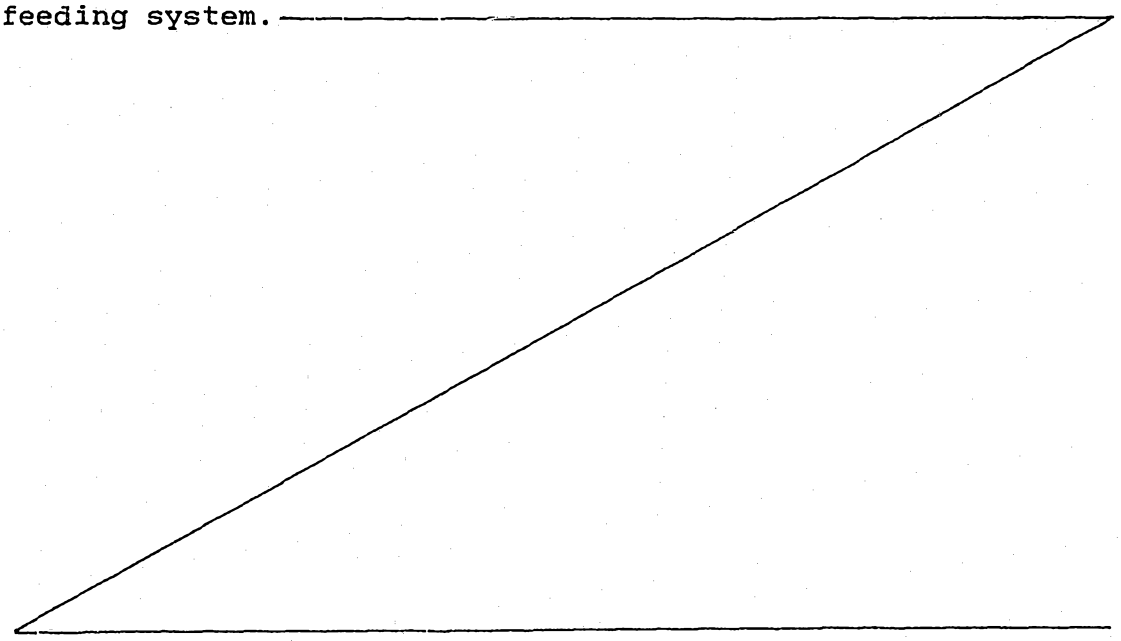
The present invention therefore provides a port/spike assembly that includes an enteral spike having a diameter substantially less than the diameter of a standard parenteral spike. The assembly also thus includes a port including a membrane tube having an outer wall which defines a generally

cylindrical elongated bore. A frangible membrane is appropriately disposed inside the bore and divides the bore into upper and lower bore sections. Preferably, a selector ring is provided in the upper bore section for permitting insertion of the reduced diameter enteral spike and for preventing insertion of a standard parenteral spike through the membrane.

In an embodiment, the ring may be constructed from a rigid polypropylene or polyethylene, and the bag is constructed from a polyvinyl chloride resin or polyolefin resin.

The present invention also provides a container that will only accept an enteral set and prevents a parenteral set from accessing the container.

Accordingly, it is an advantage of the present invention to provide a port/spike assembly that prevents the inadvertent insertion of a parenteral spike into an enteral feeding system.



An additional advantage of the present invention is that a selector ring is provided that can be inserted into a standard port allowing the port to be adapted to only receive an enteral set.

A further advantage of the present invention is that it overcomes the disadvantages of the prior art with minimum piece part and tooling costs.

Additional features and advantages are described in, and will be apparent from, the detailed description of the presently preferred embodiments and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an exploded view illustrating an embodiment of the port/spike assembly of the present invention.

Figure 2 illustrates a sectional view of the selector ring of the present invention.

Figure 3 illustrates a sectional view of the port/spike assembly of Figure 1 in an installed position.

Figure 4 illustrates an exploded view of a standard parenteral spike and the port of the present invention.

Figure 5 illustrates a sectional view of the components shown in Figure 4 with an attempted insertion of a standard parenteral spike into the port of the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention provides a port/spike assembly for an enteral bag that prevents the inadvertent insertion of a parenteral spike, and thereby a parenteral set, into the port of an enteral

container. The present invention prevents the inadvertent infusion of an enteral solution parenterally into a patient.

Referring now to the Figures, Figure. 1 illustrates an embodiment of the port/spike assembly 10 of the present invention. The assembly 10 includes a set 13 having a spike 12 including a mounting section 14 and a piercing section 16. A point 18 is formed at the terminal end of the piercing section 16.

The set 13 functions to access a container 22 allowing the infusion of the contents of the container into a patient. To this end, the spike 12 is connected by the mounting section 14 to a flexible hollow tube 17. The flexible hollow tube 17 is in fluid communication with, for example, an enteral feeding tube (not shown) that allows the contents of the container to be infused into the stomach of a patient.

The set 13, and specifically the spike 12, is designed to be received within a port 20 mounted on a container 22. The container 22 can be made from a variety of materials including polyvinyl chloride resin. The port 20 includes a port tube 24 that is in fluid communication with an interior of the container 22.

In the embodiment of the port 20 illustrated, a membrane tube 26 is disposed inside, and coaxial with, the port tube 24. The membrane tube 26 includes an outer wall 28 defining a generally cylindrical elongated bore 30. A frangible membrane 32 divides the elongated bore 30 into an upper bore section 34 and a lower bore section 36.

Pursuant to the present invention, a selector ring 38 is disposed within the upper bore section 34 of the elongated bore 30 of the membrane tube 26. The selector ring 38 is generally annular, and can be made from a variety of materials such as, for example, rigid polypropylene.

As illustrated in Figure 2, the selector ring 38 has an outer diameter D1 that allows the selector ring 38 to be interference-fitted within the elongated bore 30 of the membrane tube 26. Of course, if desired, the selector ring 38 can be sealed within the bore 30 of the membrane tube 26. For example, the selector ring 38 can be sonically welded within the membrane tube 26. However, as illustrated in Figures 3 and 5, preferably, the ring 38 is displaceable within the upper bore 34.

The selector ring 38 has an inner diameter D2 that is larger than the outer diameter D3 of a piercing section 16 of the spike 12 of an enteral set. The selector ring 38 has a length L1 that is less than the length L2 of the piercing section 16. In an embodiment that has been found to function satisfactorily, L1 is approximately 0.15 inches, D1 is approximately 0.2 inches, and D2 is approximately 0.14 inches.

Referring now to Figure 3, the insertion of the spike 12 of an enteral set 13 into the port 20 of the present invention is illustrated. The diameter D2 and D3 of the selector ring 38 and spike 12, respectively, are chosen so that the selector ring 38 permits the passage of the piercing section 16. This allows the point 18 to pierce the frangible membrane 32, thus permitting fluid communication between the spike 12

and enteral set 13 and the interior of the bag 22. Accordingly, the enteral set 13 is allowed to access the container and thereby infuse the solution housed within the container into a patient.

Figures 4 and 5 illustrate a standard parenteral set 39 including spike 40. The parenteral set 39 includes a spike 40, for accessing a container, and flexible tube 41 for communicating fluid within the container to a cannula (not shown) or other means for infusing a fluid intravenously into a patient.

As illustrated, the diameter D4 of the spike 40 of the parenteral set 39 is substantially greater than the inner diameter D2 of the selector ring 38. If a medical personnel inadvertently attempts to insert the parenteral set spike 40 into the port 20 of the enteral container 22, as illustrated in Figure 5, the spike 40 will contact the selector ring 38 located above the frangible membrane 32. Although, the selector ring 38 may be displaced downwardly toward the frangible membrane 32 by the spike 40, the selector ring 38 prevents the spike 40 from piercing the frangible membrane 32.

Accordingly, the present invention prevents a parenteral set 39 and spike 40 from piercing the membrane 32 of an enteral container 22 and accessing the solution in the container. Thus, the accidental introduction of an enteral fluid parenterally is avoided.

It should be understood that various changes and modifications to the preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present

invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A port/spike fluid connection assembly for the administration of an enteral product comprising:

an enteral set having a spike with a diameter substantially less than a diameter of a standard parenteral set spike;

a port including an elongated tube, with a frangible membrane disposed inside a bore of the tube and dividing the bore into an upper bore and a lower bore; and

means, in the upper bore, for permitting the enteral set spike to pierce the membrane and preventing the standard parenteral set spike from piercing the membrane, the means being slidably movable from a first position located at a top of the upper bore to a second position located near the frangible member.

2. The port/spike assembly of claim 1 wherein said means includes a member having an outer diameter corresponding to an inner diameter of the bore, and an inner diameter smaller than a diameter of the standard parenteral set spike, but larger than a diameter of said enteral set spike.

3. The port/spike assembly of claim 2 wherein the member is an annular ring.

4. The port/spike assembly of claim 1 wherein said means comprises a rigid polypropylene annular ring secured within the bore.

5. The port/spike assembly of claim 2 wherein the member has a length that is less than a length of the spike of the enteral set.

6. The port/spike assembly of claim 1 wherein said means is interference fitted into said bore.

7. A container for housing fluid that is not infused intravenously comprising:

a port including an elongated tube defining a generally cylindrical elongated bore and a frangible membrane disposed inside the tube dividing the elongated bore into upper and lower bore sections; and

a selector ring, in said upper bore section, for preventing insertion of a spike from a parenteral set through said membrane, said ring having a diameter that is less than the diameter of the spike of the parenteral set.

8. The container of claim 7 wherein the selector ring means is interference fitted within the bore.

9. The container of claim 7 wherein the selector ring has a length that is less than a length of a spike of an enteral set.

10. The container of claim 7 wherein the selector ring has an outer diameter of approximately 0.2 inches, an inner diameter of approximately 0.14 inches, and a length of approximately 0.15 inches.

11. The container of claim 7 wherein the selector ring is displaceable within said upper bore section.

12. The container of claim 7 wherein the selector ring has an outer diameter corresponding to an inner diameter of the bore, and an inner diameter smaller than a diameter of the parenteral spike, but larger than a diameter of an enteral spike.

13. An enteral set and container comprising:

an enteral set having a spike with a diameter substantially less than a diameter of a spike of a standard parenteral set;

an enteral container including a port including an elongated bore, with a frangible membrane disposed inside the elongated bore and dividing the bore into upper and lower bore sections; and

an annular ring, in the upper bore section, for permitting the spike of the enteral set to pierce the membrane and preventing the spike of the standard parenteral set from piercing the membrane.

14. The enteral set and container of claim 13 wherein the annular ring includes an outer diameter corresponding to an inner diameter of the bore, and an inner diameter smaller than a diameter of the spike of the standard parenteral set, but larger than a diameter of the spike of the enteral set.

15. The enteral set and container of claim 13 wherein the annular ring has a length that is less than a length of the spike of the enteral set.

16. The container of claim 13 wherein the selector ring is displaceable within the upper bore section.

17. A method for providing an enteral solution for infusion into a patient including the steps of:

providing an enteral set having a spike having a diameter substantially less than a diameter of a standard parenteral spike;

ABSTRACT OF THE DISCLOSURE

A port/spike assembly (10) including an enteral spike (12) having a diameter substantially less than the diameter of a standard parenteral spike. The assembly (10) also includes a port (20) having a tube (26) with an outer wall (28) which defines a generally cylindrical elongated bore (30). A frangible membrane (32) is disposed inside the elongated bore (30), and divides the bore into upper and lower bore sections (34, 36). A selector ring (38) is provided in the upper bore section (34) for permitting insertion of the reduced diameter enteral spike (12) and for preventing the insertion of a standard parenteral spike through the membrane (32). The assembly prevents inadvertent insertion of a parenteral spike into an enteral feeding system.

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FIG. 1

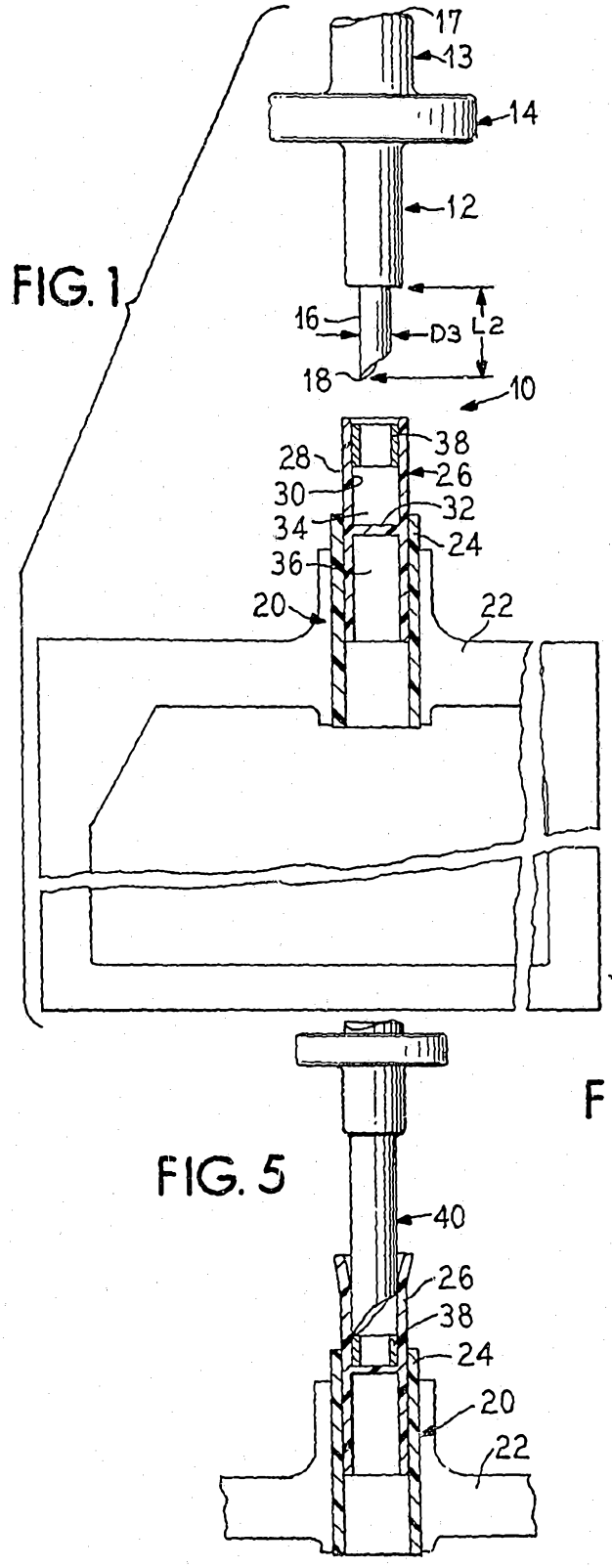

FIG. 2

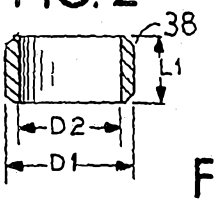

FIG. 3

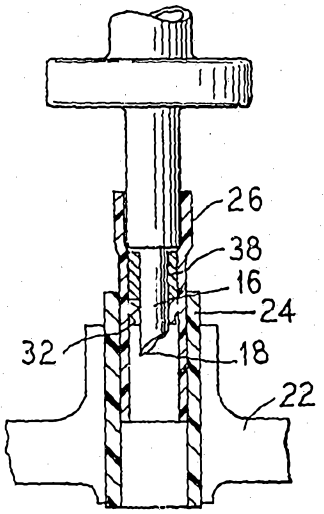

FIG. 4

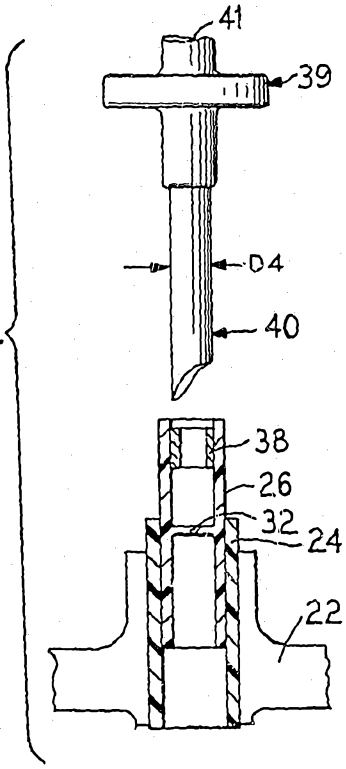

FIG. 5