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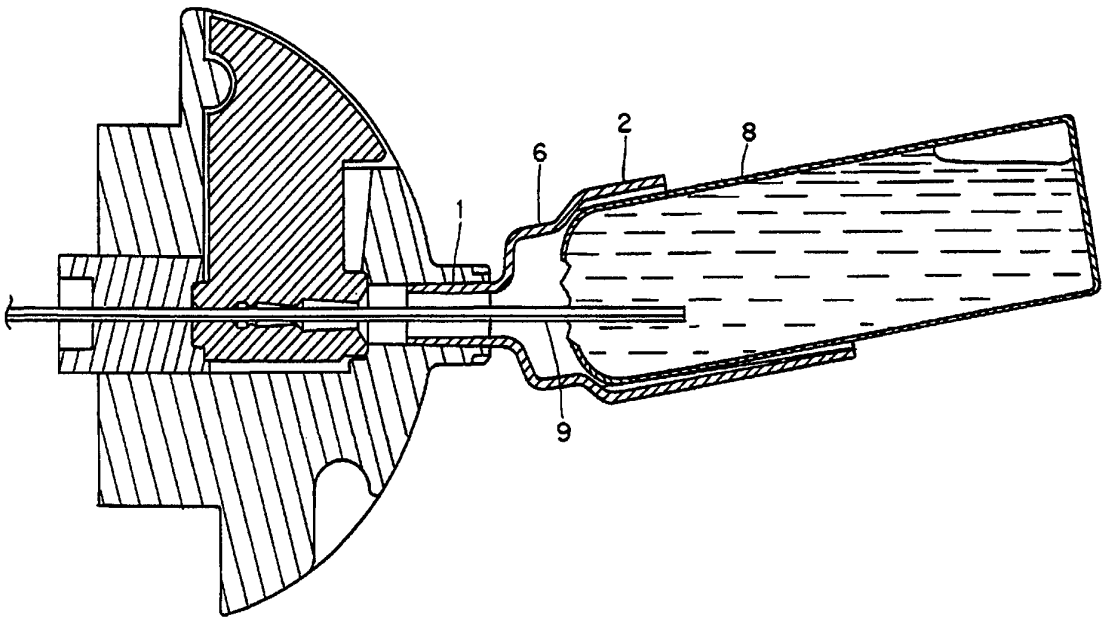
(54) Title: AMPULE ADAPTER



(57) Abstract

An adapter (2) for connecting an ampule (8) to a clinical instrument has been developed. The adapter (2) allows the continuous connection of the ampule (8) to the instrument so that the contents of the ampule (8) could remain protected from exposure to air, and aliquots of solution from the ampule (8) can be periodically, and easily, withdrawn from the ampule (8). In addition, the preferred embodiment permits usage of much of the contents of the ampule (8) and helps reduce the risk of technician exposure to the sharp glass edges of the open ampule.

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AMPULE ADAPTER

BACKGROUND

The present invention deals with a device (an adapter) which allows the connection of an ampule to an instrument, so that the instrument can periodically withdraw samples from the ampule.

In the use of clinical instruments, it is often desirable to utilize control materials which are packaged in ampules. Ampules, typically made of glass, are inert and generally retain the sample in a stable form longer than if it were packaged in a container made of a different material. The disadvantages of an opened ampule include 1. there remains exposed a sharp edge of glass which is potentially dangerous to laboratory personnel, 2. there existed a risk of decomposition of the contents of the ampule when exposed to air and 3. there has been no way to keep the opened ampule in such a position that samples could easily be withdrawn from the ampule.

Existing techniques in use now for sampling from ampules require the user to manually move the ampule to a tube that withdraws samples from the ampule. Not only does this require technician time, preventing the worker from attending to other tasks in the laboratory, but it also allows for more exposure of the sample to air, thus risking degradation of the sample. Existing procedures are also variable due to the non-reproduceability of laboratory technique from worker to worker.

SUMMARY

An adapter for connecting an ampule to a clinical instrument has been developed. The adapter allows the continuous connection of the ampule to the instrument so that the contents of the ampule could remain protected from exposure to air and aliquots of solution from the ampule can be periodically, and easily, withdrawn from the ampule. In addition, the preferred embodiment permits usage of much of the contents of the ampule and helps reduce the risk of technician exposure to the sharp glass edges of the open ampule.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a side view of the adapter. Figure 2 shows an elevated view of the adapter. Figure 3 shows a view into the adapter. Figure 4 shows a view of an adapter actually in use, connecting the ampule to an instrument.

DETAILED DESCRIPTION

An adapter for connecting an ampule to an instrument has been developed. The adapter allows for the continuous connection of an opened ampule to an instrument, thus allowing the instrument to withdraw samples whenever necessary, without requiring intervention by the laboratory technician. The technician can be doing other tasks in the laboratory, thus providing a more cost-effective use of the technician's time. In addition, automated withdrawal of aliquots from the ampule is more reproducible that manual sampling, thus decreasing variations between samples.

Although the adapter was intended for use with a clinical instrument, it can also be used on other instruments, such as a gas chromatograph, and any other instrument that requires the sampling one or more times from a container of the solution or component contained in that container, generally with the contents being aspirated via a probe inserted through the adapter. Although the device was intended primarily for connecting an ampule containing a control material, it could also be used to connect a large ampule or sealed flask of an air-sensitive reagent to an instrument or to glassware wherein a synthesis is being conducted. Although rigid containers were primarily contemplated, a flexible container (e.g., a pouch or balloon) containing a gaseous material could be connected via an ampule-like connector to the adapter, from which samples of gas could then be withdrawn.

Many variations of the adapter are contemplated. One preferred embodiment includes a special connecting device, namely a tapered joint that is similar to the tapered joint on a syringe, that allows the adapter to be connected, as a syringe would be, to the instrument. It also is designed with an angle between the body of the adapter and the syringe-like connector so that the ampule will be inclined, allowing most or all of the contents to be consumed. Any obtuse angle can be used, with the preferred angle being determined by the flow characteristics of the contents of the ampule, with more viscous materials requiring an angle closer to 90 degrees. (The discussion of the angle assumes that the inlet to the instrument is horizontal. If it is anything other than horizontal, the angle should be adjusted accordingly, with more viscous fluid contents of the ampule requiring the ampule to be closer to the vertical.) The preferred embodiment is shown in the figures. Figure 1 shows the side view of the adapter, with **1** being the outlet portion, a tapered joint, having the taper of a syringe, that is inserted into the instrument; **2** is the body of the adapter, which holds the ampule; **3** is the inlet portion of the adapter; **4** is an optional indicator which shows the user the top of the adapter to assure maximum flow of the contents of the ampule into the

adapter; **5** are optional external ribs for simplifying the grasping of the adapter. **6** is the neck of the adapter, through which the probe extends when being inserted into the ampule or into the contents of the adapter which have flowed into the neck of the adapter. Figures 2 and 3 also shows the optional internal ribs, 7, which hold the ampule securely in the adapter. Figure 4 shows the insertion of the ampule **8**, whereby the broken edge of the ampule projects farther into the adapter than the internal ribs and makes a tight connection with the adapter itself. Figure 4 also shows one means contemplated for sampling from the adapter, namely the insertion by the instrument of a probe **9** into the ampule to permit withdrawal of the control material.

Variations of the device are also contemplated. Although the device is intended primarily for sampling from ampules containing control materials, it is also contemplated that calibrators or other solutions or individual ingredients could be contained in the ampule. For example, the device could be sufficiently flexible or could contain an optional component therein which would allow the breaking of the ampule after it is inserted into the adapter, thus further reducing the exposure of the contents to air. This would also reduce the risk to the operator of exposure to the sharp edges on the broken ampule. Furthermore, the adapter could be designed with a screw thread, in order to allow the connection of a vial or bottle having a screw closure to the instrument. In addition, the adapter could be made entirely or in part of a material that would allow injection of a material, for example a solvent, into the ampule in order to allow the dissolution of the contents thereof. Further variations thereof will be contemplated by those having skill in the art.

It is contemplated that the adapter will be made from polypropylene, such as type 6331, natural color, made by Himont, or equivalent materials. However, the use of other materials, such as polyethylene, is also contemplated. Preferably, the adapter will be sufficiently rigid or semi-rigid to support the

weight of the ampule and maintain it at the indicated angle so that the probe can extend through the neck of the adapter. The adapter should be inert to the ingredients in contact therewith. In addition, it must be sufficiently pliable to allow the tight connection of the ampule thereto. Variations described above contemplate the use of different materials in portions of the adapter in order to accomplish the added attributes described above. For example, if it is desired to inject a solvent into the ampule after it is connected to the adapter, a small portion of the adapter must be made of a material that allows injection of the solvent, followed by repair of the injection point, if the syringe needle is to be withdrawn subsequent to injection. If the needle is not to be subsequently withdrawn, a syringe containing a stopcock could be used on the syringe. Furthermore, the partial use of a semi-rigid, flexible material or an "accordion" design (i.e., design allowing bending of the adapter) could be included if it is desired to break the ampule after insertion into the adapter. Variations in materials of construction will be contemplated by those with expertise in the properties of materials.

What is claimed is:

1. An adapter for connecting an ampule or other container to an instrument, said adapter being formed as a unitary plastic rigid or semi-rigid unit and comprising;

a cylindrical body having opposite ends and a central bore defining a central axis of said cylinder therethrough;

a partial closure to said body at one end terminating in an aperture about said axis;

a tapered joint projecting from said apertaure and having an outer shape emulating that of a syringe outlet and an inner bore tilted with respect to said axis such that when said joint is positioned horizontally, said axis and said cylindrical body are angled to the horizontal;

indicia associated with said body identifying when said cylindrical body is angled upwardly with respect to said joint in a horizontal position;

said bore of said cylindrical body adapted to receive and hold an ampule with said ampule substantially filling said bore of said cylindrical body

2. An adapter of claim 1 in which said angle is obtuse.

3. An adapter of claim 1, wherein said cylindrical body contains ribs on at least one of an outer or bore facing surface.

4. An adapter of claim 1 which additionally contains a portion through which a material can be injected into said ampule or said adapter via use of a syringe.

5. An adapter of claim 1 which additionally contains a flexible portion which allows bending between the joint and cylindrical body and opening of an ampule inserted therein.

6. A unitary at least semi-rigid adapter for connecting an ampule to an instrument in lieu of a syringe, said adapter being made of plastic and comprising

a. an outlet having the tapered design of a syringe outlet

b. communicating at an obtuse angle with a body adapted to receive an ampule substantially entirely therein and

c. said outlet and body being angled to permit a needle to extend without obstruction through said outlet and into a broken end of any ampule located within said body.

7. An adapter for connecting an ampule-type container of a fluid to an instrument for fluid withdrawal said adapter being fabricated of a rigid or semi-rigid material to comprise:

a body portion in the form of a cylindrical wall extending a length in an axial direction for holding an ampule and having a dome-shaped end;

the dome-shaped end being terminated with a tapering cylindrical syringe adapter portion set at an angle to said body portion and of a diameter a small fraction of a diameter of said body portion;

said body portion having approximately a third of the cylindrical wall thereof removed form an end opposite said dome-shaped end over approximately a half the axial length of the cylindrical body portion;

said cylindrical body portion further having a plurality of gripping ridges extending, on opposite sides of said cylindrical body portion, a short distance therearound over substantially the entire axial length of said cylindrical body portion to facilitate gripping; and

said cylindrical body portion having on an interior surface thereof, a plurality of internal ribs extending axially within said cylinder and protruding progressively farther inwardly from said interior surface in the direction of said dome-shaped end.

8. The adapter of Claim 7 further including positioning indicia on said body portions.

9. The adapter of Claim 8 where said indicia is in the shape of an arrow.

10. The adapter of Claim 9 wherein said indicia is adjacent a region of removed cylindrical wall.

11. The adapter of Claim 10 further including a flexible portion which allows bending of the adapter and opening of an ampule inserted therein.

12. The adapter of Claim 10 adapted to receive a broken ampule.

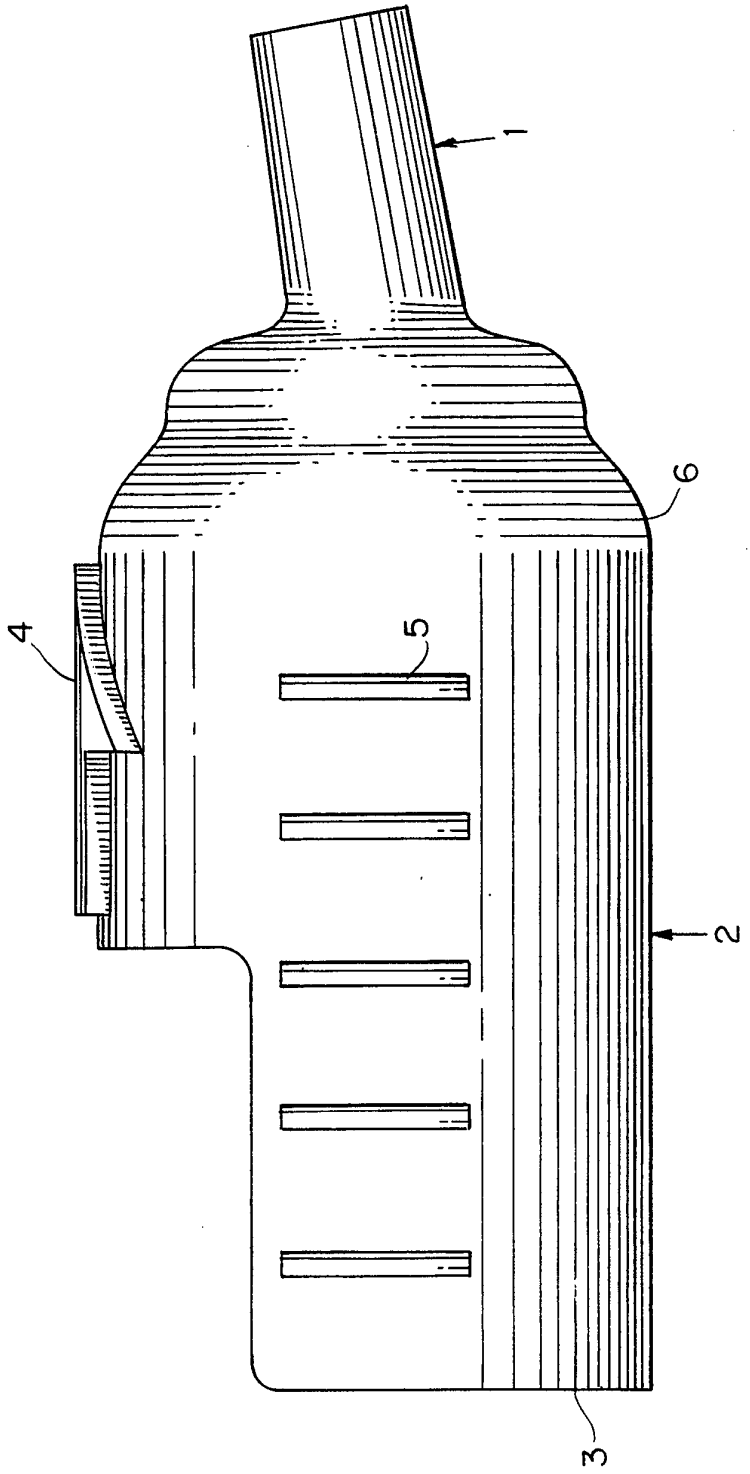

FIG. 1

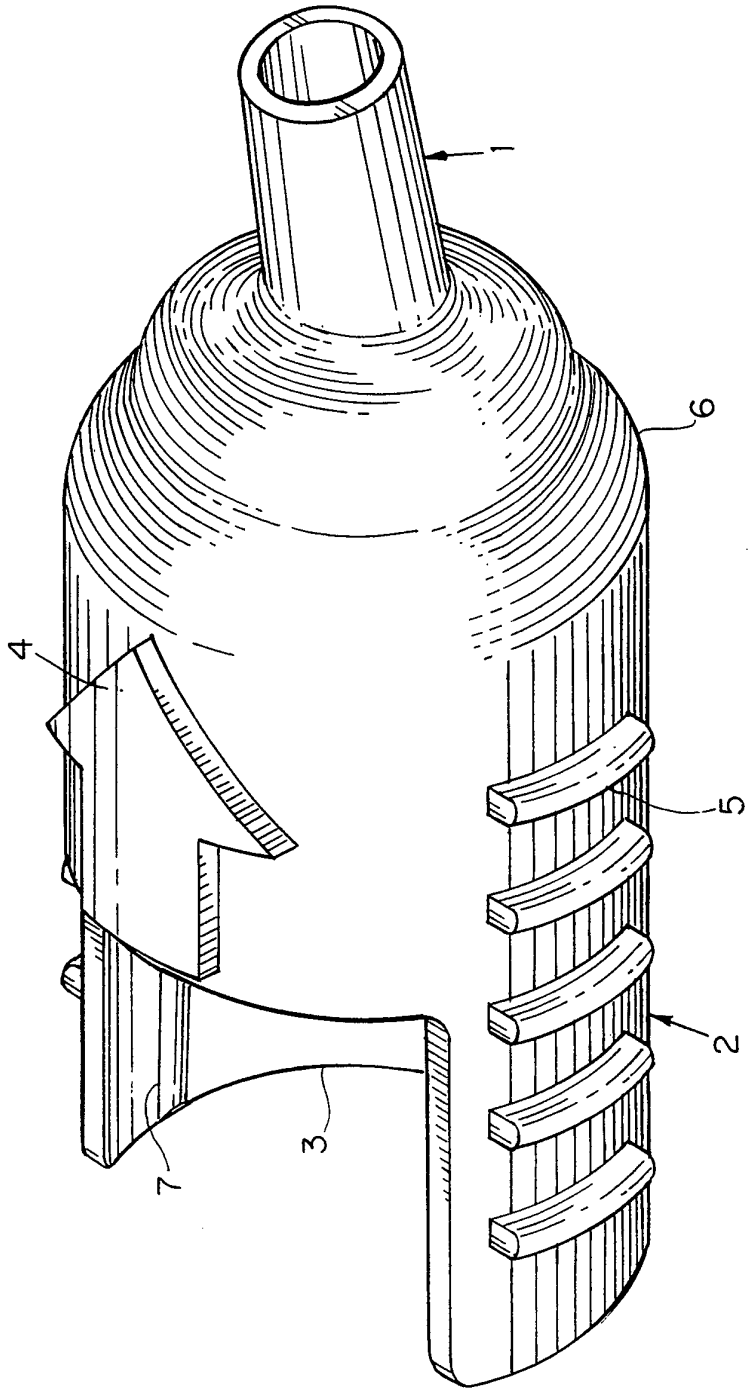

FIG. 2

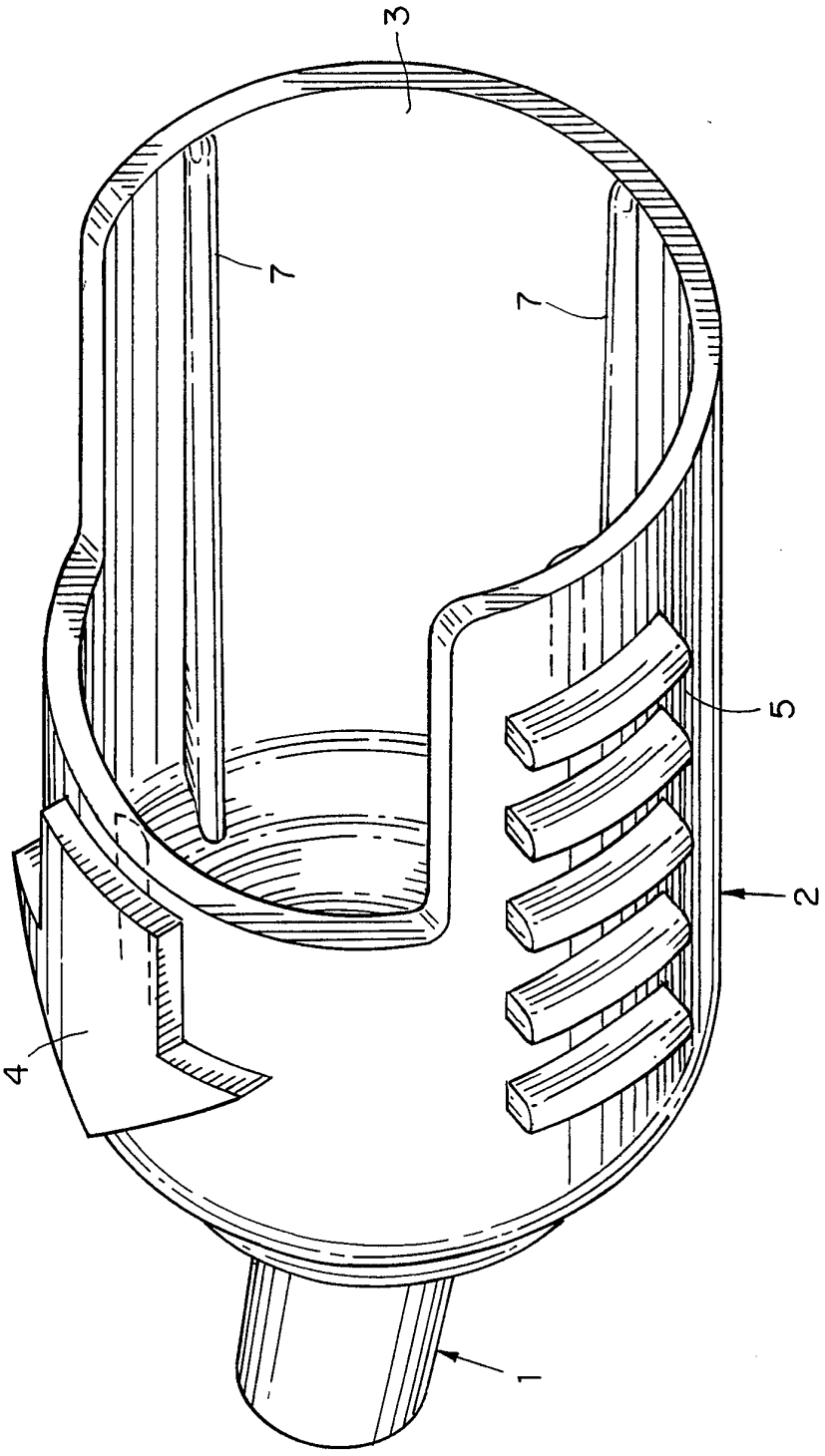

FIG. 3

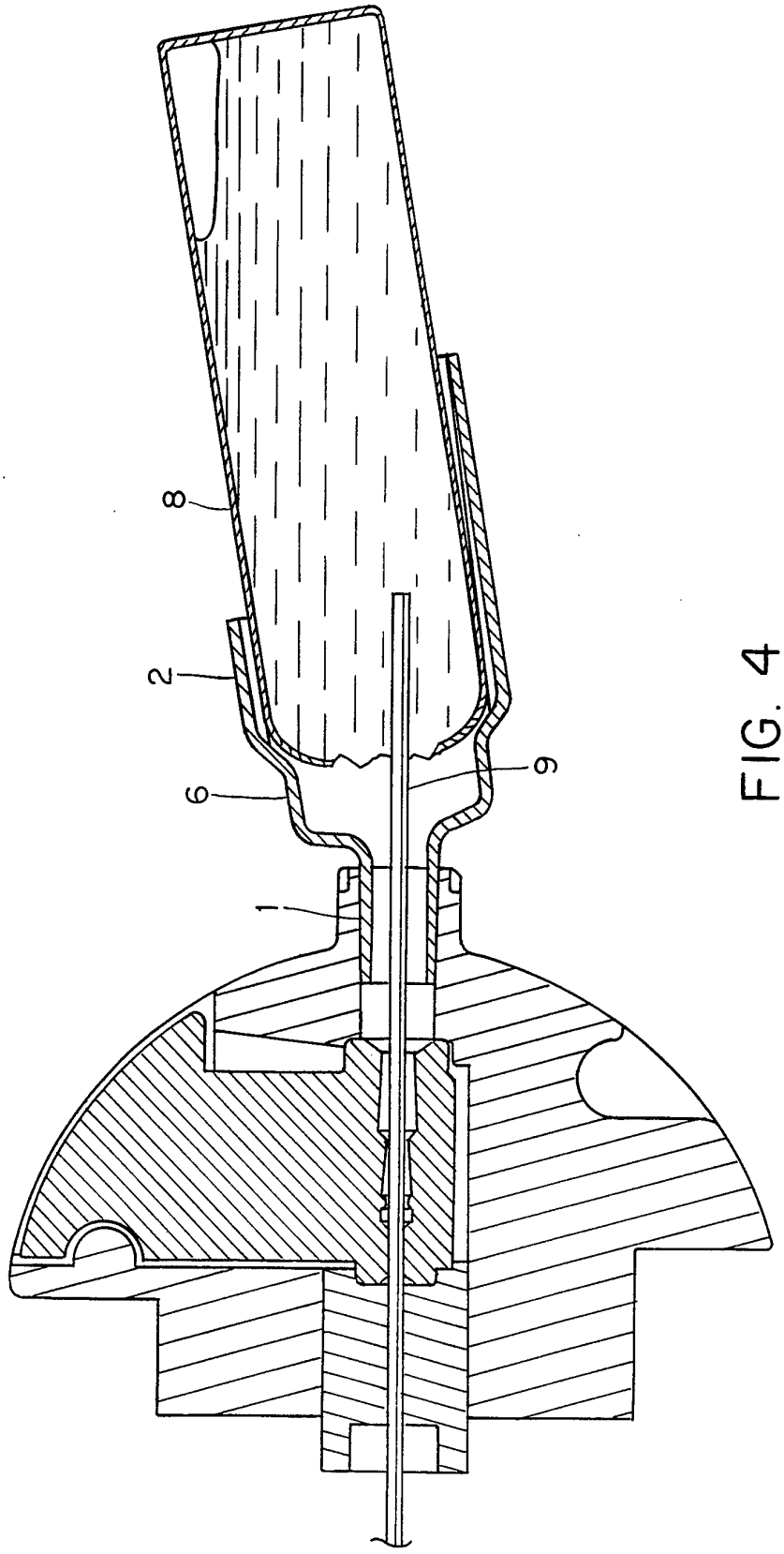

FIG. 4

INTERNATIONAL SEARCH REPORT

Ir ıtional Application No
PCT/IB 96/00580

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N1/00

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 G01N

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

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 361 253 (FLYNN WILLIAM E ET AL) 30 November 1982 see the whole document	1,6,7,12
A	US,A,4 454 095 (HOLT JOHN K) 12 June 1984 see column 3, line 58 - column 5, line 53; figures 1-5	1,6,7
A	US,A,4 353 869 (GUTH RICHARD U) 12 October 1982 see the whole document	1,6,7
A	EP,A,0 299 662 (FISHER SCIENTIFIC CO) 18 January 1989 see column 3, line 20 - column 4, line 32; figures 1-6	1,6,7

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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A	EP,A,0 431 352 (BOEHRINGER MANNHEIM GMBH) 12 June 1991 see column 4, line 18 - column 5, line 38; figures 1-3	1,6,7
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Information on patent family members

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