COMMONWEALTH OF AUSTRALIA

Patents Act 1952

608840

CONVENTION APPLICATION FOR A STANDARD PATENT

XXX/WE, Becton Dickinson and Company, a company incorporated under the laws of New Jersey, of One Becton Drive, Franklin Lakes, New Jersey 07417-1880, United States of America

hereby apply for the grant of a Standard Patent for an invention entitled:

BLOOD CULTURE SYSTEM

which is described in the accompanying complete specification.

This application is made under the provision of Part XVI of the Patents Act 1952 and is based on an application for a patent or similar protection made

in United States of America on 1 June 1987
No. (056518)

~~xxx~~ ~~on~~
~~Nxxxx~~

~~Xxx~~/Our address for service is:

F.B. RICE & CO.,
28A Montague St.
Balmain NSW 2041

Dated this 6th day of May ~~1987~~ 1988.

BECTON, DICKINSON AND COMPANY

By: _____
Registered Patent Attorney

LODGED AT SUB-OFFICE
- 9 MAY 1988
Sydney

To: The Commissioner of Patents
COMMONWEALTH OF AUSTRALIA

ACCEPTED AND AMENDMENTS ALLOWED 21.1.91

P12152

Commonwealth of Australia
The Patents Act 1952
DECLARATION IN SUPPORT

In support of the (Convention) Application made by: Becton, Dickinson and Company of One Becton Drive, Franklin Lakes, New Jersey, 07417-1880, United States of America

for a patent for an invention entitled: Blood Culture System

I (We) Raymond P. Ohlmuller, Assistant Secretary

of and care of the applicant company do solemnly and sincerely declare as follows:

~~a) I am (We are) the applicant(s) for the patent~~

XX

b) I am (We are) authorised by the applicant(s) for the patent to make this declaration on its behalf.

Delete the following if not a Convention Application.

The basic application(s) as defined by section 141 (1A2) of the Act was (were) made

on 1 June 1987 in United States of America

XX XX

XX XX

by Rainer Hammann

The basic application(s) referred to in this paragraph is (are) the first application(s) made in a Convention country in respect of the invention the subject of the application.

~~a) I am (We are) the actual inventor(s) of the invention~~

XX

b) Rainer Hammann of Heinbuckel 18, D-6901 Wiesenbach, Federal Republic of Germany

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

The applicant is the assignee of the invention from the said actual inventor.

Declared at Franklin Lakes, New Jersey, USA this 28th day of April, 1988.

Signed R.P. Ohlmuller Status Assistant Secretary

Declarant's Name Raymond P. Ohlmuller

F. B. RICE & CO PATENT ATTORNEYS

This form is suitable for any type of Patent Application. No legalisation required.

(12) PATENT ABRIDGMENT (11) Document No. AU-B-15839/88
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 608840

(54) Title
BLOOD CULTURE SYSTEM

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(57) In accordance with the present invention, a culture bottle assembly for the detection of microorganisms in body fluids is provided which is extremely simple and which avoids the disadvantages of the prior art.

The present invention consists in a culture bottle assembly comprising:

a) a container, said container having a first lower compartment for receiving a fluid culture medium, and a second upper compartment, said first compartment and said second compartment being in fluid communication,

b) a tray member having a congealed layer of solid medium in said second compartment,

c) an internal flange between said first compartment and said second compartment,

d) a frame adapted for insertion into said second compartment, said framed having a resilient material around the periphery of the lower edge of said frame,

e) closure means for said container,

f) means for moving said closure means axially with respect to said container, whereby said resilient material of said frame is compressed against said flange to provide a liquid tight seal between said first compartment and

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said second compartment, wherein said frame includes a conduit therethrough so that a liquid sample may be inserted through an aperture in said closure means into said first compartment of said container.

CLAIM

1. A culture bottle assembly comprising:
a) a container, said container having a first lower compartment for receiving a fluid culture medium, and a second upper compartment, said first compartment and said second compartment being in fluid communication,
b) a tray member having a congealed layer of solid medium in said second compartment,
c) an internal flange between said first compartment and said second compartment,
d) a frame adapted for insertion into said second compartment, said framed having a resilient material around the periphery of the lower edge of said frame,
e) closure means for said container,
f) means for moving said closure means axially with respect to said container, whereby said resilient material of said frame is compressed against said flange to provide a liquid tight seal between said first compartment and said second compartment, wherein said frame includes a conduit therethrough so that a liquid sample may be inserted through an aperture in said closure means into said first compartment of said container.

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COMPLETE SPECIFICATION

(ORIGINAL)

	Class	Int. Class
Application Number	:	
Lodged	:	
Complete Specification Lodged	:	
Accepted	:	
Published	:	
Priority	: 1 June 1987	
Related Art	:	

This document contains the amendments made under Section 49 and is correct for printing.

Name of Applicant : Becton, Dickinson and Company

Address of Applicant : One Becton Drive, Franklin Lakes, New Jersey, 07417-1880, United States of America

Actual Inventor/s : Rainer Hammann

Address for Service : F.B. RICE & CO.,
Patent Attorneys,
28A Montague Street,
BALMAIN 2041.

Complete Specification for the invention entitled:

BLOOD CULTURE SYSTEM

The following statement is a full description of this invention including the best method of performing it known to us/~~me~~:-

Background of the Invention

Field of the Invention

The present invention relates to the detection of microorganisms in a fluid sample such as, for example, body fluids. More particularly, the present invention relates to a culture bottle assembly wherein a liquid nutrient medium is provided in combination with a solid medium and wherein a fluid sample is incubated in the liquid nutrient medium which is then used to inoculate the solid medium and to continue the growth of organisms which are initially grown in the liquid nutrient medium.

Prior Art

The detection of microorganisms in body fluids, particularly bacteria in blood, requires that a sample of the fluid be used to inoculate a liquid nutrient medium. Subsequently, the liquid medium is in turn used to inoculate a solid medium to continue the growth of the organisms and to make them visible to the naked eye as colonies.

Normal monophasic systems consist of a liquid medium in a culture bottle or vial which is inoculated with a sample of the fluid and is then incubated for a desired period of time (24-48 hours). After that, a sample is withdrawn from the bottle and is used to inoculate a solid nutrient medium (agar in a Petri dish).

This procedure is laborious, sometimes hazardous and includes the risk of contamination with microorganisms from the environment. Therefore detection systems have been developed in which liquid and solid culture media are combined in the same container. Such systems avoid the troublesome and sometimes hazardous transfer of the liquid culture to the solid culture medium. United States Patent No. 2,992,974 to Belcove et al, for example, describes a biological testing device in which a solid medium is restrained in the top portion of a rectangular culture bottle while a liquid nutrient medium is provided in the lower most portion of the bottle. United States Patent No. 3,589,983 to Holderith et al describes a culture bottle which is designed to hold a solid agar nutrient material at a location along the axial centerline of a bottle. The bottle also houses a liquid nutrient broth which may be separated from the solid agar by positioning the bottle on its side.

The above described prior art devices which combine a liquid nutrient medium in a single container with a solid medium have a major disadvantage in that the culture assembly must be positioned in a certain manner prior to contacting the solid medium with the precultured liquid medium. The above described prior art devices for separating solid and liquid culture media are complicated and facilitate separation of the liquid media and the solid media only during incubation, but not during transport.

United States Patent No. 4,308,347 to Forrer et al describes a device for detection of microorganisms in a fluid sample which includes a first container holding a liquid nutrient medium and a second container containing one or more solid nutrient

medium. The containers are detachably connected so that the media can be brought into contact when desired. The device described in the Forrer Patent is complicated and requires several manipulative steps to bring the precultured liquid media into contact with the solid medium.

The above disadvantages of the prior art are overcome in accordance with the present invention which provides a simple culture bottle assembly which contains a liquid media and one or more solid nutrient media in a single container with easily effected means for bringing the precultured liquid media into contact with the solid media when desired.

~~Summary of the Invention~~

In accordance with the present invention, a culture bottle assembly for the detection of microorganisms in body fluids is provided which is extremely simple and which avoids the disadvantages of the prior art. The culture bottle assembly of the present invention consists of a single container divided into a first lower compartment and a second upper compartment by an internal flange. A frame is provided for insertion into the second upper compartment. The frame has a lower peripheral edge which can be lowered into mating relationship with the internal flange. A resilient material is disposed on the lower peripheral edge. Closure means are provided which cause the frame to move downwardly and compress the resilient material against the flange to close the container and to provide two compartments which are sealed from each other. The first lower compartment contains a liquid nutrient medium and the second upper ~~compartment contains one or more solid media. A fluid~~

Summary of the Invention

In accordance with the present invention, a culture bottle assembly for the detection of microorganisms in body fluids is provided which is extremely simple and which avoids the disadvantages of the prior art.

The present invention consists in a culture bottle assembly comprising:

a) a container, said container having a first lower compartment for receiving a fluid culture medium, and a second upper compartment, said first compartment and said second compartment being in fluid communication,

b) a tray member having a congealed layer of solid medium in said second compartment,

c) an internal flange between said first compartment and said second compartment,

d) a frame adapted for insertion into said second compartment, said framed having a resilient material around the periphery of the lower edge of said frame,

e) closure means for said container,

f) means for moving said closure means axially with respect to said container, whereby said resilient material of said frame is compressed against said flange to provide a liquid tight seal between said first compartment and said second compartment, wherein said frame includes a conduit therethrough so that a liquid sample may be inserted through an aperture in said closure means into said first compartment of said container.

~~conduit is provided thru the frame whereby a specimen~~ can be inserted through an aperture in the closure means into the fluid medium in the lower compartment. After a sample is incubated in the ~~liquid~~ medium for a desired period of time the ~~closure~~ means are moved to a second position ~~which~~ provides an open space above the internal flange through which the precultured liquid medium can be transferred into contact with the ~~solid media when the container is turned over.~~

Further details and features of the invention will become more apparent from the following detailed description and the drawings which disclose what is presently considered to be the best mode of the invention.

The Drawings

In the drawings:

Figure 1 is a longitudinal cross section of the container in accordance with the present invention which shows the relative location of the liquid nutrient medium and the solid medium;

Figure 2 is a top view of the container;

Figure 3 is a perspective view of the frame of Figure 2 and a solid media holder showing details of the frame and the solid media assembly;

Figure 4 is cross section of the frame of the culture bottle assembly of the invention;

Detailed Description of the Invention

Referring now to the drawings:

A container 11 is divided into a first lower compartment 13 and a second upper compartment 15 by means of an internal flange 17. A frame 19, as shown in Figure 2, is provided for insertion into the second

upper compartment 15. The frame 19 has a lower peripheral edge 20 which generally conforms to the shape of internal flange 17. A resilient material 21 is disposed on the lower peripheral edge 20. A fluid conduit 23 is provided through the frame 19 for insertion of a fluid specimen into the first lower compartment 13. A fluid medium 25 is disposed into the first lower compartment 13 for incubating the fluid specimen when desired. During the filling process of the media the normal oxygen containing atmosphere might be exchanged by oxygen-free gas, such as nitrogen and CO_2. By this an enhanced environment is created to provide growth for anaerobic (oxygen-intolerant) bacteria in the broth and subsequently on the surface of the solid media.

Closure means 27 are provided for closing the second upper compartment 15 and for causing the frame 19 to be moved axially so as to cause engagement of the resilient material 21 with internal flange 17 and to seal the first lower compartment with the second upper compartment.

As shown in Figure 3, a solid medium holder 29 is disposed around the frame 19 prior to placing the frame into the second upper compartment 15. The solid medium holder contains a suitable solid medium, such as an agar medium. As shown in Figure 3, the solid medium holder contains two trays 31 and 33. The solid medium holder 29 is made ready for use by first dispensing an agar nutrient material in liquid form at an elevated temperature into the tray sections of the holder 29. The agar nutrient material may be the same or different in each tray. The agar is allowed to cool and solidify before the solid media holder is inserted into mating relationship with the frame 19.

While not shown, it should be understood that a third tray could be disposed on the outwardly facing side of solid medium holder 29.

After the solid media holder 29 is moved into mating relationship with the frame 19 the frame 19 is placed into the second upper compartment 15. The frame rests lightly on internal flange 17. Closure means 27, such as a cap, is placed on the open mouth of the container. As shown in Figure 1, the cap is provided with screw threads as a means for moving the cap into and away from a position where the resilient material 21 mates with the internal flange 17. The displacement means consist of screw threads 35 located in the outside sidewall of container 11 and mating screw threads 37 located in the inside wall of the cap 27.

When the cap is secured firmly into place, the resilient material 21 is compressed against internal flange 17 and a liquid tight seal is formed between the first lower compartment 13 and the second upper compartment 15.

It should be understood that the term "resilient material" as used herein refers to any material which may be sufficiently compressed by the closure means to form a liquid tight seal against internal flange 17 between the first lower compartment and the second upper compartment. Suitable resilient materials include, but are not limited to, polyethylene, polypropolyene, polyurethane, silicone rubber and nylon.

An inoculation port 39 is provided in the cap 27 for injecting a sample into the fluid conduit 23. The inoculation port 29 comprises an opening in the closure means 27 over which a septum 41 is secured.

The septum 41 is a suitable material which is capable of being pierced by a cannula or other injection means and which subsequently recloses upon extraction of the cannula. Means, not shown, can be provided for permitting air to penetrate through the fluid conduit 23 and into the first lower compartment 13 for aerobic incubation of the inserted sample. Such means would consist merely of a device with a hollow annular opening therethrough for penetration of the septum 41 to permit air to be admitted into the first lower compartment 13.

The container 11, frame 19, solid medium holder 29 and cap 27 are formed from any suitable material, such as glass, plastic or metal. The container 11 is preferably formed from a transparent material, such as glass or plastic, so that microbial growth on the the solid media can be seen from the outside. The container may be any suitable cross sectional shape but is preferably cylindrical or a regular polygon in shape for ease of manufacture.

During transport and inoculation the cap 27 is in a position such that the resilient material 21 is compressed in mating relationship with the internal flange 17 and the fluid medium is contained in the first lower compartment. A sample is inserted through the septum 41 and downwardly through the fluid conduit 23 into the liquid medium contained in the first lower compartment. After a suitable incubation period, the cap 27 is moved upwardly so that a space is provided between the resilient material 21 and the internal flange 17. The container is inverted to permit the liquid medium to flow from the first compartment into the second compartment. Subsequent growth then occurs on the solid medium contained on the solid medium

holder 29.

In accordance with the present invention an extremely simple device is provided for transporting and utilizing a liquid medium followed by subsequent inoculation of a solid medium with a sample incubated in the liquid medium. The culture bottle assembly of the present invention permits transportation of the liquid medium and the solid medium in separate compartments during transportation and provides easy means for transferring the precultured liquid medium into contact with the solid medium when desired.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A culture bottle assembly comprising:

a) a container, said container having a first lower compartment for receiving a fluid culture medium, and a second upper compartment, said first compartment and said second compartment being in fluid communication,

b) a tray member having a congealed layer of solid medium in said second compartment,

c) an internal flange between said first compartment and said second compartment,

d) a frame adapted for insertion into said second compartment, said framed having a resilient material around the periphery of the lower edge of said frame,

e) closure means for said container,

f) means for moving said closure means axially with respect to said container, whereby said resilient material of said frame is compressed against said flange to provide a liquid tight seal between said first compartment and said second compartment, wherein said frame includes a conduit therethrough so that a liquid sample may be inserted through an aperture in said closure means into said first compartment of said container.

2. A culture bottle assembly in accordance with claim 1 which includes a liquid nutrient medium in said first compartment.

3. A culture bottle assembly in accordance with claim 1 wherein said closure means include screw threads on the outside side wall of said container and mating screw threads on the inside side wall of a cap.

4. A culture bottle assembly in accordance with claim 1 wherein the cross sectional shape of said first compartment is the same as the cross sectional shape of said second compartment.

5. A culture bottle assembly in accordance with claim 1 wherein the cross sectional shape of said first compartment, said second compartment and said internal flange is cylindrical.

6. A culture bottle assembly in accordance with claim 1 wherein said aperture in said closure means has a needle piercable septum placed therein.

7. A culture bottle assembly in accordance with claim 1 wherein the cross sectional shape of said first compartment, said second compartment and said internal flange is a regular polygon.

8. A culture bottle assembly substantially as hereinbefore described with reference to the accompanying drawings.

DATED this 11 day of December 1990

BECTON DICKINSON AND COMPANY
Patent Attorneys for the
Applicant:

F.B. RICE & CO.

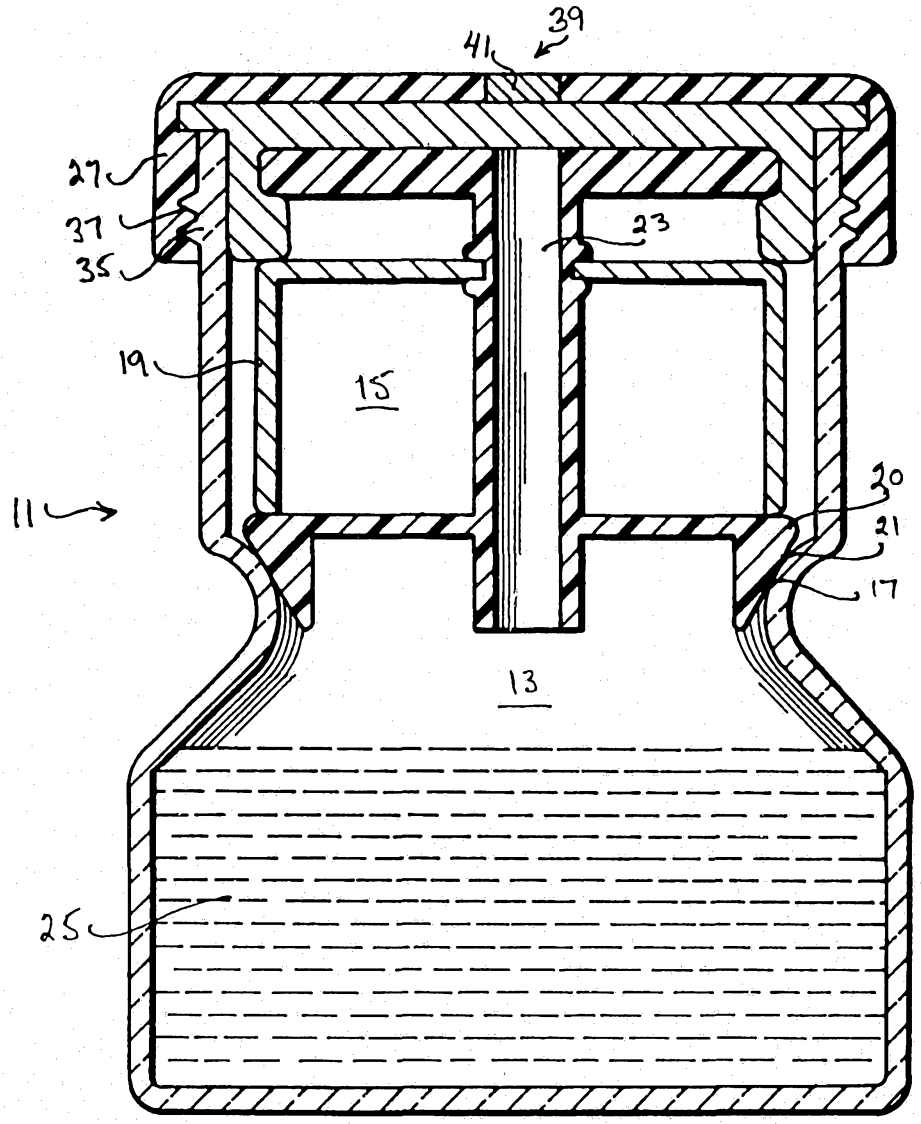

Fig. 1

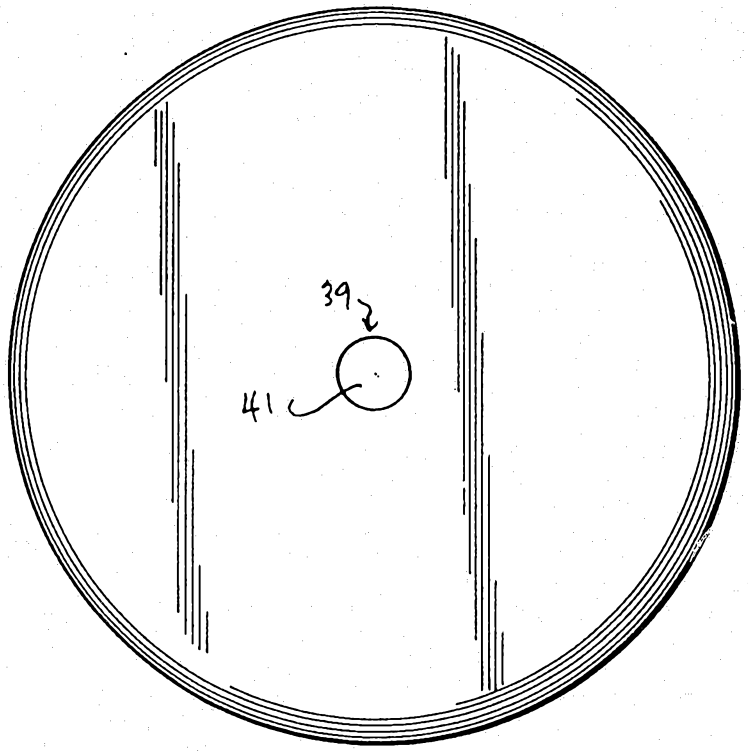

Fig. 2

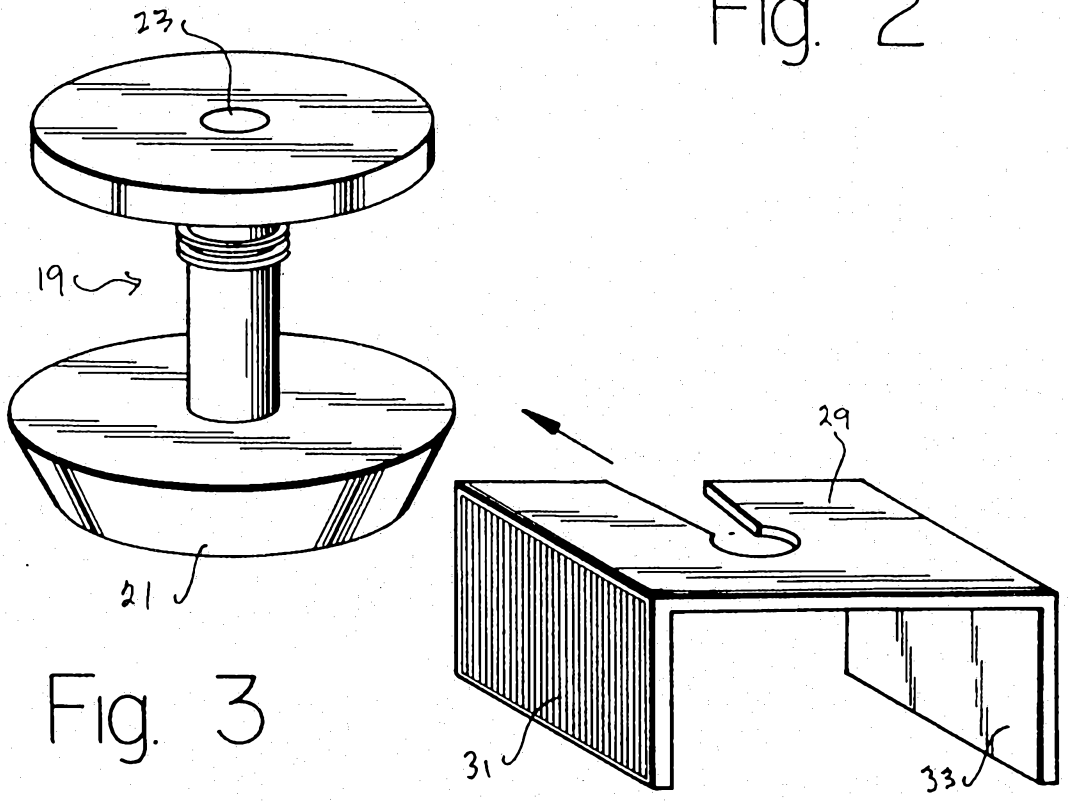

Fig. 3

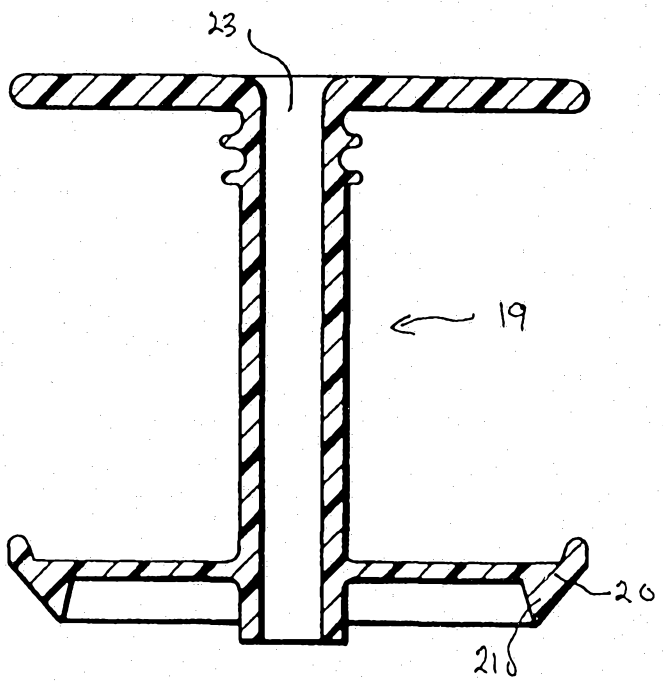

Fig. 4