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(54) Head for a container intended for repeated use.

(57) A head for a container whose contents are intended to be discharged as separate aliquots, which comprises one or more narrow elongate passages (3) having a length of at least 3 mm and a maximum separation between the walls (1), when the passage is closed, of 1 mm and which provides a lasting barrier against microbial invasion of the contents. The barrier is mechanical in principle, but can be augmented by the incorporation of antimicrobial agents in the head.

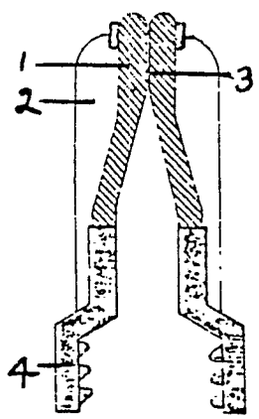

Fig 1

EP 0 302 575 A1

HEAD FOR A CONTAINER INTENDED FOR REPEATED USE

This invention relates to novel heads for different types of containers, whose contents are intended to be discharged as separate aliquots.

The containers for which the heads of the invention are intended, e.g. collapsible tubes, are widely used in pharmacy, cosmetics and food industry, and their contents are always more or less susceptible to microbial infection. The chances of invasion are greater when the container is repeatedly used, and the chances of multiplication depend firstly on the water content and secondly on the presence of nutrients suitable for the growth of the invading microorganisms. Such microbial overgrowth, while potentially deleterious to any sort of contents, is currently recognized by authorities as being hazardous in particular when the contents of the containers are pharmaceuticals. There are therefore government regulations prescribing the sterile production of containers containing pharmaceuticals and also the incorporation of antimicrobial agents in these contents. Challenge experiments are prescribed, in order to ensure that the contents remain free of microbial overgrowth during their entire useful life.

Sterile production is not always technically possible or economically feasible. Besides, even absolutely sterile production can only conserve the contents of a container until it is opened for the first time. Therefore, anti-microbial agents are generally mixed into the contents. When these anti-microbial agents are the only protection against overgrowth due to invasion from outside, they have to meet such a great variety of requirements, some of which conflict, that out of the vast arsenal of available chemicals virtually none is completely satisfactory.

Examples of such requirements, which a good disinfectant has to meet when used for this purpose, are:

- Broad spectrum of activity against a great many different potential invaders;
- Persistent activity during the entire useful life of the contents;
- Absence of deleterious interactions with any other component of the contents (absence of incompatibility);
- Absence of toxicity;
- Absence of sensitisation;

From the foregoing it will be clear, that it is desirable to eliminate or at least substantially reduce the need to incorporate relatively high concentrations of long-acting and broad-spectrum anti-microbial compounds in the contents of the containers. A substantial reduction of the requirements which disinfectants have to meet, for example when only short activity is needed to deal with low contamination which may occur during production, would enable the use of smaller concentrations of less drastic disinfectants, which have the advantage of being free from the dangers of toxicity and/or sensitisation. Under these circumstances short-acting disinfectants could also be used.

In order to prevent microbial overgrowth in the contents of the containers without the need to incorporate high concentrations of long-acting and broad-spectrum anti-microbial compounds in the contents, it was considered advantageous to prevent the invasion of the microorganisms in the first place.

One possibility known in the art for circumventing the danger of contamination arising from repeated use, is to avoid such repeated use altogether, that is to produce small single-use containers. However, this has the disadvantage of a fixed dose which cannot be adapted to individual requirements. It is also relatively expensive and wasteful.

Another option is to prevent contamination by measures taken at the outlet of the container.

Conventional heads have considerably large openings through which the contents can easily be expressed, but which also allow free entry of microorganisms. These openings are usually closed simply with fitted caps, which have to be removed before each discharge of material.

To date, the art discloses strikingly few devices directed to the prevention of contamination through the head of the container. DE 1,492,296, US 3,917,116, GB 2,041,896 and WO 83/03572 are all directed to heads intended for protection of containers of pharmaceutical liquids only until they are opened for the first time.

DE-OS-1,586,758 discloses a tube with a closing device to prevent drying out of the tube contents in which point closure is effected by contact between the lips of a tubular member attached to the tube itself. GB 417,793 is directed to an opening and closing device which prevents the oxidation of the contents in a tube, and comprises a number of displaceable members held together by a ring which separate to form an aperture when the tube is squeezed. GB 326,683 discloses a valve-type closing device for a tube where the opening through which the tube contents are extruded is very short.

It is therefore an aim of the present invention to provide to the containers, whose contents are to be discharged as separate aliquots, a head which will form such a barrier to microbial contamination as to eliminate or at least to reduce substantially the need to incorporate anti-microbial compounds in the

contents of the containers.

It has now been found that the danger of microbial contamination of the contents is eliminated or substantially minimized when the opening or openings in the head, through which the contents of the container are extruded, are long and narrow and are automatically closed when not used, thereby providing a lasting mechanical barrier against bacterial invasion. In accordance with the invention the passage length is no less than 3 mm and is preferably no less than 5 mm, and its width when closed is a maximum of 1 mm, preferably of 0.1 mm.

Surprisingly this simple but novel principle of a mechanical barrier has been found to suffice in most cases for preventing contamination of the contents through the head of the container, even when it is used repeatedly.

The head according to the invention is not to be removed, but stays in its place while the container is being used. The head may be fitted with a cap for cover and protection, e.g. against desiccation, which cap must be removed before each use.

The head according to the invention may form an integral part of the outlet of the container, or it may be attached to said outlet by any means known in the art.

The containers may be of any type known in the art, in particular those in which the volume is reduced and no air is introduced as the contents are extruded. Such containers are those provided with a plunger and collapsible tubes, in combination with which the heads of the invention are particularly suitable.

The contents of the containers for which the heads of the invention are intended may be any of those materials which are susceptible to deterioration by microbial infection, such as pharmaceuticals, cosmetics or foodstuffs. The contents should pass readily through the narrow opening or openings of the head, therefore they will be semisolid or liquid.

When an exceptionally great risk of contamination is deemed to exist, it is also possible to augment the barrier for microorganisms by incorporating certain anti-microbial agents in the head of the container.

Therefore, in some embodiments of the invention, the heads may contain certain anti-microbial agents. Also, when a removable cap is used to cover the head, this cap may contain an anti-microbial agent.

The incorporation of an anti-microbial agent in the head or cap can be realised by e.g. mixing this agent with the plastic material before setting, by impregnation of the complete head or cap with the agent or by providing a separate compartment for the agent.

An anti-bacterial agent incorporated in the head or cap according to the present invention has to meet quite different requirements as compared with an anti-bacterial agent which is incorporated in the contents. When the anti-bacterial agent is incorporated in the head or cap, its anti-bacterial effect has to be built up very quickly (due to the frequent transit of fresh contents) in a very small volume of contents, which is consequently unlikely to affect the user in any undesired way.

The anti-bacterial agent in the head or cap should not be exhausted before the end of the useful life of the container itself. The requirements as to the range of anti-microbial activity are substantially similar to those posed for anti-microbials incorporated in the contents.

Suitable are anti-microbial organic and inorganic substances such as iodine, halogen compounds, phenols and antibiotics.

Also anti-microbially active metals such as silver, copper or zinc, or pharmaceutically acceptable derivatives thereof, can be used in the form of, for example bound powder, wires and strips.

Based on these principles of the invention, several embodiments have been found practicable and these are illustrated in the accompanying drawings.

FIGURE 1 is a longitudinal cross-sectional view of a first embodiment of the head;

FIGURE 2A is a longitudinal cross-sectional view of a second embodiment of the head;

FIGURE 2B is a top plan view of the head of Figure 2A, when open;

FIGURE 3 is a cross-sectional view of a third embodiment of the head;

FIGURES 4A and 4B show two longitudinal cross-sectional views of a fourth embodiment of the head in which the tube is closed (Figure 4A) and the other in which it is open (Figure 4B);

FIGURE 4C shows a plan view of the head of Figures 4A and 4B;

FIGURES 5A and 5B show two cross-sectional views of a fifth embodiment of the head, one in which the tube is closed (Figure 5A) and the other in which it is open (Figure 5B); and

FIGURES 6A and 6B show two cross-sectional views of a sixth embodiment of the head, one in which the tube is closed (Figure 6A) and the other in which it is open (Figure 6B).

Referring to Figure 1, the head comprises an elastic tube (1), preferably made of silicon rubber and having an inside diameter preferably from 2 to 5 mm. The tube is externally provided with a spring-loaded clip (2), the jaws of which act radially on the tube to keep the tube walls in contact, thereby closing the container, when at rest, and force the walls apart when pressure which outweighs the spring resistance is

applied to the container. This allows extrusion of the container contents through the narrow elongate channel (3) between the opposed walls of the tube as the walls yield to separate. The channel has a length of at least 3 mm and preferably at least 5 mm. The tube and external clip are attached to a conventional cap (4) provided with a thread enabling it to be screwed onto a container.

The head illustrated in Figure 2 comprises an elastic rod (1), the lower part of which has a conical exterior which is connected to the inner face of an internally threaded frusto-conical cap (3). The bottom end of the rod has a conical concave form. The rod has a nearly complete diametral slit (2) opening into a conical concave lower end of the rod near the top of the container so as to facilitate opening of the slit when the contents of the container are pressurized. The elastic rod may be made of one or more materials, at least one of which may be silicone rubber, and it is preferably between 1 and 2.5 cm long. The slit, which extends for the full length of the rod, has a length of at least 5 mm, preferably 10 mm. The passage defined by the slit is less than 0.1 mm when closed. When pressure is applied to the container, its contents are forced through the slit; on release of this pressure the slit closes and the inner faces of the rod approach one another.

The embodiment depicted in Figure 3 resembles a Dunlop-type tyre valve. The head comprises a hollow, preferably tapering part (1) which is internally provided with a thread at its wider end, to allow it to be screwed onto a container. One or more small holes (2, 3) are provided towards the narrower end, which is closed. The holes are preferably 1.0 to 1.5 cm from this closed end. The head further comprises a length of elastic tubing (4) which extends the length of the hollow part, covering the holes, and which preferably ends flush with its closed end. When pressure is applied to the container its contents are forced into the hollow part of the head and extruded out through the channel between the outer surface of the hollow section and the elastic tubing (5, 6). The radial spacing between the tubing (4) and the narrow end of the head (1) is no more than 1 mm when the tube is closed. When the pressure is released the head closes automatically by contraction of the tubing (4).

The embodiment illustrated in Figures 4A, 4B and 4C comprises a housing (11) which may be screwed onto the top of a container (2), and which is provided with a plurality of, in this case, four, openings (13) which extend into the body of the housing. The inner surface of the housing extends cylindrically from its upper end for between a quarter and a third of its total length and then tapers radially inwards to meet the top of the container. The frusto-conical cavity described by the tapering inner surface is provided with a plug (15) which is made from an elastic material and which comprises an upper stem (15a) that is attached inside the central cavity of the housing (16) ending flush with the end surface of the housing. When the container is squeezed the plug stem (15a) is compressed such that its shoulders end flush with the lower surface of the central cavity (17). A narrow elongate channel (18) is thereby formed between the tapering plug tip (15b) and the tapering inner surface of the housing through which the container contents are extruded. The channel (17) has a length of at least 5 mm, preferably 10 mm and the separation between its walls is no more than 0.1 mm when the passage is closed.

The embodiment illustrated in Figures 5A and 5B comprises a housing (22) formed from a rigid material, the inner surface of which tapers inwards for about a quarter of its total length and then extends cylindrically to meet the top of the container to which it is attached. The housing comprises a central part (24) which is separated from the cylindrical inner surface of the housing by an annular channel (23) and into which the stem (21a) of a frusto-conical plug (21) is secured. The plug is made from an elastic material and, when the container is not in use, it is in contact with the tapering inner surface of the housing. The plug is joined to the stem by a neck section (25) and when the container is squeezed, the pressure caused by the contents in the channel (23) causes elongation of the neck which in turn allows the plug (21) to lift and thereby form an extended elongate channel between the housing and the plug through which the container contents are extruded. The channel has a length of at least 5 mm, preferably 10 mm and the separation between its walls is no more than 0.1 mm wide when the passage is closed.

The embodiment illustrated in Figures 6A and 6B closely resembles that in Figures 5A and 5B, and comprises a rigid housing (32), a compressible plug (31) with a resilient neck (35) and a stem (31a) which is secured inside the central section of the housing (34) that is separated from the main housing by an annular channel (33).

The plug has a concave surface which fits against the slightly convex tapering surface of the housing, so that when pressure is applied to the container and the neck of the plug extends to allow the plug to move upwards, the opening between the housing and the plug forms an extended elongate channel (36) of 1 cm length, which is slightly divergent, and through which the container contents are extruded. The separation between the walls of the passage (36) is no more than 0.1 mm at the inlet end of the passage when the container is closed.

It will be understood that although all the embodiments described are provided with a thread to enable

the head to be attached to a container, alternative means of attachment may be used.

Furthermore, although various different values are given for the dimensions of the passage, it will be appreciated that these are indicative of the range of lengths of at least 3 mm and a width of no more than 1 mm contemplated for the invention.

The invention includes heads as hereinbefore described, provided with anti-microbial agents, as hereinbefore described.

The following Examples illustrate certain embodiments of the invention.

EXAMPLE 1

The head according to the third described embodiment (Figure 3), but differing in that the elastic tubing extends for about 3 mm beyond the closed narrow end of the cone, was used for testing against contamination with Enterobacter aerogenes (chosen for its great motility). Dummy heads, used for positive control, were identical cones but without the elastic tubing.

The complete heads and dummy-heads were mounted on the needle-ends of luer-locked disposable plastic 2 ml injection syringes, and the combination was filled with sterile nutrient cream of one of the following compositions (% w/v):

	Cream I	Cream II
BHI* - broth, 10 x concentrated	7	7
cetostearyl alcohol	6	6
Cetomacrogel 1000^{R}	3	3
liquid paraffin	6	6
white petrolatum	15	15
phenol red	-	0.0027
sodium hydroxide, 1 N	-	1.4
water	63	62.6

*Brain Heart Infusion broth 0037, marketed by DIFCO Laboratories.

Cream II is useful for indicating bacterial mutiplication by changing its colour at the place of multiplication to yellow due to acidic metabolism products. Preliminary experiments have ascertained, that the addition of phenol red and sodium hydroxide to cream II does not affect the growth and motility of Staphylococcus or Enterobacter as compared to cream I.

Infection of the tested combinations was performed by inserting a liquid culture of Enterobacter, containing about $5x10^5$ CFU (Colony Forming Units), at the free end of the elastic tubing.

Subsequently the combinations were incubated at 30 ° C. On the 2nd, 3rd, 4th, 7th and 8th day a small portion of the paste was extruded and the combination re-infected in the same manner. Before each reinfection and on the 15th day the combinations were examined for bacterial presence immediately behind the complete head or dummy-head, by inspection for yellow discoloration in the case of cream II, and/or by culturing samples on agar (Bacto Brain Heart Infusion Agar, 0418, marketed by DIFCO Laboratories). The results are presented in Table 1, printed hereinafter.

EXAMPLE 2

Substantially the same experimental design was employed as in Example 1, the difference being that here infection of every head was done only once, followed by an incubation period at 30 ° C of 7 or 28 days.

The results are presented in Table 2 printed hereinafter.

EXAMPLE 3

Substantially the same experimental design was employed as in Example 1, the difference being that here Staphylococcus aureus (chosen because it is a common pathogen) was used as the test bacterium. For infecting the free ends of the elastic tubes, about $5x10^5$ CFU were used each time.

The results are presented in Table 3, printed hereinafter.

EXAMPLE 4

The same heads and dummy heads as in Example 1 were employed, and also the same microorganism.

However, here the medium in the container was the liquid DIFCO BHI-broth instead of the cream.

The heads or dummy heads were attached to disposable plastic 5 ml injection syringes, and the combination was filled with the sterile broth.

Subsequently the combinations were placed for the further duration of the experiment with their heads immersed in vessels containing at the start of the experiment about $5x10^5$ CFU/ml Enterobacter aerogenes (the bacterial content of this broth developed to a maximum of $5x10^8$ CFU/ml within the first 24 hours, and did not drop below $5x10^6$ CFU/ml for the duration of the experiment).

On the first second, third, sixth and seventh day 0.5 ml broth was expelled out of the syringe and through the head or dummy head into the infected broth.

Control for bacterial colonisation within the syringe was performed visually (in the liquid broth, multiplication of bacteria is readily evident by the development of turbidity) and by culturing samples.

The results are presented hereinafter in Table 4.

EXAMPLE 5

Substantially the same experimental design was employed as in Example 4, the difference being that here Staphylococcus aureus was used as the test bacterium for infecting (10^5 CFU/ml) the broth in the vessel.

(The bacterial contents of this organism did not drop below 10^8 CFU/ml for the duration of the experiment).

The results are presented hereinafter in Table 5.

EXAMPLE 6

The head according to the first described embodiment (Figure 1) was used for testing against ingrowth of six different micro-organisms.

The heads were mounted on the open ends of 30 ml collapsible tubes, filled with the sterile nutritive cream I of Example 1.

Infection of the tested combination was performed by inserting a liquid culture of Enterobacter aerogenes, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Candida albicans or Aspergillus niger into the free end of the head. Subsequently the combinations were incubated at 30 °C for 24 hours.

Samples of the paste were then taken before and immediately behind the closing clip of the head, and analysed for microbial presence by culturing on agar.

The results are presented hereinafter in Table 6.

Table 1

Bacterial colonisation after repeatedly infecting the free end of dummy or complete third-model heads with Enterobacter aerogenes.									
Heads	Bacterial colonisation indicated by	number of heads tested	Number of heads with colonisation following serial infection						Total percentage heads with colonisation
			First	Second	Third	Fourth*	Fifth**	Sixth***	
Dummy	phenol red discoloration	3	3	3	3	3	3	3	100
"	culturing samples	3	3	3	3	3	3	3	100
Complete	phenol red discoloration	10	0	0	0	0	0	0	0
"	culturing samples	10	0	1	2	0	2	0	8****

* 7th experimental day
** 8th experimental day
*** 15th experimental day
**** only scant colonisation.

Table 2

Bacterial colonisation after single infection of the free end of dummy or complete third-model heads with Enterobacter aerogenes.				
Heads tested	Incubation period (days)	Bacterial colonisation indicated by	Number of heads tested	Number of heads with colonisation
Dummy	7	phenolred discoloration	3	3
"	"	culturing samples	3	3
"	28	phenolred discoloration	3	3
"	"	culturing samples	3	3
Complete	7	phenolred discoloration	10	0
"	"	culturing samples	10	0
"	28	phenolred discoloration	10	0
"	"	culturing samples	10	0

Table 3

Bacterial ingrowth after repeatedly infecting the free end of dummy or complete third-model heads with staphylococcus aureus.									
Heads	Bacterial colonisation indicated by	number of heads tested	Number of heads with colonisation following serial infection						Total percentage heads with colonisation
			First	Second	Third	Fourth*	Fifth**	Sixth***	
Dummy	phenolred discoloration	5	5	5	5	5	5	5	100
"	culturing samples	10						10	100
complete	phenolred discoloration	9	0	0	0	0	0	0	0
"	culturing samples	19					0	2	5

* 7th experimental day
** 8th experimental day
*** 15th experimental day

Table 4

Bacterial colonisation after placing the free end of dummy or complete third model heads in broth infected with Enterobacter aerogened.								
Heads	Bacterial colonisation indicated	Number of heads tested	Number of heads with colonisation					Total percentage heads with colinisation
			First day	Second day	Third day	Sixth day	Seventh day	
Dummy	visually	5	5	5	5	5	5	100
"	by culturing samples	5					5	100
complete	visually	5	0	0	0	0	0	0
"	by culturing samples	5					0	0

Table 5

Bacterial colonitation after placing the free end of dummy or complete third model heads in broth infected with Staphylococcus aureus.								
Heads	Bacterial colonisation indicated	number of heads tested	Number of heads with colonisation					Total percentage heads with colonisations
			First day	Second day	Third day	Seventh day	Eight day	
Dummy	visually	5	3	5	5	5	5	92
"	by culturing samples	5					5	100
complete	visually	5	0	0	0	0	0	0
"	by culturing samples	5					0	0

Table 6

Microbial colonisation after infection of free end of first model heads.				
test - microorganism	starting infection (CFU)	number of combinations infected	Number of microbiologically positives after 24 hours incubation at 30¤C	
			before the clip	behind the clip
Enterobacter aerogenes	$2.2x10^7$	2	2	0
Escherichia coli	$1.3x10^6$ $1.0x10^3$	1 1	1 1	0 0
Pseudomonas aeroginosa	$1.4x10^5$ $2.2x10^2$	1 1	1 1	0 0
Staphylococcus aureus	$2.4x10^5$ $1.7x10^3$	1 1	1 1	0 0
Candida albicans	$4.8x10^3$ $2.0x10^2$	1 1	1 1	0 0
Aspergillus niger	$1x10^4$ $1x10^3$	1 1	1 1	0 0

Claims

1. A head for a container whose contents are intended to be discharged as separate aliquots, characterised in that the or each opening through which the contents are extruded is defined between two opposed walls which separate to open the discharge passage; and in that said passage (6; 16; 26; 36) has a length no less than 3 mm and preferably no less than 5 mm, and the separation between the walls, when the passage is closed, is a maximum of 1 mm, preferably of 0.1 mm, and is automatically closed when the container is not in use thereby providing a lasting mechanical barrier against microbial invasion.

2. A head according to claim 1, characterised by including an elastic tube (1) and an externally positioned spring-loaded clip (2), acting radially on the tube to close said passage within the tube.

3. A head according to claim 1, characterised by including an elastic rod (1), provided with an internal longitudinal slit (2) serving as said passage.

4. A head according to claim 1, characterised by a hollow part (1), having one closed end and one or more small holes (2, 3) positioned at a distance from said closed end, and a length of elastic tubing (4) covering said hollow part and holes to define said passage between the hollow part and the elastic tubing.

5. A head according to claim 1, characterised by comprising a frusto-conical cavity fitted with a plug (15) having a resilient stem (15a).

6. A head according to claim 5, characterised in that the cavity walls are slightly convex and the plug surface is concave.

7. A head according to claim 5 characterised in that the head is provided with a plurality of said discharge passages.

8. A head according to any of the foregoing claims, in combination with a container.

9. A head according to claim 8, characterised in that the container is a collapsible tube.

10. A head according to claim 8 or 9, characterised in that the contents of the container comprise a pharmaceutical, a cosmetic or a foodstuff. .

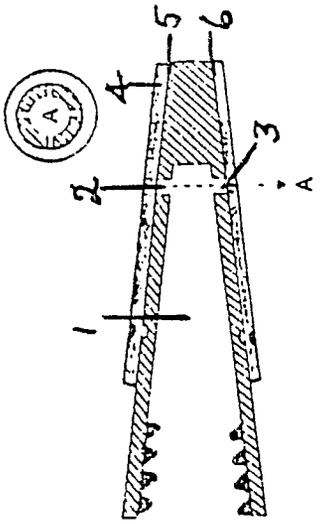

Fig 3

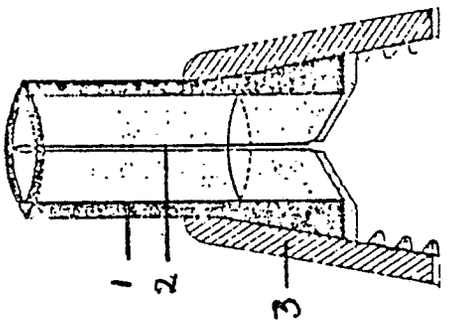

Fig 2A

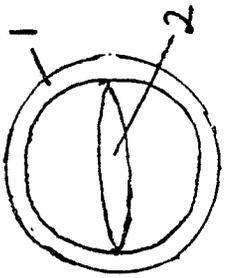

Fig 2B

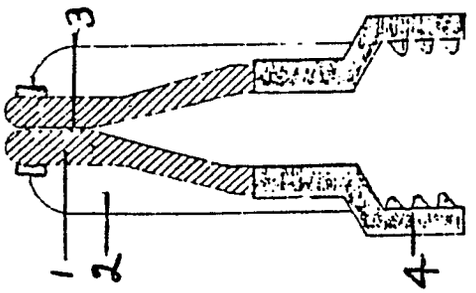

Fig 1

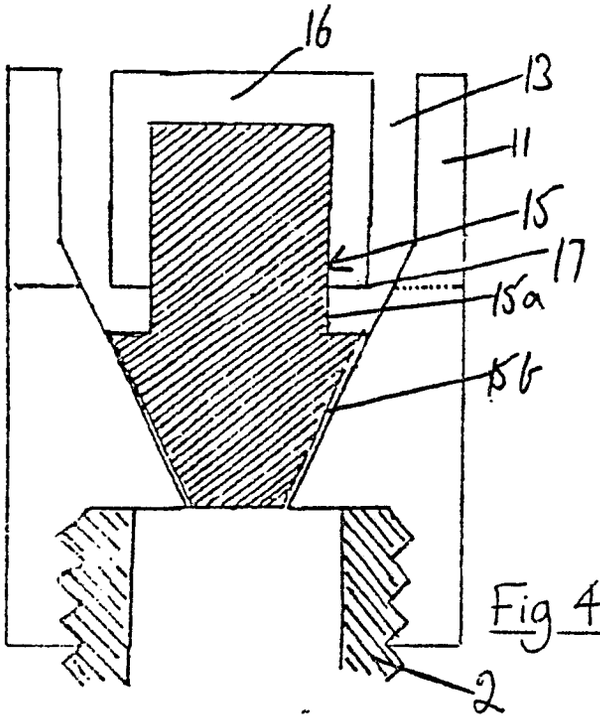

Fig 4A

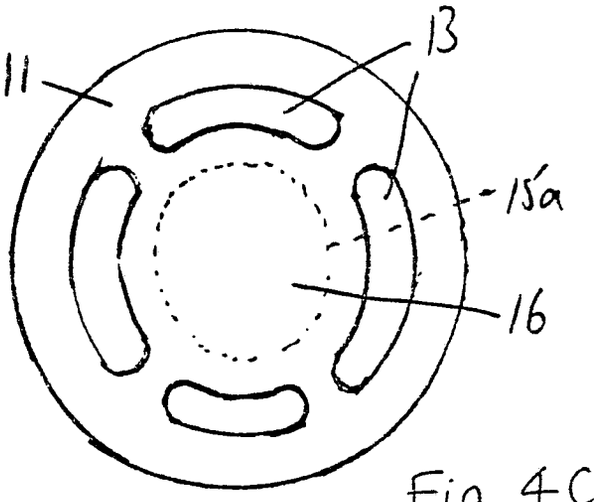

Fig 4C

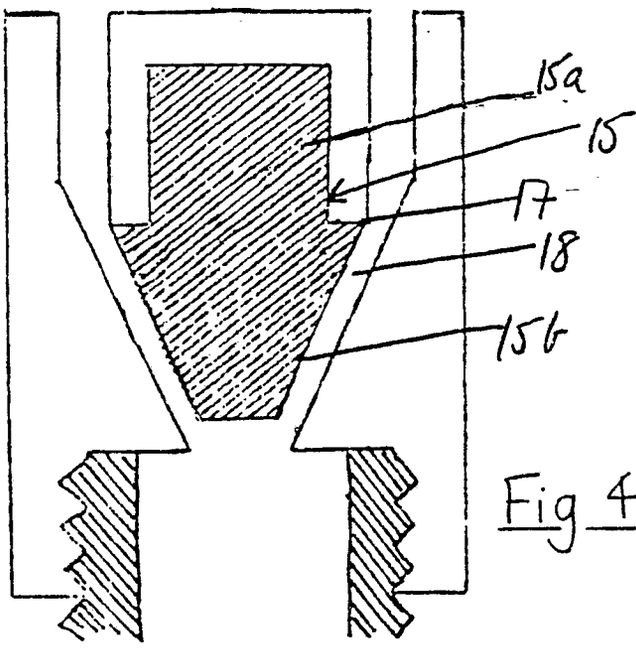

Fig 4B

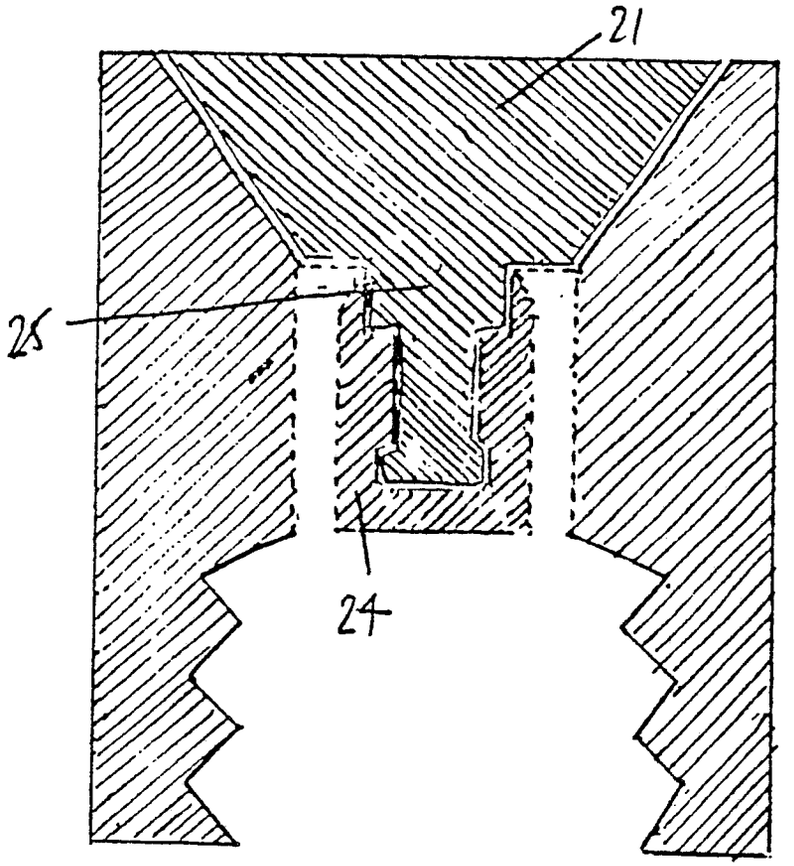

Fig 5A

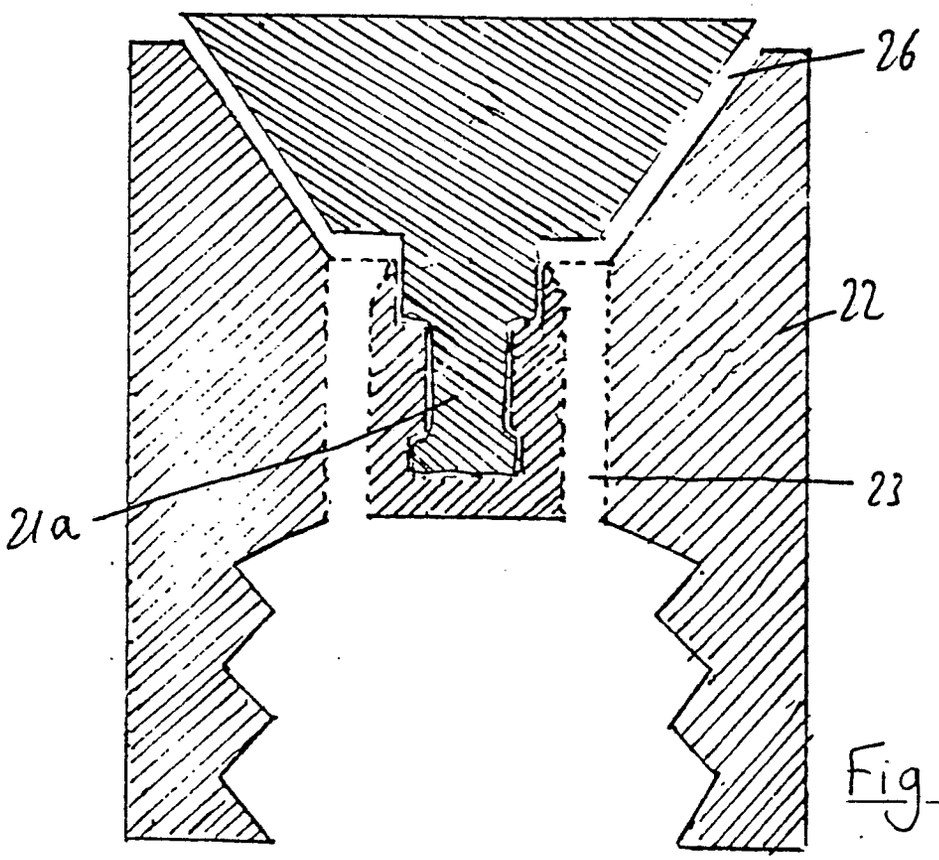

Fig 5B

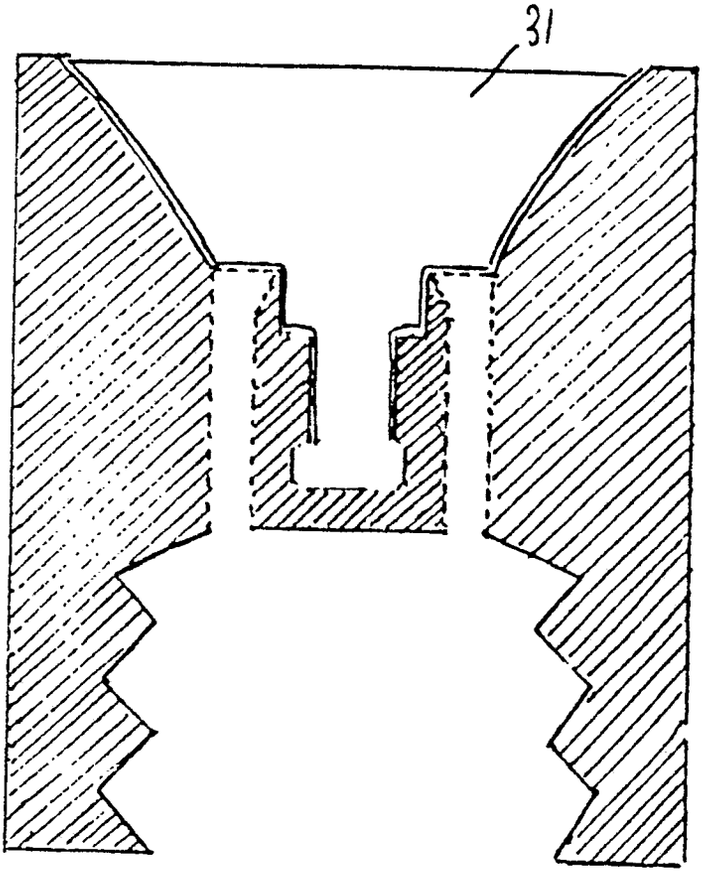

Fig 6A

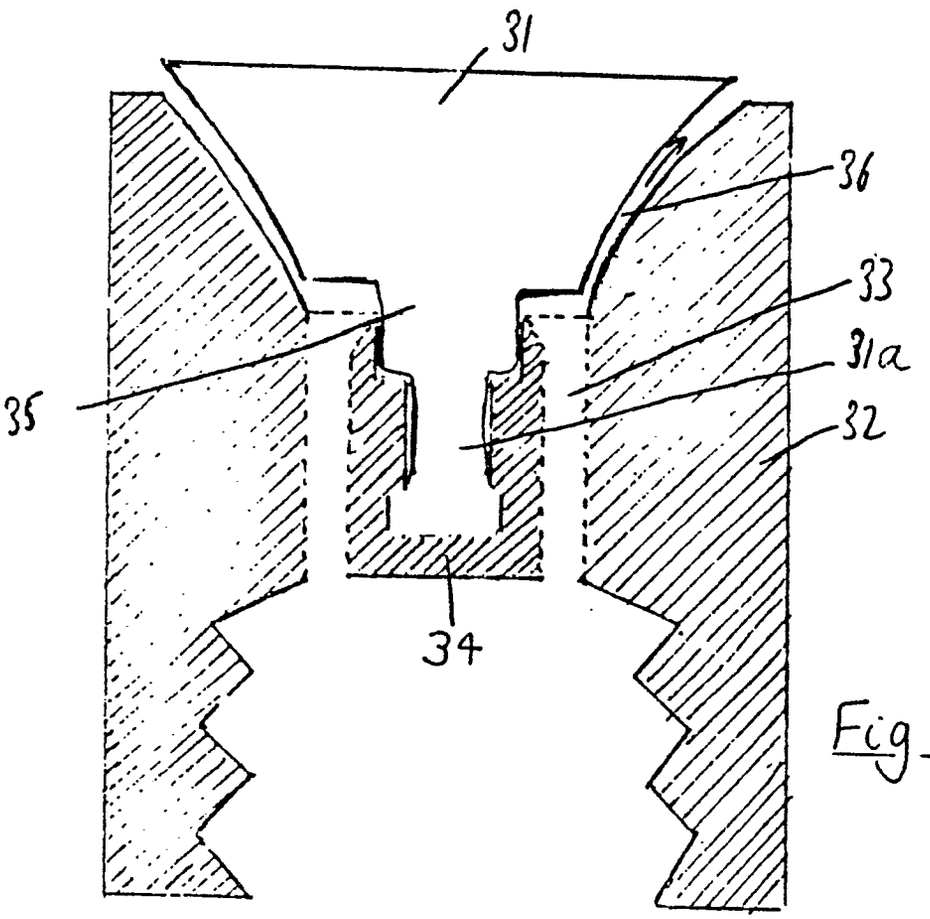

Fig 6B

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 88 20 1691

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US-A-2 753 091 (HERZIG) * claim 1; figures 1-6 *	1,2,8-10	B 65 D 35/52
A	FR-A- 834 140 (JACOB et al.) * page 1, lines 1-8; abstracts 1,2a; figures 3-6 *	1,2,8, 10	
A	FR-A-1 092 480 (GARDES) * abstract; figure 5 *	1,5,8,9	
A	DE-C- 834 524 (SEREGI et al.) * claim 1; figures 1,3 *	1,8,9	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 J 1/00
B 65 D 35/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	28-10-1988	GRUNFELD D.P.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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