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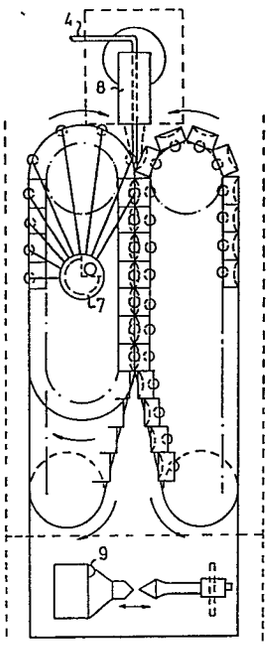
(54) **One way container filled with liquid and a process for its preparation.**

(57) One way container of plastic filled with liquid and a process for the production of such containers by continuous extrusion, filling and sealing by welding and cutting of the said containers, whereby an aseptic product is obtained.



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One way container filled with liquid and a process for its preparation

The field of the invention

The present invention is directed to new one way containers filled with liquid and made of plastic and a new process for the preparation of such containers. The new containers are small plastic bags. The bags are filled with a sterile solution and are used to administer drugs parenterally. Such bags on the market are often called minibags.

Background of the invention

Minibags, are most often filled with a physiological solution of NaCl and are being used in the administration of drugs, e.g. antibiotics, to patients, who are being fed by infusion. The drawbacks of the minibag, most commonly used are several. First the cost of the raw material is relatively high. Furthermore the process of fabrication is laborious as it must be done in several steps. First a film and one or more openings are produced, which are welded together in several steps to form a container. The container (the minibag) is then filled through one of its openings, whereafter the minibag is sealed by welding or alternatively by a rubber plug, sealed by a capsule of aluminium. If the minibag is produced in PVC it must in addition be packed in an outer bag in order to ensure adequate shelf life. The production of minibags by the usual methods is thus complicated and time-consuming.

There has thus been a demand for the development of a simple and cheap method to produce, aseptically, minibags and other one way containers, e.g. vials and ampoules, in plastic.

From e.g. US-A-3 913 299 it is known to produce plastic containers by extrusion, filling and sealing. According to the process described therein a heat treatment in three chambers must be performed in order to obtain an acceptable product. In addition US-A-3 190 441, US-A-3 269 079 and DK-B-118 998 describe methods to produce one way containers, where the tube is being sealed in its lower part, filled and sealed in its upper part. As the tubes are sealed in their lower part before filling, none of the described processes is continuous. DE-A-2 817 291 describes a process for filling with milk containers made of plastic. Also in

that process the lower part of the container is sealed before the container is filled and thus nor is the latter process continuous.

The invention

According to the present invention it has been shown that one way plastic containers, e.g. minibags, which are filled with a liquid may be produced by a continuous process. A plastic granulate is fed into an extruder, from which a plastic tube or profile is extruded, moulded, filled, sealed by welding and cut into containers of suitable size. The container is furnished with one or more openings, "ports" directly on the container. The opening is laminated on the container when it is being moulded. By the moulding there is a difference in the air-pressure between the outside and the inside of the container. It is not necessary to have vacuum but a certain difference in the pressure is important when the container is being moulded. Without the difference in pressure it is impossible to fill out the mould completely and the container does not get the exact form desired.

For the continuous production of the containers filled with liquid, a tube is extruded vertically through a die, which has a filling drain through its middle. The filling drain can easily be removed and replaced in order to undergo special treatment, e.g. sterilization. The diameter of the drain may vary in diameter between 2 and 40 mm. From a tank and through the filling drain the liquid contents are introduced continuously in such a way that the liquid level is kept at a constant location, which may vary between two fixed locations, one being the lowest possible location and the other being the highest possible location. The filling drain ends under the highest possible location but above the lowest possible location and may thus end within the liquid or above the liquid level. Above the level of the liquid there is a gas cushion, which may be sterile filtered inert gas. The moulding of the tube is performed in a hot state. The plastic, being extruded has a temperature of 200°C and is completely sterile. Evacuation of the air in the mould is performed in order to avoid air entrapment between the plastic and any peaks of the mould profile, in which the tube is moulded. It is not necessary with complete vacuum, only a difference in the pressure between the outside and the inside of the container just being moulded. If desired a vibrator is connected to the system in order to eliminate

air-bubbles from the liquid. The process from extrusion to filling is a completely closed system when in use. As a result the contents of the produced container can if desired be maintained aseptic. The filled tube obtained is sealed and cut into containers of the desired size, e.g. by ultrasonic welding directly through the liquid. The container is not filled through the opening but through the sides dividing the bags from each other, which after the filling are welded together. Also the welding is performed within the closed system. The welding can be performed by the use of one or more welding devices depending on the capacity desired. After the welding the tube is cut at the welds to obtain separate containers.

Alternatively two containers may be moulded simultaneously. The container is separated from the parallel container before filling and are then filled through two filling drains placed beside each other. Although the two simultaneously formed containers are separated from each other they are still connected to each other and the sides between the containers below each filling drain are still open between each other. It is not until the filling has been completed that all the walls of the containers are closed by welding.

In a further alternative embodiment according to the invention a V- or U-formed profile is extruded horisontally. Also according to this embodiment the containers are moulded in a continuous process. The containers are moulded with an opening through which the liquid to be dispensed is introduced through a filling drain. According to this embodiment the walls between the containers are welded together before filling. The filling drain and the containers move along the production line at the same rate. The containers are sealed alternatively with welding or a cap. As the last step of the process the containers are separated from each other by cutting along the side walls.

In a further alternative embodiment two or more different liquids are filled into the containers and the containers are being furnished with arrangements for mixing the different liquids without destroying the sterility inside the container.

According to the invention plastic material, preferably polypropene and polyethylene, is used to produce the containers. The mentioned material has the advantage that no harmful compounds are solved out into the liquid inside the container. The containers can also be produced in two or more layers by using coextrusion.

The thickness of the extruded plastic is preferably 0.15 - 0.35 mm for small plastic bags such as minibags. If desired each container may be given a varying wall thickness by the moulding of thicker parts in the form of ribs simultaneously with the extrusion. This is carried out by using a die, which extrudates more plastic material at specific parts of the circumference of the die. It might also be appropriate to make one or more parts of the wall of the container thinner, whereby the collapse is facilitated when the container is being emptied. The thinner parts are made by stretching or blowing of the plastic material.

According to one embodiment of the invention the container has thinner parts placed either directly opposite each other or dislocated on the sides. The thinner parts may be placed along the whole length of the container. Containers with varying thickness of the walls may also be formed by the coextrusion of different materials with different properties.

The produced containers have a smallest inner dimension of 5 mm and a biggest outer dimension of 400 mm. The cross section may vary in form and be e.g. round, oval, square, e.g. rectangular or polygonal. The length of the container is between 20-500 mm and the thickness of the walls between 0.15-1 mm. The containers may if desired be packed into an outer package. This is especially desired when the container is small and as thin as 0.15 - 0.35 mm. The containers hold between 2 ml and 10 l, especially between 50 ml and 5 l.

Small plastic bags, minibags, are used when drugs are administered intermittently, i.e. the infusion is interrupted for a certain time and instead the drug is administered. The minibag is therefore connected to an infusion set in connection with the infusion bag. For use of the minibag it is punctured at the opening region. This is done by the tearing off of a tear-off patch covering the opening region, to expose

a sterile area at which a sterile puncture may be performed. The manufacture of the minibag is performed in a closed system and also the opening is laminated on under sterile conditions. Thereby high hygienic demands are met and usually no outer bag is needed for protecting the minibag. An outer bag has the drawback that the time for sterilization is extended considerably.

The mould opposite the opening on the containers are provided with arrangements to punch a hole which suspends the container in use. The hole is usually placed in the middle of the weld region on the side opposite the opening.

The small plastic bag according to the invention holds usually 50 - 100 ml of liquid. It is calculated that 4000 - 5000 units/hour shall be produced by the new method whereby the conventional method used at the moment only gives 1000 - 2000 units/hour.

Detailed description of the invention

The invention is described in detail referring to the following figures.

Fig. 1 illustrates production and filling of a one way container.

Fig. 2A - 2C illustrate the principle of production of the plastic container with the method according to the invention.

Fig. 3A - 3B illustrate in detail the moulding of the bag and the lamination of the opening.

Fig. 4A - 4C illustrate in detail the filling of the small plastic bags.

Fig. 5A - 5B illustrate an alternative container produced according to the invention.

Fig. 6 illustrates the production of a further alternative container according to the invention.

Fig. 1 illustrates continuous production of a container having the form of a tube (1). The tube is extruded through a die [comprising an outer part (2) and an inner part (3)], through the middle of which a filling drain (4) passes. Through the drain the desired liquid contents are introduced up to a constant liquid level (5), which varies around a mean level. Above the level of the liquid is a gas cushion (6), which e.g. is sterile filtered inert gas. In addition a system which evacuates air is applied to the production line at the moulding station in order to avoid air between the plastic and any peaks of the mould cavity profile.

Fig. 2A illustrates in detail the production of plastic containers. (8) is the extruder wherein plastic granules are filled and from which the plastic tube is extruded. The container is formed in two mould halves. (7) is a system which evacuates air from the moulds. (9) is the welding device.

Fig. 2B illustrates in a side view how the opening is laminated onto the container. (14) is means for evacuation of air and feeding of the opening.

Fig. 2C shows a section along the line A-A in figure 2B. Fig. 2C illustrates in detail the means (14), which feeds the opening. Through the evacuation tube (11) the air evacuated by moulding passes out.

Fig. 3A illustrates the two halves of the mould in open position in which the container is formed. (10) is the opening which is laminated onto the container.

Fig. 3B illustrates the closed mould when the opening (10) is being laminated onto the container. Superfluous air is evacuated through the tube (11) with the evacuation system (7).

Fig. 4A - 4C illustrate a specially preferred plastic container.

Fig. 4A illustrates the filling of plastic bags already furnished with openings (10) and holes (12) for suspending the final container. The containers are filled through the filling drain (4). The filling drain

may as illustrated end above the level of the liquid (5), but it may also be inserted into the liquid. After the filling the containers are separated from each other by e.g. ultrasonic welding (9).

Fig. 4B illustrates a side view of Fig. 4C.

Fig. 4C illustrates a single plastic bag having an opening (10) with a tear-off patch (13). When the patch has been torn off it uncovers a part of the wall of the container, which then may be punctured sterile. The container may be suspended in the hole (12).

Fig. 5A illustrates an alternative container. Two containers are produced simultaneously and filled through two different filling drains. Before filling a future opening is formed in the top of the container. The opening has a sealed cap (moulded), which for use is torn off the container. On this container the tearing off of the cap opens the container and the liquid may be poured out. This kind of containers are useful for dispensing and packing of doses of medicaments, such as mixtures, elixirs, suspensions and solutions, e.g. liquid antacides, expectorantia or vitamins.

Fig. 5B is a view from below of Fig. 5A.

Fig. 6 illustrates in detail the production of a further alternative embodiment. The opening (10) with the tear-off patch (13) is laminated onto the container synchronously with the moulding.

Further detailed description of a container according to the invention and the process for its production

Plastic granules are filled into an extruder. A plastic tube (1) is extruded through a die (2, 3). The plastic tube is formed in moulds and the opening (10) is laminated on the container. A system which evacuates superfluous air (7) from the moulds is connected to the moulding process. After moulding the containers, which still are connected to each other and form a tube having openings in the walls adjacent to the successive container are filled through a filling drain (4) with a sterile solution e.g. of isotonic sodium chloride. First when the

containers are completely filled they are sealed in the two walls adjacent the container in front and the successive container, i.e. the walls at right angles to the wall having the laminated opening. The sealing is made by e.g. ultrasonic welding through the liquid. After welding the containers are separated from each other. The containers may then whenever wanted be packed into an outer bag and autoclaved, in order to obtain the highest possible sterility.

CLAIMS

1. One way container of plastic filled with liquid and being a small plastic bag c h a r a c t e r i z e d in that the plastic is extruded and moulded to form a container at the same time as one or more openings are laminated on, filled, sealed by welding and cut into separate containers all in one single process, whereby said moulding, filling and welding are performed continuously in a closed system.

2. Container according to claim 1 c h a r a c t e r i z e d in that the two sides sealed by welding are at right angles to the side having the opening.

3. Container according to claims 1 and 2 c h a r a c t e r i z e d in that the welding along the sides at right angles to the side having the opening is performed after the filling.

4. Container according to one or more of the claims 1 and 3 c h a r a c t e r i z e d in that the smallest inner dimension is 5 mm and the greatest outer dimension is 400 mm.

5. Container according to one or more of the claims 1-4 c h a r a c t e r i z e d in that the length of the said container is between 20 and 500 mm.

6. Container according to one or more of the claims 1-5 c h a r a c t e r i z e d in that the side, opposite the side where the opening is laminated on has a hole for suspending the said container when the liquid of the said container is administered.

7. Processes for simultaneous production and filling of a one way container of plastic, filled with a liquid c h a r a c t e r i z e d in that plastic is a) extruded hot and moulded to form a container and simultaneously one or more openings are laminated onto said container b) said container is filled continuously in such a way that the level of the liquid is kept on a level varying around a mean level, whereafter c) the container is sealed and d) the containers are separated by cutting at the welds, whereby said extrusion, moulding, filling and welding are performed continuously in one single closed system.

8. Process according to claim 7 c h a r a c t e r i z e d in that the containers are sealed by welding through the liquid after the filling at the two sides adjacent the neighbouring containers.

9. Process according to claim 6 c h a r a c t e r i z e d in that the continuous filling is through a filling drain.

10. Process according to claim 9 c h a r a c t e r i z e d in that the filling drain is placed in the centre of a die through which the extrusion is performed.

FIG.1

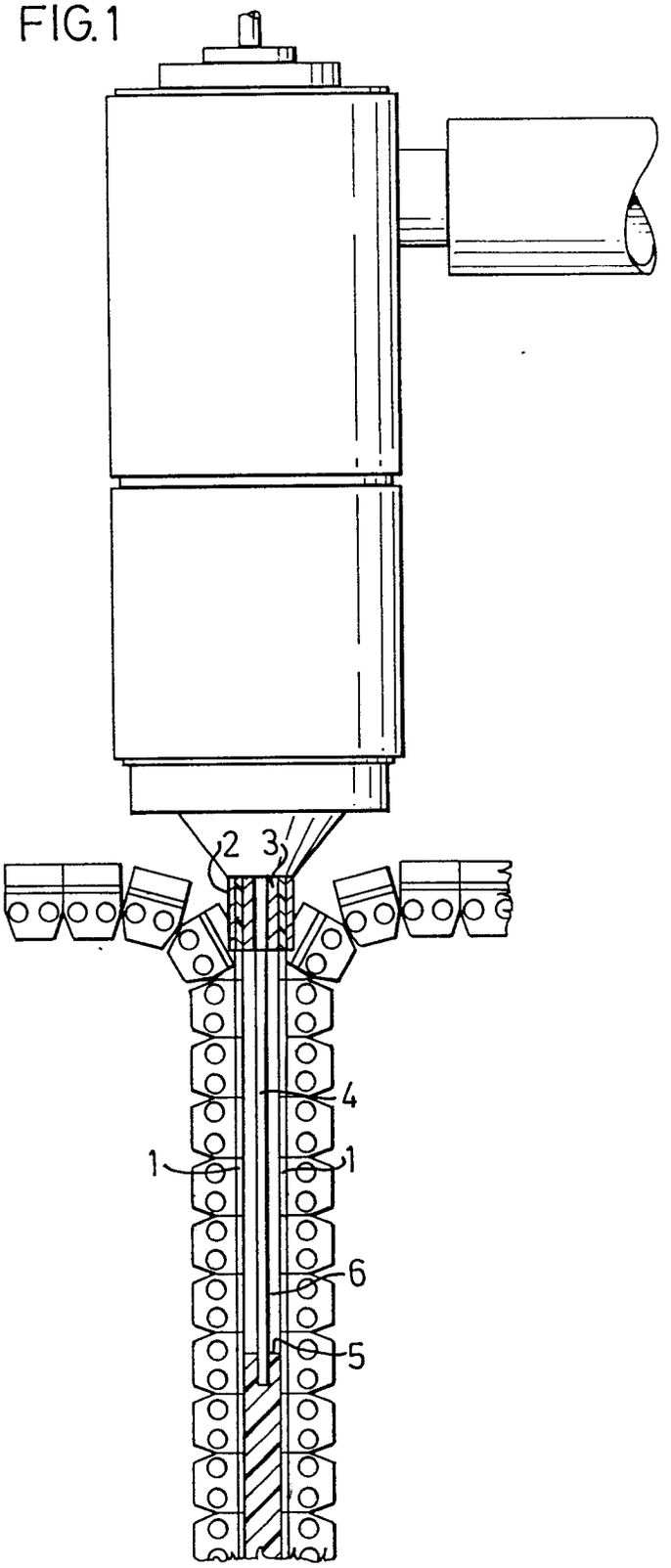


FIG.2A

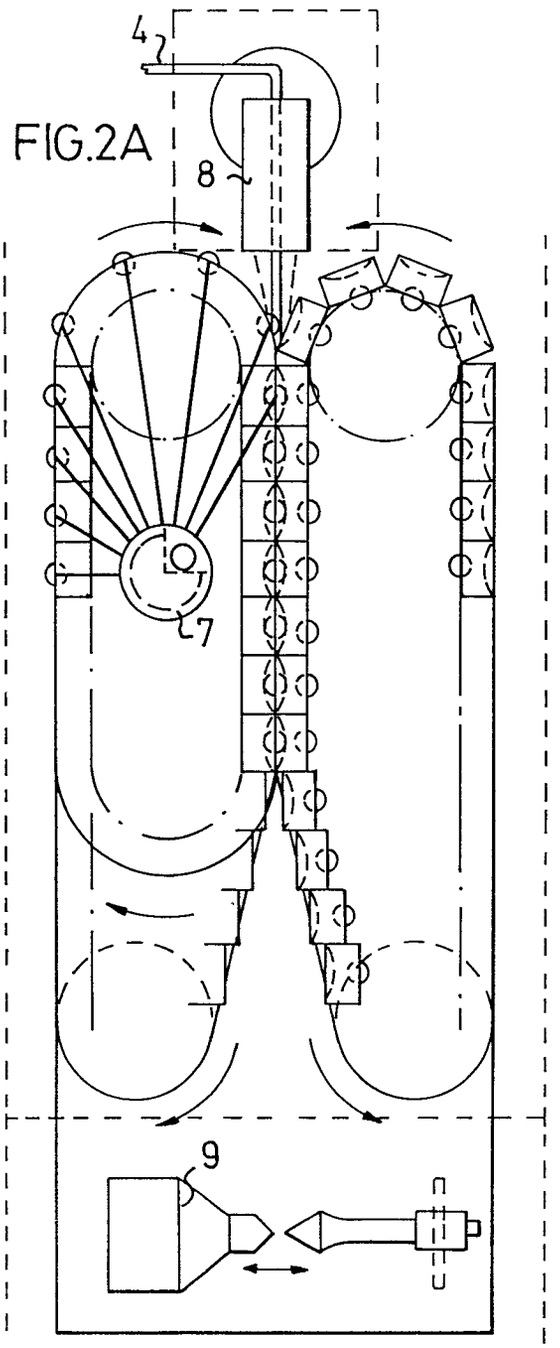


FIG. 2C
A-A

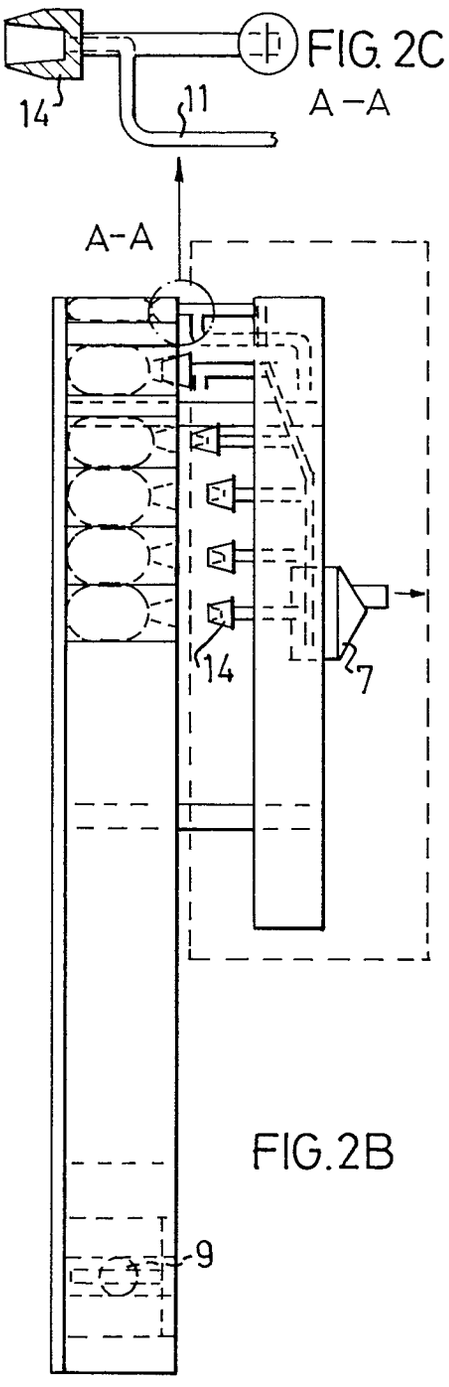


FIG.2B

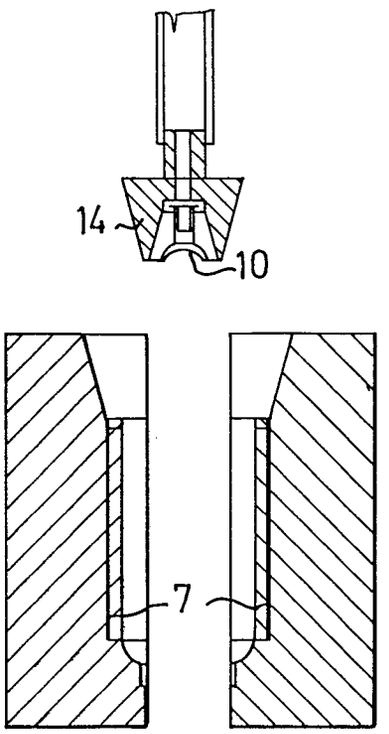


FIG. 3A

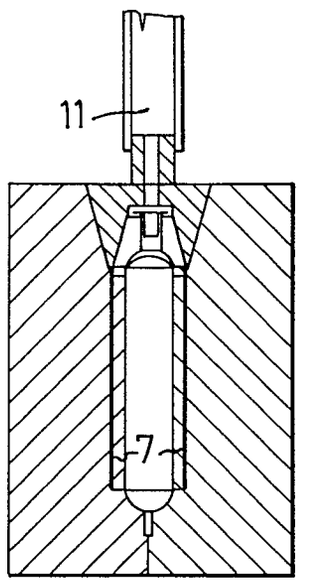


FIG. 3B

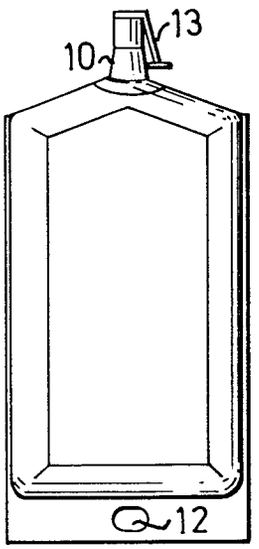


FIG. 4C

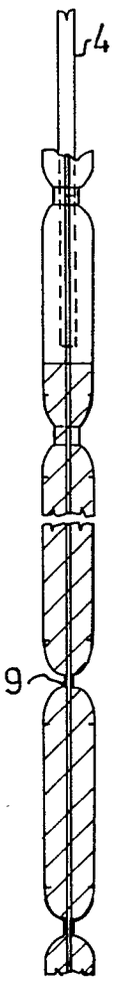


FIG. 4B

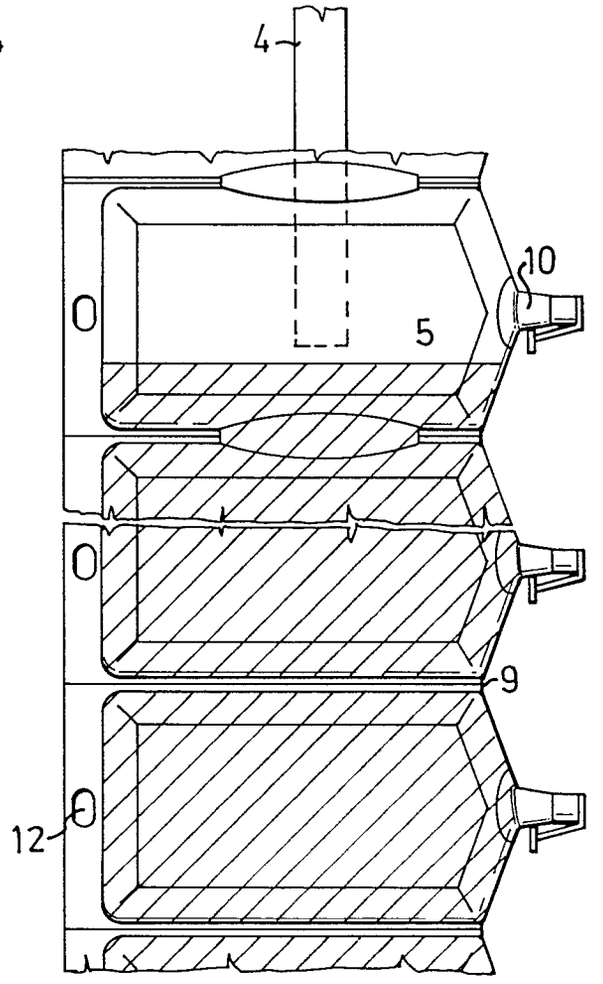
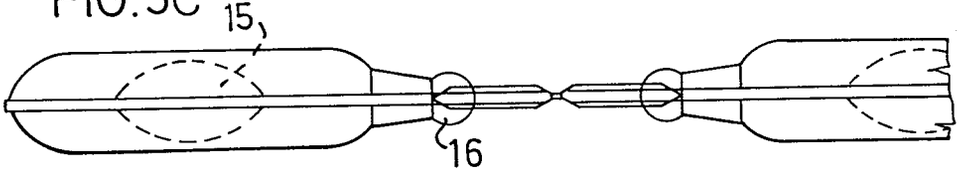


FIG. 4A

FIG.5C



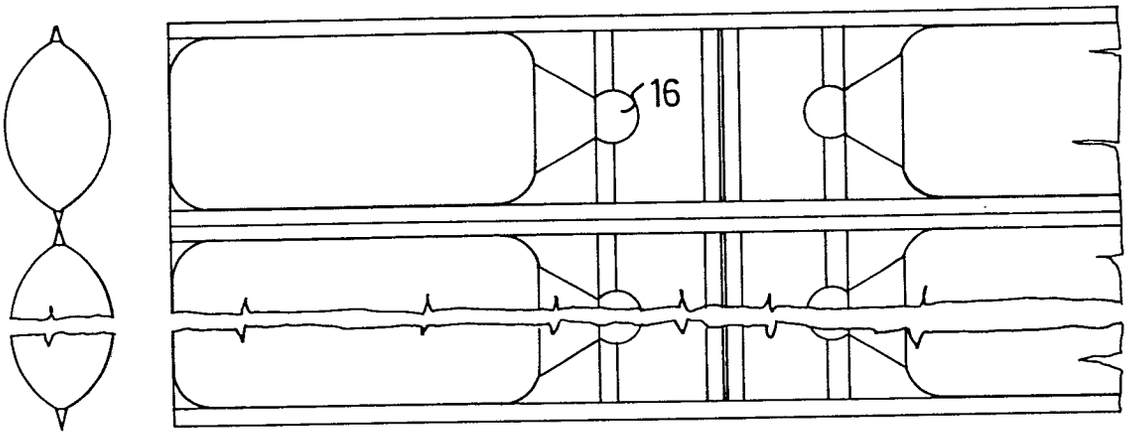


FIG.5B

FIG.5A

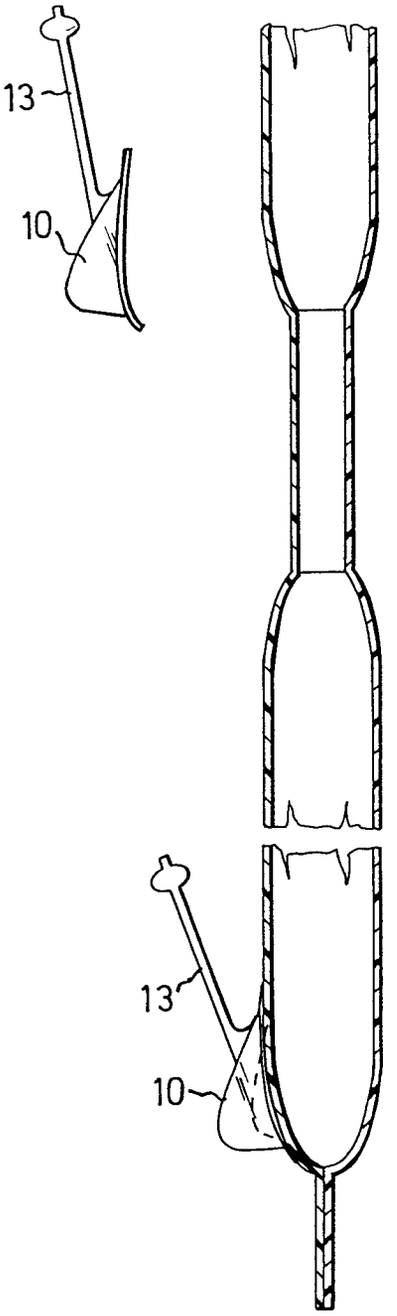


FIG.6