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Schmitt

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[54] **METHOD OF MAKING AND FILLING AN ASEPTIC PACKING CONTAINER**

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[52] **U.S. Cl.** **53/14,** 53/30

[51] **Int. Cl.** **B65b 61/00**

[58] **Field of Search** ..... 53/14, 30, 37, 184; 206/56 A, 56 AB

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Assistant Examiner—John Sipos
Attorney—John J. McGlew et al.

[57] **ABSTRACT**

A method for the production of aseptic packings, particularly a single use packing such as an ampoule, etc., comprises a plurality of oppositely directed substantially identical indentations on a foil on each side of a fold line. Thereafter, the foil material is folded along the fold line to align the indentations so that they form half portions of individual containers. The foil sections are welded or otherwise sealed together so that they close the container around the juncture line. Each container indentation includes a neck portion terminating in an outwardly widening funnel opening adjacent the edge of the foil material. The individual containers are then filled through the funnel and the neck portion is thereafter sealed directly below the bottom of the funnel by pressure welding. The area adjacent the closed weld line is provided with tear lines to facilitate easy opening and removal of the contents from the containers. An aseptic packing comprises a strip of two superposed foil sheets, each having aligned recessed portions forming container halves which together form a complete closed container which is closed around the periphery by the foil material. The strip includes tear line portions for both separating individual containers from the strip and for opening the mouth of each container.

10 Claims, 11 Drawing Figures

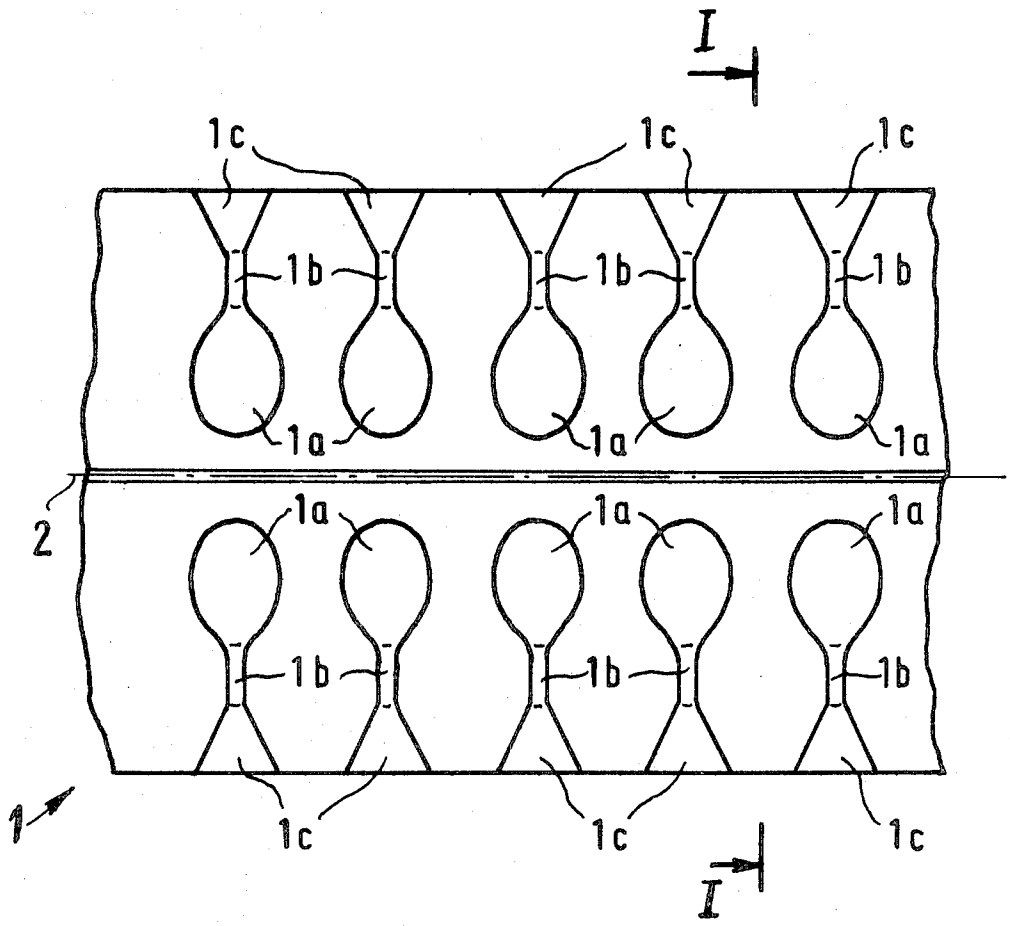


FIG. 1

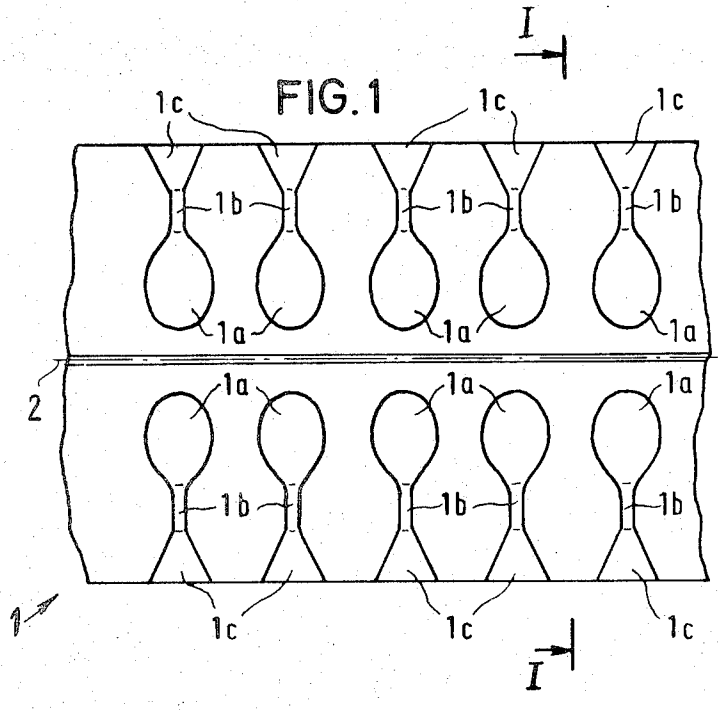


FIG. 1a

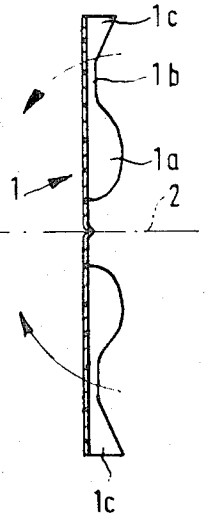


FIG. 2

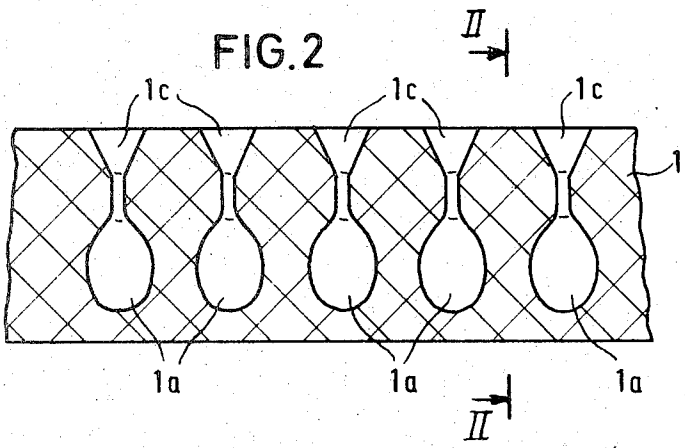


FIG. 2a

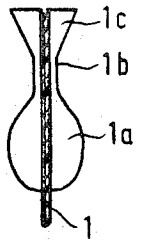
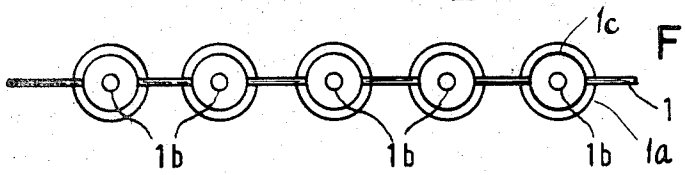


FIG. 2b



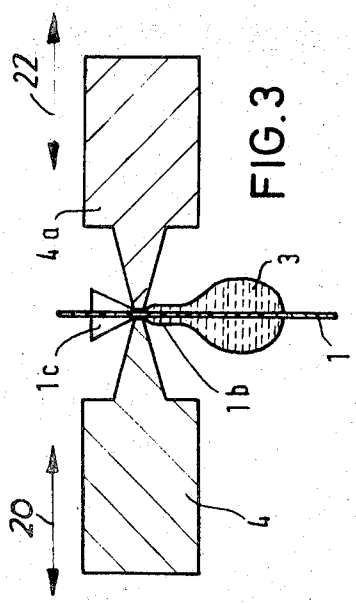


FIG.3

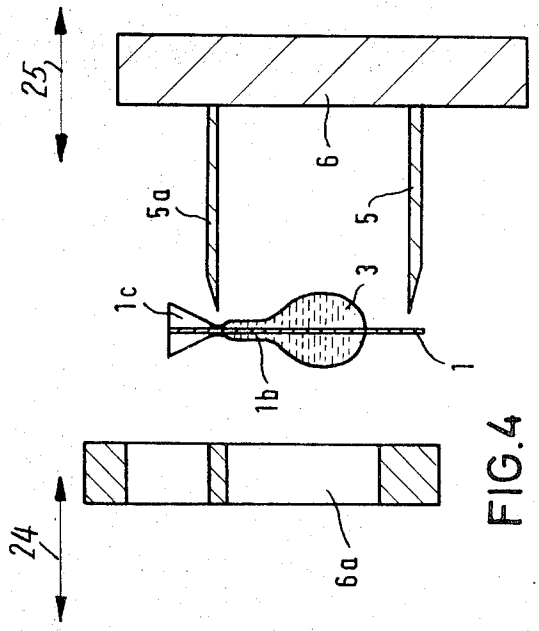


FIG.4

FIG.5

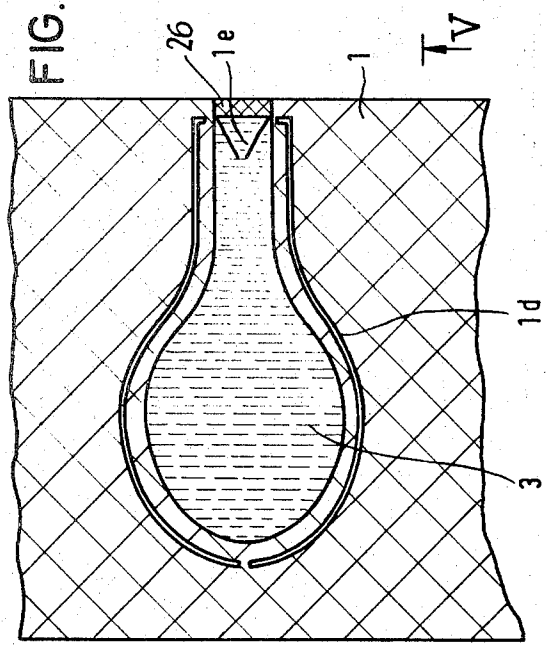


FIG.5a

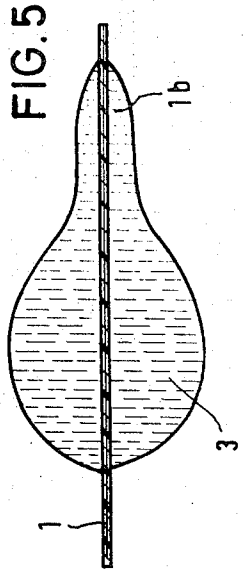


FIG. 6

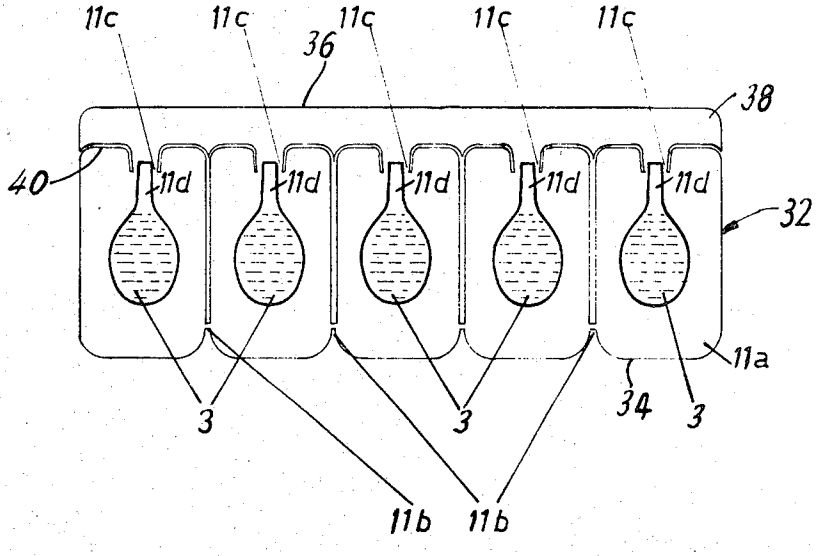
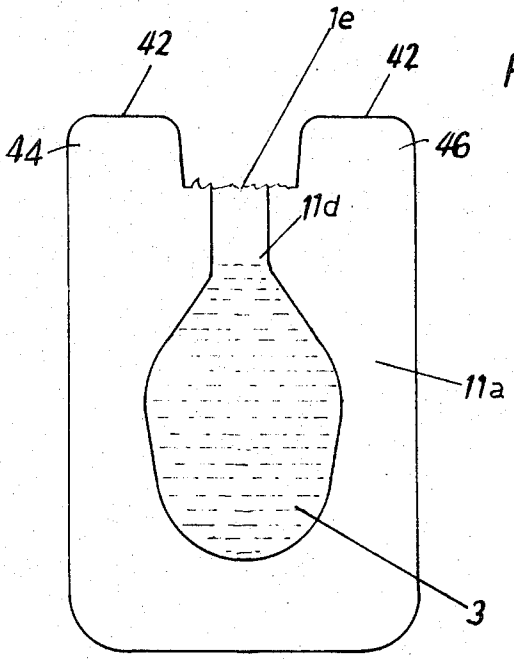

11c
11c
11c
11c
11c
36
38
40
11d
11d
11d
11d
11d
32
11a
34
3
3
3
11b
11b

FIG. 6a


42
1e
42
44
46
11d
11a
3

METHOD OF MAKING AND FILLING AN ASEPTIC PACKING CONTAINER

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates in general to a construction of containers, and in particular, to a new and useful method for the production of aseptic packings, particularly packings designed for single use such as ampoules which are formed by superimposed and welded foil sheet portions which are folded in juxtaposition after they have been initially subjected to a pressure to form individual container half portions.

2. Description of the Prior Art

In the pharmaceutical field, it is sometimes necessary to pack drugs aseptically, for example, those of a liquid or solid consistuency. It has been known for a long time to use ampoules of glass or plastic, for example, for this purpose. For solid substances such as suppositories, it is known to use plastic coated light metal foils or thermoplastically deformable plastics. Although glass ampoules can meet all of the constructional requirements as far as the necessary asepis is concerned, their production is both expensive and it can only be used once. In addition, they are difficult to open and they are subject to breakage in storage or in shipment. The sealed filling opening of such ampoules can only be opened by means of a saw or a file which must be enclosed with the ampoule packing in order to permit removal of the contents.

With the presently known coated light metal foils used for packing solid substances, it is readily possible to pack the contents aseptically. There are difficulties, however, in keeping the contents sterile after it has been removed since the packing must be torn open and the contents removed by hand.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a method of forming inexpensive packing ampoules or containers in a simple manner and which may be packed with contents which will remain aseptic until used. In addition, the materials required are so inexpensive that their disposal loss after use is extremely minimal.

In the known construction, when an ampoule is opened by tearing the material away from the mouth, a burr is sometimes formed in the range of the breaking point which has been provided for easy opening. This burr can cause injuries to the eyes, ears, or nose when the contents of the ampoules are used for these sensitive body parts. The present invention provides a container or ampoule construction which is such that it is substantially impossible to provide these undesirable burr formations.

In the preferred method of the invention, a sheet of foil material is subjected to pressure in order to form the plurality of pairs of permanent container-form depressions arranged in a mirror fashion in respective rows. The foil is then folded about a line midway between the foil depressions in order to superimpose the foils and align the congruent depressions to form a whole container from the depression half portions, with the complimentary depressions on each side of the fold line forming a respective container half part. The folded foil is then welded together in the areas not overlying the depressions in order to seal the peripheries around the depressions and to form individual closed containers, each having a neck portion terminating in a widened filling funnel leading to the foil edge. Each chamber is then filled through the funnel and the bottom end of the funnel is closed by welding after which a perforation or tear line is imparted to cross the neck, or an area adjacent the neck in order to permit easy opening thereof. The tear line defines a preset breaking line to facilitate the opening of the ampoule directly below the filling funnel. The folding of the foil material is preferably carried out along a longitudinal fold line or axis.

Preferably a plurality of pairs of permanent depressions are arranged in a mirror fashion during the deformation process on two independent foil bands extending substantially parallel to each other. These bands are then superimposed such as by completing the fold about the mid-point line separating the depressions. After the foil material is welded around the depression areas, which forms the vessel or container, the attached filling filter of the filling device is removed by means of a known cutting device. The preferred form includes a tear strip arranged along a row of the formed containers which may be selectively torn to open one or more containers. The depressions are advantageously spaced apart sufficiently so that there is no large area of foil material between each depression forming the container so that they will be sealed tightly at all sides.

A packing such as an ampoule, vial, etc., produced with the method of the invention and destined particularly for one time use, is formed by mirror-like indentations made in two foil sheets which are aligned to form substantially pear-shaped containers with a mouth portion having an outwardly tapered end defining a filling funnel. The area surrounding the containers and surrounding the top of the filling funnel is sealed by the superimposed foil sheets which are secured together. A strip of such containers is advantageously formed with a preset breaking point in the area of the juncture of the mouth portion, with the filling funnel and is constructed so that the strip may be removed to open the top of the mouth to permit discharge of the contents.

The tubular mouth or pipette construction of each container is formed directly below the preset breaking point of the foil material and extends below the top of the mouth portion so that the foil material may be easily broken across the mouth to open the same. The upper edge surface of the foil material which surrounds the container which is formed by the foil sheets is provided with a large radius tear line which extends downwardly on each side of the mouth of the container.

The method of the invention is extremely simple in concept and economical to carry out. The invention makes it possible to use as foils or foil materials, thermoplastic materials which may be heat sealed or welded together in order to provide a relatively inexpensive and disposable ampoule packing. The foils may advantageously comprise polyvinyl chloride (PVC), a polypropylene (PP), or a polyethylene (PE). Foil combinations of polyethylene and polypropylene are also suitable for the method of the invention, particularly in view of the fact that a blocking effect against the penetration of steam is insured under the influence of polyethylene and this is an indispensible prerequisite for certain packing media, for example, with regard to storage capacity. On the other hand, in the foil combination of polyethylene and polypropylene, the latter

component has a blocking effect against permeability to gas.

Due to the fact that there is an incompatibility of polyethylene when packing certain oils or fats, it is readily possible according to the method of the invention to combine instead polyvinyl chloride and polyethylene with each other in such a way that any negative effect of the polyethylene is compensated by respective other coating, namely, the polyvinyl chloride.

In addition to plastic or thermoplastic foils, metal foils, for example, aluminum or "Dural" may be used especially in conjunction with a coating of polyvinyl chloride, polyethylene, or polypropylene or other weldable or heat sealable plastic foil. In the selection of the material for the ampoule packing, it is of importance that the materials used have no restoring properties after the deformation process and are weldable or heat sealable. Due to the natural elasticity inherent in such materials this further enhances the deformation process which is carried out in the course of the method to form the individual container outlines or ampoule configurations. The removal of the material to form the necessary indentations in each of the sheets which are to be employed may be carried out merely by the manual pressure on the sheet to define a portion of the final container. The method is such that the containers are formed so that a person removing the contents does not come into direct contact with the contents of the individual containers. The pouring mouth or pipette of the container according to the invention, is constructed so that it permits, for example, for use on the case of application to a person's nose, throat, ear or eye drugs without direct application to the respective body organ.

In accordance with one embodiment of the invention, the container or ampoule is formed with a relatively elongated vertically extending mouth and the foil material directly above the mouth is formed with tear lines which extend downwardly in a large radius at a location below the top of the mouth so that the mouth is opened when the tear strip at the upper marginal edge of the foil material is torn away. The arrangement is such that when the tear strip is removed, the mouth is opened evenly, thereby preventing injuries in respect to the use of the contents of the ampoule. When the tear strip is removed, a high portion of foil material with rounded corners on each side of the mouth of the container remains to form outwardly extending protective projections which prevent contact of a torn edge of the mouth with a body organ. Contact can only take place between the upper edge of the foil material which forms the projections but by no means between the part of the mouth which is torn away and which might possibly be formed with burrs. The projections are presented in the part of the body organ to be treated and a distance between the body organ, and the mouth of the containers is relatively small so that the distance can be bridged over by the pressure on the container to cause a variation in the dosing stream. For example, the distance between the mouth of the container and the body organ to be treated such as an ear, can be bridged over with a thin continuously reissuing jet of the material being dispensed or by drops which issue at intervals.

Accordingly, it is an object of the invention to provide an improved method of forming individual containers or ampoules from foil or similar material which comprises crimping the foil material at spaced locations along the length to form oppositely directed indentations of identical but oppositely facing configuration on each side of a centrally disposed fold line for the material, juxtaposing the material parts together so that the indentations are aligned and the foil material is secured together around the outline thereof to form the containers.

A further object of the invention is to provide a plurality of containers and a strip of material wherein container half portions are formed by indentations in respective foil strips which are superimposed and connected together, with the foil strips forming the closure around the container elements and including a tear strip oriented around the one edge of the foil strips which overlies a mouth and which is provided with a weakened area in the vicinity of the mouth to permit the removal of a portion of the tear strip and the opening of the mouth.

A further object of the invention is to provide a small container construction which is simple in design, rugged in construction, and economical to manufacture.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects atained by its uses, reference should be had to the accompanying drawing and description matter in which there are illustrated preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWING

In the drawings:

FIG. 1 is a plan view of a portion of a foil material showing the outlines of container indentations for half portions of containers which are constructed in accordance with the method of the invention;

FIG. 1*a* is a section taken along the line I—I of FIG. 1;

FIG. 2 is a plan view of the foil material shown in FIG. 1 with the lower portion folded over the upper portion;

FIG. 2*a* is a section taken along the line II—II of FIG. 2;

FIG. 2*b* is a top plan view of the foil shown in FIG. 2;

FIG. 3 is a schematic transverse sectional view showing the operation of a machine for effecting the welding and sealing of the foil material at the mouth after the ampoule or container is filled with liquid;

FIG. 4 is a view similar to FIG. 3 but showing a machine for cutting of portions of the foil material from the container directly below the filling funnel after it has been filled;

FIG. 5 is a medium sectional view of a filled ampoule having an outer contour with a perforation which joins it wih a remaining portion of its foil wall material;

FIG. 6 is a side elevational view of a strip of interconnected ampoules or containers; and

FIG. 6*a* is an enlarged view of a single ampoule having the closure strip removed therefrom.

FIG. 5*a* is a section taken along the line V—V of FIG. 5.

GENERAL DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, in particular, the invention embodied therein in FIGS. 1 and 1*a*, shows a continu-

ous strip of foil or sheet material after it has been removed from a roll, band, etc., and which is generally designated **1**. The foil strip **1** has been first subjected to a pressure deformation to form a plurality of rows of container-like depressions **1***a* formed in sets with one row oriented to face in one direction and the other facing in a mirror-like manner in an opposite direction. Each depression **1***a* includes an elongated mouth portion or pipette **1***b* and a filling funnel portion **1***c* which extends from the upper end of the mouth to the outer edge of the foil material **1**.

After the deformation process is completed, the foil material **1** is folded along a media line **2** located between adjacent rows to align the indentations **1***a* so that they form half portions of finished containers or ampoules or similar vessels. The indentations **1***a* are congruent so that when the flat portions of the funnel sheets are superimposed, the portions form the half portions of the whole finished container. The superposed folded foil sheet is secured together such as by head welding to form it into the configuration indicated in FIGS. **2**, **2***a* and **2***b*.

In FIG. **3**, the foil **1** includes attached and filled ampoules **3** which have been filled by mechanism (not shown), and they are moved into association with means for sealing the mouth **1***b* which is accomplished by welding or hot-sealing jaws **4** and **4***a* which move together and define a welded closure line across the mouth of the container. The jaws **4** and **4***a* are moved in the direction of the arrows **20** and **22** during each operating cycle by means (not shown). The ampoule **3** is advantageously closed tightly between its neck and the filling funnel **1***c* by high frequency, ultra sound impulse welding or by infra-red preheating.

After the ampoule is filled, it is moved into association with cut-off means which include blades **5** and **5***a* movable in the directions of the arrows **24** and **25** and carried by a tool **6** which cooperates with a counter tool **6***a*.

As indicated in FIG. **5**, the juxtaposed foil sheet portions are provided with a perforation **1***d* at a safety margin spaced outwardly from the surface of the ampoule **3** in order to permit easy removal of the ampoule from the foil when it is to be used. The mouth **1***b* is provided with a preset breaking point or tear line **1***e* directly below a closure weld **26**.

In FIG. **6**, there is shown a modified construction of a strip generally designated **32** made up of individual ampoules **3** which are formed on a foil strip **11***a*. The ampoules **3** receive aseptic drugs and comprise the same material as the surrounding strip **11***a*. For the continuous strip **11**a may be provided two superposed sheets of a material such as polyvinyl chloride, polypropylene or polyethylene. As an alternative to the plastic, materials may be employed such as aluminum or Duraluminum which can be combined with the polyvinyl chloride or polyethylene.

The strip **32** is provided with inwardly extending slots **11***b* at the midpoint between each ampoule which extend inwardly from the edge **34**. The opposite edge **36** forms an outer edge of a tear strip **38**. The tear strip is defined at its inner end by perforation elements or tear lines **40** which terminate in ends **11***c* which extend downwardly on each side of a mouth **11***d* of each ampoule **3**. The tear lines **40** define present breaking points which, when removed, leave a break line **1***e* extending across the mouth **11***d* of the container. The tear line **1***e* can have burrs which may cause injury, for example, to sensitive body organs such as the eye, ear, nose, etc., when the ampoule is handled improperly. In order to avoid this, the break lines define edges **42** which form smooth edges which provide protective projections which prevent damage to the body cavities by use of the ampoule. The projections **44** and **46** provide safe engagement edges for orienting the mouth **11***d* for the discharge of the fluid into the body cavity. This special design keeps the burr portion **1***e* away from the sensitive body organ when the ampoule is used so that injuries are avoided. The corners of the perforation line **40** are rounded off with a relatively large radii on each side of the mouth tear line **1***e*. Tests have shown that danger of injuries increases if only one radius is provided, for example, on the side of the mouth **1***d*.

While specific embodiments of the invention have been shown and described in detail to illustrate the application of the principles of the invention, it will be understood that the invention may be embodied otherwise without departing from such principles.

What is claimed is:

1. A method for producing an aseptic package, particularly a one-time use container, such as an ampoule, using one or more foil sheets, comprising forming in the foil sheet a plurality of depressions in the outline of a container each depression including a container body depression and a container mouth depression extending outwardly from said body depression and including an outer funnel-shaped filling depression, said depression being formed at spaced locations along the length of a respective foil sheet, superimposing two sheet portions over one another with one row of depressions arranged over the other so as to align the depressions in a position in which they form complimentary portions of a whole individual container with a mouth and a filling funnel, securing the foil sheet portions together around the periphery of the whole containers and mouth except at the outer end of the mouths, filling the container through the mouths, sealing the foil material across the mouth to close the filled container, and forming a break line across the foil sheet to define a tear line for facilitating the severance of the material through the plane of the mouth.

2. A method, according to claim **1**, wherein the pairs of depressions are formed in rows on a single sheet of foil material and arranged in mirror-like fashion with the mouths or respective rows oriented in respective opposite directions, and including folding the material between the rows of said depressions in order to place one sheet portion on one side of the fold line in juxtaposition with the sheet portion on the other and to align the depressions together.

3. A method, according to claim **1**, wherein said funnel-shaped portions extend in an outwardly flaring direction from said mouth to the adjacent edge of each said foil sheet and including sealing the foil material by welding the material directly below said funnel portion across said mouth.

4. A method, according to claim **1**, wherein said permanent depressions of each row are formed on separate foil sheets and wherein said foil sheets are placed in juxtaposition to form said whole individual containers.

5. A method, according to claim **4**, wherein one of said sheets is fed into juxtaposition with the other by

feed-it along an angle extending at 90° to the other sheet.

6. A method, according to claim **3**, including removing the funnel formation from the mouth after the mouth is closed by welding.

7. A method, according to claim **1**, including a break line across said foil sheets to define weakened areas extending above the ends of said mouth with down turned portions terminating on each side of said mouth adjacent the closed end thereof, sand perforation line defining a movable tear strip which may be torn across the defined smooth projections on each side of said mouth and a tear line across said mouth.

8. A method of producing aseptic packages, particularly ampoules from a plastic foil or plastic-coated foil or sheet, comprising forming in a horizontally arranged foil a plurality of oppositely facing and/or aligned sets of mouth and funnel-shaped depressions at spaced locations along the foil, each depression including a wide body portion tapering to a filling mouth portion and a filling mouth portion having an intermediate uniform diameter portion with an outwardly flaring funnel-shaped filling end; after submitting the foil to a sterilization treatment, folding the foil about a central fold line between the sets of depressions to move each sheet portion upwardly into interengagement so as to align the depressions of the oppositely facing set so that they form complementary portions of a whole individual container body, container mouth and filling funnel, filling the container through the filling funnel, and thereafter closing the container by forming a seal across said intermediate uniform diameter portion adjacent said filling funnel-shaped end.

9. A method according to claim **8**, including defining a tear line extending along said folded portions of said foils to facilitate tearing along the intermediate uniform diameter portion to open this portion and provide a filling connection for a pipe bed or nozzle for withdrawing the contents of the container portion.

10. A method according to claim **9**, wherein the tear line defined on the sheets terminates at a spaced location from the intermediate mouth portion so that a safety margin securing the container closed on all sides to insure its tightness is maintained.

* * * * *