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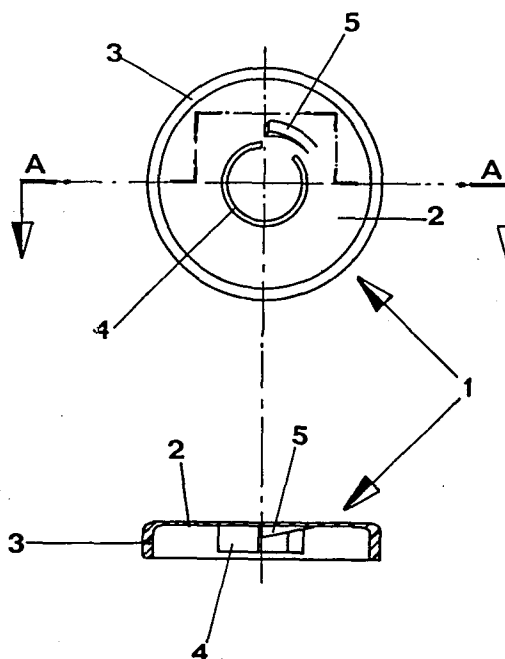
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⑤④ **Improved membrane type pierceable safety seal for multi-dose bottles.**

⑤⑦ An improved sealing device is described which is especially suited for multi-dose bottles for medical products and is provided with a pierceable membrane; an outer plastic cover (1) is pre-assembled on the bottle neck by thermoforming with an air tight closing element (6), having a center through opening (9). The thus obtained assembly is applied and secured firmly to the neck of the bottle with the interposition of a rubber membrane.

The detachment of cover (1) from metal closing element (6) is greatly facilitated and does not require the use of any special tools; the cover can be removed manually by rotating it counterclockwise, exploiting the principle of the inclined plane.



"IMPROVED MEMBRANE TYPE PIERCEABLE SAFETY SEAL FOR
MULTI-DOSE BOTTLES"

This invention relates to a pierceable membrane type safety seal suitable for use on multi-dose bottles. It relates, more specifically to a simplified opening and closing device concurrently forming a safety
5 seal for the contents.

Sealing systems for bottles or open vials have long been known in the pharmaceutical field; these consist, essentially, of a real rubber sealing element, tightly secured on the mouth of a vessel by a metal
10 operculum caulked on the rim of the bottle neck and having in its center part an opening or a stress-raising line for removal of a metal disc corresponding to an underlying thinned portion of the rubber membrane apt to be easily perforated.

15 While these known types of closing elements afford a satisfactory protection for the contents of the bottles or vials to which they are applied, they all have the drawback of not being easy to open; in fact opening requires the use of tools which may not be
20 always available; otherwise they may have to be torn off by hand and the sharp cutting edges of the metal portion may injure the user's fingers.

The object of this invention is to provide a type of plastic closure which allows an easy access to
25 the elastic membrane to be perforated, without the aid of tools, while protecting the content of vessel against possible tampering.

The sealing device according to this invention consists substantially of a plastic cover movably secured to a metal closing and locking element tightly applied by caulking to the mouth of the bottle or
5 vial, with a pierceable elastic membrane interposed between.

The closing device according to this invention will now be described in detail, in conjunction with the annexed drawings showing a preferred embodiment
10 of the invention and in which:

FIGURE 1 is a bottom view of the plastic covering according to the invention;

FIGURE 2 is a cross sectional view taken on lines A-A of Fig. 1;

15 FIGURE 3 is a top view of the metal sealing element according to the invention; and

FIGURE 4 is a cross sectional view along line B-B of Fig. 3.

As shown in Figs. 1 and 2, cover 1 consists of
20 a plastic disc 2, provided with a cylindrical circumferential flange 3, obtained by integrally moulding with disc 2. A second cylindrical flange 4, located centrally and facing in the same direction as circumferential flange 3, is provided in disc 2 and is coaxial with
25 respect to the cylindrical circumferential flange 3. For a limited length of its circumference, central cylindrical flange 4 is discontinuous or interrupted; in this position and slightly offset in a radial direction a wedge 5 is provided, the development of which slightly
30 exceeds the interruption or discontinuity of cylindrical central flange 4 and the maximum thickness of which is equal to about one third the height of central

flange 4.

The locking metal element or capsule 6, as shown in Figs. 3 and 4, is provided with a cylindrical circumferential flange 8 the height of which considerably exceeds that of circumferential flange 3 of plastic cover 1. An opening 9 is provided in the center of metal disc 7; the size of said opening is sufficient to permit access to the pierceable rubber membrane to be applied on the mouth of the container to be sealed. At one of its diameters opening 9 extends in two symmetrical eyelets 10. To confer a certain planar rigidity to disc 7 and obtain a circumferential projection apt to tightly compress the underlying rubber membrane, an outer circumferential rib 11 can be formed by drawing in a radial direction with respect to eyelets 10.

For a correct application on the container to be sealed, the metal securing element 6 thus constructed is inserted in the hollow part of cover 1 of adequate size, so that the outer surface of disc 7 and cylindrical flange 8 coincide exactly with the inside surface of the plastic disc 2 and relevant circumferential flange 3. To achieve this it is necessary that the higher portion of wedge 5 penetrates in one of the two eyelets 10, while the cylindrical center flange 4 enters exactly into hole 9 projecting inside the metal element 6.

Once this exact arrangement of metal element 6 in cover 1 has been achieved, the assembly is subjected to the action of a suitable heated punch of adequate shape and size which is pressed against the cylindrical flange 4 so as to thermally deform, expand and simulta-

neously flatten it against the inner surface of disc
7. Since the outer original diameter of flange 4 corresponds
exactly to the diameter of center opening 9, the heat
expansion and flattening of center flange 4 block
5 element 6 inside cover 1, after cooling.

The integral assembly thus obtained is then applied
to the mouth of the bottle or vial to be sealed (on
which the sealing elastic membrane has been previously
applied) and is firmly secured by a caulking procedure.

10 To remove plastic cover 1 and thus gain access
to the center part of the rubber membrane defined
by opening 9, the container must be seized by one
hand whereas the other hand grasps the outer edge
of cover 1 effecting a 180° counterclockwise rotation.
15 In this manner, wedge 5 (which during assembly of
the pair of elements 1 and 6 had been partially blocked
by the edge of disc 7 defining the opening 9), exerts,
with its higher part, a thrust against the inner edge
of metal disc 7 deforming it upward, extracting it
20 and disengaging it from the cleft formed between the
inner surface of disc 2 and the outer deformed surface
of center flange 4. Cover 1 can thus be easily removed
(by a simple manual operation), from metal element
6, through which it is possible to gain access to
25 the underlying pierceable rubber membrane.

It should be noted that whereas plastic cover 1,
once it has been removed, cannot be returned to its
original position of engagement with metal element
6, due to the particular structure of its component
30 elements, it can however be re-utilized as a temporary
covering and protection for metal element 6 and for
the underlying rubber membrane when the contents of

- 5 -

the bottle are to be partially used.

While the present invention has been illustrated on the basis of one preferred embodying example, it is obvious that variations and/or modifications may
5 be introduced by those skilled in the art, without departing from the scope and spirit of the invention. In particular, the slant of the inclined plane formed by wedge 5 may be right-hand or left-hand, so that the above discussed disengagement motion may be either
10 clockwise or counterclockwise.

C L A I M S

1. A safety closure, in particular for multi-dose bottles, comprising substantially a metal closing and gripping element associated with an underlying elastic pierceable membrane, characterized in that
5 a cover (1) of rigid thermoplastic material is removably secured to said gripping element (6).

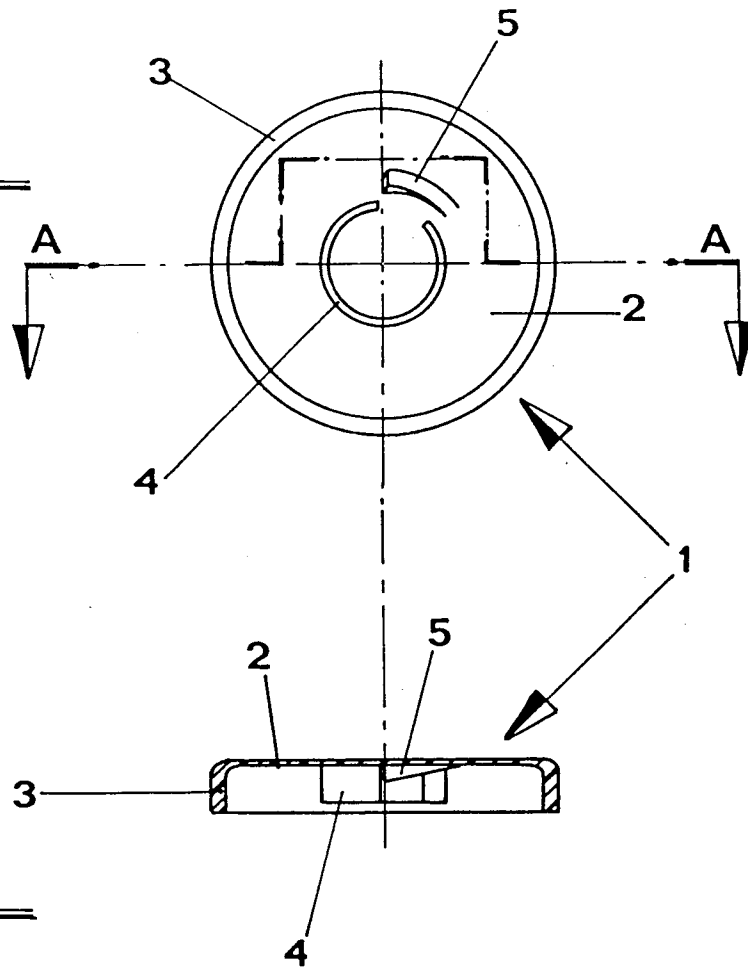
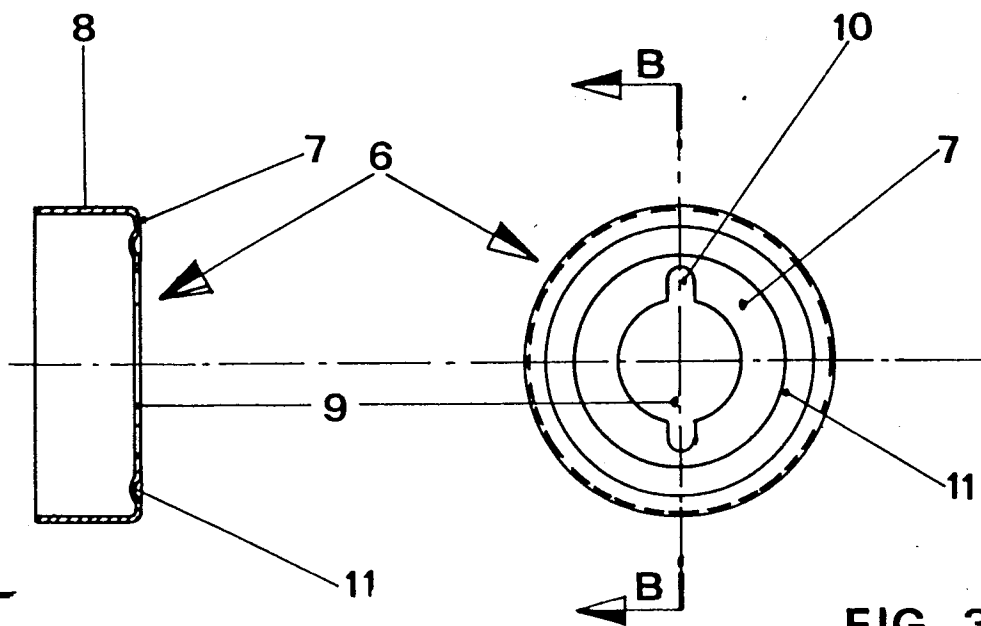
2. The closure according to claim 1, characterized in that said cover (1) is formed, before applying to said gripping metal element, by a disc (2) provided
10 with a cylindrical circumferential flange (3) and a discontinuous cylindrical central flange (4) as well as a wedge (5) placed at and outside the discontinuous portion of said cylindrical central flange (4).

3. The closure according to claim 1, characterized
15 in that said gripping metal element (6) is provided with a central opening enlarged at one of its diameters to form two symmetrical opposite eyelets (10).

4. A closure according to any of the above claims, characterized in that said cover of thermoplastic
20 rigid material (1) is removably secured to said metal gripping element (6) by thermal deformation and compression of said discontinuous cylindrical central flange (4).

5. The closure according to claim 4, characterized
25 in that the most projecting portion of said wedge (5) is inserted in one of said eyelets (10) of the central opening (9) of the metal gripping element (6).

6. Improved safety closure, particularly used for multidose bottles, substantially as described and
30 illustrated in the attached drawings.

FIG 1FIG 2FIG 4FIG 3