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PARENTERAL LIQUID CONTAINER HAVING FRANGIBLE PART STRUCTURE

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FIG. 1.

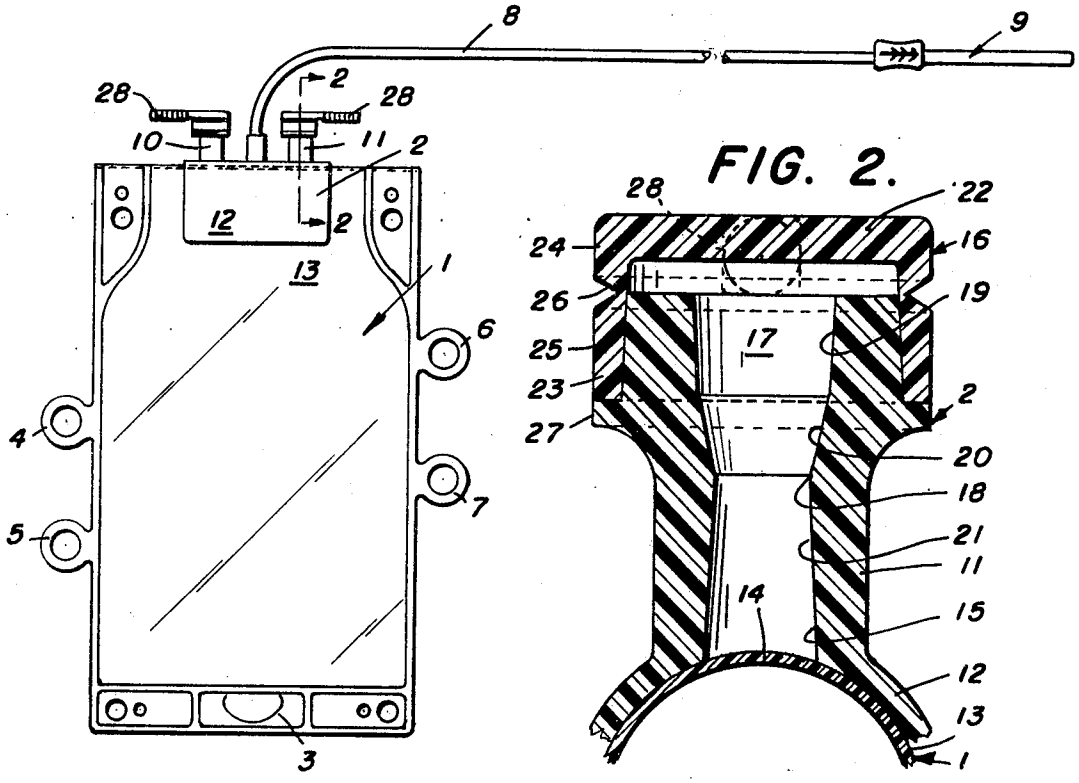


FIG. 2.

FIG. 3.

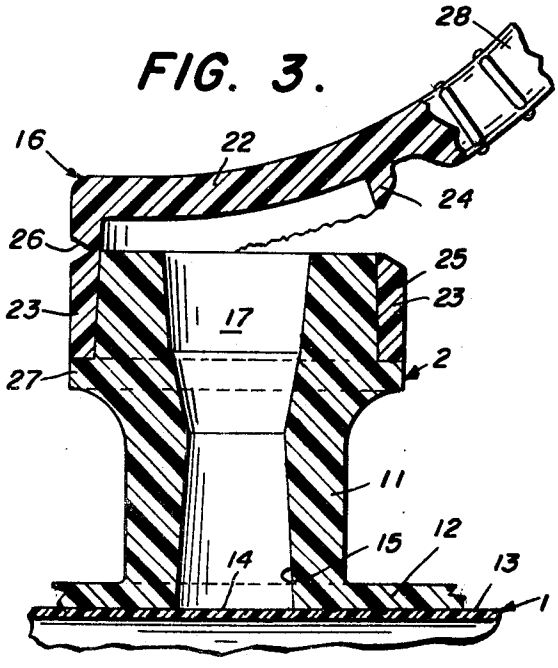
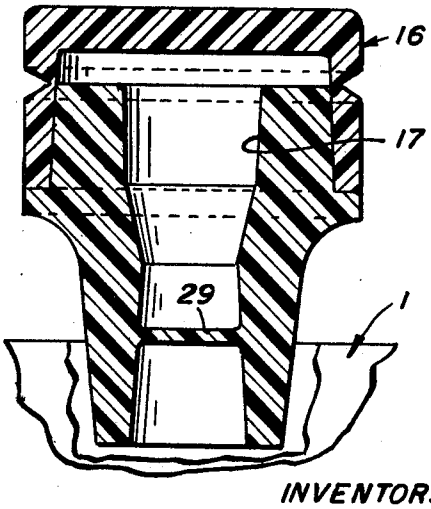


FIG. 4.



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PARENTERAL LIQUID CONTAINER HAVING FRANGIBLE PART STRUCTURE

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ABSTRACT OF THE DISCLOSURE

A flexible blood bag with an improved outlet port structure including a donor tube and two tubular necks sealed to the wall of the bag. These tubular necks each have a puncturable membrane closing off a neck passage, which passage has an internal construction for sealing with puncturing spikes having various diameters. A tear-off cap seals an outer end of each neck and an external grasping flange at a midpoint of each neck keeps an operator's fingers from contaminating the outer end of each neck.

This invention relates to an improved port structure for a flexible blood bag. Blood is often stored in flexible bags and these bags usually have a tubular connector spout for dispensing the blood. To remove blood from the bag, a sharp hollow spike is inserted through this spout and pierces a barrier membrane to give access to the blood.

This invention has to do with an improved construction for keeping this tubular spout sterile, particularly at its outer end where the spike is inserted. The invention includes in combination a tubular neck sealed to the bag, a tear-off cap integrally sealed to an outer end of the tubular neck, and an external gripping flange on the tubular neck below the cap but spaced from the bag wall. Thus, an operator can wedge his fingers between the bag wall and the grasping flange as he rips off the cap to expose the tubular neck. This grasping flange keeps his fingers well below the critical outer end of the tubular neck and gives him something to push against as the connecting spike is shoved into the tubular neck.

Perhaps this invention can be better understood with reference to the following drawings, in which:

FIGURE 1 is a front elevational view of the blood bag with port structure;

FIGURE 2 is a cross-sectional view taken along line 2—2 of FIGURE 1 showing a first embodiment of the invention with the puncturable membrane being an integral part of the bag wall;

FIGURE 3 is a cross-sectional view similar to FIGURE 2, but rotated 90° about its longitudinal axis to show the laterally extending handle as it is used to tear apart the cap; and

FIGURE 4 is a cross-sectioal view similar to FIGURE 2, but showing a second embodiment of my invention with the puncturable membrane being an integral part of the tubular neck.

Taking up the specific structure of the invention, in FIGURE 1 we have a flexible blood bag **1** which has a port structure **2** at its upper end and has a hanger structure **3** at its bottom end for suspending the bag upside down when administering blood. On each side of the bag are circular loops **4**, **5**, **6** and **7** for holding small test tubes used in taking samples of blood for typing, cross matching, etc.

The port structure at the top of the bag includes a donor tube **8** with an attached needle assembly **9** for collecting blood in the bag and a plurality of tubular necks

10 and **11** joined to the bag wall for dispensing blood from the bag.

The invention has to do with the construction of the tubular neck as seen in a first embodiment (FIGURES 2 and 3) and also in a second embodiment (FIGURE 4). In the first embodiment, the tubular neck is integrally joined to a base flange **12** at its bottom and this base flange is permanently sealed by a polyvinyl chloride solvent or by heat to the bag wall **13**. The bag wall itself forms a puncturable membrane **14** closing off the neck passage **17** and the base flange aperture **15**. Prior to puncture of the membrane **14** the blood is completely sealed in the bag, the blood having been collected through the donor tube **8** and the donor tube sealed off. When the bag is opened a cap-like closure **16** is removed and a hollow spike is pushed down through the neck passage **17** until it punctures membrane **14**.

As the spike enters passage **17**, a constriction **18** of the neck's internal wall tightly seals the spike to the neck in a liquid-tight seal. A first wall section **19** of the neck converges inwardly from its top at a slight angle to the longitudinal axis of the neck passage and joins to a second wall section **20**, which in turn converges inwardly at a steeper angle to the passage's longitudinal axis, forming a constriction **18** at the second section's lower end. A third wall section **21** of the neck converges inwardly from a bottom end of the tubular neck toward the constriction. We have found that this wall construction surrounding the passage accepts various puncturing spikes, each of which has a different external diameter. For instance, spikes with diameters ranging from .200 inch to .240 inch have been used successfully in this neck passage construction.

As discussed above, a hollow spike is shoved into the passage until it ruptures the puncturable membrane. Therefore, it is of utmost importance to keep this passage and the spike sterile so the spike does not carry contaminating bacteria into the bag. In this invention the passage in the tubular neck is kept sterile by a tear-off closure **16**. The closure **16** has a top wall **22** and a depending skirt **23** that fits over an upper portion of the tubular neck and is permanently sealed to this neck. The skirt is divided into an upper portion **24** and a lower portion **25** integrally joined by a section with a peripheral groove **26**. The skirt can be between .005 and .015 inch thick at the groove but is preferably about .010 inch thick. This groove **26** is at approximately the same level as the upper end of the tubular neck so tearing forces can be concentrated at the groove by the outer edge of the tubular neck.

When a nurse or physician is ready to open up the tubular neck, he places a thumb and forefinger of one hand under the laterally extending grasping flange **27** which is spaced below the closure groove **26** but above the base flange **12**. With his other hand he grasps the laterally extending handle **28** and pulls upwardly, breaking the closure apart at the peripheral groove. Keeping one hand still below the grasping flange, he shoves the puncturing spike down through the neck passage until it punctures the membrane **14**. Thus, the operator's hand which holds the tubular neck is kept away from the critical upper end and mouth portion of the tubular neck, which are exposed after the closure's upper portion has been removed.

In the above description of the first embodiment, we have referred to the rupturable membrane as being part of the bag wall. However, as shown in the second embodiment of FIGURE 4, this puncturable membrane can be an integral web **29** across the passage of the tubular neck. In this latter embodiment, the tubular neck can be sealed directly between two layers of the bag material forming the bag walls and no base flange is needed.

The bag and port structure of our invention are made of plasticized polyvinyl chloride, but other medically acceptable thermoplastic materials could also be used.

We have described the invention in specific structural details. However, it is understood that persons skilled in the art can make certain modifications to these structural details without departing from the spirit and scope of the invention.

We claim:

1. In apparatus for storing and handling sterile parenteral liquids including a flexible, collapsible bag (**1**), a donor tube (**8**), and at least one port structure (**2**) integrally sealed to a wall of the collapsible bag, the improvement comprising: said port structure including a rigid, tubular neck (**11**) having a longitudinal passage (**17**) and a transverse, puncturable membrane (**14** or **29**) thereacross,

said neck including intermediate its end, an external shoulder (**27**) projecting laterally above an external reduced in cross section portion therebelow and spaced above said collapsible bag for conveniently receiving a user's fingers to promote a firm grasp thereat and to prevent a user's fingers from moving thereabove, the transverse wall structure of said neck being substantially thicker than the bag wall to which said port is sealed; and

a closure (**16**) permanently and hermetically sealed to the tubular neck above said shoulder,

said closure including a top wall portion having an integral handle (**28**) projecting laterally therefrom,

said closure including a frangible section (**26**) defining upper and lower portions,

the upper portion of said closure being integral with said handle whereby said rigid tube provides a rigid base against which said upper closure portion can be manually severed, and in which said shoulder maintains the sterile integrity of the neck by maintaining

a grasped user's fingers below the severed closure during removal of the upper portion and insertion of a donor tube spike.

2. The structure as claimed in claim **1** in which said tubular neck has an upper edge substantially coplanar with said frangible section of said closure and substantially above the intermediate shoulder.

3. The structure as claimed in claim **2** in which said tubular neck includes an upper, reduced diameter portion above said shoulder, said closure being telescopically sealed on said upper reduced diameter portion and defining an annular collar below said frangible section.

4. The structure as claimed in claim **1** in which said puncturable membrane comprises a portion of said collapsible bag.

5. The structure as claimed in claim **1** in which said membrane comprises a seal integral with said tubular neck and extending intermediately of said neck passage above said bag wall.

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