April 24, 1962 W. L. ELDER 3,030,952

SOLUTION ADMINISTRATION DEVICE AND METHOD OF FORMING THE SAME

Filed Dec. 24, 1956

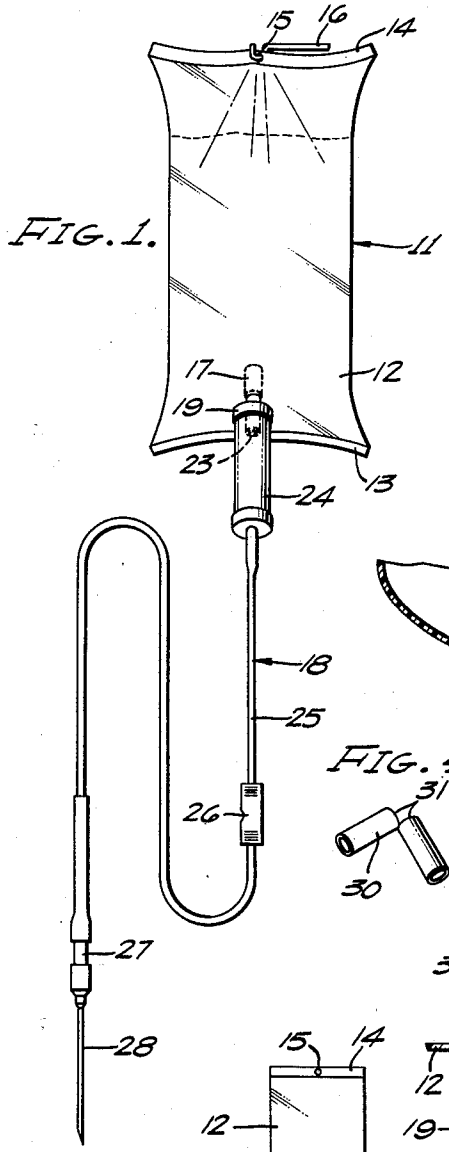

FIG. 1.

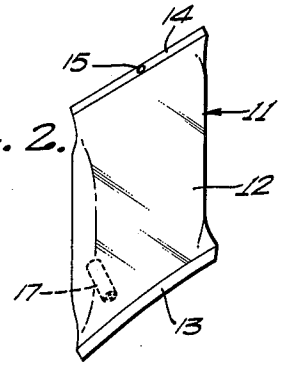

FIG. 2.

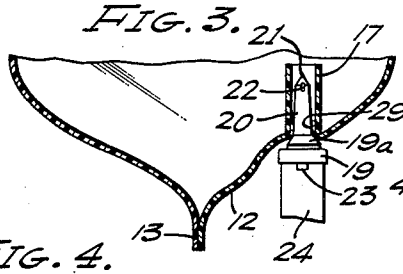

FIG. 3.

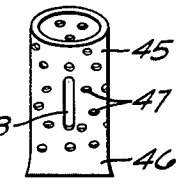

FIG. 9.

FIG. 4.

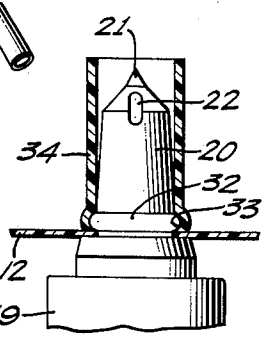

FIG. 5.

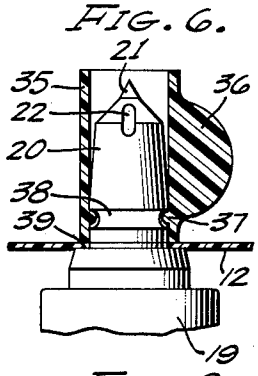

FIG. 6.

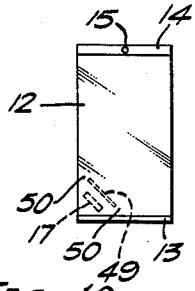

FIG. 10.

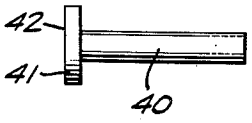

FIG. 7.

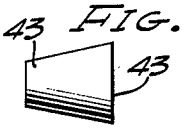

FIG. 8.

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SOLUTION ADMINISTRATION DEVICE AND METHOD OF FORMING THE SAME

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This invention relates to a flexible plastic container for sterile injectable fluids. The invention is particularly concerned with a container suitable for manufacture on mass production machines.

Flexible plastic containers have numerous advantages over the glass containers now in use. Problems arise, however, in attaching an administration set to the container. The set must be fastened securely in place so that it will not leak or be easily dislodged. The connecting element of the set should easily pass through the container wall but it should not puncture the opposite wall of the container. This is particularly important when solutions are administered rapidly by squeezing the container. When the container is only partially filled, as in the case of a blood container, the walls tend to stick together and it is even more difficult to force the connector through the wall without puncturing the opposite wall. The entry device should also be inexpensive and easy to apply to containers while they are being manufactured by machine.

It is the general object of this invention to provide a plastic container to which an administration set may be firmly attached.

Another object of the invention is to provide a plastic container with an inexpensive, leak-proof means of attaching an administration set.

Another object of the invention is to provide a means for attaching an administration set to a plastic container at any point on the container.

Another object of the invention is to provide a plastic container to which an administration set can be connected by exerting only relatively small force.

A further object of the invention is to provide a means for attaching an administration set to a plastic container, whereby puncturing of the container wall opposite the point of attachment will be prevented.

A still further object of the invention is to provide a plastic container for parenteral solutions which can be easily manufactured on high-speed, mass production machinery.

Plastic containers of the present invention will be more fully understood from the description of the preferred form of the invention given with the accompanying drawings, in which:

FIGURE 1 is a side elevation of the invention with an administration set attached;

FIGURE 2 is a perspective of the invention;

FIGURE 3 is a sectional view showing detail of the administration set attachment;

FIGURE 4 is a perspective showing a modified tube for use in the invention;

FIGURE 5 is a sectional view showing a modification of the invention;

FIGURE 6 is a sectional view showing a modification of the invention;

FIGURES 7, 8 and 9 are side elevations showing modified tubes for use in the invention;

FIGURE 10 is a side elevation showing another modification of the invention.

Referring now to FIGURES 1 to 3, the plastic container is generally indicated as **11**. The container body **12**, containing solution, may be made from a tubing heat-sealed transversely along the ends **13** and **14**. The tubing may be extruded as a closed continuous tube, or

it may be formed from a cast or calendered flexible film, sealed longitudinally by one or more seals. The upper end **14** is provided with a hole **15** which may be used to suspend the container on a hanger **16**. An unattached tube **17**, of relatively small diameter, floats freely in the solution in the container body **12**.

The tube **17** may be made of a short length of extruded, plastic tubing. It should be made of such a material and shape that the ends of the tube remain open and do not collapse, even when the tube is held firmly between the fingers of the operator's hand. The walls of the tube **17** should be somewhat resilient so that they will make a tight fit with a connecting member, as will be shown subsequently. On the other hand, the walls of the tube **17** should not be stretched too easily, or they will not hold the connector in place firmly enough. Extruded, polyvinylchloride tubes having a wall thickness of 0.04 inch, an inside diameter of 0.20 inch and a length of 1½ inches have been found ideal.

The administration set **18** is connected to the container **11** by the connector **19**. The connector **19** is provided with a shaft **20**, a piercing point **21**, louvered openings **22** and a drip tube **23**. The drip tube **23** extends into the drip housing **24** to which a flexible tube **25** is attached. The tube **25** is provided with a clamp **26**, a needle adapter **27**, and a needle **28**. The set **18** is attached to the container **11** by forcing the piercing point **21** of the shaft **20** through the wall of the body **12** into one of the open ends of the tube **17**. The portion **29** of the container wall pierced by the point **21**, is drawn in around the shaft **20** and wedged between the shaft and the wall of the tube **17**.

The shaft **20** of the connector **19** is preferably tapered to allow for variation in the size of the tube **17**, and to form a tight, firm, leak-proof joint with the tube. Preferably the tube **17** should be approximately the same size as the tapered shaft **20** at a point about halfway between the point **21** and the hub **19***a*. In this way the tube **17** is stretched as the shaft **20** is forced in, and a tight fit is obtained. By close control of the dimensions involved, however, both the shaft **20** and the tube **17** can be cylindrical. Alternatively a cylindrical, pointed shaft could be used with a tapered tube. In the example shown, a relatively large shaft **20**, and therefore a large tube **17**, is used. A smaller shaft, such as an ordinary hypodermic needle may, however, be used with a smaller tube.

As shown in the example, the tube **17** is longer than the shaft **20** and prevents the point **21** from puncturing the side of the container wall opposite the pierced portion **29**. If it is not necessary to protect the container wall, a shorter tube can be used. In this case the tube need only be long enough for the operator to grasp firmly through the sides of the flexible walls of the body **12**.

Too stiff a tube does not hold the set as well as a more resilient tube that is thoroughly stretched by the connecing member. The material from which the tube is made should have a specific gravity greater than the solution so that it will fall to the bottom of the container, where it can be located for use.

By making the tube **17** from a moisture absorbing plastic, such as polyvinylchloride, the tube becomes opaque and milky in appearance after steam sterilization. This is apparently due to moisture absorbed by the hot tube. The change in appearance can be used to indicate that the container has been sterilized. Moreover, the tube **17** retains the milky appearance while the container **11**, which may be made of the same material, becomes transparent.

In use, the clamp **26** of the administration set **18** is closed. The container **11** is held by the upper seal **14** and the tube **17** allowed to settle to the bottom of the con-

tainer. The tube 17 is then grasped through the flexible wall of the body 12 with the thumb and forefinger. The upper part of the container 11 is folded over so that a portion 29 of the flexible wall presses against the open end of the tube 17. If desired, the portion 29 of the container wall, through which the set is to be connected to the container, may be swabbed with alcohol or other antiseptic solution. Alternatively the portion 29 of the container wall may be covered with an adhesive tape or pressure-sensitive tape to maintain that portion in sterile condition. The tape is then removed to expose a sterile surface.

A sterility protector (not shown) is then removed from the connector 19. The piercing point 21 is pushed against the portion 29 of the container wall, pushing it into the open end of the tube 17. When the point 21 punctures the wall, the portion 29 is drawn in about the shaft and wedged firmly between the shaft and the inner wall of the tube 17. The administration set 18 may be connected at any point on the wall 12 of the plastic container. Preferably, however, it should be connected slightly above the bottom seal 13 and at any position more than about one-half inch in from the sides of the container.

The container 11 is then suspended from the hanger 16; the drip housing 24 filled; the clamp 26 opened; the tube 25 filled; a sterility protector (not shown) removed from the needle 28; venipuncture made; and the administration started.

With shaft 20 forced into the tube 17, and a portion 29 of the container wall wedged between the shaft and the tube, the set 18 is firmly attached to the container 11. The administration set connector 19 may be removed from the container 11 by holding the tube 17 through the flexible container walls and twisting and pulling on the connector 19.

In the modification shown in FIGURE 4 the tube 30 is cut at the center 31 to provide additional connecting tubes. In the modification of the invention shown in FIGURE 5, the tapered shaft 20 is provided with a ring 32 which locks in a corresponding groove 33 of the tube 34. This interaction between the ring 32 and the groove 33 serves to hold the connector 19 even more firmly to the container 11.

In the modification of the invention shown in FIGURE 6, tube 35 is provided with a handle 36 and an annular flange 37. The flange 37 locks into the groove 38 in the shaft 20, to increase the strength of the connection between the set and the container wall 12. The connector 19 may be provided with a shoulder 39 so that the container wall 12 is wedged between the shoulder and the end of the tube 35 to prevent leakage.

In the modification shown in FIGURE 7, the tube 40 is provided with an enlarged head 41 having a flat end surface 42. This enlarged surface 42 would help squeeze the container wall 12 against the shoulder 39 to further guard against leakage.

The modification of FIGURE 8 shows a short tapered tube 43. The short tube may be used only if it is not necessary to protect the opposite side of the container wall from the piercing point 21. The base 43 of the tapered tube must be approximately the same size as the base of the shaft 20, to prevent leakage between the container wall 12 and the shaft.

In the modification shown in FIGURE 9, one end 46 of the tube 45 is closed. The wall of the tube 45 has holes 47 or slots 48. Solution, such as blood, flowing to the openings 22 is strained before leaving the container 11. Since blood is opaque, the tube 45 would be difficult to locate if it floats freely in the container 11. The modification of FIGURE 10 shows the tube restricted in one corner of the container by heat-sealing the walls of the body 12 together along the seal 49. Openings 50 at the end of the seal 49 allow fluid to flow past the seal 49.

While this invention has been described as one for a container for sterile injectable fluids, it also could be used as a container into which blood for transfusion, or other purposes, can be drawn. In such a device, the plastic container 11 with the free tube 17 therein is sterilized, sealed, and at the time of sealing, evacuated. In such case, if it is desired to use the present invention for the collection of blood and the like, a connector 19 with a shaft and piercing point 21, which have attached thereto the necessary device for collecting blood from a donor, can be inserted into the container 11 by use of the tube 17 and the piercing point 21 just as previously described and the blood will then flow inwardly into the container. The sealing member 29 will still prevent a leakage around the shaft 20 and the flexible walls of the container 11 will permit the blood to flow into the container 11.

I claim:

1. A fluid container comprising: a body having a flexible plastic wall; a cylindrical tube within said body, said tube having at least one open end and an inner surface, said surface defining a passage extending axially inwardly from said end; a hollow pointed connecting member passing through said body wall into the open end of said tube and having an outer surface; a portion of the body wall being drawn inwardly to form an inwardly-extending collar about said connecting member, said collar being wedged between the outer surface of said connecting member and the inner surface of said tube to constitute the sole means of attachment between the open end of the tube, the body wall, and the connecting member.

2. A plastic container for fluids comprising: a sealed, layflat, flexible plastic body having at least one end, a clear solution in said body, a cylindrical tube in said body, the length of said tube being short relative to the length of the body so that both ends of the tube will be located in the same end of the body, said tube being free to move in said solution, said tube being sufficiently stiff to be grasped firmly without collapsing, and being formed from a plastic material which is transparent when inserted in said body but which will become opaque when said container is heat sterilized and remains opaque while in the solution.

3. An administration device for liquids comprising: a closed container formed by a flexible, plastic wall, portions of said wall being sealed together to form a pocket within the closed container, and a tube in said pocket, said tube being free to move within said pocket.

4. A plastic container for fluids comprising: a body formed by an imperforate flexible wall and having an end, a resilient, cylindrical tube movable in said body, said tube having a wall and two ends, the length of said tube being short relative to the length of the body so that both ends of the tube will be located in the same end of the body, said tube being adapted to fit tightly around a pointed tubular member connecting to an outlet device when the point of said member is forced through the body wall, both ends of said tube being open and having smooth, flat surfaces cutting across the tube, the wall of said tube being formed of polyvinyl chloride approximately 0.04 inch thick.

5. A method of administering a solution from a container having flexible plastic walls and containing a short, loose tube with at least one open end comprising: grasping the loose tube through the flexible container wall; holding the open end of said tube against the inner surface of a portion of the container wall near one end of the container; deforming and stretching said portion of the container wall inwardly by pressing the point of a pointed tubular connecting member against the outside surface of the container wall portion; further pressing said connecting member against said portion of the container wall, piercing it and drawing the deformed and stretched portion inwardly to form a sealing collar about said member; telescoping said connecting member into said tube to wedge the collar portion between the connecting

member and the tube; and withdrawing the solution through said connecting member.

6. A method of administering a solution from a container having flexible plastic walls, an inner wall surface, and at least one end, and containing a short, loose tube having an outer circumferential surface, an axial passage and at least one open end comprising: holding the container so that the loose tube assumes a position of rest near one end of the container; grasping portions of the flexible container wall on each side of the tube and deforming said portions around the outer circumferential tube surface; gripping the tube through the flexible container walls and turning the tube so that the open end butts against a portion of the inner surface of the container wall; piercing said portion of the container wall with a pointed, tubular, connecting member; telescoping the connecting member into the axial tube passage; and withdrawing the solution through a withdrawal tube attached to the connecting member.

7. A liquid administration device comprising: a body having a flexible plastic wall; a generally cylindrical tube within said body, said tube having an annular wall, an axial passage and at least one open end, said annular wall being at least as thin in the portion of the tube adjacent the open end as in the remainder of the tube, and a hollow, pointed connecting member passing through a portion

of the body wall, telescoping into the tube from the open end thereof and wedged tightly in the tube to provide a friction fit between the tube and the connecting member, said friction fit being the sole means of attachment between the open end of the tube, the body wall and the connecting member.

References Cited in the file of this patent

UNITED STATES PATENTS

2,653,606	Ryan	Sept. 29, 1953
2,702,034	Walter	Feb. 15, 1955
2,784,716	Broman	Mar. 12, 1957
2,808,829	Butler	Oct. 8, 1957
2,824,642	Stoltz	Feb. 25, 1958
2,849,321	Lhermitte et al.	Aug. 26, 1958
2,949,712	Bieberdorf et al.	Aug. 23, 1960

FOREIGN PATENTS

642,256	Great Britain	Aug. 30, 1950
763,178	Great Britain	Dec. 12, 1956

OTHER REFERENCES

Brown et al.: "A Simple, Expendable Blood Oxygen-Gas Exchanger," Surgery, vol. 40, No. 1, July 1956, pp. 100–101.