

- [54]
- SYRINGE WITH PUNCTURABLE STEM**

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|-----------|--------|------------|---------|
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| 3,739,780 | 6/1973 | Ogle..... | 128/220 |

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- [73] Assignee: **Nasco Plastics, Incorporated, Erie, Pa.**

FOREIGN PATENTS OR APPLICATIONS

- | | | | |
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| 366,126 | 1/1963 | Switzerland..... | 128/218 R |

- [22] Filed: Feb. 28, 1973

- [21] Appl. No.: 336,534

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Assistant Examiner—J. C. McGowan
Attorney, Agent, or Firm—Ralph Hammar

- [52] U.S. Cl..... 128/218 DA, 128/220

- [51] Int. Cl. A61m 5/24

- [58] **Field of Search** 128/220, 218 NV, 218 P,
128/218 N, 218 DA, 218 M, 218 D, 272,
128/215, 216, 218 R

[57] ABSTRACT

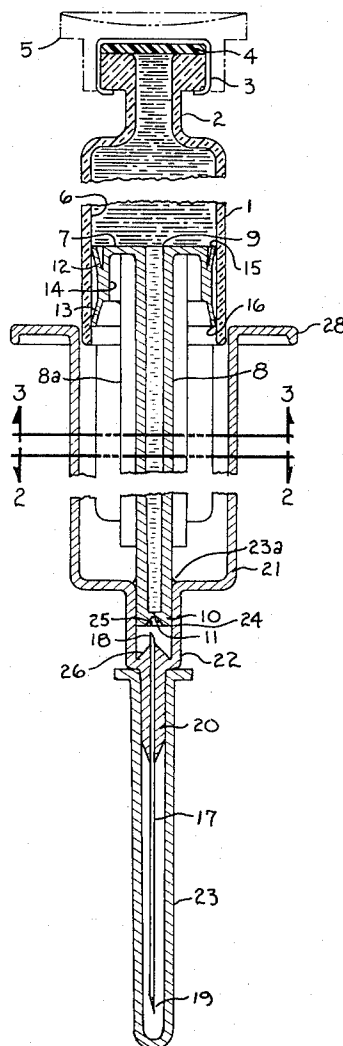
A syringe adapted to be shipped with the barrel filled with the fluid to be dispensed. The barrel is closed by a piston having a head slidably received in the open end of the barrel and a stem with its inner end continuously open to the fluid contents of the barrel and its outer end extending outside the barrel and closed by a puncturable seal. A needle holder slidably mounted on the outer end of the piston has a needle with its inner end presented to the seal and its outer end delivering fluid to the injection site. The syringe is readied for injection by moving the needle holder so that the inner end of the needle pierces the seal.

- [56]
- References Cited**

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4 Claims, 4 Drawing Figures



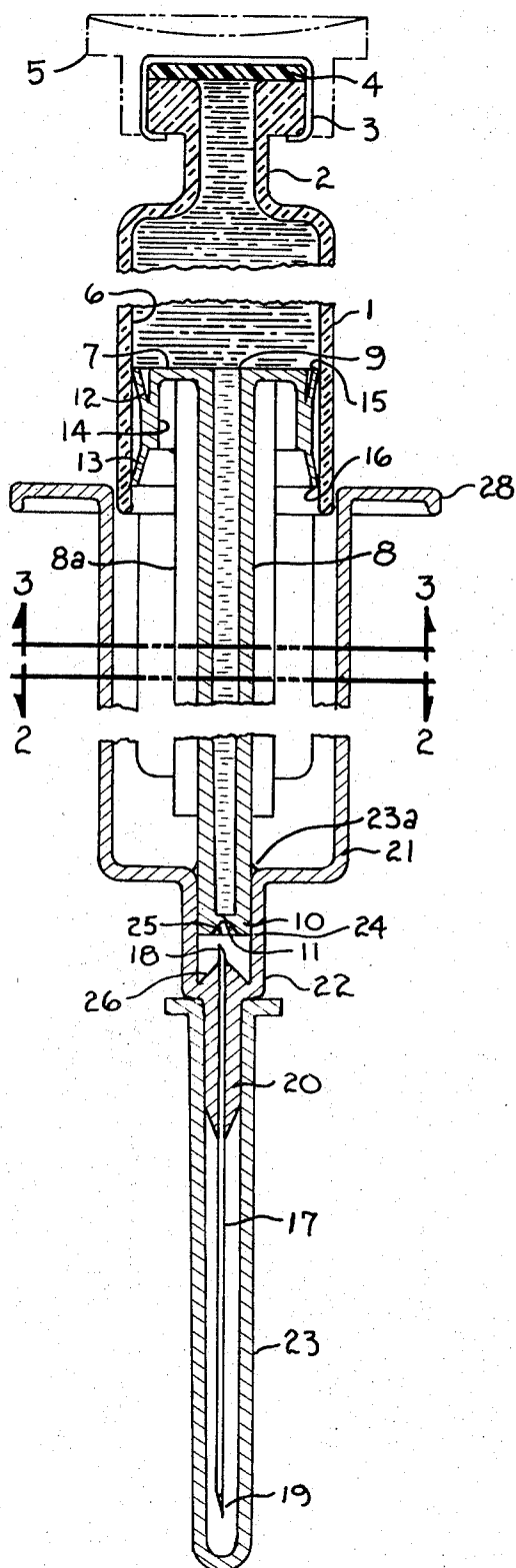


FIG. 1

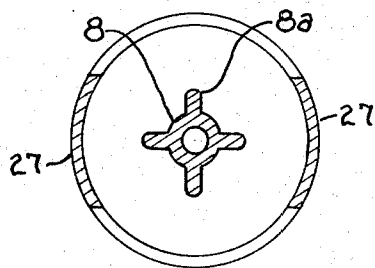


FIG. 2

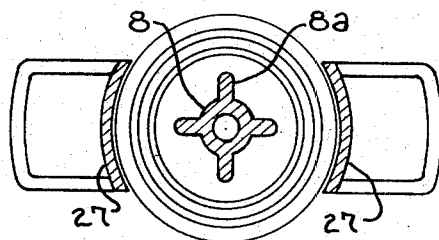


FIG. 3

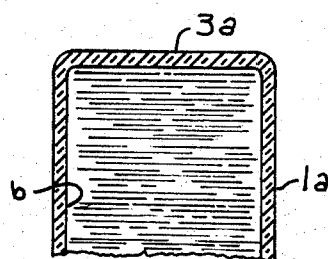


FIG. 4

SYRINGE WITH PUNCTURABLE STEM

This invention is intended to simplify the construction and use and reduce the cost of one time user syringes which are shipped filled with the fluid to be dispensed.

Specific reference is made to earlier filed applications Ser. Nos. 747,608, filed July 25, 1968 (abandoned); 67,590, filed Aug. 27, 1970 (abandoned); 75,121, filed Sept. 24, 1970; 98,225, filed Dec. 15, 1970; 98,226, filed Dec. 15, 1970 (U.S. Pat. No. 3,766,919); 279,504, filed Aug. 10, 1972; and 290,436, filed Sept. 20, 1972 (abandoned).

In the drawing, FIG. 1 is a longitudinal section through the syringe.

FIG. 2 is a section on line 2—2 of FIG. 1,

FIG. 3 is a section on line 3—3 of FIG. 1, and

FIG. 4 is a detail of an alternate end closure for the body of the syringe.

In a preferred form, the syringe has a glass or plastic vial or barrel 1 with one end open and with a neck 2 at the other end closed by a sealing ring 3 and gasket 4. If desired, a thumb rest 5 may be mounted on the sealing ring. The ring 3 is a form of bottle cap. In an alternate vial 1a shown in FIG. 4, the neck is replaced by a solid wall 3a. The vial 1 is filled through the neck while the vial 10 is filled through the end opposite wall 3a.

Both vials have a cylindrical bore 6 having the open end closed by a piston or stopper having a head 7 making sliding sealing engagement with the bore. Extending from the center of the head is a hollow stem 8 having its inner end 9 continuously open and presented to the fluid contents of the barrel and having its outer end 10 extending outside the open end of the vial and closed by a seal 11. Stiffening ribs 8a extend from the head 7 almost to the outer end of the stem. In the construction shown where the piston stem and seal are injection molded in a single piece from flexible synthetic thermoplastic resin, the seal 11 may be in the form of a thin puncturable diaphragm having a thickness of a few thousandths of an inch. The piston unit may be molded from a wide variety of flexible synthetic thermoplastic resins which are indifferent to the fluid contents of the syringe such as polyethylene, polypropylene, etc.

The seal between the piston head 7 and the barrel preferably comprises flanges 12, 13 oppositely inclined at an acute angle toward the bore and having inner ends integral with a rearwardly extending cylindrical flange 14 and outer ends or edges 15, 16 making sealing engagement with the bore of the barrel.

As molded, the outer edges 15, 16 of the flanges have a diameter preferably from 0.005 to 0.025 inch greater than the bore of the barrel. The flanges are thick enough so that the deflection which occurs upon insertion into the bore of the barrel creates enough pressure to produce a fluid tight seal. The outer edges 15, 16 are preferably thick or blunt to prevent loss of sealing pressure which would result if the edges 15, 16 were thin or feathered so as to be easily bent over by contact with the bore. Fluid tight seals which prevent leakage of the contents during the shock, vibration and temperature changes encountered during shipment and storage have been made in which the flanges corresponding to 12, 13 have had thicknesses ranging from 0.020 inch to 0.075 inch. The flanges will also accommodate the variations in diameter and out-of-roundness of the bore of the vial which may range from plus or minus 0.010 inch

in diameter and 0.010 to 0.015 inch of out-of-roundness. The deflection of the flanges varies with the cube of the thickness so small increases in thickness produce large increases in sealing pressure. During shipment and storage the piston 7 functions as a stopper in which the entire seal is developed by static deflection so flanges designed with this concept will of necessity be thick and stiff. During injection, in addition to the sealing pressure from static deflection of the flanges, there is also a dynamic or hydraulic force which increases the sealing pressure. On the pressure stroke of the piston, the flange 12 is forced against the bore by hydraulic pressure. On the suction or aspiration stroke of the piston, the flange 13 is forced against the bore by atmospheric pressure. The dynamic or hydraulic action is much less than in prior art syringes having thin or feather edged flanges designed to respond to hydraulic pressure.

The hypodermic needle 17 is shown as having pointed ends 18, 19, although for some uses the needle may consist of a short length of metal tubing. The needle is fixed in a hub 20 of a needle holder 21, for example by the method and apparatus described in U.S. Pat. No. 3,330,004. The hub has an integral cylindrical sleeve extension 22 slidably mounted on the outer end 10 of the stem 8. A slight projection 23a on the stem acts as a stop which positions the needle holder in the position shown in FIG. 1 with the inner end 18 of the needle aligned with and presented to the puncturable seal 11.

FIG. 1 shows the barrel filled and the parts in the position for shipping. In this position, all of the parts are protected from contamination. The piston 7 and the seals between the flanges 12, 13 and the bore 6 protect the sterility of the liquid contents of the barrel. The telescoping fit between the sleeve extension 22 and the end 10 of the stem 8 protects the needle point 18. A needle cap 23 telescoped over the hub 20 protects the needle point 19. The parts are sterilized before assembly, assembled and filled in a sterile room and then enclosed in an overpack.

Upon arrival at the point of use, the assembly is first removed from the over pack and then while grasping the stem 8, a pressure is exerted on the needle holder 21 to move the needle point 18 through the puncturable diaphragm 11. This establishes communication between the fluid contents and the needle without applying any pressure to the piston 7. In the punctured position, a fluid tight seal is effected by interengagement of the annular edge 24 of recess 25 in front of the seal 11 and the conical surface of a projection 26 on the hub 20. To puncture the seal 11, the restraining force exerted by the projection 23a must be overcome so that the needle holder moves with a snap action causing the conical surface 26 to bottom solidly against the edge 24 as the seal is punctured. The projection 23a also introduces a restraining force holding the projection 26 in engagement with the edge 25. As shown in FIGS. 1, 2 and 3, the needle holder has spaced axially extending sections or wings 27 which straddle and have arcuate inner surfaces in telescoping engagement with the outer surface of the barrel 1. Since the wings occupy only part of the circumference, the spaces between the edges of the wings 27 expose the outside of the stem 8 as shown in FIGS. 2 and 3 and make it easy to grip the stem while exerting a force on the needle holder necessary to puncture the seal 11.

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After insertion of the point 19 into the injection site, it is desirable to aspirate to determine whether the needle point has penetrated a vein. This can be done by grasping the stem 8 in one hand and the barrel 1 in the other and pulling back on the barrel to move it away from the piston 7. This produces a suction which will introduce blood into the stem 8 if the needle point 19 has penetrated a vein. If the aspiration indicates that the injection site is suitable, injection of the fluid contents is effected by pressure exerted between the closed end of the vial and the finger grips 28 on the wings 27.

Each of the required operations is independent of the other operations. Neither puncturing of the seal 11 nor insertion of the needle point in the injection site nor aspiration exerts a thrust on the piston 7. Neither aspiration nor injection exerts a thrust on the needle point 19.

In some cases, the needle 17 may be cut or broken off at the outer end of hub 20 and another needle substituted for the point 19. Or the syringe could be made with a short length of metal tubing substituted for the needle 17 to eliminate the need for cutting off the point 19.

Since the only function of the needle point 18 is to pierce the seal 11, it can be quite abrupt as compared to the point 19. When the seal is thermoplastic, there is no coring as the seal is pierced. The seal is ruptured or torn. Leakage of fluid around the needle is prevented by the seal 25, 26.

For shipping and storage, each syringe may be broken into two packages, a first package consisting of the vial or barrel 1 and the piston 7 and a second package consisting of the needle holder 21 and needle cover 23. This might be used for fluids requiring refrigeration.

What is claimed is:

1. A syringe comprising

1. a barrel for holding a fluid to be dispensed having a bore closed at one end and open at the other end,
2. a piston having a head slidably received in the open end of the bore and movable in one direction to expel fluid from the barrel and provided with an annular flange flaring outward in said one direction at an acute angle from the head of the piston to the

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inner barrel wall, the flange in its unstressed condition having its outermost edge thick and non-feathered and of outside diameter greater than the diameter of the bore so the flange is deflected by engagement with the inner barrel wall and the thickness of the flange being great enough, about 0.020 to 0.075 inch, so such mere deflection develops fluid tight sealing pressure under conditions of shock, vibration and temperature encountered during shipment and storage, said piston having a hollow stem of smaller diameter than the head extending from the head out the bore with the end of the stem adjacent the head within and continuously open to the fluid contents of the bore and with the end of the stem remote from the head closed by a puncturable section, the piston being of flexible synthetic thermoplastic resin indifferent to said fluid,

3. a needle holder having a hub, a double ended hollow needle fixed in and extending through the hub with one end presented to the puncturable section and the other end open for feeding an injection site, a sleeve integral with the hub slidably received on the end of said stem remote from the head permitting movement of the hub to puncture said section by said one end of the needle, the hub of the needle holder and the end of the stem remote from the head having sealing means interengaging as the needle punctures said section to prevent leakage around the outside of the needle.

2. The syringe of claim 1 in which the piston head, flange and stem are molded in a single piece from a flexible synthetic thermoplastic resin indifferent to said fluid.

3. The syringe of claim 1 in which the needle holder has angularly spaced axially extending wings with arcuate inner surfaces in telescoping engagement with the outer surface of the vial and provided with finger pieces for withstanding injection pressure forces exerted on the vial.

4. The syringe of claim 1 in which there is another annular flange similar to said one annular flange but flaring outward in a direction opposite said one direction and engaging the inner barrel wall.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,845,763 Dated November 5, 1974

Inventor(s) Harold S. Cloyd

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

On the cover sheet in item [73] "Nasco" should read
-- Nosco --.

Signed and Sealed this

Twenty-fourth Day of May 1977

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks