

[54] PACKAGED SYRINGE CONSTRUCTION

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[58] Field of Search..... 206/43, 17.5, 16.5, 63.2 R;
128/218 D, 218 NV, 218 P, 218 N, 218 R,
215, 221

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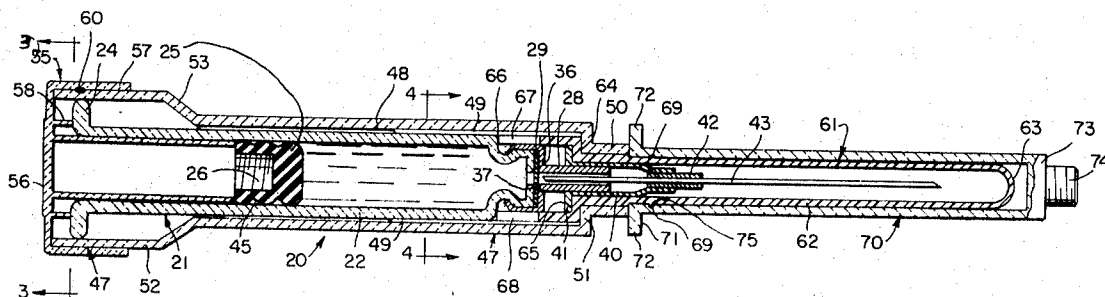
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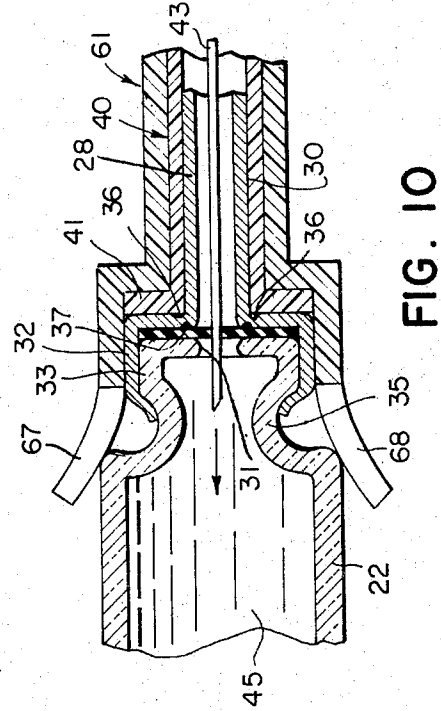
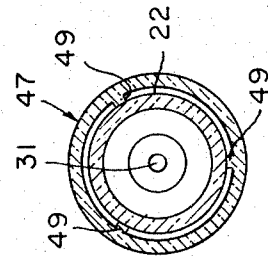
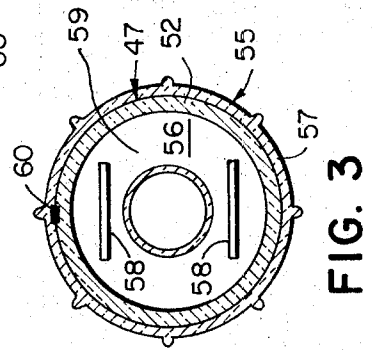
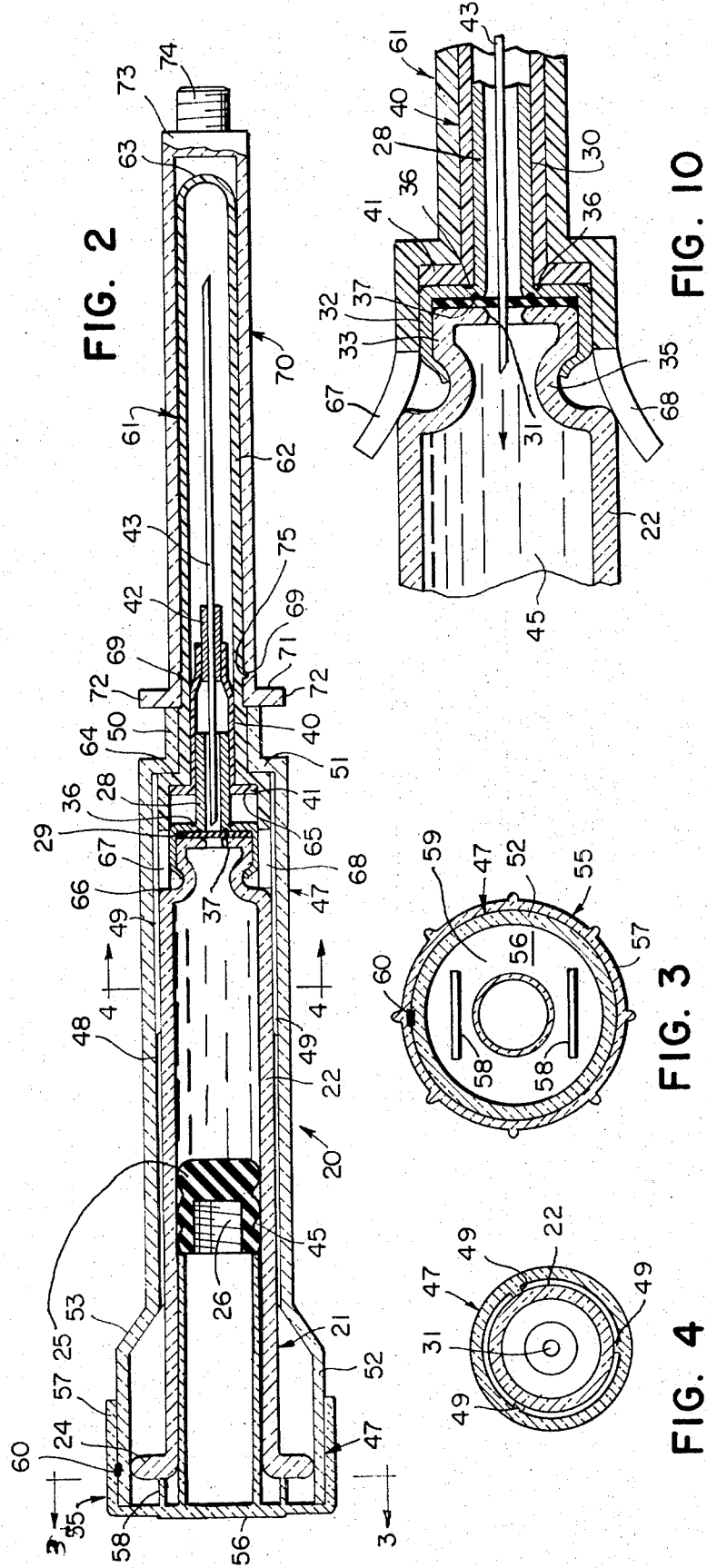
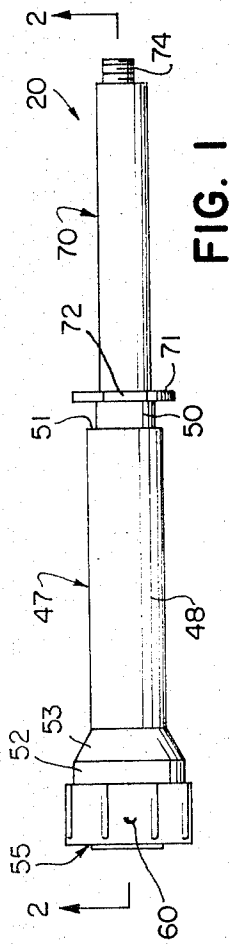
Primary Examiner—William T. Dixon, Jr.

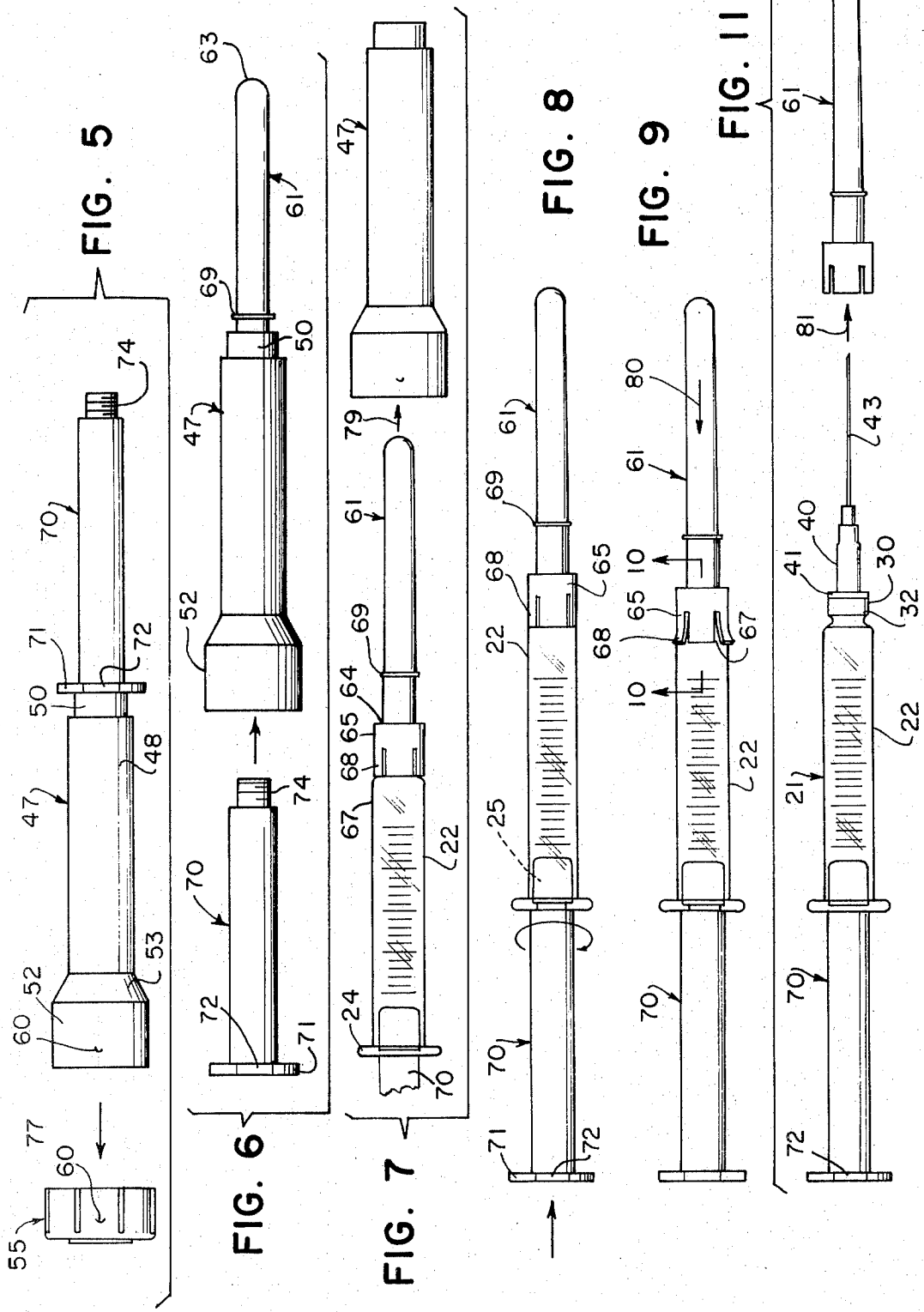
[57] ABSTRACT

A cylinder for containing medicine having one end closed and a piston in the other end, a needle mounted on the closed cylinder end in a storage position exteriorly of the cylinder and shiftable to a used position impaled through the closed cylinder end, an open ended outer protector or shield about the cylinder having an internal shoulder adjacent to the closed cylinder end and an end closure on the end adjacent to the piston, and a needle sheath extending into the shield past the shoulder where it is provided with a retaining enlargement, so that the cylinder and needle are completely enclosed.

11 Claims, 13 Drawing Figures







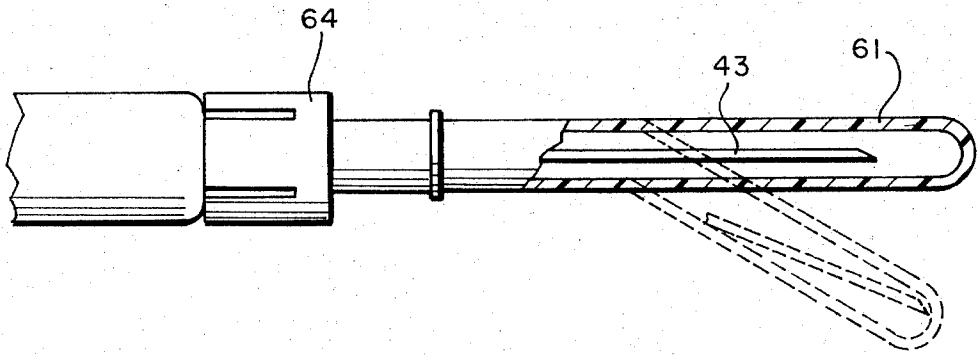


FIG. 12

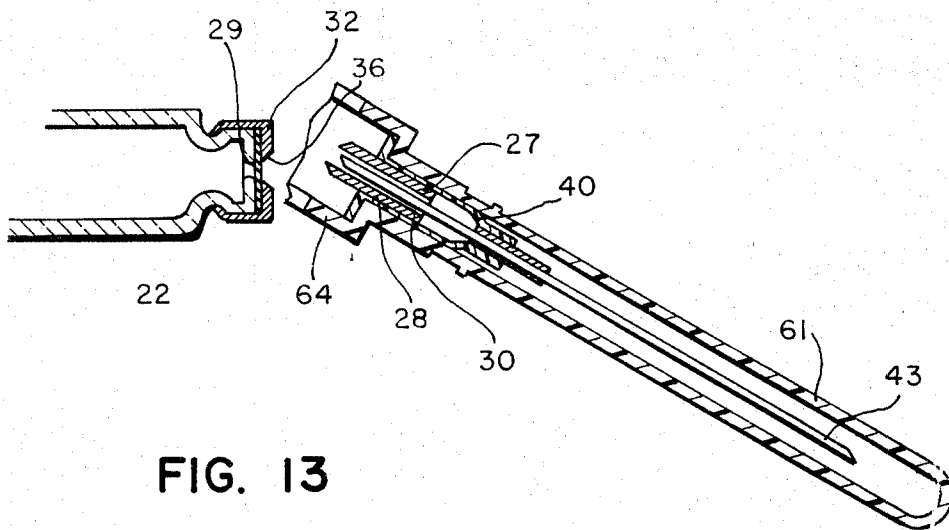


FIG. 13

PACKAGED SYRINGE CONSTRUCTION

BACKGROUND OF THE INVENTION

As is well known to those versed in the medical field, the accurate control of medicines, particularly drugs, presents considerable difficulty. For example, the filling of conventional syringes by a hospital pharmacist for transport to the patient continues to result in substantial diversion of drugs out of their intended paths, and frequent substitution of materials, such as approximately colored water, in the syringe, together with loss of sterility and great potential for serious contamination.

Of course, many other forms of tampering, loss of sterility, and other problems exist.

SUMMARY OF THE INVENTION

It is, therefore, an important object of the present invention to provide a syringe to the administering technician which is reliably sterile, prefilled for assurance of contents, completely disposable, highly tamper resistant, being compact in space requirements, and entirely complete in its individual package up to the moment its contents are to be administered.

It is a more particular object of the present invention to provide a prefilled, packaged syringe having the advantageous characteristics mentioned in the preceding paragraph, which is entirely enclosed to preserve the sterility and sealed against surreptitious opening and reclosure, while the syringe is effectively protected in the package against damage or leakage of the contents, and further is capable of quick and easy destruction for effective disposal without possibility of unauthorized reuse.

Other objects of the present invention will become apparent upon reading the following specification and referring to the accompanying drawings, which form a material part of this disclosure.

The invention accordingly consists in the features of construction, combinations of elements, and arrangements of parts, which will be exemplified in the construction hereinafter described, and of which the scope will be indicated by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal elevational view showing a syringe package constructed in accordance with the teachings of the present invention.

FIG. 2 is a longitudinal sectional view taken generally along the line 2—2 of FIG. 1.

FIG. 3 is a transverse sectional view taken generally along the line 3—3 of FIG. 2.

FIG. 4 is a transverse sectional view taken generally along the line 4—4 of FIG. 2.

FIG. 5 is a longitudinal view illustrating an initial step in the procedure of use, being that of removing an end closure from the package.

FIG. 6 is a longitudinal elevational view similar to FIG. 5, showing a slightly later step in use of the instant device, wherein a hollow piston rod is removed from the opposite end of the package and affixed to the piston.

FIG. 7 is a longitudinal elevational view of the instant device showing a slightly later step in use, wherein a protective shield or guard of the package is removed from the syringe cylinder or cartridge.

FIG. 8 is another longitudinal elevational view showing the piston rod being assembled with the piston.

FIG. 9 is another longitudinal elevational view showing the needle sheath as employed to impale the needle into the contents of the syringe.

FIG. 10 is a partial sectional view taken generally along the line 10—10 of FIG. 9, illustrating the operation of the impaling step in greater detail.

FIG. 11 is a longitudinal elevational view showing a final step, removal of the needle sheath, preparatory to administering of the medicine to a patient.

FIG. 12 is a partial longitudinal sectional view showing a syringe of the present invention after use and illustrating one mode of needle destruction.

FIG. 13 is a longitudinal view, partly in section, illustrating a syringe of the present invention and showing another mode of destruction rendering the syringe useless.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now more particularly to the drawings, and specifically to FIGS. 1 and 2 thereof, a packaged syringe is shown therein and generally designated 20. As best seen in FIG. 2, the syringe, there generally designated 21, is disposed entirely within the interior of the package, and includes an elongate cylinder or cartridge 22 which may conventionally be glass or other suitable material. The cylinder or cartridge 22 has one end open, as at 23, there being provided externally with an annular circumferential flange 24. Inserted into the open end 23 of the cylinder 22 is a piston 25, which may be of rubber or other suitable material, and formed in its outer end with internal screw threads, as at 26, for interfitting formation with complementary external screw threads, as will appear presently.

The other end of the cylinder or cartridge 22, remote from the plug or piston 25, is closed, as by a centrally open fitting 28 spun or swaged about the adjacent end portion of the cylinder 22 and retaining a seal 29 in sealing relation with the adjacent cylinder end. The fitting 28 may include an open ended tubular portion 30, of relatively small diameter in alignment with an end opening 31 of the cylinder 22, and a relatively large diameter portion 32 engaged about the adjacent end region 33 of the cylinder, and having its edge portion 34 spun or turned into an external groove 35 of the cylinder. This construction effects firm sealing of the inner end of cylinder 22 by the frangible or pierceable sealing plug 29.

The fitting 28 may advantageously be fabricated of aluminum or other suitable material, and may further be formed with annular grooves or lines of weakening, as at 36 and 37 located interiorly and exteriorly at the juncture of tubular portion 30 and enlargement 32. The scores or weakened portions 36 and 37 permit of easy breakage for irreparable destruction after use.

A needle mount or carrier 40 is slidably circumposed about the tubular portion 30 of the cylinder end member 28, being generally tubular and having its inner end provided with an annular enlargement or collar 41 movable toward and away from the cylinder or cartridge 22. The other end of the tubular needle mount is provided with a plug 42 which receives and carries a hollow tubular element or needle proper 43. The needle 43 extends from its mount or carrier leftward or inward spacedly into the tubular region 30 of end piece

28 terminating short of the closure element or seal 29, and extends backwardly or rightwardly considerably beyond the carrier. As will appear more fully hereinafter, the needle carrier 40 is shiftable inwardly or leftward to cause the inner end of the needle to pierce the seal 29 and establish communication through the needle between the interior and exterior of the cylinder 22, as for discharging the contents 45 of the cylinder.

The cylinder or cartridge 22 may be fabricated of glass, if desired. However, should the contents 45 require protection during storage from light, the glass of the cylinder 22 need not be special light shielding glass, as the package 20 serves to completely enclose the cylinder, as by plastic components or other suitable light shielding means.

Conformably surrounding and entirely receiving the cartridge 22 is a generally cylindrical shield or enclosure 47 including a medial portion 48 conformably and spacedly surrounding the cylinder 22. The medial shield portion 48 is formed internally with a plurality of circumferentially spaced, longitudinally extending ribs, holders or spacers 49, see FIG. 4, which engage with and support the cylinder 22 in concentrically spaced relation within the shield portion 48. One end portion of the shield 47, the rightward end portion at 50 in FIG. 2, is reduced and joined to the medial portion 48 by an annular shoulder 51 surrounding the needle mount 40 spaced from the enlarged region 32 of the cylinder and piece 28.

The opposite, leftward end of the shield 47 is enlarged, as at 52, being joined to the medial portion by a tapering connecting portion 53. A closure member or cap 55 is engaged in closing relation with respect to the enlarged shield end portion 52, including a circular flat end portion 56 and a circumferential skirt 57 circumposed about the end portion 52. A pair of spaced, internal projections or wings 58 are provided on the interior of the closure cap end wall 56 for engagement with the end flange 24 of the cylinder 22, to maintain the cylinder properly positioned within the shield 47. Further, a frangible, tamper indicating seal 60, such as a thermoweld, positively retained the closure member 55 in its closed relation with respect to the end portion 52 of shield 47. That is, while the seal or securement means 60 permits manual detachment or removal of the cap 55 from the shield, such removal cannot, without the use of very special tools, be concealed. The closure member or cap 55 is further formed interiorly thereof with a central or generally coaxial, generally tubular projection or boss 59 extending into the open end 23 of the cylinder 22 into end abutting engagement with the plug or piston 25 to limit outward movement of the latter, as will appear more fully hereinafter.

A needle guard or sheath is generally designated 61, including an elongate tubular body 62 having one end closed, as at 63 outward of the free end of needle 43, and having its other, inner end open. The inner end region of the sheath body 62 is closely circumposed about the needle carrier 40 and provided with an external enlargement enlargement or flange 64 interposed between the shield shoulder 51 and the needle carrier enlargement 41. Further, the sheath enlargement 64 is formed with a circumferential inwardly extending skirt 65 which may surround the enlarged portion 32 of the cylinder end piece 28, terminating at an eand edge 66, which is of sufficient thickness so as to be incapable of passing between the medial shield portion 40 and cylin-

der 22 when the latter is within the former, as shown in FIG. 2. The skirt 65 is of a material capable of flexible distension, and the skirt may be formed with a plurality of angularly spaced slits 67 extending through the end edge 66, so as to define of the skirt a plurality of resiliently flexible fingers 68. Additionally, the sheath 61 is provided on its tubular body 62 with detent means, say in the form of an annular external bead 69, all for a purpose appearing presently.

Closely circumposed about the sheath 61 is a hollow, tubular elongate member or plunger rod 70. The plunger rod 70 has one end open for receiving there-through the sheath 61, being formed about its open end with an external circumferential flange 71. The flange 71 is advantageously noncircular, say as best seen in FIG. 4, being formed with one or more flats 72 to resist undesired rolling of the package.

The other, outer end of the rod 70 may be closed, as by a closure 73, and provided externally with a threaded extension 74. Internally of the hollow rod 70, adjacent to the end flange 71, there may be formed an annular notch or groove 75, or other mating formation for snap reception of the detent means 69. Thus, the hollow rod 70 is detachably engaged about the sheath 61, being retained thereon by interfitting relation of the detent means 69, 75, permitting of deliberate removal of the rod, as desired.

Considering the method of use in accordance with the teachings of the present invention, it will be seen in FIG. 5 that the closure member or cap 55 has been initially removed, as in the direction of arrow 77, from the container of shield 47, as by separation of the weld or seal 60.

The next step is shown in FIG. 6, wherein the hollow rod or tube 70 has been removed from the sheath 61, sufficient force being applied to disengage the snap retention formations 69 and 75.

The hollow rod 70 may then have its threaded end 74 threadedly engaged into the exposed cavity 26 of piston 25. Such rotary threaded interengagement of the rod 70 into the piston 25 is aided by the firm frictional engagement of the ribs 49 with the cylinder 22 maintaining the latter and its received piston 25 stationary for threaded reception of the rod 70.

The shield or outer container 70, see FIG. 7, is then easily slid longitudinally outward over the sheath 61 in the direction of arrow 79, to assume the condition shown in FIG. 8.

In FIG. 9 is illustrated the method of piercing the seal 29, which may be accomplished by merely moving the needle sheath 61 inward, in the direction of arrow 80, which is permitted by resilient expansion of the skirt 65 by outward flexure of the fingers 68 about the cartridge or container 22. This effects impaling of the inner end of the needle 43 through the seal 29, best seen in FIG. 10.

It is then only necessary to longitudinally outwardly withdraw the sheath 61, in the direction of arrow 81 as seen in FIG. 11, and the syringe 21 is ready for use in the conventional manner.

Prior to use, as in storage and transit, the syringe 21 is effectively protected by the package 20. For example, the wings or spacers 58 of cap 55 and the skirt 65 of sheath 61 serve to maintain the glass cylinder or cartridge 22 in longitudinally spaced relation within the outer container or shield 74, while the ribs 49 serve to

retain the glass cartridge in radially spaced relation within the outer container.

As noted hereinbefore, the needle 43 is positively maintained against communication with the contents 45 prior to removal of the shield of the shield or outer enclosure 47 as the skirt 65 cannot pass between the outer enclosure and glass cylinder. Thus, even with removal of the plunger rod or tube 70 from the sheath 61, the sheath positively prevents impaling of the seal 29 without prior removal of the end closure 55 and outer enclosure 47. This impaling of the seal 29 or "activation" of the syringe may be effected without jeopardizing sterility of the needle by mere inward longitudinal shifting of the sheath. More particularly, activation is effected by longitudinal inward movement of the sheath shoulder 64 against the needle carrier enlargement 41, all without contacting the needle.

Additionally, the sheath may be safely employed to destroy the syringe after use, by mere replacement over the needle carrier 40, and flexure to break the end piece 28 at the weakened region 36, 37. This will effectively separate the needle 43 and its carrier 40 from the cylinder 22. This condition is shown in FIG. 13, the fitting, adaptor or end piece 28 having its longitudinally extending tubular portion 27 detached from the remainder by severance or fracture along the previously weakened annular regions 36, 37. In this way, the syringe is rendered entirely useless, thereby preventing unauthorized refilling, and the like.

Another mode of quick and easy destruction to render the syringe useless is shown in FIG. 7, it there being seen that the sheath 61 is flexed intermediate its ends, the flexible nature of the sheath permitting bending to the phantom position, in which condition the needle 43 is fractured or otherwise rendered useless, a broken endpiece being shown in the phantom position.

While the instant packaged syringe construction may be prefilled under sterile conditions, as in a proper pharmaceutical laboratory, it is often necessary to fill syringes in other than sterile conditions, say in a hospital pharmacy, after which sterilization must take place. Thus, it is desirable that the syringe construction be capable of being autoclaved subsequent to filling. Toward this end, the above-described syringe construction is admirably well suited. The previously described extension or boss 59 interiorly of the closure cap 55 abuts the piston 25 to insure proper location of the latter and prevent its displacement under the influence of heat and pressure, as in autoclaving.

From the foregoing, it is seen that a packaged syringe is provided which is extremely simple in construction, durable and entirely reliable in use, economic in manufacture and assembly, and which otherwise fully accomplishes its intended objects.

Although the present invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is understood that certain changes and modifications may be made within the spirit of the invention.

What is claimed is:

1. A packaged syringe construction comprising a cylinder for containing medicine and having one end open and the other end sealed with a penetrable diaphragm, a piston in closing relation with the open end of said cylinder, a needle mount slidably carried on said other cylinder end, a needle carried by said needle mount for movement between a storage position entirely exteri-

orly of said cylinder and a use position impaled through said other cylinder end for communication between the interior and exterior of said cylinder, a protective shield circumposed about said cylinder having its opposite ends open and longitudinally shiftable on said cylinder, an internal shoulder in said shield adjacent to said other cylinder end, an end closure on said shield adjacent to said one cylinder end, a needle sheath extending endwise into said shield past said shoulder, an enlargement on said sheath inwardly of said shoulder for retention thereby, and resiliently flexible finger means extending from said sheath enlargement for limiting endwise abutting engagement with said cylinder and sized to be incapable of passing between said cylinder and the surrounding shield, whereby sheath movement inwardly is limited by said finger means engagement when said shield is on the cylinder to protect the sterile integrity and activation of the device before use.

2. A packaged syringe construction according to claim 1, in combination with an elongate hollow rod removably engaged over said sheath, and interfitting fastener elements on said piston and rod for connection therebetween, whereby said rod is actuatable to shift said piston into said cylinder.

3. A packaged syringe construction according to claim 2, in combination with interfitting snap formations on said rod and sheath removably retaining the former on the latter.

4. A packaged syringe construction according to claim 1, in combination with a frangible seal retaining said end closure on said shield, for positive indication of tampering.

5. A packaged syringe construction according to claim 1, said sheath being engageable with said needle mount on inward sheath movement to effect said impaling, and said finger means being flexible radially outwardly in the absence of said shield for inward sheath movement.

6. A packaged syringe construction according to claim 1, said shield shoulder retaining said shield against withdrawal toward said one cylinder end, and said end closure retaining said shield against withdrawal toward said other cylinder end.

7. A packaged syringe construction according to claim 1, said finger means being arranged about and defining a resiliently distensible skirt on said sheath enlargement and abuttingly engageable with said cylinder to limit sheath movement and expansile for additional sheath movement to shift said needle to its use position, said skirt being closely circumposed by said shield to prevent expansion of said skirt without prior removal of said shield.

8. A packaged syringe construction according to claim 1, said sheath being of flexible material permitting of flexure to break an enclosed needle and render the syringe useless.

9. A packaged syringe construction according to claim 1, in combination with a tubular end fitting affixed to said other cylinder end and carrying said needle mount, said end fitting being formed with a circumferential weakening adapted to be deliberately severed to destroy said syringe and render it useless.

10. A packaged syringe construction according to claim 1, in combination with a retaining extension on said closure in abutting engagement with said piston to

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limit outward movement of the latter during autoclaving.

11. A packaged syringe construction according to claim 1, in combination with frictional means on said

shield engaging said cylinder to retain the latter in position during interfitting of said rod and piston fastener elements.

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