

Sept. 2, 1958

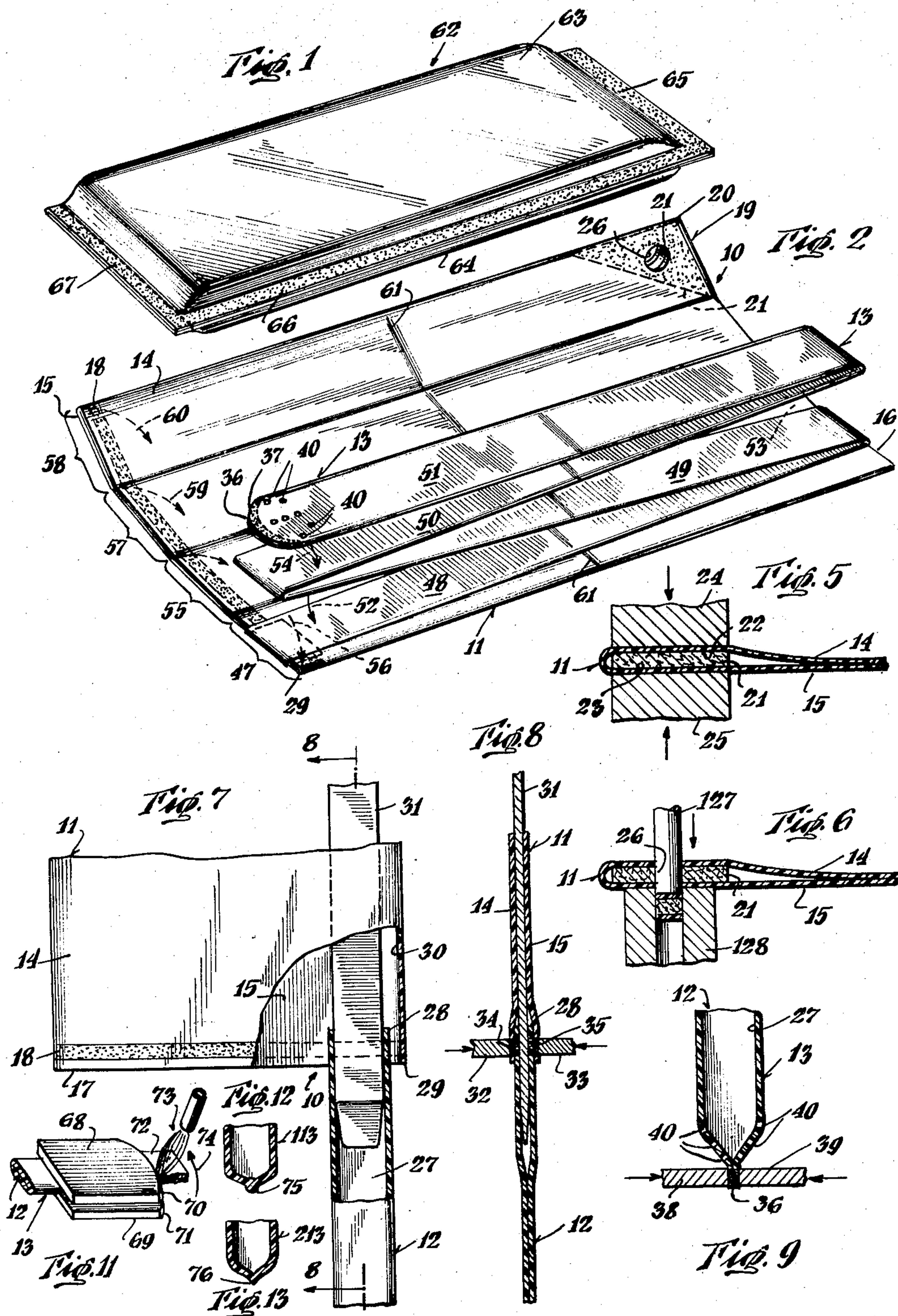
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SINGLE-USE DISPOSABLE VAGINAL SYRINGE

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2 Sheets-Sheet 1



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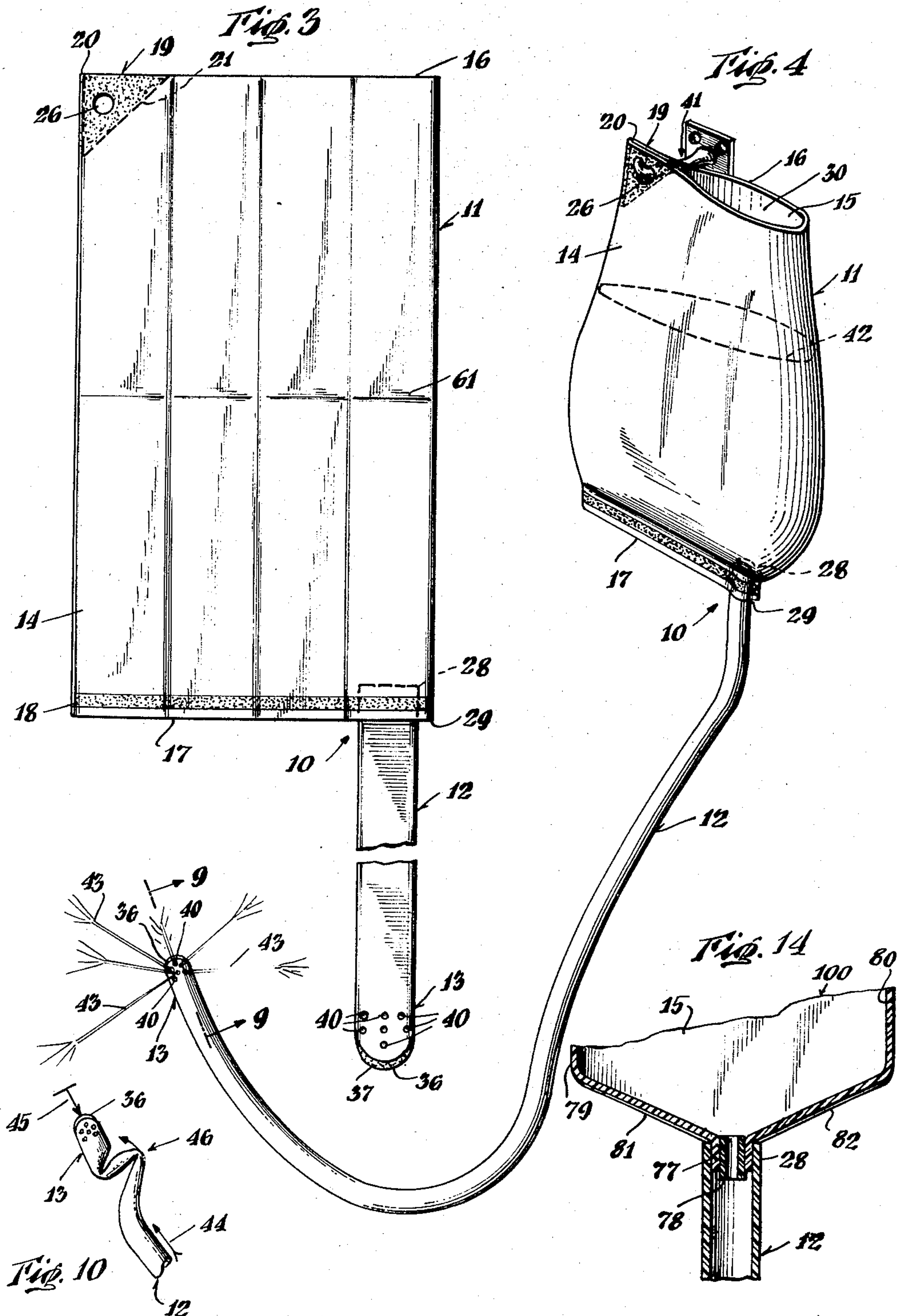
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SINGLE-USE DISPOSABLE VAGINAL SYRINGE

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5 Claims. (Cl. 128—227)

The present invention relates to vaginal syringes or douche devices of the single-use disposable type which is readily portable.

A general object of the present invention is to provide such a syringe which can be very economically manufactured in a rapid and semi-automatic manner in mass production and at a cost permitting disposal thereof after a single use, which effectively includes all of parts necessary to efficient use, which permits compact folding into an unusually small flat package, which through use assures a maximum degree of sanitation and which automatically limits the degree of insertion to avoid any injury or irritation particularly when employed in the treatment of painful or inflammatory infections or conditions.

A more specific object of the invention is to provide such a syringe in the form of a flexible foldable bag having sealed to a low point, such as a corner or depending margin thereof, a flexible foldable tube which swells under pressure provided by liquid head to a cylindrical duct having a sufficient degree of stiffness for proper insertion but which is of sufficient flexibility for maximum comfort and for flow-choking collapse or kinking automatically to limit the degree of insertion when an excessive degree of thrust is applied, the tip end of the flexible tube also serving as spray nozzle means having appreciable give and flexibility.

A further object of the invention is to provide such syringe in a relatively cheap but effective form to facilitate and encourage a single use and then disposal thereof in hospitals, and in home treatments prescribed by a physician as well as in his office treatments, thereby avoiding any possibility of reinfection of a patient or transfer of infection from patient to patient by re-use of a syringe or parts thereof, the device being marketable or distributable and stored or carried in the form of a small flat bundle enclosed under aseptic conditions in a small flat protective envelope and thus being readily carried in a hand bag or luggage of limited capacity.

An additional object of the invention is to provide a structural embodiment of the invention which is readily constructed and permits unusually efficient use thereof.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises the features of construction, combination of elements, and arrangement of parts, which will be exemplified in the construction hereinafter set forth, and the scope of the invention will be indicated in the claims.

For a fuller understanding of the nature and objects of the invention reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

Fig. 1 is a perspective view to about full scale of an envelope housing in an aseptic condition the embodiment of the invention illustrated by way of example in the other figures of the drawings;

Fig. 2 is a perspective view of an embodiment of a syringe of the present invention in partially folded con-

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dition, indicating further folding steps to form a small rectangular and relatively flat bundle to be housed under aseptic conditions in the envelope of Fig. 1;

Fig. 3 is a plan view, with parts broken away, of the syringe structure shown in Fig. 2 as it is unfolded to completely laid out condition;

Fig. 4 is an elevational perspective view of the syringe structure shown in Fig. 3, supported or suspended on a hook and carrying a liquid load for use, spray jets emitting from the nozzle means being illustrated;

Fig. 5 is a sectional view of the diagonally opposite top corner of the bag which carries the means for suspending it from a hook and illustrating reinforcing and heat-sealing procedure employed in the production thereof;

Fig. 6 is a sectional view similar to Fig. 5, illustrating a subsequent hole-punching procedure;

Fig. 7 is a detailed plan view, with parts broken away and in section, of the bottom portion of the bag of the illustrated embodiment showing a suitable procedure for sealing in a fluid-tight manner the upper end of the outlet passage tube or hose into a bottom corner of the bag;

Fig. 8 is a sectional view taken substantially on line 8—8 of Fig. 7;

Fig. 9 is an enlarged longitudinal section, with parts broken away, taken substantially on line 9—9 of Fig. 4 for further illustration of details of the nozzle means;

Fig. 10 is a side view, with parts broken away, of the free end of the outlet hose including the nozzle means portion thereof as distended by a liquid head, and illustrating pinching kink thereof when excessive thrust is applied thereto;

Fig. 11 is a perspective view, with parts broken away, illustrating an alternate flame-beading operation for heat-seal formation of a bead seam across the end of the nozzle section of the outlet tube;

Fig. 12 is a small axial sectional view, with parts broken away, of the nozzle section of the outlet tube, depicting the bead seam sealing thereof as performed by the operation illustrated in Fig. 11;

Fig. 13 is a sectional view similar to Fig. 12, illustrating the sealing of the end of the nozzle section by a different type of seam as formed by a hot knife; and

Fig. 14 is an elevational section, with parts broken away, of a modified form of the bottom end of the bag and illustrating a variation of the sealing of the top of the outlet tube thereto.

In the drawings, in which like numerals identify similar parts throughout, an embodiment of the invention is illustrated by way of example in Figs. 1 to 10 inclusive. As there indicated, one embodiment of the syringe structure 10 comprises a bag 11, an outlet tube or hose 12 and nozzle means 13. The bag 11 is of the open top type and is formed from flexible sheet material which is substantially chemically inert to douche liquids and body fluids. Although polyethylene composition may be preferred for this purpose a variety of types of flexible plastic sheet material may be employed, for example, vinylidene chloride resin polymers or copolymers, frequently referred to by the trade name "Saran"; rubber hydrochloride in film form, which is marketed by Goodyear Rubber Co. as "Pliofilm"; and the like. Although the thickness of the sheet material may vary it may, for example, be of a gauge of about 0.002". The bag 11 may be formed as a section of an extruded seamless tube of polyethylene which when flattened has opposed walls 14 and 15. The top end 16 of bag 11 is open, as best seen in Fig. 4, and the bottom end 17 is closed by a transverse bottom seam 18, which may be formed by cementing with suitable adhesive, but preferably, due to the heat-sealing properties of the thermoplastic synthetic resin, is formed by

heat-sealing at a temperature in the range of about 250° F. to 300° F. between suitable heat-sealing jaws which co-operatively clamp the opposed walls together along the seam line rendering the bag liquid-tight.

For the purpose of suspending the liquid-loaded bag 11, suitable suspending means 19 are provided at one top corner 20. In the preferred embodiment such suspending means 19 preferably is in the form of a piece 21 of relatively strong sheet material sealed between the walls 14 and 15 of the bag 11, preferably at its top corner 20. The stiffening and reinforcing piece 21 may be of any desired shape, such as triangular, as illustrated in Figs. 2, 3 and 4, such shape being desirable when the suspending means is applied at one corner, such as at 20, as may be preferred when the outlet tube is anchored to a diagonally opposite bottom corner, as hereinafter described. Although a variety of methods may be employed to anchor the reinforcing piece 21 to one or more wall portions of the bag top 16 this may be accomplished to advantage in the Figs. 1 to 10 inclusive embodiment by providing the opposite faces of the piece with adhering coatings. For example, as illustrated in Fig. 5, the opposite faces 22 and 23 of reinforcing piece 21 may carry coatings of thermoplastic resin composition. Reinforcing piece 21 may be made of forty-pound kraft paper initially coated on both sides with a polyethylene coating about one mil in thickness or, if desired, a piece of cardboard about 0.010" to 0.018" thick so coated on both sides. With the coated piece 21 inserted between opposed portions of bag walls 14 and 15, the resulting stack of layers or sandwich may be inserted between opposed pressure-applying heated jaws 24 and 25 and the piece heat-sealed in the interposed position shown in Fig. 5, with its face 22 adhered to the inner face of bag wall 14 and face 23 adhered to the inner face of bag wall 15. Thereafter, aligned holes may be punched through the opposed bag walls 14 and 15 and the intervening piece 21 at 26 by suitable die means, such as the cooperative male and female dies illustrated respectively at 127 and 128 in Fig. 6, to provide a reinforced hook-receptive opening for suspension of the bag.

The outlet hose 12 preferably is in the form of an elongated tube of similar flexible sheet material, which may be, for example, a flattened section of an extruded tube of polyethylene. It is preferred that the outlet tube 12 have a fair degree of wall stiffness while being flexible enough to be flattened and folded. Thus the gauge of the flexible sheet material employed for the outlet tube 12 may be of the order of 0.004" thick. The elongated tube 12 defines a longitudinal liquid outlet passage 27 and has its upper end 28 sealed into the bag wall at the lower corner 29, which is diagonally opposite the suspending top corner 20, with the tube passage communicating with the chamber 30 defined between the bag walls 14 and 15 in cooperation with the bottom transverse seam 18. As illustrated in Figs. 7 and 8, the top end 28 of the outlet tube 12 may be sealed into the bag wall by insertion between the opposed side walls 14 and 15 at the bottom corner 29 and sealed thereto in the formation of the transverse bottom seam 18. As indicated in Fig. 7, in order to prevent opposed wall portions of the top end 28 of the tube 12 from being sealed together to block passage of liquid, a suitable strip 31 of material which will not become heat-sealed thereto in the forming of the heat-sealed seam 18, may be inserted into the top end of the tube. For this purpose strip 31 may comprise a suitable strip of metal or other suitable material, such as a strip of thin gauge tetrafluorethylene polymer which is marketed by E. I. du Pont de Nemours & Co. under the trade name of "Teflon." With the strip 31 inserted into the open top end 28 of the tube 12, when suitable opposed heated jaws 32 and 33 are brought together to form the transverse bottom seam 18 the opposed wall portions of the tube top end become heat-sealed respectively at 34 and 35 to the inner surfaces of the opposed bag walls 14 and

15, as illustrated in Fig. 8. The strip 31 is then withdrawn. If desired, and in order to assure that there will be no possibility of closing off the entrance to the tube passage 27 at the tube top end 28 by liquid pressure against free portions of the end of the tube which projects into the bag chamber 30 beyond seam 18, the walls of the tube end may be suitably thickened and provided with a physical set which will assure that it is gapped open at least to some degree when freed from lateral pressure in a folded pack. This may be accomplished by providing such thickened top end of the tube as a separate section of thicker tubing having its top end sealed through the bag wall in the proposed manner, if desired, and its bottom end sealed to the top end of the tube 12 in any suitable manner, such as by telescoped lapping and heat-sealing or cementing. Such an open-throat anchorage of the top end 28 of outlet tube 12 into the bag wall is more fully explained later in connection with the showing in Fig. 14.

In accordance with the present invention the nozzle means 13 is formed as an integral tip end section of the elongated outlet tube 12 so that it has desired flexibility for maximum comfort. For this purpose, the free end 36 is closed off by a convexed or outwardly curved sealed cross seam 37 and with the opposed wall portions of the tube trimmed off along the curved seam to provide a rounded free end, as will be seen from Figs. 3 and 4, Fig. 9 illustrating the formation of the end seam between suitable heat-sealing jaws 38 and 39. A plurality of jet orifices 40—40 which may be of a size of the order of 0.025" in diameter are then provided in the opposed wall portions of the free end 36 of the tube 12 upstream of the curved cross seam 37 by providing a plurality of relatively small punctured apertures therein which may be formed by a pair of opposed dies (not shown) carrying mating sockets and punching projections. The jet orifices 40—40 together have a flow capacity appreciably less than the flow capacity of tube outlet passage 27 to apply a pressure head on the tube end nozzle section 13 which swells it out into substantially cylindrical form having appreciable self-supporting stiffness while being collapsible under excessive thrust, as explained hereinafter.

In use and operation of the embodiment illustrated in Figs. 1 to 9 inclusive, the bag 11 may be suitably supported, such as by inserting a wall-mounted fixed hook 41 through the receptive opening 26, either before or after loading of the bag chamber 30 with a quantity of suitable douche liquid, such as that indicated in Fig. 4 at 42. The bag chamber capacity in the preferred form may be about two quarts. The liquid head which consequentially is applied to the depending tube 12 applies pressure in the outlet passage 27 so as to swell the tube out to substantially cylindrical form with jets of the liquid emitting from the jet orifices 40—40, as illustrated at 43—43 in Fig. 4. Further flow of the liquid through the jet orifices is shut off by pinching the filled tube 12 and the nozzle 13 is inserted. Limited insertion is assured by the flexibility of the walls of the nozzle structure 13 since it is made as an integral part of the flexible tube 12. Any excess inserting force or thrust, such as in the direction of arrow 44 in Fig. 10, resisted by obstructive contact, illustrated by the arrow 45, causes a flow-choking collapse or buckling, such as that indicated at 46 in Fig. 10, thereby automatically limiting the degree of insertion with excessive thrust applied so as to avoid irritation or injury in situations of treatment of painful or inflammatory infections or conditons. Such flexibility also assures maximum comfort and the swelled tubing which results from restricted flow through the nozzle jet orifices 40—40 with a hydraulic head applied to the tube passage 27 assures sufficient stiffness for effective insertion.

Compact packaging of the embodiment of the invention illustrated in Figs. 1 to 10 inclusive will be apparent and, for example, it may be folded in the manner illustrated in Fig. 2. If desired, the outlet tube 12, which is nor-

mally flat when free from internal pressure of an hydraulic head, may be folded back and forth down upon a longitudinal edge zone 47 of the bag 11, in zigzag fashion so as successively to stack sections 48, 49, 50 and 51, one upon the other, in the direction of the arrows 52, 53 and 54. The bag 11 may then be folded up or wrapped there-around by lapping longitudinal bag zone 55 adjacent the edge zone 47 up over the zig-zag folded tube 12 in the direction of the arrow 56 and then successively lapping over the remaining longitudinal bag zones 57 and 58 respectively in the directions of the arrows 59 and 60. The resulting folded elongated body may then be lapped back upon itself along a mid-line 61, so as to form a compact substantially rectangular and flat bundle which will then be enclosed under aseptic conditions in a relatively small, substantially flat, protective envelope 62, illustrated in Fig. 1. Such envelope may likewise, if desired, be formed of similar sheet material, for example, polyethylene with half portions thereof folded or lapped back upon each other to provide opposed side walls 63 and 64 and sealed together in edge seams 65, 66 and 67, such as by heat-sealing.

As illustrated in Figs. 11 and 12, the cross seam at the free end of the outlet 212 may be formed in a manner to assure greater comfort in use, such as by means of a heat-beading procedure. For this purpose, the nozzle section 113 of outlet tube 12 may be inserted between protective templates 68 and 69 provided with substantially aligned curved end edges 70 and 71 beyond which the free end 72 of the tube extends, as shown in Fig. 11. A flame, such as that illustrated at 73, may then be moved across the tube end 77 in the direction of the arrow 74 along the aligned edges 70 and 71 of the templates to burn away the excess length of the tube and heat-seal opposed walls thereof in a transverse bead seam 75, illustrated in Fig. 12. If desired, the transverse of cross seam may be formed by heat-sealing with a hot knife along a convexed or outwardly curved line to form a nozzle section 213 having a cross seam somewhat of the shape illustrated at 76 in Fig. 13.

If desired, as illustrated in Fig. 14, the connection of the outlet tube 12 to the bottom of the bag may be provided with an open throat under all conditions, as previously indicated. For this purpose, the bag, a modified form of which is shown at 100 in Fig. 14, may have a depending tubular outlet neck 77 over which the top end 28 of the outlet tube 12 is telescoped. A section 78 of suitable tubing, such as polyethylene cylindrical tubing having an I. D. of $\frac{3}{8}$ " and an O. D. of $\frac{1}{2}$ " to provide a wall thickness of $\frac{1}{16}$ " may then be inserted into the bag neck 77 to swell the latter out into snug contact with the inner wall of the outlet tube upper end 28. A liquid-type seal may be assured in such a connection either by a heat-sealing together the opposed faces of the plastic parts or by snugging a wire clamp about the tube upper end 28. The cylindrical tubing section 78 will maintain an open throat at the inlet end of the outlet tube 12.

The type of connection illustrated by way of example in Fig. 14, of course, may be employed at one bottom corner, such as 29 of the Figs. 1 to 8 inclusive embodiment, with opposed depending flaps or tabs of the opposite side walls 14 and 15 being sealed together along side edges to provide the depending neck. However, it may be desired to provide the connection at some other point of the bottom of the bag and for this purpose, as illustrated in Fig. 14, the bottom edges of the opposite side walls 14 and 15 may be obliquely cut from a central point up toward the side folds 79 and 80 with provision of depending tabs at the central point to be edge-sealed together to provide the depending neck 77. The oblique bottom edges of the opposite side walls will be heat-sealed together to provide the oblique bottom seams 81 and 82 so that the bottom of the bag is in the shape of a funnel

to feed the contained liquid to the throat of the outlet tube 12. When the connection of the outlet tube 12 to the bag is provided at a point other than one of the bottom corners, such as centrally as proposed in Fig. 14, it may be desired to provide the suspending means at the top of the bag vertically thereabove so as to assure that the outlet connection will be at the lowest elevation when the bag is supported in suspended position.

It will thus be seen that since the syringe of the present invention may be rapidly manufactured by semi-automatic machinery at very low cost, it is effectively adapted to employment as a single-use douche device and which after use is readily disposable. Such a syringe structure, accordingly, will provide an answer to the demand for a greater assurance of sanitary conditions in treating infections and diseases in hospitals and doctors' offices. A patient can be supplied with a plurality of such relatively small packs to assure continuance of a treatment at home without danger of reinfection by re-using improperly sterilized equipment. Also such compact syringe structure permits ready transportation thereof for use when travelling. It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described my invention, what I claim as new and desire to secure by Letters Patent is:

1. A single-use disposable vaginal syringe comprising, in combination, an open top bag of flexible sheet material substantially chemically inert to douche liquids and body fluids defining a storage chamber, means at the top of said bag to suspend it from a support, an elongated tube of similar flexible sheet material defining a longitudinal liquid outlet passage and having its upper end sealed to the bag wall substantially at a point of lowest elevation when the bag depends from its suspending means with the tube passage communicating with the chamber, and a spray nozzle provided as an integral end section of said tube at the other end thereof having a rounded free end defined by a convexed sealed cross seam with a plurality of relatively small jet orifices defined in said rounded end by relatively small apertures.

2. The syringe structure as defined in claim 1 characterized by said bag being substantially rectangular, said suspending means comprising a body of relatively strong sheet material adhered to opposed sidewall portions of one corner of said bag top with said sidewall portions and said intervening body having aligned holes extending therethrough for reception of a suspending hook, and said outlet tube being sealed to said bag at the lower corner thereof which is diagonally opposite the suspending top corner.

3. The syringe structure as defined in claim 1 characterized by said bag having its bottom defined by a sealed transverse seam, said tube upper end being interposed between opposed bag wall portions and sealed thereto by said transverse seam.

4. A foldable, single-use, disposable vaginal syringe comprising, in combination; an open top, substantially rectangular bag formed as a section of seamless tubing of flexible sheet material substantially chemically inert to douche liquids and body fluids, said tubing section having a sealed transverse bottom seam thereby defining a storage chamber; a reinforcing piece of relatively strong material sealed between opposed wall portions of said

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bag in one top corner thereof, said opposed wall portions and intervening piece having aligned through holes for reception of a suspending hook; and an elongated tube of flexible sheet material similar to that of said bag defining a longitudinal liquid outlet passage and having its upper end interposed between opposed wall portions of said bag in said transverse seam and sealed thereto by the latter at the lower corner which is diagonally opposite the top corner carrying said reinforcing piece, the free end of said tube being provided with a convexed sealed cross seam defining a rounded nozzle end, the walls of said tube upstream and in the vicinity of said cross seam being punctured at a plurality of points thereby providing a plurality of relatively small jet orifices.

5. In a foldable, single-use, disposable vaginal syringe having a bag for holding a supply of douche liquid, an elongated outlet tube of flexible sheet material substantially chemically inert to douche liquids and body fluids defining a longitudinal liquid outlet passage, the free end of said tube being provided with a convexed sealed cross

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seam defining a rounded nozzle end with the tube section adjacent thereto constituting an integral nozzle section, the walls of said nozzle section in the vicinity of said cross seam being punctured at a plurality of points to provide a plurality of relatively small jet orifices together having a flow capacity appreciably less than the flow capacity of said outlet passage to apply a pressure head on said nozzle section thereby swelling it out into substantially cylindrical form having appreciable self-supporting stiffness while being collapsible under excessive thrust.

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