

June 11, 1963

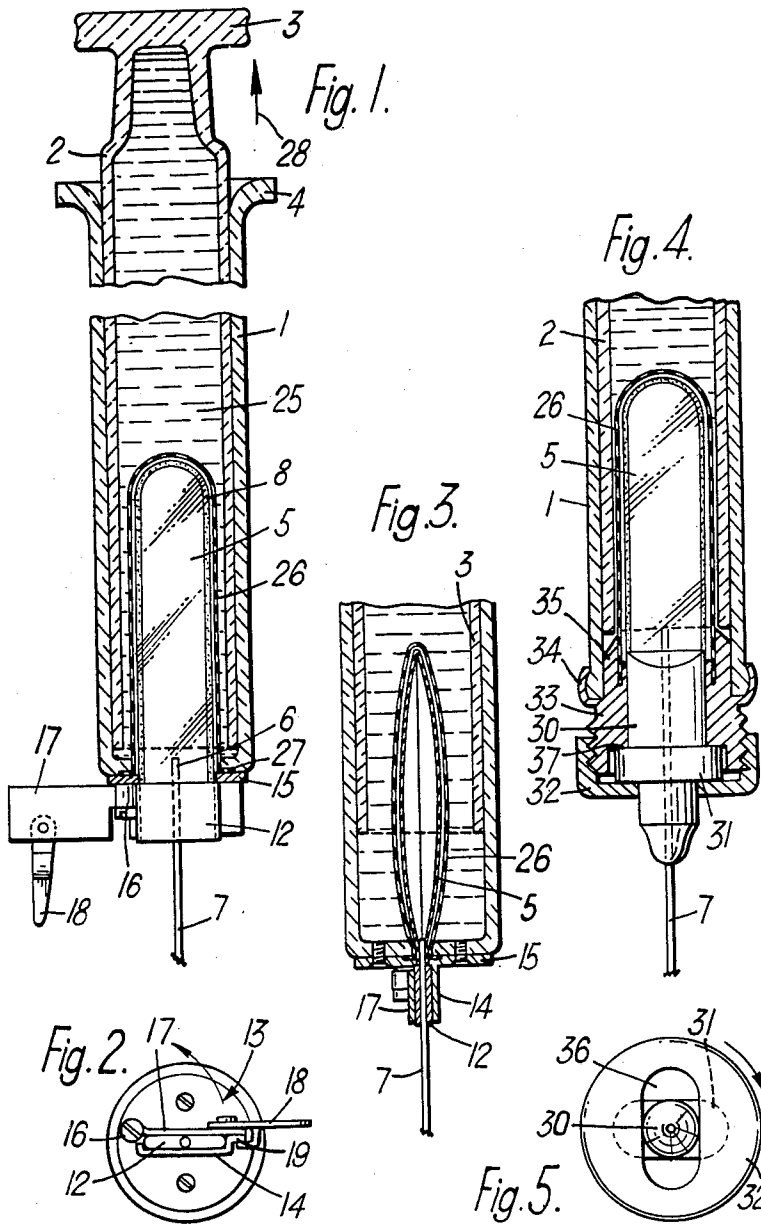
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HYPODERMIC APPARATUS

Filed July 1, 1959

2 Sheets-Sheet 1



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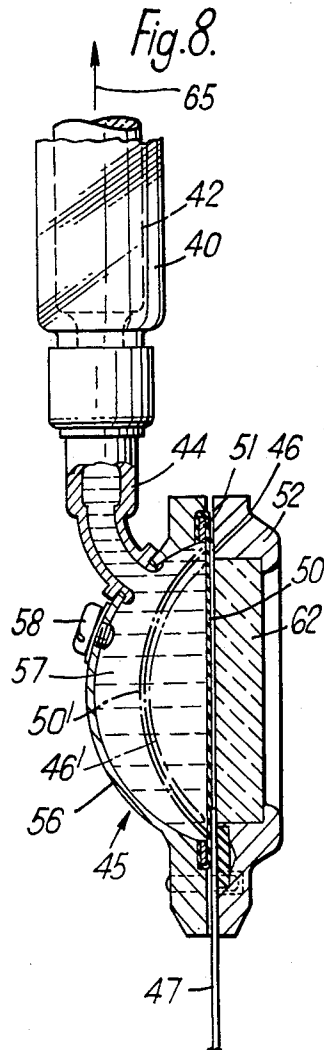
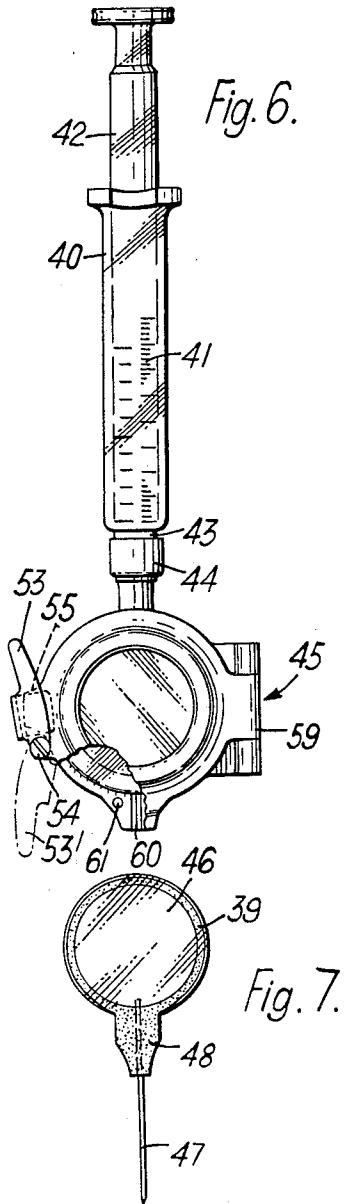
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HYPODERMIC APPARATUS

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Filed July 1, 1959, Ser. No. 824,306
Claims priority, application Great Britain July 1, 1958
8 Claims. (Cl. 128—216)

The need for sterilisation of surgical hypodermic apparatus has always presented a problem both in time and expense. For satisfactory sterilisation it is necessary either to heat the apparatus in steam in an autoclave when meticulous care is required to ensure the correct temperature, or preferably to heat the apparatus in a dry air steriliser at a temperature of 160° C. for one hour. If the same apparatus has previously been used for an injection prior to sterilisation however, it has first to be washed out thoroughly. Due to the time required before the same piece of apparatus can be used again, and the possible risk of cross infection due to incorrect sterilisation, expendable plastic syringes have been developed, which are only used once. Although the risk of cross infection no longer occurs, the syringes are expensive and have the disadvantage that when pre-filled for use, deterioration of the medicament takes place over a period. Moreover they are often clumsy and will not aspirate, and may require special techniques for their use.

According to the present invention use is made of a unit comprising a substantially flat bag of flexible material having the butt end of a hypodermic needle fitted in its mouth and which is removably mounted in a holder arranged for the supply of liquid pressure by means of a piston acting in a cylinder. The pressure acts directly or indirectly on the bag so as to extend it or collapse it in accordance with movements of the piston and thus to carry out the required operations of filling injection or aspiration. At the start of operation the flat bag, together with the hypodermic needle, is inserted in the holder and a negative liquid pressure is applied to it by means of movement of the piston which is conveniently the piston of a slightly modified form of hypodermic syringe. The negative pressure acting on the bag causes it to distend and provided the needle is inserted in liquid the liquid is drawn into the interior of the bag.

Thus if the needle is inserted in a supply of medicament this is drawn up into the bag in the same way as it would be drawn into the interior of a normal syringe. By moving the piston in the opposite direction so as to apply a positive pressure to the bag the medicament is expelled again and may thus be injected into the patient as required. If, instead of drawing up medicament, the needle is inserted in a patient the equipment may be used for aspiration in the usual way. Since in general it will be necessary to determine whether or not blood is being aspirated it is convenient for the bag to be made of transparent or translucent material.

When the unit consisting of the bag, together with the hypodermic needle, has been used once, whether for injection or aspiration, it may be thrown away and a fresh unit used for the next operation. Since neither the tissue of the patient, nor the liquid drawn up into the bag, comes into contact in any way with the operative parts of the mechanism the need for sterilisation of any permanent part of the equipment is obviated. The only part which can become contaminated is the unit consisting of the bag and the needle. This is supplied initially in a completely sterile condition, enclosed in a sterile wrapper and as just mentioned is thrown away after each operation. In this way an extremely simple equipment is provided which requires no sterilisation and in which the part thrown away

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is extremely cheap and simple and is sterilised as part of the original manufacturing process.

Preferably the holder for the unit is constituted by the end portion of the cylinder by means of which the liquid pressure is applied. If, as previously mentioned, the cylinder is in the form of a slightly modified syringe the unit fits into the end of the syringe and the complete equipment can be handled in almost exactly the same way as a normal syringe.

Most conveniently the piston is hollow and the bag extends into its interior. In this way the overall length of the assembly is reduced. Thus if the equipment is in the form of a modified syringe the piston may be constituted by a hollow glass cylinder which takes the place of the normal glass piston.

The liquid pressure may conveniently be applied to the bag through a sac of flexible material, the mouth of which is sealed around the end of the cylinder and into which the bag fits. In this way the bag is kept from direct contact with the liquid exerting the pressure and the pressure is thus exerted indirectly through the wall of the sac. Since the sac is sealed around the end of the cylinder it is impossible for the liquid in the cylinder, which may conveniently be water, to be split. The sac is by no means essential, however, and the bag may be inserted directly in contact with the water or other liquid in the cylinder, in which case the liquid pressure acts directly on the bag. In the absence of the sac it is necessary to hold the cylinder in an inverted position while inserting the bag to avoid spillage of the liquid.

As an alternative to being constituted by the end portion of the cylinder the holder may be a separate adaptor connected to the cylinder and formed with a liquid reservoir from which pressure is applied to the bag. In this event an almost entirely normal construction of syringe may be used for applying the liquid pressure to the bag, the only minor modification lying in the fact that instead of the mount of a hypodermic needle, a connecting pipe to the adaptor is fitted to the nozzle of the syringe. The adaptor may conveniently be cup-shaped and the bag may be held in position across the mouth of the cup by a retaining member which exerts sufficient mechanical pressure to form an airtight seal. The body of the cup forms the liquid reservoir and when negative pressure is applied to the bag by withdrawal of the piston in the cylinder, the bag is caused to distend into the body of the cup so as to cause liquid to be drawn up through the needle in the same way as previously described.

A flexible diaphragm may be secured across the mouth of the cup so as to separate the liquid applying the pressure from the bag. The pressure then acts indirectly on the bag and the presence of the diaphragm prevents any spillage of liquid. As in the form of construction previously mentioned, however, the presence of the diaphragm is not essential and the liquid may act directly on the bag.

Constructions in accordance with the invention will now be described in more detail by way of example with reference to the accompanying drawings in which:

FIGURE 1 is a sectional view to an enlarged scale with parts broken away of a unit constituted by a bag and a hypodermic needle in position in a holder formed by the end portion of a modified hypodermic syringe;

FIGURE 2 is an underneath plan view corresponding to FIGURE 1;

FIGURE 3 is a view of the lower part of the construction of FIGURE 1 when viewed in a direction at right angles to that of FIGURE 1 and showing the piston of the syringe slightly withdrawn.

FIGURE 4 is a sectional view of the lower part of a modified construction;

FIGURE 5 is an underneath plan view corresponding to FIGURE 4;

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FIGURE 6 is a view showing a form of construction in which a holder for a unit comprising a bag and hypodermic needle is constituted by an adaptor fitted to a hypodermic syringe;

FIGURE 7 shows a sterile unit for use in the adapter of FIGURE 6; and

FIGURE 8 is a sectional view to an enlarged scale of the lower part of the construction of FIGURE 6.

Turning first to FIGURE 1 a cylinder 1 is fitted with a hollow piston 2 operated by a knob 3. The cylinder 1 is formed with a flange 4 and the piston and cylinder together operate in substantially the same manner as a normal construction of hypodermic syringe. The lower end of the cylinder 1, however, is not provided with the normal type of syringe nozzle but with a sealing arrangement for holding in position a unit constituted by a flat bag 5 having the butt end 6 of a hypodermic needle 7 secured in its mouth.

The bag 5 is formed from two sheets of transparent plastic such as polythene welded together over a narrow area 8 around their edges. The mouth of the bag is closed by a mount 12 made of rubber-like material which supports the hypodermic needle 7. The mount 12 is of substantially rectangular cross-section, as best seen from FIGURE 2, and it is held in position by means of a clamping arrangement indicated generally as 13 in FIGURE 2. This comprises a fixed side plate 14 extending from a plate 15 screwed to the bottom of the cylinder 1. Hinged to the side plate 14 by a pin 16 is a second side plate 17 which may be swung back into the position of FIGURE 1 to allow for the insertion of the bag 5 with its mount 12. When the bag is in position the plate 17 is swung into the position of FIGURE 2 where it is held by a pivoted latch 18 which engages an end portion 19 of the side plate 14 and presses the side plate 17 against the fixed side plate 14 so as to exert a slight compression on the mount 12, thus holding the needle 7 rigidly and forming an airtight seal against the plate 15.

The cylinder 1 is filled with water shown as 25 which is prevented from coming into direct contact with the bag 5 by a sac 26 also of transparent plastic material which may conveniently be made of silicone rubber. The mouth of the sac is trapped at 27 between the end of the cylinder and the ring 15 to form a liquid-tight joint which prevents any spillage of water from the interior of the instrument. The sac 26 is a close fit around the bag 5 and before the bag is initially inserted in position the sac is expanded by raising the piston in the direction of the arrow 28. This provides space for the insertion of the bag, after which the piston 3 is brought to its lowermost position as shown in FIGURE 1, the sac then fitting closely against the surface of the bag.

After the mount 12 has been clamped firmly in position by means of the arrangement 13 the assembled equipment is ready for use in a practically identical manner to a normal hypodermic syringe. Thus when the piston 3 is withdrawn slightly to the position shown in FIGURE 3, negative pressure is applied through the wall of the sac 26 to the bag 5, causing both the sac and the bag to distend slightly, as shown in FIGURE 3. This causes liquid to be drawn up the needle 7, as in the manner of a normal syringe but instead of passing into the barrel of the syringe itself the liquid is contained wholly within the bag 5 and is prevented from coming into contact in any way with any of the other operating parts. Since the volume of liquid drawn into the bag 5 is exactly equal to that displaced by movement of the piston 3, the cylinder 1 may be calibrated directly as for a normal syringe. In general the cylinder 1 may be made of glass and since both the sac 26 and the bag 5 are also transparent the liquid drawn up is clearly visible which is, of course, of great importance for purposes of aspiration in order to confirm whether or not the needle has been inserted in a vein.

After the completion of an operation the unit compris-

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ing the bag 5 and the needle 7 is removed from the sac 26 by releasing the side plate 17 and is then thrown away. The only parts liable to any form of contamination are the bag and the needle and there is thus no need to sterilise the remainder of the equipment. For the next operation a fresh sterile unit comprising a needle and a bag is inserted in position and is used as just described.

FIGURES 4 and 5 show a modification of the construction of the first three figures in respect of the construction of the needle mount and the method by which it is held in position. Corresponding parts are identified by the same reference numerals and the bag 5 is provided with a rigid mount 30 supporting the needle 7. The mount 30 is formed with a flange 31 which, as seen in end view in FIGURE 5, is oval in shape. The mount 30, and consequently the attached bag 5 and needle 7, are held in position by a cap 32 which is screwed on to a bush 33 secured to the end of the cylinder 1 at 34 and having a portion 35 extending into the interior of the cylinder.

The cap 32 has an oval aperture 36 which is slightly larger than the flange 31. Before the sterile unit comprising the bag and needle is inserted in position the cap 32 is turned one quarter turn in an anti-clockwise direction from the position shown in FIGURE 5. This enables the bag 5 together with the mount 30 and its flange 31 to be passed through the aperture 36 to allow the bag 5 to be fitted in position within the sac 26 which has been expanded by partial withdrawal of the piston 2. After returning the piston 2 to its lowest position to expel all air between the sac and the bag the cap 32 is turned back in a clockwise direction to the position of FIGURE 5. This not only prevents the flange 31 from being withdrawn through the aperture 36 but the screw action presses the flange 31 firmly against a seating 37 formed in the bush 33. The screwed connection and the pressure of the flange against the seating provide an airtight joint so that when the sac 26 is distended by retraction of the piston 3 the bag 5 is similarly distended to enable the equipment to operate in the same manner as described in connection with the preceding three figures.

Also, as previously described, the complete unit which is originally sterile is used only once and is then thrown away. Since none of the remainder of the equipment becomes contaminated the need for sterilisation is obviated. When assembled, the complete equipment bears a close resemblance to a syringe, and there is substantially no change in the operating technique. The user can thus accept the equipment as a complete substitute which resembles and can be handled in the same way as a normal syringe but has the great advantage of requiring no sterilisation.

The alternative form of equipment shown in FIGURES 6, 7 and 8 is intended not so much as a substitute for a normal syringe but as an adjunct which can be fitted to a normal syringe when required. As shown in FIGURE 6 a normal syringe comprises a glass barrel 40 provided with normal calibrations at 41 and a glass piston 42. The nozzle 43 of the syringe, instead of being fitted directly with a hypodermic needle is fitted instead with a connector 44 forming part of an adaptor shown generally as 45 constituting a holder for a unit comprising a bag 46 and hypodermic needle 47 seen in FIGURE 7.

The bag 46 is formed from two substantially circular sheets of transparent plastic sealed together over a narrow area 39 around their edges. The two sheets are formed with extensions 48 which are sealed together on either side of the needle 47 so as to form a support for the needle. In FIGURE 8 the sterile unit is shown to an enlarged scale fitted into the adaptor 45 which is shown in cross-section.

As seen in FIGURE 8 the adaptor 45 has a cup-shaped body 56 constituting a reservoir for liquid shown

as 57 which in practice is water. This is in communication by way of the connector 44 with liquid contained within the barrel 40 where it is acted on by the piston 42. The reservoir is provided with a filler opening closed by a screw 58.

The mouth of the cup 56 is sealed by a flexible diaphragm 50, the edges of which are turned around a ring 51 and received in a recess around the mouth of the cup. The bag 46 is held in position across the mouth of the cup in contact with the diaphragm 50 by means of a retaining member 52 which is hinged to the body of the cup 56 at 59. The member 52 is locked in the closed position by a clamp 53 turning about a screw 54. The clamp has a turned-over portion engaging behind a projection 55 on the body 56, as seen in FIGURE 6. The free position of the clamp is shown in dotted lines at 53' in FIGURE 6.

When the clamp 53 is locked the retaining member 52 is pressed firmly against the bag 46 to form an airtight seal between the edge of the bag and the diaphragm 50. Consequently when the piston 42 is withdrawn in the direction of the arrow 65 the negative pressure applied to the diaphragm 50 is transmitted to the bag 46 and as the diaphragm 50 is drawn in to the position 50' shown in dotted lines, so the bag 46 is distended, one side of it remaining in contact with the diaphragm 50 and taking up the position 46' also shown in dotted lines. It is, of course, essential that a fully airtight joint be formed round the whole of the edge of the bag because any leakage of air between the side of the bag and the diaphragm would prevent the movement of the diaphragm being fully reproduced as distention of the bag. In these circumstances displacement of the piston would not be accurately reproduced by the quantity of liquid drawn into the bag and the calibrations 41 would then be useless. The retaining member 52 fits evenly round the edge of the bag 46 and the application of mechanical pressure by means of the clamp 53 provides the necessary seal.

The needle 47 is received in a groove 60 in the body 56 and a corresponding small groove is formed in the retaining member 52 to assist in location of the needle. This is further assisted by a pair of small pins, one of which is seen at 61 in FIGURE 6. The projecting portion of the body 56 on either side of the groove 60 acts as a support for the needle 47. It is convenient that the needle 47 should be sealed into the bag 46 but this is not essential because the pressure exerted by the retaining member is sufficient in itself to provide an airtight joint between the extensions 48 and the needle 47. As previously mentioned the bag 46 is made of transparent material and the retaining member 52 is provided with a window 62, thus enabling the contents of the bag to be inspected during aspiration.

As with the previous construction the unit consisting of bag and needle is used only once and then is thrown away. This is the only part of the equipment which is in any way liable to contamination so that no sterilisation of the syringe and adaptor is required, and the unit itself is supplied in a sterile condition. The presence of the diaphragm 50 prevents any spillage of liquid but this is not essential. In the absence of the diaphragm 50 the liquid pressure acts directly on the surface of the bag 46 but, of course, when inserting the bag in position it is essential that the equipment be held in a horizontal position in order to prevent the overflow of liquid. In the same way it is possible to omit the sac 26 from the constructions of FIGURES 1 to 5 but if this is done the equipment must be held in the inverted position when inserting the bag.

I claim:

1. Hypodermic injection equipment comprising a cylinder a piston slidable in said cylinder and extending through an end of said cylinder, resilient liquid-tight sealing means at the other end of said cylinder; liquid disposed within said cylinder, retaining means mounted at said other end of said cylinder, a combination flexible medicament holder and hypodermic needle secured by said retaining means adjacent the resilient sealing means wherein inward and outward movement of said piston with respect to said cylinder produces a corresponding movement of the resilient sealing means and a corresponding expansion and contraction of the medicament holder.

2. Hypodermic injection equipment according to claim 1 wherein the combination flexible medicament holder and hypodermic needle comprises a flat flexible bag having a mouth portion and a hypodermic needle, an end portion of which is secured within the mouth portion of the bag.

3. Hypodermic injection equipment according to claim 1 wherein the resilient sealing means comprises a flexible sac extending inwardly of the cylinder and the flexible holder extends into the sac.

4. Hypodermic injection equipment comprising a cylinder having open ends, a piston slidably mounted in one of said open ends, a flexible sac mounted in the other of said open ends, said flexible sac extending inwardly of said cylinder, a holder mounted adjacent said other end of the cylinder, a combined bag and hypodermic needle secured with said holder with the bag extending into said sac, liquid disposed between the piston and sac whereby upon outward and inward movement of the piston with respect to the cylinder, both the sac and bag are expanded and contracted respectively.

5. Hypodermic injection equipment according to claim 4 wherein said needle is fitted in a resilient mount secured to the mouth of the bag.

6. Hypodermic injection equipment according to claim 5 in which said mount has a flange thereon and the holder comprises a retaining cap seating said flange against the end of the cylinder.

7. Hypodermic injection equipment comprising a cylinder, a piston slidable in said cylinder and extending through one end of said cylinder, an adaptor secured to the other end of said cylinder, a resilient diaphragm secured across the end portion of the adaptor, fluid disposed within the cylinder and adaptor between the piston and diaphragm, retaining means mounted on said adaptor adjacent said diaphragm, a combination flexible medicament holder and hypodermic needle secured by said retaining means whereby inward and outward movement of said piston with respect to the cylinder produces outward and inward movement respectively of said diaphragm and corresponding expansion and contraction of the medicament holder.

8. Hypodermic injection equipment according to claim 7 wherein said retaining means comprises a ring shaped retainer hinged to said adaptor and a clamp for securing said retainer to said adaptor.

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