Nov. 12, 1963 J. L. HIGGINS 3,110,309

PLASTIC CARTRIDGE NEEDLE ASSEMBLY

Filed Aug. 15, 1960 2 Sheets-Sheet 1

Fig. 1

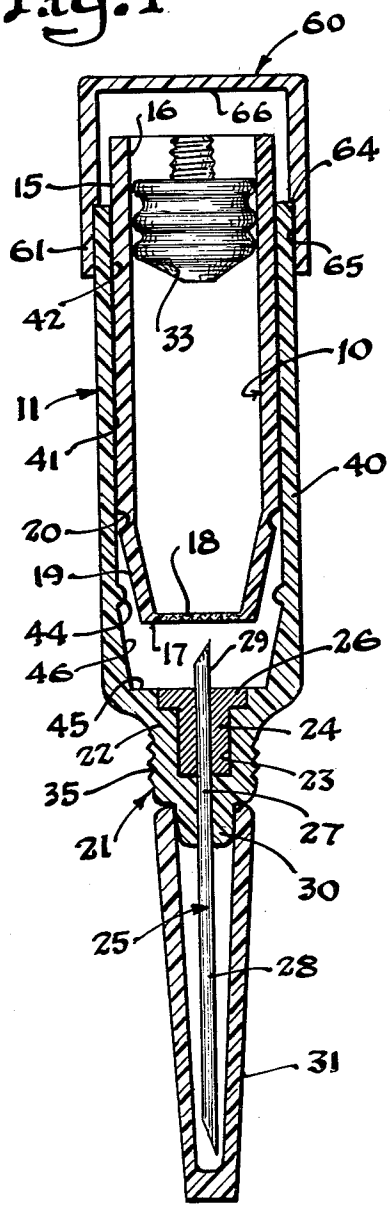
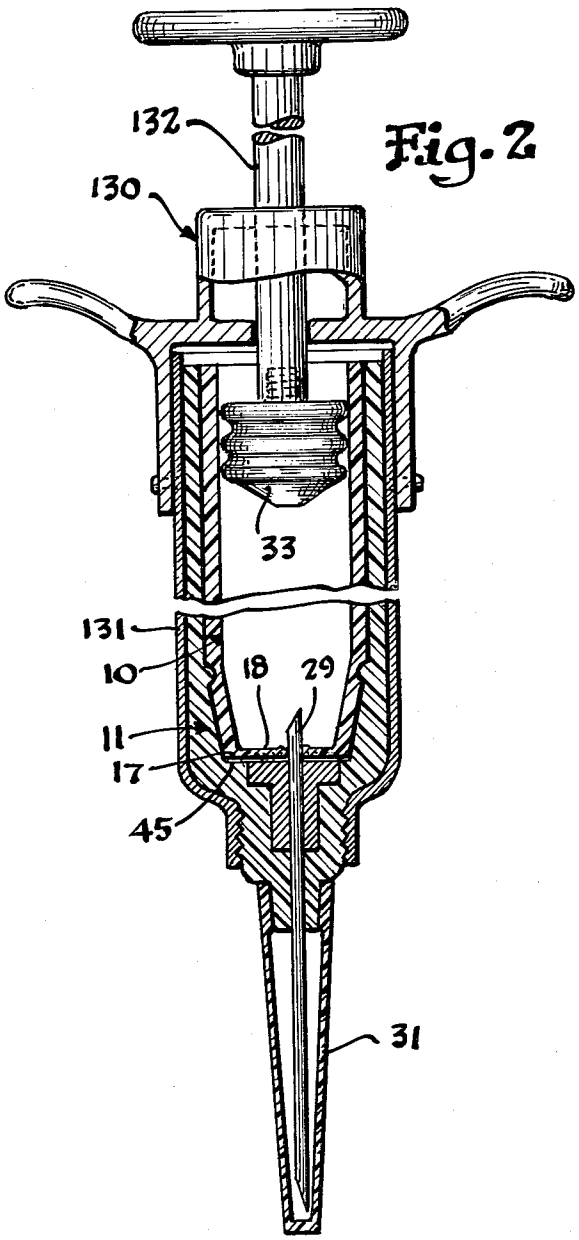


Fig. 2



Inventor
John L. Higgins
By Davis, Lindsey, Hibben & Noyes
Attorneys

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Filed Aug. 15, 1960 2 Sheets-Sheet 2

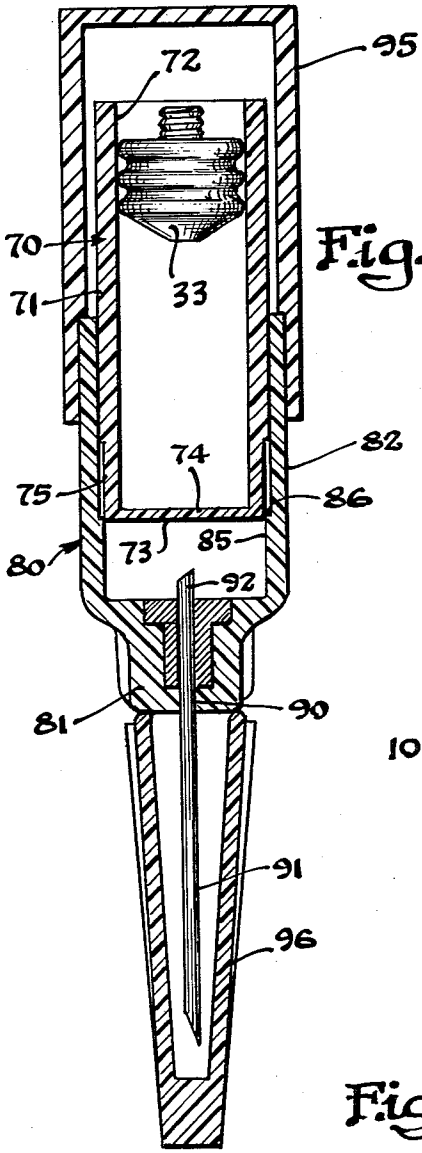

Fig. 3

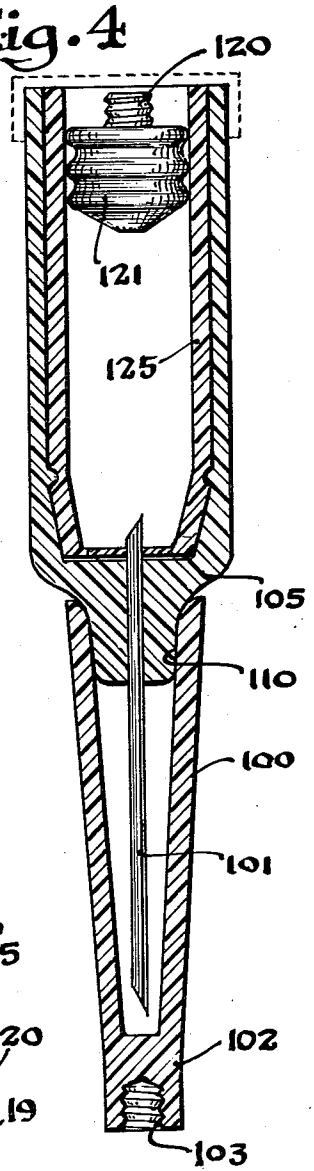

Fig. 4

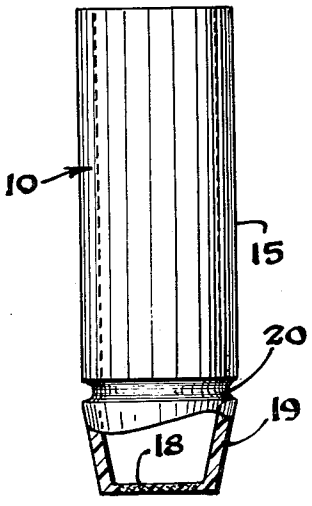

Fig. 5

Inventor
John L. Higgins
By Davis, Lindsey, Hibben & Noyes
Attorneys

United States Patent Office 3,110,309 Patented Nov. 12, 1963

3,110,309

PLASTIC CARTRIDGE NEEDLE ASSEMBLY

John L. Higgins, Daytona Beach, Fla., assignor, by mesne assignments, to Brunswick Corporation, a corporation of Delaware

Filed Aug. 15, 1960, Ser. No. 49,584
4 Claims. (Cl. 128—218)

The present invention relates generally to a disposable medicinal cartridge structure and assembly adapted for insertion into a hypodermic cartridge syringe or for use directly as a hypodermic syringe for injecting a medicament. More particularly, the present invention relates to an improved disposable plastic cartridge and plastic cartridge-needle assembly for use in a hypodermic cartridge syringe.

Therapeutic doses of medicaments are frequently packaged in disposable sterile cartridges or disposable cartridge-needle assemblies which are adapted to be inserted in a hypodermic cartridge syringe or used directly for administration of a medicament. Various cartridge syringe units have been devised to accommodate a disposable cartridge or cartridge-needle assembly and the particular form of cartridge syringe is of no importance to the present invention which is concerned primarily with the disposable cartridge and cartridge-needle assembly.

The present invention is particularly concerned with a novel plastic cartridge and plastic cartridge-needle assembly of the foregoing type which is adapted for insertion in an axial opening of a reusable "Tubex" type dental syringe or the like, and wherein the cartridge containing an injectable medicament is maintained in spaced relation to a diaphragm piercing cannula. Preferably the plastic cartridge is slidably held in a sleeve section which also fixedly supports a hypodermic needle so that the needle can be readily brought into communication with the interior of the cartridge by having one end of the hypodermic needle pierce the diaphragm section of the cartridge when the cartridge is moved longitudinally inwardly within the sleeve section.

In the medicament-containing cartridges and cartridge-needle assemblies of the instant type which have a reciprocable piston member slidably mounted in one end thereof, the cartridges have heretofore been fabricated by providing a tubular section of rigid material, such as glass, which is open at both ends with the reciprocable piston member sealably mounted therein and a penetrable closure or diaphragm stopper sealably disposed in the opposite end thereof. The diaphragm stopper which is mounted fixedly in the lower opening of the cylindrical section is usually formed of rubber or similar penetrable and resilient material which can be readily pierced by a hypodermic needle cannula and which forms a sealing engagement about said hypodermic needle cannula to prevent leakage of the medicament. Since the diaphragm stopper has heretofore been preformed of relatively expensive rubber or the like resilient material and requires individually mounting in the end of the cartridge, the cost of the cartridge is substantially increased and in some instances is a significant part of the total cost of the cartridge. It is thus evident that there would be several economic advantages if a cartridge unit could be molded entirely of a synthetic plastic material and thereby avoid the step of fixedly mounting a rubber diaphragm stopper in one end of a tubular section. Nevertheless, there has heretofore been no successful all plastic cartridge devised which has an integral plastic diaphragm sealably closing one end thereof.

Since it is necessary to have the wall section of the cartridge of the instant type formed of relatively rigid material and have the walls thereof sufficiently thick to

be form-retaining so that the piston mounted on one end thereof could be readily reciprocable therein, a diaphragm-end wall integrally formed with the lateral walls of the cartridge and having appreciable thickness is found to be difficult to penetrate by a diaphragm-piercing cannula, particularly if the diaphragm is formed with the same wall thickness as that of the cartridge. And, when the integrally formed cartridge diaphragm is made sufficiently thin to permit ready penetration by a diaphragm piercing cannula there is a definite tendency for the medicament to leak from the cartridge during administration thereof. Thus, it has been observed that when the reciprocable piston member is moved forwardly to discharge the medicament through the needle cannula communicating with the interior of the plastic cartridge, considerable force is exerted on the inner surface of the diaphragm and the diaphragm frequently ruptures with small slits radiating outwardly from the cannula, thereby increasing the amount of leakage which occurs around the cannula.

It is therefore an object of the present invention to provide a more economical medicinal-containing cartridge-support assembly having means for preventing leakage of a medicament from a medicinal-containing cartridge during administration thereof while held in said support.

It is a further object of the present invention to provide an improved plastic medicinal-containing cartridge-support assembly which reduces leakage of a medicament through the diaphragm portion thereof which is penetrated by a diaphragm piercing cannula held in said support.

A still further object of the present invention is to provide an inexpensive plastic cartridge-support assembly having means for forming a sealable engagement with a cylindrical supporting section in which it is slidably mounted.

It is still another object of the present invention to provide in a plastic cartridge-support assembly a novel fluid sealing engagement between said plastic cartridge and said support to prevent the loss of medicament.

Another object of the present invention is to provide a medicinal plastic cartridge-support assembly of the instant type which can safely employ a hard plastic material for molding the pentrable diaphragm portion of the cartridge regardless of any splintering thereof during penetration by a needle cannula.

Other objects of the present invention will be apparent to those skilled in the art from the following detailed description and claims to follow when read in conjunction with the accompanying drawing wherein:

FIG. 1 is a vertical sectional view of a medicinal cartridge-needle assembly of the present invention with the cartridge disposed in spaced relation to the needle thereof and having protective means sealably enclosing the ends thereof.

FIG. 2 is a vertical sectional view partially in side elevation showing the cartridge-needle assembly of FIG. 1 operatively mounted in a hypodermic cartridge syringe;

FIG. 3 is a vertical sectional view of a modified form of medicinal-containing cartridge-needle assembly;

FIG. 4 is a vertical sectional view of a still further modified form of a medicinal-containing cartridge-needle assembly of the present invention; and

FIG. 5 is a side elevational view partially in vertical section of a medicinal containing cartridge of the present invention.

In FIGS. 1 and 2 of the accompanying drawing is shown a preferred embodiment of the present invention wherein a novel medicinal containing cartridge 10 is reciprocably disposed within a sleeve or cartridge hypodermic needle retaining member 11 which coacts with the cartridge 10 in a unique manner to provide a unitary sealable

structure adapted to be removably mounted in a hypodermic cartridge syringe 130. The medicinal cartridge 10 is comprised of an elongated body section having a generally cylindrical plastic wall 15 with an unrestricted opening 16 at one end and a transversely extending end wall 17 integrally formed with the lateral wall 15 to sealably close the other end. The transverse end wall section 17 contains a plastic diaphragm portion 18 integrally formed therein and preferably thinner than the lateral wall of the cartridge so that a diaphragm piercing cannula can readily penetrate therethrough. The lateral walls 15 adjacent the end wall 17 is preferably provided with a frustoconical or tapered section 19 which is adapted to form a sealing engagement with the needle retaining sleeve member 11. The frustoconical section 19 preferably begins at the periphery of the diaphragm 18 and extends axially a short distance forming a small angle with the longitudinal axis of the cartridge 10. The end of the frustoconical section 19 which is spaced axially and radially upwardly from the end wall 18 terminates in an annular recess 20 which forms an annular connecting portion having a reduced wall thickness between the frustoconical section 19 and the cylindrical wall section 15 which imparts a degree of flexibility to the wall section. The annular recess 20 coacts with a complementary ring section 44 formed on the inner surface of the sleeve 11 to form a locking engagement therebetween.

The cartridge-needle retaining member 11 has a generally stepped cylindrical body section 21 with a generally cylindrical hub engaging section 22 provided with a stepped cylindrical axial passage 23 extending therethrough and which is adapted to fixedly receive therein the hub 24 of the double-ended hypodermic needle 25. The hub 24 has a collar or flanged ring section 26 fixedly secured to the cannula 27 of the hypodermic needle 25 intermediate the ends thereof to provide an administration cannula portion 28 extending in one axial direction and a shorter diaphragm piercing portion 29 extending axially in the opposite direction. The ring section 26 is frictionally held in the axial passage 23 to fixedly retain the needle 25 therein.

Extending forwardly from the body section 21 is an axial post section 30 which is adapted to removably support thereon a cannula sheath 31 which sealably encloses the cannula portion 28. The body section 21 is also provided on the outer surface with syringe engaging means 35, such as a threaded section, which is adapted to retain the body section 21 in threadable engagement with the lower end of the cartridge syringe 130.

The body section 21 has an integrally formed elongated sleeve section 40 with a generally cylindrical inner wall section 41 extending axially beyond and symmetrically disposed about the said diaphragm piercing cannula portion 29. The cylinder wall section 41 has an unrestricted opening 42 at one end thereof with an inner diameter sufficient to slidably receive therein the cartridge 10. The sleeve section 40 is adapted to slidably retain therein by frictional engagement the medicinal cartridge 10 in spaced relation to the end of the diaphragm piercing cannula portion 29 until such time as it is desired to administer the medicament.

In order to prevent leakage of medicament from the cartridge around the cannula portion 29 after the plastic diaphragm 18 is pierced, means are provided in the lateral wall section of the sleeve section 40 for radially compressing the end of the cartridge unit surrounding the diaphragm 18 and simultaneously forming a sealing engagement between the lateral wall sections of the sleeve section 40 and the cartridge 10 adjacent the plastic diaphragm portion 18. In the preferred form illustrated in FIGS. 1 and 2 of the drawing, the portion of the inner wall section 41 of the sleeve section 40 adjacent the closed end wall 45 which has the cannula portion 29 extending axially therethrough is provided with an inner lateral surface defining a frustoconical section 46. The frustoconical section 46 has substantially the same longitudinal length as the corresponding section 19 of the cartridge 10 but has the inner lateral wall surfaces thereof spaced slightly less than the corresponding lateral wall surfaces of section 19. Thus, the closed end of the cartridge 10 including the diaphragm 18 thereof is compressed radially inwardly and simultaneously a fluid sealing engagement is formed between the lateral wall section of the cartridge 10 and the sleeve section 40 adjacent the end of the cannula portion 29 when the cartridge 10 is fully seated in the sleeve section 40. The cartridge 10 is preferably held in sealing engagement with the sleeve section 40 by the interengagement of projection and recess means on the sleeve section 40 and cartridge 10, respectively, as illustrated in FIG. 2 of the drawing.

It will be evident that the frustoconical section 46 effectively exerts a radially inwardly compression force on the diaphragm 18 of the cartridge 10 and thereby forming a fluid-tight sealing engagement about the cannula portion 29, because the inwardly tapered form of the lower end of the cartridge 10 tends to transmit any inwardly directed force thereon to the diaphragm-end wall section. Also, with the frustoconical section 19 being connected to the cylindrical wall section 15 by means of an annular recess 20 having a reduced wall thickness, the radially inwardly compression of the diaphragm section 18 by the frustoconical section 19 is greatly facilitated.

It will also be evident that the fluid sealing engagement between the two frustoconical sections 19 and 46 of the cartridge 10 and the sleeve section 40, respectively, provides an improved means for substantially preventing any loss of medicament from the interior of the plastic cartridge 10, even in the absence of a fluid-tight seal being formed between the diaphragm 18 and the cannula portion 29. Thus, by providing the cartridge 10 with a tapered outer lateral surface adjacent the inner end thereof which forms a fluid-tight sealing engagement with the similarly tapered inner lateral wall surface of a needle-supporting sleeve member, such as sleeve section 40 or a suitable formed barrel of a cartridge syringe, any medicament which may leak from the cartridge 10 around a cannula extending therethrough or through a rupture in the diaphragm section during administration will be sealably retained between the transverse end wall 17 of the cartridge 10 and the closed end wall 45 of the sleeve 40. Since only a very small volume of medicament can collect between the wall surfaces 17 and 45, the tapered sealing engagement between the cartridge 10 and sleeve 40 prevents leakage of any significant amount of the medicament from the cartridge 10. Thus, with the improved sealing structure of the present invention, loss of medicament from the all-plastic cartridge is reduced to a minimum, thereby making it economically feasible for the first time to use an all plastic cartridge for storing and dispensing a medicament.

The foregoing needle-cartridge assembly is preferably supplied as a complete sterile package, as shown in FIG. 1, by providing the needle-retaining member 11 with a protective sheath member 31 which is removably mounted on the lower end thereof to sealably enclose the axially extending administration or flesh piercing portion of the needle and a cap member 60 mounted on the upper end of the member 11. In the form illustrated in FIGS. 1 and 2, the open end of the sheath member 31 frictionally engages the cylindrical post 30 at the end of the member 11 to form a bacterial seal therewith. The open upper end of the retaining member 11 and the projecting end of the cartridge 10 are enclosed by the cap member 60 which forms a facterial seal with the end of the sleeve member 11. In its preferred form the closure cap member 60 is provided with an interior end section 61 at the open end thereof which has a diameter such that the end section forms a tight frictional sealing engagement with the outer surface of the sleeve 11. A shoulder section 64 is also preferably formed on the inner surface of the

cap 60 spaced from the open end which engages the transverse end wall 65 of the sleeve so that the closed end wall 66 of the cap 60 is spaced from the end of the cartridge 10, thereby preventing accidentally forcing the cartridge 10 into engagement with the diaphragm piercing cannula 29.

In the modified form of the present invention shown in FIG. 3 of the drawing, the plastic medicinal cartridge 70 has a generally cylindrical lateral wall section 71 with an unrestricted opening 72 at one end and a transversely extending end wall 73 integrally formed with the lateral wall section 71 which has a plastic diaphragm section 74 integrally formed therewith. The wall section 71 adjacent the end wall 73 and for a short distance axially thereof is in the form of a reduced diameter cylindrical section 75.

The cartridge-needle retaining member 80 has a generally stepped cylindrical body section 81 similar in form to that of the embodiment shown in FIGS. 1 and 2. The body section 81 holds securely therein a double-ended needle 90 with an elongated administration or flesh piercing portion 91 extending axially outwardly and a shorter diaphragm piercing portion 92 extending axially inwardly. A sleeve section 82 extends axially in the same direction as the diaphragm piercing portion 92 of the needle 90 and performs the same functions as the sleeve 40 of FIGS. 1 and 2. However, the sleeve section 82 differs structurally from sleeve 40 by having the inner surface adjacent the closed end thereof in the form of a cylindrical section 85 having a diameter slightly less than the exterior diameter of the cylindrical section 75 of the cartridge 70. The cylindrical section 85, in addition to compressing the diaphragm section 74, forms a sealing engagement with the lateral wall surface of the cartridge 70 adjacent the diaphragm 74 when the later is pierced by the needle 90. The cylindrical section 85 also provides a shoulder stop portion 86 at the end thereof spaced from the closed end of the sleeve 82 which engages the end of the cartridge 70 and prevents the diaphragm 74 accidentally being moved into contact with the diaphragm piercing portion 92 of the needle 90.

As in the form shown in FIGS. 1 and 2, the body section 80 and the sleeve section 82 are provided with a protective sealing closure cap 95 and a detachable needle sheath 96, respectively, to form a complete sterile package.

In the further modified form of the invention shown in FIG. 4, substantially the same medicinal cartridge and sleeve structures of FIGS. 1 and 2 are used except the needle is molded integrally with sleeve. In the latter modification, however, the sheath 100 which protectively encloses the administration cannula 101 has the open end thereof detachably mounted in bacterial sealing engagement with the generally cylindrical unthreaded lateral surface 110 of the body section 105. The longitudinally spaced closed end 102 of the sheath 100 is provided with an axial recess 103 which is threaded for engagement with a correspondingly threaded post 120 affixed in the piston head 121 reciprocably and sealably mounted in the end of the medicinal cartridge 125. It will be apparent that in the latter embodiment, the sheath 100 can, if necessary, be used as the piston rod for moving the head 121 axially within the cartridge 125.

When the medicinal cartridge-needle assembly of FIGS. 1 and 2 is used, the closure cap member 60 is removed and the cartridge 10 is fully seated in the sleeve section 40 by applying axial pressure on the end of the cartridge 10. This is conveniently done by placing the end of the cartridge 10 which projects from the end of the sleeve section 40 against a flat surface while holding the assembly with the body section between the fingers of one hand and applying axial pressure. As the axial pressure is increased, the cartridge 10 is moved into engagement with the diaphragm piercing cannula portion 29 and the diaphragm 18 is pierced. When the cartridge 10 is fully seated, as evidenced by the outer end of the cartridge being flush with the outer end of the sleeve, the diaphragm 18 of the cartridge 10 is compressed radially inwardly by the tapered lateral walls of the sleeve section to prevent leakage of fluid around the cannula. Simultaneously, as sealing engagement is formed between the lateral walls of the cartridge 10 and the sleeve 40 at points adjacent the diaphragm 18 to retain in a confined area at the lower end of the assembly any medicament or blood which leaks from the cartridge 10 during administration or aspiration. The cartridge 10 is maintained in sealing engagement with the sleeve section 40 by the interengagement of complementary locking means formed on the cartridge and sheath, respectively, or, in the absence of locking ring 44, the cartridge 10 can be held in the barrel and sleeve 40 by means of the syringe structure.

The cartridge needle assembly having the parts thereof disposed in the relative positions shown in FIG. 2 of the drawing is then inserted into the open end of a standard cartridge-type syringe 130, such as a "Tubex" dental syringe as shown in FIG. 2, without removing the protective sheath 31 which encloses administration needle. The cartridge-needle assembly is then securely mounted within the barrel 131 of the syringe, as by threadably engaging the threaded means 35 with a short threaded section formed in the lower end of the syringe body. The plunger rod 132 of the syringe is then operatively connected with the plunger 33 mounted in the end of the cartridge 10 to permit reciprocably moving the plunger.

While it is preferred to mount the plastic cartridge 10 in the needle-retaining sleeve section 11, it is within the broad scope of the present invention to mount the cartridge directly in the barrel of the cartridge syringe with the pivotal upper end assembly of the syringe adapted to hold the cartridge within the barrel or by providing conventional threadable means for holding the cartridge therein.

The modified forms of the invention shown in FIGS. 3 and 4 of the drawing can also be operated in substantially the same manner as described in connection with the embodiment shown in FIGS. 1 and 2.

In the modified form of the invention shown in FIG. 4, the cartridge-needle assembly can also be operated without inserting in a cartridge-type syringe. When used directly, the cartridge 125 is moved into piercing engagement with the cannula 101 in the same manner as described in connection with FIGS. 1 and 2. Thereafter, the sheath 100 is removed from the lower end of the body section 105 and the threaded recess 103 is brought into threaded engagement with the post 120 of the piston head 121. The sheath thus serves as the piston rod to administer the medicament within the cartridge or for drawing fluid into the cartridge.

The medicinal cartridge including the diaphragm portion of the present invention is preferably made of unplasticized polypropylene, since polypropylene is inert to most medicines and has a very low moisture transmission rate, while at the same time being relatively light in weight. Other plastic materials having similar chemical and physical properties can be used, such as polyethylene and nylon plastics. The sheath, cap and the cartridge sleeve needle-retaining member do not necessarily have to possess the same low moisture vapor transmission properties nor the chemically inert properties of the medicinal-containing cartridge. Thus, the latter parts of the assembly can be made from polypropylene, polyethylene, nylon, polyvinyl chloride, and the like plastic materials.

It will now be apparent to those skilled in the art that the material from which the diaphragm portion of the cartridge of the present invention can be made is not limited to a soft, rubber-like material and, in fact, is preferably made of a hard plastic material, such as unplasticized polypropylene. The use of such a material, however, is made possible only because the occurrence of "splintering" or radial fracturing of the diaphragm

during penetration thereof by a hypodermic needle cannula does not result in leakage of medicament from the cartridge. Any leakage of medicament which does occur through the diaphragm is sealably confined between the diaphragm end wall of the cartridge and the transverse end wall of the support member by the sealable engagement formed between the contiguous lateral surfaces of the cartridge and support member.

It will also be evident to those skilled in the art that making the diaphragm portion of a hard plastic material also makes it possible to use any type of needle point to penetrate the cartridge diaphragm, even a needle which has no point, such as a single ended needle. It is entirely unnecessary for the needle to cut through the diaphragm and thereby form a small plastic core or slug which floats loosely within the cartridge and tends to block the needle or cause serious injury if injected into the patient. With the present cartridge, it is possible and preferred to simply push a hole through the plastic diaphragm without cutting and completely severing a portion of the diaphragm.

It will be further understood by those skilled in the art that the plastic medicinal cartridge of the present invention which has a reciprocable piston sealably closing one end with the other end being closed by an integral plastic diaphragm section can, if desired, also be used in a cartridge syringe other than the "Tubex" syringe shown in FIG. 2 of the drawing, with or without the supporting sleeve member.

It will be apparent to those skilled in the art that many changes and modifications may be made in the specific embodiments disclosed herein without departing from the present invention. The specific description is not intended to limit the scope of the invention, which is defined by the appended claims.

I claim:

1. A cartridge-needle assembly which comprises in combination: a plastic cartridge adapted to retain a fluid therein formed of a substantially hard plastic material which has low vapor transmission properties and which in sections readily pierceable by a hypodermic needle is inherently lacking in ability to form a permanent sealing engagement with a hypodermic needle cannula, said cartridge having a cylindrical lateral wall section with a piston means slidably mounted therein and having one end of said cylindrical lateral wall section sealably closed by a readily pierceable plastic diaphragm end wall section integral with contiguous portions of said cylindrical lateral wall section and being formed of said substantially hard plastic material, and a cartridge-needle support member having a cylindrical sleeve section in which said cartridge is supported with one end of said sleeve section open to receive said cartridge and the other end closed by a sleeve end wall adapted to support a diaphragm piercing needle cannula with one end of said cannula extendable axially within said sleeve section, and said sleeve section having formed at the end thereof adjacent said sleeve end wall a reduced diameter section providing a sleeve lateral wall section engageable with said cylindrical lateral wall section adjacent said one end to form a fluid sealing engagement between said lateral wall sections of said cartridge and said sleeve section for retaining within said sleeve section fluid leaking from said diaphragm section when said cartridge and cannula are disposed in diaphragm piercing seating engagement within said sleeve section.

2. A cartridge-needle assembly as in claim 1, wherein said cylindrical lateral wall section adjacent said one end of said cartridge and said reduced diameter section of said sleeve section each have inwardly tapering lateral walls providing frustroconical sections which form said fluid sealing engagement.

3. A cartridge-needle assembly as in claim 1, wherein said cylindrical lateral wall section adjacent said one end of said cartridge and said reduced diameter section of said sleeve section each have cylindrical lateral walls providing cylindrical sections which form said fluid sealing engagement.

4. A cartridge-needle assembly as in claim 1, wherein said plastic cartridge is formed of a plastic material selected from the group consisting of substantially unplasticized polypropylene, polyethylene and nylon.

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