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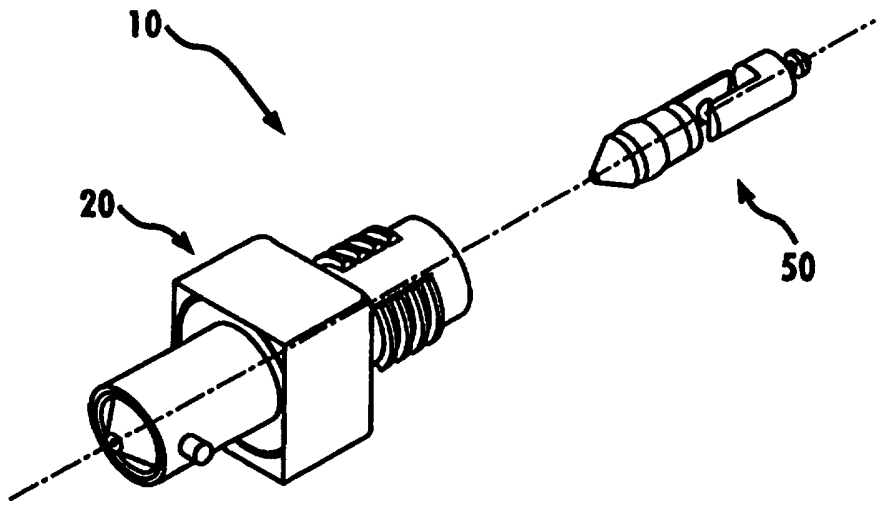

(57) Abstract

The present invention is directed toward a plunger (50) provided for use in a nozzle assembly (20). The plunger includes a frangible portion (80) and has a first (60) and second driving member (70) connected to the frangible portion. The first and second driving members are spaced apart by a predetermined gap using a frangible bridge (80). When a predetermined force is applied to the second driving member, it breaks the frangible bridge and moves the second driving member across the gap. This causes the second driving fluid out of the nozzle. Thereafter, as the second driving member is separated from the first driving member, the first driving member remains lodged in the chamber preventing the reuse of the nozzle assembly.

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FRANGIBLE PLUNGER FOR NOZZLE ASSEMBLY

TECHNICAL FIELD

The present invention relates to a plunger for use in a nozzle assembly made out of two halves separated by a gap therebetween and connected by a frangible bridge.

BACKGROUND

Medical communities have become concerned over the possibility of accidental communication of disease, such as Acquired Immune Deficiency Syndrome (AIDS), hepatitis, and other diseases communicable through bodily fluids, through accidental needle sticking and improperly sterilized multiple-use needle injector. One way to curb some of these mishaps is to discard the entire needle injector after a single use.

A number of single use needle injectors have been contemplated in this regard, as described in U.S. patent Nos. 5,226,882 to Bates; 5,423,756 to van der Merwe; 5,135,507 to Haber et al; and 5,407,431 to Botich et al. As with all needle injectors, they provide a barrel for holding medication and a plunger/piston assembly slidingly received within the barrel for ejecting medication out of the barrel The Bates and van der Merwe patents disclose a piston (the forefront part that pushes medication) that separates from a plunger (the rod-like portion that pushes the piston) after medication is ejected. The Haber and Botich patents achieves a similar result by locking the piston to the barrel after the injection stroke is completed to prevent reuse.

Needleless injectors have no needle. They thus completely remove any apprehension or the possibility of being pierced. At least in this regard, the needleless injectors are superior in eliminating accidental disease transmission. Different needleless injector types have been contemplated, as described, for instance, in U.S. Patents 5,062,830 issued to Dunlap; 4,790,824 to Morrow et al.; 4,623,332 to Lindmayer et al.; 4,421,508 to Cohen; 4,089,334

to Schwebel et al.; 3,688,765 to Gasaway; 3,115,133 to Morando; 2,816,543 to Venditty et al.; and 2,754,818 to Scherer. These injectors have been contemplated to administer medication as a fine, high velocity jet, delivered under sufficient pressure to enable the jet to pass through the skin tissue without requiring a hypodermic needle. These injectors typically have a nozzle assembly which has a barrel-like nozzle body for holding medication therein. The nozzle member has an orifice through which a jet stream of medication is forced out from the chamber when a plunger/piston is actuated by an energy source, such as a coil spring, gas spring, and gas cartridge.

Even though needleless injectors eliminate known problems associated with the needle injector type, nevertheless, as an added safety precaution, it would be desirable to discard the nozzle assembly after each use to prevent its reuse. For example, after a single use the high pressure applied by the energy source may cause the seal between the plunger/piston and the nozzle assembly to partially fail or leak. Thereafter, a subsequent use of the same nozzle may have inadequate pressure transmitted to the medication to ensure proper delivery. Additionally, this high pressure may enlarge the orifice in the nozzle assembly so that subsequent uses of the same assembly would not produce a jet having sufficient velocity to penetrate to a desired depth.

SUMMARY OF THE INVENTION

The present invention relates to a single use nozzle assembly and a plunger. The nozzle assembly is adapted for use with an injection device comprising a chamber for holding a fluid, a force generating component for generating force to expel fluid out of or to draw fluid into the chamber, and a plunger. The chamber has first and second ends with an orifice at the first end for passage of the fluid.

The plunger is slidingly movable within the chamber for expelling fluid out of or drawing fluid into the chamber by

moving the plunger relative to the chamber. The plunger includes first and second driving members and a frangible connection therebetween, with the second driving member being spaced apart from the first driving member by a gap. The first and second driving members are retained in spaced relation by the frangible connection. When a force sufficient to break the frangible connection is applied to the second driving member in a direction toward the first driving member, the frangible connection is broken and the second driving member moves across the gap toward the first driving member for urging the first driving member towards the end of the chamber to expel fluid therefrom. Thereafter, when the second driving member is moved away from the first driving member, the first driving member remains in the chamber to prevent reuse of the nozzle assembly.

The frangible connection preferably has a smaller cross-sectional area than either of the first and second driving members and is disposed substantially perpendicularly to the longitudinal axis of the first and second driving members. Particularly, the first and second driving members can be cylindrical and have D-shaped end portions which face each other and are joined by the frangible connection. The frangible connection can be a rectangular bridge connecting straight sides of the D-shaped portions of the first and second driving members.

Alternatively, the plunger may be cylindrical with the first and second driving members meeting to define the frangible connection therebetween. The frangible connection may include at least a portion which extends across the diameter of the plunger. The frangible connection may be disposed substantially perpendicularly to the planes formed by the surfaces of the end portions, or may be spaced radially relative to the longitudinal axis of the plunger. The end portions may be configured and dimensioned to occupy more than half the cross-sectional area of the plunger and are positioned in subjacent relation after the second driving member moves across the gap.

Preferably, the end and base portions of the first and second driving members face each other and are joined by the frangible connection. The frangible connection may then extend from the second driving member to connect the end portions of the first and second driving members. Thus, when a force sufficient to break the frangible connection is applied to the second driving member, the frangible connection is broken. The second driving member moves across the gap toward the first driving member with the base portion of the second driving member contacting the end portion of the first driving member as the end portion of the second driving member contacts the base portion of the first driving member. The first driving member is then urged toward the end of the chamber.

Advantageously, the first driving member has a seal in contact with an inner wall of the chamber to prevent fluid from exiting the chamber around the first driving member and through the open end. Also, the chamber can include means for releasable connection to an injection device.

If desired, the second driving member may include means for releasably connecting to a force generating component. The connecting means may be an end post which can be grasped to move the second driving member in a direction away from the chamber orifice to either draw fluid into the chamber or to remove the second driving member from the chamber. This movement can also dispel air from the chamber before introduction of the liquid therein. To assist in the movement of fluid, the chamber may include a tapered portion adjacent the orifice and the first driving member may include a tapered member which conforms to the tapered portion of the chamber.

Advantageously, the plunger and nozzle assembly may be color coded either together or independently with a specific color corresponding to a predetermined width of the gap. The plunger may be constructed of a material which includes a polymer such as polycarbonate, polypropylene, polystyrene, and acrylic.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the invention may be obtained from a review of the appended drawing figures, which illustrate preferred embodiments and wherein:

Fig. 1 is an exploded perspective view of a nozzle assembly according to the present invention;

Fig. 2 is an elevational view of a frangible plunger according to the present invention, showing the plunger before injection;

Fig. 3 is a view similar to Fig. 2, but with the plunger during or after injection;

Fig. 4 is a cross sectional view taken along line 4-4 of Fig. 2;

Fig. 5A is a cross-sectional view of the present nozzle assembly with the plunger pulled away from the nozzle member;

Fig. 5B is a cross-sectional view of the present nozzle assembly before withdrawing medication into the ampule chamber;

Fig. 5C is a view of the injector of the present injector after medication has been introduced into the barrel of the injector;

Fig. 5D is a view of the injector of the present invention after the frangible member of the piston is broken;

Fig. 5E is a view of the injector of the present invention after the piston has pushed the liquid out of the barrel;

Fig. 6 is a partial cross-sectional view of another embodiment of the frangible plunger of the present invention;

Fig. 7 is a cross-sectional view of the plunger at area 7-7 as shown in Fig.6;

Fig. 8 is a cross-sectional view of the plunger of Fig. 6 installed in the internal chamber of the nozzle assembly prior to loading the chamber with medicament;

Fig. 9 is a cross-sectional view of the plunger of Fig. 6 installed in the internal chamber of the nozzle assembly after the injector has been fired; and

Fig. 10 is a cross-sectional view of the plunger of Fig. 6 installed in the internal chamber of the nozzle assembly after the injector has been fired, the nozzle assembly has been rotated out of locked position, and the piston of the injector is about to be withdrawn.

DETAILED DESCRIPTION OF THE DRAWINGS

The nozzle assembly 10 according to the present invention is adapted for use with any conventional injector, including the needleless type disclosed in the aforementioned patents, the disclosure of which are incorporated herein by reference. When a needle type injector is to be used, the orifice is in fluid communication with the bore of an appropriately sized needle.

Referring to the figures, the nozzle assembly 10 has a nozzle member 20 including an orifice 22 of a suitable diameter that would produce a uniform jet stream under a given desired pressure range and depth of injection. Preferably, this diameter may be about 0.07 - 0.4 mm, and most preferably about 0.165 mm (0.0065 inches). If a highly precise jet stream is desired, the orifice can be formed of a synthetic gem material, such as a synthetic ruby or sapphire, as disclosed in U.S. patent 4,722,728 to Dixon. Hereinafter, the term "orifice" shall mean any type of opening, including a straight, convergent, divergent, convergent-divergent, etc.

The orifice 22 may also be used to withdraw a fluid or liquid medication into the chamber 26. In this regard, a medication filling device such as an adapter (not shown) for filling the internal chamber of a nozzle assembly from a liquid medication supply vial directly through the ejection orifice can be used to fill the chamber with medication, as described in U.S. Patents 4,507,113 to Dunlap; and 4,883,483 and 4,662,878 to Lindmayer, the disclosure of which is incorporated herein by reference. Other coupling devices can also be used if desired.

The nozzle member 20, as shown in Figs. 5A-5E, includes a cylindrical ampule chamber 26 terminating in a right

circular cone 28. The chamber includes external ridges 40 for attachment to an injection device. The plunger 50 has a pressure wall contoured to the cone 28 and is received through an open end of the chamber. It is positioned to slide longitudinally within the ampule chamber 26 to expel fluid medication out of the chamber and may also draw fluid medication into the chamber.

As better shown in Figs. 2 and 3, plunger 50 is frangible and has a first driving member 60 and a second driving member 70. As shown in Fig. 4, these members have a generally cylindrical shape with D-shaped end portions 65, 75. These driving members are connected together in a spaced apart relationship across a predetermined gap G by a frangible connection or bridge 80. Each end portion 65, 75 is spaced relative to an opposed base portion 71, 61, respectively. The preferred frangible bridge 80 is a relatively thin rectangular member connecting the D-shaped end portion of the first driving member 60 to that of the second driving member 70. Advantageously, the frangible bridge 80 has a square cross-section. The frangible bridge 80 may be disposed in a perpendicular position to both straight sides of the D-shaped end portions 65, 75 of the first and second driving members as well as to the longitudinal axis of the first and the second driving members, which are parallel to the longitudinal axis (direction of the sliding movement) of the plunger. Preferably, the plunger 50, including the frangible bridge 80 is made out of a plastic, such as polycarbonate, polystyrene, polypropylene, or an acrylic polymer and is configured and dimensioned such that frangible bridge 80 can withstand a force "p" for moving or withdrawing the plunger to draw liquid medication into chamber 26 without breaking.

Alternatively, the frangible plunger 50 can be used with a prefilled ampule, thereby eliminating the need for moving the plunger longitudinally to draw liquid medication into ampule 26 or to expel excess liquid or bubbles therefrom.

The leading end of the first driving member 60 includes a seal 62, such as O-ring or the like, preferably formed around its outer periphery to provide a seal with the inner wall of the chamber 26. The plunger itself can be a seal. Other seals or seal members can be included in the trailing end of the second driving member if desired to provide a better seal to prevent leakage of fluid from the chamber by minimizing the entry of air into the chamber from around the first and second driving members and by preventing air from entering the orifice due to liquid exiting the chamber around the driving members.

Referring to Figs. 5A-5E, the nozzle assembly is attached to an injector body by releasably connecting the end post 72 of the second driving member to the ram 90 of the injector, as shown in Fig. 5A, and connecting the bayonet mount 40 to the front of the injector body (not shown). The connection between the plunger and the ram 90 can be any conventional connection that holds these elements together but enables separation, such as a ball and slot configuration as depicted, or the prongs, as depicted in Figs. 6-10.

The plunger is pushed into the chamber, in the direction shown by the arrow in Fig. 5A, to purge air. Fig. 5B shows the plunger fully pushed, before the liquid medication is drawn into the chamber. As the plunger is pulled to the direction shown by the arrow in Fig. 5B, a partial vacuum is established inside the chamber 26 and liquid medication is drawn into the chamber through the orifice 22.

It will be noted that the frangible connection is dimensioned and configured such that pushing or pulling action requiring force "p" normally affiliated with withdrawal and slow ejection of air or medication before injection does not break the bridge. Upon an application of a relatively large injection force "P" on the ram, which may be significantly larger than the force "p", the ram 90 transmits this force P to the second driving member 70 and breaks the frangible bridge 80. This allows the second driving member 70 to close the gap and transmit force to the

first driving member 60 to eject medication out of the chamber 26, as shown in Fig. 5D. Finally, Fig. 5E shows the position where the injection is completed and all the medication has been ejected. At this point, the nozzle assembly 10 can be rotated until the ridges 40 are free of the injection device and it can be removed. Since the first driving member 60 is broken away from the second driving member, which remains connected to the ram 90, the first driving member 60 remains inside the chamber 26. The second driving member 70 is then removed from the ram 90 and discarded along with the nozzle assembly 10. This prevents unwanted re-use of the nozzle assembly 10.

In a normal operation of the injector, ram 90 of the injection device is operatively connected to an energy source and imparts sudden force or impact "P" to the second driving member 70, enough to drive the second member 70 into the first member 60. This action is sufficient to drive the liquid contained in ampule 26 outward through orifice 22 as a peak jet stream pressure, for example, in excess of 5,000 psi out of the orifice 22. This sudden force is capable of breaking the frangible bridge 80 before the injection begins. Specifically, the force "P" applied to the second driving member is transmitted to the first driving member 60 through the bridge 80. Initially, the frictional force in the seal 62 generates enough friction to momentarily prevent the plunger 50 from moving. Once this frictional force is overcome, the plunger 50 starts to move and imparts pressure to the medication in the chamber 26. This creates resistance or back pressure on the first driving member 60. When the difference between the resistance force imparted to first driving member 60 by the fluid and the force imparted by the second driving member 70 toward the first driving member 60 reaches a predetermined level, the bridge 80 breaks and the second driving member 70 rams into the first driving member 60. Moreover, as shown in Fig. 3, end portion 75 of second driving member 70 rams into base portion 61 of first driving

member 60 and base portion 71 of second driving member 70 rams into end portion 65 of first driving member 60.

Alternatively, frangible bridge 80 may be broken by an intermediate force larger than the force "p," before the relatively large injection force "P" is applied on ram 90. Such an intermediate force can be generated for example by a pressure exerted on the liquid contained in ampule chamber 26 through orifice 22 or by other triggering mechanism.

The gap G plays an important role in creating a preferred pressure spike necessary to pierce through the patient's skin. Changing the gap G will change the initial force imparted on the first driving member 60. The peak pressure thus can be varied with the gap G. It can also vary depending upon the viscosity of the medication, the desired injection penetration depth and other parameters which may affect the initial injection pressure output. One of ordinary skill in the art can determine by routine experimentation the optimum gap for any frangible plunger that is to be used with a particular medication.

Advantageously, frangible plunger 50 or nozzle member 20 or both can be manufactured with different colors, wherein each color denotes a predetermined width of gap G. This color coding scheme will assist the user in choosing a proper nozzle assembly for a specific application.

Once the first and second driving members 60, 70 are separated, the first driving member 60 remains stuck in the chamber 26. The chamber 26 and the plunger 50 thus become unusable. The amount of force to break the gap can be adjusted by changing the dimension of the bridge 80.

Additionally, scoring lines or lines of breakage (not shown) can be provided to controllably break the bridge 80. These can also be determined by routine experimentation to optimum performance criteria.

The nozzle assembly 10 can be releasably connected to an injection device using any known structure for attaching and detaching two components together. The present invention preferably contemplates a bayonet-mount, which has

diametrically opposed ridges 40. These ridges 40 are first aligned in an opening having a similar cross-sectional configuration provided in an injector so that the ridges can be inserted. Thereafter, the nozzle member 20 is rotated relative to the injector body by a predetermined degree to prevent the nozzle body from detaching in the axial direction. The bayonet-mount enables a quick attachment and detachment of the nozzle assembly. Alternatively, threads can be used to secure the nozzle assembly 10 to the injection device. Other connection means can be used, if desired for a particular application.

A second preferred embodiment of plunger 50 is shown in Fig. 6. This plunger 50 exhibits the same features as the plunger shown in Figs. 2 and 3, but includes a differently configured frangible portion 80. The plunger 50 includes a distal end and a proximal end and is preferably cylindrical in shape and sized to fit snugly, but slideably within the internal chamber 26 of the nozzle member 20. The tip 84 of the plunger 50 is located at the distal end and is preferably shaped to substantially match the internal contours 28 of the internal chamber 26 of the nozzle member 20 at its distal end. The plunger 50 preferably includes a seal 86 adjacent the tip 84. The seal 86 helps to prevent any medicament from passing by the seal 86 before or during firing of the injector. The seal 86 is preferably compressed during use in order to provide a tight fit within the internal chamber 26, as shown in Figs. 8-10.

As shown in Fig. 6, plunger 50 has a first driving member 110 and a second driving member 120. As shown, these members have a generally cylindrical shape with specially shaped base 112, 122 and end portions 114, 124. It is preferred to use a modified D-shape wherein portions of the arcuate part of the D 81 have been removed, as shown in Fig. 7. These driving members 110, 120 are connected together in a spaced apart relationship across a predetermined gap G by a frangible connection or bridge 80.

As shown in Figs. 6 and 7, the preferred frangible bridge 80 is a relatively thin, overlapping and connecting portion of the first and second driving members 110, 120. It is preferred that the height of the frangible bridge be minimal to provide a localized shear zone. The frangible portion 80 may be disposed adjacent both straight sides of end portions 114, 124 of the first and second driving members 110, 120. A leading or distal edge 111 of frangible portion 80 is preferably shaped as a sharp corner. This sharp corner provides stress concentration for assisting in shearing the frangible portion when an appropriate load is applied to the second driving member 120. A trailing or proximal edge 121 of frangible portion 80 is preferably rounded, defining a radius. This radius is defined to provide a clean two-part break which allows the second driving member 120 to close the gap G between the first 110 and second 120 driving members.

Further, recesses 123 are defined at the end of the channels which define the frangible portion 80. These recesses are positioned in the base portions 112, 122, adjacent the frangible portion 80, and are configured and dimensioned to accept flash or waste which may break away from the frangible bridge 80 during shearing. Recesses 123 are provided in order to avoid any interference between any flash and the movement of the first and second driving members 110, 120.

Frangible portion 80 is preferably spaced a small distance from longitudinal axis X - X in order to aid in providing a frangible connection which will shear when a sufficient amount of force is applied. Preferably, the plunger 80, including the frangible bridge is made out of a plastic and is configured and dimensioned such that frangible portion 80 can withstand a force "p" for moving or withdrawing the plunger to draw liquid medication into chamber 26 without breaking. Typically, an acrylic polymer, such as acrylic resins VS-100-UVT, V920-100-UVT, SG-7, and V052, all of which are produced by AtoHaas N.A., will provide the strength necessary to withstand loading or medication

filling procedures, but is also sufficiently brittle to break when the firing force is applied. The present frangible portion 80 is designed to shear when force "P," which is greater than force "p," is applied.

Alternatively, the frangible plunger 50 can be used with a prefilled chamber 26, thereby eliminating the need for moving the plunger 50 longitudinally to draw liquid medication into chamber 26 or to expel excess liquid or bubbles therefrom.

The leading end of the first driving member 110 includes the seal 86, such as an O-ring or the like, preferably formed around its outer periphery to provide a seal with the inner wall of the chamber 26. The plunger 50 itself can be a seal. Other seals or seal members can be included in the trailing end of the second driving member 120 if desired to provide a better seal to prevent leakage of fluid for the chamber by minimizing the entry of air into the chamber from around the first and second driving members 110, 120 and by preventing air from entering the orifice 22 due to liquid exiting the chamber around the driving members.

As part of the filling operation, the plunger 50 is pushed into the chamber 26, in the distal direction to purge air from the internal chamber, as shown in Fig. 8. As the plunger 50 is pulled in the proximal direction, a partial vacuum is established inside the chamber and liquid medication is drawn into the chamber 26 through the orifice 22.

It will be noted that the frangible connection is dimensioned and configured such that pushing or pulling action requiring force "p" normally affiliated with withdrawal and slow ejection of air or medication before injection does not break the bridge 80. Upon an application of a relatively large injection force "P" on the ram 90, which may be significantly larger than the force "p", the ram transmits this force "P" to the second driving member 120 and breaks the frangible portion 80. This allows the second driving member 120 to close the gap G and transmit force to

the first driving member 110 so that the respective base 112, 122 and end 114, 124 portions meet to eject medication out of the chamber 26. Specifically, the end portion 114 of the second driving member 120 contacts the base portion 112 of the first driving member 110 while the base portion 122 of the second driving member 120 contacts the end portion 124 of the first driving member 110 for urging the first driving member 110 towards the chamber orifice 22 to expel fluid therefrom.

Fig. 9 shows the position of the plunger 50 after the injection is completed and all the medication has been ejected. In this position, the frangible connection 80 has been broken so that the first 110 and second 120 driving members are in contact and the plunger 50 is positioned in the distal end of the chamber 26.

Finally, Fig. 10 shows the position of the plunger 50 after the injection is completed and the nozzle assembly 10 has been rotated or unlocked from the injector. The nozzle assembly has been rotated so that external ridges 40 are free of the injector and can be removed. At this point, as the nozzle assembly 10 is withdrawn or pulled back from the injector, the piston 90 and second driving member 120 move proximally within the chamber 26 until the piston is released from prongs 82, thereby allowing nozzle assembly 10 to be completely removed from the injector. Thus, the first 110 and second 120 driving members remain inside the nozzle member 20 and are easily removed from the injector and the nozzle assembly 10 then may not be reused and must be discarded. This prevents unwanted re-use of the nozzle assembly.

If a different connection means, other than the prongs 82, is employed to connect the second driving member 120 to the piston 90, the second driving member 120 may remain connected to the piston when the nozzle assembly 10 is removed from the injector. In this case, which is the same as that presented for the first embodiment of Fig. 1, the second driving member 120 may be manually removed from piston

90 after the nozzle assembly 10 is removed. The nozzle assembly will be rendered unusable because the first driving member 110 will remain lodged in the distal end of chamber 26. Thus, the embodiment shown in Fig. 6 is not dependent upon the connection means 82 and may be used with any type of connection means.

In a normal operation of the injector, piston 90 of the injection device operatively connected to an energy source imparts sudden force or impact "P" to the second driving member 120, enough to drive the second member 120 into the first member 110. This action is sufficient to drive the liquid contained in chamber 26 outward through orifice 22 as a peak jet stream pressure for example in excess of 5,000 psi out of the orifice 22. This sudden force "P" is capable of breaking the frangible bridge 80 before the injection begins. Specifically, the force "P" applied to the second driving member 120 is transmitted to the first driving member 110 through the bridge 80. Initially, the frictional force in the seal 86 generates enough friction to momentarily prevent the plunger 50 from moving. Once this frictional force is overcome, the plunger 50 starts to move and imparts pressure to the medication in the chamber 26. This creates resistance or back pressure on the first driving member 110. When the difference between the resistance force imparted to first driving member 110 by the fluid and the force imparted by the second driving member 120 toward the first driving member 110 reaches a predetermined level, the bridge 80 breaks and the second driving member 120 rams into the first driving member 110.

Alternatively, frangible bridge 80 may be broken by an intermediate force larger than the force "p," before the relatively large injection force "P" is applied to piston 90. Such an intermediate force can be generated for example by a pressure exerted on the liquid contained in chamber 26 through orifice 22 or by other triggering mechanism.

It will be understood that the frangible plunger according to the present invention can also be used with

syringes having hypodermic needles where the frangible bridge breaks either before the injection begins or after the completion of the injection.

Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly to be defined as set forth in the appended claims.

THE CLAIMS

What is claimed is:

1. A plunger slidingly movable within a fluid chamber for expelling fluid out of or drawing fluid into the chamber by movement of the plunger relative to the chamber, the plunger comprising first and second driving members which include respective end and base portions retained in spaced relation by a frangible connection therebetween, with the second driving member being spaced apart from the first driving member by a gap, such that when a force sufficient to break the frangible connection is applied to the second driving member in a direction toward the first driving member, the frangible connection is broken and the second driving member moves across said gap toward the first driving member for urging the first driving member towards an end of the chamber to expel fluid therefrom, and when the second driving member is thereafter moved away from the first driving member, the first driving member remains in the chamber.

2. The plunger according to claim 1, further comprising means for releasable connection to a force generating component.

3. The plunger according to claim 2, wherein the connection means is an end post which can be grasped to move the second driving member in a direction away from the chamber orifice to either draw fluid into the chamber or to remove the second driving member from the chamber.

4. The plunger according to claim 1, wherein the frangible connection has a smaller cross-sectional area than either of the first and second driving members.

5. The plunger according to claim 1, wherein the first driving member has a seal in contact with an inner wall of

the chamber to prevent fluid from exiting the chamber around the first driving member and through the open end.

6. The plunger according to claim 1, wherein the frangible connection is disposed substantially perpendicularly to the longitudinal axis of the first and second driving members.

7. The plunger according to claim 1, wherein the first and second driving members are cylindrical and have D-shaped end portions which face each other and are joined by the frangible connection.

8. The plunger according to claim 7, wherein the frangible connection is a rectangular bridge connecting straight sides of the D-shaped portions of the first and second driving members.

9. The plunger according to claim 1, wherein the plunger is cylindrical and the first and second driving members meet to define the frangible connection therebetween, said frangible connection having at least a portion which extends across the diameter of the plunger.

10. The plunger according to claim 1, wherein the frangible connection is disposed substantially perpendicularly to the planes formed by the surfaces of the end portions of the first and second driving members.

11. The plunger according to claim 1, wherein the frangible connection is spaced radially relative to the longitudinal axis.

12. The plunger according to claim 1, wherein the chamber includes a tapered portion adjacent the orifice and the first driving member includes a tapered member which conforms to the tapered portion of the chamber.

13. The plunger according to claim 1, wherein the end and base portions of the first and second driving members face each other and are joined by the frangible connection.

14. The plunger according to claim 13, wherein the frangible connection extends from the second driving member to connect the end portions of the first and second driving members, such that when a force sufficient to break the frangible connection is applied to the second driving member, the frangible connection is broken and the second driving member moves across the gap toward the first driving member with the base portion of the second driving member contacting the end portion of the first driving member as the end portion of the second driving member contacts the base portion of the first driving member for urging the first driving member towards the end of the chamber.

15. The plunger according to claim 1, wherein each of the end portions is configured and dimensioned to occupy more than half the cross-sectional area of the plunger, wherein the first and second end portions are positioned in subjacent relation after the second member moves across the gap.

16. The plunger according to claim 1, wherein the plunger is color coded with a specific color corresponding to a predetermined width of said gap.

17. The plunger according to claim 1, wherein the plunger is constructed of a material which includes a polymer selected from the group consisting of polycarbonate, polypropylene, polystyrene, and acrylic.

18. A single use nozzle assembly adapted for use with an injection device comprising:

a chamber for holding a fluid and having a first and second end with an orifice at the first end for fluid passage;

a force generating component for generating a force to expel fluid out of or to draw fluid into the chamber; and the plunger of claim 1.

19. The single use nozzle assembly of claim 18, wherein the chamber includes means for releasably connecting the chamber to an injection device.

20. The single use nozzle assembly of claim 18, wherein the nozzle assembly is color coded with a specific color corresponding to a predetermined width of said gap.

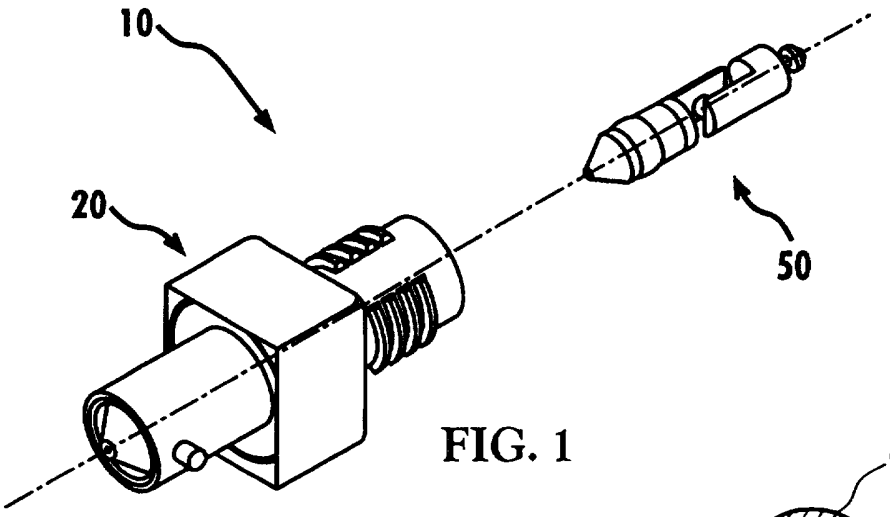

FIG. 1

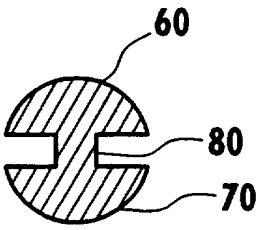

FIG. 4

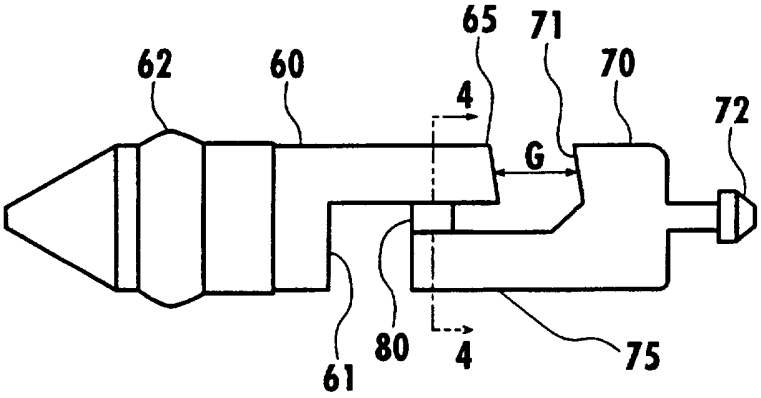

FIG. 2

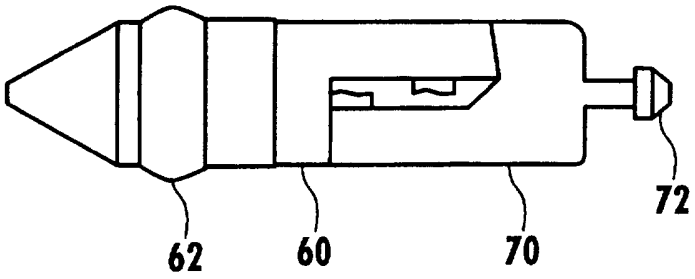

FIG. 3

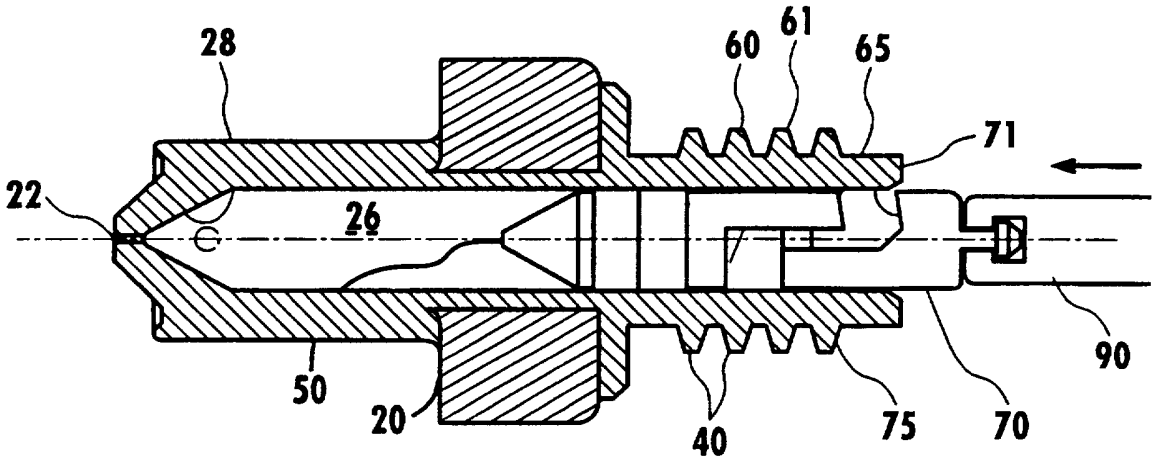

FIG. 5A

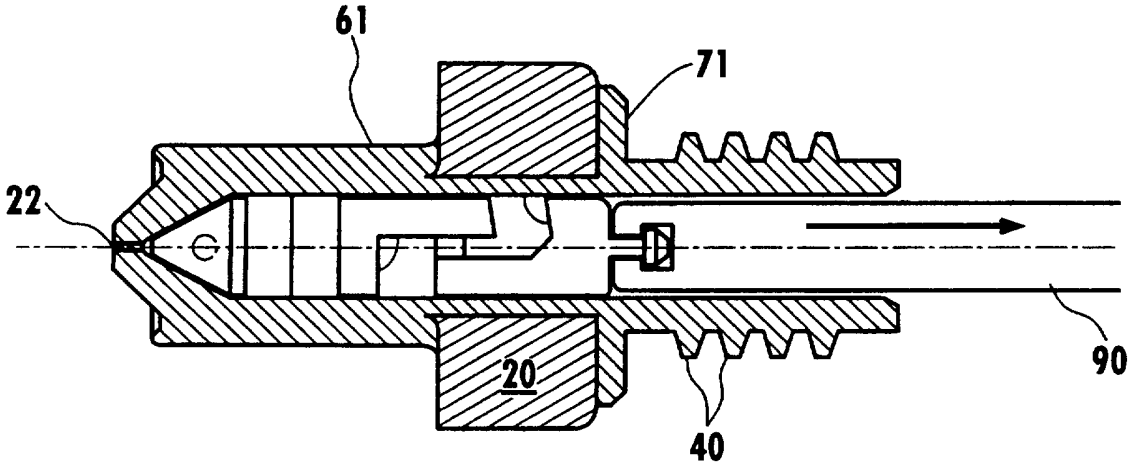

FIG. 5B

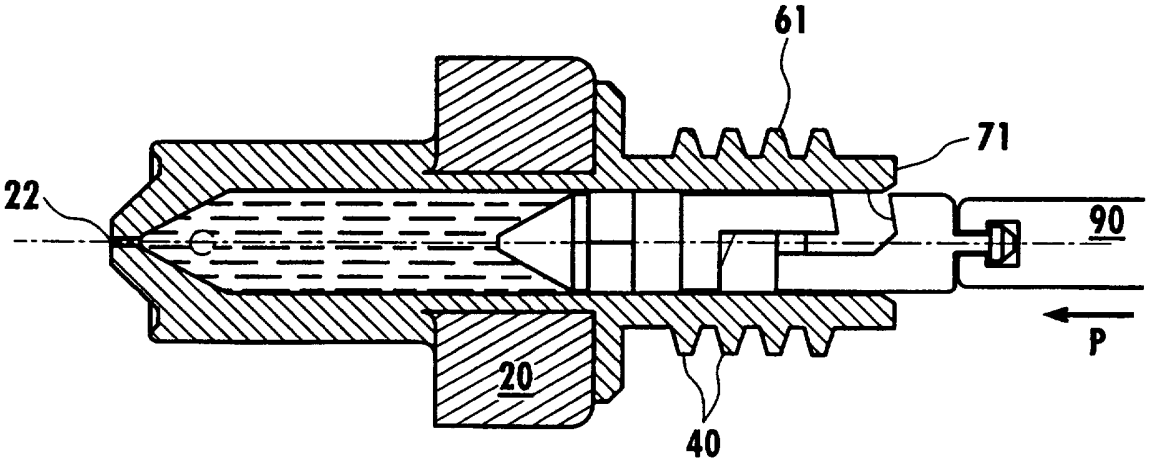

FIG. 5C

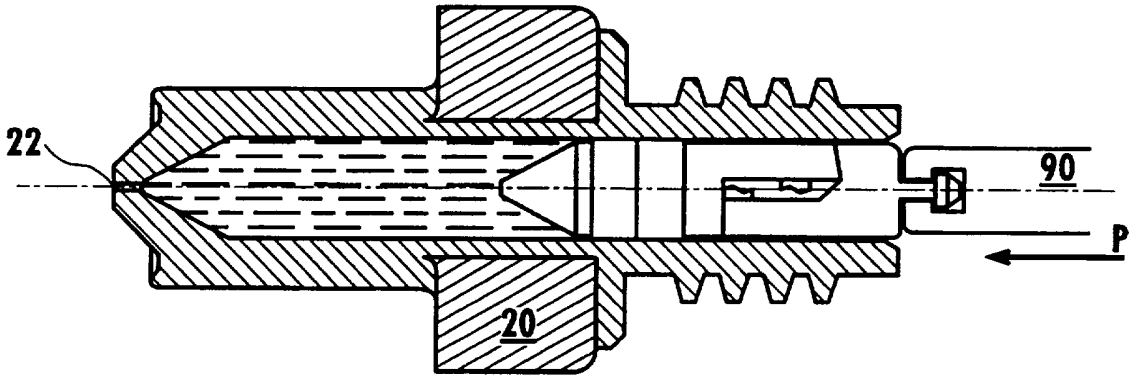

FIG. 5D

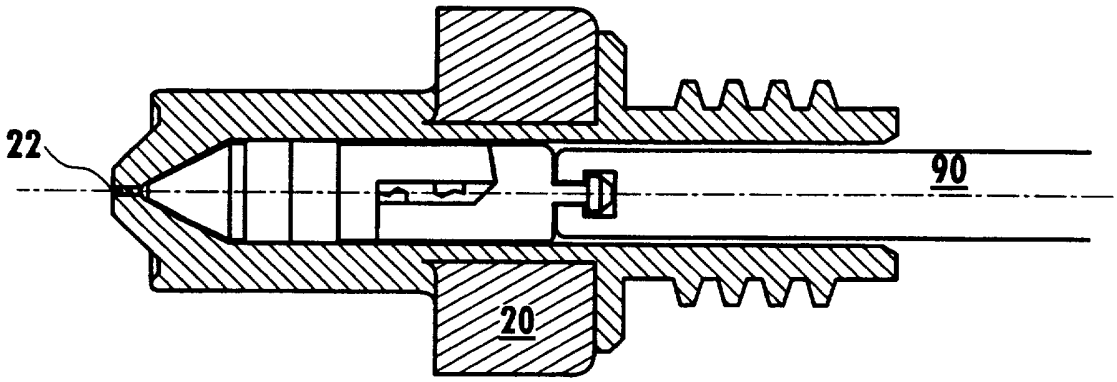

FIG. 5E

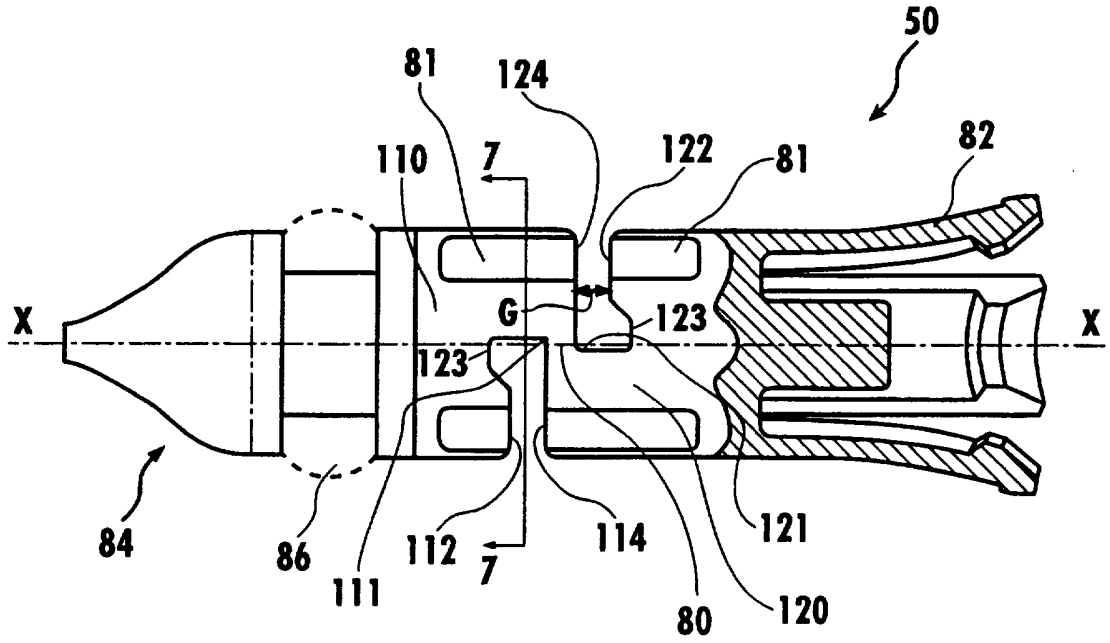
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FIG. 6

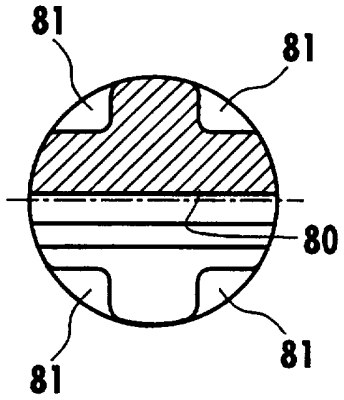
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FIG. 7

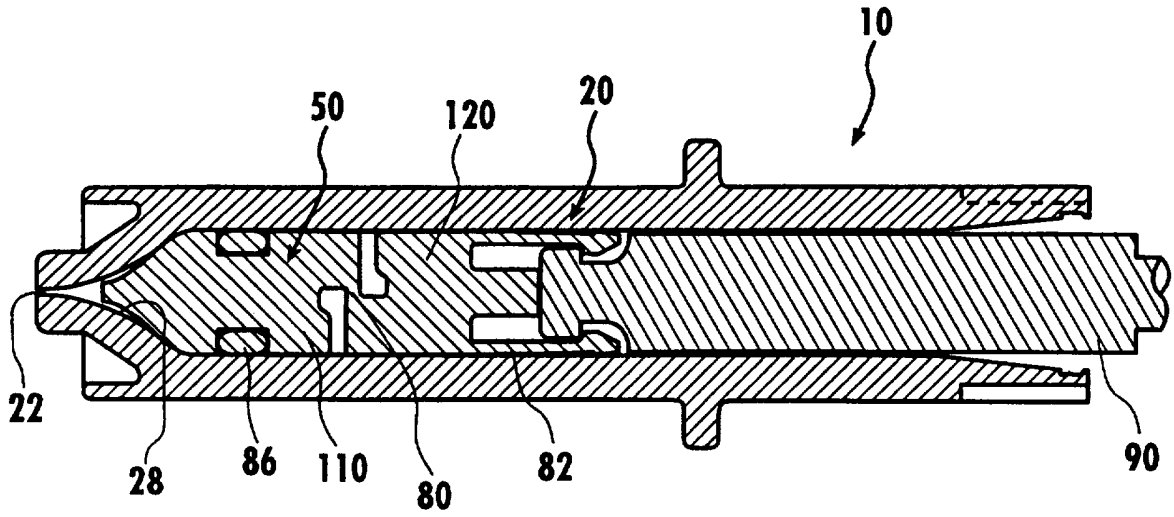

FIG. 8

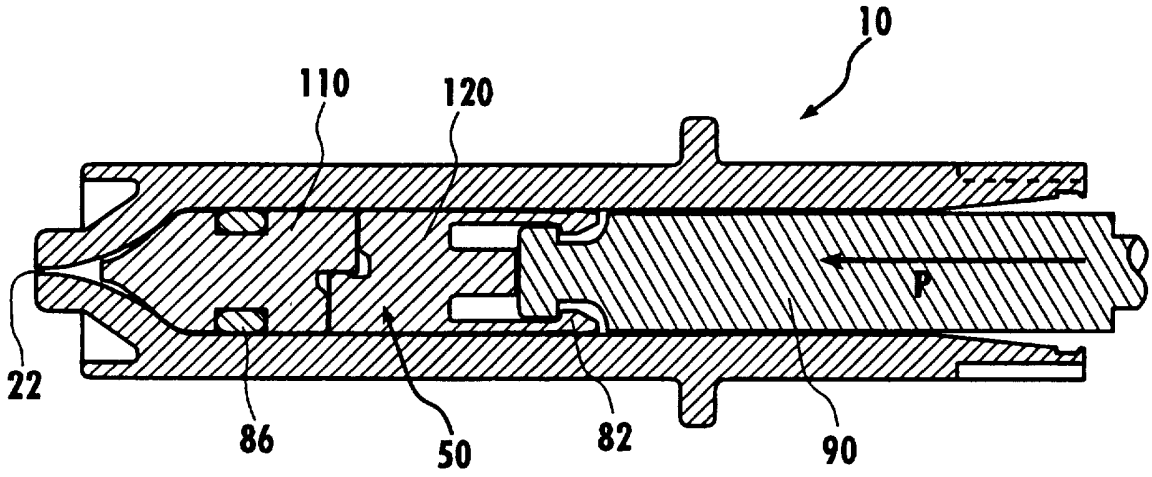

FIG. 9

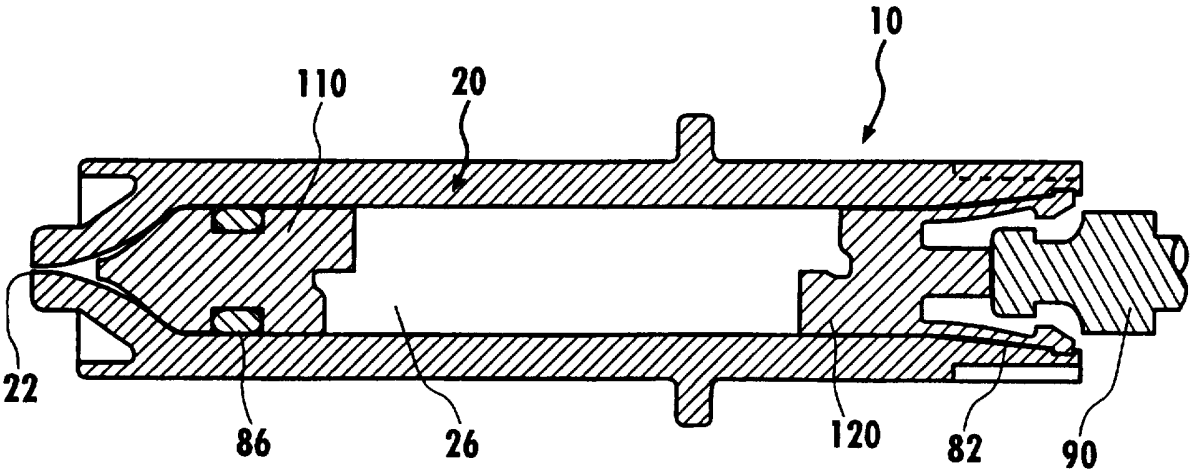

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/02854

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00
US CL :604/110

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/187, 218, 220-222, 228

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,863,427 A (COCCHI) 05 September 1989, entire document.	1-20
A	US 4,950,240 A (GREENWOOD et al) 21 August 1990, entire document.	1-20
A	US 5,181,912 A (HAMMETT) 26 January 1993, entire document.	1-20
A	US 5,352,203 A (VALLELUNGA et al) 04 October 1994, entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
30 APRIL 1997

Date of mailing of the international search report
09 JUN 1997

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