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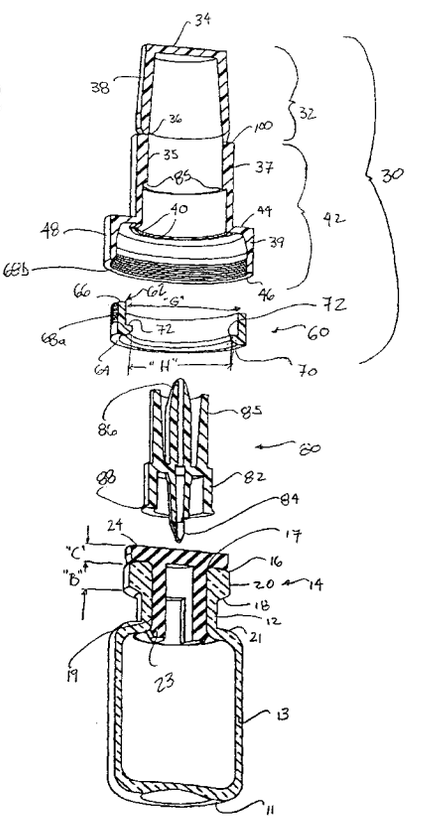
(54) A locking ring connector assembly for a vial

(57) A connector assembly for a vial is disclosed. The connector assembly features a protective cap, a collar attachable to the rim of the vial, and a locking ring disposed between the rim of the vial and the collar. One or more ribs provided on an internal region of the collar, adjacent the distal end of the collar, seal against the stopper obturating the vial. The locking ring features an internally projecting ridge for engaging the underside portion of the rim. Cooperative locking structure is provided between the locking ring and the collar. The locking ring is thrust distally with respect to the collar such that the cooperative locking structure secures the locking ring to the collar in a locked position, with the ridge of the locking ring engaging the underside of the rim and the ribs pressing against the stopper. A vial access device may be provided within the connector assembly.

FIG-2



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Description

Field of the Invention

[0001] The invention relates to a connector assembly for a vial, and more particularly, to a locking ring connector assembly for a vial which minimizes the number of components in the connector assembly and which reduces the number of microbial barriers necessary to safeguard sterility of the system.

Background

[0002] In the art, it is generally known that to reduce inventory space or to increase the shelf life of certain drugs, or both, it is advantageous to reduce these drugs to a dry or powdered form. These dry or powdered drugs are normally stored in a sealed container such as a vial, and reconstituted into liquid form with an appropriate diluent or solvent solution prior to administration to a patient. The vials, typically formed of glass or plastic materials, include an elastomeric stopper sealing the open end of the vial. The stopper includes a portion inserted into the neck of the vial as well as a planar portion which rests on top of the vial, against the vial rim. The planar portion is normally tightly affixed to the vial rim with an aluminum crimp cap. Owing to the malleable nature of aluminum, the crimp cap readily adapts itself any differing dimension or tolerances which may exist between the stopper and the vial. The result is that the crimp cap evenly distributes sealing forces between the stopper and the vial. Thus, it has been generally recognized in the art that the vial/stopper/aluminum crimp cap solution safeguards the sterility of the drug contained within the vial over suitably long storage periods and prescribed conditions. The sizes and dimensions of the various vials and stopper components may be configured to given standards, such as given ISO standards.

[0003] One way to reconstitute the drug stored in the vial is to introduce the solvent or diluent from a syringe by piercing the stopper sealing the vial. Owing to various considerations, such as the convenience of the healthcare worker charged with reconstituting the drug, the art has recognized ways to transform the standard sealed vial into a system suitable for permitting safe, effective reconstitution of the drug contained within the vial. In these systems, typically, a fluid transfer assembly is connected to the neck of the vial. The fluid transfer system includes structure for connecting the vial to a source of diluent, such as diluent held in bottles, bags or syringes. The transfer assembly is thereafter activated to permit the flow of fluid into the vial to from the source of diluent, thereby reconstituting the drug.

[0004] In some configurations, the systems are such that the standard vial stopper is eliminated in favor of fluid transfer assembly having a rubber stopper which is inserted into the neck of the vial, without the need for a planar portion which rests against the rim of the vial. This stopper remains within the neck until such time as reconstitution of the drug is desired. When the transfer assembly is activated, the stopper is urged towards the interior of the vial to open the neck, thereby permitting fluid to flow through the transfer assembly and into the vial body. Examples of such approaches include the MONOVIAL® line of drug delivery devices manufactured and sold by Becton Dickinson Pharmaceutical Systems of Le Pont de Claix, France and exemplified, for instance, by US Patent No. 5,358,501. While forming an excellent drug reconstitution system displaying superior properties, particularly convenience of use and sterility maintenance of the drug held in the vial, as typically configured these systems are useful for vial applications where the vial is of a relatively large size, typically 12 millilitres ("ml") or more. Accordingly, some pharmaceutical companies have expressed the desire for a reconstitution approach where the vial is of a size smaller than the sizes for which the aforementioned system is normally configured.

[0005] In response to the aforementioned concerns, then, one logical way around the dilemma would be to convert, as exactly as possible, the characteristics associated with vial components already in use by the pharmaceutical companies, such as the ISO standard vial/stopper/aluminium crimp cap components, and to implement a reconstitution system around these components for use by the healthcare worker. The prior art has considered some attempts in that regard. For instance, as exemplified by PCT Patent Application No. WO 97/10156 to Biodome, SA of Issoire Cedex, France, the aluminum crimp cap which would normally hermetically affix the planar portion of the standard stopper to the vial rim is replaced by a rubber-piercing fluid transfer assembly affixed around the neck of the vial. This rubber piercing fluid transfer assembly is activated by an end user when it is desired to reconstitute the drug held in the vial. The transfer assembly disclosed in this patent application features a fairly rigid, outermost plastic locking ring which, in theory, should lock the plastic transfer assembly firmly against the planar portion of the stopper and, hence, sealing this portion stopper against the vial rim. As has been pointed out, though, in practice, there may be significant variance between the dimensional tolerances of the glass components (the vial), the rubber components (the stopper) and the plastic components (the fluid transfer assembly) forming the system. The malleable nature of the aluminum crimp cap takes into account differences in tolerances. However, owing to the rigid characteristics of the sealing ring, with this approach, there may be the possibility that given a particular vial, stopper, or transfer assembly, the sealing forces realized by the outside sealing ring against the stopper and the vial may not be sufficient or otherwise uniform. Accordingly, the potential contamination of the drug, given the environmental stresses to which the vial may be subject to during manufacture, shipping, or storage, presents a concern.

[0006] Accordingly, there is a need for a safe and effective drug reconstitution system, wherein a fluid transfer assembly is affixed to a standard vial and stopper arrangement in a manner such that the sealing forces achievable by an aluminum crimp cap are effectively replicated. Such a drug reconstitution system is disclosed herein.

Summary of the Invention

[0007] The present invention addresses the aforementioned concerns in a convenient and cost-efficient manner. A connector assembly in accordance with the present invention is designed to be employed with a standard vial and stopper so as to be able to be processed by a pharmaceutical manufacturer with standard processing equipment. The connector assembly is fully able to account for dimensional variances or tolerance variances in the vial or stopper components or in the components forming the connector assembly itself, so as to ensure good microbiological barrier characteristics.

[0008] The connector assembly features a protective cap for covering the open end of the vial neck. The cap includes an open proximal end, a closed distal end, and a shield wall formed therebetween. A collar is provided adjacent the open proximal end of the cap. The collar can be molded with the cap, or it can be separately manufactured and thereafter affixed to the cap. The collar features a proximal end, a distal end, and a sidewall therebetween. One or more rib elements are provided on an interior portion of the collar adjacent the distal end, and the ribs designed to form a tight seal against the stopper as the collar is positioned against the stopper. Interior portions of the collar can be configured to mate with a vial access device provided to pierce the stopper.

[0009] A locking ring is provided between the collar and the rim of the vial. The locking ring features a proximal end, a distal end, and an annular section therebetween. An internally projecting ridge is provided adjacent the proximal end of the locking ring. In addition, a cooperative locking structure is provided between the collar and the locking ring to retain the locking ring in a locked position respective of the collar. In one embodiment, the cooperative locking structure can be formed as ratcheting teeth provided between the side wall of the collar and the annulus section of the ring. Alternately, the cooperative locking structure can be formed as cooperating threads. The locking ring may also feature a skirt portion located proximally of the ridge, which serves to engage a shoulder portion of the vial located proximally of the rim.

[0010] The connector assembly can be shipped to a pharmaceutical manufacturer such that the locking ring is retained in an unlocked position respective of the collar. In the cleanroom environment where the vial is filled with a medicament and the stopper is placed against the rim, the connector assembly can be attached to the vial. The connector assembly is transferred from a first position, whereby the locking ring is placed around the rim and the cap spaced from the stopper, to a second position, whereby the internally projecting ridge of the locking ring is thrust about the outside surface of the rim and against an underside portion of the rim. By this action also, the ribs provided in the interior of the collar are thrust into sealing relation with the stopper, to form a microbiological barrier safeguarding the sterility of the vial access device contained by the connector assembly. Thereafter, while still in the cleanroom environment, the locking ring may be urged distally of the collar towards a locked position respective of the collar. The locking ridge of the ring is thus urged against the underside portion of the rim, ensuring that the collar is securely locked to the vial.

[0011] If desired, the cap and collar can be manufactured in such a manner such that the cap is removable from the collar by a twisting action, permitting a user a convenient way to engage the vial access device held by the connector assembly. In one configuration, the cap can be formed with the collar, with a frangible connection formed from a material--such as a thermoplastic elastomer--that is different from the material forming the cap and collar itself, such as polypropylene or polyethylene. The user may simply twist the cap such that the frangible connection shears, allowing the user to remove the cap to expose the vial access device. One way to achieve this construction is through a co-injection process. All in all, the minimization of the number of components forming the connector assembly results in a concomitant reduction in the number of biological barriers necessary to safeguard the sterility of the vial access device as well as the medicament contained within the vial.

Brief Description of the Drawings

[0012] The invention will now be described in detail by way of reference to the appended drawings, wherein:

Figure 1 is an exploded view of a first embodiment of the connector assembly in accordance with the present invention;

Figure 2 is a cross-sectional view of Figure 1;

Figure 3 is a cross-sectional view depicting placement of the connector assembly against the vial in a first position, wherein the locking ring is placed around the rim;

Figure 4 is a cross-sectional view depicting placement of the connector assembly against the vial in a second position, whereby the locking ridge provided on the ring is thrust against an underside portion of the rim;

Figure 5 is a cross-sectional view depicting movement of the locking ring to a locked position respective of the collar;

Figure 6 is a cross-sectional view depicting the cooperative locking structure as threads provided be-

tween the locking ring and the collar;

Figure 6A is a cross-sectional view depicting the cooperative locking structure as ratcheting teeth provided between the locking ring and the collar;

Figure 7 is a cross-sectional view of a second embodiment of the connector assembly in accordance with the present invention; and

Figures 8A and 8B depict two manners of configuring a frangible section between the cap and the collar to allow removal of the cap to expose the vial access device.

Detailed Description of the Preferred Embodiments

[0013] A convention used throughout this application is that the term "proximal" denotes a distance closest to rim 14 of vial 10, while the term "distal" denotes a distance furthest from the rim of the vial.

[0014] Turning to the drawings, wherein like numerals denote like components, Figures 1 and 2 illustrate a first embodiment 30 of a connector assembly for a vial 10 in accordance with the present invention. Vial 10 is characterized by a bottom wall 11, a sidewall 13, a neck 12 and an annular rim 14. A shoulder 21 is located between rim 14 and sidewall 13 Annular rim 14 includes an underside portion 18, a side portion 20, and a top surface 16. A stopper 22 is typically employed to obturate an open end 17 associated with the vial. Stopper 22 features a planar portion 24 covering top surface 16 of the rim, and a plug portion 23 obturating the inside surface 19 of neck 12. Vial 10 is typically filled with a desired medicament, such as a dry drug or a lyophilized drug, and thereafter affixed with stopper 22, in a cleanroom environment. For the purposes of this invention, it will be realized that the dimensions and characteristics of vial 10 and stopper 22 can be conformed to various accepted standards, such as ISO standards, governing vials and stoppers intended for medicamental use.

[0015] As previously explained, a drawback in the art is ensuring that proper sealing forces exist between stopper 22 and vial 10. It would also be advantageous to incorporate a solution to this problem in a vial connector assembly that is easily processed by the pharmaceutical manufacturer and which, desirably, can be fully processed in the cleanroom environment where medicaments are processed, introduced into the vial, and stoppered within the vial.

[0016] With the foregoing in mind then, a first embodiment 30 of the connector assembly of the present invention is provided. Connector assembly 30 is formed of three principal components, namely, a cap 32, a collar 42, and a locking ring 60.

[0017] Cap 32 is characterized by a closed distal end 34, an open proximal end 36, and a shield wall 38 therebetween. Cap 32 is provided adjacent collar 42. Cap 32 and collar 42 can be formed together, such as by a co-injection process, or they can be separately formed and joined together by mechanical means, welding, adhesives, or the like. In a preferred construction, cap 32 and collar 42 are formed together and connected by a frangible section 100, as will be hereinafter discussed.

[0018] Collar 42 is designed to mate with rim 14 of the vial. Collar 42 is located adjacent open proximal end 36 of the cap. Collar 42 includes an upstanding tubular section 37 defining an interior portion 35. Interior portion 35 serves to engage and otherwise enclose a vial access device 80, as will be more fully explained hereinbelow. Adjacent tubular section 37 there is provided a vial attachment section 39. Vial attachment section 39 of the collar displays a distal end 44, an open proximal end 46, and a sidewall 48 therebetween. One or more sealing ribs 40 are provided, on an interior portion of vial attachment section 39, adjacent distal end 44. Ribs 40 can take any shape appropriate to their sealing function, such as rounded, peaked, square, or other geometries.

[0019] As will be described hereinbelow, collar 42 is disposed between a first position, wherein sealing ribs 40 are spaced from planar portion 24 of stopper 22 (Figure 3) to a second position, wherein sealing ribs 40 are engaged against the planar portion in sealing contact with it (Figures 4 and 5).

[0020] A locking ring 60 is disposed between rim 14 and collar 32. Locking ring 60 serves to lock the collar to the rim in the second position. Locking ring 60 includes a proximal end 64, a distal end 62, and an annulus section 66 therebetween. Annulus section 66 preferably displays an inside diameter "G" at least equal to, if not slightly greater than, outside diameter "F" of rim 14 (Figures 2 and 3). Locking ring 60 includes an internally projecting ridge 70 adjacent proximal end 64. A distally facing locking surface 72 is provided on ridge 70. Locking surface 72 is designed to mate with underside portion 18 of rim 14. Locking surface 72 displays an inner diameter "H" which is smaller than outside diameter "F" of rim 14 (Figures 2 and 3).

[0021] Cooperating locking structure is provided between the locking ring and the collar. This locking structure, denoted by numeral 68b for the collar and numeral 68a for the locking ring, can be structured in a variety of manners. Referring to Figures 2 and 6A, locking structure 68a and 68b can take the form of cooperating ratcheting teeth formed about the respective circumferences of sidewall 48 of the collar (68b) and annulus section 66 of the ring (68a). Alternately, as seen in Figure 6, the locking structure can be configured as cooperating threads provided between collar 42 and locking ring 60. Alternate structure can also be envisioned for the locking structure. Regardless, locking structure 68b is preferably placed adjacent proximal end 46 of the collar and locking structure 68a placed adjacent distal end 62 of the ring.

[0022] Connector assembly 30 typically encloses a vial access device 80. Vial access device 80 is structured to pierce stopper 22 so as to gain access to the medicament held by vial 10. While not limited in scope, in general vial access device 80 may feature a body 82 in

frictional engagement with an interior surface 35 associated with tubular section 37 of the collar. A distally facing piercing element 84 is mounted to the body. A connector end 86, attached in fluid communication to piercing element 84, is provided to mount the vial access device to an external component such as a syringe, a rigid bottle, a flexible bottle, or the like. It will be realized by the skilled artisan that piercing element 84 can take various configurations, such as a pointed metallic or plastic needle, a spike, or any pointed structure serving to pierce stopper 22. Similarly, connector end 86 can be configured as a spike (here illustrated), a needle, as a luer connector, or any other desirable configuration to mate with the various external components, such as rigid fluid bottles, luer lock or luer slip syringes, flexible fluid bags, or the like, with which an end user will want to employ with the connector assembly. A protective shield 85 may be placed about connector end 86, particularly desirable when the connector end is configured as a needle.

[0023] Operation of the connector assembly will now be explained, referring principally to Figures 3-5.

[0024] In practice, the pharmaceutical customer would process or otherwise fill a desired medicament in vial 10, thereafter applying stopper 22 to the vial neck. Both of these operations would occur in a cleanroom environment. As illustrated in Figure 3, the component manufacturer would normally supply connector assembly 30 to the pharmaceutical manufacturer in a pre-assembled sterile state, ready to apply to an already stoppered vial.

[0025] As illustrated in Figure 3, in the pre-assembled state, locking ring 60 is positioned respective of collar 42 such that cooperative locking structure 68a, 68b define an unlocked position. That is to say, proximal end 64 of the ring is displaced proximally way from proximal end 46 of the collar, such that the distance "K" between locking surface 72 of ridge 70 and distal end 44 of the collar is at least equal to, if not slightly greater than, the combined thicknesses "B" and "C" of rim 14 and planar portion 24 of the stopper, respectively. Locking structure 68a, 68b retains the ring to the collar. Vial access device 80 is enclosed inside cap 32 and collar 42. Pre-assembled connector assembly 30 is thus placed over vial 10 directly in the cleanroom, with open proximal end 64 of the ring passing around side portion 20 of rim 14.

[0026] Figure 4 illustrates placement of the connector assembly towards its second position relative to vial 10. Here, ridge 70 has been urged over outside portion 20 of the rim, with locking surface 72 facing underside portion 18 of the rim. In this position, it is seen again that distance "K" is still at least equal to, if not slightly greater than, the combined thicknesses "B" and "C" of the rim and planar portion of the stopper. At the same time, ribs 40 provided on collar 42 have descended upon stopper 22 such that they are engaged in sealing contact with planar portion 24. Note that ring 60 continues to be located in an unlocked position relative to collar 42 during this stage.

[0027] Once the connector assembly has been urged to the second position, the connector assembly is "locked" to the vial. As illustrated by Figure 5, locking ring 60 is displaced distally respective of collar 42 (or, viewed in another way, collar 42 is displaced proximally relative to locking ring 60) until a locked position is reached. As shown, locking surface 72 of the ridge is projected distally towards underside portion 18 of the rim. In the embodiment 30 disclosed in Figures 1-5, this operation can occur in the cleanroom through the use, for instance, of an appropriate jig mounted to a conventional vial stoppering machine. The jig will exert a distally directed force on ring 60 and a proximally directed force upon collar 42, effectively "squeezing" ridge 70 and distal end 44 of the collar towards one another until locking surface 72 of the ridge meets underside portion 18 of the rim, and ribs 40 of collar 42 tightly bite into planar portion 24 of stopper 22. A compressive force thus applied between the planar portion the stopper and top surface 16 of vial rim 14. Moreover, sealing ribs 40 are urged to tightly bite into planar portion 24 of the stopper. The effect is that two microbiological barriers are created -- one between the sealing ribs and the planar portion of the stopper, and one between the planar portion of the stopper and the top surface of the rim -- in a uniform manner across the entire planar portion of the stopper. Vial access device 80 is thus secured in microbiological isolation within connectior assembly 30, and stopper 22 tightly sealed to vial 10 so as to isolate the drug held by the vial. Locking structure 68a, 68b between the locking ring and the collar will retain the two in the locked position. Connector assembly 30 is now securely affixed to the vial, and the filled vial may now be removed from the cleanroom and shipped to the end user as desired.

[0028] The squeezing action between ridge 70 and distal end 44 of the collar is enhanced by the "ratcheting" effect created by employing cooperative locking structure configured, for instance, as the ratcheting teeth shown in Figure 6a. That is to say, by employing ratcheting teeth for the cooperative locking structure, connector assembly 30 can more flexibly compensate for any tolerance or dimensional variations in the rim or the stopper, to better ensure that equal sealing forces will be exerted by the collar across the surface of the stopper. This contributes, of course, to a proper seal both between the stopper and the vial rim and between the collar and the stopper. The same benefits can be realized by the threaded cooperative locking structure illustrated in Figure 6.

[0029] To employ the vial, cap 32 is removed from collar 42 so as to expose vial access device 80 While various ways can be configured to so remove the cap, Figures 8A and 8B illustrate forming cap 32 and collar 42 together and providing a frangible section 100 between them. Frangible section 100 permits a user to apply a twisting force to cap 32 so as to remove the cap from the collar to expose vial access device 80. Cap 32 and

collar 42 may be formed together by a co-injection process, wherein a material having a low shear resistance is employed for frangible section 100, and a material having a higher shear resistance is employed for the rest of the cap and the collar. For instance, frangible section 100 can be formed by employing various thermoplastic elastomers ("TPE") displaying low shear resistance, and which display good adhesion properties to the material chosen for the rest of the cap, which typically can be polypropylene or polyethylene.

[0030] As illustrated in Figure 8A, frangible section 100 can be configured as a series of TPE pockets, or "teeth", 110 that are molded into an interior section 112 defined between cap 32 and collar 42. Teeth 110 are interspersed with intervening sections 116 of the section 100, the intervening sections formed from the more shear resistant material that makes up the remainder of cap 32 or collar 42. The resulting frangible section 100 allows a user to exert a moderate twisting force "TF" against the cap to remove it. At the same time, the presence of intervening sections 116 strengthen the frangible section against inadvertent removal of the cap caused, for instance, by jostling during shipment, inadvertent opening by an end user, or the like. Alternately, as illustrated in Figure 8B, if desired, frangible section 100 can be formed as a solid section 120 of TPE material across interior section 112. In any event, by forming cap 32 and collar 42 as a single unit, an additional, potential area for microbiological contamination--the juncture between the cap and the collar--is eliminated, leading to a concomitant reduction in the number of microbiological barriers needed.

[0031] It will also be realized that cap 32 and collar 42 can be formed separately and attached by various means, such as by welding, adhesives, or the like. That will safeguard integrity of the connection between the cap and the collar, but that will provide a reasonable twisting force TF to permit a user to remove the cap. As before, the cap and the collar can be formed from suitable materials, such as polyethylene or polypropylene.

[0032] In use then, cap 32 is removed from collar 42, and vial access device 80 exposed. An external component is attached to connector end 86, and a proximally directed force applied. Piercing element 84 is urged through stopper 22 and into communication with the interior of the vial. Body 82 is slidably disposed with respect to interior surface 35 of collar 42. The engagement between body 82 and interior surface 35 can be by frictional engagement, via mechanical engagement such as by threaded engagement or by a lot and follower arrangement, or by other arrangements within the realm of the skilled artisan. If desired, body 82 can be retained against inadvertent removal from interior surface 35 by providing a stop 88 adjacent a proximal end of body 82 that is arrested by a shoulder 89 inside collar 42.

[0033] Figure 7 illustrates a second embodiment 230 of a connector assembly in accordance with the present invention. In describing this embodiment, like components are described as for embodiment 30 of Figures 1-5 above, except that a prefix "2" is supplied to the numerical designation for those components. Accordingly, detailed description of these like components need not be repeated for embodiment 230.

[0034] Here, connector assembly 230 is substantially as before described, except that a skirt portion 290 is provided on locking ring 260 in an area proximal to internally projecting ridge 270. Skirt 290 displays a length "L" that is at least equal to distance "M" measured between underside portion 218 of the rim and shoulder 221 of the vial The purpose of skirt 290 is to provide a way to more automatically engage locking ring 260 in locked position with collar 242 during placement of the connector assembly to the vial.

[0035] That is to say, as connector assembly 230 is placed over rim 214, proximal end 291 of the skirt will eventually make contact with shoulder 221 of the vial. At that time, skirt 290 will be arrested from further proximal movement respective of rim 214 by a distally directed force exerted by shoulder 221 upon skirt 290. Continued proximal motion of collar 242 and ring 260, thus, will result in locking ring 260 reversing direction respective of collar 242 (because of the distally directed force exerted by the vial upon the skirt), such that internally projecting ridge 270 will be thrust against underside portion 218 of the rim. As before, the cooperating locking structure 268a,b provided between the locking ring and the collar will retain the two in locked position respective of vial 210. As before, connector assembly 230 is supplied to a pharmaceutical manufacturer in a pre-assembled, sterile state, with vial access 280 engaged within cap 232 and collar 242. Also as before, a frangible section (here again denoted by numeral 100) can be incorporated between cap 232 and collar 242.

[0036] The various components can be constructed from materials standard in the art. For example, the cap, the collar, and the ring can be injection molded from various thermoplastics (the construction of the frangible section having been already explained). The vial access device can be made from various medical grade plastics, medical grade stainless steels, combinations of these materials, or the like. Various rubbers or elastomers can be chosen for the stopper, and the vial can be made from suitable glass or plastics materials adapted to the drug held therein. If desired, various tamper evidence means, such as heat shrunk plastic strips, can be incorporated between the vial and the collar.

[0037] It will be appreciated and understood by those skilled in the art that further and additional forms of the invention may be devised without departing from the spirit and scope of the appended claims, the invention not being limited to the specific embodiments shown.

Claims

1. A connector assembly for a vial, said vial including

a neck, an open end at the proximal end of the neck, a rim bounding the open end, and a stopper obturating the open end of the vial, the rim having a side portion and an underside facing away from the open proximal end of the vial, the stopper having a planar portion covering the rim, the connector assembly comprising:

a protective cap for covering the open end of the vial, the cap comprising an open proximal end, a closed distal end, and a shield wall formed therebetween;
a collar provided adjacent the open proximal end of the protective cap, the collar defining a proximal end, a distal end, and a sidewall therebetween, the collar movable between a first position wherein the distal end of the collar is spaced from the stopper, and a second position, wherein the distal end of the collar engages the planar portion of the stopper;
a locking ring provided between the collar and the rim of the vial, the locking ring having an proximal end, a distal end, and an annulus section therebetween, an internally projecting ridge provided at the proximal end of the locking ring; and
cooperative locking structure provided between the collar and the locking ring to retain the locking ring in a locked position respective of the collar,
whereby after the collar is placed in the second position, the locking ring is urged to the locked position, such that the ridge engages the underside portion of the rim to secure the collar in the second position.

2. The connector assembly of claim 1 further comprising a vial access device having a piercing element for piercing the stopper.

3. The connector assembly of claim 2, wherein the vial access device is engaged against an interior portion of the collar.

4. A connector assembly for a vial, said vial including a neck, an open end at the proximal end of the neck, a rim bounding the open end, and a stopper obturating the open end of the vial, the rim having a side portion and an underside facing away from the open proximal end of the vial, the stopper having a planar portion covering the rim, the connector assembly comprising:

a protective cap for covering the open end of the vial, the cap comprising an open proximal end, a closed distal end, and a shield wall formed therebetween;
a collar provided at the open proximal end of the protective cap, the collar having a proximal end, a distal end, and a sidewall therebetween, one or more rib elements provided adjacent the distal end of the collar, the collar movable between a first position wherein the distal end is spaced from the stopper, and a second position, wherein the one or more rib elements engage the planar portion of the stopper;
a locking ring provided between the collar and the rim of the vial, the locking ring having an proximal end, a distal end, and an annulus section therebetween, an internally projecting ridge provided at the proximal end of the locking ring; and
cooperative locking structure provided between the collar and the locking ring to retain the locking ring in a locked position respective of the collar,
whereby after the collar is placed in the second position, the locking ring is urged to the locked position, such that the ridge engages the underside portion of the rim to secure the collar in the second position.

5. The connector assembly of claim 4, further comprising a vial access device having: a body engageable with an interior portion of the collar; a piercing element for piercing the stopper on the vial; and a connector end in fluid communication with the piercing element to connect the vial access device to an external component.

6. The connector assembly of claims 1 or 4, wherein:

the vial includes a shoulder portion, and the locking ring includes a skirt portion located proximally of the ridge, whereby as the collar is urged towards the second position, the skirt portion engages the shoulder of the vial to thrust the locking ring towards the locked position; and/or
the cooperative locking structure comprises one or more cooperative ratcheting teeth provided between the collar and the locking ring or the cooperative locking structure comprises one or more threads provided between the collar and the locking ring.

7. The connector assembly of claims 1, 4 or 6, wherein the cap is molded from a material selected from the group comprising polypropylene or polyethylene, and the cap and the collar include a frangible section between them, with the frangible section being formed from a thermoplastic elastomer.

8. The connector assembly of claims 2 or 5, wherein the connector end of the vial access device is selected from the group comprising a luer connector,

a spike, or a needle.

9. The connector assembly of claims 1 or 4, wherein said cap is affixed to said collar by welding, adhesives, or mechanical means or the collar is integrally formed with the cap.

FIG−1

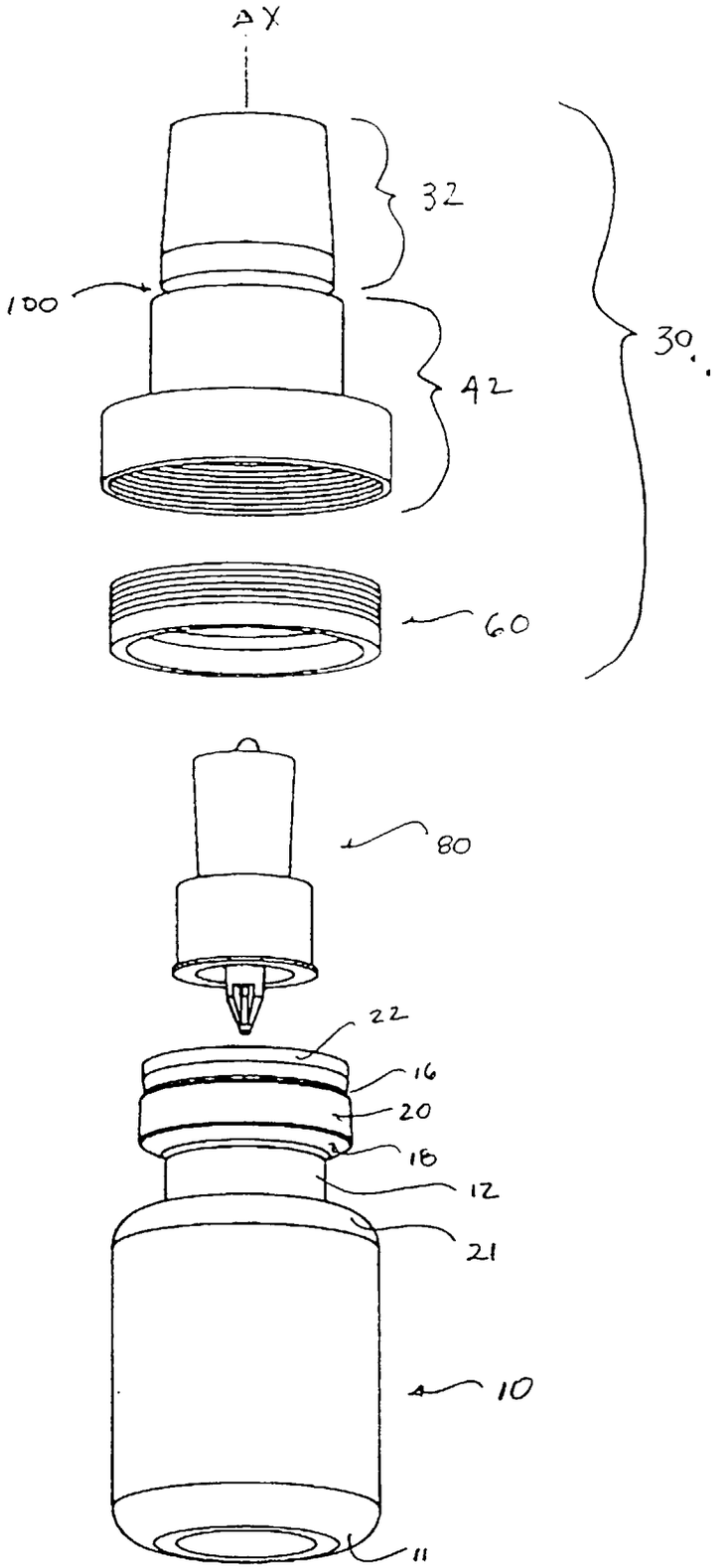


FIG-2

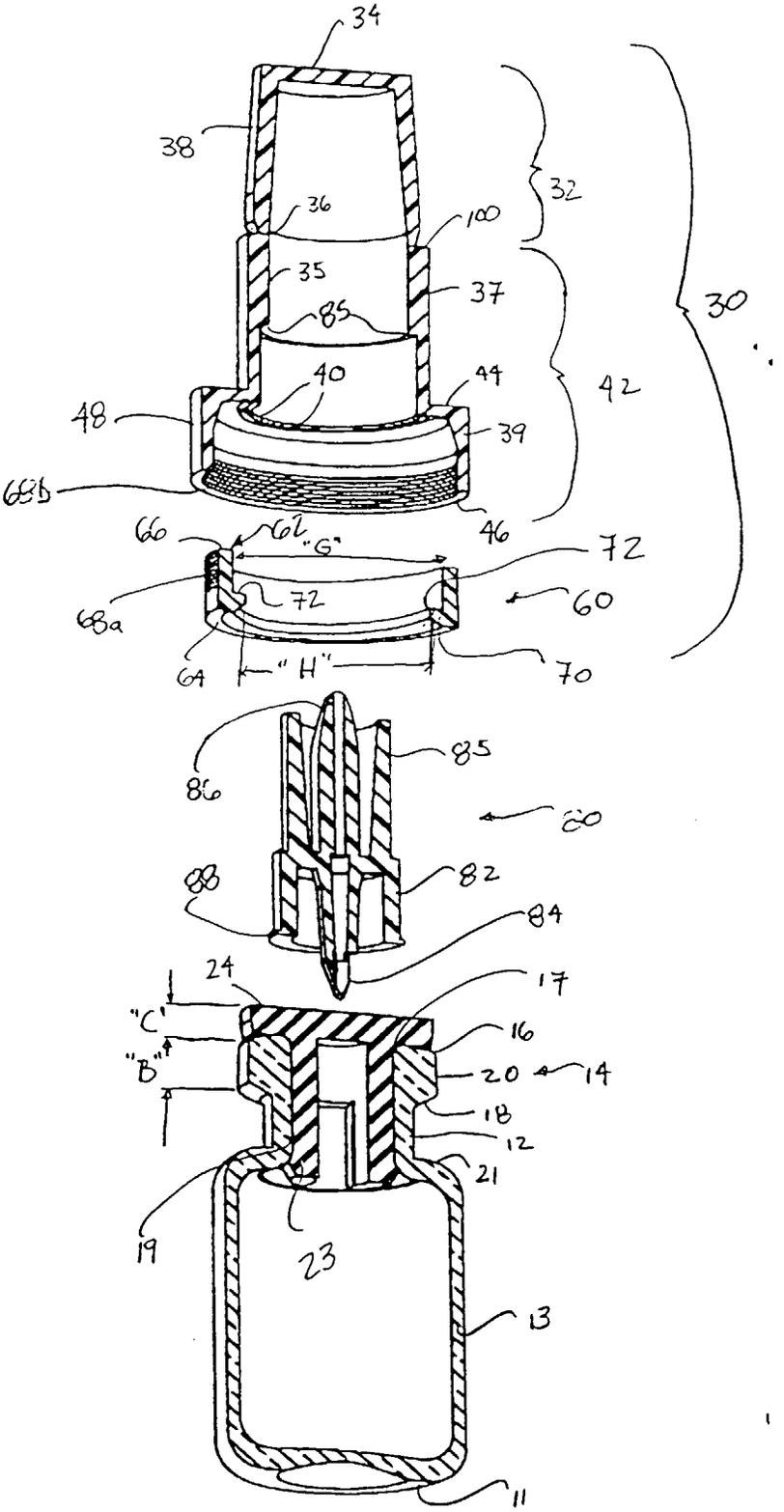
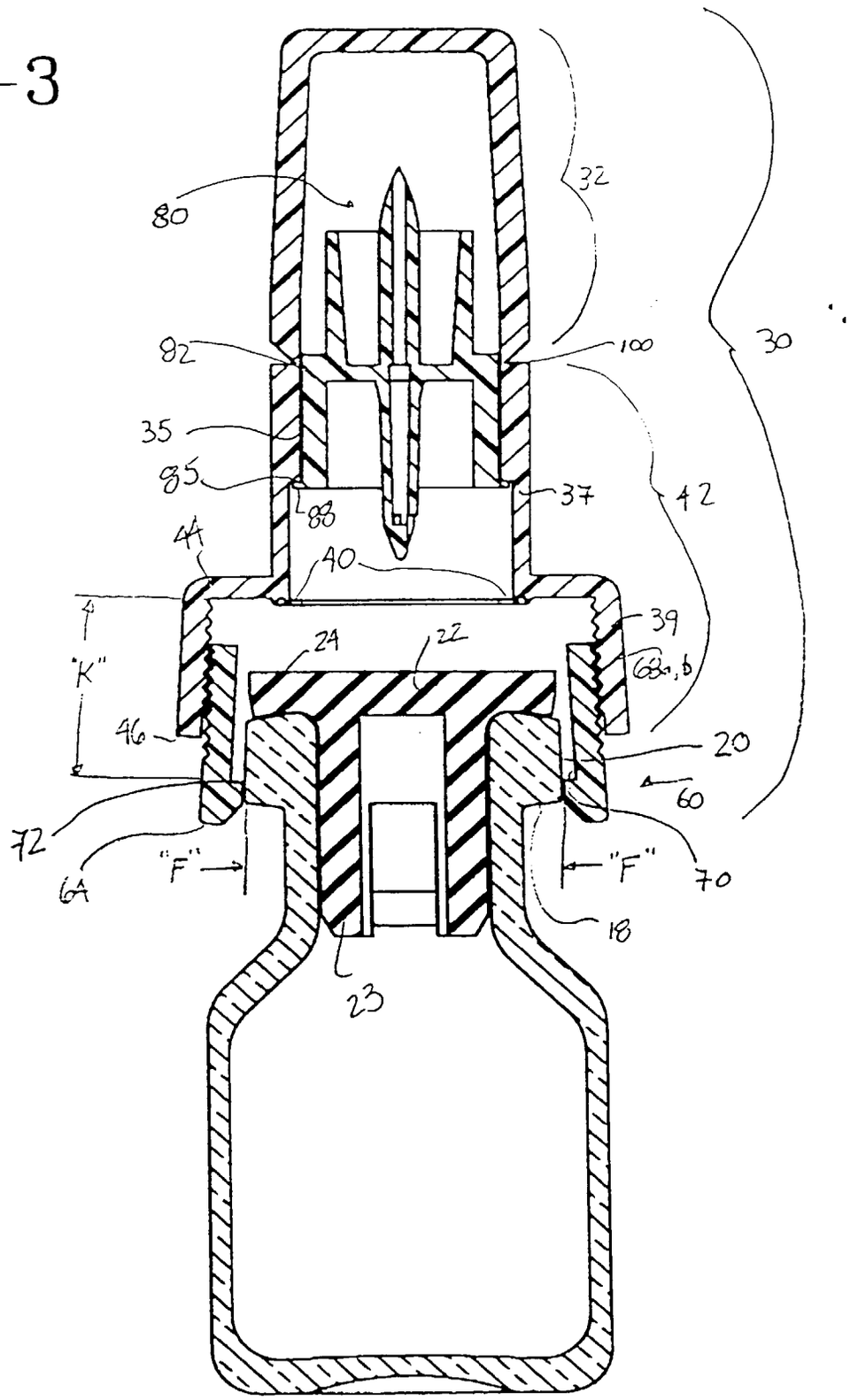

34
38
32
36
100
35
37
30
85
40
44
42
48
39
68b
46
66
62
"G"
72
72
60
68a
64
"H"
70
86
85
80
88
82
84
24
17
"C"
16
"B"
20
14
18
12
21
19
23
13
11

FIG-3


80
32
82
100
30
35
85
37
42
88
44
40
39
24
22
"K"
46
20
60
72
64
"F"
"F"
70
18
23

FIG–4

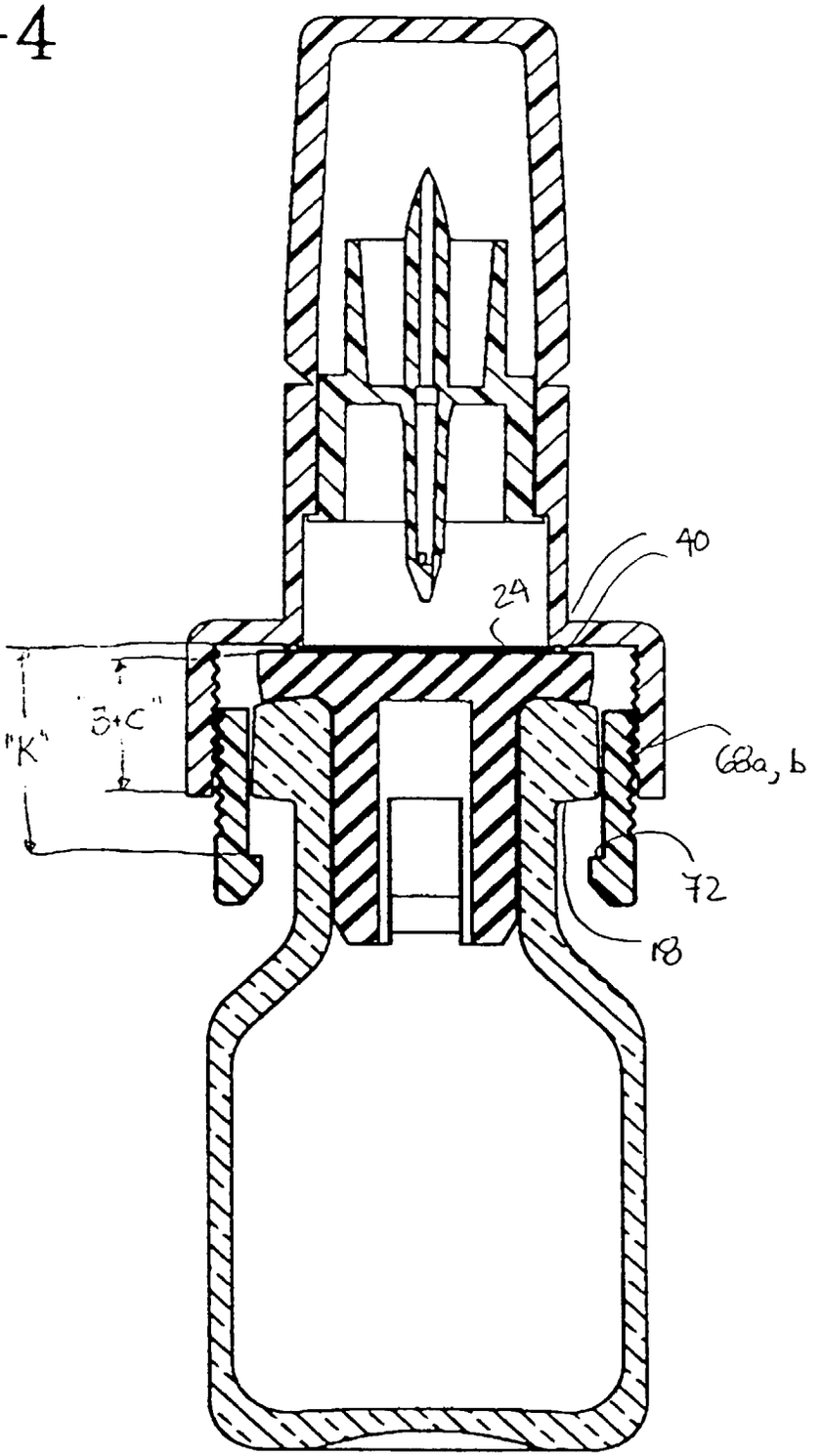


FIG-5

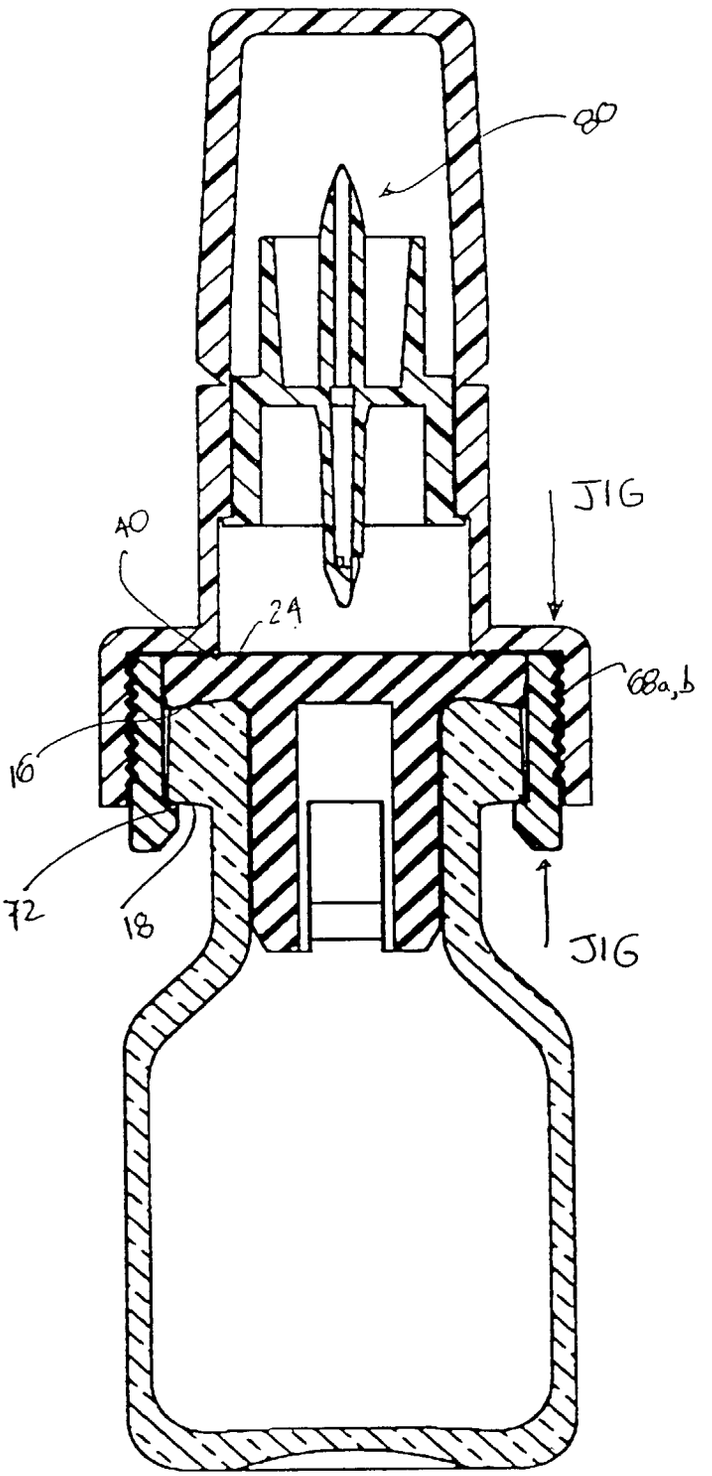


FIG-6

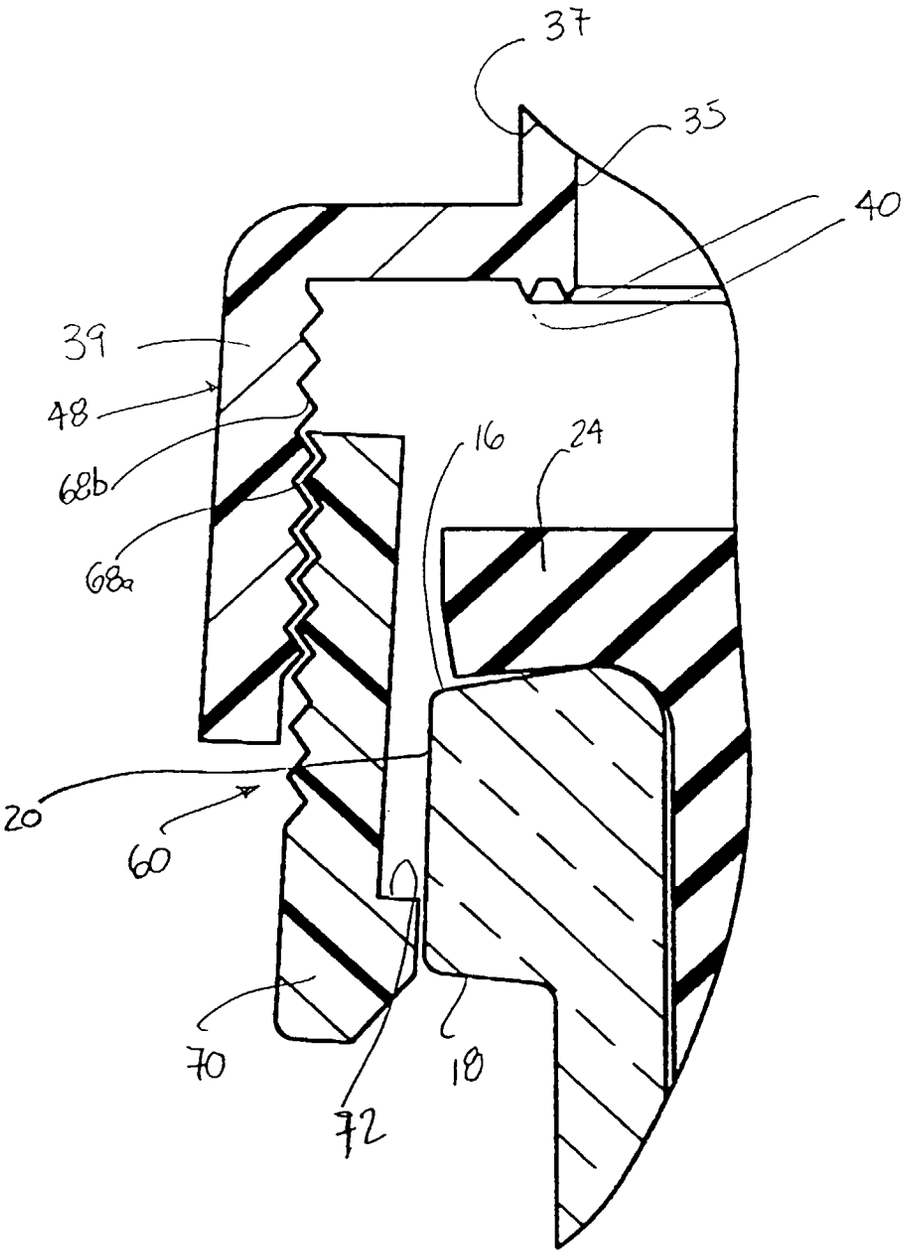


FIG-6a

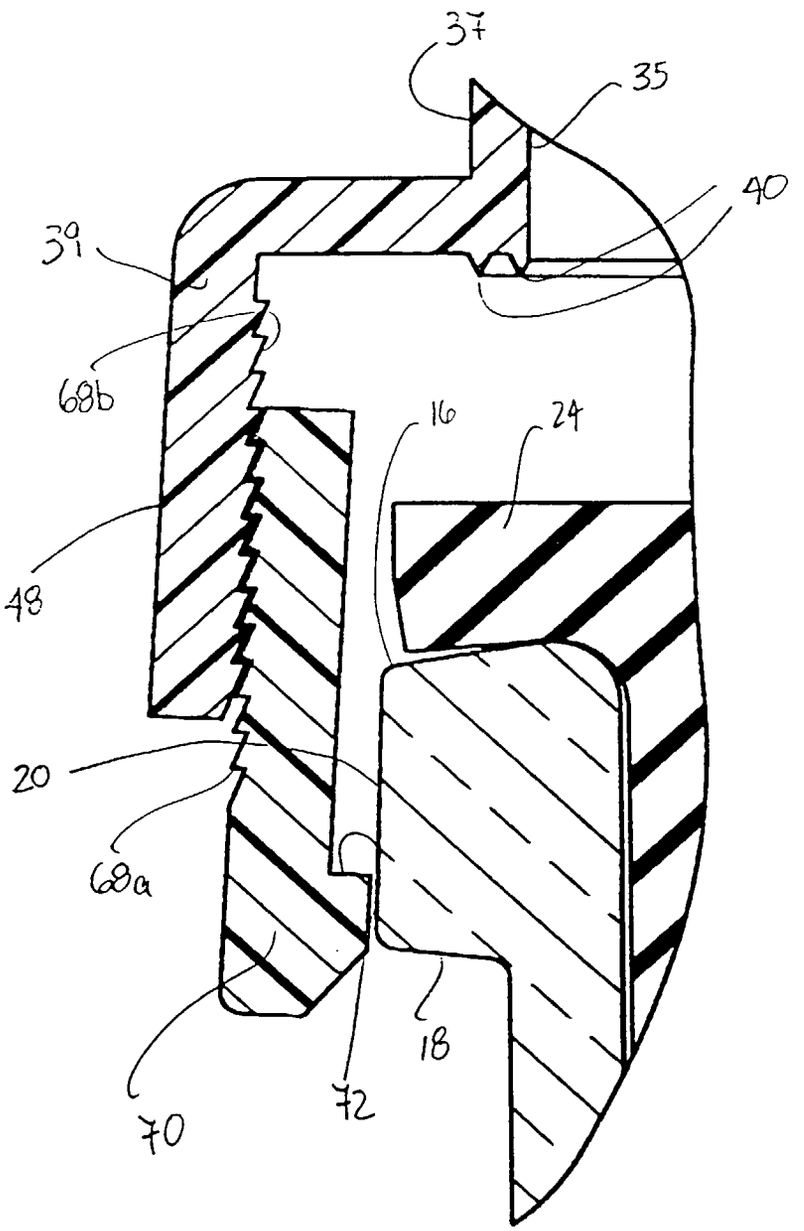


FIG-7

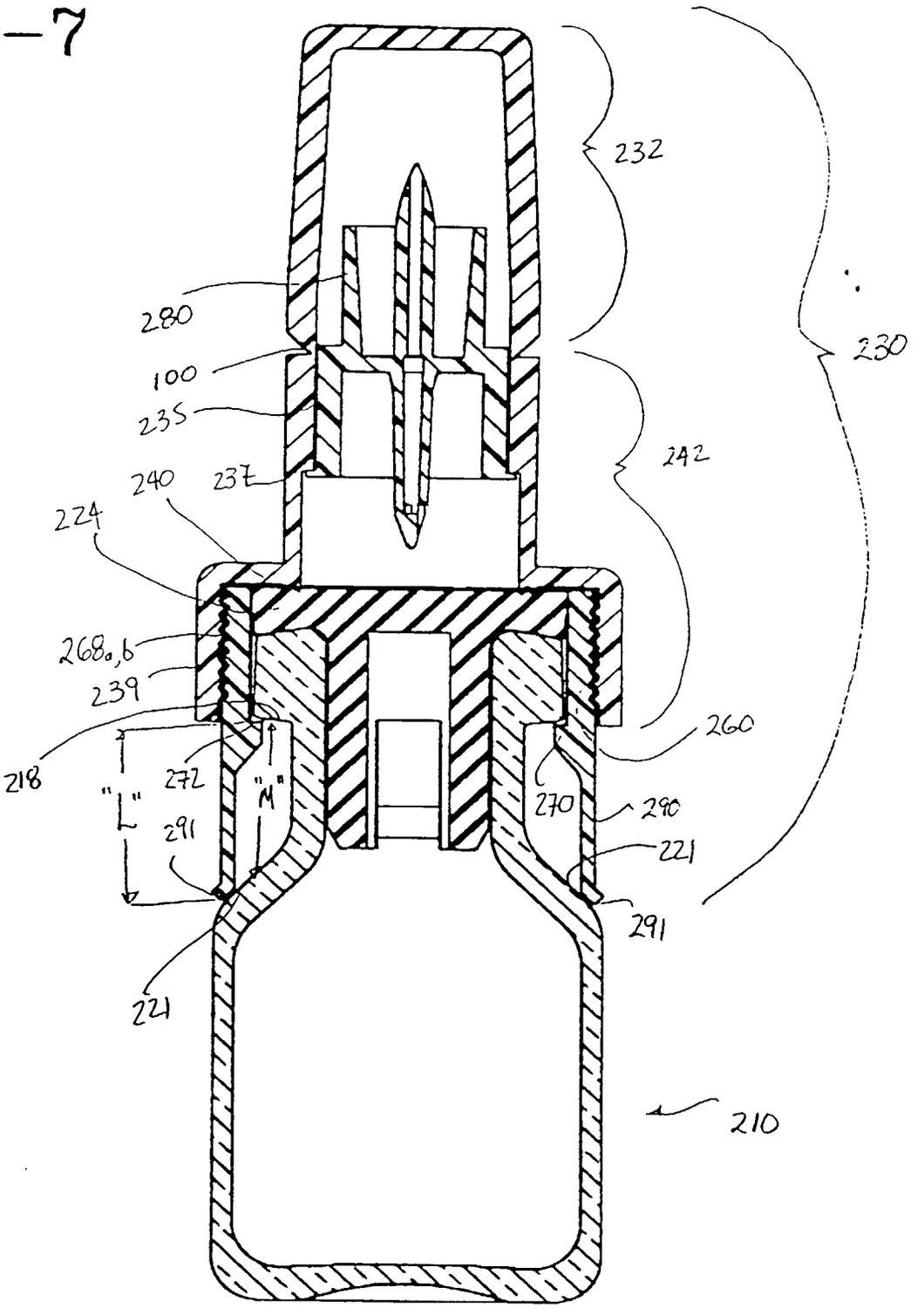

232
230
280
100
235
242
240
237
224
268a,b
239
218
"L"
272
"M"
291
260
270
290
221
291
221
210

FIG-8A

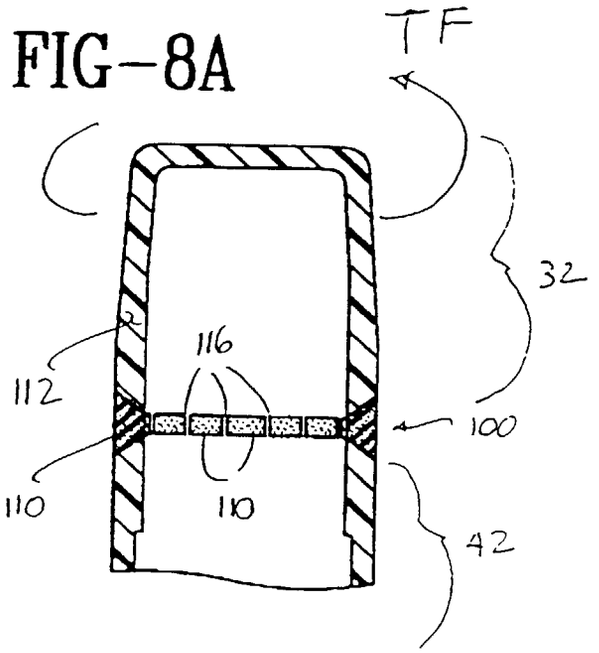


FIG-8B