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(54) **Fluid access assembly and a method for preparing a syringe with a liquid drug**

Zugangsvorrichtung für eine Flüssigkeit und Verfahren um eine Spritze mit einer flüssigen Arznei zu füllen

Dispositif d'accès vers un liquide et méthode pour remplir une seringue avec un médicament liquide

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Description

[0001] The present invention relates to a fluid access assembly as defined in the preamble of claim 1 and a method for preparing a liquid drug.

[0002] In EP 0 637 443, there is illustrated and described a fluid access assembly (10) having a vial access pin (12) and an ampoule access tube (14) for enabling access to a liquid drug contained either in a vial or an ampoule, respectively. The vial access pin (12) has a mounting hub (20) constituted by a female Luer connector, a flange (30) and a cannula (36) with a piercing end and on which the ampoule access tube (14) is sealingly and detachably mounted for aspiration of an ampoule's contents. The fluid access assembly does not facilitate neither the handling nor the discarding of a spent vessel and particularly an ampoule. In particular, it is relatively difficult to slide an opened ampoule's opened end which is of a small cross section area onto the ampoule access tube whilst its attendant exposed sharp edge when opened further militates against convenient use and its discarding when spent.

[0003] In one procedure to prepare a syringe with a liquid drug, a needle is typically attached to an initially empty syringe for insertion into a previously opened ampoule for aspirating its contents therein. Thereafter, the syringe is employed for puncturing a vial's stopper so that the syringe's contents can be injected therein for mixing with the vial's contents. Finally, the vial's contents are aspirated into the syringe for injection to a patient, another vial or a Y-site fitting of an intravenous set. In this procedure, in addition to the above mentioned difficulties, the needle which is required for a subsequent step is often shorter than an ampoule and therefore militates against aspirating all of its contents.

[0004] In accordance with a first aspect of the present invention, there is provided a fluid access assembly for use with a syringe in accordance with claim 1.

[0005] The ampoule adapter of the present invention affords easier handling of an ampoule by virtue of its gripping members which facilitates sliding an ampoule onto its cannula. Additionally, the body portion of the ampoule adapter precludes injury from an opened ampoule's exposed sharp edge during handling and also provides for safer discarding of a spent ampoule together therewith. The fluid access assembly of the present invention can be employed as a universal adapter for use with either an ampoule or a vial and can be employed for mixing liquid drugs in a convenient manner.

[0006] In accordance with a second aspect of the present invention, there is provided a method for preparing a syringe with a liquid drug from one component contained in a vial having a stopper and another component contained in an ampoule having a frangible end and a sealed end, in accordance with claim 9.

[0007] The method of the present invention provides for a convenient preparation of a liquid drug mixed from at least two components by the fluid access assembly

of the present invention thereby affording safer and easier handling of spent parts and in particular a spent ampoule.

[0008] In order to understand the invention and to see how it may be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

10 Fig. 1 is a pictorial view of a vial, an ampoule and an empty syringe for use with a fluid access assembly of the present invention for the preparation of the syringe with a liquid drug;

15 Fig. 2 is a partially cut-away perspective view of the fluid access assembly of Figure 1;

Fig. 3 is a longitudinal cross section view of the ampoule adapter of the fluid access assembly of Figure 1 with an ampoule received therein;

20 Fig. 4 is a longitudinal cross section view of the vial adapter of the fluid access assembly of Figure 1 with a vial received therein;

Figs. 5A-5F show the use of the fluid access assembly of Figure 1;

25 Figs. 6A and 6B are longitudinal cross sectional views of a first embodiment of an ampoule adapter in accordance with the present invention for use with ampoules of different lengths prior to and after insertion of a short ampoule, respectively;

30 Figs. 7A and 7B are longitudinal cross section views of a second embodiment of an ampoule adapter in accordance with the present invention for use with ampoules of different lengths prior to and after insertion of a short ampoule, respectively;

35 Figs. 8A-8C are longitudinal cross section views of a first embodiment of an ampoule adapter in accordance with the present invention for use with ampoules of different diameters prior to insertion of an ampoule, after insertion of a small diameter ampoule and after insertion of a large diameter ampoule, respectively;

40 Figs. 9A and 9B are respectively perspective and end views of a second embodiment of an ampoule adapter in accordance with the present invention for use with ampoules of different diameters after insertion of a small diameter ampoule; and

45 Figs. 9C and 9D are respectively perspective and end views of the ampoule adapter of Figures 9A and 9B after insertion of a large diameter ampoule.

50 **[0009]** In Figure 1, a fluid access assembly 1 includes a vial adapter 2 and an ampoule adapter 3 for preparing a syringe 4 with a liquid drug mixed from a first component stored in a vial 6 having a mouth portion 7 housing a rubber stopper 8 and a second component stored in an ampoule 9 having a frangible end 10 and a sealed end 11. In this case, the vial 6 contains a dry powder, however, it can equally contain a liquid component.

[0010] In Figure 2, the vial adapter 2 has a first can-

nula 12 having a female Luer® connector 13 (constituting a proximal portion) for sealingly receiving a syringe's male Luer® connector and a puncturing member 14 (constituting a distal portion) for piercing the vial's stopper 8. The first cannula 12 has a flange 16 disposed along a central portion thereof, the flange 16 having four resiliently flexible gripping members 17 shaped and dimensioned to snap fit under the vial's mouth portion 7 on the insertion of the vial 6 into the vial adapter 2 (see Figure 4). The first cannula 12 is dimensioned so as to be slightly longer than the thickness of the vial's stopper 8 (see Figure 4) for facilitating aspiration all of the vial's contents.

[0011] The ampoule adapter 3 has a tubular shroud 18 constituting a body portion and attached to a second cannula 19 having a proximal portion 19A and a distal portion 19B terminating in a V-shaped tip 21, the shroud 18 having a flange 22 with a downward depending rim 23 substantially co-directional with the second cannula 19. Two pairs of oppositely disposed gripping members 24 downwardly depend from the rim 23 and are co-directional with the second cannula 19. The ampoule adapter 3 is longitudinally dimensioned to receive substantially the entire opened ampoule 6 when fully inserted therein i.e. when further insertion is prevented by the cannula tip 21 abutting against the ampoule's sealed end 11. On such insertion, the ampoule's opened end is received in the shroud 18 and the gripping members 24 friction fit grip substantially its entire periphery (see Figure 3).

[0012] In the assembled state of the fluid access assembly 1, the ampoule adapter 3 is detachably mounted on the vial adapter 2 by means of its second cannula's proximal portion 19A being initially sealingly and detachably mounted on the puncturing member 14.

[0013] The use of the fluid access assembly 1 for preparing an initially empty syringe with a reconstituted drug is now described with reference to Figures 5A-5F. The syringe 4 is inserted into the ampoule adapter's female Luer® connector 13 (see Figure 5A). The ampoule 9 is broken open and fully slid up the second cannula 19 until the cannula's tip 21 abuts against its sealed end 11 whereby its opened end 10 is contained within the ampoule adapter's shroud 18 and its lower portion is gripped by the gripping members 24 (see Figure 5A). The ampoule's contents are aspirated into the syringe 4 (see Figure 5B). The ampoule adapter 3 is detached from the vial adapter 2 together with the spent ampoule 9 and discarded (see Figure 5C). The vial 6 is positively inserted into the vial adapter 2 so that its puncturing member 14 punctures the vial's stopper 8 (see Figure 5D). The syringe's contents are injected into the vial 6 which is then shaken so as to reconstitute the dry powder concentrate contained therein. The reconstituted drug is aspirated into the syringe 4 which is then removed from the vial adapter 2 which is then discarded together with the spent vial 6.

[0014] While the invention has been described with

respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention can be made by those ordinarily skilled in the art.

[0015] In particular, an ampoule adapter can have a telescopic second cannula whereby it is suitable for use with ampoules of different lengths. In particular, Figures 6A and 6B show an ampoule adapter 26 having a second cannula 27 with a proximal portion 27A rigidly attached to its shroud 18 and a distal portion 27B slidingly mounted on the proximal portion 27A, the distal portion 27B being initially extendingly mounted on the proximal portion 27A for sliding up thereon on the full insertion of a short ampoule 28 into the ampoule adapter 26. In a similar fashion, Figures 7A and 7B show an ampoule adapter 29 having a second cannula 31 with an initially extended compressible bellows-like portion 31A whereupon the bellows-like portion 31A is at least partly compacted on the full insertion of the short ampoule 28 into the ampoule adapter 29.

[0016] In addition, an ampoule adapter has gripping members which can be suitable for use with ampoules of different widths. In particular, Figures 8A-8C show an ampoule adapter 32 with gripping members 33 each having a lower portion 33A movable from a normal inwardly radially disposed state toward the second cannula 19 for gripping a small diameter ampoule 34 (see Figure 8B) to a flexed outwardly radially disposed state for gripping a large diameter ampoule 36 (see Figure 8C). Alternatively, Figures 9A-9D shows an ampoule adapter 37 with gripping members 38 each having a flange portion 38A substantially co-extensive therewith and resiliently foldable from a normally inwardly radially disposed state for gripping the small diameter ampoule 34 (see Figures 9A and 9B) to a flexed circumferentially disposed state for gripping the large diameter ampoule 36 (see Figures 9C and 9D).

[0017] In connection with the second aspect of the present invention, the syringe can initially contain a liquid drug component whilst the ampoule can contain a dry powder. In addition, rather than the syringe being removed from the vial adapter, the spent vial can be removed whereby the vial adapter can then be inserted into another vial or a Y-site fitting of an intravenous set

Claims

1. A fluid access assembly (1) for use with a syringe (4), for a vial (6) having a stopper (8) or an ampoule (9, 28, 34, 36) with a frangible end (10) and a sealed end (11), the assembly comprising:

a vial adapter (2) having a first cannula (12) with proximal portion (13) for sealingly receiving the syringe and a distal portion (14) for puncturing the vial's stopper; and

an ampoule adapter (3, 26, 29, 32, 37) having a second cannula (19, 27, 31) with a proximal portion (19A) initially sealingly and detachably mounted around said first cannula distal portion, said second cannula being dimensioned to abut against the sealed end of the previously opened ampoule on the ampoule's sliding onto said second cannula thereby enabling aspiration of its contents into the syringe,

characterised in

said ampoule adapter (3) having a body portion (18) with at least one pair of oppositely disposed gripping members (24, 33, 38) co-directional with said second cannula for respectively receiving the ampoule's opened end therein and gripping opposite sides of at least the ampoule's lower portion towards its sealed end on said sliding.

2. The assembly according to claim 1 wherein said body portion is tubular and includes a downward depending rim (23) co-directional with said second cannula for receiving the ampoule's opened end therein.
3. The assembly according to either claim 1 or 2 wherein said ampoule adapter has a plurality of gripping members for gripping substantially the entire periphery of an ampoule.
4. The assembly according to any one of claims 1-3 wherein said second cannula (27, 29) is telescopic.
5. The assembly according to claim 4 wherein said ampoule adapter (26) comprises the second cannula (27) with a proximal portion (27A) rigidly connected to said tubular body portion and a distal portion (27B) slidably mounted on the proximal portion, said distal portion being initially extendibly mounted on said proximal portion whereby the distal portion is urged towards said proximal portion on said sliding of a short ampoule.
6. The assembly according to claim 4 wherein said second cannula (29) includes an initially extended compressible bellows-like portion (29A) at least partially compacted on said sliding of a short ampoule.
7. The assembly according to an one of the claims 1-6 wherein a gripping member (33) has a lower portion (33A) remote from said body portion outwardly urgeable from a normal inwardly radially disposed state for gripping a small diameter ampoule (34) to a flexed outwardly radially disposed state for gripping a large diameter ampoule (36).
8. The assembly according to any one of claims 1-6

wherein a gripping member (38) has a flange portion (38A) co-extensive therewith and resiliently foldable from a normally inwardly radially disposed state for gripping a small diameter ampoule (34) to a flexed circumferentially disposed state for gripping a large diameter ampoule (36).

9. A method for preparing a syringe (4) with a liquid drug from a first component contained in a vial (2) having a stopper (8) and a second component contained in an ampoule (9, 28, 34, 36) having a frangible end (10) and a sealed end (11), the method comprising the following steps:

- (a) providing a vial adapter (2) having a first cannula (12) with a proximal portion (13) for sealingly receiving the syringe and a distal portion (14) for puncturing the vial's stopper, and an ampoule adapter (3, 26, 28, 32, 37) having a second cannula (19, 27, 31) with a proximal portion (19A) initially sealingly and detachably mounted on first cannula distal portion; said ampoule adapter includes at least one pair of oppositely disposed gripping members (24, 33, 38) co-directional with the second cannula for facilitating insertion of the second cannula into the ampoule and gripping opposite sides of at least the ampoule's lower portion towards its sealed end;
- (b) sliding a previously opened ampoule onto the second cannula;
- (c) connecting the syringe to the first cannula's proximal portion;
- (d) aspirating the ampoule's contents into the syringe;
- (e) detaching the ampoule adapter from the vial adapter;
- (f) inserting the vial into the vial adapter so as to puncture its stopper;
- (g) injecting the syringe's contents into the vial;
- (h) mixing the syringe's contents with the vial's contents; and
- (i) aspirating the vial's contents into the syringe.

10. The method according to claim 9 wherein the second cannula is dimensioned to abut against the sealed end of the previously opened ampoule on the ampoule's insertion thereinto.
11. The method according to any one of the claims 9 or 10 wherein said ampoule adapter includes a body portion (18) for receiving at least the ampoule's opened end therein.
12. The method according to any one of the claims 9 to 11 wherein said vial adapter (2) includes resiliently flexible gripping members (17) for snap fitting under the vial's mouth portion on positively inserting the

vial into the vial adapter.

Patentansprüche

1. Flüssigkeits-Zugriffseinheit (1) zur Verwendung mit einer Spritze (4) für ein Fläschchen (6) mit einem Verschluss (8) oder eine Ampulle (9, 28, 34, 36) mit einem abbrechbaren Ende (10) und einem abgedichteten Ende (11), wobei die Einheit umfasst:
- einen Fläschchenadapter (2) mit einer Kanüle (12) mit einem naheliegenden Bereich (13) zum abdichtenden Aufnehmen der Spritze und einem entfernten Bereich (14) zum Einstechen in den Verschluss des Fläschchens; und
- einen Ampullenadapter (3, 26, 29, 32, 37), der eine zweite Kanüle (19, 27, 31) mit einem naheliegenden Bereich (19A), der unmittelbar abdichtend und entfernbar um den entfernten Bereich der ersten Kanüle montiert ist, wobei die zweite Kanüle so dimensioniert ist, dass sie an das abgedichtete Ende der vorher geöffneten Ampulle anstößt, wenn die Ampulle auf die zweite Kanüle aufgleitet, wodurch ein Ansaugen ihrer Inhaltsstoffe in die Spritze möglich wird, **dadurch gekennzeichnet, dass** der Ampullenadapter (3) einen Körperbereich (18) mit mindestens einem Paar gegenüberliegend angeordneter Greifelemente (24, 33, 38) aufweist, die sich mit der zweiten Kanüle co-erstrecken, um jeweils das geöffnete Ende der Ampulle aufzunehmen und gegenüberliegende Seiten von mindestens dem unteren Bereich der Ampulle in Richtung auf das abgedichtete Ende während des Gleitens ergreifen.
2. Einheit nach Anspruch 1, wobei der Körperbereich rohrförmig ist und einen sich nach unten erstreckenden Steg (23) aufweist, der sich in gleicher Richtung wie die zweite Kanüle zum Aufnehmen des geöffneten Endes der Ampulle erstreckt.
3. Einheit nach Anspruch 1 oder 2, wobei der Ampullenadapter eine Vielzahl von Greifteilen zum Ergreifen im Wesentlichen des gesamten Umfangs einer Ampulle aufweist.
4. Einheit nach einem der Ansprüche 1 bis 3, wobei die zweite Kanüle (27, 29) teleskopisch ausgebildet ist.
5. Einheit nach Anspruch 4, wobei der Ampullenadapter (26) die zweite Kanüle (27) umfasst, wobei ein naher Bereich (27A) fest mit dem rohrförmigen Körperbereich und ein entfernter Bereich (27B) gleitend auf dem nahen Bereich montiert ist, wobei der
- entfernte Bereich zunächst verlängerbar an dem nahen Bereich montiert ist, wobei der entfernte Bereich in Richtung auf den nahen Bereich beim Gleiten einer kurzen Ampulle gedrückt wird.
6. Einheit nach Anspruch 4, wobei die zweite Kanüle (29) einen anfänglich verlängerten, zusammendrückbaren, faltenbalgähnlichen Bereich (29a) enthält, der mindestens teilweise beim Gleiten einer kurzen Ampulle zusammengedrückt wird.
7. Einheit nach einem der Ansprüche 1 bis 6, wobei ein Greifteil (33) einen unteren Bereich (33a) entfernt vom Körperbereich aufweist, der von einem normalerweise innenliegenden, radial angeordneten Zustand zum Ergreifen einer Ampulle (34) mit kleinem Durchmesser nach außen in einen nach außen gebogenen, radial angeordneten Zustand zum Ergreifen einer Ampulle (36) mit großem Durchmesser drückbar ist.
8. Einheit nach einem der Ansprüche 1 bis 6, wobei ein Greifteil (38) einen Flanschbereich (38A) aufweist, die sich in die gleiche Richtung erstrecken, und flexibel faltbar ist von einem normalerweise innenliegenden, radial angeordneten Zustand zum Ergreifen einer Ampulle (34) mit kleinem Durchmesser in einen gebogenen, in Umfangsrichtung angeordneten Zustand zum Ergreifen einer Ampulle (36) mit großem Durchmesser.
9. Verfahren zum Vorbereiten einer Spritze (4) mit einem flüssigen Arzneimittel aus einer ersten Komponente, die in einem Fläschchen (2) enthalten ist, das einen Verschluss (8) umfasst, und einer zweiten Komponente, die in einer Ampulle (9, 28, 34, 36) mit einem abbrechbaren Ende (10) und einem abgedichteten Ende (11) enthalten ist, wobei das Verfahren die folgenden Schritte umfasst:
- (a) Vorbereiten eines Fläschchenadapters (2) mit einer ersten Kanüle (12) mit einem nahen Bereich (13) zum abdichtenden Aufnehmen der Spritze und einem entfernten Bereich (14) zum Punktieren des Verschlusses des Fläschchens, und einen Ampullenadapter (3, 26, 28, 32, 37) mit einer zweiten Kanüle (19, 27, 31) mit einem nahen Bereich (19a), der anfänglich abdichtend und entfernbar am entfernten Bereich der ersten Kanüle montiert ist; wobei der Ampullenadapter mindestens ein Paar gegenüberliegend angeordneter Greifteile (24, 33, 38) aufweist, die sich in die gleiche Richtung wie die zweite Kanüle erstrecken zum Erleichtern des Einsetzens der zweiten Kanüle in die Ampulle und zum Ergreifen gegenüberliegender Seiten von mindestens dem unteren Bereich der Ampulle in Richtung auf ihr abgedich-

tetes Ende;

(b) Schieben einer vorher geöffneten Ampulle auf die zweite Kanüle;

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(c) Verbinden der Spritze mit dem nahen Bereich der ersten Kanüle;

(d) Ansaugen des Inhalts der Ampulle in die Spritze;

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(e) Abnehmen des Ampullenadapters vom Fläschchenadapter;

(f) Einsetzen des Fläschchens in den Fläschchenadapter, so dass sein Verschluss punktiert wird;

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(g) Einspritzen des Inhalts der Spritze in das Fläschchen;

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(h) Mischen der Inhaltsstoffe der Spritze mit den Inhaltsstoffen des Fläschchens; und

(i) Ansaugen der Inhaltsstoffe des Fläschchens in die Spritze.

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10. Verfahren nach Anspruch 9, wobei die zweite Kanüle so bemessen ist, dass sie an dem abgedichteten Ende der vorab geöffneten Ampulle beim Einsetzen der Ampulle anstößt.

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11. Verfahren nach einem der Ansprüche 9 oder 10, wobei der Ampullenadapter einen Körperbereich (18) zum Aufnehmen mindestens des geöffneten Endes der Ampulle aufweist.

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12. Verfahren nach einem der Ansprüche 9 bis 11, wobei der Fläschchenadapter (2) federnd flexible Greifteile (17) für einen Schnappsitz unter dem Maulbereich des Fläschchens aufweist nachdem das Fläschchen positiv in den Fläschchenadapter eingesetzt wurde.

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Revendications

1. Un ensemble d'accès à un fluide (1) pour utilisation avec un seringue (4), pour un flacon (6) munie d'un bouchon (8) ou d'une ampoule (9, 28, 34, 36) munie d'une extrémité (10) fracturable et d'une extrémité (11) sous scellée hermétiquement, l'ensemble comprenant :

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- un adaptateur de flacon (2) muni d'une première canule (12) ayant une partie proximale (13) pour recevoir de façon étanche la seringue, et une partie distale (14) pour perforer le bouchon

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de flacon ; et

- un adaptateur d'ampoule (9, 26, 29, 32, 37) ayant une deuxième canule (19, 27, 31) munie d'une partie proximale (19A) qui, initialement, est montée de façon étanche et détachable autour de ladite première partie distale de canule, ladite deuxième canule étant dimensionnée pour venir buter contre l'extrémité, scellée de façon étanche, de l'ampoule antérieurement ouverte lors du coulisement de l'ampoule sur ladite deuxième canule, de manière à permettre l'aspiration de son contenu à l'intérieur de la seringue,

caractérisé en ce que :

ledit adaptateur d'ampoule (3) est muni d'une partie formant corps (18) avec au moins une paire d'éléments de saisie (24, 33, 38) disposés de façon opposée, co-directionnelle avec ladite deuxième canule, pour recevoir respectivement en son sein l'extrémité ouverte de l'ampoule et saisir les faces opposées d'au moins une partie inférieure de l'ampoule, en direction de son extrémité scellée lors dudit coulisement.

2. L'ensemble selon la revendication 1, dans lequel ladite partie formant corps est tubulaire et comprend une bordure (23) dépendant vers le bas, co-directionnelle envers ladite deuxième canule, afin de recevoir en son sein l'extrémité ouverte de l'ampoule.

3. L'ensemble selon la revendication 1 ou 2, dans lequel ledit adaptateur d'ampoule comporte une pluralité d'éléments de saisie, devant saisir pratiquement la totalité de la périphérie d'une ampoule.

4. L'ensemble selon l'une quelconque des revendications 1 à 3, dans lequel ladite deuxième canule (27; 29) est télescopique.

5. L'ensemble selon la revendication 4, dans lequel ledit adaptateur d'ampoule (26) comprend la deuxième canule (27) avec une partie proximale (27A) reliée rigidement à ladite partie formant corps tubulaire, et une partie distale (27B) montée à coulisement sur la partie proximale, ladite partie distale étant initialement montée de façon extensible sur ladite partie proximale, de manière que la partie distale soit déplacée vers ladite partie proximale lors dudit coulisement d'une ampoule courte.

6. L'ensemble selon la revendication 4, dans lequel ladite deuxième canule (29) comprend une partie en soufflet (29A) compressible, initialement déployée, au moins partiellement compactée lors dudit coulisement d'une ampoule courte.

7. L'ensemble selon l'une des revendications 1 à 6,

dans lequel un élément de saisie (33) a une partie inférieure (33A) distante de ladite partie formant corps, déplaçable vers l'extérieur depuis un état normal disposé radialement à l'intérieur, pour saisir une ampoule (34) de petit diamètre, à un état fléchi, disposé radialement à l'extérieur, pour saisir une ampoule (36) de grand diamètre.

8. L'ensemble selon l'une quelconque des revendications 1 à 6, dans lequel un élément de saisie (38) a une partie formant bride (38A) s'étendant conjointement avec lui et repliable élastiquement d'un état normal, disposé radialement intérieurement pour saisir une ampoule (34) de petit diamètre, à un état fléchi, disposé circonférentiellement pour saisir une ampoule (36) de grand diamètre.

9. Un procédé de préparation d'une seringue (4) avec un médicament liquide à partir d'un premier composant contenu dans un flacon (2) muni d'un bouchon (8), et d'un deuxième composant contenu dans une ampoule (9, 28, 34, 36) ayant une extrémité (10) fracturable et une extrémité (11) scellée, le procédé comprenant les étapes suivantes :

(a) fourniture d'un adaptateur de flacon (2) ayant une première canule (12) munie d'une partie proximale (13) pour recevoir de façon étanche la seringue, et une partie distale (14) pour perforer le bouchon du flacon, et un adaptateur d'ampoule (3, 26, 28, 32, 37) ayant une deuxième canule (19, 27, 31) munie d'une partie proximale (19A) qui, initialement, est montée de façon étanche et détachable sur la partie distale de la première canule; ledit adaptateur d'ampoule comprend au moins une paire d'éléments de saisie (24, 33, 38) disposés de façon opposée, co-directionnels avec la deuxième canule, afin de faciliter l'insertion de la deuxième canule dans l'ampoule et saisir des faces opposées d'au moins une partie inférieure de l'ampoule en direction de son extrémité fermée de façon étanche;

(b) faire coulisser une ampoule antérieurement ouverte sur la deuxième canule;

(c) relier la seringue à la partie proximale de la première canule;

(d) aspirer le contenu de l'ampoule et l'introduire dans la seringue;

(e) détacher l'adaptateur d'ampoule installé sur l'adaptateur de flacon;

(f) insérer le flacon dans l'adaptateur de flacon de façon à perforer son bouchon;

(g) injecter le contenu de la seringue dans le flacon;

(h) mélanger le contenu de la seringue avec le contenu du flacon; et

(i) aspirer le contenu du flacon dans la serin-

gue.

10. Le procédé selon la revendication 9, dans lequel la deuxième canule est dimensionnée pour venir buter contre l'extrémité fermée de façon étanche de l'ampoule antérieurement ouverte lors de l'insertion de l'ampoule dans celle-ci.

11. Le procédé selon l'une quelconque des revendications 9 à 10, dans lequel ledit adaptateur d'ampoule comprend une partie formant corps (18) pour recevoir en son sein au moins l'extrémité ouverte de l'ampoule.

12. Le procédé selon l'une quelconque des revendications 9 à 11, dans lequel ledit adaptateur de flacon comprend des éléments de saisie (17) flexibles élastiquement prévus pour un montage par encliquetage sous la partie d'embouchure du flacon, lors de l'opération d'insertion positive du flacon dans l'adaptateur du flacon.

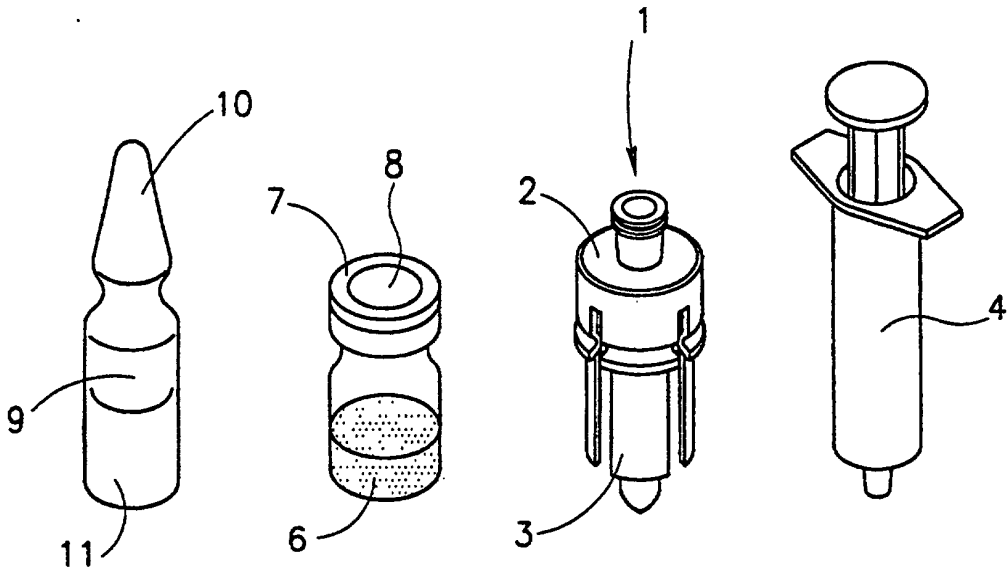


FIG. 1

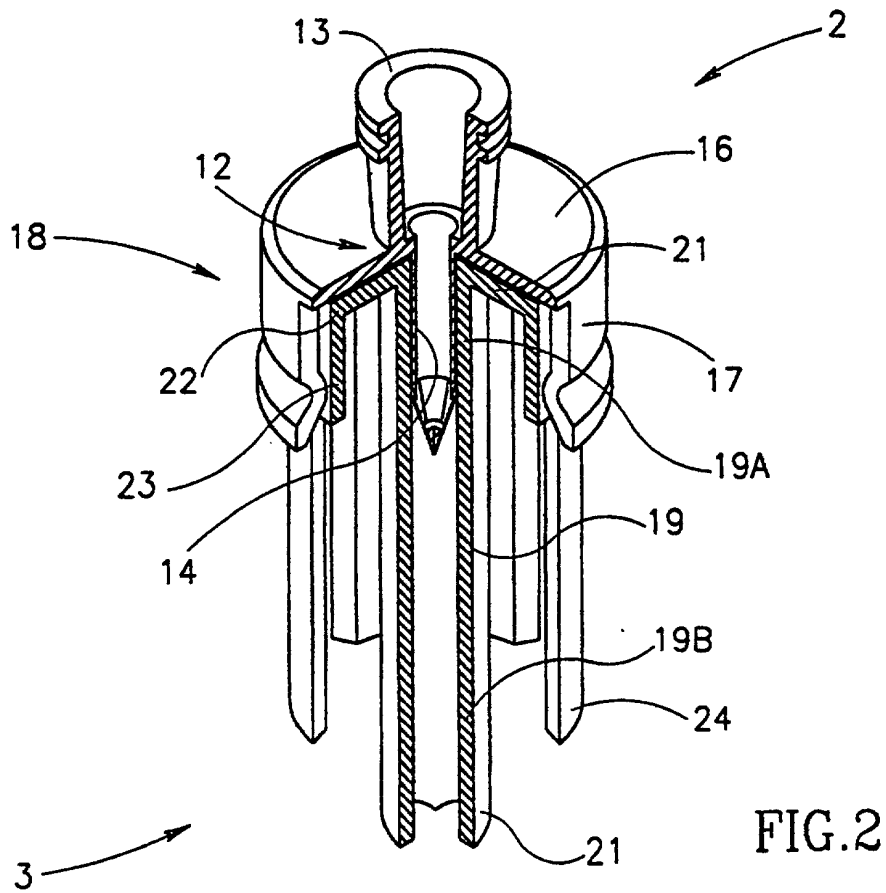


FIG. 2

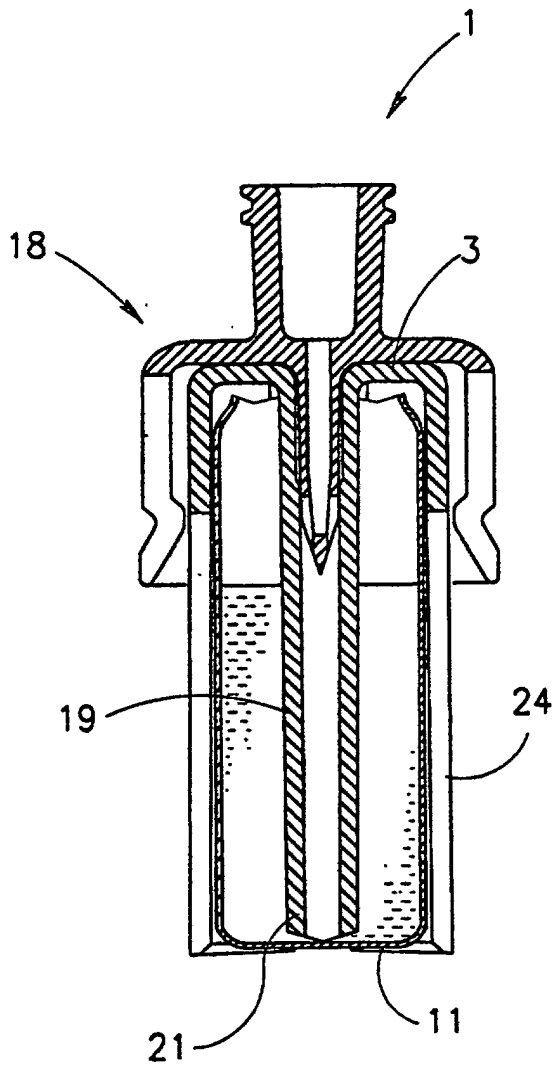


FIG. 3

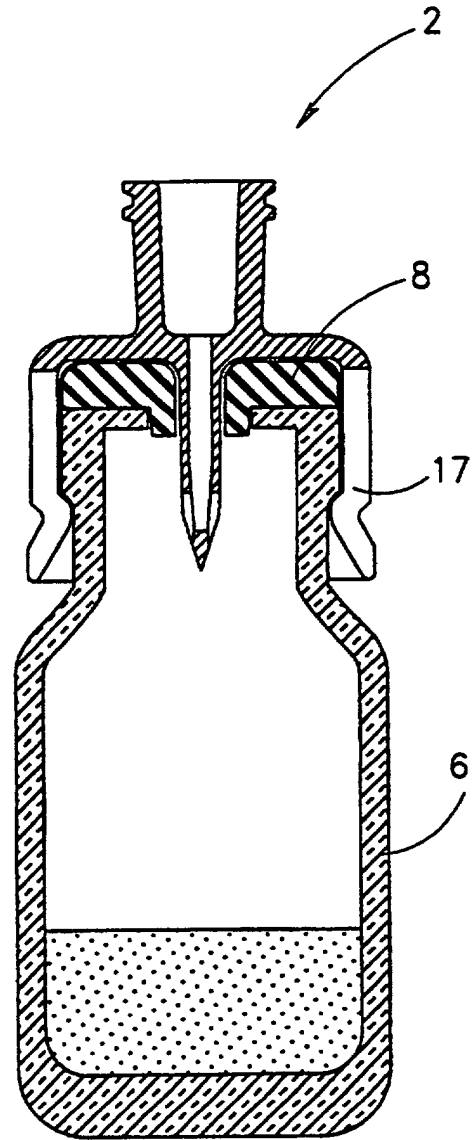
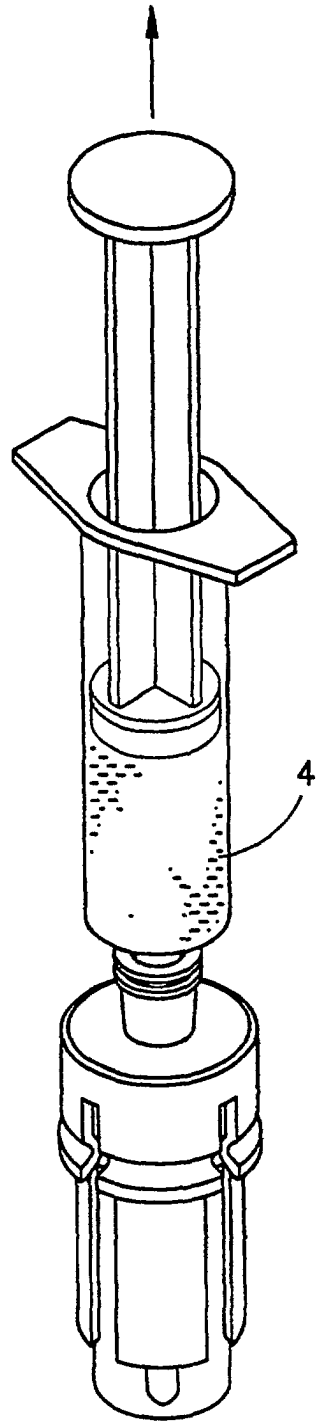
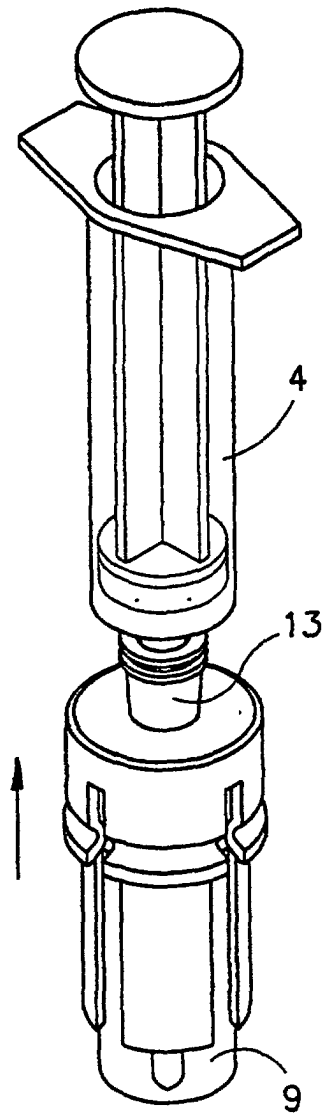


FIG. 4



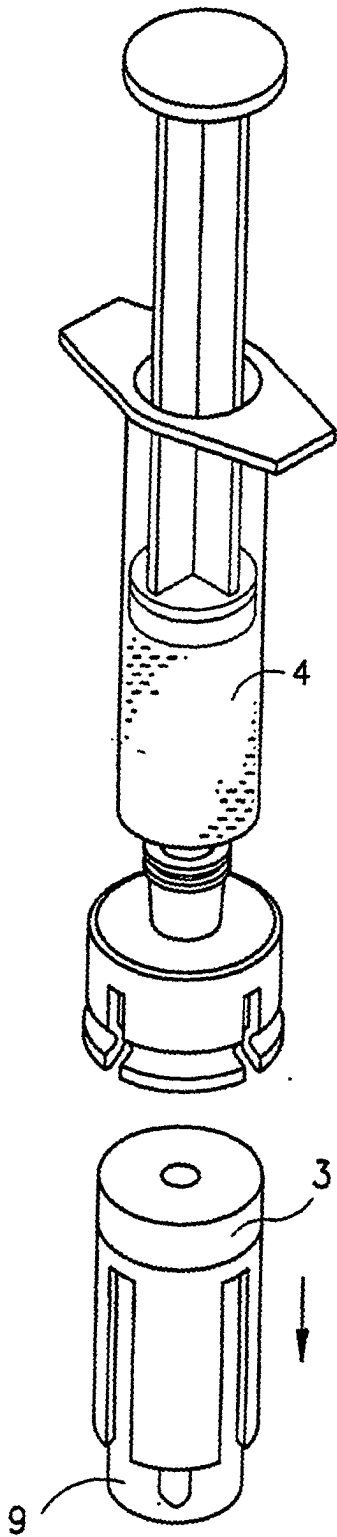


FIG. 5C

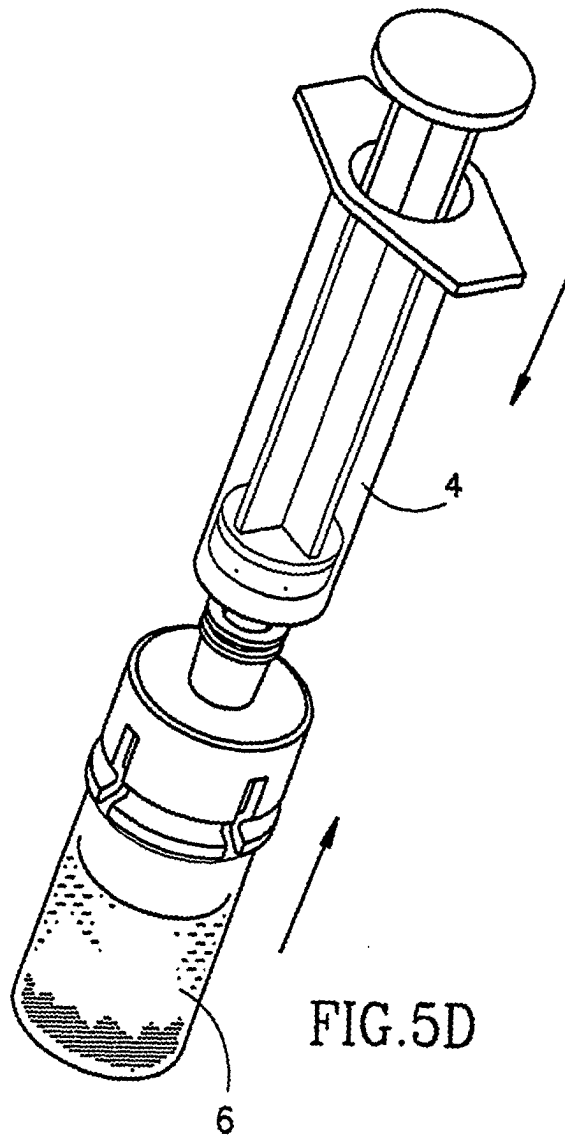


FIG. 5D

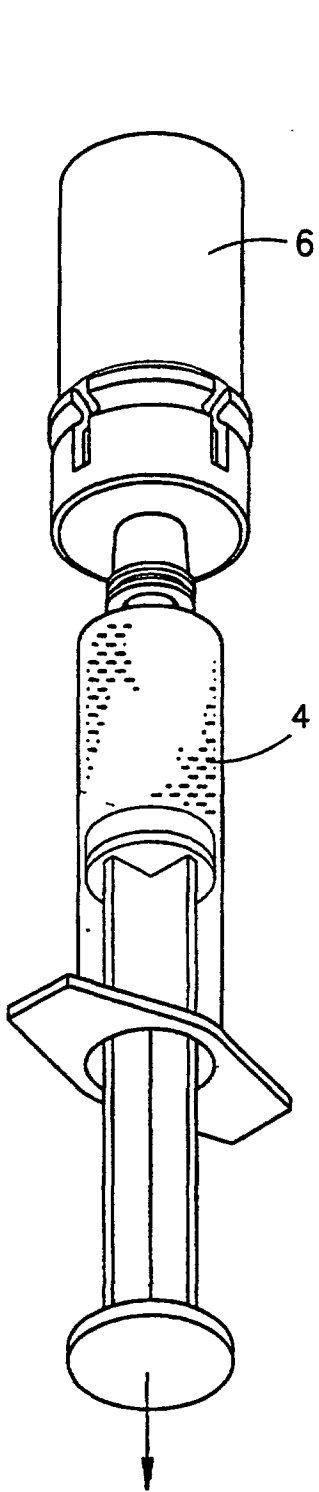


FIG. 5E

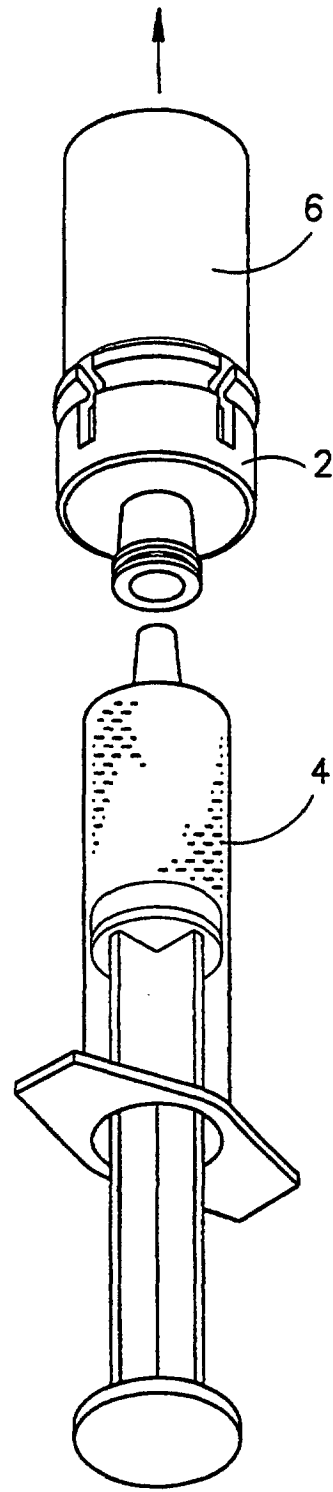


FIG. 5F

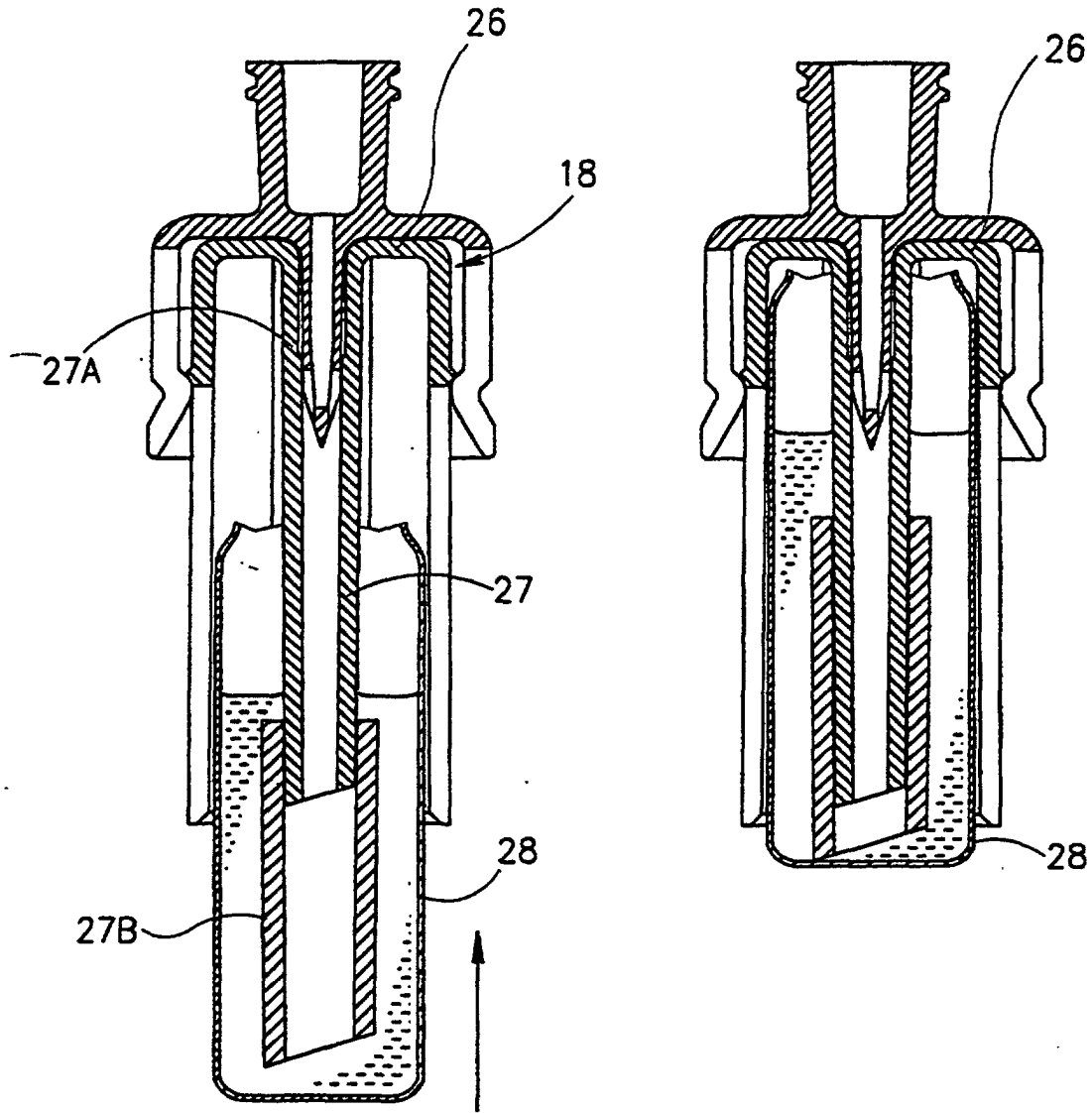


FIG. 6A

FIG. 6B

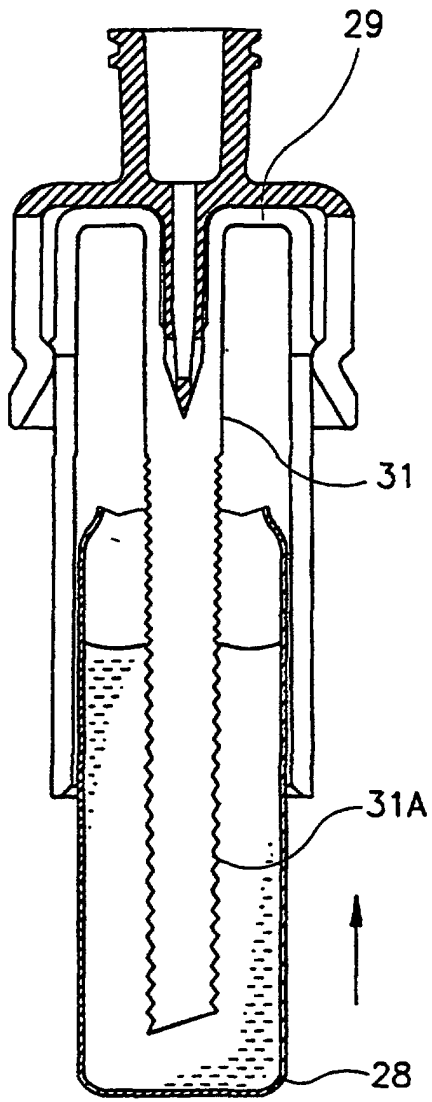


FIG. 7A

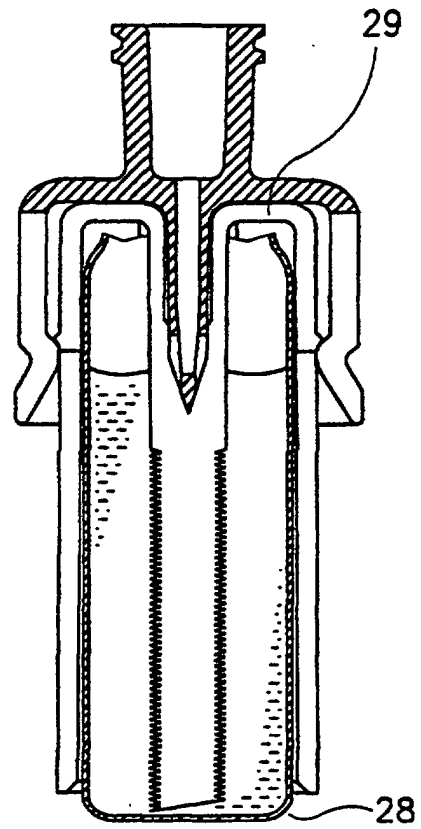


FIG. 7B

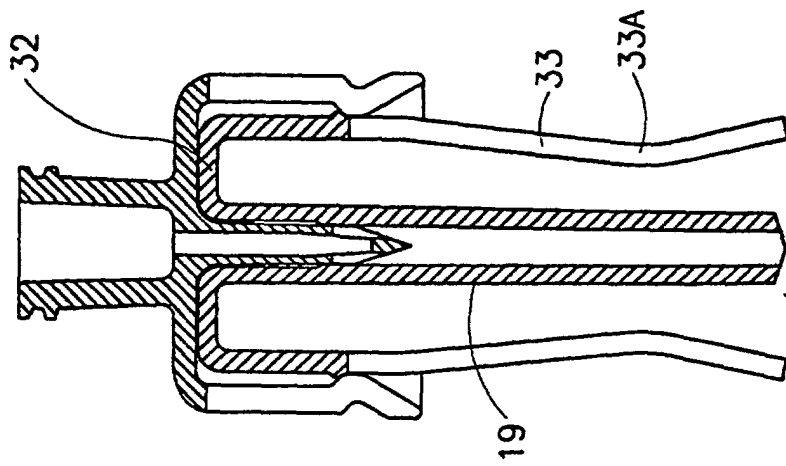


FIG. 8A

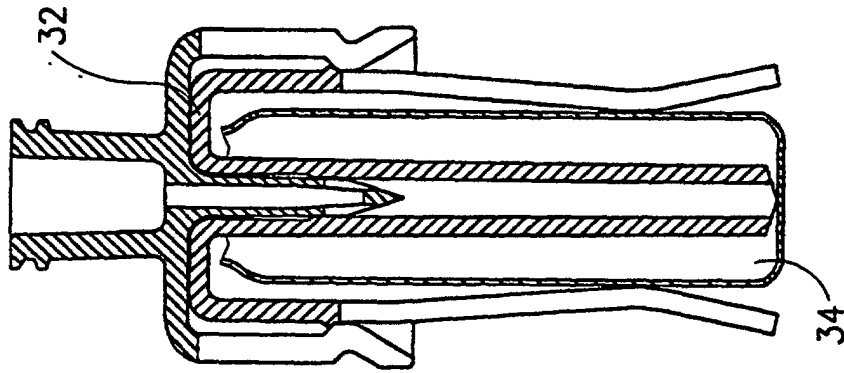


FIG. 8B

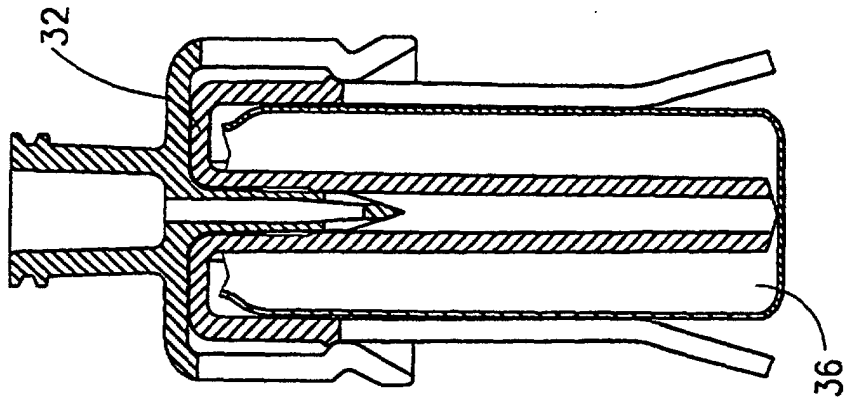


FIG. 8C

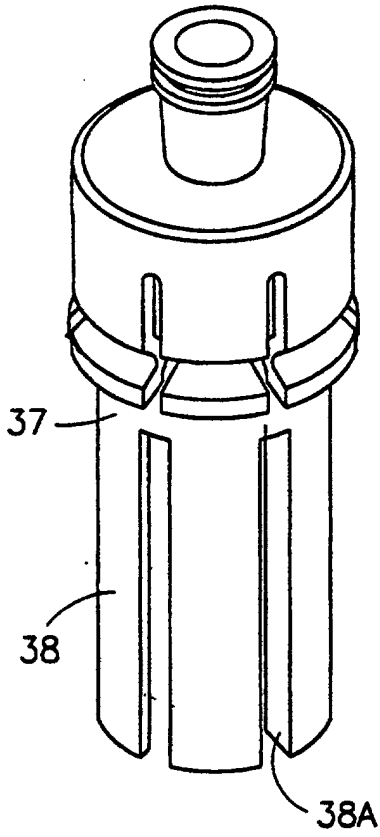


FIG. 9A

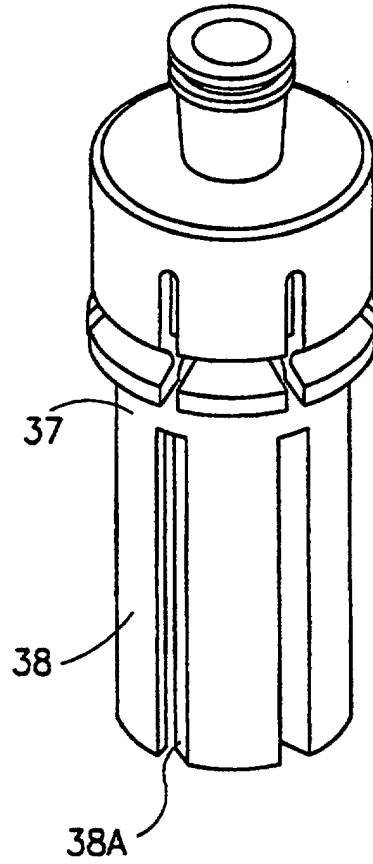


FIG. 9C

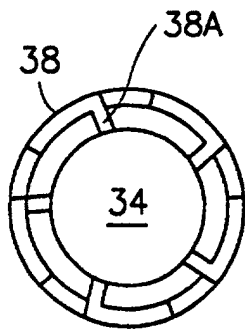


FIG. 9B

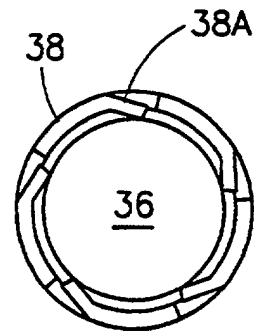


FIG. 9D