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(54) **Withdrawing drugs from containers using cannulae**

(57) A cannula 1 has a hollow metal shaft 3 laterally flattened at its distal end with a width exceeding that of the shaft (Figure 5), the shaft 3 being formed with a shallow tip 6, which is insufficiently pointed to pierce skin but which can be pushed through a self-sealing bung on a medicine container (16, 21, Figure 7). A side aperture 5 is located just to the rear of the tip 6 (Figure 3) to enable medicine in the container to be withdrawn into a syringe connected to a tubular body 2 at the proximal end of the shaft 3. The bung may have depressions in its outer surface to aid location of the cannula tip 6. The tubular body of the cannula may be provided with grip portions 13.

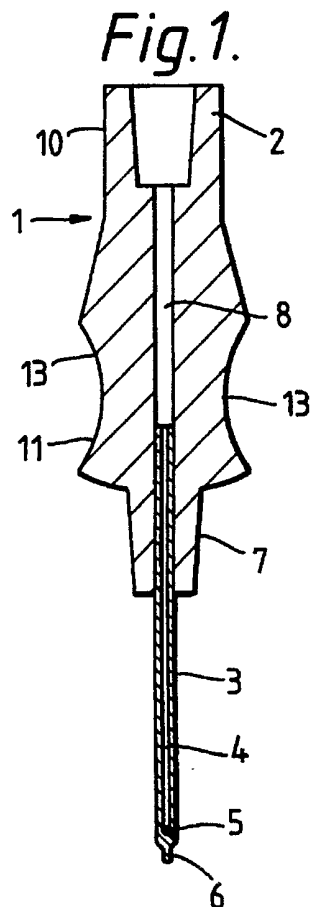


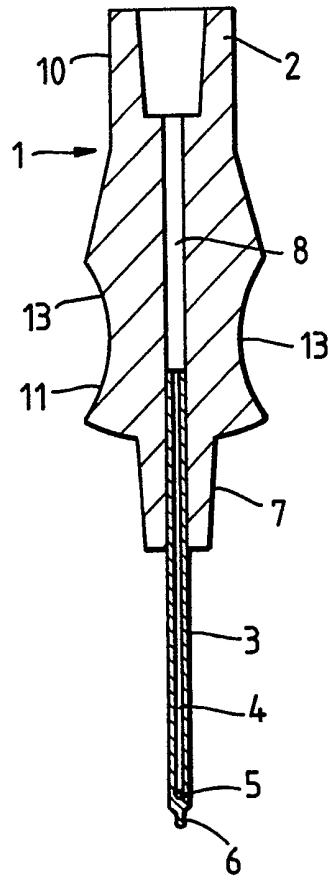
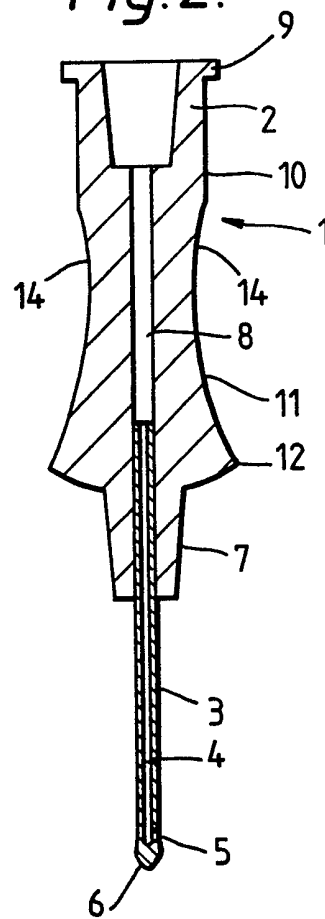
Fig. 1.*Fig. 2.*

Fig. 3.

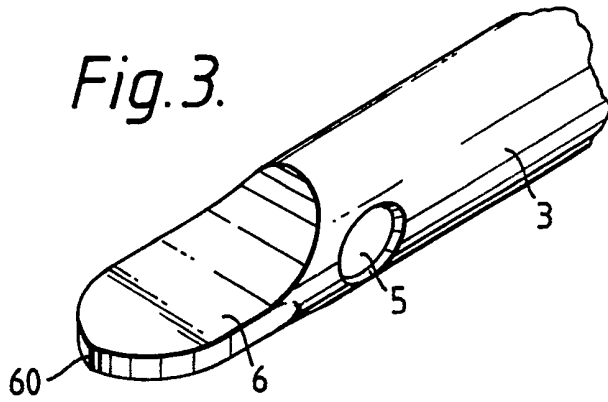


Fig. 5.

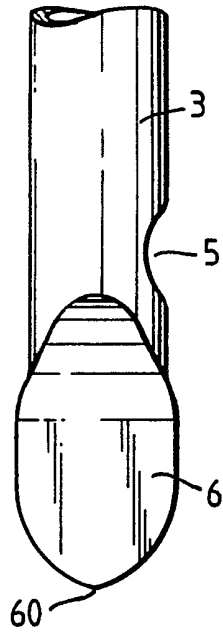


Fig. 4.

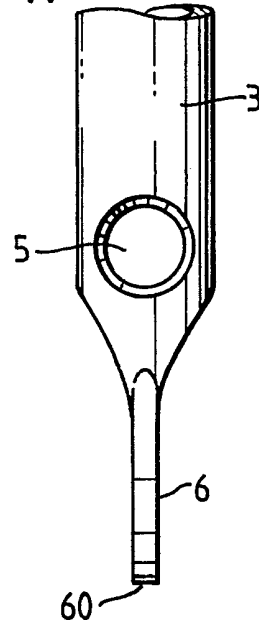


Fig. 6.

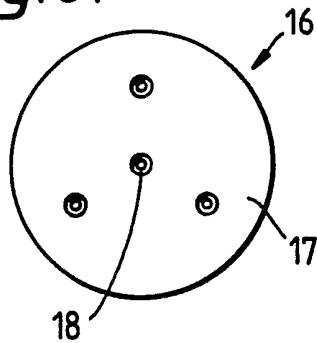
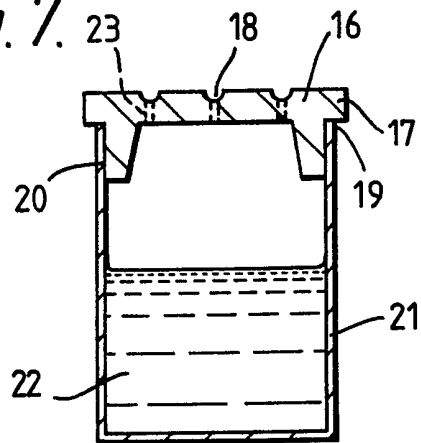


Fig. 7.



CANNULAE AND ASSEMBLIES INCLUDING A CANNULA

This invention relates to cannulae and to assemblies including a cannula.

The invention is more particularly concerned with filling cannulae or quills used for withdrawing drug from a container or delivering the drug. Such devices are usually in the form of a fine tube with a connector at a proximal end for connection with a conduit, syringe or the like.

Medicinal liquids such as drugs are often provided in multiple-dose containers with a resilient rubber bung, or in glass ampoules. With glass ampoules it is usual to break the glass ampoule along its weakened line and to withdraw the drug by means of a filling cannula or quill. Although such a quill is not sharp at its distal open end, there are two principal difficulties with arrangements of this sort. In the first place it is possible to draw fine slivers of glass into the open end of the quill, which may be subsequently inadvertently transferred to a patient. Furthermore, the quill may be mistaken for a sharp needle and an attempt may be made, particularly by inexperienced staff, to puncture tissue with it.

These quills are not suited to use with a multi-dose container since piercing the bung with an open-ended quill tends to core the rubber of the bung, thereby introducing small particles of rubber into the quill lumen. For this reason, it has previously been assumed that a sharp needle is required for use with multiple-dose containers.

Needle stick injury is an inescapable hazard associated with medical use of sharp needles. It is thus preferable to eliminate sharp needles in so far as is possible.

It is an object of the present invention to provide an improved cannula and assembly including such a cannula.

According to one aspect of the present invention there is provided a cannula including a shaft having a lumen extending therethrough and an aperture at the distal end of the shaft, the distal end of the shaft terminating in a laterally-flattened tip insufficiently pointed in normal use to pierce human skin, and the aperture in the distal end of the shaft being positioned proximal to the distal end and generally normal to the axis of the shaft thereby to provide a side entry to the lumen.

The flattened tip preferably has a width that exceeds that of the shaft. The aperture preferably is chamfered at its edge and the tip of the shaft has a shallow point with a shape defined by two intersecting arcs. The cannula may include a tubular body joined with the proximal end of the shaft, the proximal end of the body having a female tapered connector portion. The tubular body may be provided with a grip portion or two grip portions of different shapes on different parts of the body.

According to another aspect of the present invention there is provided an assembly including a cannula according to the above one aspect of the invention and a liquid container having a member of a self-sealing material closing the container, the tip of the shaft being adapted to penetrate the self-sealing member such that the tip can be pushed through the member into the container and the aperture pushed below the surface of liquid in the container.

The member of a self-sealing material may be a bung inserted in an opening of the container and the member may have a depression in an outer surface to aid location of the tip of the shaft.

A cannula and assembly including a cannula, in accordance with the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

- Figure 1 is a sectional elevation of the cannula;
- Figure 2 is a sectional elevation of the cannula of Figure 1 from a direction at right-angles;
- Figure 3 is an enlarged perspective view of the tip of the cannula;
- Figure 4 is an enlarged elevation of the tip of the cannula from the direction of Figure 1;
- Figure 5 is an enlarged elevation of the tip of the cannula from the direction of Figure 2;
- Figure 6 is a plan view of a bung from above; and
- Figure 7 is a partly sectional elevation of a multi-dose container.

With reference to Figures 1 to 5, the cannula or quill 1 has an upper, generally tubular body 2 of metal or plastics joined to a hollow stainless steel shaft 3 having an external diameter of about 1.5 mm. The length of the body 2 is between about 20 and 50 mm and the length of the shaft 3 is between about 30 mm and 70 mm. If the shaft 3 were too long, the quill would become unwieldy and significant amounts of additional liquid would be retained in the length of the lumen, whereas if it were too short the shaft would not be able to reach the bottom of a container with which the quill is used.

The body 2 of the quill 1 is seen in a first aspect in Figure 1 and has a female luer taper connector portion 10 at its upper end, with radially-projecting lugs 9, as shown in Figure 2. Situated immediately below the luer connector portion 10, is a grip portion 11 having a pair of opposite concave surfaces 13 that accommodate the thumb and forefinger of an operator and allow for ready manipulation.

Figure 2 shows the second aspect of the body 2 having two opposed concave surfaces 14, which are shallower than the surfaces 13 and which are flared outwardly at their lower end 12. The surfaces 14, when gripped between finger and thumb, are particularly adapted for driving the quill shaft 3 through the rubber bung 16 (Figure 6). Either of the surfaces 13 or 14 may be used for manipulation between the finger and thumb as desired, although it has been found that the particular shape of the second aspect, utilizing the flared lower portion 12, is particularly suited to driving the shaft through the bung, whereas the shorter, re-entrant surfaces 13 are particularly useful for manipulation.

The body 2 has a central lumen 8 passing co-axially from the top of the body to a lower tapered portion 7. The lumen 8 in the body opens into a lumen 4 through the shaft 3, which passes throughout the length of the shaft until it reaches a point adjacent its distal end. At this point, the shaft 3 has a side entry distal aperture 5, which is slightly chamfered at its point of juncture with exterior periphery of the shaft (Figure 4) and which has its axis arranged normal to the axis of the shaft.

The shaft 3 terminates in a laterally-flattened tip 6, which is about 2 mm long and 2 mm wide, that is, slightly wider than the main body of the shaft 3. The shape of the tip 6 is defined by two off-centre intersecting convex arcs of radius 1.3 mm providing a shallow point 60 where they intersect. The plane of the flattened tip 6 is aligned with the axis of the shaft.

With reference now to Figures 6 and 7, there is shown a container 21 for medicinal liquid 22 and having a bung 16 formed of a resilient, self-sealing pharmaceutically-acceptable, elastomeric material inserted in the opening of the container. The bung 16 is formed with a crown portion 17 having four spaced recesses 18 for location of the tip 6 of the quill 1. The bung 16 is also formed with a flanged portion 19 and an annular sealing

portion 20, which together provide a biological seal with the inside upper edge of the container 21.

In use, the nose of a syringe (not shown) is coupled to the female connector portion 10 of the cannula 1, with the syringe, cannula and container 21 forming an assembly. The shaft 3 is directed down with the shallow point 60 located in one or other of the recesses 18 in the bung 16. Additional pressure is then exerted on the flared portion 12 of the body 2 and this causes a point loading to be applied to the floor of the recess 18 in the bung 16. An increase in pressure will open a pathway 23 between the recess 18 and the interior of the container 21, thereby allowing the shaft 3 to pass through the bung so that the distal aperture 5 passes beneath the surface of the medicinal liquid 22. The medicinal liquid may then be drawn up the lumens 4 and 8 into the syringe, in the usual way, until the liquid in the container 21 is exhausted. It is usual to tip the container 21 to one side and to press the shaft 3 into the remote lower edge of the container 21 thereby to extract as much medicinal liquid 22 as possible. When liquid withdrawal has been completed, the operator may change his grip from one aspect of the body to the other, and may with a rotational movement about the axis of the body, gently withdraw the shaft 3 from the bung 16. The withdrawal of the shaft 3 allows the resilient material to re-seal, thereby maintaining sterility.

Because the side aperture 5 is located to the side of the flattened tip 6, it is protected by the tip during insertion into the bung. The edge of the tip 6 projects beyond the side wall of the main part of the shaft 3 so the tip tends to hold the material of the bung 16 away from the shaft just to the rear of the tip. In this way, contact of the side aperture with the bung 16 is minimized and hence there is a reduced risk of any material from the bung being scraped or cut off and entering the bore of the shaft.

It will be appreciated that the shallow point of the present invention is much safer for the operator since, although it is capable of forcing a passage through the bung, it is insufficiently pointed in normal use, to pierce the human skin. There is, therefore, much less

chance of needle stick injury. The problems of coring are also avoided by utilising the side entrance 5 to the distal aperture 6. Since the distal aperture 5 is in a fixed relation to the body portion 2 it is possible to extract the maximum amount of medicinal liquid from the

container 21 by rotating the quill such that the entrance 5 to the lumen 4 is located relatively downwardly. Since the position of the aperture cannot be seen readily when in the container, a mark may be positioned on the body to assist the operator. The laterally-flattened tip 6 makes entry into the bung considerably easier than other shapes because of the relatively small surface area of contact between the edge of the tip and the material of the bung.

Various modifications are possible to the cannula and the assembly of cannula and container. For example, the body of the cannula could be of a plain cylindrical shape.

Claims

1. A cannula including a shaft having a lumen extending therethrough and an aperture at the distal end of the shaft, wherein the distal end of the shaft terminates in a laterally-flattened tip insufficiently pointed in normal use to pierce human skin, and wherein the aperture in the distal end of the shaft is positioned proximal to the distal end and generally normal to the axis of the shaft thereby to provide a side entry to the lumen.
2. A cannula according to Claim 1, wherein the flattened tip has a width that exceeds that of the shaft.
3. A cannula according to Claim 1 or 2, wherein the said aperture is chamfered at its edge.
4. A cannula according to any one of the preceding claims, wherein the tip of the shaft has a shallow point.
5. A cannula according to Claim 4, wherein the point has a shape defined by two intersecting arcs.
6. A cannula according to any one of the preceding claims, wherein the cannula includes a tubular body joined with the proximal end of the shaft, and wherein the proximal end of the body has a female tapered connector portion.
7. A cannula according to Claim 6, wherein the tubular body is provided with a grip portion.
8. A cannula according to Claim 7, wherein the tubular body has two grip portions of different shapes on different parts of the body.

9. A cannula substantially as hereinbefore described with reference to the accompanying drawings.
10. An assembly including a cannula according to any one of the preceding claims and a liquid container having a member of a self-sealing material closing the container, wherein the tip of the shaft is adapted to penetrate the self-sealing member such that the tip can be pushed through the member into the container and the aperture pushed below the surface of liquid in the container.
11. An assembly according to Claim 10, wherein the member of a self-sealing material is a bung inserted in an opening of the container.
12. An assembly according to Claim 10 or 11, wherein the member of a self-sealing material has a depression in an outer surface to aid location of the tip of the shaft.
13. An assembly substantially as hereinbefore described with reference to the accompanying drawings.
14. Any novel feature or combination of features as hereinbefore described.

Relevant Technical Fields

- (i) UK Cl (Ed.M) B8T (TEDP, TWP)
- (ii) Int Cl (Ed.5) B67B 7/48; A61M 3/00

Databases (see below)

- (i) UK Patent Office collections of GB, EP, WO and US patent specifications.
- (ii) ON-LINE DATABASES; WPI

Search Examiner
 Linda Harden

Date of completion of Search
 19 January 1994

Documents considered relevant following a search in respect of Claims :-
 1-13

Categories of documents

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| <p>X: Document indicating lack of novelty or of inventive step.</p> <p>Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.</p> <p>A: Document indicating technological background and/or state of the art.</p> | <p>P: Document published on or after the declared priority date but before the filing date of the present application.</p> <p>E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.</p> <p>&: Member of the same patent family; corresponding document.</p> |
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Category	Identity of document and relevant passages	Relevant to claim(s)
Y	GB 2218076 A (W BATES) see page 3 lines 12-14	Y:12
X,Y	GB 1570708 (ILLINOIS TOOL) see Figure 2	X:1,10,11 Y:12
X,Y	WO 79/00279 A1 (SAKAI) see abstract and figures	X:1,4,10,11 Y:12

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