May 31, 1960 T. H. GEWECKE ET AL 2,938,238

PLASTIC COLLAR SECURED TO A MEMBER AND METHOD OF ATTACHING SAME

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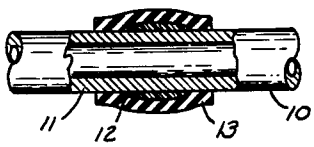

Fig. 1.

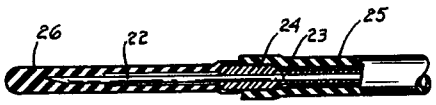

Fig. 3.

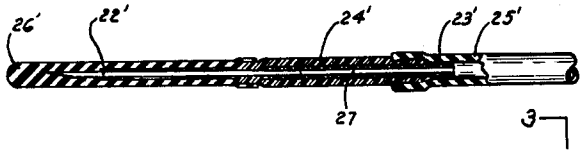

Fig. 4.

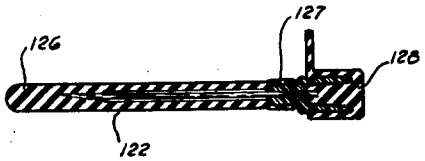

Fig. 5.

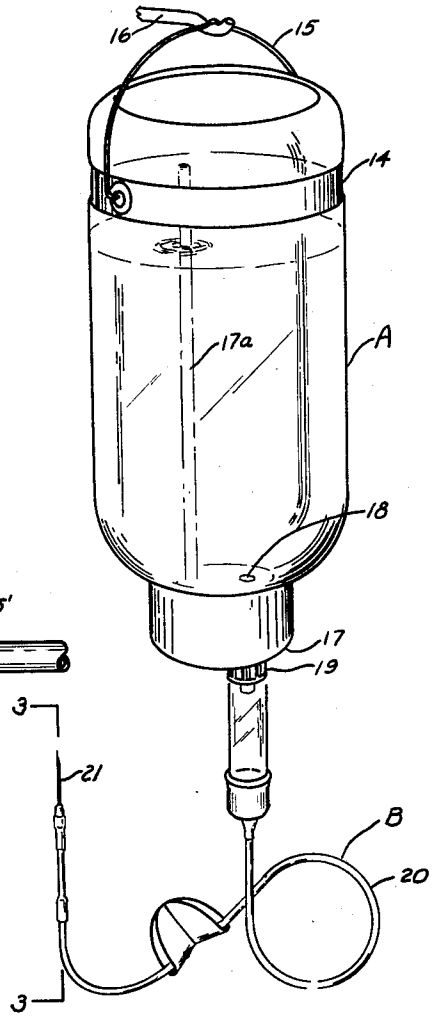

Fig. 2.

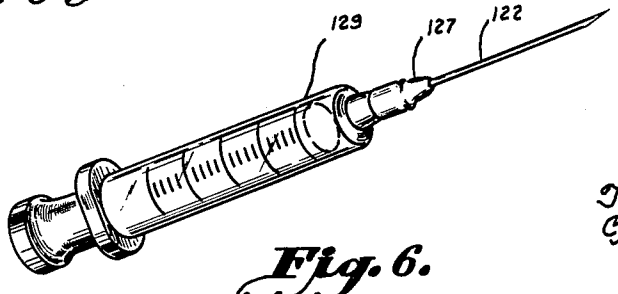

Fig. 6.

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PLASTIC COLLAR SECURED TO A MEMBER AND METHOD OF ATTACHING SAME

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2 Claims. (Cl. 18—59)

This invention relates to a plastic collar secured to a member and, more particularly, to a parenteral needle equipped with a plastic shank and the method of attaching the same.

In the past, in many instances, it has been the practice to provide needles separate from parenteral dispensing means, such as administration sets, syringes, and the like. This necessitated the attachment of the needle just prior to the administration of the parenteral substance and, in order to make this attachment secure, the needle was provided with an elaborate shank, usually of metal integral with the needle, so as to facilitate the attachment. Since the provision of such a shank was costly, needles, of necessity, were reused. Consequently, many parenteral administrations were made with dull needles.

In the case of administration sets for use with containers of parenteral fluids, the additional operation of attaching a needle for insertion into the body of the recipient was time-consuming. Such loss of time could be critical, as for example when the administration was to be performed on the battlefield. The administration sets equipped with recipient needles are considerably more expensive because of the costly materials used therein and the involved operations required to form a needle suitable for attachment to the tubing making up the administration set.

We have invented an easy and inexpensive method for securing a shank to a needle which overcomes the disadvantages associated with needle attachment in the past.

It is, therefore, an object of this invention to provide a new method for providing a plastic collar or flange for an insert-piece or member made of a material not substantially deformable at the melting point of the plastic and the securement of the collar thereto. Another object is to provide a method for securing a plastic band to a metal tube or cylindrically-shaped member. Another object is to provide a method for equipping a parenteral needle with a plastic shank. A further object is to provide a method for securing a plastic shank to a parenteral needle which permits the needle to be readily attached to dispensing means like a parenteral administration set or a syringe. Yet another object is to provide a method for securing a plastic shank to a parenteral needle during sterilization of the same.

Still another object of our invention is to provide a needle equipped with a plastic shank that is inexpensive to produce, yet sterile.

Other features and advantages will appear from the following specification and drawing in which:

Fig. 1 is an elevational view, partially broken away, of a tube equipped with a plastic collar according to the method of our invention. Fig. 2 is an elevational view of a parenteral container and parenteral administration set equipped with a needle produced by the method of our invention; Fig. 3 is a cross-sectional view taken along the line 3—3 of Fig. 2 showing a modified form of shank-equipped parenteral needle; Fig. 4 is an elevational view, partially in cross-section, of one form of shank-equipped

parenteral needle produced by the method of our invention; Fig. 5 is a cross-sectional view of yet another form of shank-equipped parenteral needle, particularly suitable for use with a syringe; and Fig. 6 is an elevational view of the shank-equipped needle of Fig. 5 mounted on a syringe.

Referring to the drawings, and Fig. 1 in particular, an insert-piece equipped with a plastic collar by the method of our invention is generally designated **10**. In the preferred embodiment the insert-piece is a metal tube **11** but may be of any material not substantially deformable in the melting range of the plastic of which the collar is made and may be of any shape capable of having a band secured thereto. Loosely mounted on tube **11** is plastic collar **12**. Collar **12** is made of a thermoplastic material which is substantially rigid at room temperature. Pressure band **13** is mounted on collar **12** and is in concentric relation to it and tube **11**. Band **13** is adapted to constantly exert a uniform compressive pressure on collar **12** during the subsequent heat treatment. In the preferred embodiment as hereinafter described, band **13** is formed of an elastic material such as rubber. However, uniform external pressure may be applied by any means known to the art, as for example by a spring-tensioned metal band. It is also to be noted that band **13** need not be greater or even coextensive in width with collar **12**, but need be only of the width corresponding to the width of the area of securement desired.

Essentially, the method of our invention involves the assembly of tube, plastic collar and pressuring means as outlined above, followed by subjecting the assembly to a temperature in the heat distortion or "plastic" range of collar **12**, followed by cooling.

However, the method of our invention may be practiced equally well by inserting tube **11** into pressure band **13** and inserting between the tube and band a plurality of spaced thermoplastic elements rather than the above-mentioned collar. Upon heating, the elements disposed about the tube fuse to form a collar tightly secured to the tube. At least three elements should be used to position the tube centrally with respect to the walls of the band.

An environment in which a tube equipped with a collar by the method of our invention is especially useful is shown in Fig. 2. A container A containing a parenteral fluid is provided with suspension means by which it can be suspended in a mouth downward condition. The suspension means ordinarily consists of a band **14** mounted in a peripheral groove in the wall of container A. Attached to band **14** is bail **15** which is suspended from an external hook means **16**. Container A is provided with a plug closure **17** fitted into the mouth of the container. Closure **17** has an air inlet opening and associated air tube **17***a*, and a liquid outlet opening **18**. Administration set, generally designated B, is provided with a plug-in connector **19** shown inserted into liquid outlet **18**. Attached to connector **19** is tubing **20** which acts as a conduit for the parenteral solution contained in containter A. Affixed to the other end of tubing **20** is recipient needle **21**. The method of our invention is readily adapted to securing the recipient needle to an administration set of the type shown in Fig. 2. It is to be noted, however, that our invention may also be used to attach other needles than recipient needles to flexible tubing.

Referring now to Fig. 3, in which a specific form of shank-equipped parenteral needle is shown, a conventional metal needle is designated **22**. Disposed coaxially on needle **22** is loose-fitting sleeve **23**, which sleeve is made of a plastic having the characteristics outlined above. Sleeve **23** is of a length sufficient to permit a portion of

it to extend beyond the unsharpened end of needle 22. Mounted on sleeve 23 is second plastic sleeve 24 (shown fused to sleeve 23) of material similar to the plastic used in sleeve 23, and which is in concentric relation to both sleeve 23 and needle 22. Sleeve 24 is shorter than sleeve 23 and is also characterized by fitting loosely thereon. Mounted on sleeve 24 is a length of rubber tubing 25 which may be part of the conduit tubing of administration set B. The inner diameter of rubber tubing 25 when unexpanded is smaller than the outer diameter of sleeve 24, thereby exerting an inward radial pressure on the assembled sleeves and needle. Additional inward pressure is supplied by rubber protector 26 which is also mounted concentrically to sleeves 23 and 24 but adjacent to tubing 25. In addition, protector 26 protects the sharpened end of needle 22.

The portion of inner sleeve 23 which extends beyond the unsharpened end of needle 22 serves as a handle for the person inserting needle 22 into the body of the recipient.

After the needle, sleeves and one or both lengths of rubber tubing are assembled as outlined above, it being immaterial whether protector 26 or rubber tubing 25 applies external pressure to the sleeves, the resultant assembly is subjected to sterilization temperature. Temperatures commonly used for the sterilization of parenteral administration sets are in the range of about 230–250° F. When sleeves 23 and 24 are of a material which becomes distorted or "plastic" by application of heat in the range of temperatures commonly associated with commercial sterilization, the sleeves constrict under the external pressure of the rubber tubing and, upon subsequent cooling, grip the needle firmly so as to become a permanent attachment thereto. This grip may be improved by scoring the needle prior to assembly so as to provide depressions for the plastic to conform to.

We have found that plastic materials such as cellulose acetate butyrate, cellulose acetate, and polysytrene are especially suitable for use in the sleeves to be sterilized at these temperatures. These materials all possess the characteristics indicated above, namely being thermoplastic materials which are substantially rigid at room temperature. We have found that materials possessing the requisite rigidity are also substantially inelastic. This permits the collar, after deformation in its "plastic" range through the application of external pressure, to retain its assumed shape upon subsequent cooling.

For example, the forms of the plastic materials noted above are substantially non-elastic and substantially rigid at room temperature while being heat-deformable in the range of commercial sterilization temperatures. When these forms have been tested by the method of our invention, it has been found that they result in a tightly-secured collar. On the other hand, forms of plastic materials that are substantially flexible, as being substantially elastic and substantially non-rigid at room temperatures, have been found unsuitable for use as collars to be secured to insert-pieces by the method of our invention. However, forms of plastic materials that are semi-rigid are also suitable for use as collars to be secured to insert-pieces by the method of our invention, depending on the tightness of the fit desired. It is to be noted, therefore, that the plastics suitable for such use are not to be limited to plastics of any particular composition because the same plastic can be rendered substantially flexible by the addition of a solvent or plasticizer material.

Upon removal from the sterilization chamber, the sleeves have been found to be tightly secured to the needle. On the other hand, the rubber protector and the rubber tubing can be removed if desired. It is to be noted that easy removal of the protector piece is a prerequisite, inasmuch as this removal must be performed before the needle can be inserted into the body of the recipient. However, it is not desirable to remove the tubing constituting part of the administration set. This preferential ease of removal can be achieved by using rubber tubing of slightly smaller diameter for tubing 25 than for protector 26.

It is to be noted that only one of the aforementioned sleeves need be of the substantially rigid, thermoplastic material described above. Furthermore, it is immaterial which sleeve is made of the described plastic. When only one sleeve of the assembly shown in Fig. 3 is of the described material, it is necessary to construct the other sleeve of a plastic material that is not substantially rigid in the "plastic" temperature range of the sleeve constructed of the described plastic, otherwise the uniformly distributed radially compressive pressure exerted by the rubber tubing would not effect a tight fit of the sleeves with the needle. Thus, it is not even necessary that the substantially rigid, thermoplastic collar which forms the needle shank be immediately adjacent the needle. We have produced satisfactory shank-equipped needles by interposing a sleeve 23 of a relatively unrigid plastic material such as a polyvinyl plastic between needle 22 and rigid sleeve 24.

In addition, we have produced satisfactory plastic shank-needles with the positions of sleeves 23 and 24 relative to needle 22 reversed. When the longer sleeve, designated 23 in Fig. 3, is external to the shorter sleeve 24, it is necessary to construct the longer sleeve of a plastic material having a "plastic" range somewhat higher than that of the shorter sleeve in order to prevent collapse of the unsupported portion of the walls during heating which might result in obstructing the fluid channel.

For example, we have produced a needle equipped with a tightly secured shank where the shank is made up of a short sleeve of cellulose acetate butyrate and the long sleeve, external to the short sleeve, is a polyvinyl plastic. These sleeves are assembled prior to insertion of the needle therein by first forming a liquid solution of the cellulose acetate in a highly volatile solvent such as acetone. The previously formed polyvinyl sleeve is then dipped into the acetate-acetone solution, whereupon a coating of the acetate is formed on the interior of the longer polyvinyl sleeve. This coating stiffens in a short time because of the high volatility of the solvent. After successive dippings, a substantial inner layer of acetate is formed on the polyvinyl sleeve. The cylindrical laminate thus formed is then assembled and heat treated as above.

A preferred form of shank-equipped needle is shown in Fig. 4. It is essentially the same arrangement of elements as shown in Fig. 3. For the sake of clearly indicating this similarity, the elements are designated with primed numerals. A needle 22' is inserted into a pair of concentrically-disposed sleeves 23' and 24'. The assembly thus effected is then inserted into a length of rubber tubing 26' closed at one end, thus serving as a needle protector. The end portions of either sleeve 23' or 24' adjacent the unsharpened end of needle 22' may be inserted into a length of rubber tubing 25'. It is preferred that sleeve 23' be in sliding fit engagement with sleeve 24', and needle 22' be in press fit engagement with sleeve 23'.

In this preferred embodiment, plastic sleeve 23' is made of a plastic which is also substantially rigid but is not distorted by the application of heat in the temperature ranges commonly associated with commercial sterilization. We have found nylon to be especially suitable for this purpose. As above, sleeve 24' is made of a plastic which is heat-distortable by application of temperatures in the range indicated and has the further characteristic of being at least semi-rigid.

Another essential difference between the embodiment shown in Fig. 4 and that shown in Fig. 3 is that the length of rubber tubing attached to the portion of the assembly adjacent the unsharpened end of the needle is positioned so as to expose a portion of the parenteral fluid channel 27' to the view of the administrator. In the preferred

embodiment, the plastics selected are transparent, thereby permitting the observer to see the flow of liquid in channel 27'. This view is obscured when rubber tubing 25' extends over the concentrically-disposed sleeves 23' and 24' to a point where it overlaps needle 22'. It is desirable to permit the administrator to view channel 27' because in that way it can readily be determined whether a blood vein has been punctured by the insertion of the needle. In the administration of some parenteral fluids, it is desirable that they be administered intravenously only (as contrasted to intramuscularly) so that it is vital to ascertain that the puncture has been made into a vein. A vena-puncture can be ascertained by causing a slight vacuum in channel 27', as by distorting the length of rubber tubing 25', whereupon blood will "back up" into the needle and its associated shank. On the other hand, where it is vital not to administer the parenteral solution into a vein, the same operation can be performed to ascertain that no blood backs up into the administration set.

We have found a convenient method for assembling plastic sleeves 23' and 24' and achieve the desired sliding fit by the application of the liquid layer of the plastic used for sleeve 24' to an already extruded length of tubing corresponding to that designated 23'. This can be readily performed by various forms of "cross head" extrusion now known to the art. Upon cooling the extruded coaxial sleeve, we have found it possible to displace the length of sleeves slightly with respect to each other causing the ends thereof to overlap, as shown in Fig. 4. The displaced concentric sleeves are now mounted on needle 22' and the portion of the heat-distortable plastic designated 24' which overlaps the inner sleeve 23' is pressed against needle 22' by protector 26'. After submission of the assembly to sterilization, it has been found that the overlapping portion of sleeve 24' is firmly bonded to needle 22'. Unless sleeve 23' is at least coextensive or overlaps sleeve 24' at the end adjacent the unsharpened end of needle 22', the subsequent heating operation may cause sleeve 24' to collapse under the pressure of tubing 25', and destroy channel 27'.

Maximum economy is achieved in our method if the entire administration set is assembled prior to the sterilization step which, in the preferred embodiment, required the encasing of sleeves 23' and 24' with tubing 25' which may be part of tubing 20 shown in Fig. 2. Thus, the shank made up of sleeves 23' and 24' is secured to needle 22' at the same time the entire set is sterilized. It is to be noted that the administration set may be provided with needles at both ends by the method of our invention, in which case connector 19 is replaced by needle and sleeve assembly as set forth above.

However, our invention may be practiced by using for the shank a plastic having a higher distortion temperature than commercial sterilization temperatures, in which case the sterilization step occurs subsequent to the shank attachment step.

Another form of our invention which is particularly adapted for use with a conventional syringe is shown in Fig. 5. Inasmuch as many syringes now known to the art are equipped with a tapered male outlet, the embodiment shown in Fig. 5 has been modified so as to adapt a plastic shank to receive the tapered male outlet of a syringe. In the past, as stated above, the shank of the needle to be used in conjunction with a syringe, was formed of a metal integral with the needle and was the result of a costly operation. This necessarily resulted in an increased cost of a shank-equipped needle so that it was uneconomical to dispose of the needle after one use. As a consequence, many parenteral administrations were made with dull needles. The plastic shank-equipped needle of our invention is relatively inexpensive to produce so that the needle may be disposed of after a single administration. To permit the attachment of a shank-equipped needle produced by the method of our invention to a syringe, the shank is formed during the heat distortion step which again can be achieved during sterilization into a shape adapted to receive the tapered outlet of the syringe. For this purpose, a rubber molding piece 128 is used in conjunction with plastic sleeve 127, needle 122 and protector 126.

A shank-equipped needle produced by the method of our invention is shown mounted on a conventional syringe 129 in Fig. 6. Thus, it is to be noted that only a portion of the concentric sleeve 127 may be attached to needle 122 in order to provide a shank, the remaining portion of the sleeve being deformable to implement attachment of the shank-equipped tube to an independent element, such as threaded or slotted attachment.

The foregoing, detailed description is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications should be obvious to those skilled in the art.

We claim:

1. In a method for securing a thermoplastic shank to a needle for parenteral use, the steps of inserting a needle into a thermoplastic sleeve and positioning the sleeve adjacent the unpointed end of said needle, said sleeve being substantially non-elastic and substantially rigid at room temperature while being heat-deformable in the range of commercial sterilization temperatures, said sleeve fitting loosely over said needle, mounting a length of rubber tubing concentric to said sleeve and said needle, the internal diameter of said rubber tubing when unexpanded being smaller than the outside diameter of said sleeve, heating the needle, sleeve and tubing so assembled to a temperature in the commercial sterilization temperature range and capable of causing the said sleeve to deform to grip said needle in immovable relation therewith, cooling the assembly, and retaining the rubber tubing as part of the assembly at least up to the time the needle is to be used.

2. In a method of securing a thermoplastic sleeve to a hypodermic needle while sterilizing the same, the steps of inserting said needle into said sleeve to position said sleeve adjacent the unsharpened end of said needle, said sleeve being rigid at room temperature while being heat-deformable in the temperature range of about 230°–250° F., mounting rubber tubing concentric to said tube and sleeve, said rubber tubing having a bore when undilated smaller than the outside diameter of said sleeve, heating the assembly thus effected to a temperature in the range of 230°–250° F. to cause said sleeve to tightly grip said needle in a movable relation therewith while still dilating said tubing and also thereby to sterilize said assembly, cooling the said assembly, and retaining the rubber tubing in place on the assembly at least until the time the needle is to be used.

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