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(54) COVERED CANNULAS

(71) We, ILLINOIS TOOL WORKS INC., a corporation organised under the laws of the State of Delaware, United States of America, of 8501 West Higgins Road, Chicago, Illinois 60631, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us and the method by which it is to be performed, to be particularly described in and by the following statement:—

Various forms of covers for cannulas are known whose main purpose is to maintain aseptic conditions to avoid contamination of the cannulas before their use in administering intraveneous injections, intermuscular injections or any other subcutaneous injections.

According to the present invention, a cannula has an elongate tubular cover disposed therearound, the cover extending from one end which encircles an intermediate part of the cannula to its other end which lies beyond a sharpened end of the cannula, said other end of the cover presenting a chamber within which the sharpened end of the cannula is located, and said chamber being formed by a bubble-like portion of said other end of the cover which projects laterally from a sealing portion of said other end of the cover, said sealing portion surrounding said bubble-like portion, all of an inner wall of the bubble-like portion being spaced from the sharpened end of the cannula, with a part of said inner wall intermediate the ends of the cover sealing around the cannula at a position adjacent to but spaced from the sharpened end of the cannula.

Preferably, said sealing portion of said other end of the cover, from which said bubble-like portion projects, is generally flat and co-planar with the cannula, thereby offering a convenient finger hold which can be used for leverage to break the cover away from its sealing engagement with the cannula, and expose the cannula for use by sliding the cover therefrom.

Also preferably, said one end of the cover is frangibly connected to a support body in association therewith, the support body engaging the cannula at a position remote from the sharpened end of the cannula, whilst allowing fluid access to and through the cannula. In such a preferred device, it is possible to determine whether there has been tampering (for example, replacement of one support body by another) merely by inspection of the frangible connection. This is of considerable advantage when the support body is itself in retentive association with a medicament container.

Moreover, the covered cannula of the present invention, optionally in association with the above-mentioned support body, is preferably manufactured by reforming an initially open-ended elongate tube by trapping that open end between a mating anvil and die, and then sealing said other end of the cover by applying a source of energy thereto. This is again of considerable advantage, because it is found that none of the material of the cover can enter the cannula to, alternatively, prevent fluid flow therethrough or provide particles which can be introduced into a patient's bloodstream.

Several embodiments of covered cannulas will now be described, by way of example only, with reference to the accompanying drawings, in which:—

Figure 1 is an elevational view of an infusor embodying the present invention;

Figure 2 is an inverted partial elevation of the specific detail shown at one end of the cover of the infusor of Figure 1;

Figure 3 is a side view of the arrangement shown in Figure 2;

Figure 4 is a partial section taken along the line 4—4 of Figure 3;

Figure 5 is a perspective view of a scalp vein needle embodying the present invention;

Figure 6 is a blood donor needle embodying the present invention;

Figure 7 is a needle having a hub with split threads thereon, for use with a unit-dose medicament system, embodying the present invention;

Figure 8 is an exploded view in partial section of a device before the cover thereof is reformed;

Figure 9 is the device shown in Figure 8 when assembled to embody the present invention;

Figure 10 is a partial elevation in section of an anvil and die, of the general type used to form the sealed end of a cover, shown before flattening of the cover;

Figure 11 is a similar view to Figure 10 showing the anvil and die in the holding position after forming and welding; and

Figure 12 is a schematic diagram of a typical machine for accomplishing the forming of the sealed end.

Referring now to the drawings, wherein similar numerals are used to designate similar parts, a cover 10 for an elongate cannula, having a sharpened distal end, generally includes a tubular body 12 provided with a closed end wall 14 having a central aperture encircling and sealing around the body of a cannula 20.

The present invention could similarly be utilised on double-ended cannulas having a central hub with separate covers extending outwardly from the hub and being frangibly connected to the hub to provide aseptic sealing of both of the cannula ends.

In the infusor shown in Figures 1 to 4 the end wall 14 is interconnected to a hub 16 of a support body by means of a frangible section 18. The opposite end of the tube 12 is initially open and extends beyond sharpened distal end 22 of the cannula 20. A substantial length of the cover (see Figures 1 and 2) is generally cylindrical in configuration. This is flattened, as will be described hereinafter, by appropriate means to form a flattened sealing portion 30 having a bubble-like portion 32 extending outwardly from opposite sides of the flattened portion 30 to form a sealed chamber 34 surrounding but spaced from the bevel ground edges of the distal end of the cannula.

The reader will recognise that the bubble-like portion 32 is of generally rectangular outline where it joins the sealing portion 30, and will further recognise that all of the inner wall of the bubble-like portion 32 is spaced from the sharpened end 22, a part of that inner wall sealing around the cannula 20 at a position adjacent to but spaced from the sharpened end, in the manner described immediately hereinafter.

Each face of the flattened portion 30 also includes a semicylindrical portion 36, or raised rib, which embraces the cannula adjacent to but spaced from the sharpened end in sealing relationship thereto. Each semi-circular portion blends into beveled portion 38 which assists in the transition from the tubular cylindrical form of the cover into the sealing portion 30. The tube 12 in its initial condition is shown in phantom in Fig. 2 and Fig. 3 to illustrate the condition of the cover prior to formation of the sealed end. Extending transversely to the end of the flattened portion are one or more grooves 40 which serve, as described below, as high energy source receivers to ensure that the free end of the cover is sealed; this is a safeguard in the event of failure of the flattened portion 30 from being totally sealed at the perimeter around the bubble-like portion 32.

As can be appreciated by those skilled in the art, the beveled ground end of a cannula used for intravenous or other forms of injection is extremely sensitive and the least amount of touching will dull the edges which have been sharpened by grinding. In the present invention, the provision of the chamber 34 spaced in all directions from the sharpened distal end 22 of the cannula 20 ensures that the end 22 is protected from dulling. Secondly, the presence of the chamber 34 with its spaced walls and inner surfaces ensures that no plastics materials will be allowed to flow into the bore of the cannula and set thereby preventing drug flow through the cannula. Further, it ensures that no particles of plastics will become lodged in the bore of the cannula 20 which could be inadvertently injected into the vein of a pateint to whom drugs are being administered and thereby create a deleterious situation. By sealing the chamber 34 with the semicylindrical portions 36 an additional benefit is realized, namely, that if an infusor of the type shown in Fig. 2 is attached to a drug source which is inadventently activated, then only a limited amount of drug can be expelled to the limits of the volume of chamber 34. In the prior art the entire elongated cover could be filled and hence the patient would not receive the full doseage desired.

When the cover is frangibly connected as at 18 to the main body or hub 16, positive evidence is available as to when the device is tampered with.

The embodiment just described is preferably injection moulded of polypropylene, a substance which is acceptable when it comes in contact with drugs.

Referring to Figs. 10 through 12, one method of sealing the end of the cover is through the use of a mating anvil 60 having vertical side walls 62 and a compressing die 64 that is integral with horn 70 of an

ultrasonic energy source, with the facing surfaces of the anvil and die being mirror images of the flattened portion 30 and bubble-like chamber 34. An ultrasonic energy source 72 would have a 350 watt energy level while producing substantially 20,000 cycles per second. The cover, cannula and body are suitably supported by a jig and fixture with the end of the cover being accurately positioned between anvil 60 and die 64. Suitable means, not shown such as a hydraulic or pneumatic cylinder, moves the horn 70 with the die 64 carried thereon toward the anvil 60 to compress the round tube into the flattened condition. A welding cycle of 0.3 to 0.5 seconds is used with the energy source being activated for a fraction of the cycle before the tube is totally compressed. This ultrasonic energy transmitted through the die 64 causes the contacting material to fuse or melt at the interfaces formed on the interior of the cover. The natural tendency of the plastics material, sometimes referred to as "memory", is to want to remain in its original moulded form which causes the tube 12 to readily form into the cavities of anvil 60 and die 64 to form the bubble-like portion 32. When the energy source is turned off, the welded cover is maintained for a holding cycle of generally 1.0 to 1.5 seconds to ensure total cooling and bonding of the plastics material, with the die 64 being maintained in the general position shown in Fig. 11.

While the energy source is generally acceptable to seal the flattened portion 30, the anvil 60 and die 64 each have one or more transverse ribs which act as energy concentrators and produce the grooves 40 in the end area of the flattened portion 30. In ultrasonic techniques these ribs will concentrate the energy and ensure sealing of the end of the cover 12.

While ultrasonics have been discussed hereinabove as the energy source for welding the end of the cover, it will be recognized that R.F. circuits or controlled heat sources may also be utilized, either of the induction or direct resistance heater element types.

While a cover of the type described hereinabove has been illustrated as being attached to an infusor, in Fig. 1, it should be recognized that the techniques are applicable to other devices which will utilize a sharpened cannula. As an illustrative example, Fig. 5 shows a cover 10*a*, of the type already described, as applied to and used with a scalp vein needle having a pair of laterally extending flaps 44 generally utilized to accept tape, not shown, for maintaining piping retained by the cannula relative to the patient's epidermis. Fig. 6 shows a cover 10*b*, of the type discussed hereinabove, as it is applied to a blood donor needle 46. Fig. 7 shows a cover 10*c* of a similar construction attached to a cannula having a hub 48 provided with annular screw threads 50 of the type adapted to be utilized with a container for acceptance of unit-dose vials.

Fig. 8 is an exploded perspective view showing a cannula 20*d* provided with a support body 52 having a finger grip and a leur tapered female fitting 54. In this device, which is shown in two halves for purposes of illustration, the tube 12*d* is generally flat or rectangular in cross-section and is connected to the body 52 by frangible connections 18*d*. Fig. 9 illustrates such a device when assembled, with the cover provided with a flattened sealed portion 30*d*, a bubble-like chamber 34*d* and sealing grooves 40*d*.

WHAT WE CLAIM IS:—

1. A cannula having an elongate tubular cover disposed therearound, the cover extending from one end which encircles an intermediate part of the cannula to its other end which lies beyond a sharpened end of the cannula, said other end of the cover presenting a chamber within which the sharpened end of the cannula is located, and said chamber being formed by a bubble-like portion of said other end of the cover which projects laterally from a sealing portion of said other end of the cover, said sealing portion surrounding said bubble-like portion, all of an inner wall of the bubble-like portion being spaced from the sharpened end of the cannula, with a part of said inner wall intermediate the ends of the cover sealing around the cannula at a position adjacent to but spaced from the sharpened end of the cannula.

2. A covered cannula according to claim 1, in which said sealing portion is generally flat and co-planar with the cannula.

3. A covered cannula according to claim 2, in which said bubble-like portion is of generally rectangular outline where it joins said sealing portion.

4. A covered cannula according to claim 2 or claim 3, in which said sealing portion includes a pair of opposed raised ribs following the outline of the cannula.

5. A covered cannula according to any one of claims 2 to 4, in which said sealing portion includes at least one groove extending thereacross both beyond and transversely to the length of the cannula.

6. A covered cannula according to any one of claims 1 to 5, in which a substantial length of the elongate tubular cover is of cylindrical cross-section.

7. A covered cannula according to any one of claims 1 to 5, in which a substantial

length of the elongate tubular cover is of rectangular cross-section.

8. A device comprising a covered cannula according to any preceding claim in association with a support body engaging the cannula at a position remote from the sharpened end of the cannula.

9. A device according to claim 8, in which said one end of the cover is frangibly connected to the support body.

10. A device according to claim 8 or claim 9, in which the support body is shaped to allow fluid access to and through the cannula.

11. A device according to claim 10, in which the support body is also shaped to allow retention of piping or a container in fluid communication with the cannula.

12. A device according to claim 11, in which the support body includes at least one laterally extending wing for assisting in securing the device to a patient.

13. A device according to claim 11, in which the support body includes a screw-threaded portion.

14. A device according to claim 11, in which the support body includes both finger gripping and tapered Leur fitting portions.

15. A device according to claim 8 and substantially as hereinbefore described with reference to Figures 1 to 4, Figure 5, Figure 6, Figure 7, or Figure 9 of the accompanying drawings.

16. A method of manufacturing a covered cannula according to any one of claims 1 to 7, or a device according to any one of claims 8 to 15, comprising the step of providing the chamber at said other end of the cover by reforming an initially open-ended elongate tube by trapping that open end between a mating anvil and die, and then sealing said other end of the cover by applying a source of energy thereto.

17. A method according to claim 16, in which the initially open-ended elongate tube is injection moulded in place around the cannula prior to the reforming.

18. A method according to claim 17, in which the elongate tubular cover is formed of polypropylene.

19. A method according to any one of claims 16 to 18, in which the source of energy for sealing the reformed end of the cover is ultrasonics.

20. A method according to any one of claims 16 to 18, in which the source of energy for sealing the reformed end of the cover is an R.F. circuit.

21. A method according to any one of claims 16 to 18, in which the source of energy for sealing the reformed end of the cover is a controlled heat source.

22. A method according to claim 16 and substantially as hereinbefore described with reference to Figures 10 to 12 of the accompanying drawings.

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1573949 COMPLETE SPECIFICATION
2 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 1

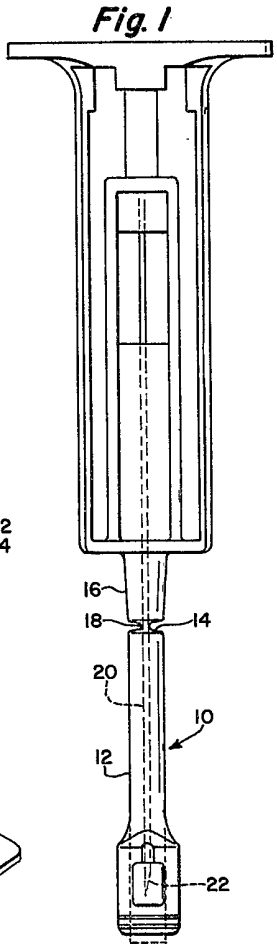

Fig. 1

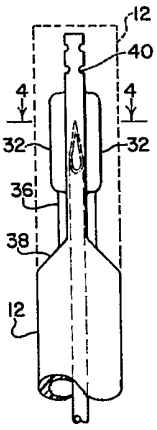

Fig. 3

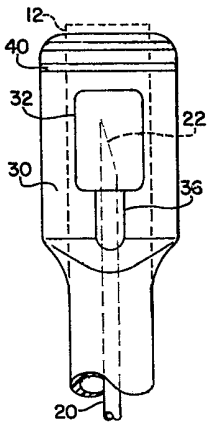

Fig. 2

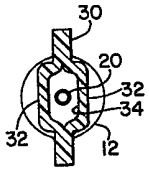

Fig. 4

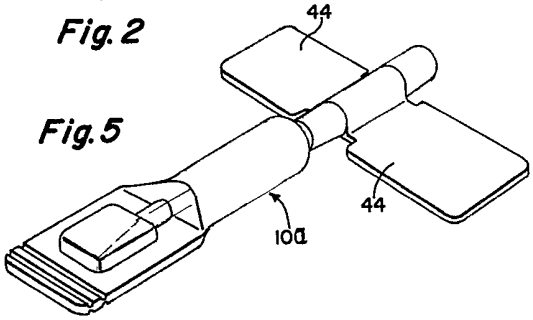

Fig. 5

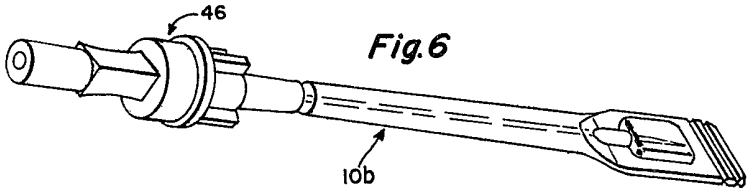

Fig. 6

Fig.7

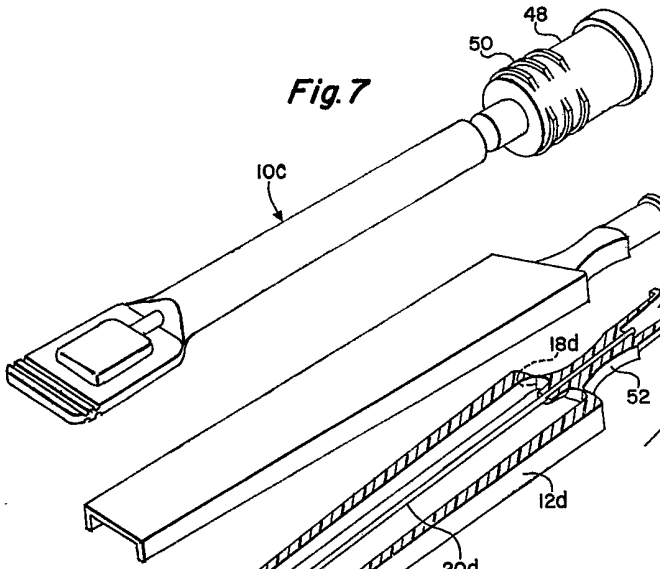

Fig.8

Fig.9

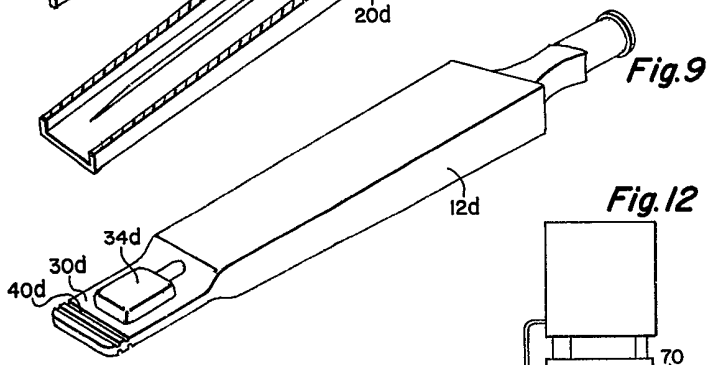

Fig.12

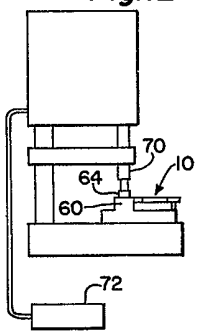

Fig.10

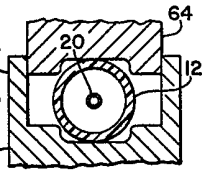

Fig.11