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(54) A DEVICE FOR THE TRANSFER OF LIQUID MEDICATION

(71) We, IMS LIMITED, a Corporation organized under the Laws of the State of Delaware, United States of America, of 1886 Santa Anita Avenue, South El Monte, California 91733, 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:—

This invention relates to devices for the packaging and transfer of liquid medication, and especially to devices which are useful for the addition of medicinal solutions to flexible intravenous solution bags.

Various devices have been proposed for the addition of such solutions to such solution bags. In general, the devices involve the use of metal conventional syringes. The problems are several. First, medication for addition to intravenous solution bags is frequently of high concentration, much too high for direct injection into the patient. Thus, the packaging of concentrated medication in a syringe presents the hazards of mistaken use, viz, direct injection rather than dilution by addition to the intravenous solution. Secondly, the orifice or inlet on the typical intravenous solution bag is flexible as is the bag itself. The insertion of an ordinary syringe into the orifice tube can result in the puncturing of the orifice tube and/or bag unless great care is observed.

The present invention provides a device for the introduction of liquid medication into a flexible bag for the adminstration of intravenous solutions which comprises an elongated generally cylindrical hollow tubular member having an open end and a closed end, a boss extending from said closed end, carried by the boss a cannula having a sharpened outer end, a rigid sheath surrounding said cannula and fixed to said boss, said sheath serving to limit the advancement of the cannula into an orifice having a diameter greater than that of said cannula, a thrust portion within said tubular member, a fluid passage within said tubular member extending longitudinally through the centre of said thrust portion, said fluid passage communicating with said cannula at one end and having piercing means associated with the other end, a cylindrical vial having a resilient stopper in its open end sealing on the inside walls of said vial, interlocking means on said thrust portion and co-operating interlocking means on said stopper, the arrangement being such that, upon interlocking of said stopper with said thrust portion, said vial is first held in an assembled but inoperative position and, upon further interlocking of said stopper with said thrust portion, said stopper is pierced by said piercing means associated with said fluid passage and said fluid passage communicated with said vial without the application of substantial axial pressure on said stopper and said stopper is locked securely to said thrust portion to permit aspiration upon withdrawal of said vial or to permit expulsion of the contents of said vial upon exertion of pressure on said vial.

The provision of the rigid sheath tends to prevent the accidental injection of medication contained in the device directly into the human body and the puncturing of intravenous solution bags. The tendency to prevent such accidental injection is a significant safety feature. Medication for addition to intravenous solutions may well be in a concentration unsuitable for direct injection into the human body. In fact, many of these additives are fatal if directly injected. In addition, if the device is used with an intravenous solution bag having a rubber diaphragm, the sharpened cannula end of the device tends to prevent coring of the rubber diaphragm. Coring would result in bits of rubber falling into the solution which could result in the injection of this dangerous blood clotting material into the patient.

The device may be disposable.

The device may be combined with a flexible bag for intravenous solution having an additive-receiving tube-like orifice and an outlet adapted to lead to an intravenous

solution set, the orifice having a diameter greater than that of the cannula and being capable of engaging said sheath to limit the advancement of said sharpened outer end of said cannula into the orifice.

The invention will now be described, by way of example, with reference to the accompanying drawings, of which:

Figure 1 is a perspective view of a conventional intravenous solution bag;

Figure 2 is a partial side view of the bag in Figure 1;

Figure 3 is a sectional view of the upper portion of the bag of Figure 1 taken along the line 3—3 in Figure 2;

Figure 4 shows, in assembled form, the bag of Figure 1 in relationship to the device for the introduction of liquid medication according to the invention;

Figure 5 is a sectional view of the device according to the present invention in disassembled form;

Figure 6 is an enlarged partial sectional view of the combination shown in Figure 4; and

Figure 7 shows, in assembled form, the use of the intravenous administration bag after the addition of the liquid medication.

Turning to the drawings in greater detail, the holder of Figures 4 to 6 comprises a generally cylindrical hollow thrust portion 10 having an open end 12 and a closed end 14. A cylindrical vial 16 has a resilient stopper 18 in its open end sealing on the inside walls of the vial 16. The stopper 18 generally, although not necessarily, has a thin imperforate central diaphragm portion. The stopper 18 is provided with an externally threaded projection 20 thereon. The thrust portion 10 has a needle 22 therein and a boss 24 on its exterior from which cannula 26 extends. The cannula 26 has a sharpened outer end 28. A sheath 30 is carried by boss 24 and surrounds cannula 26. The sheath 30 terminates short of the sharpened outer end 28 of cannula 26. The sheath 30 has an offset or shoulder 32 which functions as further hereinafter described. Thrust portion 10 may be surrounded by holder 34.

The upper end of needle 22 has a sharp terminal portion 38. The thrust portion 10 may have internal threads 40 in proximity to its upper end, the threads on the projection 20 and the threads 40 being adapted when made up to cause said sharp terminal portion 38 of the needle 22 to puncture said stopper 18. When the projection 20 is made up with threads 40, the stopper 18 functions as a piston to expel the contents of the vial 16 through needle 22 as said vial 16 is advanced with respect to said thrust portion 10.

The flexible intravenous solution bag 42 usually has a heat-sealed peripheral portion 44 and a solution-containing zone 46. The bag also has a flexible orifice or inlet tube 48 and an outlet tube 50 which leads to a conventional intravenous solution administration set 52. The inlet tube and outlet tubes are provided with imperforate diaphragms 54 and 56, respectively, and removable caps or closures 58 and 60, respectively.

In operation, caps 58 and 60 are removed, the cannula 26 and sheath 30 are positioned as shown in Figure 6, that is, the offset or shoulder 32 limits the advancement of cannula into tube 48 so that the sharpened end 28 of cannula 26 pierces diaphragm 54 but the inside of shoulder 32 engages the outer end 62 of tube 48, limiting the advancement of the cannula 26 within tube 48. The flat surface of the shoulder 32 also serves to maintain the cannula 26 in a parallel or longitudinal relationship with respect to the inside walls of tube 48, thereby reducing the possibility of the sharpened end 28 piercing the side of tube 48. By limiting the advancement of the cannula 26 in tube 48 there is no chance that the sharpened end 28 can pierce the solution-containing zone 46. Thus, the escape of solution and the introduction of contaminated hospital air into the system are prevented.

With the parts as shown in Figure 4, the vial is normally first withdrawn slightly to aspirate from the bag into the vial approximately that volume of air corresponding to the volume of additive medication in the vial. Then, the contents of the vial are expelled into the bag. The purpose of such aspiration is to prevent rupture of the bag due to over-pressurization.

Once the contents of vial 16 have been transferred to zone 46, the bag 42 is then hung up as shown and connected to the patient via set 52, as shown in Figure 7.

WHAT WE CLAIM IS:—

1. A device for the introduction of liquid medication into a flexible bag for the adminstration of intravenous solutions which comprises an elongated generally cylindrical hollow tubular member having an open end and a closed end, a boss extending from said closed end, carried by the boss a cannula having a sharpened outer end, a rigid sheath surrounding said cannula and fixed to said boss, said sheath serving to limit the advancement of the cannula into an orifice having a diameter greater than that of said cannula, a thrust portion within said tubular member, a fluid passage within said tubular member extending longitudinally through the centre of said thrust portion, said fluid passage communicating with said cannula at one end and having piercing means associated with the other end, a

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solution set, the orifice having a diameter greater than that of the cannula and being capable of engaging said sheath to limit the advancement of said sharpened outer end of said cannula into the orifice.

The invention will now be described, by way of example, with reference to the accompanying drawings, of which:

Figure 1 is a perspective view of a conventional intravenous solution bag;

Figure 2 is a partial side view of the bag in Figure 1;

Figure 3 is a sectional view of the upper portion of the bag of Figure 1 taken along the line 3—3 in Figure 2;

Figure 4 shows, in assembled form, the bag of Figure 1 in relationship to the device for the introduction of liquid medication according to the invention;

Figure 5 is a sectional view of the device according to the present invention in disassembled form;

Figure 6 is an enlarged partial sectional view of the combination shown in Figure 4; and

Figure 7 shows, in assembled form, the use of the intravenous administration bag after the addition of the liquid medication.

Turning to the drawings in greater detail, the holder of Figures 4 to 6 comprises a generally cylindrical hollow thrust portion 10 having an open end 12 and a closed end 14. A cylindrical vial 16 has a resilient stopper 18 in its open end sealing on the inside walls of the vial 16. The stopper 18 generally, although not necessarily, has a thin imperforate central diaphragm portion. The stopper 18 is provided with an externally threaded projection 20 thereon. The thrust portion 10 has a needle 22 therein and a boss 24 on its exterior from which cannula 26 extends. The cannula 26 has a sharpened outer end 28. A sheath 30 is carried by boss 24 and surrounds cannula 26. The sheath 30 terminates short of the sharpened outer end 28 of cannula 26. The sheath 30 has an offset or shoulder 32 which functions as further hereinafter described. Thrust portion 10 may be surrounded by holder 34.

The upper end of needle 22 has a sharp terminal portion 38. The thrust portion 10 may have internal threads 40 in proximity to its upper end, the threads on the projection 20 and the threads 40 being adapted when made up to cause said sharp terminal portion 38 of the needle 22 to puncture said stopper 18. When the projection 20 is made up with threads 40, the stopper 18 functions as a piston to expel the contents of the vial 16 through needle 22 as said vial 16 is advanced with respect to said thrust portion 10.

The flexible intravenous solution bag 42 usually has a heat-sealed peripheral portion 44 and a solution-containing zone 46. The bag also has a flexible orifice or inlet tube 48 and an outlet tube 50 which leads to a conventional intravenous solution administration set 52. The inlet tube and outlet tubes are provided with imperforate diaphragms 54 and 56, respectively, and removable caps or closures 58 and 60, respectively.

In operation, caps 58 and 60 are removed, the cannula 26 and sheath 30 are positioned as shown in Figure 6, that is, the offset or shoulder 32 limits the advancement of cannula into tube 48 so that the sharpened end 28 of cannula 26 pierces diaphragm 54 but the inside of shoulder 32 engages the outer end 62 of tube 48, limiting the advancement of the cannula 26 within tube 48. The flat surface of the shoulder 32 also serves to maintain the cannula 26 in a parallel or longitudinal relationship with respect to the inside walls of tube 48, thereby reducing the possibility of the sharpened end 28 piercing the side of tube 48. By limiting the advancement of the cannula 26 in tube 48 there is no chance that the sharpened end 28 can pierce the solution-containing zone 46. Thus, the escape of solution and the introduction of contaminated hospital air into the system are prevented.

With the parts as shown in Figure 4, the vial is normally first withdrawn slightly to aspirate from the bag into the vial approximately that volume of air corresponding to the volume of additive medication in the vial. Then, the contents of the vial are expelled into the bag. The purpose of such aspiration is to prevent rupture of the bag due to over-pressurization.

Once the contents of vial 16 have been transferred to zone 46, the bag 42 is then hung up as shown and connected to the patient via set 52, as shown in Figure 7.

WHAT WE CLAIM IS:—

1. A device for the introduction of liquid medication into a flexible bag for the adminstration of intravenous solutions which comprises an elongated generally cylindrical hollow tubular member having an open end and a closed end, a boss extending from said closed end, carried by the boss a cannula having a sharpened outer end, a rigid sheath surrounding said cannula and fixed to said boss, said sheath serving to limit the advancement of the cannula into an orifice having a diameter greater than that of said cannula, a thrust portion within said tubular member, a fluid passage within said tubular member extending longitudinally through the centre of said thrust portion, said fluid passage communicating with said cannula at one end and having piercing means associated with the other end, a

cylindrical vial having a resilient stopper in its open end sealing on the inside walls of said vial, interlocking means on said thrust portion and co-operating interlocking means on said stopper, the arrangement being such that, upon interlocking of said stopper with said thrust portion, said vial is first held in an assembled but inoperative position and, upon further interlocking of said stopper with said thrust portion, said stopper is pierced by said piercing means associated with said fluid passage and said fluid passage communicated with said vial without the application of substantial axial pressure on said stopper and said stopper is locked securely to said thrust portion to permit aspiration upon withdrawal of said vial or to permit expulsion of the contents of said vial upon exertion of pressure on said vial.

2. A device as claimed in claim 1, in which the sheath is cylindrical and has two portions of different diameter, the outer portion having a diameter greater than the inner portion, a shoulder being provided at the junction of said portions whereby a stop is provided to limit the advancement of the cannula into the orifice.

3. A device as claimed in claim 1 or claim 2, in which said sharpened outer end of said cannula extends slightly beyond the free end of said sheath.

4. A device as claimed in any one of claims 1 to 3, in which the cannula extends into the thrust portion and is double-ended, thereby defining the fluid passage and piercing means.

5. A device as claimed in any one of claims 1 to 4, in combination with a flexible bag for intravenous solution having an additive-receiving tube-like orifice and an outlet adapted to lead to an intravenous solution set, the orifice having a diameter greater than that of the cannula and being capable of engaging said sheath to limit the advancement of said sharpened outer end of said cannula into the orifice.

6. A combination as claimed in claim 5, wherein the outer end portion of the orifice is capable of being received inside the outer end portion of the sheath.

7. A combination as claimed in claim 5 or claim 6, in which said tube-like orifice is provided with a lateral imperforate diaphragm capable of being pierced by said sharpened outer end of the cannular when it is advanced into said orifice.

8. A device for the introduction of liquid medication into a flexible bag substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

9. A cambination of a device for the introduction of liquid medication into a flexible bag, and a flexible bag substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

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