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HYPODERMIC AND COUPLING NEEDLE

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My present invention relates to needles and more particularly to hypodermic needles for subcutaneous injections and for piercing puncturable closures in the collection and administration of blood, parenteral, intravenous and other fluids. More particularly, the invention relates to blood-letting, coupling and infusing needles adapted particularly for use with apparatus including flexible plastic blood conducting the storing element in a system by which the sterile, deterioration-free handling of the blood may be effected, such as disclosed and claimed in my copending application Serial No. 174,891.

The nature and characteristic features of my invention will be better understood from the following description taken in conjunction with the accompanying drawings which illustrate by way of example preferred embodiments and in which:

Fig. 1 is an elevational view of one needle;

Fig. 2 is a longitudinal sectional view of the same;

Fig. 3 is a view like that of Fig. 1, showing a protective sheath and a fragmentary section of flexible tubing installed at the opposite sides of the manipulating portion;

Fig. 4 is a sectional view on the line 4—4 of Fig. 2;

Fig. 5 is an end elevation looking at the end distal to the point of the needle; and

Fig. 6 is a side elevation, partly in section, of a similar needle having a molded coupling and manipulating portion, the needle being shown in association with a mold for making the same.

The requirements for the sterile collection and infusion and the coagulation-free and degradation-retarding storage of whole blood are numerous. Similar requirements apply also to the handling of medical and surgical fluids in general. The apparatus used should be sterilizable, either by time and temperature treatment as in an autoclave or by electrical, electro-magnetic or radiative treatment. It must lend itself to a technique by which the blood is kept sealed off from contact with the atmosphere. To prevent or delay substantially the deterioration of the blood, the blood contacting elements of the apparatus must be fashioned of a material having a non-wettable, impermeable surface i. e. anti-coagulant to blood and which must be flexible and collapsible to a degree substantially eliminating liquid gas interface between the blood and the retaining wall. The needle assembly must also be designed for and capable of easy manipulation, firm and relatively air-tight assembly with the associated blood conducting tubing, and sterile handling and storage prior to use.

By my present invention I provide a novel needle capable of general application but meeting the above-mentioned requirements and adapted particularly for use with apparatus having the above-described characteristics.

Referring now to the drawings in greater detail, the needle in the embodiment of Figs. 1 to 5, indicated generally at A, comprises a relatively rigid tube or cannula 10, preferably of stainless steel, which has a smooth and uniform lumen or bore 11 extending uninterruptedly throughout its entire length to promote laminar flow of the blood and facilitate cleaning. The cannula may be manufactured in any desired size, as for example 15 gauge, a size causing minimum physiologic disturbance to a donor and thus found desirable for phlebotomy, or 19 gauge, which is a size permitting a desired rate of flow for infusion purposes. The cannula 10 will be cut or

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ground obliquely at one end to form a puncturing or piercing point 12 in the conventional manner.

A coupling and manipulating portion or element 20 is rigidly and permanently mounted on the cannula at the end distal to the point 12 in any convenient manner, as by sweating or fusing. Such element may be of metal, which may be the same as or similar to that of the cannula 10, or a more easily machinable metal or alloy such as a brass with chrome plating. Both parts, the cannula and the element 20, are machined and smoothed to eliminate depressions and cavities at the joint at opposite ends of said coupling element, precluding entry of non-sterile foreign matter thereat. This cannula-surrounding element 20 will be seen to have an intermediate, manipulating body 21 of four-sided or other outside contour, preferably non-round, merging oppositely into aligned, tapered conical coupling hubs 22, 23 which are dimensioned to fit within and seize to the open end of a flexible tubular member, such as flexible tubing of standard proportions, as indicated in Fig. 3. Hub 22, at the end away from the needle point and over which the tubing or other resilient tubular element is fitted when the apparatus is assembled for use, is somewhat longer and of a flatter taper than hub 23, as shown, to provide additional tube anchoring surface and especially secure inter-gripping action. The distinctive functions of the respective hubs in this regard will be referred to later.

As noted, my novel needle is particularly advantageous for use with tubing possessing the characteristics required of blood contacting elements of sterile, anti-coagulant blood handling apparatus, as required for blood banking and like purposes. These primarily include impermeability, tensile and flexural strength and also impact strength and general toughness, preferably with stability to sterilizing temperatures of at least 120° C. and capacity for hermetic sealing by heat. Of equal importance is that the surface shall be chemically clean, inert and non-reactive as generally characterized by a glossy-smooth and mirror-like texture, providing good tissue tolerance and substantially non-wettable to water and particularly to blood, in the sense of being non-coagulative as to the formed coagulative elements of blood. Preferably the material is transparent or substantially so to facilitate use of the apparatus. Equipment fabricated of a commercially available polyvinyl chloride-acetate copolymer type, has been found to meet all the requirements. Other materials which have been found suitable include a polymer of trichlorofluoroethylene such as known commercially; also a polyethylene composition, which latter however is unstable at 120° C. and therefore not susceptible of sterilization by the conventional "time and temperature" or heat method, but which may be sterilized in some other manner, as by X-ray or other radiation, as hereinafter mentioned.

The character and component materials of the flexible tubing and tubular connective elements for blood-handling apparatus are above discussed in detail because the hypodermic and coupling needles of the present invention having the differentiated opposed double conical hubs is especially adapted to afford a firm and well-sealed coupling engagement with said materials having the tensile and flexural strength and the surface properties noted, yet leaving one of the needle hubs, the shorter and steeper hub 23, relatively easily disconnectible from the tubing when so desired, as contrasted with the even firmer grip afforded at the other longer and flatter tapered hub 22.

To maintain the needle in a sterile, protected condition ready for use the cannula is enclosed in a sheath 40, shown in Fig. 3, placed over the cannula and seized to the shorter hub 23. As explained, the relatively steep taper and shorter length of said hub 23 toward the pointed end of the cannula makes for easier removal of the sheath. Such sheath 40 is conveniently fashioned of a short length of the plastic tubing which is pinched or sealed off at one end as at 41. It will be apparent from Fig. 3 that an entire apparatus for blood-handling purposes, such as that of said application Serial No. 174,891, may be kept in a sterile condition by providing the free ends of the blood conducting tubes with needles sealed in the manner described.

While the described double hub and coupling portion 20 of the needle performs satisfactorily as to tube gripping and sealing action when of a metallic construction as in Fig. 2, in a preferred embodiment it is formed of a plastic material molded directly around the non-piercing end of the needle, as shown in Fig. 6. For this purpose I have found nylon especially suitable, preferably a nylon type having a relatively low water absorptivity.

The plastic coupling and manipulating element 20a of the Fig. 6 embodiment is applied directly over the cannula 10 in a mold 30 shown as comprising opposed mating cavity portions 31, 32 separable along a line transverse to the needle axis as at 33, preferably at the manipulating portion 21a or at the juncture thereof with one of the conical hubs, the longer and flatter hub 22a in the present example. The sprue for entrance of the injection plastic is indicated at 34. Such mold may be of the multiple cavity type, for processing a like multiplicity of the needles in a single molding operation.

The needle cannula 10 is disposed and held coaxially in the mold cavity. Following the pressure molding operation the needle is substantially complete upon opposite longitudinal opening of the mold portions, as indicated by the dotted lines at the opposite ends in Fig. 6. If desired the mold cavity wall forming the intermediate manipulating portion 21a for the needle may be provided with the gauge number or other indicia as appropriate for the particular needle, so that such identifying marking is immediately applied in the molding operation.

Where the needle is to form part of apparatus designed to prevent or delay coagulation and degradation of the blood, the cannula desirably is treated with a medium which furnishes a non-coagulant bore lining or film (not shown) to prevent clotting of the blood passing there-through. For this purpose a mono-molecular film is applied from a dilute (0.1 to 1%) aqueous dispersion of such substance as exemplified by either dicocodimethyl ammonium chloride or octadecyl primary amine. Alternatively, the cannula itself may be fashioned of nylon or such other synthetic resin as possesses the desired toughness while presenting sterilizable chemically clean, inert, and anti-coagulant surfaces to the blood.

Upon assembly with the sheathing and/or tubing or other tubular connection the needle and accompanying apparatus such as that of said copending application Serial No. 174,891 are placed in condition for use by sterilizing at not less than 120° C. for a continuous period of at least 30 minutes, as for example in an autoclave, or by utilizing X-rays, inductive or di-electric heating or high frequency electromagnetic, supersonic, or other radiation as desirable or more convenient according to particular use factors and circumstances.

My novel needle is shown in the ready-for-use condition in Fig. 3. It will be obvious that it may be readily manipulated by grasping element 20 at the gripping portion 21. The needle is placed in use merely by removing the protective sheath 40, as facilitated by the shorter and steeper conical hub 23, the other hub retaining its grip with the tubing, and applying the needle to the donor or recipient, as required. The smooth uninterrupted cannular bore promotes the desired laminar flow of the blood at a rate determined by the needle gauge. The longer and flatter conical hub 22 insures a secure airtight coupling with the associated tubing section, adapted to be maintained under all conditions of use, as for instance, while supporting the weight of a recipient tube during infusion of the blood.

For such blood administering practice, the needle is adapted also to couple the plastic blood conducting tube to a blood storage vessel or bag forming part of a blood banking apparatus as in the application hereinbefore referred to. In such instance, the blood bag or container will be provided with an outlet consisting of a short length of tubing fused to the bag wall and closed at its inner end by a relatively thin diaphragm to form a puncturable wall thereat, and the length of the outlet tube will be predeterminedly such that the shorter hub 23 is seated in its outer end coincident with the puncturing of the diaphragm by the needle point, all as described and claimed in my said copending application Serial No. 174,891. It will be apparent that my novel needle is adapted to firmly and sealingly couple a bag having such an outlet with the blood administering tube, and that by the arrangement described the blood is protected in a

closed sealed passage continuously from the storage reservoir to the patient. With reasonable care in handling, chance for contamination of any blood-contacting surface is substantially eliminated.

From the foregoing it will be readily appreciated that by my present invention the sterile and deterioration-free collection, storage and administration of parenteral fluids, particularly whole blood, is made possible with a needle assembly adapted particularly for use with apparatus having blood protecting and preserving characteristics, but having general utility in phlebotomy, blood administering and other practice where a hypodermic needle is required.

It will be understood that my invention is not limited to the exemplary embodiments herein illustrated or described, and I set forth its scope in my following claims:

1. A hypodermic and coupling needle particularly adapted for use in collecting, storing and infusing whole blood and for reception and removal of a needle sheath and for coupling pierceably sealed containers to flexible tubing, said needle comprising a cannula defining the needle length, pointed at one end and of adequate rigidity for piercing tissue and puncturable closure material, and a manipulating and coupling element concentrically disposed upon and around the opposite cannula end portion, said element integrally formed and including a centrally intermediate elongate gripping body of rectilinear cross-section and presenting extensive flat faces for positioning the needle at rest upon a supporting surface, said element further including elongate conical oppositely tapering hubs extending from the central body, said hubs of like diameter at the distal ends and each individually having a uniform conicity from said ends to juncture with the body, the hub nearer the pointed end of the cannula being shorter and more steeply uniformly inclined for facilitating attachment and removal of a sealing sheath over the cannula and seized to said hub and on removal of the sheath to facilitate entrance and fixed seating of the hub in the needle-pierced tubing-size port of a container, and the other hub having a relatively flat taper and extended length promoting tight gripping sealing reception and secure retention thereof in flexible resilient tubing of unexpanded internal diameter less than the average diameter of the inclined portion of said hub, and the lumen wall of the cannula being of anti-clotting character with reference to blood passing through it.

2. The hypodermic and coupling needle of claim 1 wherein the cannula is of stainless steel.

3. The hypodermic and coupling needle of claim 1 wherein the double hub element is of nylon.

4. The hypodermic and coupling needle of claim 1 wherein the cannula and the double hub element are of stainless steel.

5. The hypodermic and coupling needle of claim 1 wherein the cannula and the double hub element are of nylon.

6. The hypodermic and coupling needle of claim 1 wherein the cannula lumen wall presents a film of dicocodimethyl ammonium chloride.

7. The hypodermic and coupling needle of claim 1 wherein the cannula lumen wall presents a film of octadecyl primary amine.

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