ABSTRACT OF THE DISCLOSURE

Surgical apparatus for delivering fluids to or withdrawing fluids from the human body which includes a catheter tube adapted to surround the shank of a piercing element having an end adapted to be introduced into the human body. A tubular member is inserted interiorly of the catheter tube at the other end the 20A and a hub is telescoped over the catheter tube and the tubular member at the other end. The hub, catheter tube and tubular member are riveted to one another to form a unitary construction. The method of fabricating such a catheter needle is also disclosed which includes cutting a predetermined length of mechanically expanded tetrafluoroethylene tubing. The tubing is then shrunk about a mandrel means to impart the dimensional and contour characteristics to the tubing. A hub is then secured to the tubing and an inner piercing element is inserted into the lumen of the tubing such that the piercing end of the piercing element projects beyond the free end of the tubing whereby the catheter needle is formed in which the catheter may be withdrawn by sliding the piercing element rearwardly while the catheter is being held.

This invention relates to an improved catheter needle and a method for its manufacture and, more particularly, to this product and method in which the catheter is formed from tetrafluoroethylene obtained commercially under the trademark Teflon of E. I. du Pont de Nemours & Co., Inc.

In the past, a number of catheter units of one form or another have been introduced commercially. A catheter unit having received acceptance, features as assembly including a piercing element, in some instances a conventional hypodermic needle, and a plastic catheter tube engaging the walls of the needle and so arranged with respect thereto that both are adapted to be introduced into the skin. When the desired degree of penetration has occurred, the needle and catheter tube are relatively shiftable whereby the needle is withdrawn with respect to the catheter tube which, under such circumstances, will remain situated for the intended catheterization purpose. The present invention relates to this accepted design and offers an improved product as well as novel method of its fabrication.

It is, therefore, an object of this invention to provide an improved catheter needle construction and a construction which advantageously utilizes tetrafluoroethylene as the catheter material; and, at the same time, a method by which the catheter needle is manufactured and the parts associated and manipulated in a relatively expeditious manner.

Another object is to provide a needle catheter combination which, due to the natural lubricity of the catheter material, slips into the skin and through arterial and venous walls readily and effectively, and also a combination in which the catheter tubing is riveted to a hub for security; and the invention is a best shrinking technique for reducing tetrafluoroethylene catheter tubing supplied in an expanded condition to obtain a closer and optimum fit between the hypodermic needle and tubing.

A further object is to provide a catheter needle of the type specified in the above which is reusable and capable of being sterilized through autoclaving; and one in which a trocar may replace the hypodermic needle as the piercing element, a fitted stylet can be employed in conjunction with the inner hypodermic needle to eliminate coring or cutting of a plug in the skin or vessel wall, and a plastic obturator with locking hub can close off the catheter during intermittent procedures.

A still further object of the catheter needle of this invention includes: smooth percutaneous punctures due to low coefficient or friction of Teflon; Teflon is also autoclavable, inert, slippery, non-toxic and tissue compatible; Teflon is non-wettable and blood clotting is minimized; Teflon has an extended indwelling time; catheter-over-needle design minimizes leakage as vessel puncture is dilated; the flexible catheter reduces guide wire bite during Seldinger procedures and is non-traumatic to artery in cardiopulmonary exercise procedures; the catheter needle is reusable and introduces a relatively low cost per injection; the inner piercing element may be reinserted into the catheter; the catheter tubing is riveted to a hub; inner stylet eliminates tissue plug cutting and closing obturator maintains catheter patency.

Other objects and advantages will become apparent from the following detailed description of the invention which is to be taken in conjunction with the accompanying drawings illustrating several somewhat preferred embodiments of the invention and in which:

FIG. 1 is an elevational view of the assembly of the catheter needle including the inner hypodermic needle having its lumen bearing a stylet and a catheter tube with riveted hub carried by the exterior of the inner needle;

FIG. 2 is an exploded elevational view of the inner needle and catheter with the stylet removed not only for clarity but for the reason that its presence and use is of an optional nature;

FIG. 3 is an enlarged sectional view taken along the line 3-3 of FIG. 1 with the stylet removed;

FIG. 4 is a similar sectional view with the stylet included;

FIG. 5 is a longitudinal exploded view of the catheter and an obturator;

FIG. 6 is an enlarged sectional view of the obturator assembled on the catheter tube; and

FIGS. 7 to 12 illustrate diagrammatically the method of manufacturing the catheter needle of this invention.

A catheter needle assembly of this invention will include an inner piercing element in the form of a hypodermic needle 20 or trocar (not shown) depending upon the desire to aspirate following puncture. Thus, the needle may include the usual bevel point 22 at one end of a tubular shank 24 providing the selected gauge. The other end of the shank suitably mounts as by swaging, a hub 26 which may be provided with a Luer-Lok fitting as shown.

A catheter 28 is assembled and associated with the needle 20 in a manner to be described in detail shortly and is adapted to be introduced hypodermically with the needle, then relatively disassociated theretofrom to be eventually left remaining in the tissue at the desired depth and for the intended purpose. The catheter 28 is comprised of an elongated expanded Teflon tube 30 shrunk to the desired degree and extent having a tapered penetrating end 32 which will ordinarily be disposed adjacent the bevel end 22 of the needle 20. The other end of the tube 30 is disposed around the length of needle tubing 34. A Luer-Lok hub 36 is placed around the tubing 30 and swaged or equivalently worked to rivet the tubing 30 between the hub 36 and needle tube 34 to prevent any disassociation of these parts.
Optional equipment is also contemplated by this invention in the form of a fitted stylus containing an elongated rod 40 having a beveled end 42 bevelled at an angle corresponding to that of the bevel end 22 of the needle 20. The other end of the stylus is provided with a hub 44 which, together with the hub 26 of the needle 20, provides an indexing means 46 which assures the proper relationship between the bevel of the stylus and bevel 22 of the needle 20. This fitted stylus has particular application in arterial and left heart work and myelography where it is desirable to utilize a special stylet as an aid in performing the procedure.

In addition, an obturator 48 is provided as optional equipment for closing the catheter lumen and minimizing clotting during intermittent procedures. Thus, the obturator 48 includes an elongated shank formed from a monofilament of Teflon having a blunt end 50. The other end of the monofilament is suitably anchored to a plastic Luer-Lok hub 52 capable of being associated with the hub 36 of the catheter 28 in a manner substantially as illustrated in FIG. 6. A solid, flexible stainless steel obturator may be used in advancing the catheter needle in an artery.

In use, the assembled catheter needle is injected percutaneously into the vessel to be catheterized. At some sites, it may be necessary to make a small "nick" through the skin and subcutaneous tissue. Position in situ is indicated by the flow of blood through the hub of the inner needle 20. The inner needle is then removed by a slight advancing of the catheter 30 and the simultaneous withdrawal of the inner needle 20. This maneuver places the catheter firmly with the lumen of the vessel. The catheter 30 and particularly its hub 36 may then be secured with adhesive tape. The blunt obturator 48 can be inserted and locked to occlude the catheter lumen in situ when not in use.

The catheter needle of this invention may be used to introduce flexible guide wires (Seldeinger-type) with greater safety, and also the wires or the special metal obturator may be used to direct and advance the catheter needle in the vessel or heart under fluoroscopy.

The catheter needle of this invention may be reused several times after a thorough cleaning and resterilization. Sterilization may be accomplished by autoclaving; and direct heat sterilization up to 200° C. maximum and gentle sterilization can be used, if necessary, as Teflon ordinarily has a temperature resistance of up to about 500° F. and is chemically inert. Teflon shrinks very slightly during sterilization; therefore, the catheter needle should be autoclaved with the catheter 30 positioned on the inner needle 20 until tip 32 is close to the end of the needle bevel 22, in order to maintain size and fit. The catheter needle of this invention has use in percutaneous intra-arterial catheterization, percutaneous intravenous catheterization, anaesthesia, left heart catheterization work, and other miscellaneous applications such as thoracentesis and myelography as well as many others.

As explained, the catheter tube 30 of the catheter 28 is formed from shrunken expanded Teflon tubing. This tubing is naturally translucent and flexible obtained through extrusion of Du Pont's tetrafluoroethylene resin. Expanded Teflon tubing is mechanically expanded to about double the extruded diameter and has the property of recovering the originally extruded dimensions after heating by flame, oven or electrical flameless torch to a temperature of about 621° F. or the gel point. Heat is removed substantially instantaneously at the gel point and when cooling it recovers its original diameter. Expanded tubing from Teflon, having successful application with this invention, may be obtained from the Pennsylvania Fluoro Carbon Co. of Philadelphia, Pa.

Referring now to the method of manufacturing the catheter needle of this invention, attention is directed to FIGS. 7 to 12 illustrating a sequence of steps involved in forming the end product. Thus, expanded Teflon tubing is initially provided (FIG. 7) and is cut to a predetermined length which will be readily ascertained in practice depending upon the ultimate length desired following the shrinking step, bearing in mind that, with recovery, the length increases depending on the ratio of expanded to recovered diameter. The catheter needle tube 34 is then inserted internally of the expanded tube and at one end thereof as shown in FIG. 8. A mandrel having a tapered end 58 is inserted into the interior of the tube 34 and tubing 54 such that the conical end 58 is disposed adjacent to the end of the tube 54 distally tubing 34, and this assembly is then inserted into a special oven 60, for example, whereby relatively high heat shrinks the Teflon tubing over this special mandrel as well as the needle tubing 34 (FIG. 9). This desirable molecular configuration of the now-shrunk Teflon tubing is fixed by subjecting the assembly to a chilling or cooling step as, for example, by subjecting the assembly to a water bath 62 (FIG. 10). The mandrel 56 is then removed and a length of wire 64 is inserted into the interior of the assembly; and the tapered end 32 of the tube 30 is formed by grinding this end by means of an abrasive wheel, for example (FIG. 11). The grinding wire 64 is removed and the assembly placed in the selected hub 36 and riveted thereto as by swaging or top riveting along the circumferential zone 66 (FIG. 12). The inner needle 20 may now be inserted into the catheter 28 such that the end of the taper 32 of the catheter tube 30 is disposed adjacent the heel of the bevel 22 of the inner needle as shown in FIG. 13.

Thus, the aforesaid objects and advantages are most effectively attained. Although several preferred embodiments of this invention have been disclosed in detail herein, it should be understood that this invention is in no sense limited thereby; and its scope is to be determined by that of the appended claims.

I claim:

1. Surgical apparatus for delivering fluids to or withdrawing fluids from the human body comprising: a tetrafluoroethylene catheter tube adapted to surround the shank of a piercing element having a penetrating end adapted to be introduced into the human body and rear end, a tubular member inserted internally of the catheter tube at the rear end thereof, a hub having a bore therein telescoped over the catheter tube and the tubular member at said rear end so that said tube and tubular member extend into the bore of said hub, said hub, catheter tube and tubular member being riveted together in construction, the penetrating end of the catheter tube having an internal surface, frustrum-conical in configuration and an outer tapered surface, a needle having a head with pointed end and a shank projected rearwardly therefrom disposed internally of the catheter tube, said needle and tube cooperating to provide means to cause the tube to follow said head through the skin and tissue to locate the end thereof at the desired position in the body, and the penetrating end of the catheter tube and the head of the needle being relatively disposable to permit the head to be withdrawn through the catheter tube, a styllet disposed internally of the lumen of the needle and including an elongated rod portion for disposition in the lumen of the needle, said rod portion having a terminal end having means for cooperating with the pointed end of the needle to minimize tissue plug cutting, a hub means at the other end of the rod portion adapted to be associated with the hub of the needle, and indexing means in the form of a notch on said styllet hub and a notch on the hub of said needle which when aligned assure that the bevel of the styllet is aligned with the head of the needle.

2. The invention in accordance with claim 1 wherein when the styllet and needle have been removed from the catheter tube, an obturator closing the lumen of the catheter tube end and having an elongated rod portion for insertion into the lumen of the catheter tube and a hub coupled with said rod portion including means for securing the obturator to the catheter is inserted therein.

3. The method of fabricating a catheter needle used
for inserting the end of the catheter into a body cavity comprising the steps of; cutting a predetermined length of mechanically expanded tetrafluoroethylene tubing, inserting a tubular member into one end of the tubing, placing the tubular member and tubing on a mandrel having predetermined dimensional and contour characteristics, heating the tubing to its gel point and removing said heat substantially instantaneously at the gel point, shrinking the tubing about the tubular member and mandrel to impart the dimensional and contour characteristics of the mandrel to the tubing, chilling the tubing to fix the molecular configuration thereof, removing the mandrel and insert therefor a length of wire, grinding a taper on the end of the tubing distal the end disposed around the tubular member, removing the wire, placing a hub around the tubing and tubular member, riveting the hub, tubing and tubular member to one another, and inserting an inner piercing element into the lumen of the tubing such that the piercing end of the piercing element projects beyond the free end of the tubing whereby a catheter needle is formed in which the catheter may be withdrawn by sliding the piercing element rearwardly while the catheter is being held.

4. The invention in accordance with claim 3 wherein the tubing is chilled following shrinking to fix the molecular configuration thereof.

5. The invention in accordance with claim 3 wherein a taper is ground on the free end of the tubing.

6. The invention in accordance with claim 5 wherein the taper is ground after chilling by the steps of removing the mandrel and inserting therefor a length of wire, grinding a taper on the end of the tubing distal the end disposed around the tubular member, and removing the wire.

7. The method of fabricating a catheter needle used for inserting the end of the catheter into a body cavity comprising the steps of, cutting a predetermined length of mechanically expanded tetrafluoroethylene tubing, inserting a tubular member into one end of the tubing, placing the tubular member and tubing on a mandrel having predetermined dimensional and contour characteristics, heating the tubing to its gel point and removing such heat substantially instantaneously at the gel point, shrinking the tubing about the tubular member and mandrel to impart the dimensional and contour characteristics of the mandrel to the tubing, chilling the tubing to fix the molecular configuration thereof, removing the mandrel and insert therefor a length of wire, grinding a taper on the end of the tubing distal the end disposed around the tubular member, removing the wire, placing a hub around the tubing and tubular member, riveting the hub, tubing and tubular member to one another, and inserting an inner piercing element into the lumen of the tubing such that the piercing end of the piercing element projects beyond the tapered end of the tubing whereby a catheter needle is formed in which the catheter may be withdrawn by sliding the piercing element rearwardly while the catheter is being held.

References Cited

UNITED STATES PATENTS

<table>
<thead>
<tr>
<th>Patent Number</th>
<th>Date</th>
<th>Inventor</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,027,962</td>
<td>1/1936</td>
<td>Currie</td>
<td>29—447 X</td>
</tr>
<tr>
<td>2,389,355</td>
<td>11/1945</td>
<td>Golland et al.</td>
<td>128—214.4</td>
</tr>
<tr>
<td>2,712,982</td>
<td>9/1955</td>
<td>Ryan</td>
<td>128—214.4</td>
</tr>
<tr>
<td>2,828,744</td>
<td>4/1958</td>
<td>Hirsch et al.</td>
<td>128—221</td>
</tr>
<tr>
<td>3,030,953</td>
<td>4/1962</td>
<td>Koehn</td>
<td>128—214.4</td>
</tr>
<tr>
<td>3,312,290</td>
<td>4/1967</td>
<td>Eisenberg</td>
<td>128—214.4</td>
</tr>
<tr>
<td>3,348,544</td>
<td>10/1967</td>
<td>Braun</td>
<td>128—214.4</td>
</tr>
<tr>
<td>2,770,236</td>
<td>11/1956</td>
<td>Uley et al.</td>
<td>128—221</td>
</tr>
<tr>
<td>3,094,122</td>
<td>6/1963</td>
<td>Gauthier et al.</td>
<td>128—221</td>
</tr>
<tr>
<td>2,938,238</td>
<td>5/1960</td>
<td>Gewecke et al.</td>
<td>18—59</td>
</tr>
<tr>
<td>2,989,785</td>
<td>6/1961</td>
<td>Stahl</td>
<td>18—59</td>
</tr>
</tbody>
</table>

OTHER REFERENCES


DALTON L. TRULUCK, Primary Examiner.