United States Patent [19]

Sheridan

[11] **3,853,130**

[45] **Dec. 10, 1974**

[54] **STERILE HANDLING CATHETER ASSEMBLIES**

[76] Inventor: **David S. Sheridan,** Hood Rd., Argyle, N.Y. 12809

[22] Filed: **Dec. 4, 1973**

[21] Appl. No.: **421,726**

[52] **U.S. Cl.** ..... **128/349 R,** 128/DIG. 26

[51] **Int. Cl.** **A61m 25/00**

[58] **Field of Search** ..... 128/348, 349 R, 350 R, 128/351, 1 R, 303 R, DIG. 26

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Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Kemon, Palmer & Estabrook

[57] **ABSTRACT**

A sterile handling catheter assembly comprises a catheter enveloped by a protective sheath which has a longitudinal slit extending the entire length thereof and a pair of ribs extending radially from the sheath which run the full length of the sheath adjacent and parallel to the slit creating a barrier which preserves sterility of the edges of the slit during manipulation of the assembly for installation of the catheter in a patient.

12 Claims, 11 Drawing Figures

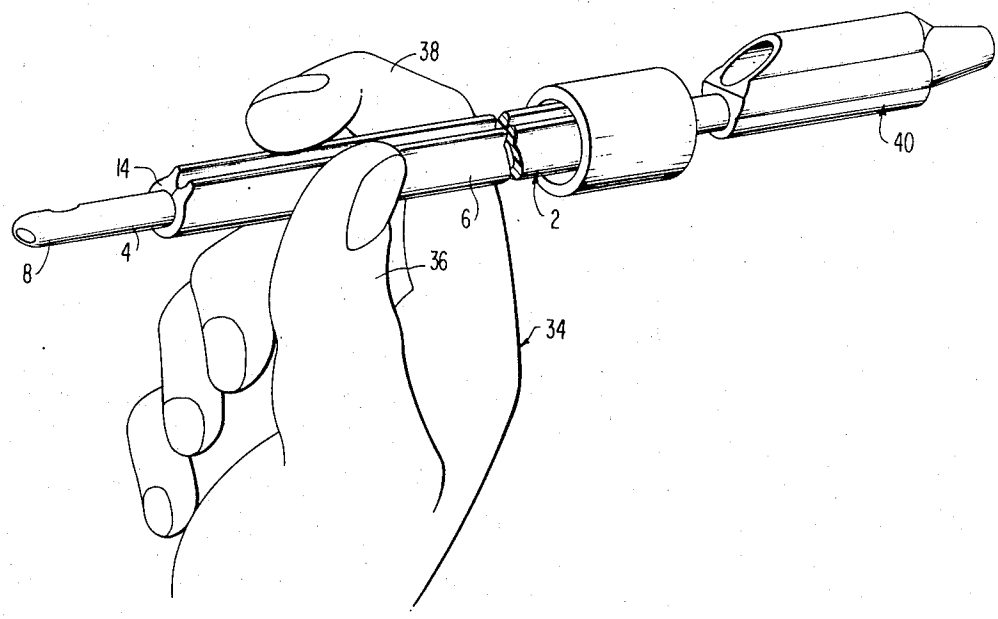
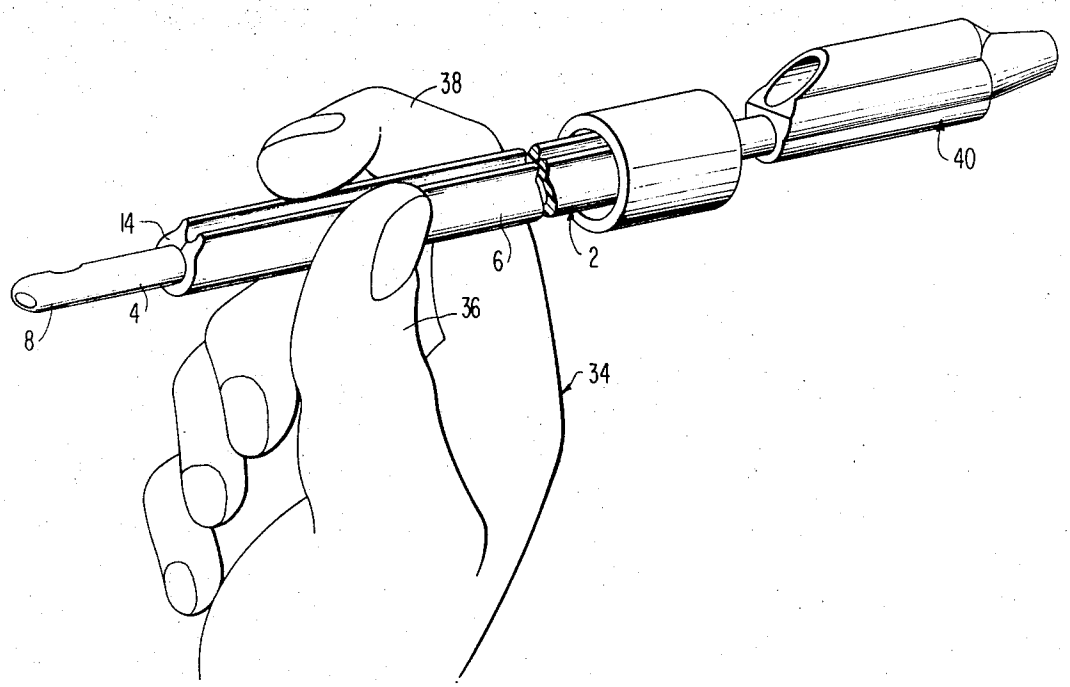


FIG. 1



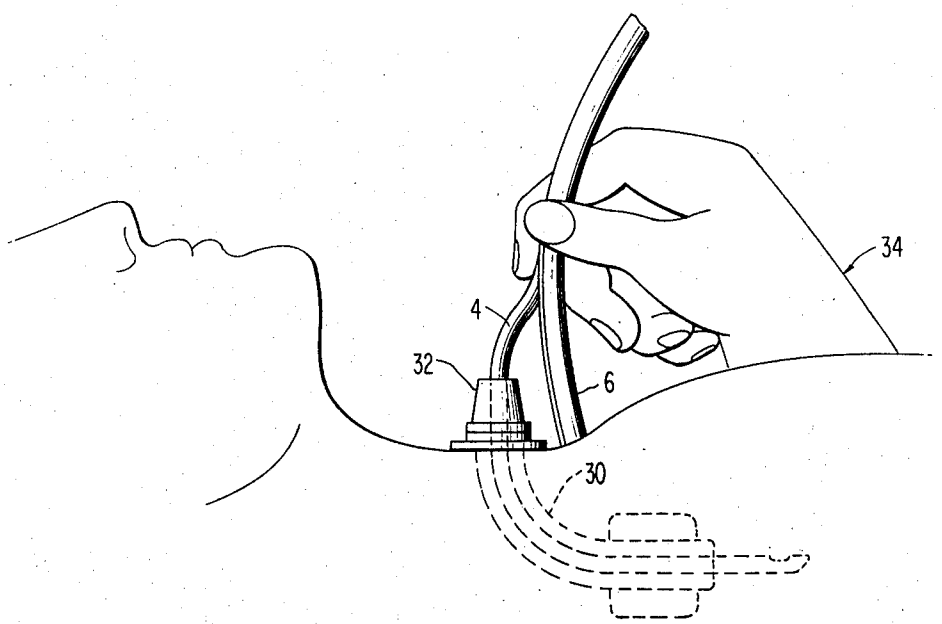


FIG. 2

FIG. 3

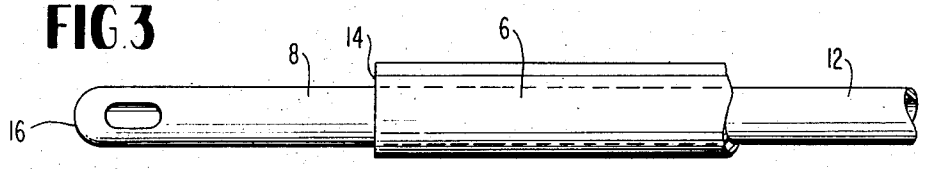
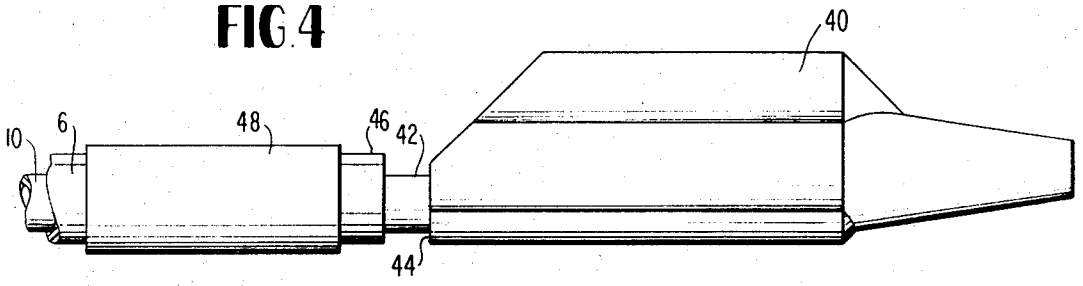


FIG. 4



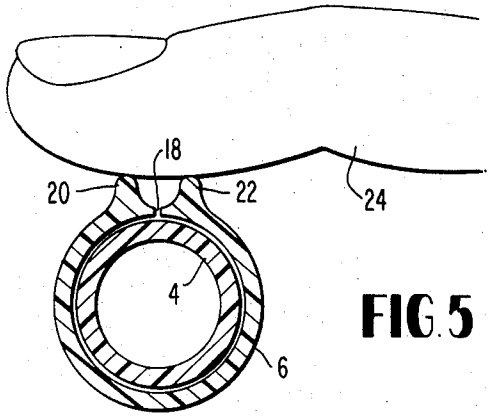


FIG. 5

FIG. 6

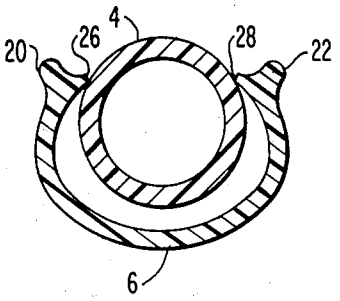


FIG. 7

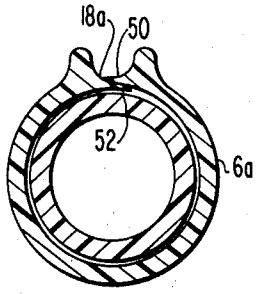


FIG. 8

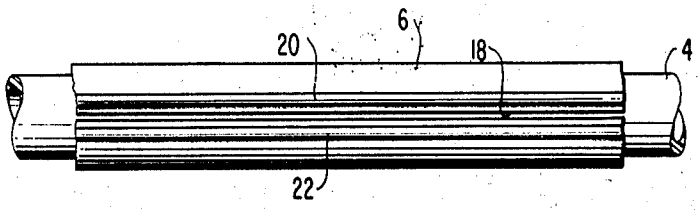
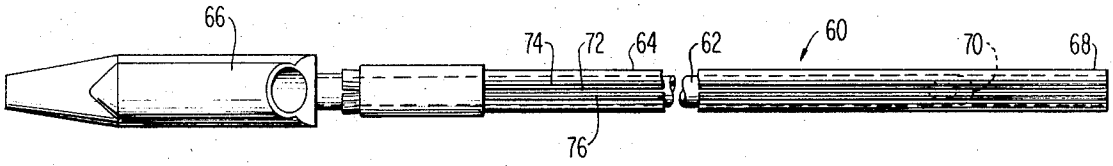


FIG. 9



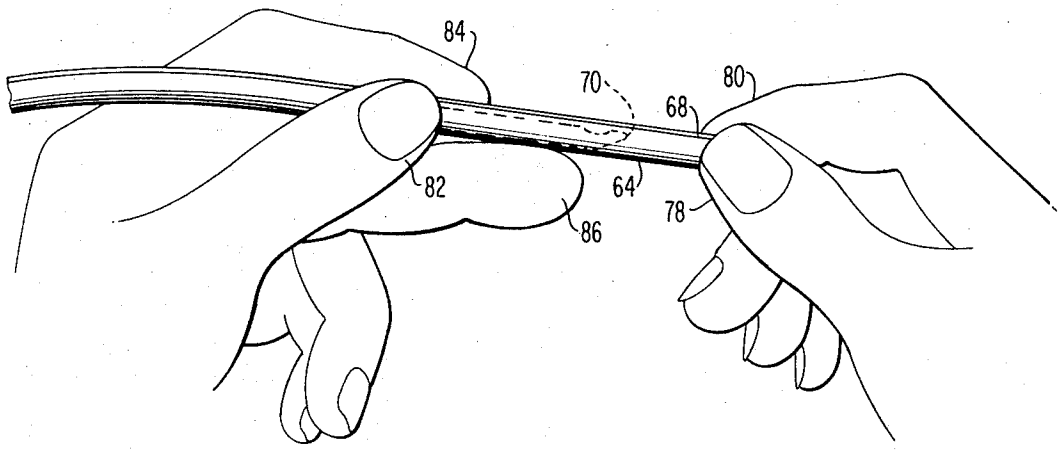


FIG. 10

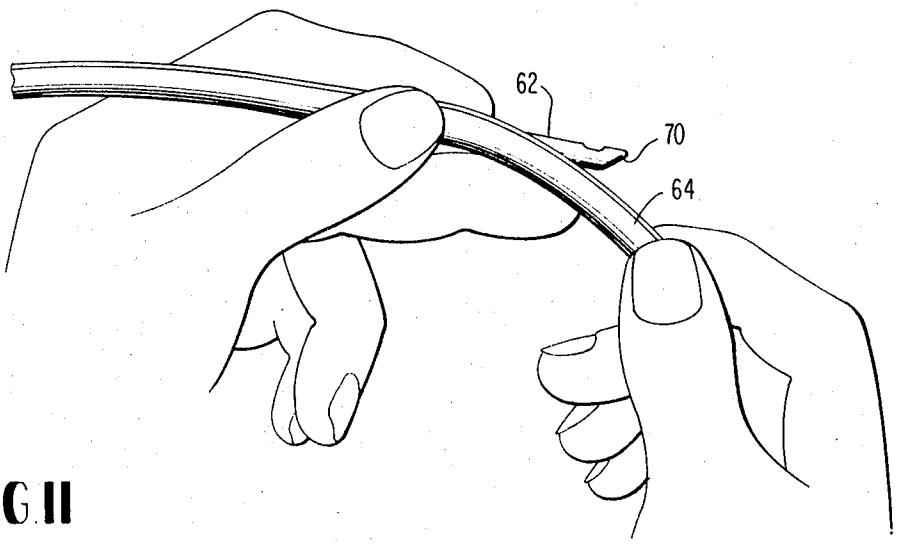


FIG. 11

STERILE HANDLING CATHETER ASSEMBLIES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention pertains to catheter assemblies designed for sterile handling without requiring use of sterile surgical gloves to preserve sterility of the catheter upon its installation in a patient. More particularly, it concerns sterile handling catheter assemblies in which the catheter is enveloped by a protective sheath of unique construction which permits the assembly to be manipulated for installation of the catheter in a patient by contact only with the protective sheath so that sterility of the catheter is completely preserved during the installation procedure. Catheter assemblies of the invention are especially useful for sterile handling of suction catheters but the new assemblies may be utilized with urethral catheters, Foley catheters or any other form of tubes or catheters known to the surgical and medical arts which require sterile handling for installation in a patient.

2. Description of the Prior Art

In the use of suction catheters, urethral catheters and similar medico-surgical tubes, it is necessary to preserve the sterility of that portion of the catheter which enters the body of a patient in order to prevent the patient from becoming infected by the insertion of the catheter. This presents difficulties to the surgeon or other person performing the catheter installation. For example, if it is necessary to catheterize a patient during a surgical operation, the surgeon's hands or gloves will normally be soiled by blood or other materials which would come in contact with the walls of the catheter and be carried into the patient's body if the surgeon were to directly contact the catheter during the installation with such soiled gloves. As a result, catheter installation under such circumstances is frequently performed by another person wearing a sterile pair of surgical gloves. As a matter of fact, this occurs so frequently that manufacturers of catheters make and sell so-called "tray" packages which enclose in sterile condition a catheter along with a pair of surgical gloves to be used in performing the installation of the catheter. Of course, not only does this add to the cost of catheterization of a patient, but the procedure consumes more time than is desirable. The magnitude of the problem can be understood if one realizes that a post-operative patient may need to be suctioned every 15 minutes and at progressively longer intervals as his condition improves. Couple this with the fact that it is the current trend for hospitals to use suction catheters for a single use only and that as many as 400 suction catheters could be used on one patient within a 2-week period and it becomes apparent great saving in time can be made by eliminating the need for sterile gloves when suction catheters are installed.

It has been proposed to enclose catheters in protective sheaths which are slit longitudinally so that the catheter can be manipulated into the body of a patient while its sterility is protected by the sheath. Catheter assemblies of this type are disclosed, for example, in U.S. Pat. Nos. 3,262,448 and 3,559,643. However, the concept of use of a protective sheath in the handling of catheters as employed in the prior art has been of relatively limited scope. Thus, in order to use the prior known catheter assemblies involving the protective sheath, the devices have required means other than the sheath itself to push the catheter for installation in the patient while preserving its sterility. Furthermore, use of the prior known catheter assemblies have essentially been limited to a two-hand type of operation.

OBJECTS

A principal object of this invention is the provision of new forms of sterile handling catheter assemblies. Further objects include the provision of:

1. Sterile handling catheter assemblies in which the catheter is carried in a protective sheath of unique construction which permits the sheath to be used as a means by which the catheter is advanced for installation in a patient.
2. Improved sterile handling catheter assemblies which are capable of being installed in a patient with a one-hand technique.

Other objects and further scope of applicability of the present invention will become apparent from the detailed description given hereinafter; it should be understood, however, that the detailed description, while indicating preferred embodiments of the invention, is given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

SUMMARY OF THE INVENTION

The stated objects are accomplished according to the present invention by provision of sterile handling catheter assemblies which comprise a catheter, and a protective sheath formed of flexible plastic material enveloping at least the proximal end and central body portions of the catheter. The protective sheath has a longitudinal slit extending the entire length thereof, a pair of ribs extend radially from the sheath and run the full length thereof adjacent and parallel to the slit. These ribs serve as barrier members above the slit to preserve the sterility of the edges of the slit while the protective sheath is manipulated by a surgeon or other person and used as the means to advance the catheter for its installation in a patient. In one embodiment of the new catheter assemblies, the sheath is shorter in length than the catheter so that the distal end portion of the catheter remains uncovered by the sheath. In another embodiment, the sheath is longer than the catheter so that even the distal end portion is covered and the sheath extends beyond the distal end, e.g., about 1–3 cm.

Advantageously, both the catheter and the protective sheath are formed by extrusion from flexible waterproof non-fibrous thermoplastic material. In such an extrusion, the ribs which constitute the barrier members for the slit are formed integrally with the remainder of the protective sheath. Although the longitudinal slit in the sheath can be formed by cutting, it is advantageously formed in the sheath during the extrusion operation. The extrusion die may be structured to form a sheath in which the edges of the slit abut one another or, alternatively, so that one edge of the slit overlaps the other edge.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the new catheter assemblies of the invention and their methods of use may be had by reference to the accompanying drawings in which:

FIG. 1 is a fragmented perspective view of a catheter assembly of the invention in the hand of a surgeon ready for insertion into a patient.

FIG. 2 is a diagrammatic fragmented side view partially in section of the catheter of FIG. 1 being inserted into a patient through a tracheostomy tube.

FIG. 3 is an enlarged fragmentary side view of the distal end section of a catheter assembly of the invention.

FIG. 4 is an enlarged fragmentary side view of the proximal end section of a catheter assembly of the invention.

FIG. 5 is an enlarged sectional end view of a catheter assembly of the invention.

FIG. 6 is an enlarged sectional end view of the catheter assembly of FIG. 5 showing the protective sheath being strippped from the catheter as the catheter is inserted into a patient.

FIG. 7 is an enlarged sectional end view of another form of catheter assembly of the invention.

FIG. 8 is an enlarged fragmentary plan view of a catheter assembly of the invention. FIG. 9 is a fragmented perspective view of another form of suction catheter assembly of the invention.

FIG. 10 is a fragmented perspective view of the catheter assembly of FIG. 9 at the beginning of the manipulation to install the catheter in a patient.

FIG. 11 is a fragmented perspective view of the catheter assembly of FIG. 9 in a further stage of manipulation prior to installation.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring in detail to the drawings, a catheter assembly of the invention **2** comprises a catheter **4** and a protective sheath **6.** The catheter has a distal end portion **8,** a proximal end portion **10** and a central body portion **12** which connects the distal end portion **8** to the proximal end portion **10.** The protective sheath **6** formed of flexible plastic material is shorter in length than the catheter **4** so that the distal end **14** of the sheath terminates proximally of the tip **16** of the catheter leaving the distal end portion **8** of the catheter uncovered. The remainder of the catheter comprising the central body and proximal end portions is enveloped by the protective sheath.

The sheath **6** has a longitudinal slit **18** which extends the entire length of the sheath. A first rib **20** runs the full length of the sheath adjacent one side of the slit and, as can be seen in detail in FIG. **5,** the rib **20** extends radially outwardly from the sheath **6.** A second rib **22** which also runs the full length of the sheath adjacent the other side of the slit **18** extends radially outwardly from the sheath **6** substantially the same distance as the first rib **20.**

With reference to FIG. **5,** it can be seen that the ribs **20** and **22** create a pair of parallel barrier members above the slit **18** preventing objects, such as the finger **24** of a surgeon, from contacting the edges of the slit during manipulation of the catheter assembly in installation of the catheter in a patient. Hence, the pair of ribs **20** and **22** preserve the sterility of the slit edges **26** and **28** and thereby insure the sterility of the catheter when these edges contact the catheter as the protective sheath **6** is stripped from the catheter **4** during insertion of the catheter in a patient (see FIGS. **2** and **6**).

The catheter assemblies of the invention require only one-hand manipulation to accomplish sterile installation of the catheter into a patient. The method of use of the new catheter assemblies can be understood by reference to FIGS. **1** and **2** which illustrate the installation of a suction catheter into a patient by way of a tracheostomy tube **30.** With reference to FIG. **1,** the protective sheath **6** of the suction catheter assembly **2** is grasped between the thumb **36** and index finger **38** of the hand **34** of the surgeon or other person installing the catheter **4** in the patient slightly proximal of the distal end **14** of the protective sheath. The exposed distal end portion **8** of the catheter **4** is then inserted into the inlet opening **32** of the tracheostomy tube **30.** The surgeon by pulling lightly on the protective sheath **6** can then cause the sheath to part (see FIG. **6**) at the slit **18** and slide past the catheter **4.** The surgeon then moves a short distance further along the protective sheath away from the junction between the catheter **4** and the parting in the sheath **6** and gently pushes the catheter assembly toward the patient so that a further section of the catheter enters the tracheostomy tube **30.** As the catheter enters the tube, a further section of the sheath will part along the slit **18** and the portion of the sheath **6** which separates from the catheter **4** will slide down the outside and away from the catheter as illustrated in FIG. **2.** This procedure is repeated a sufficient number of times so that the catheter advances into the patient to the distance required for the particular procedure being performed. The suction catheter having been joined by way of the vacuum controller **40** to a suction source, the suction catheter can be operated by manipulation of the vacuum controller **40** in the customary manner. It will be understood from this description of use and by reference to the accompanying FIGS. **1** and **2** that during the manipulation of the catheter assembly for installation of the catheter in the patient, the catheter never comes in contact with any part of the hand **34** of the surgeon. Furthermore, no part of the protective sheath which comes in contact with the fingers or other portion of the surgeon's hand will make contact with the catheter. The lumen of the protective sheath **6** is sterile and remains so throughout manipulation of the catheter assembly. The same is true of the edges **26** and **28** of the slit **18** because, as can be seen by reference to FIG. **5,** the ribs **20** and **22** prevent any contact by the fingers or other portions of the surgeon's hand so that sterility of the slit edges is maintained. This in turn preserves the sterility of the catheter **4.**

Details of construction of the proximal end portion of the catheter assembly illustrated at FIG. **1** are shown in FIG. **4.** The vacuum controller **40,** which may be of the form shown and described in U.S. Pat. No. 3,610,242 or of any other suitable structure, is joined to the proximal end **10** of the catheter by a short section of tubing **42** which is cemented at one end to the inlet port **44** of the vacuum controller **40.** The tube section **42** has an inside diameter approximately the same size as the outside diameter of the catheter and the proximal end of the catheter is inserted in the tube section **42** and cemented therein.

In the embodiment of the new catheter assemblies shown in FIG. **9,** the assembly **60** comprises a catheter **62,** a protective sheath **64** and the vacuum controller **66.** The sheath **64** is longer than the catheter **62** so that the free end **68** of the sheath extends about 1 to 3 cm. beyond the distal end **70** of the catheter. The sheath **64** has a longitudinal slit **72** extending the full length thereof and adjacent ribs **74** and **76** as in the case of the

embodiments described in connection with FIGS. **1–8.**

The use of a catheter assembly as shown in FIG. **9** begins as a two-hand operation. As seen in FIG. **10,** the free-end **68** of the sheath **64** with the slit **72** on top is grasped by the surgeon or other operator between thumb **78** and finger **80.** Simultaneously, the sheath **64** is grasped near the catheter tip **70** in the other hand between thumb **82** and finger **84.** With the finger **86** acting as a support below the catheter tip **70,** the sheath end **68** is moved downward by thumb **78** and finger **80.** This motion will bend the sheath over the tip **70** of the catheter and the slit **72** will open leaving the catheter tip **70** exposed as shown in FIG. **11.** From then on, the installation of the catheter **62** into the patient will be essentially a one-hand procedure as described previously in connection with the embodiment of FIGS. **1–8.**

Different sizes of catheters are required for a variety of reasons, e.g., different sizes of patients, different medical or surgical procedures or the like. In the preferred embodiments of catheter assemblies of the invention, each size of catheter will have a protective sheath of the most advantageous size for the particular size catheter with which it will be assembled. Preferably, the catheter sheath will be just slightly larger in inside diameter than the outside diameter of the catheter, e.g., the ID of the protective sheath **6** will be about 0.1 to 1 mm. larger than the O.D. of the catheter **4.** The wall thickness of the plastic sheath will depend, in part, upon the nature and type of material of which the plastic sheath is formed. Thus, with more rigid material, a thinner wall thickness for the sheath **6** is preferred. The sheath can be formed of any suitable flexible material including polyolefins, e.g., polyethylene or polypropylene; nylon; acrylic resins; etc., although polyvinyl chloride is preferred because this class material offers a wide range of selection and control in flexibility and strength properties making it possible to construct catheter assemblies of a wide range of sizes and shapes from a single type of material. The wall thickness of the plastic sheath advantageously will be between about 0.2 to 1 mm.

The ribs **20** and **22** which extend radially from the tubular cross-section of the plastic sheath may be varied in configuration. A preferred shape is triangular with the base formed integral with the shape per se and a rounded apex. Other shapes, however, are possible including semi-circular, rectangular, square cross-sections or the like. Advantageously, the ribs will protrude between about 0.5 and 5 mm. and particularly 1 to 3 mm. above the outer surface of the protective sheath and the distance between the central axes of the ribs will be between about 2 to 10 mm. and particularly 3 to 5 mm.

When plastic sheaths for the catheter assemblies of the invention are constructed and sized as described above, they will be relatively free to slide longitudinally along the catheters which are enclosed within the sheath. It is preferable, therefore, to arrange some means at the proximal end of the sheath to restrain the sheath from sliding along the catheter. This can be done in a variety of ways. For example, the sheath may be cemented or clamped at its proximal end about the encircled catheter. However, the surgeon or other user of the device may wish to completely separate the sheath from the catheter upon completion of the insertion procedure. Accordingly, a sheath restraining arrangement which does not permanently connect the sheath to the catheter is advantageous. An arrangement of this type is illustrated in FIG. **4.** The section of connector tubing **42** is of slightly larger outside diameter than the inside diameter of the sheath **6.** Accordingly, when the proximal end **46** of the sheath surrounds the connector tube section **42** there will be sufficient frictional engagement between these two parts **42** and **46** to restrain movement of the sheath **6** along the catheter **4.**

In certain types of operations and for other considerations, it may be desirable not to remove the protective sheath from the catheter upon completion of the insertion procedure, but allow it to remain in a draped condition as shown in FIG. **2** until the catheter is removed from the patient. Further, when the catheter is removed, it may also be desirable to return the catheter back into the sheath, e.g., to provide a means for sanitary handling of the catheter by preventing the soiled outer surface of the catheter to come into contact with objects which might be contaminated by the mucus or other soiling material upon the catheter. For this purpose, the catheter assemblies of the invention may be provided with a movable slide **48** which can be used for encasing the used catheter within the protective sheath as it is withdrawn. In such a situation, the catheter and sheath will be separated from each other back as far as the catheter had been inserted into the patient. The slide member **48** would be moved distally on the sheath to this point. By holding the slide **48** in one hand and grasping the assembly in the other hand at some more proximal position, e.g., by the attached vacuum controller **40,** the slide **48** may be moved towards the distal end of the assembly using a back and forth twisting motion. This forces the catheter back within the sheath as the catheter is simultaneously extracted from the patient. The slide member **48** is a short section of tubing, e.g., extruded plastic tubing, having an I.D. just slightly larger than the O.D. of the sheath **6.**

In the embodiment of the catheter assembly shown in FIG. **5,** the two edges **26** and **28** of the slit **18** abut one another. An alternative arrangement is shown in FIG. **7.** Here, one edge **50** of the slit overlaps the other edge **52.** A construction of this type for the sheath **6a** can easily be obtained in forming the protective sheath by plastic extrusion by shaping the extrusion die to create a thin lip or ledge on the edge **52** which will underlay the opposing edge **50** of the slit **18*a***.

DISCUSSION OF DETAILS

The catheter which comprises the assemblies of the invention may be manufactured to professional specifications and may be produced in varying degrees of flexibility or rigidity by varying the formulation of the plastic material from which the tubes are extruded. They should be water-proof, flexible over a relatively wide range of temperatures, resistant to attack by body fluids, capable of being sterilized, such as exposure to ethylene oxide or gamma radiation, and preferably produced by extrusion at high speed in order to be relatively low in cost. There are a variety of plastic materials capable of providing these requirements for the production of catheter assemblies of the invention. Advantageously, both the catheters and the protective sheaths will be formed of non-fibrous plastic material and plasticized polyvinyl chloride is preferred. A particular use-

ful material of this type can be formulated to have an extrusion temperature of about 325°–375°F. However, the invention is contemplated for use in connection with any plastic or elastomeric material known or found to be useful in the formation of disposable catheters, e.g., polyethylene, polypropylene, natural rubber, synthetic rubber, etc.

The catheters of the new assemblies may be constructed with any special features which are known to be useful with medico-surgical tubes or which may be required for particular procedures in which the catheters are to be employed. These may include a nonsparking feature (see U.S. Pat. No. 3,007,132), x-ray markings (see U.S. Pat. No. 3,605,750) or a frosted surface to reduce friction in contact with other plastic items (see U.S. Pat. No. 3,508,554). Any of the known forms of tips and side openings may be incorporated in the catheters. Moreover, the unique protective sheath assemblies of the invention may be employed with other medico-surgical tubes such as post-surgical drainage tubes including those with a capped proximal end (see U.S. Pat. No. 3,589,368).

Since the new catheters are designated particularly for disposable, single use purpose, they will be advantageously packaged as single units each in its own individual peel-back package. A variety of film or other packaging material is available for such purposes in which the new catheter assemblies may be contained for extended periods of time in sterile condition immediately available to the surgeon or other user at the location where the catheter is to be used with a patient. Once enclosed in such package, the catheter assembly may be rendered sterile by the use of known sterilization methods, e.g., exposure to ethylene oxide or gamma radiation.

CONCLUSION

The invention as described herein provides a means for removing a catheter from a sterile peel-back package and preserving the sterility of the catheter while it is being inserted into a patient, such as through the nose, mouth, urethra, an endotracheal tube, a tracheostomy tube, a body incision or the like. This is accomplished without the person making the catheter installation needing to wear sterile gloves. When the catheter is introduced into a patient, the distal portion of the catheter, which extends out of the unique protective sheath, is entered into the orifice through which the catheter is to pass. With only one hand, the surgeon or the protective sheath to advance the catheter into required position in the patient. The protective sheath being of such construction that complete sterility of the catheter is maintained during such manipulation, moves out of the way as the catheter is advanced and creates no discomfort or trauma to the patient. Hence, the invention provides new sterile handling catheter assemblies of a single-use, disposable type which can be utilized with maximum efficiency in any required surgical or other medical procedure.

The embodiments of the invention in which an exclusive property or right is claimed or defined in the accompanying claims:

1. A sterile handling catheter assembly comprising:
a catheter having a distal end portion, a proximal end portion and a central body portion integrally connecting the distal end portion to the proximal end portion,
a protective sheath formed of flexible plastic material that, throughout the length thereof, substantially completely and closely encircles said catheter, the length of said sheath being sufficient that at least the proximal end and central body portions of said catheter are so encircled,
said sheath having a longitudinal slit extending substantially the length thereof,
a first rib running substantially the length of said sheath adjacent one side of said slit extending radially outwardly from said sheath,
a second rib running substantially the length of said sheath adjacent the other side of said slit extending radially outwardly from said sheath substantially the same distance as said first rib,
said ribs creating a pair of parallel barrier members above said slit to preserve the sterility of the edges of the slit during manipulation of said assembly in the installation of said catheter in a patient.

2. The catheter assembly of claim **1** wherein said catheter is a suction catheter.

3. The catheter assembly of claim **1** wherein moveable slide means encircles a portion of the proximal end of said protective sheath.

4. The catheter assembly of claim **1** wherein said catheter is extruded of flexible water-proof nonfibrous thermoplastic material.

5. The catheter assembly of claim **4** wherein said protective sheath is extruded of flexible water-proof nonfibrous thermoplastic material with said ribs integral with the remainder of the sheath.

6. The catheter assembly of claim **1** wherein said catheter is a suction catheter having vacuum control means fixed to the proximal end thereof.

7. The catheter assembly of claim **6** wherein said sheath is retained against movement longitudinally relative to said catheter by frictional engagement between the inner surface of the proximal end of the sheath and a tubular member connecting the catheter to said vacuum control means.

8. The catheter assembly of claim **1** wherein the edges of said slit in said sheath abut one another.

9. The catheter assembly of claim **1** wherein one of the edges of said slit in said sheath overlaps the other edge of said slit.

10. The catheter assembly of claim **1** wherein the height of said ribs above the outside wall of the catheter is between about 1 to 3 mm. and the distance between the central axes of the ribs is between about 3 to 5 mm.

11. The catheter assembly of claim **1** wherein said catheter has a frosted outer surface.

12. The catheter assembly of claim **1** wherein said catheter and said sheath are both extruded plasticized polyvinyl chloride material.

* * * * *

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,853,130 Dated December 10, 1974

Inventor(s) David S. Sheridan

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

[73] Assignee: MALLINCKRODT, INC.

Signed and sealed this 11th day of February 1975.

(SEAL)
Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents
and Trademarks

ORM PO-1050 (10-69)

USCOMM-DC 60376-P69
☆ U.S. GOVERNMENT PRINTING OFFICE : 1969 O—366-334.