ABSTRACT: A preformable catheter assembly can be given a predetermined curvature while in the sterilized condition which permits the catheter, when removed from the assembly, to substantially assume the predetermined curvature. The assembly includes a plastic catheter having a malleable forming wire inserted in the lumen of the catheter and a flexible, airtight, waterproof envelope enclosing the catheter and wire with a minimum of entrapped air. The catheter is shaped by bending the catheter assembly to the predetermined curve, heating, cooling and then removing the catheter from the assembly. This catheter assembly eliminates the need for the hospital to stock preshaped catheters and permits the physician to shape the catheter to his own choosing in the sterile condition prior to the operative procedure.
PREFORMABLE CATHETER PACKAGE ASSEMBLY AND
METHOD OF PREFORMING

BACKGROUND OF THE INVENTION

This invention relates to a catheter package assembly and, more particularly, to a catheter provided with a forming wire in the lumen and packaged in a sterilized, waterproof envelope so that the catheter may be bent to a predetermined shape while in the sterile condition. Catheters such as radiopaque or radiology catheters are usually supplied to the physician with a preset curvature for use in surgical procedures. This requires the physician or hospital to maintain an inventory of catheters having different curvatures depending upon the particular operative use to which the catheter will be put.

BRIEF SUMMARY

A catheter and package assembly have now been developed to which any curvature can be imparted to the catheter by the physician while the catheter is packaged in a sterilized condition.

An object of this invention is to provide a catheter assembly which permits the catheter to be shaped to a predetermined curvature while in the sterile condition.

Another object of this invention is to provide a catheter package assembly which will permit the catheter while packaged in the sterile condition to be bent to a predetermined curvature which, by simply heating and cooling the packaged catheter, will cause a predetermined curvature to be imparted to the catheter.

Other objects and advantages will become apparent from the following description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a top plan view of the catheter package assembly;
FIG. 2 is a sectional view of the catheter showing a forming wire positioned in the lumen;
FIG. 3 shows the catheter package assembly bent about a curved forming object to impart a predetermined curvature to the catheter in the sterile condition;
FIG. 4 shows the catheter package assembly with a predetermined curvature;
FIG. 5 shows the catheter package assembly of FIG. 4 disassembled into the catheter having a curvature corresponding substantially to the predetermined curvature and the forming wire removed from the lumen.

DESCRIPTION OF THE INVENTION

In accordance with the invention, a prefearable, sterile catheter assembly which can be bent to a predetermined curvature to permit the catheter to be preformed in the sterile condition includes a plastic catheter, and a malleable forming wire positioned within the lumen of the catheter. The catheter and forming wire are enclosed in a flexible, airtight, water-proof envelope. The envelope is in the sterilized condition and contains a minimum of entrapped air when enclosed about the catheter and wire. The catheter package assembly can be bent to a predetermined curvature while in the sterilized condition, heated and thereafter cooled to permit the catheter to substantially assume the predetermined curvature.

By the use of such a catheter package assembly, the physician may perform the catheter in the sterilized condition to the particular curvature necessary for the patient receiving the operative procedure. In addition, the physician or hospital need not carry an inventory of catheters coming from the manufacturer already in a permanently preformed condition. After the catheter is shaped to the desired curvature, the catheter is removed from the envelope in the sterilized condition.

PREFERRED EMBODIMENT

Referring now to the drawings, the catheter package assembly 10 includes catheter 12 having forming or guide wire 13 inserted through the distal end and positioned in lumen 17 of catheter 12. The catheter is packaged in sterilized envelope 11 which is heat-sealed along lines 21, 22, 23 and 24 extending about catheter 12 and wire 13 so as to minimize the amount of entrapped air within the envelope and to facilitate imparting a predetermined curvature to the catheter by heating and cooling. Forming wire 13 protrudes through the distal end of catheter 12 which is provided with apertures 16. Forming wire 13 at the protruding end is provided with loop 14 to facilitate gripping of the wire for removal from the catheter after shaping.

FIGS. 3 and 4 show the catheter package with a predetermined curvature imparted thereto. FIG. 3 shows catheter package assembly 10 bent about forming object 20 having a predetermined radius of curvature. FIG. 4 shows catheter package 10 having a predetermined curvature. As can be seen from FIG. 4, the catheter package assembly 10 is still heat-sealed in the sterilized envelope 11 after being bent to a predetermined curvature.

After catheter package assembly 10 is preshaped in accordance with that shown in FIGS. 3 and 4, the sterilized envelope 11 is broken and catheter 12 removed therefrom. Forming wire 13 is then removed from the lumen of the catheter.

FIG. 5 shows the catheter and package disassembled into catheter 12 (partially cut away) and forming wire 13. Catheter 12 is now ready for use in the operative procedure by the physician without further sterilization.

It is important to note that when envelope 11 is sealed, the amount of entrapped air remaining in the sealed envelope should be a minimum because it interferes with the shaping operation and acts as an insulator when the catheter package assembly is heated and cooled to impart a predetermined curvature to the catheter.

Forming wire 13 should be malleable and capable of undergoing permanent plastic deformation when bent about a forming object. If the forming wire is too resilient it is difficult to form the catheter into the desired shape because of the considerable springback. In addition, the forming wire should not be too hard or strong so as to prevent it from being easily permanently deformed and assuming the curvature of the forming object. The preferred forming wire is stainless steel having a diameter between about 0.021 inch and 0.116 inch, e.g., about 0.027, 0.042 or 0.052 inch.

For the purpose of giving those skilled in the art a better understanding of the invention, an example is presented below showing the several steps which can be taken by the physician to impart the predetermined curvature to the catheter while in the sterilized condition.

EXAMPLE

A right heart catheter (e.g. 50 to 125 centimeters) formed of radiopaque plastic has a malleable stainless steel forming wire inserted at the distal end and protruding slightly beyond to facilitate removal. The diameter of the forming wire is dictated by the lumen size of the catheter and for example can vary in diameter between 0.021 inch and 0.116 inch. The catheter and forming wire are then sterilized and heat-sealed in an envelope formed of polyethylene terephthalate resin coated with a layer of polyethylene and sold commercially under the trademark SCOTCHPAK. The heat-seal lines follow as closely as possible the exact shape of the catheter and protruding forming wire so as to minimize the amount of entrapped air present in the sealed envelope. The catheter and forming wire packaged in the envelope and constituting the catheter package assembly is then bent about a circular forming object having a radius of curvature of about fifteen-sixteenths inch. The catheter assembly in the curved condition is then submerged in water maintained at about 212°F. and held for about 3 minutes, removed from the hot water, and then submerged in a water bath maintained at about 70°F. (e.g. about room temperature) for about 3 minutes. The seal on the
sterilized envelope is then broken, the catheter removed, and the forming wire removed from the lumen of the catheter. The radius of the reframed catheter is then measured and found to be about 13/16 inches. As can be seen, the springback amounts to about one-fourth inch but is considered to represent substantially the predetermined curvature.

Although the present invention has been described in conjunction with preferred embodiments, it is to be understood that modifications and variations may be resorted to without departing from the spirit and scope of the invention as those skilled in the art will readily understand.

What is claimed is:

1. A sterile catheter assembly adapted to be preformed to substantially any desired configuration by the user dependent upon his immediate need without affecting the sterility of the catheter prior to insertion of the catheter into a body cavity comprising:

- a plastic catheter of a material capable of being deformed and after being subjected to substantial heating and cooling to retain a desired deformed condition;
- a malleable forming wire removably positioned within the lumen of the catheter and being adapted to be deformed to substantially any desired configuration while positioned within said catheter and to substantially retain that configuration when released;
- a flexible, airtight, waterproof envelope enclosing the catheter and the wire and capable of being subjected to substantial heating and cooling thereafter without materially effect thereon;

said envelope containing a minimum of entrapped air when enclosed about the catheter and the wire and being in substantially close-fitting relation with the catheter and wire;

the catheter being deformable to a desired configuration with the malleable wire retaining the catheter in that configuration while the assembly is heated to a substantial degree so that the plastic catheter softens and thereafter cools substantially so that the catheter will harden in the deformed configuration so that when the catheter is removed from the remainder of the assembly including the envelope and the wire, the catheter will retain the desired configuration.

2. A preformable catheter assembly in accordance with claim 1 wherein the malleable forming wire extends beyond the distal end of the catheter to facilitate removal of the wire.

3. A preformable catheter assembly in accordance with claim 2 wherein the envelope is formed of polyethylene terephthalate resin provided with a coating of polyethylene.

4. A preformable catheter assembly in accordance with claim 3 wherein the forming wire is stainless steel.

5. A preformable catheter assembly in accordance with claim 4 wherein the forming wire has a diameter between 0.021 inch and 0.116 inch.

6. A preformable catheter assembly in accordance with claim 5 wherein the flexible envelope is heat-sealed about the catheter and forming wire to minimize the amount of entrapped air contained therein.

7. A preformable catheter assembly in accordance with claim 6 wherein the catheter is formed of radiopaque plastic.

8. A process of imparting substantially any desired configuration to a plastic catheter while the catheter is enclosed in a flexible, airtight, waterproof envelope and contains a malleable forming wire in the lumen thereof to provide a sterile catheter assembly adapted to be preformed by the user to the desired configuration without affecting the sterility of the catheter prior to insertion of the catheter in a body cavity comprising:

- bending the catheter assembly to form the catheter and wire within the envelope to the desired configuration;
- heating the assembly substantially until the plastic catheter softens around the wire;
- cooling the assembly substantially until the catheter hardens into the desired configuration around the forming wire thereby forming a sterile catheter within the envelope having the desired configuration for use; and
- removing the catheter from the remainder of the assembly including the envelope and the wire with the catheter retaining the desired configuration.

9. A process of imparting a desired curvature to a plastic catheter to be inserted into a body cavity and assembly in the sterilized condition, said assembly comprising the catheter, a malleable forming wire inserted in the lumen of the catheter, and a flexible, airtight, waterproof, sterilized envelope containing a minimum of entrapped air when enclosed about the catheter and wire; including the steps of bending the catheter assembly to a desired curvature, heating the catheter assembly, cooling the catheter assembly, and then removing the catheter from the remainder of the assembly including the wire, whereby the catheter assumes and retains substantially the desired curvature and may be inserted into a body cavity, the catheter assembly being heated to a temperature of about 212°F, and the catheter assembly being cooled to about room temperature.

10. A process in accordance with claim 9 wherein the catheter assembly is heated by means of a water bath.

11. A process in accordance with claim 10 wherein the catheter assembly is cooled by means of a water bath.