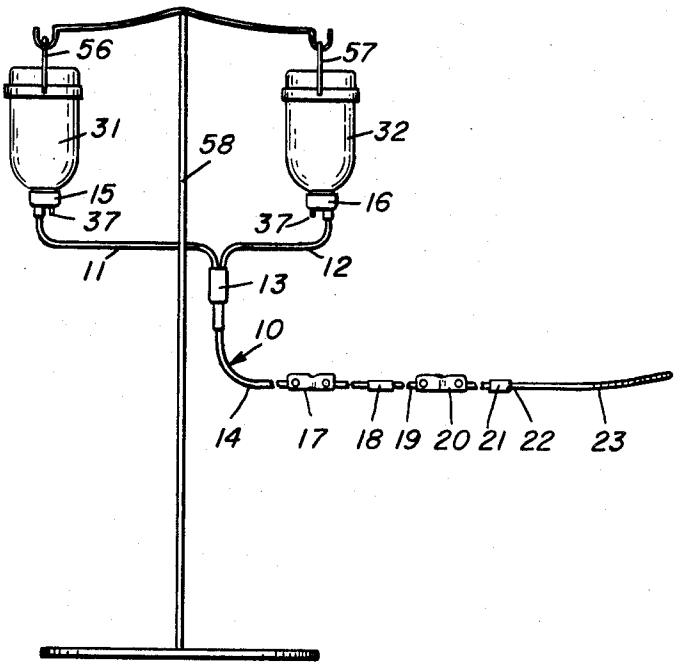
Sept. 15, 1964 G. COANDA 3,149,186

METHOD FOR MAKING A CATHETER

Original Filed June 4, 1959

FIG. 1.



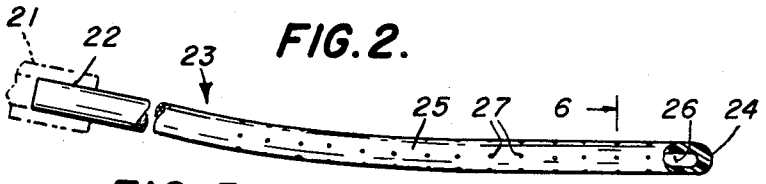


FIG. 2.

FIG. 5.

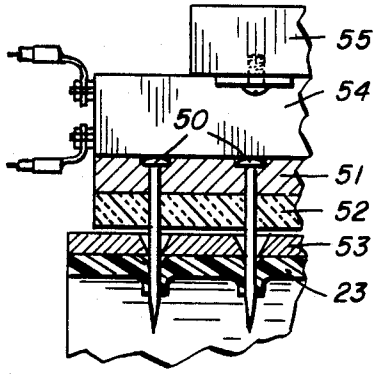


FIG. 3.

FIG. 4.

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United States Patent Office 3,149,186 Patented Sept. 15, 1964

3,149,186

METHOD FOR MAKING A CATHETER

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Original application June 4, 1959, Ser. No. 818,080, now Patent No. 3,064,653, dated Nov. 20, 1962. Divided and this application Feb. 9, 1962, Ser. No. 183,685
4 Claims. (Cl. 264—154)

This invention relates to a method for making an improved catheter for peritoneal dialysis.

This application is a division of the inventor's copending application Serial No. 818,080, filed June 4, 1959, now Patent No. 3,064,653.

Acute renal failure may be caused by infection, transfusion reactions, sulfonamide hypersensitivity, or poisoning. Excessive quantities of bromides, salicyclates, or barbiturates are among the common causes. Although the renal failure may be reversible, it is often difficult to keep the patient alive until renal function can recover.

Peritoneal dialysis has been used in patients having acute renal failure to remove toxic materials from the blood. In this procedure, the peritoneal cavity is filled with a dialyzing solution and the peritoneum serves as a living, semi-permeable membrane. Peritoneal dialysis has not been widely used however, because of certain problems. For example, continuous peritoneal dialysis may cause pooling and channeling of fluid in the abdomen or excessive losses of blood proteins. It also uses relatively large volumes of dialysis fluid and requires a somewhat complicated apparatus. Intermittent peritoneal dialysis has not been widely used because of the difficulty in draining dialysis fluid from the abdominal cavity. Attempts to improve drainage of the fluid by providing the dialysis catheter with larger holes have merely aggravated the problem. Flutes, spiral grooves, and other external catheter shapes designed to shield the catheter holes, increase irritation of the abdominal tissues and require use of a larger trocar than is desirable.

It is therefore an object of this invention to provide a method of making an improved catheter for intermittent peritoneal dialysis.

Another object of this invention is to provide a method of making a catheter which will facilitate withdrawal of the dialysis fluid.

A further object of the invention is to provide a method of making a peritoneal dialysis catheter having a small outside diameter and a smooth outer surface.

Other objects and advantages of my invention will be apparent from the following description of the preferred embodiment of the invention in which:

FIGURE 1 shows an administration set incorporating a catheter made by this invention;

FIGURE 2 is a plan view of the catheter **23** partially cut away at the tip;

FIGURE 3 is a sectional view on the line **6—6** of FIGURE 2;

FIGURE 4 is a partial enlargement of FIGURE 3; and

FIGURE 5 is a front elevation, partly in section, of a device for punching the holes in catheter **23**.

As shown in the drawings, the administration set **10** has two stoppers **15**, **16**. An inlet tube **11** or **12** is attached to each stopper and is connected, by means of a Y-shaped connector **13**, to the flexible administration tube **14**. The tube **14** has a metal clamp **17** which, when bent, adjusts or shuts off flow by squeezing the tube **14**. The distal end of tube **14** is attached by sleeve **18** to the connecting tube **19**, the latter also having a metal clamp **20**. A second sleeve **21** connects the distal end of the tube **19** to the proximal end **22** of catheter **23**.

The catheter **23** is made of an inert, semi-rigid thermoplastic material which will not soften unduly at body temperature. For the purpose of this application, a semi-rigid tube is defined as a tube which cannot be collapsed by direct hand pressure, which is relatively rigid longitudinally for lengths of one half inch or so, but which is easily bent by hand in lengths of three inches or more. Catheters made from such tubes will not kink or collapse in normal use, but they will bend along their length when necessary so as to minimize trauma. For example, the catheter **23** can be made of nylon, high density polyethylene, Teflon, or Kel-F. Catheter **23** is usually eight to fourteen inches long, has an outside diameter of about 0.1 to 0.2 inch and has a sufficient wall thickness to make it semi-rigid as defined above.

As a specific example, an excellent catheter has been made from a nylon tube having an outside diameter of 0.136 inch. A catheter of this size fits easily within the bore of a 17-French, Duke trocar so that only a small incision is necessary. A wall thickness of approximately 0.015 inch makes the catheter semi-rigid, while at the same time providing a relatively large inner passage or bore. Such a catheter will bend when it meets an obstruction, but returns to its original shape.

The distal end of catheter **23** has a smooth rounded tip **24**. A curved section **25**, having a radius of about ten to fourteen inches, extends inwardly from tip **24** for a distance of about three to four inches. A passage or bore **26** passes axially through the catheter **23**.

The distal portion of catheter **23** is provided with seventy to one hundred fifty small holes indicated as **27** which extend for a distance of about two to four inches inwardly from tip **24**. The holes **27** should have diameters of 0.010 inch to 0.025 inch, and for best results are preferably between 0.015 inch and 0.020 inch. If the holes are smaller than 0.010 inch, they will be difficult to make and they will limit the rate of fluid flow too much. If the holes are larger than 0.025 inch, portions of the omentum can pass through the holes into the bore **26**. Swelling of the omentum can then plug the bore **26**.

The outer edges of the holes **27** curve inwardly forming indented, rounded surfaces **28** and inwardly extending collars or flanges **29**. In this manner, catheter **23** is provided with a smooth, cylindrical outer surface without projecting bosses or flanges which can irritate abdonimal tissues.

The catheter **23** is formed by cutting a section of extruded nylon tubing about eight to fourteen inches long, punching holes **27**, forming the curved section **25**, washing the tubing, and finally molding the tip **24**.

As shown in FIGURE 5, the holes **27** are punched by pins **50** mounted in pin block **51**. The pin should be 0.013 inch to 0.028 inch in diameter and mounted so as to extend through the insulation **52** and the catheter holding jig **53** and to pierce the wall of the catheter tubing, without touching the opposite wall of the tubing. A heating unit **54** is located between pin block **51** and press platen **55**. Heating unit **54** preferably has a thermostatic control (not shown) by means of which the temperature of pins **50** may be adjusted.

Excellent results may be obtained in the hole-punching operation by using a one-half inch steel pin of the ordinary straight-pin or map-pin type. Such a pin usually has a diameter of approximately 0.020 inch and, after some recovery of the plastic wall, forms a hole about 0.016 to 0.018 inch in diameter.

In punching the holes **27**, the temperature of the pins **50** is adjusted to a point where they soften, but do not melt, the wall of the thermoplastic tubing. In this way the plastic material displaced by the pin, is pushed inwardly, forming an indented outer surface **28** and an inner collar or flange **29**. A silicone coating applied to

the surface of pins 50 prevents the flange 29 from adhering to the pins as they are withdrawn.

The curved section 25 is then formed by placing a stiff, curved, metal mandrel inside the tubing, and heating the tubing and mandrel in an oven for five minutes at about 275° F. The tubing and mandrel are then cooled to room temperature, the mandrel removed, and the tubing washed, rinsed and dried. The rounded tip 24 is then formed by heating and forming the end of the tubing.

I claim:

1. A method of making a catheter for peritoneal dialysis comprising: cutting a length of extruded, thermoplastic tubing, said tubing having the desired physical properties and including a bore defined by a generally cylindrical, semirigid, self-supporting wall; coating a pointed pin with silicone; heating said pin to a temperature above the softening point but below the melting point of the tubing; pressing the point of the heated pin against the outer surface of the tubing wall near one end of the tubing to form a permanent indentation; further pressing the point of the pin against the side wall forcing the pin to pierce said wall and enter the bore of the tubing; stopping the movement of said pin while the point is in the tube bore and before the point contacts the opposite wall of the tubing; retracting the pin from the tubing wall, the silicone serving to release the pin without causing projecting discontinuities on the outer surface of the tubing; forming a curved section along the perforated end portion of the tubing; and forming a smooth rounded tip on the end of said portion.

2. A method of making a catheter for peritoneal dialysis as set forth in claim 1 wherein the curved section of the tubing is formed by placing a stiff, curved wire mandrel inside the tubing, heating the tubing and mandrel; cooling the tubing and mandrel; and removing the mandrel from the tubing.

3. A method of making very small holes in a semirigid, thermoplastic peritoneal dialysis catheter comprising: heating a plurality of pointed, silicone-coated pins to a temperature above the softening point but below the melting point of the catheter; forming permanent indentations on the outer surface of the unheated plastic catheter by pressing the points of the heated pins against said outer surface; forming an opening surrounded by an annular, inwardly extending collar in the catheter wall by further pressing the points of the heated pins against said catheter wall so as to permanently displace a portion of the wall into the catheter lumen; and withdrawing the pins from the catheter wall while retaining the indentations on the outer catheter surface.

4. A method of making very small holes in a semirigid, tubular, thermoplastic catheter comprising: heating a plurality of pointed, solid, metal pins to a temperature above the softening point, but below the melting point, of the catheter material; pressing the points of the heated pins against the outer surface of the unheated plastic catheter to form a permanent indentation in said outer surface; further pressing the points of the heated pins to permanently displace a portion of the catheter wall into the catheter lumen and to form an opening in said wall, said opening being surrounded on the outer surface by an indentation, and on the inner surface by an inwardly projecting, deformed catheter wall portion; and withdrawing the pin from the catheter wall.

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