

Nov. 20, 1962

G. COANDA

3,064,653

CATHETER FOR AN ADMINISTRATION SET

Filed June 4, 1959

FIG. 1.

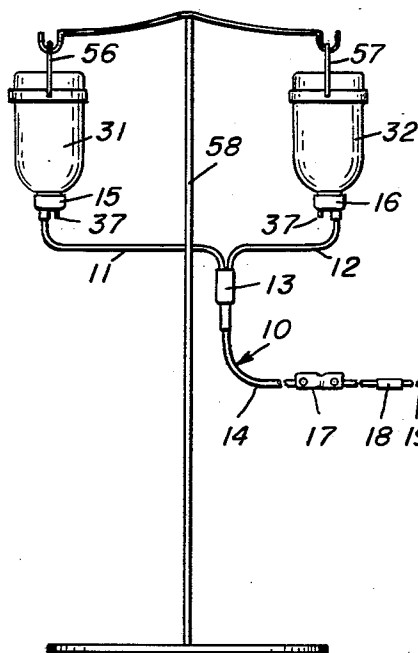


FIG. 2.

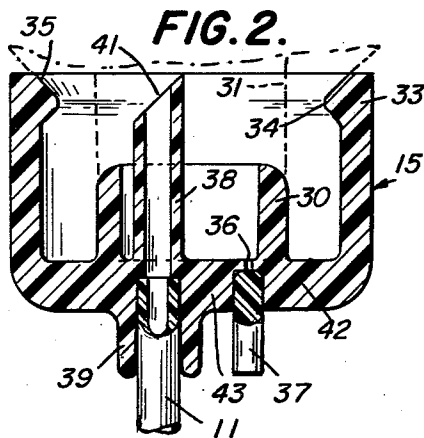


FIG. 3.

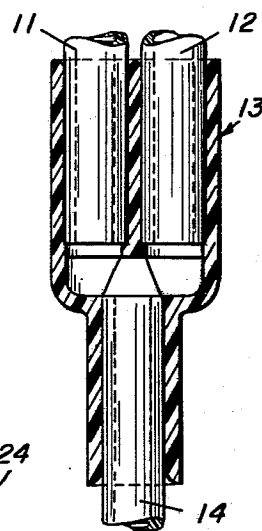


FIG. 4.

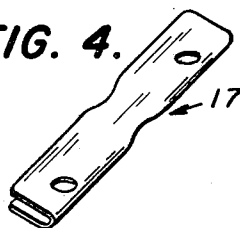


FIG. 5.

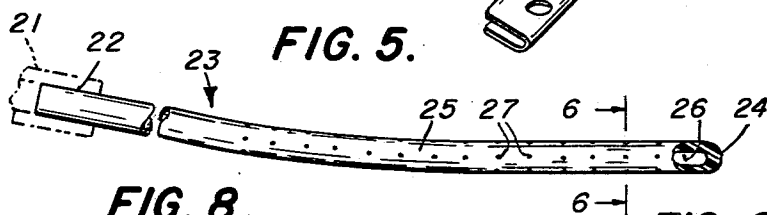


FIG. 8.

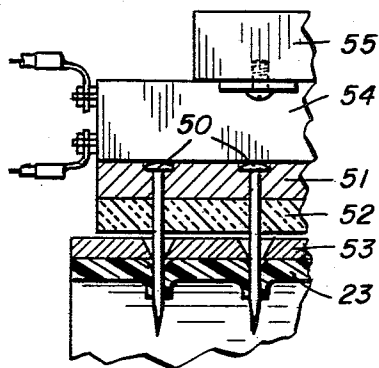


FIG. 6.

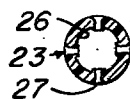


FIG. 7.



INVENTOR

GEORGE COANDA

BY

Robert F. Merrick

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CATHETER FOR AN ADMINISTRATION SET

George Coanda, North Hollywood, Calif., assignor to Don Baxter, Inc., Glendale, Calif., a corporation of Nevada
Filed June 4, 1959, Ser. No. 818,030
4 Claims. (Cl. 128—348)

This invention relates to an improved administration set for peritoneal dialysis.

Acute renal failure may be caused by infection, transfusion reactions, sulfonamide hypersensitivity, or poisoning. Excessive quantities of bromides, salicylates, 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.

Patients having acute renal failure are frequently treated with an artificial kidney. Proper use of an artificial kidney is an expensive and formidable procedure. It requires an active, permanent, trained team of personnel. The equipment is expensive and is seldom available in small hospitals, so that the patient must usually be transported to one of the large medical centers for treatment. Usually at least four to five bottles of expensive blood are needed to prime the machine. In addition to the cost involved there are the usual risks associated with transfusions, such as hemolytic reactions, allergic reactions, transmission of infections hepatitis or other diseases, and over-heparinization.

Peritoneal dialysis has been used instead of the artificial kidney 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 an improved administration set for intermittent peritoneal dialysis.

Another object of this invention is to provide an administration set having a catheter which will facilitate withdrawal of the dialysis fluid.

Another object of the invention is to provide an administration set having a catheter which can be easily worked into the desired position without using a stylet.

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

A still further object of the invention is to provide a method of making the improved administration set for peritoneal dialysis.

Other objects and advantages of my invention will be

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apparent from the following description of the preferred embodiment of the invention in which:

FIGURE 1 shows the administration set of this invention assembled and ready for use;

FIGURE 2 is a sectional view of the stopper 15 which connects the set to a solution bottle;

FIGURE 3 is a sectional view of the Y connector 13;

FIGURE 4 is a perspective view of the clamp 17;

FIGURE 5 is a plan view of the catheter 23 partially cut away at the tip;

FIGURE 6 is a sectional view on the line 6—6 of FIGURE 5;

FIGURE 7 is a partial enlargement of FIGURE 6;

FIGURE 8 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 of flanges 29. In this manner, catheter 23 is provided with a smooth, cylindrical outer surface without projecting bosses or flanges which can irritate abdominal tissues.

As shown in FIGURE 2, stopper 15 has a top 42 having a center section 43. A sleeve 30, adapted to fit in the neck of bottle 31, extends from the center section 43. An outer sleeve 33 adapted to fit around the bottle neck extends from top 42. An annular boss 34 extends from the end of sleeve 33 towards its axis. Beyond boss 34 the surface of sleeve 33 tapers out to provide a lead-in section 35.

Center section 43 has a restricted air inlet 36 sealed by a removable plug 37 and a solution outlet. On the outer surface of top section 43, the solution outlet has an annular boss 39, the bore of which is adapted to receive the end of tube 11. On the inner surface of top section 43, the solution outlet has an outlet tube 38, the axis of which is parallel to the axes of sleeves 30 and 33. The outlet tube 38 projects beyond the inner end of sleeve 30 and has a beveled tip 41 facing away from the extended axis of air inlet 36.

In the manufacture of this administration set, one end of each tube 11 and 12 is cemented to stopper 15 or 16. The other ends of tubes 11 and 12 and tube 14 are cemented to the Y-shaped connector 13. The sleeves 18 and 21 are then cemented to connecting tube 19. For convenience in attaching the tubes, the connector, and the sleeves together, they are preferably made of the same plastic. Polyvinyl chloride is a particularly suitable material.

The catheter 23 is formed by cutting a section of extrude 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 8, 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-plate 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.

In use, the dialysis solution is warmed to body temperature and medication, such as heparin and tetracycline, added. The administration set 10 is attached to two bottles 31 and 32 of dialysis solution. Due to the tapered lead-in section 35, the annular boss 34 of stopper 15 can

be pushed over threads or rings on the neck of bottle 31 without turning stopper 15. The bottles are then suspended by hangers 56 and 57 from the stand 58, the plug 37 removed from the air inlet 36, the clamp 17 opened and the set filled with solution.

With the patient in a supine or semi-supine position, the abdomen is prepared and an incision is made through the linea alba of the anterior abdominal wall. A straight, 17-French, Duke trocar with stylet is inserted through the incision into the peritoneal cavity, until only the proximal hub of the trocar protrudes above the skin.

The stylet is then removed and the plastic catheter 23 passed through the trocar. The stiffness of the catheter permits the curved portion 25 to be manipulated by rotation or angling of the exposed proximal end and also prevents the catheter from kinking or floating. On the other hand, the longitudinal flexibility of the eight to fourteen inch catheter allows it to bend if the tip 24 meets an obstruction. It is sometimes necessary to rotate the catheter in various directions trying to insert it each time, before the omentum is pushed aside and a natural passageway found.

When the catheter is in place, the trocar is withdrawn and connecting tube 19 attached to catheter 23 by sleeve 21 and to tube 14 by sleeve 18. If leakage or bleeding occurs around the catheter, it can usually be stopped with a purse-string suture which leaves the catheter free for manipulation. Clamps 17 and 20 are then opened and the solution in bottles 31, 32 is permitted to flow by gravity into the abdominal cavity. This usually requires about five to ten minutes. If a longer time is required, catheter 23 should be repositioned. Air bubbles entering the bottle through inlet 36 give the operator a continuous indication of the solution flow rate. The extended outlet tube 38 with the beveled end 41 facing away from the air inlet 36, prevents air bubbles from being drawn into the administration set 10.

When bottles 31, 32 are empty, but while the set 10 is still filled with solution, clamps 17 and 20 are closed off and the bottles placed on the floor below the patient. The solution is left in the abdominal cavity for approximately one to two hours, after which the clamps are opened and the abdomen drained by siphoning the solution back into the original bottles. In the administration set described above, drainage should require no more than ten minutes. Continuity of flow and approximate rate can be determined by watching solution entering bottle 31 through outlet tube 38. When drainage is completed, the amount of dialyzate recovered is checked against the amount administered, the clamps 17 and 20 are closed off, and the used bottles of solution disconnected at sleeve 18. New bottles of solution may then be attached to the connecting tube 19, and the dialysis repeated.

I claim:

1. In an administration set for peritoneal dialysis, a catheter comprising: an elongated tubular member having a wall, a proximal end, and a distal end, said wall defining an axial passage through the tubular member and an opening at the proximal end thereof communicating with said passage, the distal end having a smooth, rounded, closed tip, and holes defined by the wall of the tubular member and opening into the axial passage, said holes having a diameter of 0.010 to 0.025 inch.

2. In an administration set for peritoneal dialysis, a catheter as set forth in claim 1 wherein the portions of the wall surrounding the holes curve inwardly to form a smooth, rounded outer surface and an inwardly extending flange.

3. In an administration set for peritoneal dialysis, a catheter comprising: an elongated, semi-rigid, tubular member having a length of eight to fourteen inches, a diameter of about 0.136 inch, a nylon wall approximately 0.015 inch thick, a curved section on the distal portion thereof, an axial passage therethrough, an opening into

said passage at the proximal end thereof, a smooth rounded tip at the distal end thereof, and holes through said wall opening into the axial passage, said holes having a diameter of 0.010 to 0.025 inch.

4. In an administration set for peritoneal dialysis, a catheter comprising: an elongated tubular member having a wall, a proximal end, and a distal end, said wall defining an axial passage through the tubular member and an opening at the proximal end thereof communicating with said passage, the distal end having a smooth, rounded, closed tip, and transverse holes defined by the wall of the tubular member and opening into the axial passage, said holes having a diameter of 0.015 to 0.020 inch.

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