

[72] Inventor **William V. Zeman**
905 Broad St., Apt H9, Bloomfield, New Jersey 07003
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Primary Examiner—Dalton L. Truluck
 Attorney—Joseph Hirschmann

[54] **DRAINAGE CANNULA WITH TISSUE CONNECTING ASSEMBLIES ON BOTH ENDS**
 1 Claim, 6 Drawing Figs.

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[51] Int. Cl. **A61b 17/11, A61m 25/00**

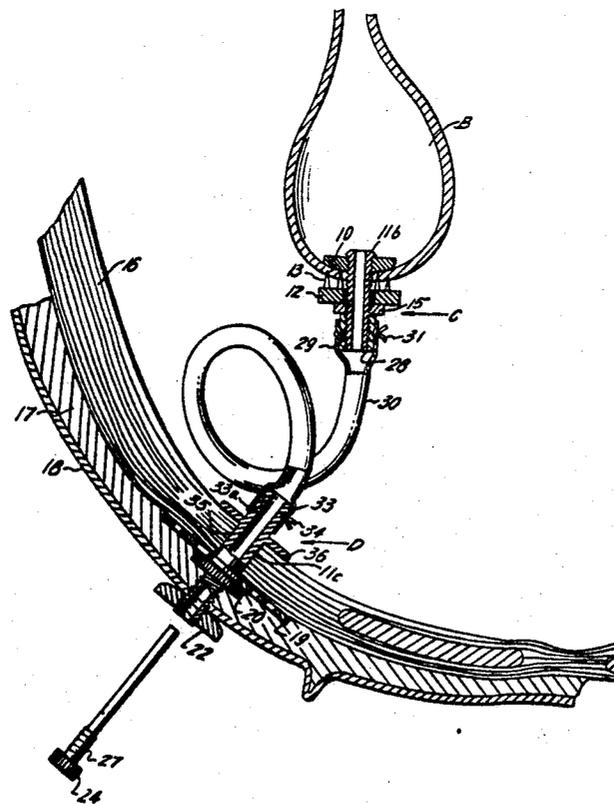
[50] Field of Search **128/348-350, 334-337, 303**

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ABSTRACT: A cannula for drainage of the abdominal cavity and of hollow internal organs is described which includes a tubular member more or less permanently implanted in the abdominal wall for drainage of the abdominal cavity, and connected by a tube to a similar tubular member implanted in the wall of the hollow internal organ where such organ is to be drained. Means are provided for anchoring the parts in the tissue of the walls without pressure, so that blood circulation is not interfered with. The cannula extends to or slightly beyond the surface of the skin and is sealed by a pin or the like, and repeated cannulation requires only the removal of the pin.



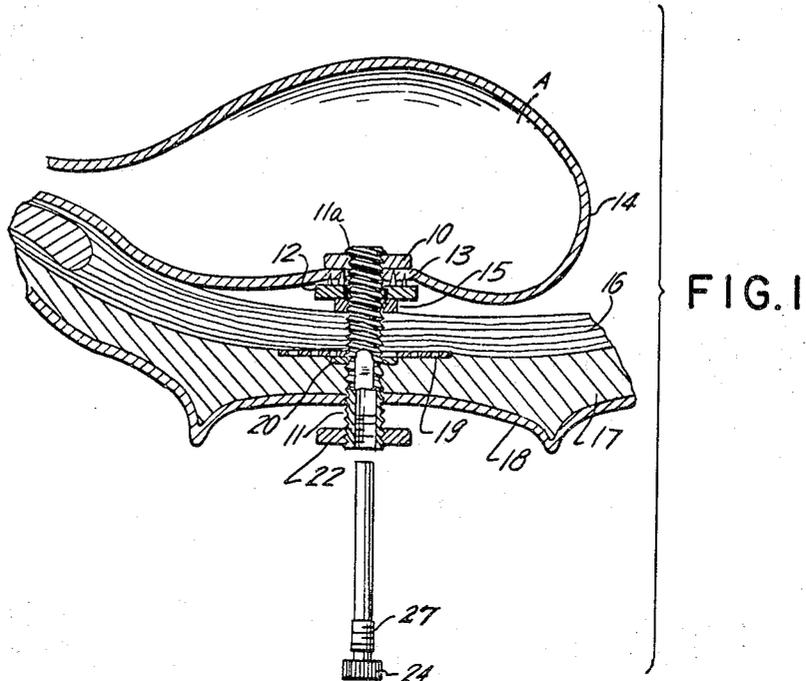
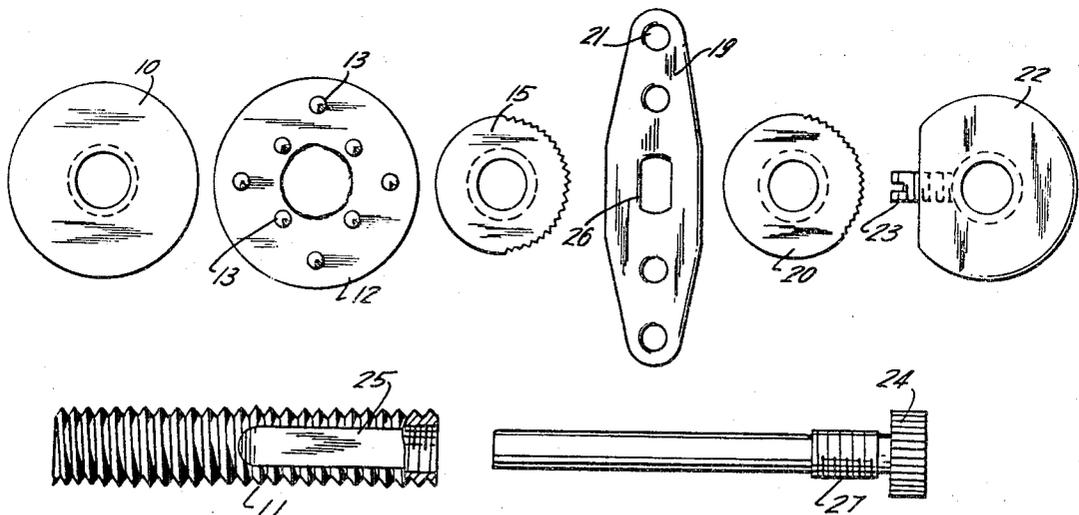
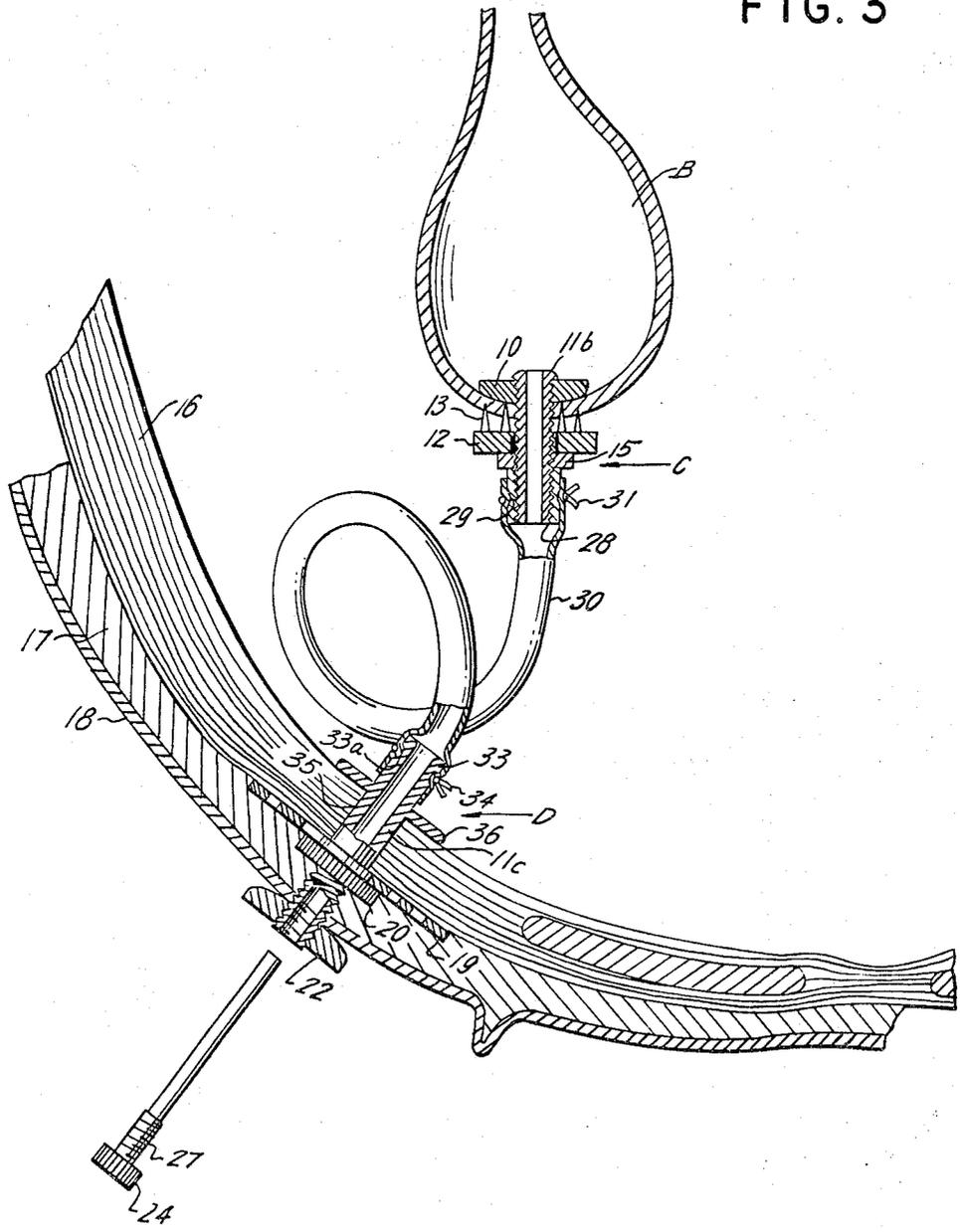


FIG. 2

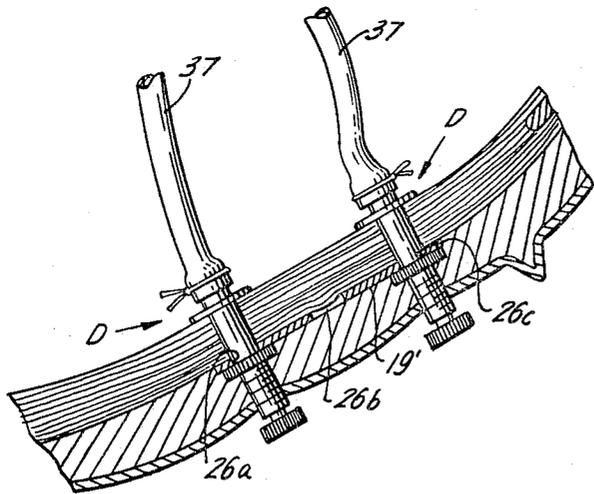
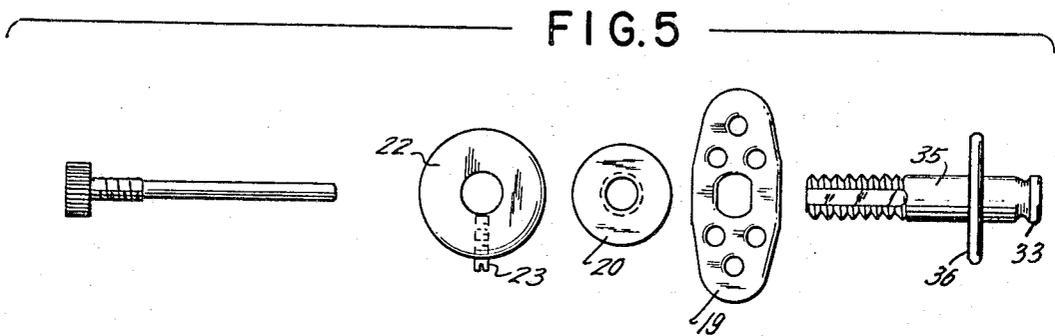
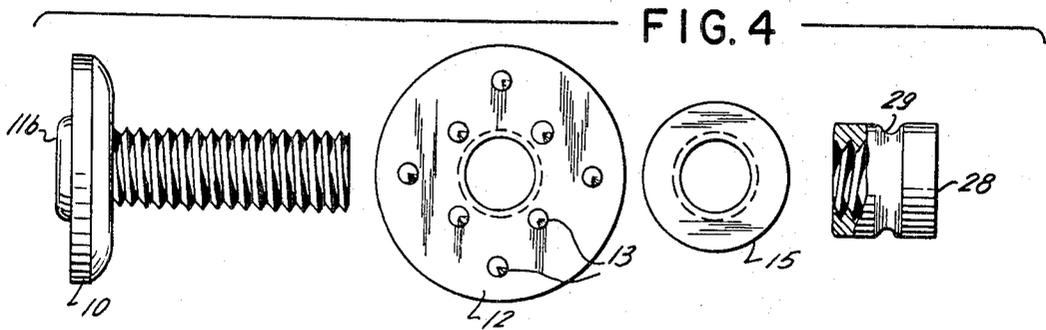


INVENTOR.
WILLIAM V. ZEMAN
BY *Joseph Herschman*
ATTORNEY

FIG. 3



INVENTOR.
WILLIAM V. ZEMAN
BY *James M. Hirschman*
ATTORNEY



INVENTOR.
WILLIAM V. ZEMAN
BY *Joseph H. [Signature]*
ATTORNEY

DRAINAGE CANNULA WITH TISSUE CONNECTING ASSEMBLIES ON BOTH ENDS

This application is a substitute for my abandoned U.S. Pat. application, Ser. No. 307,735, filed Sept. 9, 1963.

The present invention relates to cannulas useful for long-term animal experimentation and also for the therapeutic treatment of human beings.

The general object of the invention is to provide a cannula which is adapted for use in the cannulation of various hollow internal organs and regions of the body both for the withdrawal and for the introduction of fluids of various kinds, as for determining the course of an experiment; for ascertaining the effect of drugs, for feeding, for evacuating septic substances from internal organs or regions, and for the introduction of therapeutic or diagnostic substances.

More particularly, it is an object of the invention to provide a cannula which can be allowed to remain in position in the abdominal wall and in the walls of various organs for indefinite periods without danger of necrosis, infection or degeneration.

It is a further object of the invention to provide a cannula which can be connected with internal regions of the body, and particularly with the interior spaces of various organs like the gall bladder, urinary bladder, stomach, intestines, etc. with a minimum of damage to the tissues and with certainty of liquid-tight and aseptic connections.

Other objects and advantages of the invention will be apparent from the following further description thereof.

According to the present invention, there is provided what may be termed a universal cannula, as it presents a means of direct access to the bile storage organ, the urinary bladder, and the entire alimentary canal. The device of the invention is characterized by simplicity, permanency and applicability to different organs and uses, and has been used successfully in permanent cannulation of the gall bladder, urinary bladder and stomach as well as in permanent single, or chronic multiple, cannulations of the small intestine in dogs. My improved cannula has proved useful in renal and gastrointestinal pharmacology as well as in studies on alimentary absorption and bile excretion of drugs, and has made possible new or improved experimental methods in the biological study of animals.

My invention is useful generally for providing a secondary route for urination (drainage of urinary bladder), and as an alternative to cystostomy for human beings as well as for animals. My complete structure for the drainage or feeding of internal organs consists of an inner unit adapted to be attached to the organ and communicating with the interior thereof, and an outer unit connected to the inner unit and attached to the abdominal wall and leading to the exterior thereof. The outer unit can be employed alone for draining the abdominal cavity in ascites. Thus in chronic cardiac failure where there is an accumulation of ascites, the outer unit can be used for draining accumulated fluids and for peritoneal lavage.

Because of its simplicity and because it eliminates the maintenance that is necessary with other types of biliary cannulations, the present invention provides an efficient device for bile excretion studies of drugs and other materials.

The form of the invention adapted for attachment to the urinary bladder for use in renal pharmacology eliminates urethral catheterization of experimental dogs and facilitates direct and complete drainage of urine from the bladder immediately following its renal excretion during trials. Contrary to other techniques, no urinary infections due to the presence of my improved cannula have been observed. The permanent stomach cannulation makes studies of gastric motility and secretion possible with no maintenance of the preparation, that is, without repeated attention, cleaning or close surveillance of the animals.

In the form of a single intestinal cannula, the present invention affords direct studies of intestinal motility on a chronic basis. The invention makes possible also long-term multiple intestinal cannulation by provision of a small flexible modifi-

cation of the device, thereby creating a new method of increased precision for measuring drug absorption rates from specific portions of the alimentary canal.

The invention will be more specifically described by reference to the accompanying drawings illustrating preferred forms of the invention. In said drawings, wherein like reference characters denote similar parts:

FIG. 1 is a view in central longitudinal section showing my improved cannula in position for draining the urinary bladder, or for the introduction of liquids thereto over long periods of time;

FIG. 2 is an exploded view showing the parts of the cannula;

FIG. 3 is a view in section showing a cannula composed of an inner and an outer unit and connected by a flexible tubing for connection with the interior of an organ spaced some distance from the abdominal or thoracic wall;

FIG. 4 is an exploded view showing the parts of the inner unit which is adapted for connection with the intermediate flexible tubing;

FIG. 5 shows a modified form of the cannula for use in draining the abdominal cavity; while

FIG. 6 shows an arrangement for multiple cannulation of the intestines.

The cannula of the present invention is constructed to provide access to or outlet from a variety of organs, or the interior of the abdominal or thoracic cavity, while inducing minimal changes in their anatomy and physiology. This is accomplished by the use of an externally threaded hollow stem which is preferably of stainless steel or other non-oxidizing metal, but may be of plastic, which is provided with means for securing it to the abdominal wall and, in the cannulation of internal organs, also with means for anchoring it to the wall of such organ, which it penetrates. The stem may be in the form of a single continuous piece (with the associated parts described below), or, depending on the organ cannulated, may be divided into an inner and an outer section forming parts of what I term an inner and an outer unit. For urinary bladder, stomach and single intestinal cannulations, the one-piece stem is used, resulting in a compact form of the cannula.

For gall bladder and multiple intestinal cannulations, the stem is divided into an inner and an outer section and these are connected by a flexible tube made of "Tygon" or the like. During surgical insertion of a cannula with the divided stem, the inner section is implanted within the wall of the cannulated organ, while the outer section is accommodated within the abdominal wall. The flexible connecting tubing is inserted over the proximal ends of both stem sections and ligated over grooves provided in such end portions. The tubing lies freely in the abdominal cavity and gives the device an elasticity which allows substantially normal physiological motility of the cannulated viscus. It also reduces the weight of the cannula and makes its length adjustable during surgery.

No flexible tubing is required in cannulations employing the compact one-piece stem. The rigid stem is simply exteriorized through a stab wound in the abdominal body wall and is fixed permanently in its position by a stabilizing plate at the subcutaneous level.

Referring now to the drawings, there is shown in FIG. 1 a one-piece stem construction for cannulation of an organ, such as the urinary bladder A, which is close to the abdominal wall, with means for anchoring the device within the wall of the cannulated organ. The anchoring means includes a base disc 10 in threaded connection with the inner end of hollow stem 11 and is held on the stem by a flange or struck-down portion 11a acting as a stop. When placed inside the lumen of an organ, the mucosal face of the base disc adheres closely to the mucosa. It is therefore smooth, convex and made of biologically inert, chemically stable and relatively soft plastic material (e.g., "Teflon").

Following insertion of the base and stem through the incised wall of an organ, a purse-string suture previously placed in the serosa is tightened just enough to bring the tissues into snug contact around the stem. An anchor plate 12 is then inserted

over the stem and pressed with its needles 13 against the tissues 14 of the cannulated part. By threading the fixing nut 15 with reasonable firmness against the anchor plate, some of the needles partially penetrate the cannulated wall and become arrested against the base disc which is inside the organ. The anchorage of the inner end of the cannula is now completed, the wall of the cannulated organ being captured between the base disc and the anchor plate. The incision through which the cannula was admitted into the organ is repaired and sealed by the needles of the anchor plate and the possibility of leakage around the stem is eliminated. In time, the incision and needle perforations heal and additional insurance against leakage is thereby provided.

The needles of the anchor plate are sufficiently long to allow ample expansion space for the post-surgical inflammatory swelling of the captured tissues between the anchor plate and the base of the cannula. This assures no interference with circulation of the captured wall, and the possibility of pressure necrosis or other degenerative process is eliminated and never becomes a problem.

It may be mentioned that to insert the cannula, the bladder A is exposed through the usual lower midline approach for cystotomy.

The apex of the fundus is grasped by tissue forceps and mild cranial traction is applied to stabilize the bladder. The purse-string suture referred to above (4 or 5-0 Atralog silk or gut) is placed loosely within the serosa around the selected point of insertion of the cannula, preferably in an area of lower vascularization. Using small, sharp pointed scissors, the bladder wall is perforated centrally inside the purse-string suture and the perforation is enlarged by stretching it just enough to admit the base disc 10 of the cannula. To make certain that the base does not become accidentally lodged between the bladder mucosa and the muscularis layers, the mucosa during insertion is pulled out through the incision, using small hemostats at two opposite points. This facilitates insertion of the cannula through a relatively small opening in the bladder wall. Following insertion of the cannula, the tissues are approximated around the stem 11 by tightening the purse strings. The anchor plate 12 is placed in its location and secured firmly by fixing nut 15. The abdominal musculature 16 has been originally incised by a stab wound, as well as the subcutaneous tissue 17 and skin 18, but before the remaining free portion of the hollow stem 11 is pulled outward through a stab wound in the corresponding ventral abdominal wall, a small pocket for accommodation of a stabilizing plate 19 is created by separation of the subcutaneous tissues from the muscular layers in the area of the stab wound. The plate 19 is secured in position on the stem by a nut 20. The plate 19 is perforated, as shown at 21, to allow tissue to be squeezed into the perforations, so that, following its embedding in the subcutaneous tissues, the plate prevents any torsional or other undesirable movements of the entire cannula and stabilizes it permanently in its fixed position.

To accommodate the unit in the abdominal wall, an auxiliary skin incision was previously made over the area of its insertion posterior to the coastal arch. From the center of this incision a narrow stab wound is carried into the peritoneal cavity to admit the outer threaded portion of the stem which is milled and made flat at diametrically opposite sides thereof. The flat sides of the stem are grasped between the jaws of a large hemostat and pulled from the peritoneal cavity outward through the stab wound so that the circular flange of the stem is pressed firmly against the parietal peritoneum. Following insertion of the outer stem through the stab in the muscular layers, the stabilizing plate 19 is placed in its subcutaneous location on the stem and it is secured firmly by its fixation nut 20. The plate gradually becomes encapsulated by a fibrous tissue growth which, as already indicated, also traverses the perforations of the plate and holds the cannula against displacement.

To allow better apposition and repair of the auxiliary skin incision, the outer end of the stem is brought outside the skin

through the aforementioned additional stab in the skin just proximal to the incision, so that the latter may be sutured by a single straight uninterrupted line, the free end of the stem being brought under the intervening skin area and pulled out through the additional stab wound.

An outer protective button 22 is threaded over the protruding end of the stem, and it is fixed in its position by a small radially placed set screw 23. The cannula is closed hermetically by threaded sealing pin 24 which is inserted and threaded tightly into the outer portion of the stem. Routine closure of the main operative incision completes the cannulation.

The cannula is made in different sizes, but except for minor variation in technic which will be described hereinafter for different organs, similar procedures are followed in all cannulations. Using the sterile technic, surgery is performed under general anesthesia, antibiotics are given for three days following surgery and no dressing is applied. An Elizabethan collar is recommended temporarily in animals with tendency to remove sutures and mutilate the healing incisions.

The milled flat faces 25 of the stem 11 can best be seen in FIG. 2. These flat faces extend from a point intermediate the ends of the stem to the exterior end of the stem. The milled portion of the stem passes through the correspondingly shaped, noncircular opening 26 of the stabilizing plate 19, and is thus held by the latter against rotation.

While the sealing pin 24 can have a liquidtight, snug fit inside the stem I prefer to provide the pin with a thread 27 which engages an internal thread in the end portion of the stem.

FIG. 3 shows an arrangement for the cannulation of an organ, such as gall bladder, B, which is relatively distant from the abdominal wall. In this arrangement, the stem is in the form of two sections, 11b and 11c, forming parts of the respective inner unit C and outer unit D. The parts, 10, 12 and 15 are similar to the correspondingly numbered parts of FIG. 1. The stem section 11b is externally threaded and at its outer end receives an internally threaded cap 28 which is provided with an annular groove 29. Over the cap there is tightly fitted one end of a flexible plastic tube 30, which is secured to the cap by a wire ligature which presses the tube into the annular groove 29, the wire being shown at 31.

The tube 30 is preferably formed with a coil to allow for relative movement between the abdominal wall and the gall bladder B. The other end of the tube 30 is fitted over the nonthreaded inner end 33 of the stem section 11c. This inner end portion is likewise provided with an annular groove 33a, and the tube end is secured to the stem in liquidtight relation by means of the wire ligature 34. As best shown in FIG. 5, the stem section is provided with an externally smooth intermediate portion 35 which has integral therewith or secured thereto a disc 36 which bears against the inner face of the abdominal wall. The portion 35 passes through the incision in the abdominal muscle, while the outer portion of the stem 11c is threaded and milled to receive the stabilizing plate 19, nut 20, and protecting button 22 with its set screw 23.

While the outer unit shown in FIG. 5 is intended for connection with the inner unit C by means of the tube 30, it can be so constructed that it can be used independently of the inner unit, particularly for draining the abdominal or peritoneal cavity. To this end, the portion 33 can be made removable so as to leave the plate 36 more or less flush with the inner face of the abdominal wall, the central aperture of the plate opening directly into the abdominal cavity.

The bile can be withdrawn from the bladder by threading a tubular plastic extension to the outer orifice of the cannula after the sealing pin has been removed, and aspirating the cannula with a connected syringe. When no experiment is under way, there is no maintenance required for this apparatus except for the drawing off of several milliliters of stagnant bile from the portion of the cannula exterior to the gall bladder once or twice a week. Because of its simplicity and elimination of maintenance and care that is connected with other types of biliary cannulations, the device shown in FIG. 3 provides an efficient and inexpensive tool for bile excretion studies of drugs or other materials.

The high degree of flexibility of the present invention is illustrated in FIG. 6 which shows the multiple cannulation of the small intestine shown by way of example as three in number. Each cannula includes an inner unit C (not shown) and an outer unit D, which in general are constructed similarly to the units C and D shown in FIG. 3, with the principal difference that there is employed a common stabilizing plat 19' which is provided with three openings, 26a, 26b and 26c, for receiving the three stems, the plate being provided also with smaller openings, like the openings 21 shown in FIG. 2. Each pair of inner and outer units C and D is connected by a tube 37 of plastic material.

It will be seen from the foregoing that I have provided a cannulation apparatus which is easily adapted for providing continuous access to and egress from the hollow organs of the body, regardless of whether the organ is close to or distant from the abdominal wall. Thus, for cannulation of the stomach, there can be employed the form of the device shown in FIGS. 1 and 2. The cannula causes a minimum of discomfort to experimental animals and to human beings to which it is applied.

A feature of the cannulae above described is that the tissues captured between the several parts are not under pressure, so that interference with circulation and resulting necrosis are avoided. The fixing or locking nuts need be tightened only sufficiently to prevent axial play. The tissues are consequently held gently, even though firmly, between the parts of the cannula abutting them.

The cannula shown in FIG. 3 can become a permanent attachment to the intestine of animals, as of cats and dogs. Distortion of the normal outline of the intestine can be avoided by giving the disc 10 the greater curvature of the inner wall of the intestine. The extension of the device into the interior of intestine can be made quite small, so that the blockage is minimal and there is no interference with the normal function of the intestine.

I claim:

1. A cannula comprising an inner assembly and an outer assembly, said inner assembly including a base member adapted to bear against the inner surface of a hollow internal animal organ, said base member having a central opening, a threaded hollow stem extending from the base member and adapted to pass through an incision in the wall of the organ, said stem being sealed about said opening about the whole circumference thereof, and communicating through said opening with the interior of the organ, an anchor plate loosely mounted on said threaded stem for axial movement therealong, a plurality of needles extending from and projecting inwardly of the anchor plate toward said base member and adapted to penetrate the wall of the organ, said base member being of a transverse dimension at least coextensive with said needles, a nut threaded on said stem for fixing the axial position of the anchor plate, said outer assembly comprising means for penetrating and clamping an adjacent region of the abdominal wall and including a hollow member adapted to pass through said wall, and a flexible tube connecting the hollow stem and member of the inner and outer assemblies, said hollow member being threaded at its outer end and being of such length that the inner end portion thereof extends interiorly of the abdominal wall for connection with the flexible tube, said clamping means comprising a fixed flange on the hollow member at a distance from the inner end of the latter adapted to bear against the inner surface of the abdominal wall, a perforated plate slidable on said member to grip the abdominal musculature between itself and the flange, a nut on said member for fixing the plate thereon, means for limiting the perforated plate to axial movement along the hollow member, and a nut on the threaded end of the hollow member and positionable to bear against the outer surface of the abdominal wall.

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