United States Patent

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[54] **INSURED INTERNAL FLOW MEDICOSURGICAL TUBES**
6 Claims, 4 Drawing Figs.

[52] **U.S. Cl.** **128/350,** 27/24, 128/269
[51] **Int. Cl.** **A61m 25/00**
[50] **Field of Search** ..... 128/348-—351, 276, 343, 239—241, 269; 27/24

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ABSTRACT: Medicosurgical tubes have a swab member positioned inside the tube so constructed or arranged that it may be pulled through the tube and out the proximal end. In such a catheter, the lumen is positively protected throughout the tube length against the possibility of blood clots or other matter preventing liquid flow through the tube following the tube insertion procedure.

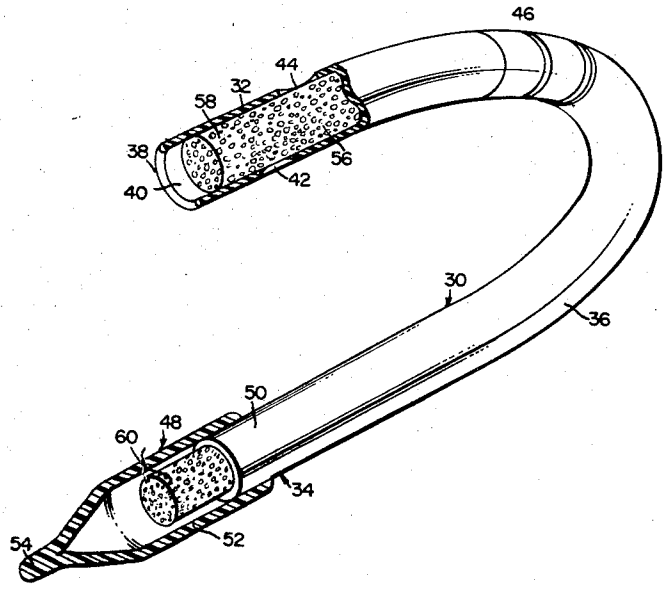


Fig 1.

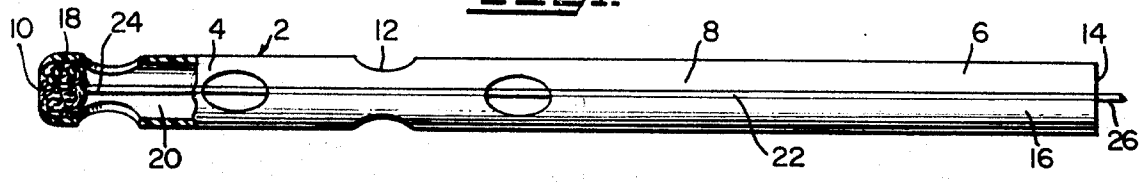


Fig 2.

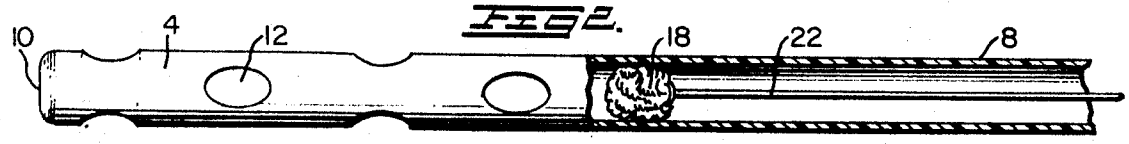


Fig 3.

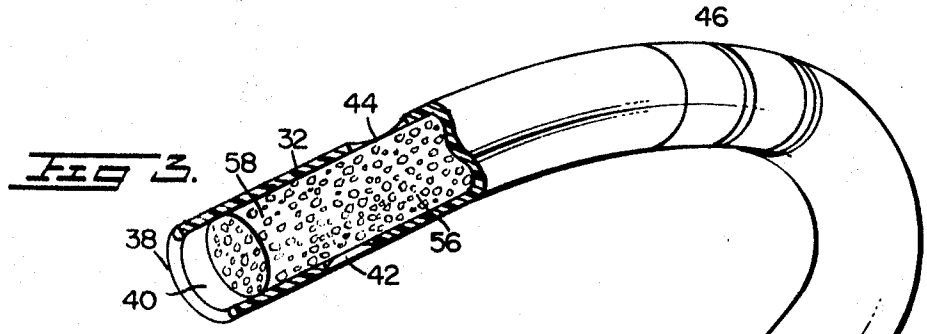
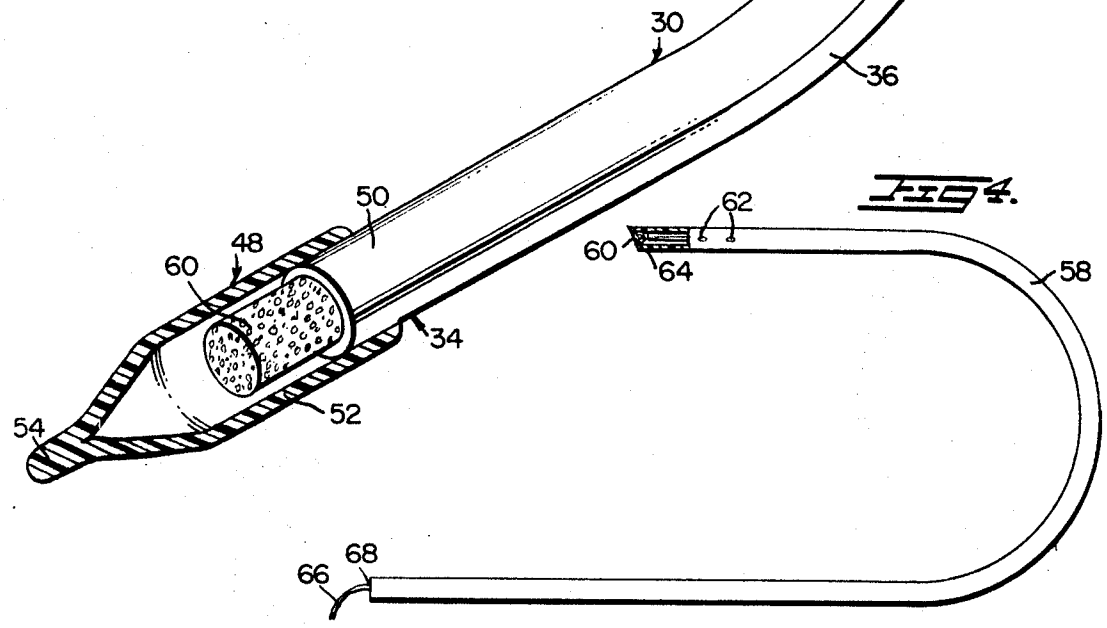


Fig 4.



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INSURED INTERNAL FLOW MEDICOSURGICAL TUBES

BACKGROUND OF THE INVENTION

The present invention relates to medicosurgical tubes, such as catheters, drain tubes, cannulae, and the like, which are ensured of liquid flow and against lumen blockage by blood clots or any other material lodged or positioned in the tube subsequent to insertion of the tube in a patient.

It is not unusual for medicosurgical tubes following insertion of the tube in a patient to become clogged or blocked by blood clots or other material which may form in the tubes or enter from the body of the patient. The danger of blockage of a catheter by blood clots is frequently experienced after the time of placement of the catheter in the patient. Until the catheter is in place and attached to necessary auxiliary equipment, e.g., an underwater seal arrangement with or without a suction source used with thoracic catheters, there is no flow of fluid through the catheter. If the formation of a blood clot occurs in a portion of the catheter external of the patient, blockage of the tube can be removed by physical manipulation, i.e., so-called "milking" of the catheter. On the other hand, blockage of a portion of the tube located internally of the patient presents a serious problem and in a severe case may require removal of the catheter. Replacement with a new one can be detrimental to the patient.

The most common form of medicosurgical tube in which blockage of fluid passage through the tube by blood clots or other solid material may occur between the period of time when the tube is inserted into the patient and the beginning of actual use of the tube for liquid flow are those used for postsurgical drainage. Examples of these are the thoracic or intercostal catheters designed for removal of pus, air, blood, serum or other fluids from the pleural cavity (see u.S. Pat. Nos. 3,190,290 and 3,295,527). Such catheters are used following thoracotomy when a portion of one or more ribs may be removed to expose the heart, lungs or the like in extensive lung or cardiovascular surgery or sternotomy when the sternum is cut through and spread for exposure. In the use of the postsurgical drainage tubes and of some other medicosurgical tubes, there is a critical period of time in which blood clots may form within the tube and block the lumen, preventing proper fluid drainage through the tube. Normal clotting time for blood is about 4 minutes and in view of the complex nature of insertion of postsurgical drainage tubes, particularly the intercostal or thoracic catheters, entrance of blood into the catheter and clotting therein can occur in the catheters which have been available heretofore.

Handling of a patient following surgery also presents possible clotting and blockage problems in rise of drainage tubes and catheters. Thus, after a drainage catheter has been placed through a stab wound and secured to the skin, closing of the major incision and related work may take up to 45 minutes. During this period there is a great possibility for formation of blood clots if steps are not taken to prevent this. One means of mitigating clot formation in the catheter is to connect it to necessary drainage equipment immediately after placement of the catheter in the patient. This can be complicated, however, particularly where the drainage system is of the three-bottle type, i.e., one trap bottle, one underwater seal and one vacuum pressure regulator. Sometimes as many as three drainage catheters are required, and each uses its own drainage system. When the surgery is completed, all this equipment must be moved into the recovery room. Hence, it would be advantageous to give the persons performing the surgical operation the choice of waiting until the patient is in the recovery room before connecting the drainage catheter to drainage equipment while ensuring that the catheter will not be blocked by a blood clot when that time arrives.

In view of the circumstances discussed above, there is a need for improvements in construction of medicosurgical tubes which would prevent blood clots or other solid material from blocking fluid passage through the tube when the tube has been inserted in the patient and before the proximal end is connected to auxiliary equipment so that the desired liquid flow through the tube will be ensured for the desired postsurgical drainage.

OBJECTS

A principal object of this invention is the provision of new improvements in the construction of medicosurgical tubes and particularly postsurgical drainage tubes. Further objects include the provision of:

1. Medicosurgical tubes in which blood clots or other related solid material will not block fluid passage through the tube between the period of insertion of the tube in a patient and the beginning of desired liquid flow through the tube.

2. Postsurgical drainage tubes of improved construction which will ensure unblocked liquid flow through the tube as soon as this is required by procedures being applied to the patient in which the medicosurgical tube has been inserted.

3. New methods for the construction and use of medicosurgical tubes to prevent blockage of liquid flow through the tubes by the formation of blood clots or entrance of other solid material in the tube during the required period for installation of the tube in the patient.

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 foregoing objects are accomplished according to the present invention by making medicosurgical tubes comprising a distal end portion having at least one fluid inlet opening therein, a proximal end portion having a fluid outlet opening and a central body portion joining the distal end portion to the proximal end portion, to contain a swab member positioned inside at least the distal end portion of the tube and with means associated with the swab member having an end extending externally of the medicosurgical tube through the proximal end outlet opening by which the swab member may be pulled through the tube and out the proximal end.

The improved constructions of medicosurgical tubes are advantageously applied to postsurgical drainage tubes, particularly thoracic catheters. In a preferred embodiment of the invention, the swab member is a resilient cylinder of porous plastic material filling the inside of the tube from the distal end portion to the fluid outlet opening in the proximal end portion. In an alternate form of the invention, the swab member is short relative to the length of the medicosurgical tube and a filamentary member longer in length than the tube, is connected at one end to the swab member while the other end of the filamentary member extends externally of the tube through the proximal end outlet opening. In this latter embodiment, the externally extending end of the filamentary member is advantageously temporarily attached to the proximal end of the medicosurgical tube.

The success of the present invention is due in part to the discovery that a member may be positioned inside at least the distal end portion of a medicosurgical tube and associated with an element extending externally of the tube by which the member may be pulled through the tube and out the proximal end after proper positioning of the tube within a patient without adversely affecting the flexibility of the tube, preventing its proper insertion in a patient or otherwise detrimentally affecting the required use or operation of the medicosurgical tube. It has further been found that such an internal flow insurance member can remain in the medicosurgical tube until the instant when the surgeon or other person using the tube on a patient decides that the time has arrived from beginning of

liquid flow through the tube for drainage or other desired purpose. At such time, the internal flow insurance member is withdrawn through the proximal end of the medicosurgical tube leaving the tube unblocked with blood clots or other related solid material for the full lumen passage of required fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational fragmentary view, partially in section, of a medicosurgical tube constructed for internal fluid flow in accordance with the invention.

FIG. 2 is a fragmentary side elevational view, partially in section, of the distal end portion of the tube shown in FIG. 1 but with the internal flow insurance member partially withdrawn in the tube towards the proximal end opening.

FIG. 3 is a perspective view partially in section, of an improved form of thoracic catheter incorporating the improvement features of the present invention.

FIG. 4 is a top elevational view, partially in section, of another form of catheter constructed in accordance with the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring in detail to the drawings, and with particular reference to FIGS. 1 and 2, the postsurgical drainage catheter 2 comprises a distal end portion 4, a proximal end portion 6 and a central body portion 8 which joins the distal end portion to the proximal end portion. The distal end portion has a fluid inlet opening 10 in its tip and a plurality of fluid inlet openings 12 through the side thereof. The proximal end portion has a fluid outlet opening 14. As illustrated, the tip 16 of the proximal end portion constitutes a straight extension of the central body portion 8, i.e., the tube is of substantially uniform diameter and wall thickness throughout its length. Alternatively, the catheter 2 could be formed with portions of varying wall thickness or tapered sections in accordance with known manufacturing methods and techniques e.g., the proximal end could be formed as an integral outwardly tapered or funnel end.

A swab member 18 is positioned inside the distal end 4 filling the lumen 20 of the tube effectively closing the open end 10. The swab member 18 is further positioned distally of all of the side extending inlet openings 12. A filamentary member 22 longer in length than the tube 2 is connected at its end 24 to the swab member 18 while the other end 26 extends externally of the tube through the outlet opening 14.

The catheter 2 would be used by first inserting it in known fashion through an incision or opening in the patient into the desired cavity or body channel. In this procedure, as with prior known catheters or equivalent medicosurgical tubes, there is a possibility that blood or other fluid could enter the lumen 20 of the tube through one or more of the inlet openings 12. further, in view of the time which might be required to effect the insertion of the catheter within the patient, the blood or other material which had entered the tube could clot or otherwise solidify within the tube. If this occurred in prior known catheters, there would be effective blockage of fluid flow through the catheter. In contrast, with catheters of the new type described herein, at the time that the surgeon or other party performing the procedure on the patient desired to initiate drainage of fluids from the patient or effect other liquid flow through the catheter, the swab member 18 would be pulled through the catheter and out the proximal end by applying appropriate tension upon the externally extending end 26 of the filamentary member 22. Partial completion of this withdrawing procedure is illustrated in FIG. 2 which shows the swab member 18 being drawn along the inside of the tube toward the proximal end. Any clots of blood or equivalent solidified material within the lumen 20 of the tube would be effectively also withdrawn out the proximal end of the catheter through the action of the swab member 18.

With particular reference to FIG. 3, the internal flow insurance feature of this invention may be constructed or arranged in another embodiment. Here the thoracic catheter 30 of improved type as described and claimed in copending application entitled: "MEDICOSURGICAL TUBES WITH CAPPED PROXIMAL END," filed on Feb. 7, 1969, Ser. No. 797,512 by David S. Sheridan and Isaac S. Jackson, comprises a distal end portion 32, a proximal end portion 34 and a central body portion 36. The distal end portion has an X-ray opaque tip 38 with an inlet opening 40 and a plurality of side-entering inlet openings 42 and 44. Depth markings 46 in the form of rings or other desired shape are placed upon the outside of the central body portion 36 of the catheter to designate the distance along the catheter from the proximal eye 44. The surge or other user of the tube may employ these depth markings 46 to determine the distance from the incision or other opening through which the catheter 30 extends into the patient to the proximal eye 44. Such distance measurement is employed in the catheter placement procedures to determine the position of the distal end portion of the catheter within the patient. Measurement from the proximal eye 44 is used in placement of the markings 46 in view of the practice which is sometimes required under certain conditions of cutting off a section of the distal end portion 32 of the catheter. Such cutting reduces the length of the catheter and would render the depth marks 46 inaccurate if the distal tip 38 were used as the datum point for establishment of the markings 46.

The proximal end portion 34 of the catheter comprises a closed cap 48 fixed to the catheter end 50. The closed cap 48 has an elongated cylindrical portion 52 which tapers to a closed tip 54. The closed cap is fixed to the end 50 by cement, solvent welding, heat fusion or in other suitable manner.

The swab member 56 is a resilient cylinder of porous plastic material longer in length than the tube of the catheter comprising the distal end portion 32, the central body portion 36 and the proximal end 50. Thus, the distal end 58 of the swab member 56 extends substantially fully to the distal tip 38 while the proximal end 60 of the member 56 extends a substantial distance beyond the proximal end 50.

Use of the thoracic catheter 30 in accordance with established surgical procedure would involve insertion of the proximal end portion 34 of the catheter through the original incision in the patient made during the surgical operation. Also a second incision or stab wound is made in the patient and forceps are inserted through it to grasp the proximal end of the catheter inserted through the original incision. The catheter is pulled by grasping its tip 54 of the closed cap 48 and pulled into the body until the distal end portion 32 is properly positioned with the catheter leading out through the second incision. At such time, the catheter placement procedure has been completed and a leading section of the closed cap 48 is cut off by cutting through the walls of the cylindrical portion 52 of the cap 48. This will expose the end 60 of the member 56 and by grasping this end 60 with forceps while retaining the proximal end 34 of the catheter in the other hand, the member 56 may be pulled out of the catheter. The remaining portion of the cap 48 then serves as a connecting means for joining the proximal end of the catheter to necessary auxiliary drainage equipment such as an underwater seal arrangement generally used with thoracic catheters. During the connecting procedure, the surgeon will not remove the member 56 completely out of the catheter until he has clamped off the catheter between the patient and the member 56. When this has been done, the member 56 can be removed completely, the the catheter connected to the drainage system and the clamp removed from the catheter. This procedure serves to keep nonsterile air from entering the pleural space of the patient and also keep the intrathoracic pressure normal.

The presence of the member 56 throughout the length of the catheter 30 during the placement procedure prevents entrance of blood or other fluid and formation of blood clots or the like from blocking the catheter lumen during and after the placement. Hence, the member 56 serves to ensure that internal flow through the catheter can be made as soon as the postsurgical drainage or other procedure requires it.

With reference to FIG. 4, a catheter of extended length 58 having an open distal end 60 and several side entering eyes 62 is provided with a swab member 64 joined to a thread 66 formed of synthetic filaments which extends out from the catheter 58 through the proximal end opening 68. Installation and use of the catheter 58 would follow normal established clinical procedures except that after required placement of the catheter within a body cavity or channel of the patient, and just prior to initiation of desired liquid flow through the catheter, the swab member 64 would be withdrawn from the catheter by application of suitable tension on the filamentary member 66.

The new constructions for medicosurgical tubes of the invention are particularly suitable for use with disposable catheters and the like designed for a single patient single end use. Such disposable catheters are advantageously formed by extrusion of flexible nonfibrous plastic material such as plasticized polyvinyl chloride, polyethylene, polypropylene, nylon or the like of suitable formulation to give the desired flexibility and wall strength required for the particular shape or style of medicosurgical tube involved. Transparent plastic material can be used to permit visual observation of the lumen of the catheter external of the patient during the clinical procedure. Alternatively, however, pigmented plastic material which is opaque to visible light, X-ray radiation or both, may be used, and the catheters may be formed with an X-ray opaque longitudinal line or other markings in accordance with known practice in the art. Further, the new internal flow insurance features of the invention may be applied to catheters or other medicosurgical tubes formed of vulcanized rubber, braided fabric construction or the like. The swab member 18 may be formed of any suitable material which would exhibit the necessary shelf life, would be nontoxic, compatible with the material from which the catheter is formed and capable of sterilization such as by exposure to ethylene oxide vapors, gamma ray radiation or similar techniques used in the manufacture of these devices. Likewise, the elongated cylindrical member 56 would be formed of material meeting these requirements. Foamed or porous plastic material can advantageously be used for this purpose, e.g., the cylinder 56 or swab member 18 can be formed of polyethylene, polyurethane material, polyvinyl chloride plastic or equivalent material which has been extruded to have a foamed or porous structure using blowing agents or other techniques known to the plastics fabrication art for the creation of foamed or porous plastics. Preferably, a plastic foam of this type would be made of closed cell construction although an open cell construction could be employed.

The filamentary member 22 can be formed of any material having the nontoxic sterilization resistance and other features noted previously for the swab member or porous plug material. Threads or cords of natural fibers, such as cotton or linen, can be employed but, preferably, spun yarns or filaments or monofilaments formed of synthetic material such as nylon, polyesters, polypropylene or the like are used to provide the filamentary member 22. A small dab of cement or any other suitable means may be used to temporarily hold the exposed end of the filamentary member to the proximal end of the catheter.

It will be recognized from the foregoing description that the internal flow insurance feature of the invention is contemplated for use with all forms of medicosurgical tubes which require protection during the installation of the tube in a patient against possibility of lumen blockage by blood clotting or the like regardless of the exact relative dimensions, style, configuration or the like of the medicosurgical tube.

The embodiments of the invention in which I claim an exclusive property or right are defined as follows:

1. A medicosurgical tube in which blood clots or related solid material will not block fluid passage through the tube between the period of insertion of the tube in a patient and beginning of liquid flow through the tube which comprises a distal end portion having at least one fluid inlet opening therein, a proximal end portion and a central body portion joining the distal end portion to the proximal end portion, a resilient cylinder of plastic foam filling the inside of said tube extending from adjacent the distal end portion to beyond the proximal end portion, the end of said resilient cylinder extending beyond said proximal end portion constituting means by which said resilient cylinder may be pulled out of said tube following insertion thereof in a patient.

2. A medicosurgical tube of claim 1 which is a postsurgical drainage tube comprising a cap that covers the proximal end of said tube and encloses the end of said resilient cylinder that extend beyond said proximal end portion.

3. A medicosurgical tube of claim 2 that is a thoracic catheter.

4. A medicosurgical tube of claim 1 formed of extruded flexible nonfibrous plastic material.

5. A medicosurgical tube of claim 1 having a plurality of fluid inlet openings extending through the side of said distal end portion, the central body portion and proximal end portion of the tube being free of any such fluid openings, said resilient cylinder extending distally of all of said side extending inlet openings.

6. A medicosurgical tube of claim 1 formed of extruded transparent nonfibrous plasticized vinyl chloride polymer.