

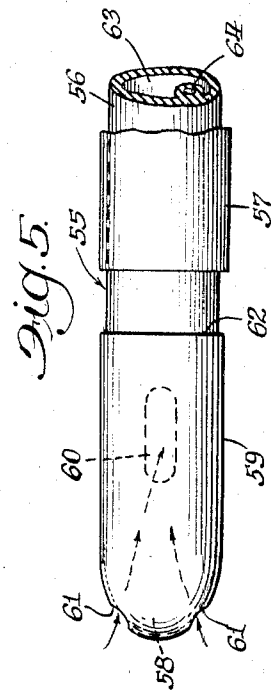
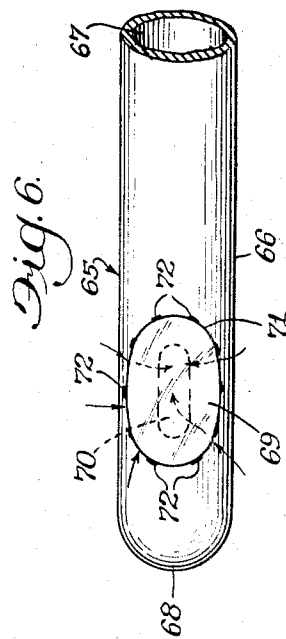
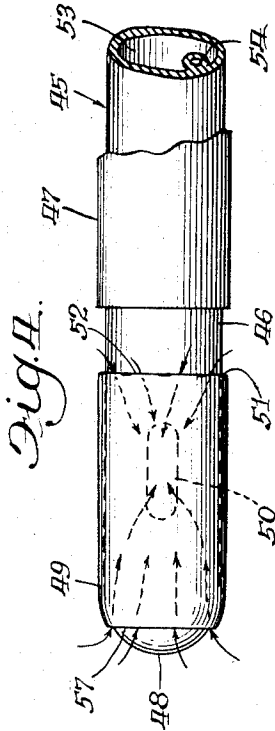
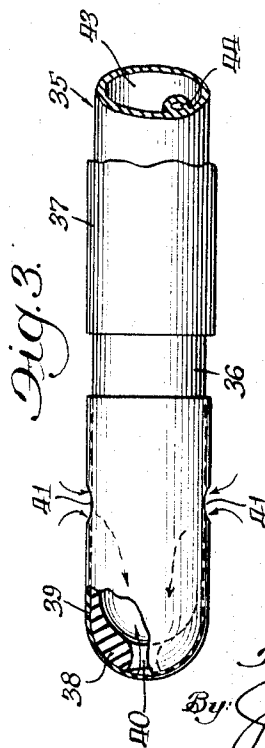
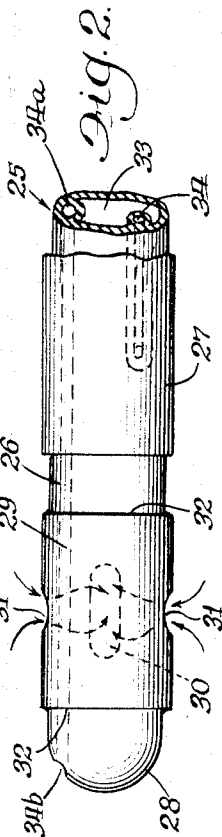
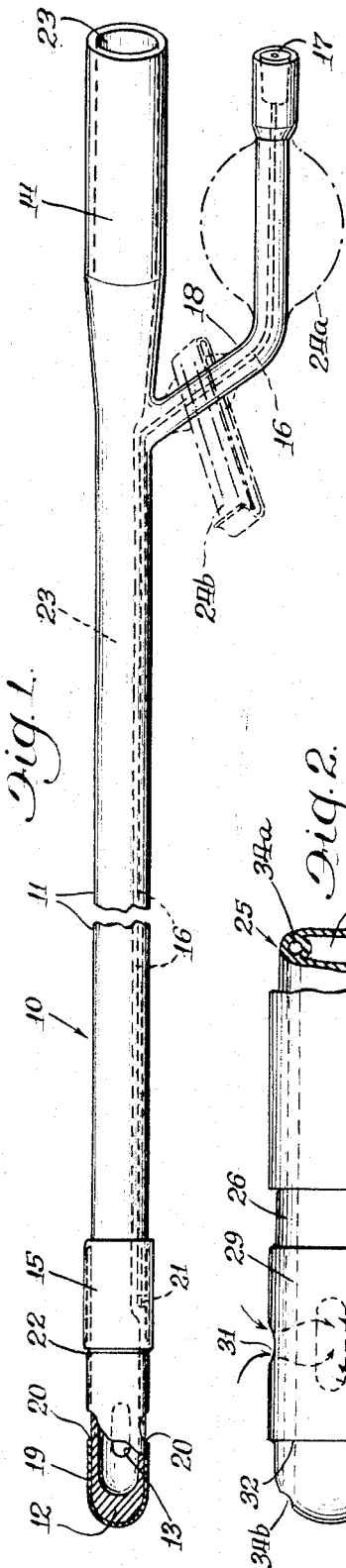
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DRAINAGE DEVICE WITH SHIELDED DRAINAGE ORIFICE

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## DRAINAGE DEVICE WITH SHIELDED DRAINAGE ORIFICE

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7 Claims

### ABSTRACT OF THE DISCLOSURE

A drainage device is described incorporating a shield member overlying but not occluding the drainage orifice uniformly spaced apart from the tubing wall and having at least one opening whereby a narrow fluid path is provided between the body cavity and the drainage orifice. This construction diminishes the trauma associated with tissue being drawn into the drainage orifice during drainage of fluids from a body cavity.

This invention is concerned with drainage devices which are intended to be inserted into an animal body for draining fluid therefrom.

Specifically, this invention is intended to provide a solution to the problems which may arise when portions of the body cavity walls enter or engage the drainage tube orifices, thus possibly resulting in trauma and possible rupture of the protective tissue of the body cavity wall. Portions of the walls of the body cavity may be drawn into the drainage orifices, for example, by suction created in the drainage tube when fluid is drained from the cavity through the tube. This suction may persist even after the fluid is exhausted from the cavity and while a column of fluid remains in the drainage tube. Disruption of such protective tissue creates possible portals of entry for invading microorganisms.

One object of this invention is the provision of a drainage device which reduces or eliminates the incidence of trauma or rupture of body tissue.

Another object of the invention is the provision of a catheter with drainage features which reduce the incidence of sites for potential bacterial infection.

Another object of the invention is to prevent body tissue from being drawn into the orifice of a drainage tube where suction exists in the drainage tube.

Other objects of the invention will be apparent from an inspection of the specification and drawings.

Referring to the drawings:

FIGURE 1 illustrates a typical drainage device of the invention in the form of a catheter wherein a sheath covering the tip and drainage orifices has perforations separated circumferentially from the drainage openings.

FIGURE 2 is a modification of FIGURE 1 wherein the covering sheath is a cylindrical band extending short of the tip and the drainage tube contains an irrigating lumen opening into the tip.

FIGURE 3 is a modification of FIGURE 1 in which the covering sheath is similar but the drainage orifice is in the tip end.

FIGURE 4 is a further modification of FIGURES 1 and 2 wherein both ends of the sheath provide multiple openings.

FIGURE 5 is a modification of FIGURE 1 wherein

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the covering sheath is similar but the perforations in the sheath are at the tip end.

FIGURE 6 illustrates a drainage device without internal retention means and wherein the drainage orifices are covered by patches having peripheral openings.

Trauma of body tissue, when an unprotected drainage tube orifice develops suction in use, occurs in at least three ways. The tissue adjacent the orifice is first drawn inwardly over the hard orifice edge. This scraping action in itself traumatizes the protective epithelial tissue. As the tissue is drawn in, the suction is applied to a more specific area and as maximum suction is applied further traumatization of the tissue occurs. At times this further traumatization results in the formation of hemorrhagic polyps. The body tissue lodged in the orifices and possibly extending into the drainage channel of the tube may be further injured, even ruptured, when the drainage tube is removed from the body cavity.

The objects of this invention are largely attained by preventing the tissue from being drawn across a hard edge into a deep open channel where it may be sucked in a restricted area. The preferred drainage devices of this invention are tubes having shields or sheaths over the normal drainage orifices. The sheaths with the tube walls provide fluid openings restricting the direct flow of fluid into the tube channel and the direct exposure of that portion thereof at the orifices to the body cavity. The sheath or shield in the area of the fluid openings are thin. Thus, even when the tissue contacts an opening as when perforation in the sheath is the embodied opening, there is no hard edge over which tissue may be drawn and the immediately underlying wall of the drainage tube prevents the epithelial tissue from being stretched resulting in a polyp. Where the openings are slit-like openings between the shield and the tube at the shield periphery, the suction is distributed over wider areas of the contacting tissue.

Referring once more to the drawings:

FIGURE 1 illustrates a typical drainage device of the invention 10 in the form of a catheter 11. The catheter has a bell 14 and a tip 12 with a drainage lumen 23 extending from the bell to a drainage orifice 13. The particular embodiment shown is a catheter having an inflatable retention means 15 which is inflated by fluid pressure from the inflating lumen 16 acting through the opening 21 into the retention means. The lumen 16 is partly contained in the main branch of the catheter and partly in the side branch 18. The lumen 16 is closed at the end of the side branch by a combination stopper and inflation plug 17. A self-inflating catheter is shown constructively with a fluid inflated reservoir 24a and a fluid retaining clamp 24b. The reservoir may be inflated with a hypodermic needle from a syringe by pushing the needle through the inflation plug 17 when the clamp is in place. However, in the absence of a clamp and reservoir, the retention means may be inflated at the time it is positioned for use by using the needle and syringe. The embodiment of the invention shown in FIGURE 1 is then an ordinary Foley catheter or a self-inflating Foley catheter except for the tip end.

In FIGURE 1, the catheter tip 12 and the drainage orifice 13 are covered by a thin sheath 19 joined to the catheter body along the peripheral edge 22. The sheath 19 has at least one opening 20 spaced circumferentially from the catheter drainage orifice 13 so that fluid entering the opening 20 must move between the catheter tube wall and

the sheath 19 to reach the orifice 13. The sheath 19 is thin in the area of the opening 20 so that tissue in contact with the opening contacts the underlying catheter wall which prevents tissue trauma due to suction.

In FIGURE 2, the insertion portion of a drainage device 25 is shown including a drainage tube 26. The tube contains a drainage lumen 33 leading to at least one drainage orifice 30, an inflation lumen 34 leading to an inflatable retention means 27, and an irrigating lumen 34a leading to an irrigating outlet 34b in the drainage tube tip 28. A cylindrical band or sleeve 29 extends over the orifices 30 covering them completely. Perforations or openings 31 through the sleeve are disposed in spaced relationship from the orifices 30 so that fluid entering the openings or perforations is constrained to pass between the sleeve and the drainage tube 26 before entering the drainage orifices 30. The fluid flow entering the opening 31 is indicated by the solid line arrows and the flow between the sleeve and the outer wall of the tube into the orifice is shown by the broken line arrows. The sleeve may be secured to the tube 26 in position over the orifice 30 along the annular lines 32 by any convenient method including latex dipping, solvent sealing, heat shrinking, adhesive bonding, heat sealing or any other suitable well-known method. The seals do not have to be continuous nor fluid impervious.

In FIGURE 3, the insertion portion of another embodiment of the invention, a drainage device 35, is shown with a drainage tube 36. The tube contains a drainage lumen 43 leading to a drainage orifice 40 in the tip end 38 of the tube 36, and an inflation lumen 44 leading to an inflatable retention means 37. The shield 39 is in the form of a cap-like structure closed over the tip end of the drainage tube 36 and the drainage orifice 40. The openings or perforations 41 in shield 39 cause fluid entering the drainage orifice 40 to pass between the drainage tube and the shield. The trailing edge of the shield may be secured to the tube in any of the ways described with respect to FIGURE 2.

FIGURE 4 represents the insertion portion of another embodiment of the invention, a drainage device 45 including a drainage tube 46 containing a drainage lumen 53 leading to at least one drainage orifice 50. The tube 46 which is closed at its tip end 48 also contains the inflation lumen 54 which leads to an inflatable retention means 47. The shield 49 is in the form of a sleeve which has ends 51 and 57 at least one of which is partially open providing slits 52 whereby fluid may enter between the tube 46 and the shield 49 before being drawn into the drainage orifices 50.

FIGURE 5 represents the insertion portion of a further species of the invention, a drainage device 55 including a drainage tube 56 containing a drainage lumen 63 leading to at least one drainage orifice 60. The tube 56 also contains an inflation lumen 64 leading to an inflatable retention means 57. The shield 59 again is in the form of a cap-like structure extending over the closed tip 58 of the tube 56. The trailing edge of the shield is secured to the tube 56 along the edge 62 in any of the ways previously described. The shield contains perforations or openings 61 in the shield tip end which provide an entry for fluid which is drawn into drainage orifice 60 between the tube and the shield.

FIGURE 6 illustrates the insertion end of a drainage device 65 including a drainage tube 66 having a closed tip 68 and containing a drainage lumen 67 leading to at least one drainage orifice 70. The tube 66 which has no internal retention means may be held in place by the hand or by other external means. The patch 69 provides an orifice-covering shield which extends beyond the orifice edges on all sides. The patch 69 is held in position by anchoring areas 72 which leave slits 71 by which fluid may pass between the patch and the tube 66 into the orifice 70. Obviously, the patch 69 may cover more than one orifice or each orifice may have an individual patch.

The preferred devices of this invention and those which are specifically illustrated show shields which cover the entire drainage orifices but it is obvious that less desirable

devices which utilize the shield principle and hence are within the invention may be made with small areas of the orifice not covered by the shield.

While the preferred material of the drainage devices of the invention is rubber latex, the devices may be made of any flexible material. Representative examples are polymeric materials such as silicone rubbers, vinyl polymers and copolymers, such as ethylene vinyl acetate, polyethylene polymers and copolymers, nylons and cellulose derivatives, however, the invention is by no means restricted to the representative materials, flexible materials broadly being suitable.

I claim:

1. In a drainage device for insertion into an animal body cavity to be drained of fluids having a length of flexible tubing, said tubing having an insertion end for insertion into the animal body cavity, said tubing provided with a drainage lumen extending the length thereof, and a drainage orifice, having peripheral edges surrounding same, proximate the insertion end communicating with the drainage lumen, the improvement comprising in combination therewith a shield member mounted on the tubing overlying but not occluding the drainage orifice and extending beyond the peripheral edges of said drainage orifice, said shield member substantially hugging the outer surface of the tubing but being slightly uniformly spaced apart from the tubing thereby providing a narrow fluid path between the tubing and the shield member and communicating the body cavity with the drainage orifice said shield being so secured to the tubing that the said fluid path spacing is maintained substantially constant at normal operating pressures.

2. A drainage device in accordance with claim 1 wherein the shield member comprises a band encircling the tubing overlying the drainage orifice and uniformly spaced apart from said tubing to form a narrow fluid path between the tubing and the band, said band having opposed edges extending beyond the peripheral edges of the drainage orifice and sealed to the tubing, and said band having at least one opening spaced circumferentially from the drainage orifice, communicating the body cavity with the drainage orifice through the fluid path.

3. A drainage device in accordance with claim 1 wherein the shield member comprises a band encircling the tubing overlying the drainage orifice and uniformly spaced apart from said tubing to form a narrow fluid path between the tubing and the band, said band having opposed edges extending beyond the peripheral edges of the drainage orifice and having at least one anchoring point on each edge of the band to secure said band to the tubing along each edge thereof, communicating the body cavity with the drainage orifice through the fluid path.

4. A drainage device in accordance with claim 1 wherein the shield comprises a patch overlying and extending beyond the peripheral edges of the drainage orifice and uniformly spaced apart from said tubing to form a narrow fluid path between the tubing and the patch, said patch secured to the tubing at a number of anchoring points around the periphery of said patch thereby communicating the body cavity with the drainage orifice through the fluid path.

5. A drainage device in accordance with claim 1 wherein the shield member comprises a cap overlying the drainage orifice and enveloping the insertion end of the tubing, said cap being uniformly spaced apart from said tubing to form a narrow fluid path between the tubing and the cap, said cap conforming substantially to the contour of the tubing and having at least one opening spaced circumferentially from the drainage orifice thereby communicating the body cavity with the drainage orifice through the fluid path.

6. A drainage device in accordance with claim 5 wherein the cap is further provided with an opening at the tip of the insertion end to provide an additional path of com-

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munication between the body cavity and the drainage orifice through the fluid path.

7. A drainage device in accordance with claim 6 wherein the cap is further provided with at least two openings spaced circumferentially from the drainage orifice to provide multiple paths of communication between the body cavity and the drainage orifice through the fluid path.

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