United States Patent [19]

Shermeta

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[54] **GASTROSTOMY TUBE**

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[52] **U.S. Cl.** **128/348**

[51] **Int. Cl.²** **A61M 25/00**

[58] **Field of Search** ..... 128/1, 341, 343, 344, 128/348–351, DIG. 25, 240–246, 283, 347

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[57] **ABSTRACT**

A gastrostomy tube for insertion into the stomach and for retention as a consequence of bearing engagement against the inside stomach wall and the outside abdominal wall. A conduit carries a stiffly flexible retention bulb which can be collapsed by a stylet for insertion through a stab wound through the stomach. In the stomach the bulb resumes its normal shape when the stylet is withdrawn and then can be pulled against the stomach wall. A second retention bulb is inflatable and spaced apart from the first retention bulb to engage the outer abdominal wall when it is inflated.

4 Claims, 6 Drawing Figures

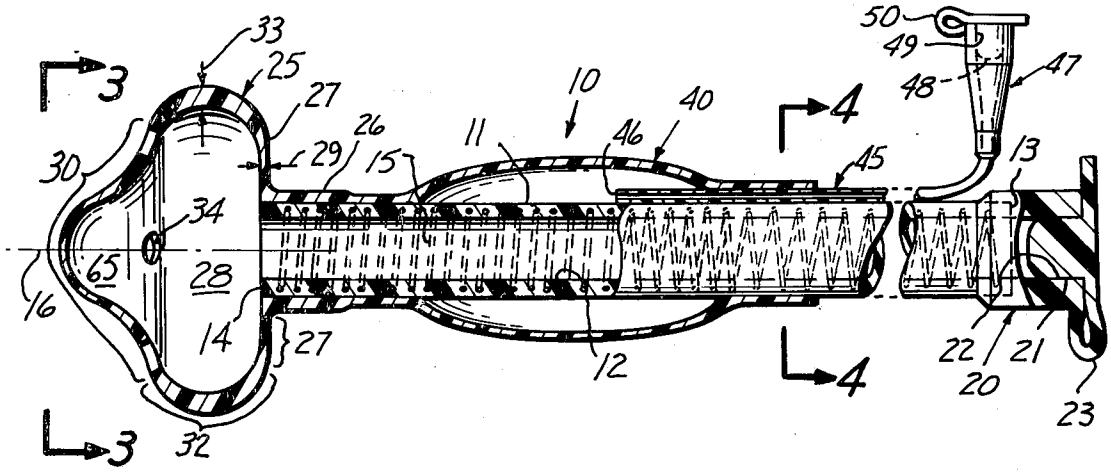


FIG. 1

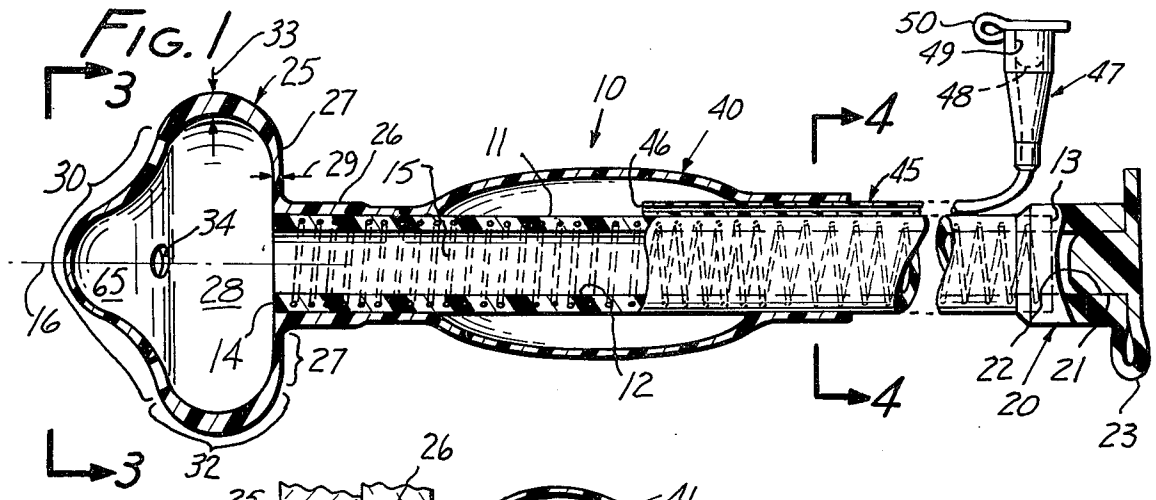


FIG. 2

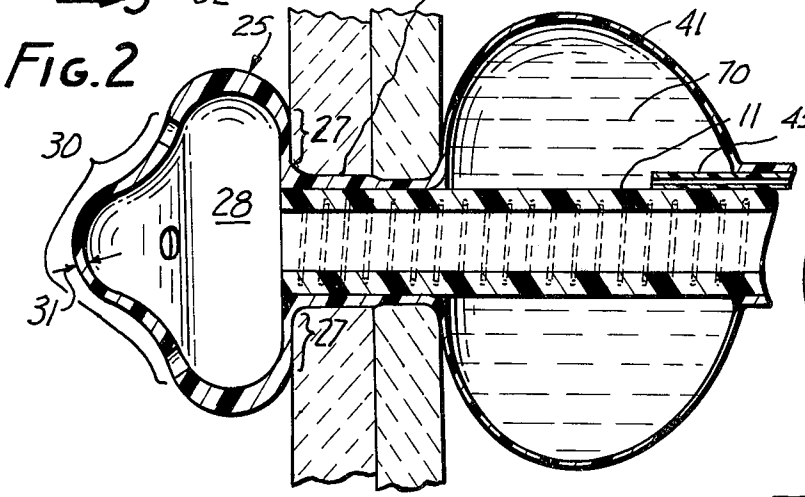


FIG. 4

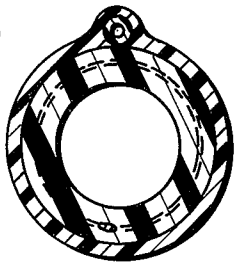


FIG. 3

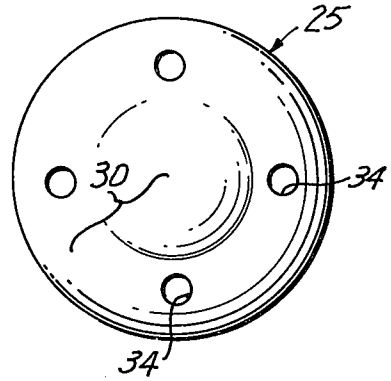


FIG. 5

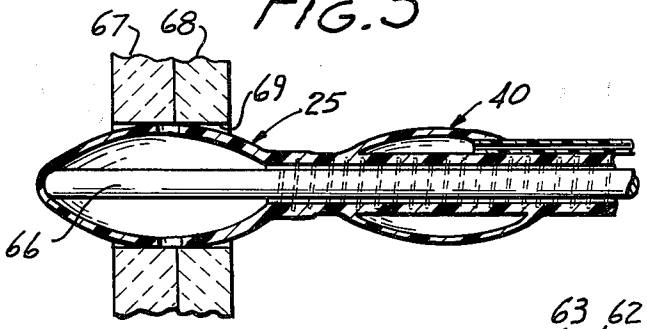
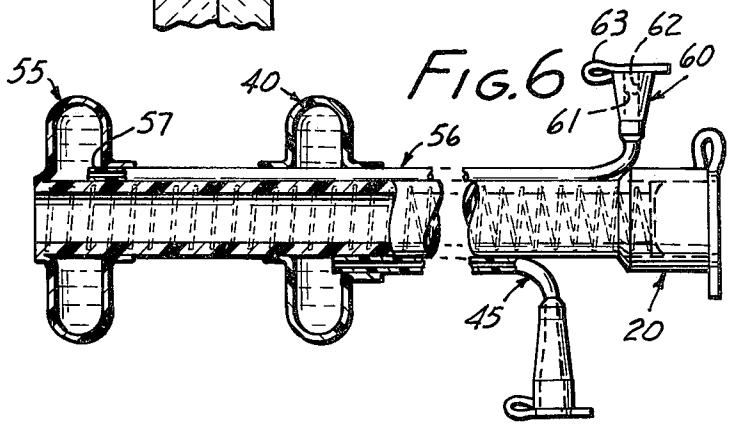


FIG. 6



GASTROSTOMY TUBE

BACKGROUND OF THE INVENTION

This invention relates to a gastrostomy tube which is passed through the wall of the abdomen and of the stomach, and is attached thereto to provide a conduit having a bore for supplying and removing fluids from the stomach.

Gastrostomy tubes are utilized to supply and to remove fluids from the stomach, when for some reason the stomach cannot be supplied or relieved through the normal channels. An example of such a condition is the consequence of severe traumatic injury to or destruction of the windpipe. Then it is necessary to feed the patient or to relieve excess gas by other means. It is an object of this invention to provide a gastrostomy tube which can be inserted into a stab wound where it will, without further trauma, make a full peripheral gas seal with the walls of the stomach and abdomen, and retain itself by clamping action against the walls. The conduit is readily and quickly put in place. Its retention means is sufficiently strong that it is unlikely to be pulled out by any forces normally to be expected on it.

A gastrostomy tube according to this invention comprises a tubular conduit to be passed through the wall of the abdomen and of the stomach. The conduit has an axis of fluid flow, an axial bore, and a first end and a second end spaced apart from one another along the axis. First closure means is spaced from the second end and is adapted to close the conduit to the flow of fluid or to leave it open thereto, whereby when the conduit passes through said wall and the conduit is open, fluid can be supplied to or removed from the stomach through the bore. When the conduit is closed, fluid can be retained in the stomach.

A first retention bulb is attached to the conduit adjacent to the second end, and it has a greater lateral dimension than the conduit, so as to bear against the inside wall of the stomach and resist pull-out of the conduit from the stomach. A second retention bulb is attached to and surrounds the conduit at a location axially spaced apart from the first retention bulb. The second retention bulb is made of flexible fluid-impermeable material, whereby it is inflatable by fluid under pressure to form a peripheral ring which has a greater lateral dimension than the conduit and which tends to retain its shape around the conduit and to bear against the outside of the abdomen, whereby to retain the walls between the two retention bulbs, thereby to attach the gastrostomy tube thereto and to form a fluid-tight seal with them.

Fluid passage means enters the second retention bulb to supply fluid under pressure to inflate the same, and second closure means in the fluid passage means is adapted to close the fluid passage means or to leave it open to the flow of fluid, whereby fluid under pressure can be injected through the fluid passage into the second retention bulb to inflate it, and the second closure means can be closed to maintain the said inflation.

According to a preferred but optional feature of the invention, the first retention bulb is stiffly flexible, whereby to tend to retain its shape.

The above and other features of this invention will be fully understood from the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an axial cross-section showing the presently preferred embodiment of the invention;

FIG. **2** is a partial showing of the device of FIG. **1** in its installed condition;

FIG. **3** is a left-hand end view of FIG. **1**;

FIG. **4** is a cross-section taken at line **4**—**4** of FIG. **1**;

FIG. **5** shows the device of FIG. **1** being installed; and

FIG. **6** is a side view, principally in axial cutaway cross-section, showing another embodiment of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a gastrostomy tube **10** according to the invention which includes a tubular conduit **11** having a central axially-extending bore **12** passing from a first end **13** to a second end **14.** A reinforcement spring **15** in the form of a coil spring may be imbedded in the wall of the conduit, or may surround the conduit, or abut the inside wall thereof as preferred. Its purpose is to resist the compressive collapse of, or the pinching closed of, the tubular conduit. The conduit and bore extend along axis **16.**

First closure means **20** comprises a plug **21** fitted in a seat **22** at the first end of the tubular conduit. A strap **23** prevents the plug from being separated from the conduit. The plug makes an interference fit in the seat. It is removable to open the tubular conduit to flow through the bore and can be closed to close the bore and prevent fluid flow therethrough.

A first retention bulb **25** is attached to the tubular conduit adjacent to the second end thereof. In its undistorted shape, bulb **25** has a greater lateral dimension than the conduit so as to resist the pull-out of the conduit from the stomach. Bulb **25** includes a neck **26** which is attached to the conduit immediately adjacent to a first face section **27.** The neck makes a peripheral fluid-sealing attachment with the outer wall of the tubular conduit. The retention bulb is a hollow body of revolution including an internal chamber **28.** The first face section faces toward the first end of the tubular conduit and has a wall thickness **29.** It is smooth, annular, and imperforate, and its surface can bear against the stomach wall to form a fluid seal. The surface substantially lies in a plane normal to axis **16** and is a continuous surface of revolution. A second face section **30** faces away from the said first end and has a wall thickness **31.** The two face sections are interconnected by a medial section **32** which has a wall thickness **33.** The second face section is connected to the tubular conduit only through the medial section and the first face section. The first face section is connected to the conduit at neck **26.** The wall thickness **33,** at least at the central portion of the medial section, is greater than the wall thicknesses **29** and **31.** This heavier wall thickness acts as a relatively strong spring when the first retention bulb is stretched axially, and tends to act as a spring-like structure to return the bulb to the illustrated shape. It springily resists distortive forces, although its resistance can be overcome. A plurality of openings **34** (sometimes called "apertures") through the second face section fluidly interconnect the outside of the first retention bulb to the bore (and the bore to the inside of the stomach when the gastrostomy tube is installed). The apertures are formed in the first retention bulb other than in the first face section.

A second retention bulb **40** is attached to the conduit and surrounds it at a location axially spaced apart from the first retention bulb. The second retention bulb is made of flexible fluid-impermeable material, whereby it is inflatable by fluid under pressure to form a peripheral ring **41**, as in FIG. **2**. The ring when inflated tends to retain its shape around the conduit and is intended to bear against the outside of the abdominal wall. It is a body of revolution, and its surface adjacent to the abdominal wall is smooth and annular. The walls are retained between the two retention bulbs, and two seals are formed.

Fluid passage means **45**, in the form of a pipe **46**, is attached along its length to the tubular conduit and enters the second retention bulb. Second closure means **47** is provided to admit and to confine fluid in the second retention bulb. Means **47** includes a removable plug **48** which makes an interference fit in a seat **49**. A strap **50** prevents the plug from being separated from the passage means.

FIG. **6** illustrates another embodiment of the invention which differs from that of FIG. **1** only in the nature of the first retention bulb. For this reason, similar parts are given identical numbers. In this embodiment, the first retention bulb is inflatable, rather than merely inherently shape-retaining as a consequence of the materials used to make it, and of its dimensions.

In the device of FIG. **6**, the tubular conduit is open directly to the stomach when it is installed, instead of first discharging into a chamber.

In FIG. **6**, the first retention bulb is attached to and surrounds the conduit. It is made of flexible fluid-impermeable material, and with the conduit forms an annular fluid-tight region, whereby the bulb is inflatable by fluid under pressure to form a peripheral ring (similar to that of the second retention bulb as shown) which tends to retain its shape around the conduit and to bear against the inside of the stomach wall.

A second fluid passage means **56** comprises a pipe **57** making a fluid communication with the first retention bulb. It includes third closure means **60** for admitting fluid under pressure to inflate the retention bulb and to retain it when the removable plug is placed in its respective seat. For this purpose, there is provided a removable plug **61**, a seat **62** and a strap **63**, as in the other closure means **47**.

In FIG. **1**, a recess **65** is formed centrally in the second face section. This is for the purpose of centering a stylet **66** (see FIG. **5**) when the device is to be installed.

The process of installation of the device of FIG. **1** is shown in FIG. **5** where there is illustrated in simplified notation the wall **67** of the stomach and the abdominal wall **68** with a stab wound **69** passing through the two of them. The stylet is passed through the bore and is centered by the recess. When the stylet is axially pressed relative to the tubular conduit, it stretches the first retention bulb, distorting its sections as shown. As it happens, this tends to form the first retention bulb into a group of small collapsed leaflets grouped around the axis, which readily pass through the stab wound. Then the stylet is withdrawn, and because of the springy construction of the first retention bulb, it will spring back toward its original shape, as shown in FIG. **2**. A pull exerted on the tubular conduit will draw it against the inside stomach wall. The thickened portion of the medial section resists too-easy pull-out of the tube.

Next, the second tubular bulb is inflated by removing the plug from the second closure and inserting a syringe into seat **49**. The syringe will insert fluid **70** under pressure (either gas or a liquid, such as sterile saline solution) into the second retention bulb, so as to inflate it as shown. Accordingly, a tight fluid seal will be formed between the walls **67** and **68** and both bulbs, which is fluid-tight relative to both the inside of the stomach and the abdominal cavity. The two walls are structurally embraced by the two bulbs. Therefore, the gastrostomy tube is attached to the body and prevents leakage from the stomach and from and into the abdominal cavity. Plug **48** will be replaced in the closure means to maintain the inflation. When it is removed, the fluid can escape, and the second tubular bulb can collapse. To remove the device, the stylet will again be inserted, and the first retention bulb collapsed, as shown in FIG. **5**, and the tube will be withdrawn while the first retention bulb is collapsed. With the gastrostomy tube installed, communication to the stomach may be made by opening the first closure means to exhaust fluids or to supply them as required.

The usage of FIG. **6** should be evident from the foregoing. In this case, no endwise force is exerted on the first retention bulb. The material of the first retention bulb will be sufficiently thin that it will readily collapse to pass through the stab wound when conduit **11** is passed through the stab wound. The installation is made by inflating both retention bulbs in the same manner as the second retention bulb was inflated in FIG. **2**, and then the usage of the device will be as described above. Removal of the device is accomplished by pulling the plug **61** from its seat so that the first retention bulb can be collapsed and the tube removed.

The device is preferably made entirely from medical grade silicone rubber, because of the compatibility of this material with human tissue and because of its elasticity and flexibility. The wall thickness of the inflatable bulbs is sufficiently thin that it can readily be stretched by fluid inserted therein, and the wall thickness of both retention bulbs in FIG. **6** and the second retention bulb in FIG. **1** may be on the order of **0.010** inch. The wall thicknesses **29, 31** and **33** may be approximately .030, **.020,** and .035 inch, respectively. The first retention bulb **25** will be of sufficiently thick dimensions that it is inherently self-retaining and is stiffly flexible.

This invention is not to be limited by the embodiments shown in the drawings and described in the description, which are given by way of example and not of limitation, but only in accordance with the scope of the appended claims.

I claim:

1. A gastrostomy tube comprising: a tubular conduit to be passed through the abdominal wall and through the wall of the stomach, said conduit having an axis of fluid flow and an axial bore, and a first end and a second end spaced apart from one another along said axis; first closure means spaced from the second end adapted to close the conduit to the flow of fluid or to leave it open thereto, whereby when the conduit passes through said wall and the conduit is open, fluid can be supplied to or removed from the stomach through said bore, and when the conduit is closed, fluid can be retained in the stomach; a first retention bulb attached to the conduit adjacent to said second end and having a greater lateral dimension than the conduit so as to bear against the wall of the stomach and resist the pull-out

of the conduit from the stomach, the first retention bulb being stiffly flexible whereby to tend to retain its shape, the first retention bulb comprising a first face section facing toward said first end of the conduit, a second face section facing away from said first end, a medial section interconnecting the said two face sections, the first face section being connected to said conduit and the second face section being attached to the conduit only through the medial section and the first face section, the wall thickness of the two face sections being relatively less than that of at least a portion of the medial section, whereby the medial section forms a spring-like structure which tends to restore the first retention bulb to its undistorted shape, an internal chamber being formed within said sections, an aperture through said first retention bulb other than through the first face section communicating with said internal chamber to provide fluid communication through the chamber between the stomach and the bore, the first face section including an outer smooth and continuous surface of revolution lying substantially normal to the said axis; a second retention bulb attached to and surrounding said conduit at a location axially spaced apart from the first retention bulb, said second retention bulb being made of flexible fluid-impermeable material whereby it is inflatable by fluid under pressure to form a peripheral ring which has a greater lateral dimension than the conduit and which tends to retain its shape around the conduit and to bear against the outside of the abdominal wall whereby to retain said walls between the two retention bulbs and to attach the gastrostomy tube thereto and to form a fluid-tight seal; fluid passage means entering the second retention bulb to supply fluid under pressure to inflate the same; and second closure means in said fluid passage means adapted to close the fluid passage means or to leave it open to the flow of fluid, whereby fluid under pressure can be injected through the fluid passage into the second retention bulb to inflate said second retention bulb and the second closure means can be closed to maintain the inflation.

2. A gastrostomy tube according to claim **1** in which a spring extends axially along the conduit to reinforce it and resist its collapse.

3. A gastrostomy tube according to claim **1** in which a central recess is formed in the undistorted first retention bulb to center a stylet inserted into the chamber through the conduit.

4. A gastrostomy tube according to claim **3** in which the first retention bulb is formed as a body of revolution around said axis, which body is continuous except for said aperture.

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