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Loseff

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[54] **WOUND SUCTION TUBE AND RETROGRADE FLUSHING**

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[52] **U.S. Cl.** ..... **128/350 R;** 128/349 B; 128/278

[51] **Int. Cl.**[2] **A61M 27/00**

[58] **Field of Search** ..... 128/349 R, 349 B, 349 BV, 128/350 R, 350 V, 240, 241, 230, 231, 128/214.2, 214 F, 349, 350, 128/276-278

[56] **References Cited**

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[57] **ABSTRACT**

A drainage tubing for wounds is described. The tubing is retained in the wound site in an improved manner by means of an inflatable balloon positioned in the intact, healthy tissue adjacent the patient's skin. The drainage tubing may also have a second, collapsible bulb portion for aseptic back-flushing of the wound site while the tubing lumen is sealed from the exterior.

10 Claims, 4 Drawing Figures

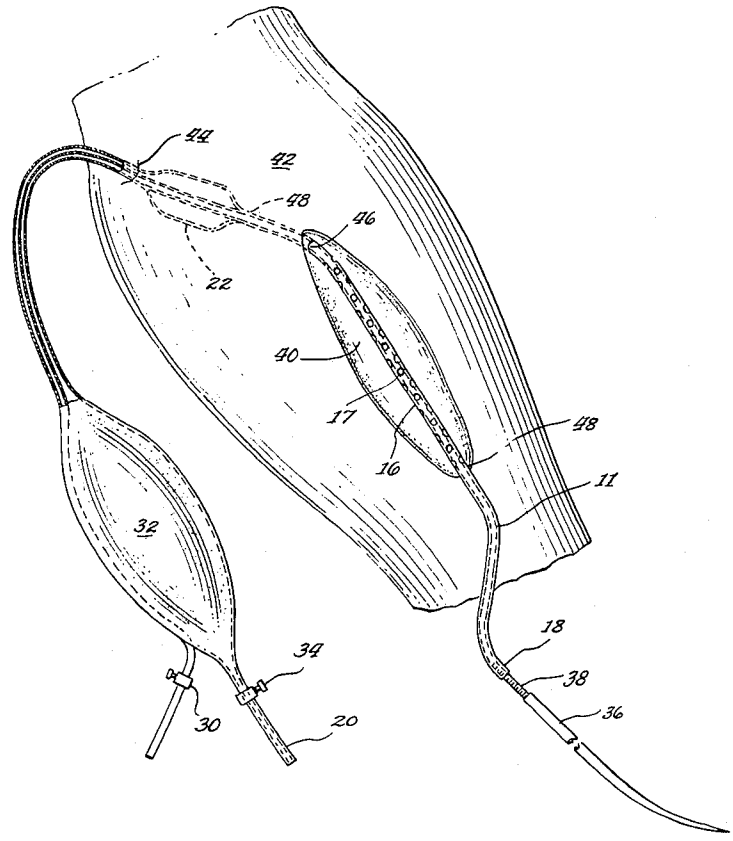

Fig. 1

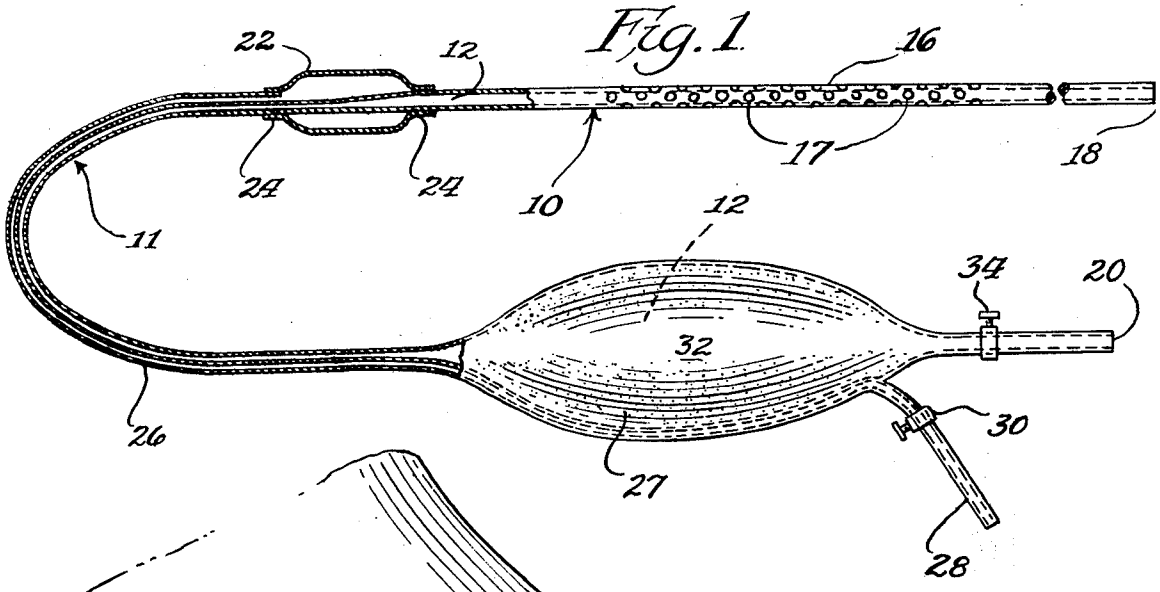
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Fig. 2.

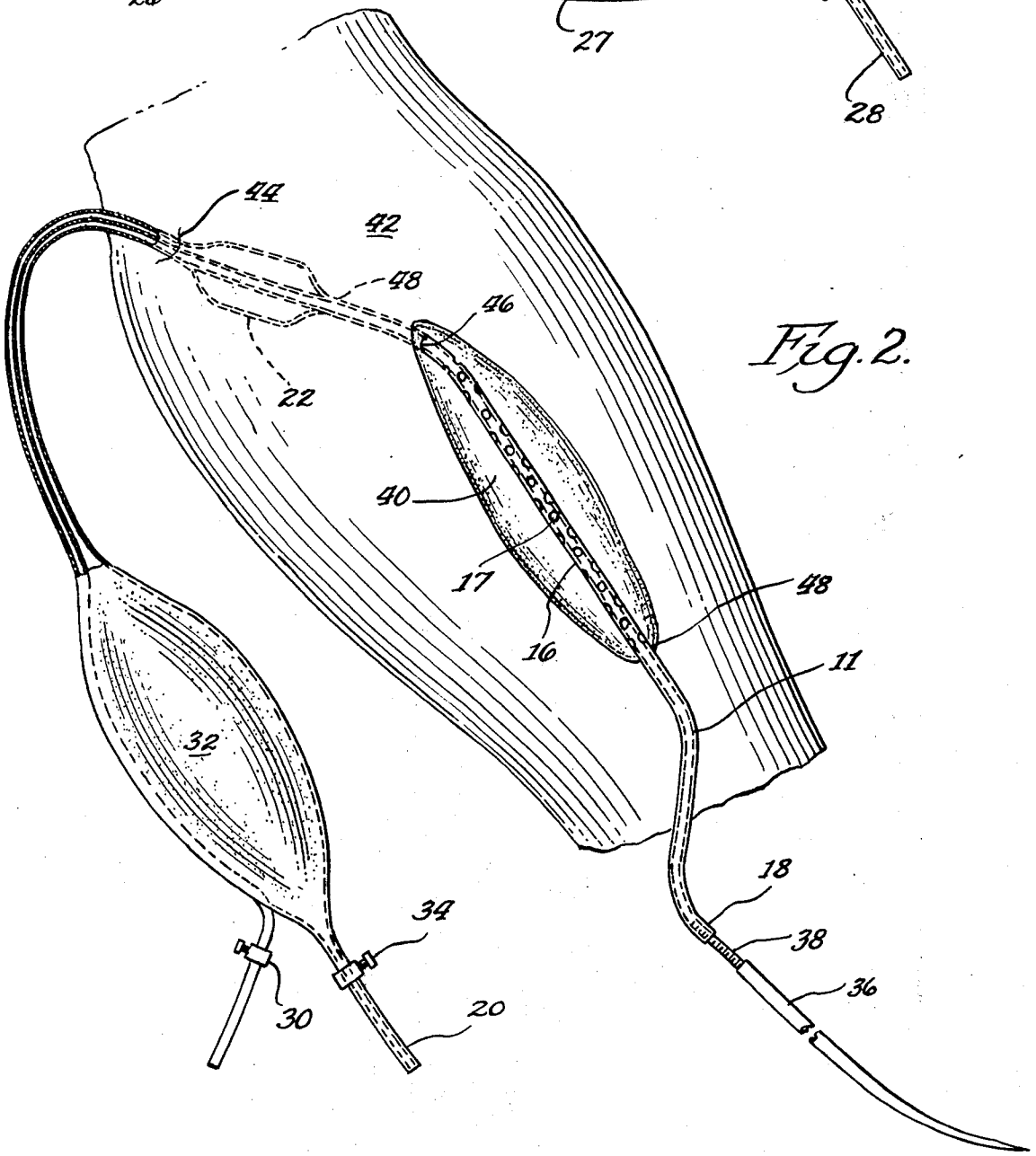
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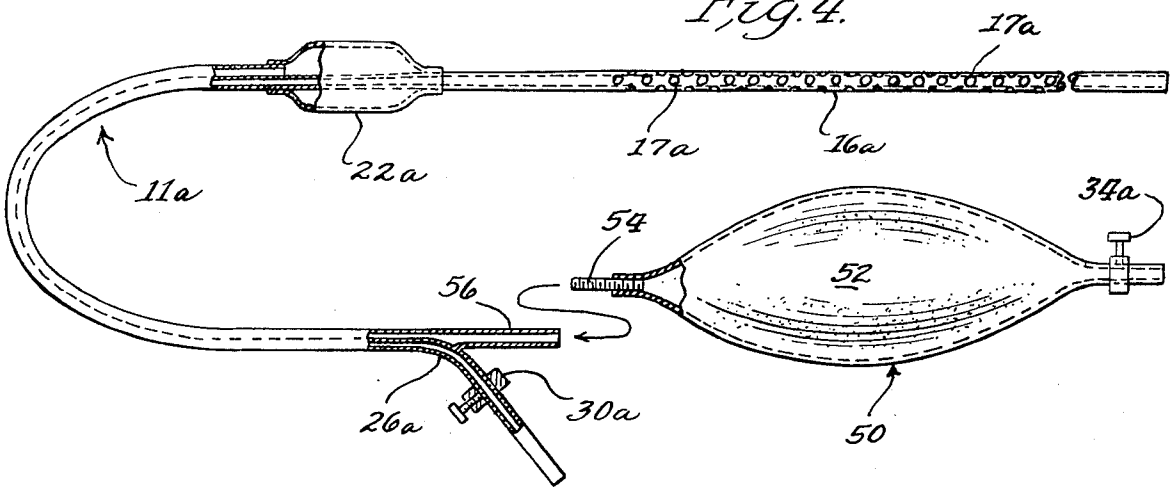
Fig. 4.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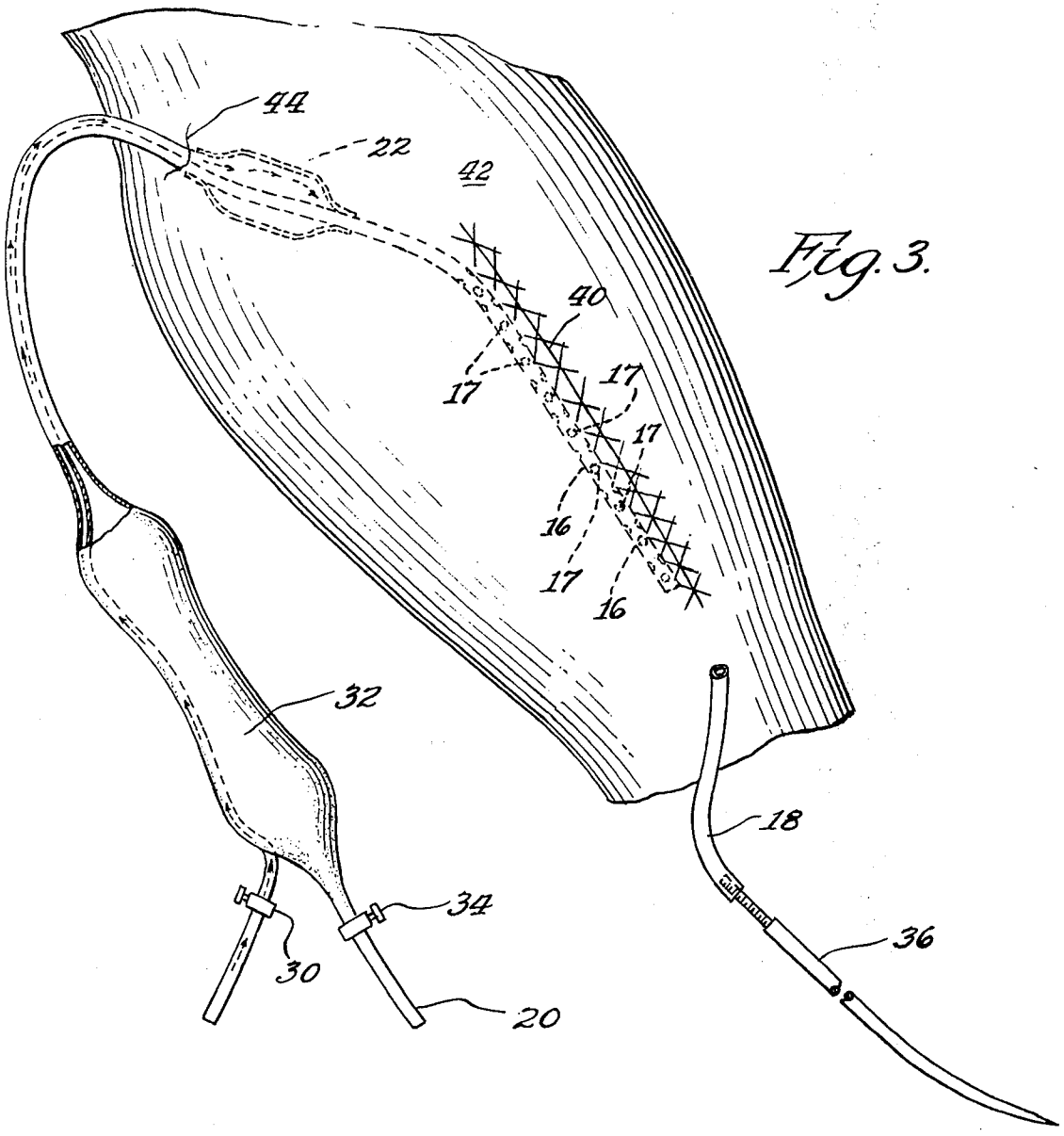
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Fig. 3.

WOUND SUCTION TUBE AND RETROGRADE FLUSHING

When a patient has a serious, deep wound, or a large abscess, osteomyelitis, or other collections of body fluids such as serum, blood, or pus in the body, drainage catheter tubing (commonly called wound tubing) is commonly used to alleviate the situation. Commonly, the wound tubing is made of flexible plastic such as polyethylene, or inert elastomers such as silicone rubber or the like. Typically, the wound tubing is fabricated to have sufficient stiffness so that fluids can be removed through it by suction without collapsing the tubing, for example, by an evacuator such as is shown in U.S. Pat. No. 3,115,138.

The wound tubing typically is manufactured with a large number of lateral perforations for communication between the lumen or bore of the tubing and the exterior, the perforations being located in a central portion of the tubing, and the ends of the tubing being free of lateral perforations.

For emplacement in the wound site, a pointed steel awl is connected to one end of the wound tubing, to pass the tubing through healthy, intact tissue adjacent the wound in such a manner that at least one end of the wound tubing is positioned exterior of the patient, while the perforated portion lies at the wound site. Following this, excess portions of the wound tubing, and the awl, are removed by severing the tubing, and the wound site is sutured.

Various significant problems exist in the prior art wound tubing. First, the restless patient can accidentally, or otherwise, pull on the wound tubing and cause it to withdraw outwardly along its path through the healthy tissue. This can happen when the patient is asleep, or irrational patients and children may intentionally try to withdraw the wound tubing.

Once the wound tubing has been partially or completely withdrawn, those portions of the tubing which have been exposed to the exterior will become contaminated with bacteria, and thus should not be simply reinserted into the patient again, even if this were possible. Accordingly, a wound tubing may have to be reinserted by connecting fresh sterile wound tubing to an awl, and once again punching it through the healthy tissue into the wound site. Also, the stitches holding the wound closed may well have to be re-opened in order to withdraw the awl and to re-position the wound tubing.

Furthermore, at the skin exit hole or holes of the wound tubing, there is a pronounced tendency for blood, lymph or irrigation solution to leak outwardly, which is clearly undesirable. Also, there is the still more undesirable possibility of the migration of bacterial contamination inwardly toward the wound site along the wound tubing, and the consequent danger of infection.

Also, the perforations and the bore or lumen of the wound tubing at the wound site frequently become plugged with debris. To avoid changing of the wound tubing, there is frequently attempted a back flushing procedure, in which sterile flushing solution, such as normal saline, is passed through the wound tubing to flush the solution into the wound site. This disperses and breaks up the debris which blocks flow in the wound tubing. This technique has its consequent dangers of introducing bacterial contamination from the exterior into the wound site.

In accordance with this invention, the above disadvantages are eliminated are greatly reduced in effect by the improved drainage tubing of this invention and its method of use.

BACKGROUND OF THE INVENTION

In accordance with this invention, a drainage device for wounds is provided which comprises a tubular drainage member having a central lumen or bore, and a plurality of drainage ports defined along a first portion of the tubular member and laterally through it for communication between the lumen and the exterior of the tubular member. An elastomeric retention balloon is carried by a second portion of the tubular member at one side of the first portion, which defines the drainage ports. The balloon is positioned to be inflatable under the skin of a patient while the drainage ports lie in the wound site. Preferably, the first portion of the tubular member described above is spaced from the ends of the tubular member by a convenient length of port-free tubing to permit connection of the tubular member with an awl, for installation of the tubular device in a manner described below, as well as to provide other flexibility of use of the wound tubing of this invention.

It is also a preferred feature of this invention to provide an enlarged lumen portion on the tubular drainage member for use as a collapsible squeeze bulb and storage portion, for retention of flushing solution in the tubular member outside of the body, when the drainage device is positioned in a patient with the drainage ports located in the wound site. With this arrangement, the lumen or bore of the tubular member can be sealed from the exterior by appropriate clamp means after filling with flushing solution, and the enlarged lumen portion of the tubular member can be squeezed and manipulated for aseptic back flushing of the drainage device, while the tubular member is sealed against possible bacterial contamination from the outside. Accordingly, the wound site can be bathed or back-flushed with any desired solution in a manner which reduces the risk of contaminating the wound site.

Another preferred feature of this invention is that the drainage ports are of smaller aperture size than the diameter of the central lumen of the tubular drainage member. As a result of this, the drainage ports serve to screen out tissue particles, small blood clots, and the like, preventing them from entering the central lumen and causing obstruction within the tubular drainage member.

It is generally desirable for the tubular drainage member and balloon member of the device of this invention to be made of silicone rubber, since such material is highly non-adherent to clots and debris, and is thus easily flushed. Also, very little tissue reaction occurs in tissue which is in prolonged contact with silicone rubber. Accordingly, the patient may experience considerably increased comfort when a silicone rubber drainage device is used in accordance with this invention.

If desired, organic plastic or rubber drainage devices made in accordance with this invention can be fabricated with a coating of room temperature vulcanizing silicone rubber or the like for essentially equivalent effect.

Other hydrophobic, flexible thermoplastic materials, such as polyethylene, can also be used with advantage to fabricate the devices of this invention. Other corresponding medical grade materials such as latex rubber and polyvinylchloride plastisol can also be used.

The drainage device of this invention is used to provide the drainage to a wound site or the like in a patient by inserting the tubular drainage member into the wound site in such a position that the lateral drainage ports are in flow communication with the wound site. Also, the tubular member is passed through healthy, intact tissue adjacent the wound site so that one end of the tubular member is exposed to and communicates with the exterior of the patient, and in such manner that the balloon retention member is positioned within the healthy, intact tissue adjacent the skin. Generally, either of the above steps may be performed first with equivalent effect.

After the tubular drainage member has been properly emplaced, the balloon member is inflated, to firmly retain the drainage member in the wound site, so that it is less likely to be accidentally or otherwise removed from proper emplacement by pulling on an exposed portion of the tubular member. Likewise, the pressurized balloon member provides an improved seal at and just below the skin level, which greatly reduces or eliminates bleeding and fluid leakage from the skin hole through which the tubular member passes. The balloon inflation also reduces the possibility that bacterial contamination can enter the skin hole to cause infection.

Other advantages of this invention will be readily apparent from the specific embodiment of this invention described below.

In the drawings:

FIG. 1 is a plan view of the drainage device or wound tubing of this invention, with some portions broken away for showing interior details;

FIG. 2 shows the wound tubing of this invention in an intermediate stage of placement into a large wound in a patient;

FIG. 3 shows the emplaced wound tubing of FIG. 2 after complete emplacement and suturing of the wound, said wound tubing being shown in the process of a back flushing operation to clear the lateral drainage ports within the wound site;

FIG. 4 is a plan view of a second preferred embodiment of the wound tubing of this invention.

Referring to the drawings, FIG. 1 shows a drainage member or wound tubing **10** which comprises a tubular member **11** of flexible, plastic tubing such as silicone rubber, polyethylene, or medical grade polyvinyl chloride plastisol, which is typically about two or three feet in length. The tubing has a lumen or bore **12** which may be about ⅛ inch in diameter or other diameters as required, and is open at one end **18.**

A first, intermediate portion **16** of tubing **11** defines a plurality of lateral drainage ports in the wall of tubing **11** for fluid communication between lumen **12** and the exterior of tubular member **11.** The portion **16** of the tube is preferably spaced from the ends **18, 20** thereof, by a convenient length of say at least 3 inches, and preferably about 6 to **8** inches of port-free tubing for purposes which will become apparent below.

A retention balloon **22** is positioned at one side of the drainage ports defined in first portion **16** of tubular member **11.** Balloon **22** is generally positioned so that it can be inflatable under the skin of a patient when the drainage ports lie in a wound site. Balloon **22** may be fabricated in a conventional manner by appropriately glueing or otherwise sealing an elastomeric sleeve at its ends **24** to tubing **11.** The balloon **22** may be inflated by passing saline solution, air, or the like through an inflation tube **26** which is carried along the distal portion **27** of tubing **11,** and enters at one end into communication with the interior of balloon **22.** Inflation tube **26** is preferably separate from tubing **11** at its distal end **28** and carries a clamp **30,** or sealing entrance stopper, as well known in the art, for sealing the inflation tube in order to retain the balloon in inflated condition for as long as desired. Balloon **22** is preferably made of an elastomer such as silicone rubber, or, alternatively, natural latex.

The distal portion **27** of tubing **11** also forms an enlarged lumen portion **32,** which may be used as a collapsible squeeze bulb, as well as a storage portion for retention of flushing solution (such as physiological saline, containing an antibiotic) in a position outside of the body when the wound tubing is positioned in a patient. The distal portion **20** of tubing **11** may be sealed in a conventional screw clamp **34** or the like, so that the entire lumen **12** of the wound tubing may be filled with flushing solution, including enlarged lumen portion **32,** and then the clamp **34** may be closed to seal the lumen from communication with the exterior.

FIG. 2 shows a desired technique for emplacement of the wound tubing of this invention in a wound. It should be noted that, for purposes of this invention, the term "wound" is also intended to include other areas of use of the device of this invention as mentioned above, such as abscesses and other accumulations of body fluid.

As shown in FIG. **2,** a conventional awl **36** having a threaded connector member **38,** of appropriate size, is threaded into end **18** of the wound tubing. The wound tubing can then be emplaced in an open wound **40** on the body **42** of a patient. The surgeon penetrates the skin at a point **44** spaced from wound **40,** to pass the awl through intact, healty tissue, manipulating the awl so that it enters the wound site at a point **46.** Tubing **11** can then be drawn through the punctured path **48** through the intact, healty tissue until the portion **16** of the tubing defining the drainage ports **17** lies in the wound site and balloon member **22** has entered skin opening **44.** Some surgeons may prefer to allow a portion of balloon member **22** to remain outside of skin opening **44.** Also, for best sealing, it is generally preferable for balloon member **22** to reside in essential contact with skin opening **44** and not to be significantly spaced therefrom.

Following this, section **16** of the tubing is positioned as desired by the surgeon in the wound **40,** and tubing **11** is severed at a location indicated generally at **49,** in accordance with the discretion of the surgeon, so that the awl **36** and usually most of the port-free end portion **18** of the tubing can be removed, as illustrated in FIG. **3.** Accordingly, first tubing portion **16** is positioned, without the need to handle or touch it, since manipulations of the tubing for mounting and using the awl **36** can be confined to imperforate end **18** of the tubing. Accordingly, section **16** of tubing **11** can more likely remain in aseptic condition.

As further illustrated in FIG. **3,** the wound **40** is then sutured, with drainage port-defining portion **16** of tubing **11** remaining positioned within the wound site.

At the discretion of the surgeon, when he believes the wound tubing to be satisfactorily positioned, balloon **22** can be inflated, typically by opening clamp **30** and inserting physiological saline solution, gas or air into lumen **26** by means of a conventional syringe or pump, to inflate balloon **22** to the degree desired, to provide firm anchoring of wound tubing **11** coupled with sealing of puncture site **44** in the skin.

FIG. **3** also shows how enlarged lumen portion **32** can be collapsed, generally by hand, to force flushing solution through drainage ports **17**, as well as the severed end of tubing **11** within wound site **40**, to flush the wound tubing in an aseptic manner as desired by the physician.

If the wound site is not open to the exterior, then the surgeon must use the awl to define another exit path through intact tissue in order to position the wound tubing properly. In this event, both ends of the wound tubing protrude from the patient, and can be used for drainage and flushing, but the retention and sealing of one end is still provided by balloon **22**. For such special use, a second balloon could be provided for sealing and retaining the second end of the wound tubing.

Optionally, clamp **34** can be opened to replace the flushing solution, or to subject the wound site with an alternating suction-irrigation treatment with antibiotics and other medicinals, for bathing the wound continuously with therapeutic agents.

FIG. **4** shows an alternative embodiment of the wound tubing of this invention, which comprises a similar tubular drainage member **11***a* which defines a plurality of drainage ports **17***a* defined through a first portion **16***a* of the tubular member which is spaced from the ends thereof in a manner similar to the embodiment of FIG. **1**. A similar balloon sleeve **22***a* is also provided, and an inflation lumen **26***a* as well as a clamp **30***a* for use in similar manner.

It will be noted that, in this embodiment, a tubular portion **50**, which is separate from tubing **11***a* is provided. Tubular portion **50** has an enlarged collapsible lumen portion **52**, and a connector means **54** for connection in aseptic, leak-proof manner with an end of tubing **11***a* when desired. Connector **54** may be a hollow tubular member with threads on the outside, proportioned to screw into the lumen of tube **11***a* for connection therewith. Connector **54** may also be a simple nipple or luer to fit into the lumen or bore of tubing **11***a*.

An advantage of the embodiment of FIG. **4** is that it may be either emplaced in a wound **40** in the manner described in FIGS. **2** and **3**, or may be emplaced in the wound in reverse manner. An awl may be emplaced in the bore of the opposite end **56** of tube **11***a*, when compared with the emplacement of the awl as shown in FIG. **3**, so that the awl may enter the intact, healty tissue at point **46** and pass through the tissue until it exits at point **44**, should the surgeon find it desirable to do so. Of course, clamp **30***a* must be temporarily removed for this operation, and the free portion of inflation port **26***a* should be secured completely to tube **11***a* and optionally tied flat for passage through the intact tissue. Tubing **11***a* can then be positioned in a manner comparable to that shown in FIGS. **2** and **3**, and the awl may be removed. Then, tubular portion **50** may, if desired, be aseptically connected to opposite end **56**, and the wound tubing arrangement used in the manner previously described.

If desired, tubing **11** or **11***a* may be connected at its respective end **20**, **56** to a parenteral solution container which is hung above the arrangement, to provide a supply of pressurized flushing solution as desired. Clamp **34**, **34***a* can be used to control the access of such solution to the tubing **11**, **11***a*.

When it is determined that the wound tubing should be removed, clamp **30**, **30***a* can be released, causing balloon **22**, **22***a* to deflate. Tubing **11**, **11***a* can then simply be withdrawn through skin hole **44** without opening of the stitches of wound **40**.

While in the preferred use of the invention, the balloon **22** is positioned to be inflatable in the patient's flesh under the skin, if the doctor feels that it is desirable or advisable, the balloon may also be located anywhere along the length of the puncture path **48** made by the awl, or even within the wound itself, and be inflated therein.

It is contemplated that two (or more) of the drainage devices of this invention may be simultaneously emplaced in a wound site. Accordingly, one of the drainage devices may be used as a flushing fluid inlet, while the other drainage device serves as an outlet for the fluid and other drainage.

The above disclosure has been provided for illustrative purposes only, and is not to be viewed as limiting the invention, which is described in the claims below.

That which is claimed is:

1. In a drainage device for wounds and the like, said device comprising an elongated tubular drainage member having a central lumen, and a plurality of drainage ports defined along a first portion of the length of said tubular member and through said tubular member for fluid communication between said lumen and the exterior of said tubular member, the improvement comprising, in combination, an elastomeric retention balloon carried by a second portion of said tubular member located on one side of one end of the first portion, and adapted to be inflatable under the skin of a patient when said first portion is properly positioned in a wound, said tubular member also carrying means for inflating and deflating said retention balloon, a length of severable, imperforate tubing extending from the end of said first portion and having a terminus adapted for screw connection to an awl, said imperforate length of tubing permitting selective connection to an awl without contamination of the drainage ports in said first portion, an enlarged-lumen portion in communication through the central lumen with the drainage ports and for use as a combination squeeze pump and storage portion for retention of a flushing solution therein, and means for selectively sealing said enlarged-lumen portion so that squeezing said squeeze pump operates to back flush solution through the drainage ports.

2. The drainage device of claim **1** in which said drainage ports are smaller in aperture size than the diameter of said central lumen of the tubular drainage member.

3. The drainage device of claim **2** in which said tubular drainage member and balloon member are made of silicone rubber.

4. In a drainage device for wounds and the like, said device comprising a tubular drainage member having a central lumen, and a plurality of drainage ports defined along a first portion of said tubular member and through said tubular member for fluid communication between said lumen and the exterior of said drainage member, the improvement comprising, in combination,

an elastomeric, retention balloon member carried by a second portion of said tubular member, and positioned to be inflatable under the skin of a patient when said drainage ports lie in a wound, said tubular member also carrying means for inflating and deflating said retention balloon, said retention balloon being located at one side of said first portion, said tubular member also defining, at a location along said tubular member on said one side of the first portion and spaced farther from said first portion than said retention balloon, an enlarged-lumen portion for use as a collapsible squeeze bulb and storage portion for retention of flushing solution exterior of the body when said drainage device is positioned in a patient, and means for selectively sealing said enlarged-lumen portion from communication with the exterior, whereby said enlarged-lumen portion can be manipulated for aseptic back-flushing of the drainage device.

5. The drainage device of claim **4** in which said drainage ports are smaller in aperture size than the diameter of said central lumen of the tubular drainage member.

6. The drainage device of claim **5** in which said first portion of the tubular member is spaced from the ends of the tubular member by at least about six inches of port-free tubing.

7. The drainage device of claim **6** in which said tubular drainage member and balloon member are made of silicone rubber.

8. The drainage device of claim **6** in which clamping means are provided for sealing the lumen of said tubular drainage member from communication with the exterior.

9. The method of providing drainage from a wound site or the like in a patient which comprises:

inserting a tubular drainage member, having a plurality of lateral drainage ports defined along a first portion of said tubular drainage member, into the wound site in a position such that said drainage ports are in flow communication with said wound site, while also

passing a second portion of said tubular member through intact, healthy tissue so that one end of said tubular member communicates with the exterior,

positioning a balloon retention member carried by said second portion of the tubular member within the intact, healthy tissue adjacent the patient's skin at the same time that the tubular drainage member is being positioned in the wound site; and

inflating the balloon member, to firmly retain the tubular member in the wound site, and to seal the area between said tubular member and said intact, healthy tissue.

10. The method of claim **9** in which, after positioning of the tubular member and inflation of the balloon member, the lumen of said tubular member is filled with a physiological flushing solution and sealed from communication with the exterior, and thereafter a flexible, enlarged lumen portion of said tubular member, defined on a portion of the tubular member exterior of said patient, is manipulated to back-force flushing solution out of the tubular member through said drainage ports, to clear the drainage ports and to flush the wound site.

* * * * *