United States Patent

Reynolds et al.

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[54] **ASEPTIC DISPOSABLE DRAINAGE RECEIVER**

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[52] **U.S. Cl.** **128/277,** 141/61

[51] **Int. Cl.** **A61m 1/00**

[58] **Field of Search** 128/275, 276–278; 141/59, 61

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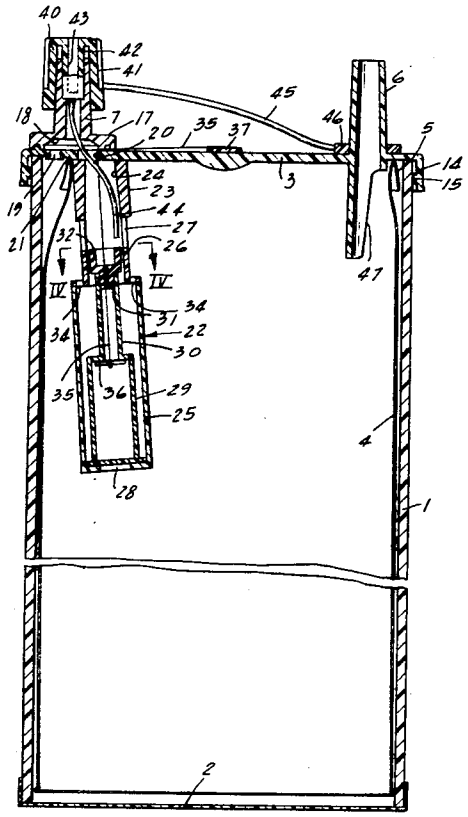
[57] **ABSTRACT**

An aseptic disposable drainage receiver for receiving drainage from the body of a patient after wounding of or surgery performed on the patient. The receiver includes a canister cover from which a flexible canister liner depends, means carried by said cover for connecting the canister and liner to a vacuum or suction system and the liner to a tube from the patient, and means to completely seal such connections to the liner, whereby the liner and cover as a unit with its contents may be aseptically disposed of after a single usage.

12 Claims, 7 Drawing Figures



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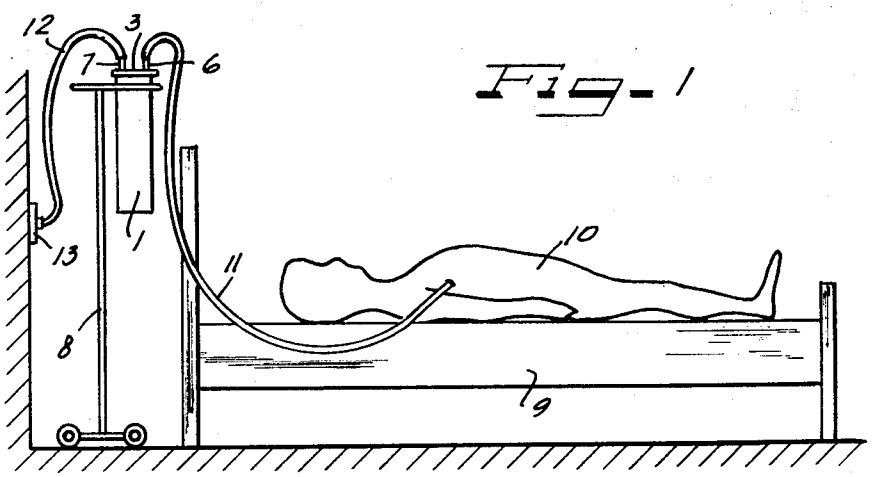

Fig-1

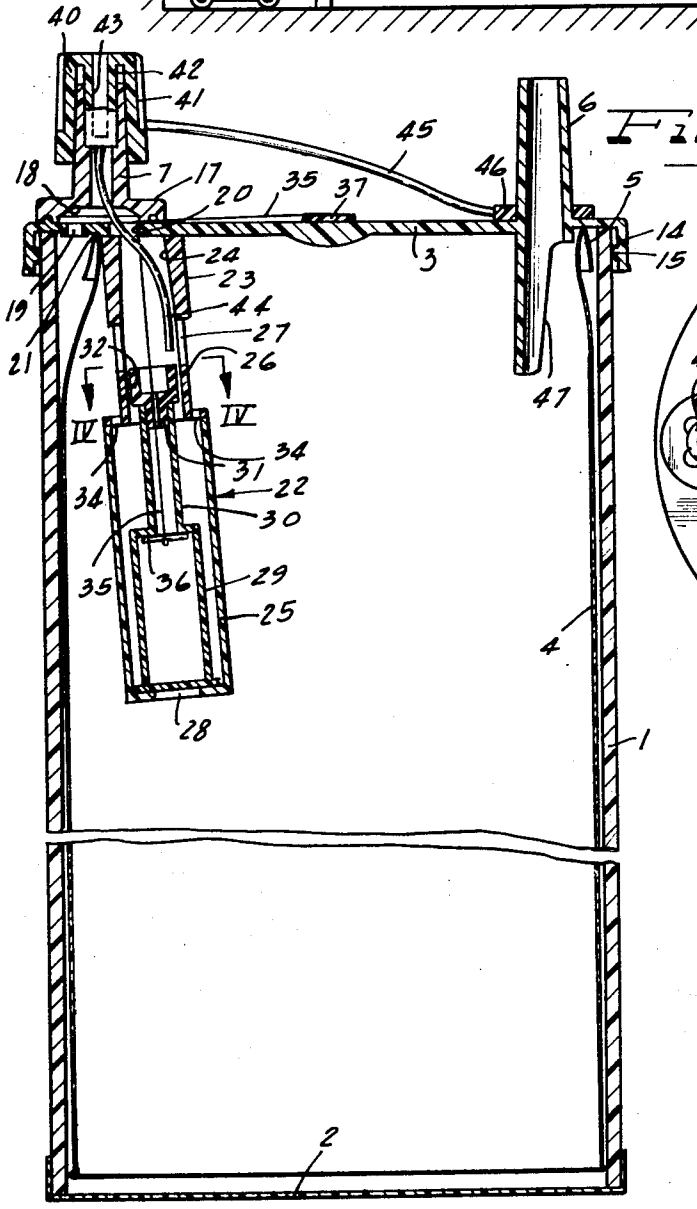

Fig-2

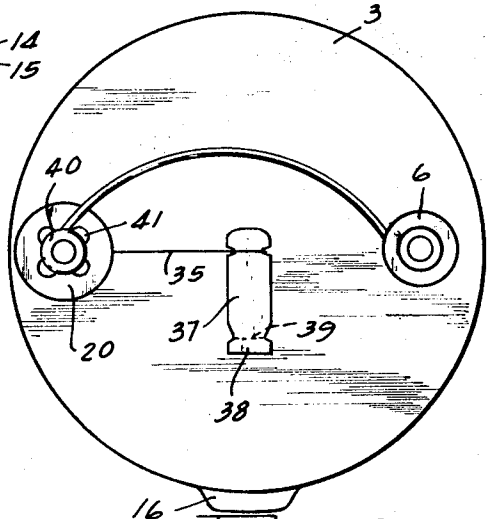

Fig-3

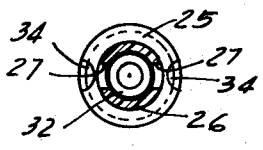

Fig-4

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Fig-5

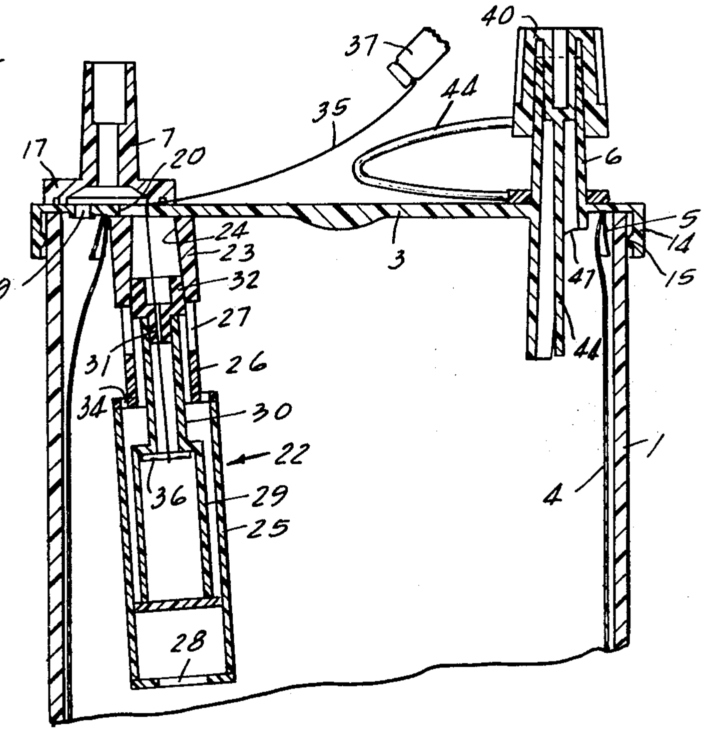


Fig-6

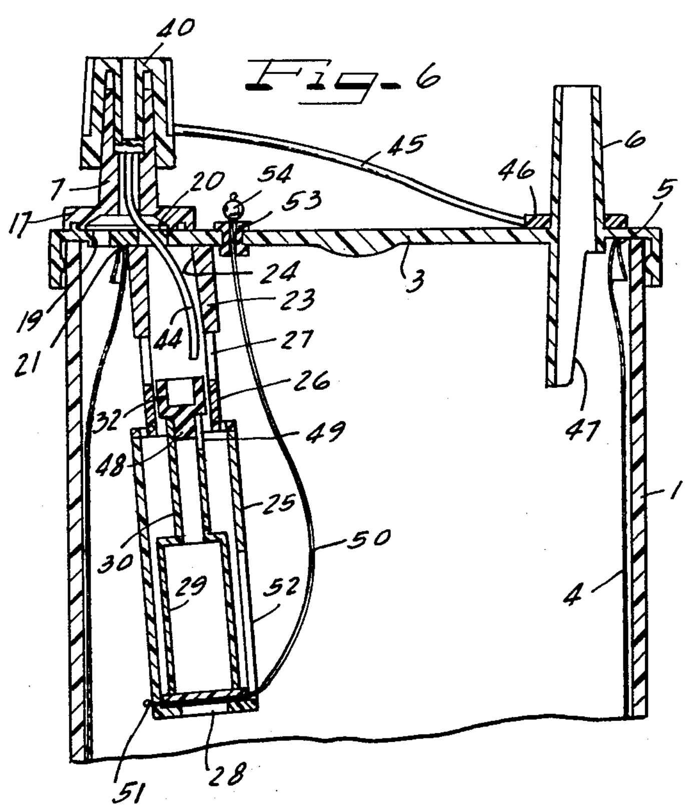
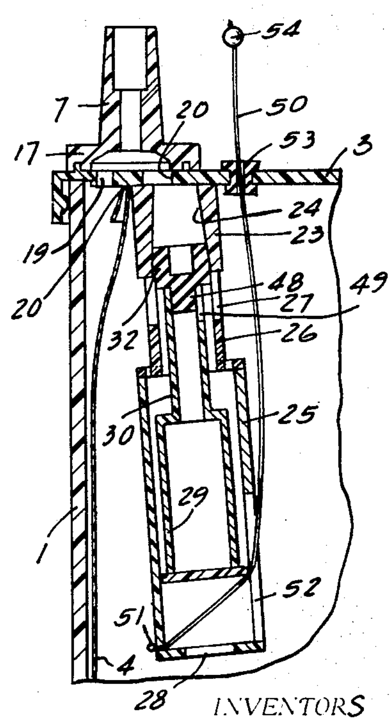


Fig-7



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ASEPTIC DISPOSABLE DRAINAGE RECEIVER

RELATION APPLICATION

The invention set forth, described and claimed in the instant application is an improvement upon the invention set forth, described and claimed in our copending application entitled "Vacuum Drainage Collecting Apparatus With Disposable Liner," filed Nov. 26, 1968, Ser. No. 778,963.

SUMMARY OF THE INVENTION

The instant invention or discovery relates to a drainage collecting unit in the form of a flexible liner for disposition in a canister, such liner being attached to the underside of a canister cover and both the cover and liner are disposable as a unit after a single usage. Economy of production, therefore, is a necessary factor to warrant such disposition. The canister, of course, is repeatedly used and may be so repeatedly used without sterilization because it does not become contaminated.

In the past, a number of attempts have been made to provide a disposable drainage receiver or a disposable canister liner for receiving drainage. In one instance, a cheaper form of container in the nature of the glass bottle with its various fittings as has been used in hospitals for many years resulted in being too costly to warrant its disposition and its bulk also required storage room both before and after disposition to a material amount. In other instances, flexible plastic canister liners were provided but in each instance of which we are aware, those liners, including that of our aforesaid copending application, were designed to be emptied before disposition of the liner. Bearing in mind that the contents of the liner drained from the body of a patient may be highly infectious and in some instances contagious, emptying of such a liner in a drainage sink is in many cases not desired, because infection, contamination, or contagion may result in a location remotely from the hospital, and in emptying such a device there is always some little risk to the operator should he be somewhat careless.

An object of the instant invention is to provide a liner or receiver for infectious or contagious drainage from the body of a patient that may be aseptically sealed prior to removal from the canister and then the liner may safely be discarded along with its contents.

Other features and advantages of the instant invention include the provision of means for firmly closing the inlet port between the liner and the tube leading to the patient's body airtightly and pressuretightly to a more than necessary extent. A valve is also provided to effectively close the port between the suction line and the interior of the liner. This valve may be actuated by hand when desired. The same valve is also automatically actuated by force from the suction line when the liner is filled to a predetermined extent. The valve is not designed to be reopened after once having been closed; and means are provided to prevent accidental closing of that valve during rough handling in transit. Further, a form of float valve is preferably utilized and the pressure within the the float valve body is countervailed with the pressure inside the liner, and the latter pressure is also countervailed with the pressure inside the canister outside the liner so that all the vacua of these separate parts are equal.

Other objects, features and advantages of this invention will be readily apparent from the following description of preferred embodiments thereof, taken in conjunction with the accompanying drawings, although variations and modifications may be effected without departing from the spirit and scope of the novel concepts of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic showing of the manner in which the drainage collection unit is used in association with a patient and a vacuum system;

FIG. 2 is an enlarged fragmentary vertical sectional view of the disposable collection unit in association with the canister prior to being put to use;

FIG. 3 is a reduced top plan view of the structure of FIG. 2;

FIG. 4 is a plan sectional view taken substantially as indicated by the line IV—IV of FIG. 2, looking in the direction of the arrow;

FIG. 5 is a fragmentary vertical sectional view of the same structure seen in FIG. 2 but showing the same after usage in sealed aseptic condition;

FIG. 6 is a fragmentary vertical sectional view of a modified form of the structure, showing the same prior to use; and

FIG. 7 is a fragmentary vertical sectional view showing the structure of FIG. 6 after usage.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Both illustrated embodiments of the instant invention are utilized with a canister **1** which may be made of relatively rigid plastic material and which is open at the top, and closed at the bottom as indicated at **2**. This canister is designed for long and repeated usage and may be repeatedly used without sterilization since it does not receive any drainage from the patient's body.

The first illustrated embodiment of this invention is shown in detail in FIGS.**2**, **3**, **4** and **5** of the drawings, and comprises a canister cover **3** from which a flexible thermoplastic liner depends. The liner is closed at the bottom, and the upper open end of the liner may be folded over as indicated at **5** or otherwise folded and is fused or equivalently secured to the inside of the cover in a completely airtight and positive manner. The cover is preferably a rigid plastic material compatible with that from which the liner or receiver **4** is formed. The cover is provided with a fitting **6** defining a port of entry into the liner for drainage from the body of a patient, and also with a fitting **7** for connection to a suction line or source of vacuum.

Referring now to FIG. **1**, the canister **1** may be supported on any suitable stand **8** or otherwise held in a convenient position adjacent a bed **9** upon which a patient **10** lies. The fitting **6** of the canister cover **3** is connected by way of a tube **11** to the body of a patient, while the fitting **7** is connected by way of a tube **12** to a suitable source of suction **13**. In the illustrated instance, the tube **11** enters the thoracic cavity of the patient which would be indicated by a chest wound, breast removal, lung surgery, and other chest injuries or operations. When suction is applied through the tube **12**,it will draw drainage from the patient through the tube **11** into the liner **4**, such drainage being blood,

pus, excess liquid, and various exudates, and such drainage is frequently highly infectious and sometimes contagious. The structure by which such drainage will be confined entirely to the inside of the liner **4** will now be described.

The canister cover **3** may satisfactorily have a skirt **14** with a bead **15** or other formation on the inside thereof so that it can be snapped on to the canister in an airtight manner. A tab **16** integral with the skirt may be added to facilitate removal of the cover. Also, a bail (not shown) may be connected to the cover in any suitable or known manner.

With reference more particularly to FIG. **2**, it will be noted that the fitting **7** has an enlarged base **17** thereon which is attached to the cover **3**, and that base is provided in its underside with an enlarged opening **18** which communicates with the passage through the fitting **7** and also overlies a pair of spaced apertures **19** and **20** through the cover **3**. It will be noted that the liner **4** is deviated in the region of the base **17** and secured tightly to the solid portion of the cover **3** between the two apertures as indicated at **21** so that the aperture or port **19** communicates with the interior of the canister outside the liner, while the port **20** communicates only with the inside of the liner. Thus, the vacuum acts both inside the canister but outside the liner and inside the liner so that the vacua therein are equalized or countervailed. If the vacuum were only applied to the inside of the canister but outside the liner, the liner would expand but there would be no constant and proper suction to draw drainage from the body of the patient. On the other hand, if vacuum were only applied to the inside of the liner alone, the liner would tend to collapse and not expand properly owing to the air pressure within the canister itself. Consequently, for a desirably satisfactory performance the vacua should be equalized, in which event there is constant and proper suction from the body of the patient, and the liner remains in fully expanded position.

Beneath the port **20** to the liner are closure means to seal off the port **20**. In the illustrated instance the closure means are in the form of a valve assembly generally indicated by numeral **22**. This valve assembly includes a tubular valve seat depending from the inner side of the cover **3** and having a tapering bore **24** therethrough which gradually decreases in size toward the cover and the opening **20** therein. A float housing **25** is provided which is affixed to the hollow valve seat **23** by means of a neck portion **26** of reduced diameter secured at its upper end to the valve seat. The neck of the float housing is provided with diametrally opposed slots **27—27** to establish communication between the interior of the liner and the suction port **20**. It will be noted also that the float housing **25** has a bottom opening **28** therein. Inside the housing **25** is a hollow float **29** having an upstanding hollow neck **30** in which the hollow stem **31** of a hollow-head valve **32** is inserted. The valve and stem are made of a resilient and compressible material such as rubber or synthetic rubber. The housing **25** acts as a guide for the float **29** and the stem **26** of the housing acts as a guide for the valve itself. The float, of course, will rise within the housing **25** provided the drainage in the container reaches a level for it to enter through the opening **28** and buoy up the float. In order to prevent any hinderance of the movement of the float by virtue of a quantity of air being entrapped in the upper end of the housing **25**, the top of the housing is provided with diametrally opposed apertures **34—34**.

The construction just above described has a distinct and definite advantage in that the valve and its stem being hollow and having a passage therethrough eliminates any pressure differential between the interior of the float and inside the liner **4**, the pressure inside the float being countervailed or equalized with the pressure inside the liner. Thus, there can be no injury to or explosion of the float regardless of the liquid depth in the liner and regardless of any sudden variation in the amount of vacuum in the liner.

The valve assembly **22**, with the exception of the valve itself, is preferably fabricated from pieces of thermoplastic material and the parts are fused, welded, or equivalently secured together, as are the various other parts of the structure of the disposable unit.

While the valve is automatically closed when the drainage within the liner **4** reaches a predetermined level and raises the float **29**, it is also important that the valve can be manually closed in case it is desired to remove and discard the disposable unit before the drainage reaches a sufficient level to close the valve. To this end, means are provided to manually close the valve whenever desired. While means embodying mechanical linkages of various types might be utilized for this purpose, it will be noted that the entire valve assembly is disposed at an angle to the side wall of the canister of approximately 5° to accommodate flexing of the cover **3** under extreme vacuum in the liner and canister. Should the cover so flex, such a mechanical linkage may not remain positive in its operation. With that in mind, we have provided simple means for manually actuating the valve. These means comprise a thin pull cord **35**, which may satisfactorily be a fine nylon thread which possesses more than ample strength for the purpose. This thread is secured at one end to a cross bar **36** within the body of the float **29**, and the cord extends upwardly through the valve and the port **20** and turns laterally beneath the base **17** of the fitting **7**, and the other end of the cord is tied around the free end of a flip-tab **37**, FIG. **3**, which is secured to the external face of the cover only at the opposite end portion **38** to one side of a line of weakness **39**. THe flip-tab may be easily actuated by the fingers of an operator and bent through 180° along the line of weakness or broken off at that line, and the movement of the flip-tab through 180° is normally sufficient to forcibly close the valve, although in most instances an extra pull on the cord for insurance will be made.

Once the valve is closed and in the position seen in FIG. **5**, firmly seated in the valve seat **23**, it cannot be reopened. Therefore, means are provided to prevent the valve becoming accidentally closed such as by inverting the disposable unit prior to usage, rough handling during shipment of the units, or otherwise. To this end, a cap **40**, fluted as indicated at **41** to establish a firm grip thereon, is disposed over the fitting **7**. This cap has an annular recess **42** therein to space a center portion **43** away from the outer portion of the cap so that the cap will engage both the external and internal surfaces of the tubular fitting **7**. The engagement is firm and airtight by virtue of the fitting **7** having opposite

tapers on the inside and outside thereof, the cross-sectional area of the fitting decreasing externally upwardly and internally downwardly. To the closed end of the inner portion **43** of the cap one end of a stylet **44** is secured, the stylet extending downwardly through the fitting **7**, the port **20** and through the valve seat **23** to terminate adjacent the upper end of the valve **32**. While this stylet is flexible, it nevertheless is sufficiently rigid or stiff to prevent the valve from closing in the seat **23** as long as the cap **40** remains in position on the fitting **7**. A tie cord **45** is secured at one end to the cap **40** and at the other end to a collar **46** disposed around the fitting **6** so that the cap cannot be misplaced when removed from the fitting **7** at the time the unit is put into operation.

The fitting **6** has the same opposite external and internal tapers as the fitting **7**, and the cap may be pressed over the fitting **6** at the conclusion of operation in a leak-proof engagement, and the cap requires considerably more strength to dislodge than to place it in position. On the inside of the cover the fitting **6** is substantially half cut away as indicated at **47** leaving a half tube with the convexity thereof facing the valve assembly. This shaping performs two functions, namely, directs incoming patient drainage downwardly and does not permit it to cross directly toward the valve; and it also prevents siphoning if for any reason the drainage fluid rises to the lower end of the fitting.

In operation, the use of the disposable unit is extremely simple, Originally the disposable unit is packaged in collapsed style and so little storage space is needed for a quantity of the units. Each unit is wrapped in a sterile wrapper and when put to use it is simply necessary to insert the liner **4** inside the canister, press the cover **3** in airtight engagement with the canister, remove the cap **40** and connect the fitting **7** to a source of suction, and connect the fitting **6** to the patient's body. When suction is then turned on, drainage immediately begins and the vacua inside the canister and outside the liner, and inside the liner and inside the float are all countervailed or equalized. It is important to note that when the drainage collects in the liner to a point where it starts elevating the float, moving the valve toward closed position, buoyancy of the float alone is not relied upon to seat the valve. When the valve rises where it is partially between the notches **27—27** in the neck **26** of the float housing, the valve is directly in the air stream caused by suction through the port **20** and this suction then closes the valve with much more force than buoyancy alone can provide and the valve will not thereafter become dislodged.

If operation is manually stopped before the level of drainage reaches the float, this is simply accomplished by snapping the flip-tab **37** and pulling the cord **35** using as much force as desired. Of course, if the pull cord **35** is used to raise the valve while the vacuum is still applied the vacuum, in the manner above described, would aid in seating the valve, but such aid is not necessary since adequate seating can be obtained by pulling on the pull cord.

After the valve is closed in either manner, the vacuum tube **12** may be disconnected from the fitting **7**, the patient tube **11** disconnected from the fitting **6**, and the cap **40** pressed into position over the fitting **6**. The disposable unit then is completely sealed aseptically and may be disposed of along with its contents without fear of leakage, and nothing is left to be sterilized before a new unit is placed back in the canister.

The modification shown in FIGS. **6** and **7** operate substantially the same as that previously described and is equally as efficient. In this instance, however, the valve **32** has a solid stem **48** seated in the neck **30** of the float. It is therefore necessary to provide a slot **49** in the float neck which is longer than the valve stem so that the vacuum in the float may be countervailed or equalized to the vacuum in the liner **4**. A pull cord **50** is provided to manually close the valve, one end of the cord being tied at **51** to the outside of the float housing immediately above the bottom thereof and the cord extends transversely through the housing underneath the float exiting from the housing through an elongated slot **52** and then extending upwardly through a self-sealing plug **53** in the cover **3** and terminates exteriorly of the cover in a knob **54** by which the cord may readily be grasped. With this form of the invention, it is merely necessary to grasp the knob **54** and pull up on the cord **50** from the position seen in FIG. **6** to that seen in FIG. **7** in order to manually seat the valve. Once the valve is seated, the connections to the patient and the suction line removed from the fittings **6** and **7**, and the cap **40** place over the fitting **6**, the disposable unit including its contents is ready for discarding.

We claim as our invention:

1. A body drainage receiving assembly including an open-top canister, an aseptic disposable unit for receiving body exudates comprising a cover for said canister, a canister liner depending from said cover, and tubular fittings carried by said cover for connecting the interior of the liner to a tube leading from the body of a patient and to connect the interior of said canister outside said liner and the interior of the liner in communication with a suction system, wherein the improvements comprise

valve means in said liner to positively seal off the communication between the interior of the liner and suction line fitting,

said valve means being of the type that once closed will remain closed, and

a cap for disposition over the patient tube fitting to aseptically seal the liner and its contents after use of the liner.

2. The receiving assembly of claim **1**, wherein said cap is initially engaged over the suction line fitting until the liner is put to use, and including a cord connecting the cap to the patient tube fitting to prevent misplacement of the cap during use of the liner.

3. The receiving assembly of claim **2**, wherein said cap has an annular recess therein spacing a central portion away from the outer portion, and each of said fittings having opposite internal and external tapers to insure a tight fit with the cap.

4. The receiving assembly of claim **1**, including manually operable pull means associated with said valve means and extending through said cover for manual closing of the valve means whenever desired.

5. The receiving assembly of claim **4**, including a flip tab secured at one end to the outside of said cover, and the outer end of said pull means being attached to the other end of said flip tab.

6. The receiving assembly of claim 4, including a self-sealing plug in said cover through which said pull means extend, and

an element to be grasped by the fingers of an operator attached to said pull means outside of said cover.

7. The receiving assembly of claim 1, including a tubular valve seat depending from said cover in said liner around the opening to the suction system,

said seat decreasing internally in area toward the cover, and

said valve means comprising a resilient valve recessed to compress and jam in said seat when closed.

8. The receiving assembly of claim 7, including

a float housing having a hollow neck secured to said valve seat,

a hollow float in said housing having a hollow neck carrying said valve,

said float having an opening at the top of its neck, and

the neck of said housing having an opening therein to open the vacuum line to the interior of the liner.

9. The receiving assembly of claim 8, wherein said housing has an opening in the bottom and an opening in the top outside the neck of the housing to prevent any trapped air from interfering with the free action of the float and valve carried thereby.

10. The receiving assembly of claim 1, including a float carrying said valve means and positioned to move the same into the path of suction in the liner upon drainage filling the liner to a predetermined extent, whereby the valve means are forcibly closed by the suction.

11. The receiving assembly of claim 1, wherein said cap is initially disposed over the suction line fitting, and including a stylet depending from the cap through the suction line fitting to a point adjacent said valve means to prevent accidental closing of the same during shipment and handling of the unit.

12. The receiving assembly of claim 1, including

a float having a hollow body,

a tubular neck extending upwardly from said body and carrying said valve means, and

said neck having an opening at the top thereof so the vacua in the float and in the liner outside the float are countervailed.

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