

[54] **SYSTEM FOR EVACUATING FLUIDS FROM THE BODY**

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

[58] Field of Search..... **128/276, 278, 297; 222/210, 213; 417/472; 141/25; 16/110**

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Primary Examiner—Richard A. Gaudet

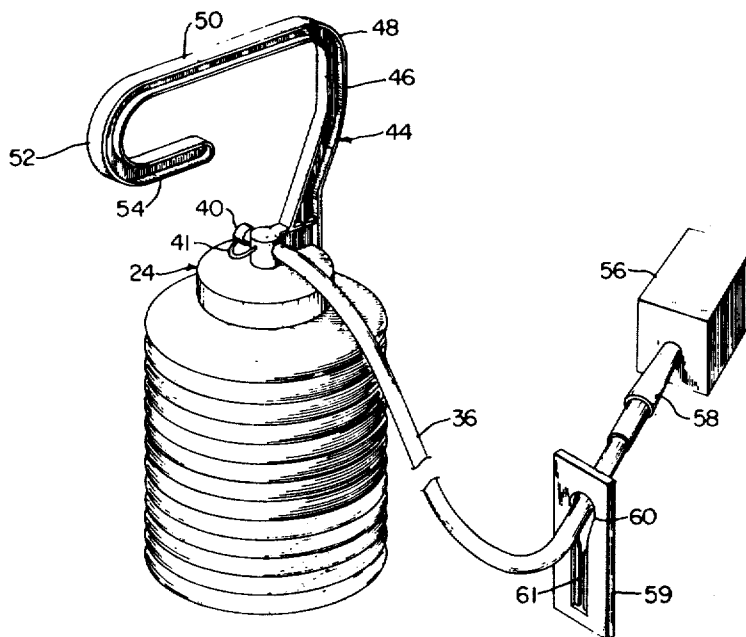
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[57] **ABSTRACT**

An evacuation system for removing fluids from the body including a bellows-type bottle or container made of resilient elastomeric material for receiving the fluid connected to a body drainage device, the bottle provided with a handle constructed to maintain it in vertical orientation while being carried or suspended, the bottle adapted to be vertically suspended by the handle while in use and to expand under the weight of fluid beyond its normal nester or rest condition to create vacuum so that fluid is forced into the bottle under the force of initial vacuum created by the bottle expanding to its normal rest position and thereafter by the combined force of gravity on the fluid and the vacuum created by further expansion of the bottle from the weight of fluid in the container as it fills.

17 Claims, 5 Drawing Figures



SHEET 1 OF 2

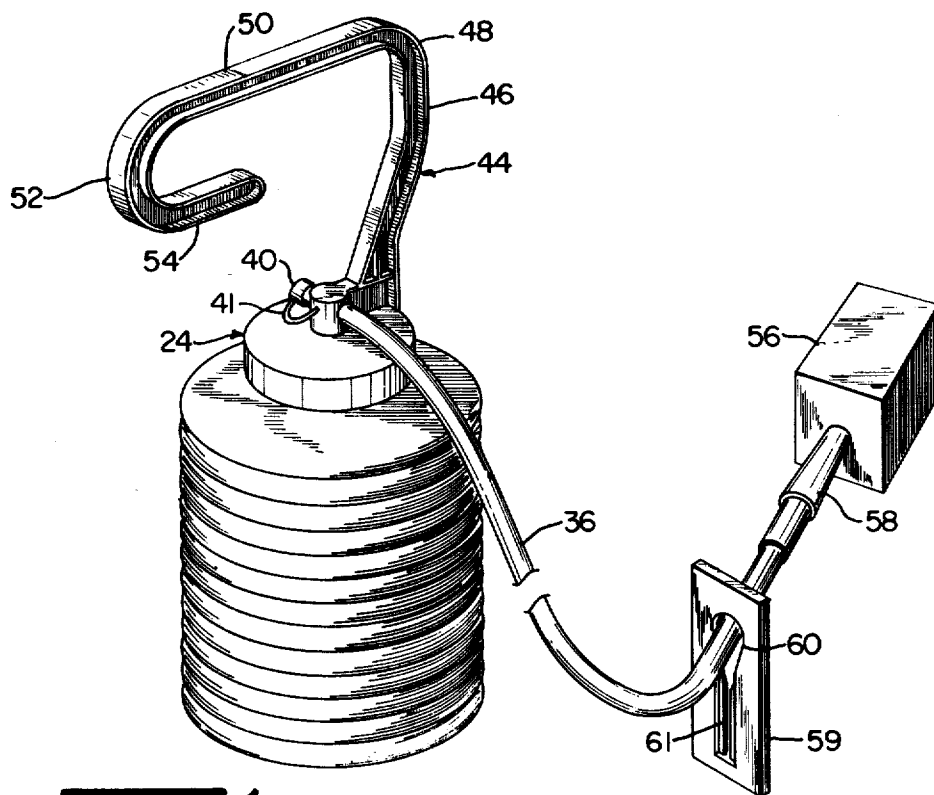


FIG. 1

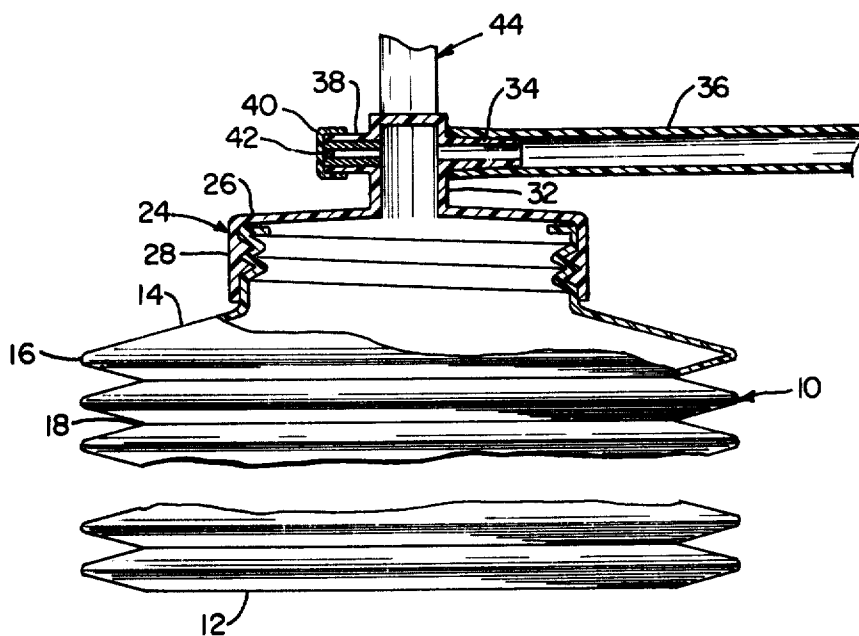


FIG. 2

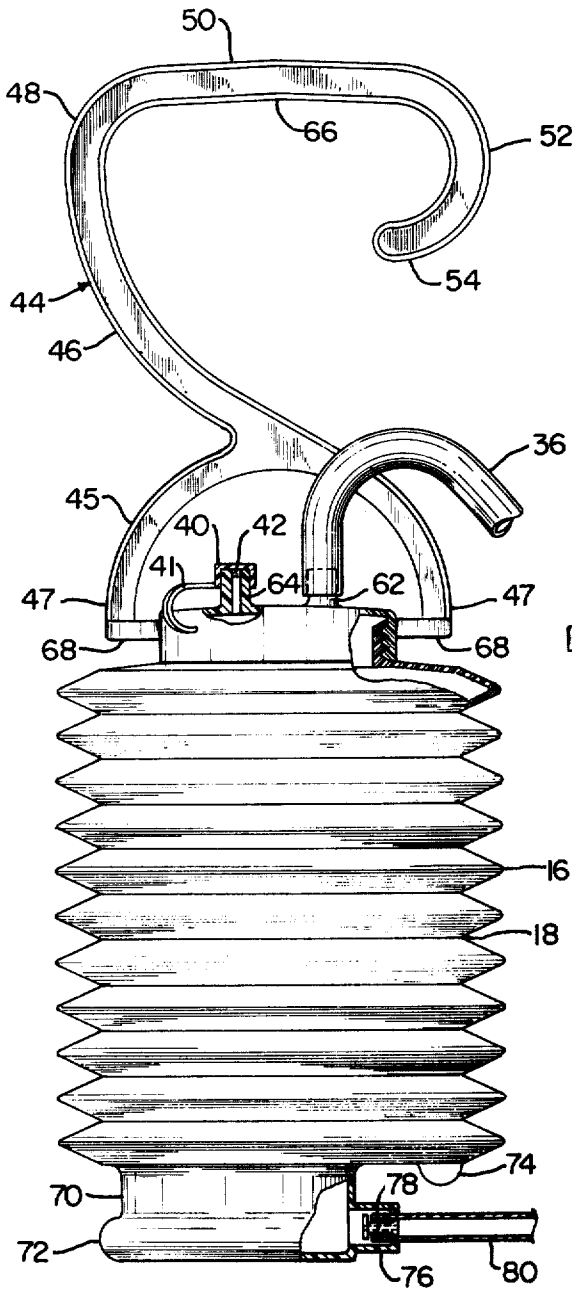


Fig. 3

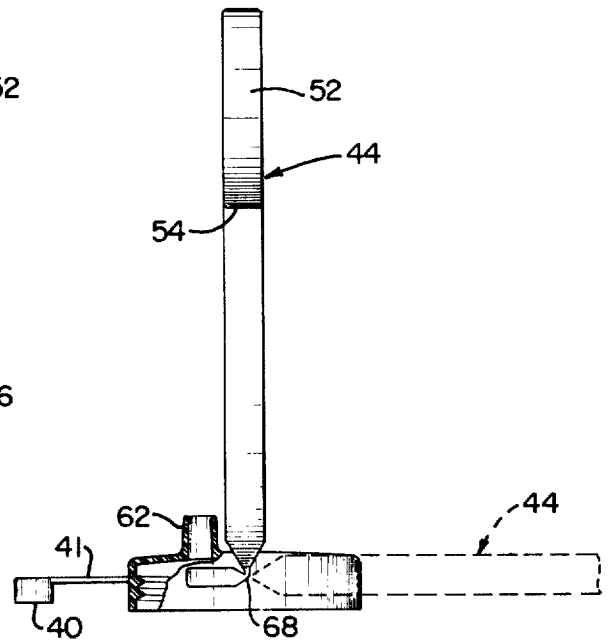


Fig. 4

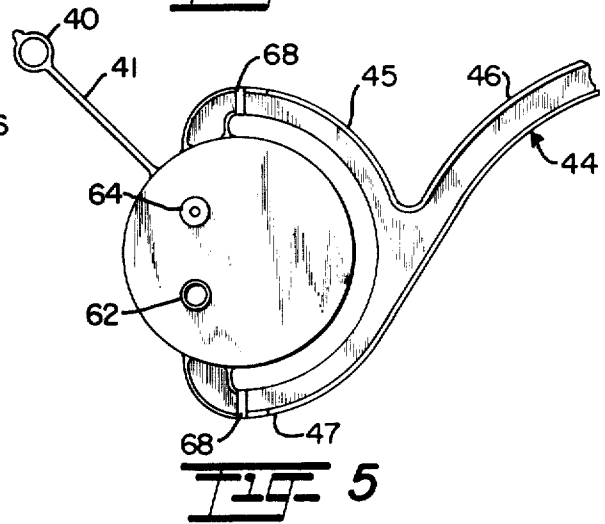


Fig. 5

SYSTEM FOR EVACUATING FLUIDS FROM THE BODY

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention lies in the field of drainage systems utilizing vacuum bottles for draining fluids from body cavities.

2. Description of the Prior Art

Patents which relate to the use of bellows pump-type containers for evacuating fluids from the body are as follows: U.S. Pat. Nos. 3,084,691; 3,115,138; 3,376,868; 3,421,504; 3,690,315; 3,752,158; 3,742,952; 3,774,611 and 3,779,243.

The bellows-type containers disclosed in all of these patents are constructed for manual operation to produce vacuum, and to be supported on a surface during operation. None of them are adapted to be suspended during prolonged use with vacuum being created from expansion of the bellows by the weight of fluid being discharged therein.

Any carrying or suspending handle provided for the bellows-type containers of these prior art patents does not rigidly support them with the vertical axis of the device in a vertical plane. Further, no suspension devices for the bellows-type bottles are provided for fitting securely over the various places where such bottles are ordinarily suspended and for satisfactory carrying by an ambulatory patient so that there is no relative movement between the handle and the container. Accordingly, it is comparatively easy for spillage of the contents to occur by tipping of the container or otherwise while the bellows-type bottles of the prior art are being carried or suspended by their suspension means.

Vacuum drainage systems are often used for draining a body cavity wherein there is a slow accumulation of body fluids to be drained over a long period of time. Accordingly, it is important to be able to secure the vacuum bottle in a substantially vertical position while in use for long periods of time. Further, it is important to maintain the body cavity being drained under vacuum for significant periods while body fluids are accumulating in the cavity which must be drained. This is important because the continuous vacuum insures that the cavity will be drained in the minimum time after accumulation of fluid and it prevents voiding around the catheter or other body drainage device. In addition, it is important to be able to create vacuum in the body cavity by means other than the normal expansion of the bellows bottle from its compressed condition and by means other than manual operation of the bellows bottle.

It is of further importance that the vacuum bottle be provided with a handle which can be readily attached to bedside rails, chairs, wheelchairs, and other hospital equipment with the bottle being maintained in vertical orientation at all times to prevent spillage. The handle should permit easy carrying by an ambulatory patient with the bottle being maintained in a substantially vertical orientation.

Accordingly, it is an object of this invention to provide a system for evacuating fluids from the body into a bellows container for which a handle is provided which is easily attached to hospital equipment and carried by an ambulatory patient with practically no relative movement between the bottle and the handle and the bottle being supported in a substantially vertical po-

sition at all times. A further object of the invention is a provision of a body evacuating system utilizing a bellows-type container for removal and storage of body fluids which can be used to create vacuum in the body cavity over an extended period from expansion of the bottle due to the weight of fluids being discharged therein.

SUMMARY OF THE INVENTION

The invention is a system for evacuating fluids from the body including the combination of a body cavity drainage device such as a catheter and a bellows-type bottle made of resilient elastomeric material, the bellows sidewall designed to have a normal rest position of the folds between the fullest compressed condition of the folds and the fully expanded position of the folds so that in use it can be compressed to its fully compressed position and allowed to expand to its normal rest position to create vacuum to start a drainage operation, and expanded on vertical suspension to its fully expanded condition by the weight of fluids discharged therein to provide further vacuum to maintain the cavity being drained under continuous vacuum for an extended period of time. The invention includes a rigid handle attached to the top of the bottle to prevent relative movement between the handle and the bottle and designed to fit over most places where such a vacuum bottle is ordinarily hung and maintained in a substantially vertical position, and to be easily carried by an ambulatory patient without spillage.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of the evacuating system of the invention showing the bellows bottle in its normal rest position;

FIG. 2 is a side elevational view in partial cross section of the bellows bottle assembly of the system with the bellows bottle in substantially fully expanded position;

FIG. 3 is a side elevational view partially in cross section of a modification of the bellows bottle assembly;

FIG. 4 is a front view of the handle showing the cap to which it is attached in partial cross section; and

FIG. 5 is a top plan view of the cap and handle assembly for the bellows bottle.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The numeral 10 indicates the bellows-type bottle comprised of bottom portion 12, top portion 14, and the accorian-like folds consisting of ridges 16 and valleys 18. The construction of this feature of the bellows bottle is well known to the art. The bottle is made of transparent or translucent resilient elastomeric material, such as, polyethylene or polypropylene plastic. The walls of the bottle or container are constructed of such a thickness and the elastic memory of the plastic is such that in its normal rest position the bottle is only partially expanded as shown in FIG. 1. In this particular application, the bottle in its normal rest position is expanded only about one-third of its fully expanded position. It will be apparent that if the bottle is suspended with its bottom free to travel outwardly or downwardly during expansion, sufficient weight of fluid inside the bottle will expand it to its fully expanded position.

The top 14 of the bottle is extended to form reduced diameter neck portion 20 provided with external

threads 22. Cap 24 for the bellows bottle is constructed with depending rim 28 provided with internal threads 30 which mate with external threads 22 for threaded attachment of the cap to the bottle.

The cap 24 is extended upwardly to form hollow neck 32 provided with nipple 24 communicating with the interior of neck 32 and adapted to receive over its exterior by press fit the discharge end of resilient flexible evacuator tube 36. The neck 32 is also provided with hollow nipple 38 communicating with the interior of the neck which is for the purpose of venting the interior of the bottle to the atmosphere. A closure member 40 for closing the air vent off as required is secured to the neck 32 by means of a flexible strap 41. A perforate web means 42, such as, a washer or diaphragm, of material permeable to gas but impermeable to liquid is positioned in the hollow of nipple 38 to prevent spillage of liquid from the bottle if it is tilted or overturned while the closing member 40 is off of the end of nipple 38. These perforate materials are well known to the art, and one such material is sold under the trade name "Zitex."

A rigid handle 44 of plastic or other suitable material is integrally attached to cap 24. The handle assembly is made in one molding operation as is the bellows bottle 10. The handle is constructed with rearwardly curved portion 46 connected by curved portion 48 with gripping section 50 which extends substantially perpendicular to the vertical axis of the bellows bottle and across top portion 14. The handle 44 terminates in locking section 54 extending substantially parallel to the gripping section in the direction of rearwardly curved portion 46 and connected to the gripping section by curved portion 52. The handle when mounted on a structure or carried by the gripping section will maintain the bellows bottle 10 in a substantially vertical orientation. The parts of the handle all lie in the same plane.

The handle, and particularly the gripping and locking sections, are constricted and oriented for easy attachment to bedside rails, chairs, wheelchairs, and other structure from which such bottles are ordinarily suspended, and to allow easy carrying by an ambulatory patient. When the bottle is suspended or carried by the handle, it is maintained in a substantially vertical orientation with no relative movement between the handle and the bottle. The handle is particularly advantageous in applications requiring a protracted time interval for drainage as it can be suspended and allowed to expand beyond its normal rest position due to the weight of fluid entering its interior and thus create vacuum.

Flexible evacuator tube 36 is attached by connector 58 at its intake end to a body discharge device represented in block as indicated at 56. For closing tube 36 before removal of its intake end from the body drainage device 56, a slide valve 59 is provided with slot eye 60 for receiving the tube in normal open position and a slot leg 61 for closing the tube by sliding the slot leg over it. The body discharge device may be a urethral or a ureteral catheter, or other body discharge device. The assembly shown is for connection to the well known Foley catheter. Other type body drainage devices can be used in the system, such as, a nephrostomy tube, a cystostomy tube, a chest tube, etc. The system other than the body drainage device is made for packaging in a sanitized plastic container and is a disposable unit.

Reference is now made to FIGS. 3, 4 and 5 for a description of a modification of the bellows bottle assembly of the system.

In this modification the cap 24 has been modified to eliminate the neck 32 of the other modification and to mount nipples 62 and 64, corresponding, respectively, to nipples 34 and 38, in the top of cap 24.

The handle 44 has been modified to provide for mounting yoke 45 at its bottom end constructed with yoke arms 47 which are mounted 180° apart on cap 24 by means of flexible hinges 68. The hinges 68 are of plastic and are made integral with the yoke 47. The handle can be readily folded to facilitate packaging the unit. The remainder of the handle is comprised of rearwardly curved portion 46 and locking portion 54 connected to gripping portion 50 by curved elbows 48 and 52 with the handle being of one piece construction so that it can be manufactured along with the cap in a one-step molding procedure. A notch 66 is provided in the bottom surface of gripping section 50 to facilitate suspension of the bottle in a vertical orientation. The flexible hinges 68 are foldable with sufficient force but are sufficiently rigid to prevent relative movement between the handle and the bellows bottle by the usual forces encountered in carrying or use of the bellows bottle. The parts of the handle, including yoke arms 47, curved portion 46, gripping portion 50, locking portion 54 and curved elbows 48 and 52 all lie in the same plane.

A line connecting the ends of the arms 47 of the mounted yoke will, of course, pass through the vertical axis of the bottle. The central point between the arms 47 of yoke 45 as well as the notch 66 lie on the vertical axis of the container. Preferably, the curved elbows 48 and 58 extend an equal distance from the vertical axis of the bellows container, and most preferable, they extend approximately to the outer periphery of the container.

The modified container is also provided with drainage means in case the unit is made non-disposable for re-use or in case it becomes full during one operation and must be drained to complete drainage from the body cavity. In this modification hollow circular depending portion 70 is made integral with the bellows container. Depending portion 70 ends in a hollow peripheral rib 72. The bellows bottle is also provided with depending locking boss 74 for a purpose to be later described.

Hollow nipple 76 communicating with the interior of the bellows bottle through hollow depending portion 70 extends integrally from depending portion 70. This nipple has an internal peripheral flange as shown. A circular insert 78 is used to mount the intake end of flexible drainage tube 80 in nipple 76 by a press fit. With the construction described the flexible drainage tube 80 can be stowed by winding it around depending portion 70 and locking it interiorly of depending boss 74, as the distance between the end of the boss and the top of the nipple 76 is less than the diameter of the tube.

In the operation of the system, the intake end of evacuator tube 36 is connected to body drainage device 56 with the bellows bottle 10 being in its normal rest position as described above. Either before or after this connection the unit is suspended by means of handle 44 so that the bottom portion 12 is free to travel downwardly upon expansion of bellows container 10. If routine gravity drainage is to be used, the air vent is

opened by removal of closure member 40 and drainage proceeds. Some initial vacuum can be created to start drainage if necessary by fully compressing the bellows container 10 with closure member 40 off of the air vent followed by closing the air vent and allowing the bellows bottle to recover to its normal rest position.

If combined vacuum and gravity drainage is to be used, either with or without the initial vacuum just described, the closure member 40 is left over the air vent and drainage proceeds. The forces acting on the liquid being drained are the normal gravity force and the vacuum created by downward expansion of the bellows bottle due to the weight of the fluid discharged therein. This latter feature is a decided advantage over prior art devices in that continuous vacuum can be maintained within the cavity being drained for a protracted period of time thus preventing voiding of the catheter or other body drainage device as fluid accumulates in the cavity being drained. Testing showed that when the bellows bottle illustrated expanded to its normal rest position it drew 13 cm. of water. On full expansion negative pressure increased by a factor of 4.

The novel gripping handle by which the bellows container is suspended maintains the container in substantially vertical orientation at all times during drainage into the container.

A further use of the bellows bottle is to remove material from the evacuation tube 36 which may accumulate therein to halt the flow of fluid. This can be done by using the bellows bottle as a pump to disturb the material causing the stoppage so that it will be carried along the accumulator tube.

When the bellows container is removed for disposal, the accumulator tube 46 is closed near its intake end by means of slide valve 59 which is pushed upwardly so that slot eye 60 moves upwardly with slot leg 61 closing the tube. The bellows container unit can then be disposed of by sanitary procedures.

If it is desired to drain the bellows container 10 while it is still suspended, the drainage arrangement of FIG. 3 is used. The drainage tube 80 is, of course, provided with a slot valve (not shown) near its discharge end like the slot valve 59, or other type valve. This valve is, of course, closed while the unit is in use. To drain the unit, the drainage tube 80 is merely unwound from its stowed position around depending portion 10 and the slot valve on its end removed to permit drainage. Upon completion of the drainage, if the tube is to be reused, the slot valve is replaced on drainage tube 80 and the tube stowed around depending portion 70 and locked in place as previously described. Alternatively, the drainage tube can be disposed of and a new sanitized tube substituted for it.

What I claim is:

1. A fluid evacuating system for evacuating fluids from the body comprising in combination:

a. a flexible bellows-type container having top and bottom portions connected by an accordin-like sidewall of resilient elastomeric material comprised of continuous alternate ridges and valleys adapted to fold and expand to create a vacuum upon expansion;

b. first attachment means in said top portion communicating with the interior of said container for attaching thereto the discharge end of a body cavity evacuating tube;

c. a body cavity evacuation tube attached by its discharge end to said second attachment means;

d. a body fluid evacuation device connected to the intake end of said evacuation tube;

e. second attachment means in said top portion in communication with the interior of said container and the atmosphere;

f. a removable sealing means for said second attachment means movably attached to said container;

g. perforate web means seated in said second attachment means permeable to gas and impermeable to liquid to permit the passage of gas but not liquid through said second attachment means; and

h. a rigid handle attached to said top portion for suspending said container in a vertical orientation, said handle comprising an upright portion, a gripping portion extending substantially perpendicularly from the upper end of the vertical portion over said top portion in the same plane as the upright portion; and a locking portion attached to the distal end of the gripping portion by a curved portion and extending in said plane toward said upright portion substantially perpendicular to the vertical axis of said container.

2. The system of claim 1 including drainage means in said bottom portion for draining said container.

3. The system of claim 1 including an upwardly extending neck on said top portion and a hollow cup attached to the top of said neck in which said first and second attachment means are seated.

4. The system of claim 1 in which said handle is attached to said top portion by a yoke with the ends of the yoke attached at respective points of the top portion 180° apart.

5. The system of claim 4 in which said handle is attached to said top portion on a line passing through the vertical axis of the container, said handle extending outwardly and upwardly in a plane from a point substantially on said vertical axis, then forming substantially a right angle and extending in said plane substantially perpendicular to said vertical axis a distance to form a gripping section, then extending in substantially a 180° angle in said plane a distance to form a locking section.

6. The system of claim 5 including a seating notch in the bottom surface of said gripping section.

7. The system of claim 1 in which said drainage means includes a hollow reduced diameter portion depending from said bottom portion in communication with the interior of said container terminating in an integral hollow peripheral rib, a boss depending from said bottom portion near the periphery thereof, a drainage nipple in communication with the interior of said hollow portion, a circular insert in said drainage nipple, and a flexible drainage tube having its intake end secured between the interior periphery of the discharge end of said drainage nipple and the outer periphery of said insert.

8. The system of claim 5 in which said drainage means includes a hollow reduced diameter portion depending from said bottom portion in communication with the interior of said container terminating in an integral hollow peripheral rib, a boss depending from said bottom portion near the periphery thereof, a drainage nipple in communication with the interior of said hollow portion, a circular insert in said drainage nipple, and a flexible drainage tube having its intake end se-

cured between the interior periphery of the discharge end of said drainage nipple and the outer periphery of said insert.

9. The system of claim 1 including valve means associated with said evacuator tube for closing same.

10. A fluid evacuation system for evacuating fluids from a body comprising in combination;

- a. a flexible bellows-type container having top and bottom portions connected by an accordin-like sidewall of resilient elastomeric material comprised of continuous alternate ridges and valleys adapted to fold and expand and to create a vacuum upon expansion, the sidewall thickness and the elastic memory of said plastic being such that in the normal nested or collapsed position of said container a section of the sidewall is partially expanded and the partially expanded section expands back to its normal position from a compressed or folded position solely by the resiliency of the sidewall;
- b. a hollow cap attached to the top portion of said container having first and second nipples extending outwardly from its top in communication with the interior of said container;
- c. an evacuator tube attached by its discharge end to said first nipple;
- d. a body fluid evacuation device connected to the intake end of said evacuator tube;
- e. a perforate web means seated in said second nipple permeable to gas and impermeable to liquid to permit the passage of gas but not liquid through said second nipple;
- f. a removable sealing means for said second nipple movably attached to said cap;
- g. a rigid handle flexibly or hingedly attached to said cap for suspending said container in a vertical orientation, said handle comprising a yoke at its bottom end with each end of the yoke flexibly or hingedly attached to respective portions of said cap 180° apart, a main curved section attached by its bottom end to the top of said yoke extending upwardly and curving outwardly therefrom, a gripping section oriented substantially perpendicular to the vertical axis of said container, a locking section substantially parallel to said gripping section having its terminal section extending in the direction of said main curved section, and curved elbow sections connecting said gripping section with said main curved section and said locking section;
- h. a hollow reduced diameter portion depending from said bottom portion in communication with the interior of said container terminating in a integral peripheral rib;
- i. a boss depending from said bottom near the periphery thereof;

j. a drainage nipple in communication with the interior of said hollow portion;

k. a circular insert in said drainage nipple; and

l. a flexible drainage tube having its intake end secured between the interior periphery of the discharge end of said drainage nipple and the outer periphery of said insert.

11. The system of claim 10 in which the distance between the terminal end of said boss and the top of said drainage nipple is slightly less than the diameter of said drainage tube so that said drainage tube can be stowed by winding it around said reduced diameter portion between said bottom portion and said peripheral rib and locking its terminal end section between said depending boss and said drainage nipple portion.

12. The system of claim 10 including valve means associated with said evacuator tube for closing same.

13. The system of claim 10 in which said handle is flexibly or hingedly connected to said cap to permit folding to facilitate storage of said container.

14. The system of claim 13 in which said handle is connected to said cap by a flexible plastic hinge integral with said handle.

15. The system of claim 10 including a notch in the bottom surface of said gripping section substantially on the vertical axis of said container.

16. A method for evacuating body fluids from the body by the concurrent use of gravity and gravity-created vacuum comprising:

- a. establishing a drainage channel with its intake end communicating with the interior of the body area to be drained and its discharge end outside the body;
- b. establishing communication between said discharge end and the interior of a flexible bellows-type container sealed from the atmosphere, and
- c. vertically suspending said container by its top before or after step (b) to allow body fluids to be evacuated into said container; whereby said body fluids drain into said container under the concurrent force of gravity acting on said body fluids coming from said body and the vacuum created by expansion of said bottle under the force of gravity acting on fluid evacuated into said bottle.

17. The method of claim 16 in which said bellows bottle is collapsed from its normal rest position and allowed to expand to said normal rest position after said communication and suspension are effected so that evacuation of said area is initiated substantially by the vacuum created by the expansion of said bellows bottle to its normal rest position and continued entry of body fluids into said container expands it beyond its normal rest position.

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