

March 23, 1971

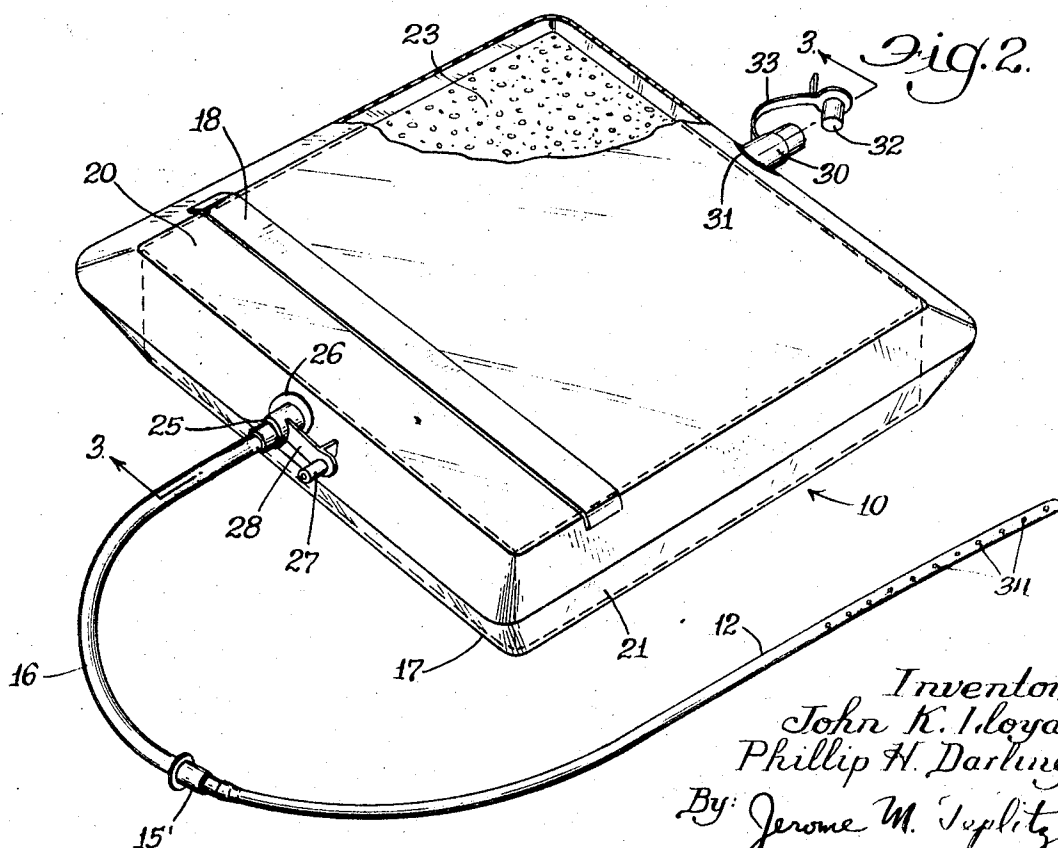
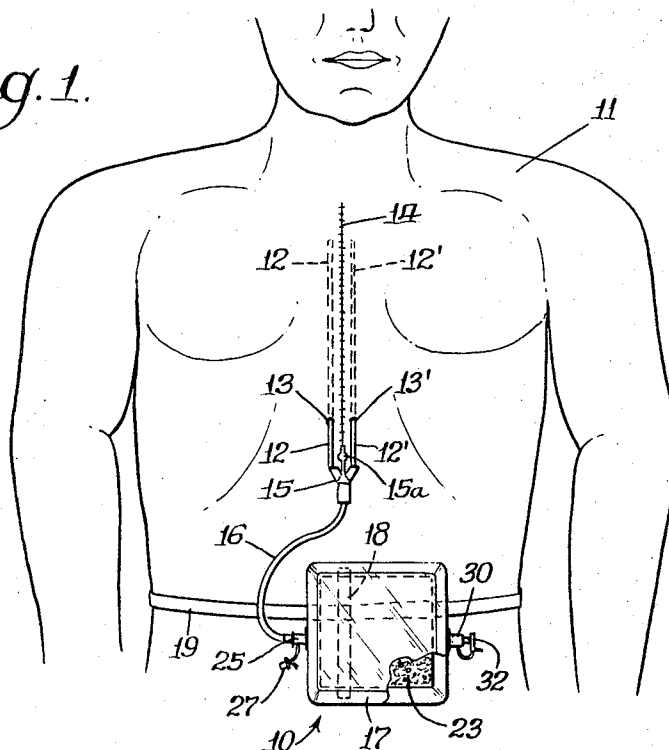
J. K. LLOYD ET AL
SUCTION DRAINAGE DEVICE

3,572,340

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4 Sheets-Sheet 1

Fig. 1.



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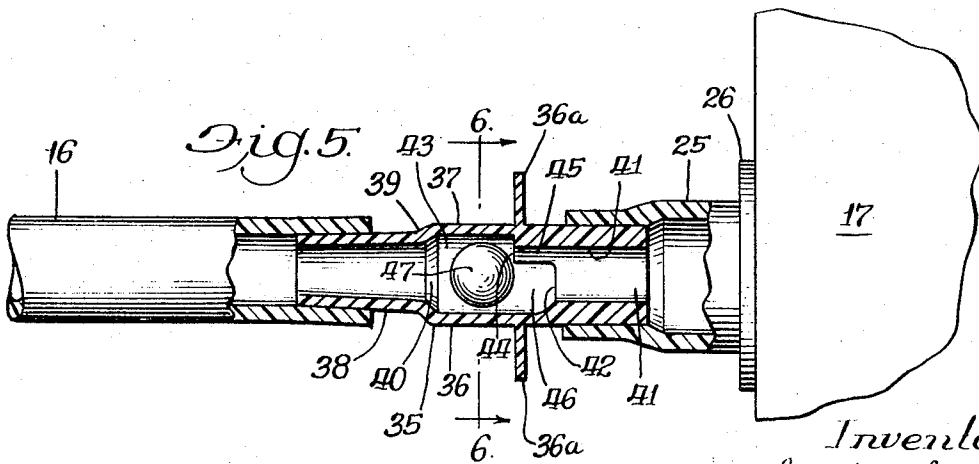
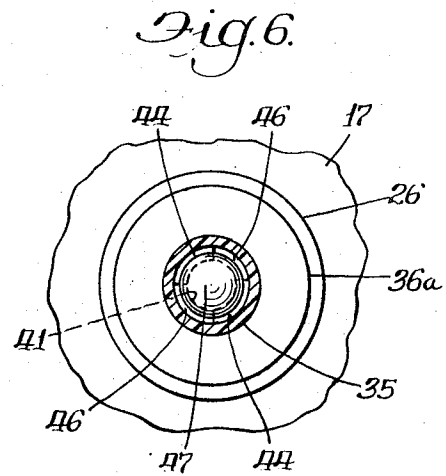
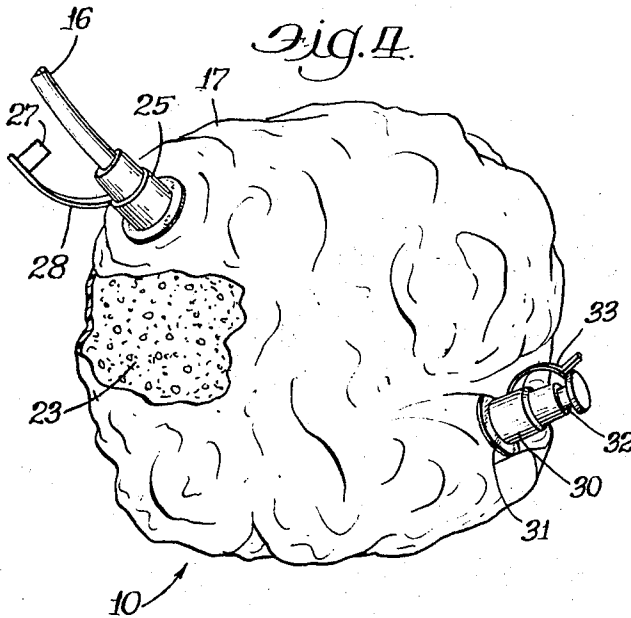
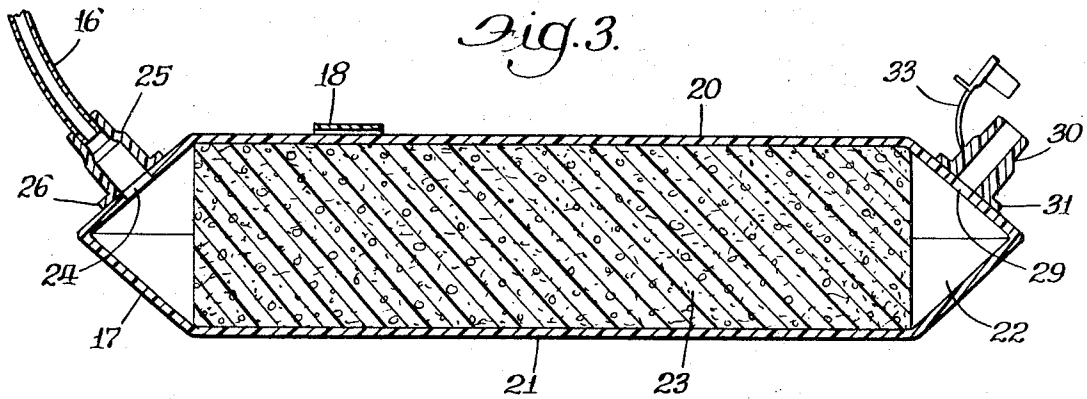
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SUCTION DRAINAGE DEVICE

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4 Sheets-Sheet 2



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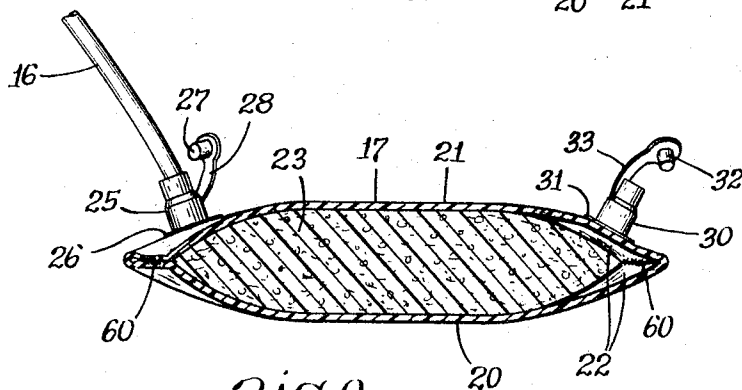
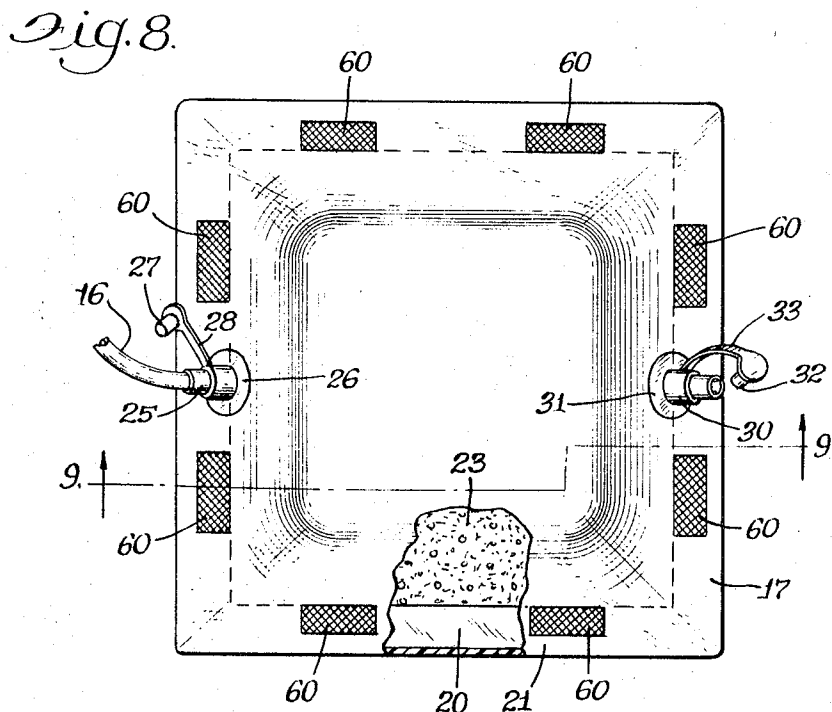
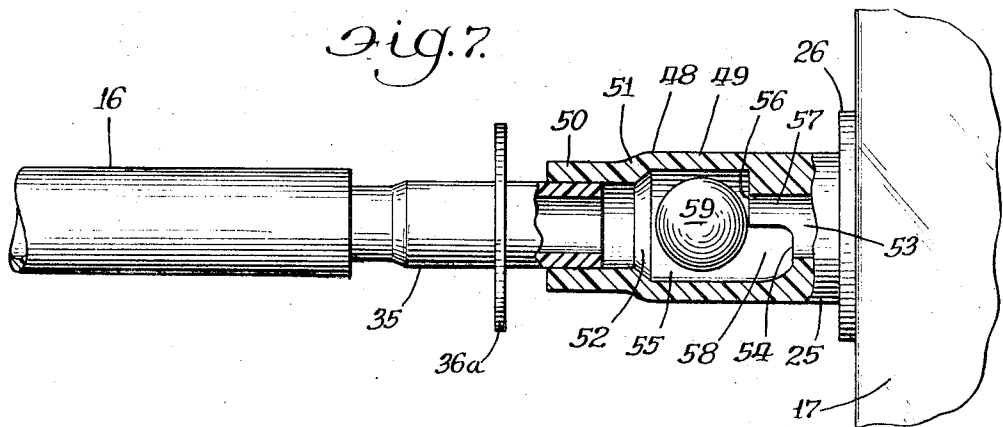
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SUCTION DRAINAGE DEVICE

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4 Sheets-Sheet 3



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3,572,340

SUCTION DRAINAGE DEVICE

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16 Claims

ABSTRACT OF THE DISCLOSURE

A portable, disposable, sterile suction drainage device for extraction and collection of body fluids from wounds. The device includes a fluid-collecting pump unit attachable to the patient's body and comprising a resiliently compressible open-cell foam pad encased within a collapsible container, to which is connected suitable tubing for insertion into a body wound. The pump unit is activated by manually squeezing the container to compress the foam pad and collapse the container, and then releasing the container so as to permit the resilient force of the foam pad against the container walls to expand the container, thereby creating suction within the container which draws the body fluids from the wound through the tubing into the container.

This invention relates to suction drainage devices and, more particularly, to surgical devices for the sterile suction drainage and collection of body fluids from wounds.

Closed wound suction is now routinely employed in a large number of surgical procedures, including the treatment of deep tissue abscesses, orthopedic procedures, radical mastectomy, radical neck dissections, inguinal, perineal and chest surgery, and other procedures involving extensive dissection wounds. This technique, which involves suction drainage of serosanguineous fluids from the sutured wound through drainage tubes inserted into the wound generally through healthy tissue spaced from the incision line, affords several advantages. The incidence of complications such as hematoma, infection, necrosis, swelling, and suture tension, as well as post-operative pain and discomfort to the patient, are greatly reduced, thereby encouraging early post-operative ambulation and exercise. Also, the skin flaps are caused to adhere to the underlying tissues by means of the negative pressure, promoting rapid healing of the wound and revascularization. Furthermore, post-operative wound dressings are kept relatively dry and free from soilage and foul odor, thereby diminishing the frequency of dressing change and reducing the possibility of wound contamination.

Previous systems for providing closed wound suction have, in general, involved the use of cumbersome, expensive and noisy electrical or mechanical suction pumps. These systems suffered from the disadvantages of requiring temporary disconnection during the patient's transfer from the operating room to his ward and thereafter confining the patient to his bed and the immediate area of the suction pump. Since ordinary operative wounds normally require a draining period of forty-eight hours after the operation, these systems have not been conducive to early ambulation of the patient.

Various attempts have been made to overcome these disadvantages by providing portable, disposable wound suction units utilizing metal springs or bellows to induce vacuum. Although these units have been sufficiently lightweight to permit use on ambulatory patients and have met with some success, their relatively high cost, particularly when operated under optimum aseptic conditions requiring periodic replacement of the fluid collector

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during the drainage period, has been a substantial drawback to their becoming more extensively employed.

It is an object of this invention to provide a suction drainage device which is capable of efficiently extracting and collecting body fluids from wounds without the need for cumbersome, expensive and noisy electrical or mechanical equipment, and which includes a fluid-collecting pump unit which is sufficiently lightweight, compact and portable so that it may conveniently be attached to the body of the patient and reliably remain in operation without interfering with the patient's ambulation.

Another object of the invention is to provide a suction drainage device having the above features which is capable of being compactly packaged, together with all necessary accessories, and stocked in sterile, ready-to-use form and which is conveniently and economically disposable after a single use.

A further object of the invention is to provide a suction drainage device having the above features wherein the fluid-collecting pump unit is less complex in construction and less expensive to manufacture than previously known units of this type.

Still another object of the invention is to provide a suction drainage device having the above features which is capable of being economically operated under optimum aseptic conditions.

Other objects and advantages of the invention will be apparent from the following detailed description and accompanying drawings, wherein:

FIG. 1 is a front view of a portion of a human body having the suction drainage device of the present invention attached thereto and operatively connected to the interior of a wound following a median sternotomy;

FIG. 2 is perspective view of the suction drainage device of this invention showing the fluid-collecting pump unit with the collapsible container forming the outer casing of the pump unit in its normally expanded position and with a portion of the container cut away in order to show a compressible foam pad encased therein in its uncompressed position;

FIG. 3 is a sectional view of a portion of the device taken along the line 3—3 of FIG. 2;

FIG. 4 is a plan view of a portion of the suction drainage device of FIG. 2 showing the fluid-collecting pump unit with the container in its collapsed position and with a portion of the container cut away to show the foam pad in its compressed position;

FIG. 5 is an enlarged fragmentary view partly in section of a portion of the device illustrated in FIG. 2 and modified to show a check valve detachably connected between the connecting tube and the tubular connector member of the fluid-collecting pump unit;

FIG. 6 is a sectional view of the check valve taken along the line 6—6 of FIG. 5;

FIG. 7 is a fragmentary view similar to FIG. 5 and also partly in section, modified so as to show an additional check valve built in to the tubular connector member of the fluid-collecting pump unit;

FIG. 8 is a plan view of a portion of a suction drainage device similar to that shown in FIG. 2, showing the fluid-collecting pump unit modified so that the foam pad is anchored in fixed position within the container, and with a portion of the container cut away in order to show the foam pad encased therein;

FIG. 9 is a sectional view taken along the line 9—9 of FIG. 8;

FIG. 10 is a sectional view similar to FIG. 3 and showing a modified form of the fluid-collecting pump unit of this invention wherein the foam pad is sealed within a fluid-permeable flexible covering sheet within the container;

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FIG. 11 is a sectional view similar to FIG. 3 and showing a modified form of the fluid-collecting pump unit of this invention wherein the walls of the container consist of an air-impermeable, non-cellular flexible skin integral with the foam pad; and

FIG. 12 is a plan view of a portion of a suction drainage device similar to that shown in FIG. 2, showing the fluid-collecting pump unit modified so that the container includes a graduated lower chamber for measuring the quantity of liquid collected therein, with a portion of the upper chamber cut away to show the foam pad encased therein.

The above objects are attained in accordance with the present invention by providing a fluid-collecting pump unit comprising a resiliently compressible open-cell foam pad encased within a collapsible container structure having walls formed of flexible plastic film or other suitable air-impermeable material, in such a manner that the foam pad exerts a separating force on the walls of the container tending to maintain the container in a normally expanded position. The walls of the container are provided with one or more openings therein to enable the interior of the container to be evacuated of air and to be operatively connected by means of suitable tubing with the interior of a wound or the like. The container structure is so designed that when it is subjected to external manual pressure, the foam pad will be compressed, air will be expelled from the container interior, and the container will assume a collapsed position, and when the external pressure is released, the resilient force of the foam pad against the container walls will move them apart toward their normally separated position, thereby expanding the container and creating a negative pressure within the container. When the interior of the container is operatively connected with the interior of a body wound by means of suitable tubing, and the system closed to the atmosphere, the negative pressure developed within the container will cause body fluids to be drawn from the wound through the tubing into the container. The fluid-collecting pump unit may also be provided with a strap member or other suitable means, secured to the outer surface of the container, for conveniently attaching the pump unit to the patient's body so as to permit its continuous operation without interfering with the patient's ambulation.

Referring once more to the drawings:

In FIG. 1, a typical suction drainage device in accordance with the invention, having a fluid-collecting pump unit 10, is shown attached to the body 11 of a patient and operatively connected to the interior of a wound following a median sternotomy. A pair of drainage tubes 12 and 12', constructed of plastic or other material which is inert to the body constituents, is inserted in the wound and brought out through stab wounds 13 and 13' through healthy tissue spaced from the incision 14. The drainage tubes 12 and 12' are connected by means of a Y-shaped adapter 15 and connecting tube 16 in fluid-tight relation with a collapsible container 17 forming the outer casing of the fluid-collecting pump unit 10. The pump unit 10 is provided with a strap member 18 secured to the outer surface of the container 17 and which may be looped around suitable means for supporting the pump unit on the patient's body, such as a belt 19 worn by the patient. The drainage tubes 12 and 12' and the connecting tube 16 are relatively flexible but sufficiently rigid to adequately resist collapse under the operational conditions involved.

As more clearly illustrated in FIGS. 2 and 3, the container 17 has its walls formed of two overlying panels 20 and 21 of plastic film or other suitable air-impermeable material joined together to form an interior 22 therebetween. At least one, and preferably both, of the panels 20 and 21 are formed of flexible material so as to render the container structure collapsible. The panels 20 and 21 may be integral panels of a flat tubular structure, or a

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single sheet of film folded and sealed together at its free edges, or two separate sheets of film sealed together around their peripheral edges. The strap member 18 for attaching the pump unit to suitable support means may be secured to the outer surface of one of the panels, as for example panel 20 as shown in FIGS. 2 and 3, by a heat seal or other suitable means.

Encased within the container 17 is a resiliently compressible open-cell foam pad 23. The size and shape of the foam pad and its position within the container are such as to enable the foam pad to exert a separating force on the walls of the container tending to maintain the container in a normally expanded position as shown in FIGS. 2 and 3, and also to enable the foam pad to undergo substantial compression upon being subjected to manual pressure applied to the outside of the container, so as to permit the container to assume a collapsed position such as shown in FIG. 4. The foam pad 23 is preferably a single solid block of foam material, having a generally rectangular shape. However, it may be of any other suitable shape, such as cylindrical or spherical or irregularly shaped, or it may have one or more portions cut away so as to leave one or more open areas within the block, or it may even consist of two or more separate blocks. The preferred material for the foam pad 23 is polyurethane foam although other resiliently compressible open-cell foam materials, such as natural or synthetic latex foam, natural sponge, cellulosic sponges, vinyl foam and the like, may suitably be employed. Furthermore, the foam pad 23 may have a composite structure of any of the above foam materials with another flexible, absorbent filler material such as cellulose, cotton or other similar non-woven fibrous absorbent material. The composite structure may consist of alternating layers of the foam material and the filler material, or it may consist of the filler material suspended within a matrix of the foam material. The filler material preferably is more highly absorbent than the foam material so that liquid absorbed within the structure will be preferentially absorbed by the filler material, thus leaving the cells of the foam unclogged.

As shown in FIG. 3, the container 17 is provided with an inlet opening 24 through one of the walls thereof, and in alignment with the inlet opening 24, a tubular connector member 25 having an outwardly extending flange portion 26 secured in fluid-tight relation to the container wall by suitable means such as cementing, welding or the like. The tubular connector member 25 is adapted to frictionally engage the connecting tube 16 in fluid-tight relation so as to operatively connect the tube 16 to the container interior 22. The tubular connector member 25 may be provided with a suitable stopper member 27, preferably integrally attached thereto by means of a thin strap 28, for releasably closing the inlet opening 24 after the container has been filled and detached from the tubing.

The container 17 may also be provided with an outlet opening 29 through one of the walls thereof, and in alignment with the outlet opening 29, a tubular member 30 having an outwardly extending flange portion 31 secured in fluid-tight relation to the container wall by suitable means such as cementing, welding, or the like. The tubular member 30 is provided with a stopper member 32 for releasably closing the outlet opening 29 of the container. The stopper member 32 may be integrally attached to the tubular member 30 by means of a thin strap 33.

In FIG. 2, the connecting tube 16 is shown connected to a straight adapter 15' to which is attached a single drainage tube 12 having a diameter smaller than that of the connecting tube 16. This form of the invention will be employed in certain surgical procedures requiring only a single drainage tube, such as in a breast biopsy. Alternatively, the Y-shaped adapter 15, shown in FIG. 1, may be employed with the opening in the unused branch being closed with a suitable stopper member 15a, preferably integrally attached to the adapter and positioned so that

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it may be used to close either one of the two branches. If the outside diameter of the drainage tube 12 is substantially the same as the inside diameter of the connecting tube 16, allowing a direct fluid-tight connection between the two, the adapter may be eliminated completely. The drainage tube 12 is preferably provided, at its end to be inserted into the wound, with a plurality of apertures 34 for more effective drainage.

The drainage device is operatively connected with the interior of the wound by procedures well known in the art. One or more drainage tubes 12, disconnected from the rest of the device and having a suitable needle attached to its non-apertured end, is placed in position within the open wound with the apertures 34 being positioned at the points where drainage is desired. The needle and the drainage tube end attached thereto are then drawn out through healthy tissue spaced from the incision, such as through stab wounds 13 and 13' of FIG. 1. The wound is then closed by suturing in the usual manner, the needle is removed from the drainage tube 12 and the drainage tube 12 is then connected to the connecting tube 16 either directly or through a suitable adapter 15 or 15', thereby operatively connecting the container interior 22 to the interior of the wound.

Activation of the pump unit 10 is effected by applying external pressure to the container 17, as, for example, by manually squeezing the container, with the outlet opening 29 of the container being open to the atmosphere through tubular member 30, so as to compress the foam pad 23, expel air from the container interior 22 through the outlet opening 29, and thus collapse the container 17. Since the foam pad 23 is omni-directionally compressible, the container 17 in its collapsed position may assume a generally spherical shape as shown in FIG. 4. The stopper member 32 is then inserted into the tubular member 30 so as to close the outlet opening 29 of the container, and the pressure on the container is then released. The resilient force of the foam pad 23 against the container walls will move them apart toward their normally separated position, thereby expanding the container and creating a negative pressure within the container interior 22. Such negative pressure will draw accumulated body fluids from the wound through the tubing and into the container interior 22 where it will be absorbed into the open cells of the foam pad 23. When the resilient action of the foam pad 23 is exhausted, or when drainage is otherwise to be discontinued or interrupted, the pump unit 10 may be detached from the connecting tube 16 and, after sealing the container 17 closed by inserting the stopper member 27 into the tubular connector member 25, may be conveniently disposed of. If additional drainage is thereafter desired, a new sterile pump unit 10 may be attached to the connecting tube 16 and activated as described above.

Although in the preferred embodiment of the invention, the container 17 is provided with a separate outlet opening 29 for permitting the evacuation of air from the container interior 22, it is also possible to have the container formed with only a single opening 24 serving as both an inlet opening and an outlet opening. In that case, the pump unit would be activated and air expelled from the container interior 22 through the opening 24 before the container is operatively connected with the drainage tube 12, and the external pressure would be maintained on the container 17 until such connection was effected.

Referring now to FIGS. 5-7, in order to prevent fluids from flowing into and through the tubing, toward and into the wound and possibly contaminating the wound, a suitable check valve 35 may be connected between the connecting tube 16 and the tubular connector member 25, and preferably is detachable at least from the tubular connector member 25. The check valve 35 will thus be effective, firstly, to prevent air from being forced into the tubing when the pump unit is being activated while connected to the tubing; secondly, to prevent the possibility of any reflux of the serosanguineous fluids from the con-

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tainer back into the tubing; and thirdly, if detachable from the tubular connector member 25, to prevent any contaminating material from entering the tubing while the pump unit is being replaced.

One form of check valve 35 which may be used in this invention, as best shown in FIGS. 5 and 6, comprises a tubular body 36, having a larger outside diameter portion 37 adapted for fluid-tight engagement with the tubular connector member 25 and a smaller outside diameter portion 38 adapted for fluid-tight engagement with the connecting tube 16 and preferably tapered so as to insure a more snugly fitting connection. Although the tubular body 36 is shown inserted into the tubular connector member 25, these elements may instead be designed so that the tubular connector member 25 has a tapered end adapted to fit into the tubular body 36. The check valve 35 may be provided with an outwardly extending integral flange portion 36a to facilitate its handling during its connection into and disconnection from the system. Between portions 37 and 38 is an annular shoulder 39 defining an internal annular valve seat 40. Portion 37 of the tubular body 36 has a smaller bored section 41 toward the end of the tubular body 36 and extending to an annular shoulder 42, and a larger bored section 43 extending from the annular valve seat 40 to an arcuate shoulder 44. The arcuate shoulder 44 is formed by a pair of diametrically opposed arcuate projections 45 extending from the annular shoulder 42 and defining circumferentially between them a pair of diametrically opposed passageways 46. The inside diameter of the tubular body 36 across the pair of arcuate projections 45 is substantially the same as that of the smaller bored section 41, while the inside diameter of the tubular body 36 across the pair of passageways 46 is substantially the same as that of the larger bored section 43. A ball 47, having a diameter less than the internal diameter of the tubular body 36 across the pair of passageways 46 and greater than the internal diameter of the tubular body 36 across the pair of arcuate projections 45 and also greater than the internal diameter of the annular valve seat 40, is disposed within the larger bored section 43.

Thus, when fluid is flowing from the connecting tube 16 into the check valve 35, the ball 47 is forced away from the annular valve seat 40 against the arcuate shoulder 44, as shown in FIG. 5, allowing fluid to flow into the larger bored section 43, around the ball 47, and then through the passageways 46 and the smaller bored section 41 into the container 17. On the other hand, when fluid is flowing in the opposite direction into the check valve 35 toward the connecting tube 16, the ball 47 is forced against the annular valve seat 40, thus effectively preventing the fluid from passing out of the larger bored section 43 and entering the connecting tube 16.

As shown in FIG. 7, the tubular connector member 25 may have a built-in check valve, designated generally by the numeral 48, integrally incorporated therein to prevent fluid from flowing out of the container 17 through the inlet opening 24. The built-in check valve 48 may be designed very similarly to the check valve 35. The tubular connector member 25 is formed with a larger outside diameter portion 49 adjacent to the flange portion 26, and a smaller outside diameter portion 50 adapted for fluid-tight engagement with either the connecting tube 16 or the check valve 35. Between portions 49 and 50 is an annular shoulder 51 defining an internal annular valve seat 52. Portion 49 of the tubular connector member 25 has a smaller bored section 53 toward the flange portion 26 and extending to an annular shoulder 54, and a larger bored section 55 extending from the annular valve seat 52 to an arcuate shoulder 56. The arcuate shoulder 56 is formed by a pair of diametrically opposed arcuate projections 57 extending from the annular shoulder 54 and defining circumferentially between them a pair of diametrically opposed passageways 58. The inside diameter of the tubular connector member 25 across the pair of arcuate projections 57 is substantially the same as that

of the smaller bored section 53, while the inside diameter of the tubular connector member 25 across the pair of passageways 58 is substantially the same as that of the larger bored section 55. A ball 59, having a diameter less than the internal diameter of the tubular connector member 25 across the pair of passageways 58 and greater than the internal diameter of the tubular connector member 25 across the pair of arcuate projections 57 and also greater than the internal diameter of the annular valve seat 52, is disposed within the larger bored section 55.

Thus, when fluid is flowing from the connecting tube 16 into the tubular connector member 25 toward the container 17, the ball 59 is forced away from the annular valve seat 52 against the arcuate shoulder 56 as shown in FIG. 7, allowing fluid to flow into the larger bored section 55, around the ball 59, and then through the passageways 58 and the smaller bored section 53 into the container 17. On the other hand, when fluid is flowing in the opposite direction into the tubular connector member 25 from the container 17, the ball 59 is forced against the annular valve seat 52, thus effectively preventing the fluid from passing out of the larger bored section 55 of the tubular connector member 25.

The built-in check valve 48 is particularly advantageous in preventing collected fluids from being accidentally squirted out of the container 17 when the pump unit is being detached from the system. With the check valve 35 being eliminated from the system and the connecting tube 16 connected directly to the tubular connector member 25, the built-in check valve 48 will also function to prevent air from being forced into the tubing toward the wound when the pump unit is being activated, as well as to prevent reflux of collected fluids from the container back into the tubing toward the wound. However, in order to insure that when the pump unit is detached from the system for replacement, there will be no opportunity for contaminating materials to enter the tubing and get into the wound, as well as no accidental leakage of collected fluids through the inlet opening 24 of the container, it is preferred to employ both the check valve 35 and the built-in check valve 48 in combination, as shown in FIG. 7.

In order to prevent the possibility of the container openings becoming blocked by the foam pad, it may sometimes be desirable to have the foam pad anchored in fixed position within the container so as to insure an unobstructed space adjacent the container openings. In FIGS. 8 and 9, the panels 20 and 21 forming the walls of the container 17 are shown sealed together, as, for example, by means of an electronic heat seal or suitable adhesive means or the like, at sealed areas 60 spaced from the container openings and adjacent to and spaced intermittently around the foam pad 23. The sealed areas 60 serve to anchor the foam pad 23 in fixed position within the container 17 without interfering with the flow of fluid from and to the foam pad 23. Instead of the sealed areas 60 around the foam pad, one or more sealed areas through the foam pad may be employed to seal the foam pad directly to one or both panels of the container.

The preferred material for the walls of the container of this invention is an air-impermeable flexible film of thermoplastic material, such as polyethylene, polypropylene, nylon, vinyl polymers, polyethylene-nylon laminates, polypropylene-nylon laminates, ethylene-vinyl acetate copolymers, laminates of polyethylene with ethylene-vinyl acetate copolymers, or the like. A number of these film materials, and in particular vinyl film, including polyvinyl chloride and vinyl copolymers, generally contain suitable plasticizers for providing the film with proper flexibility and also suitable stabilizers for preventing degradation of the film material. There may be a tendency, particularly under long periods of storage or under sterilization conditions, for these plasticizers and stabilizers to migrate from the film material into the foam pad at the film-foam interface, thereby adversely affecting the film properties. In FIG. 10 is shown a modified form of the

invention which may be employed in order to minimize the area of contact between the container film and the foam pad and thereby reduce the tendency for the film-foam interaction. As shown in FIG. 10, which in all other respects is identical to FIG. 3 with like numerals designating the same elements as described above, the foam pad 23 is wrapped and sealed within an intermediate fluid-permeable flexible covering sheet 61 of thin flexible film 62 having holes 63 formed therein. The film 62 is preferably formed of thermoplastic material, such as polyethylene, polypropylene, nylon, polyethylene terephthalate, polyethylene-nylon laminates, polypropylene-nylon laminates, or the like, and may be either a normally non-porous film mechanically perforated to form the holes 63 therein or a normally porous film of fused and coalesced non-woven thermoplastic fibers having the holes 63 formed therein as tiny pores during its manufacture. The number, size, and spacing of the holes 63 are such as to substantially reduce the area of direct contact between the foam pad 23 and the walls of the container 17 without unduly restricting fluid flow from and to the foam pad 23.

In FIG. 11 is shown an alternative container structure 64 which may be employed in accordance with this invention in place of the container structure 17. The walls of the container 64 consist of an air-impermeable non-cellular flexible skin 65 integral with the resiliently compressible open-cell foam pad 66. One way of forming such structure is by introducing into a suitable mold a foam-forming composition capable of reacting to form an open-cell foam structure. A typical polyurethane foam-forming composition may be made by combining 100 parts polyester or polyether resin with 30 to 40 parts of a 65-35 to 80-20 blend of 2,4 and 2,6 isomers of tolylene diisocyanate in the presence of about 2 to 2.8 parts emulsifier, 2.2 to 3.5 parts water and 1.2 to 3 parts of well-known catalyst, such as N-methyl morpholine, ethanolamine, triethylamine, or the like. If preferred, a prepolymer of the isocyanate and the polyester or polyether may be made and mixed with the other ingredients just prior to the molding operation. When the molding operation is completed and the material removed from the mold, it consists of a resiliently compressible open-cell foam pad encased within an integral outer flexible skin of the same material but in an air-impermeable non-cellular condition.

Another way of forming the container structure 64 is by coating a preformed resiliently compressible open-cell foam pad, for example, by dipping or spraying, with a liquid resin material, such as a vinyl plastisol, which becomes absorbed in the surface layer of the foam pad and, upon curing, forms an air-impermeable non-cellular flexible skin integral with the foam pad.

The container 64 is provided with an inlet opening 67 and an outlet opening 68 which may be formed by puncturing the outer skin 65 through to the foam pad 66. A tubular connector member 69 having an outwardly extending flange portion 70 and a tubular member 71 having an outwardly extending flange portion 72, are in alignment with inlet opening 67 and outlet opening 68, respectively, with the respective flange portions 70 and 72 secured in fluid-tight relation to the container wall by suitable means, such as cementing, welding or the like. When the container structure is formed by coating a preformed foam pad with a curable liquid resin material, as described above, the tubular connector member 69 and the tubular member 71 may be suitably attached directly to the foam pad prior to the coating operation, as, for example, by puncturing the foam pad with pointed projections, not shown, extending from the flange portions 70 and 72. The outer skin 65 is then formed around the foam pad so that it covers the flange portions 70 and 72, thereby firmly securing the tubular members 69 and 71 to the container structure and simultaneously forming the inlet opening 67 and outlet opening 68. The tubular con-

necter member 69 is adapted to frictionally engage the connecting tube 16 in fluid-tight relation so as to operatively connect the tubing to the interior of the container 64. The tubular connector member 69 and the tubular member 71 are provided with suitable stopper members for releasably closing the openings 67 and 68. A strap member 73 for attaching the pump unit to suitable support means, may be secured to the container wall by a heat seal or other suitable means.

In FIG. 12 is shown another alternative container structure 74 which may be employed in accordance with this invention in place of the container 17. The container 74 is formed of two overlying panels 75 and 76 of plastic film or other suitable air-impermeable material, at least one and preferably both of the panels being flexible. The panels 75 and 76 are suitably joined together around their peripheral edges and also sealed together, as for example, by means of an electronic heat seal, in the sealed areas 77 and 78 to form an upper chamber 79 and a lower chamber 80 interconnected by a thin throat 81. The upper chamber 79 has a resiliently compressible open-cell foam pad 82 encased therein and is provided with an inlet opening, not shown, through the walls of the container. In alignment with the inlet opening is a tubular connector member 83 having an outwardly extending flange portion 84 suitably secured in fluid-tight relation to the container wall. The tubular connector member 83 is adapted to frictionally engage the connecting tube 16 in fluid-tight relation and may be provided with a suitable stopper member 85 integrally attached thereto by means of a thin strap 86 for releasably closing the inlet opening after the container has been filled and detached from the tubing. The lower chamber 80 is graduated in volume units and may be provided with an outlet opening, not shown, through the walls of the container and, in alignment with the outlet opening, a tubular member 87 having an outwardly extending flange portion 88 suitably secured in fluid-tight relation to the container wall. The tubular member 87 is provided with a stopper member 89 for releasably closing the outlet opening of the container. The stopper member 89 may be integrally attached to the tubular member 87 by means of a thin strap 90.

When the container 74 is used in place of the container 17 in the suction drainage device of the present invention, the graduated lower chamber 80 of the container 74 serves as a convenient means for measuring the quantity of fluid collected. The body fluids entering the container 74 through the inlet opening will initially be absorbed into the open cells of the foam pad 82. At the completion of the collection period, the pump unit is detached from the tubing and, with the outlet opening closed and also preferably with the inlet opening closed to prevent any squirting out of fluids therethrough, the container 74 is held in an upright position and the foam pad 82 is compressed by squeezing the outside of the container. The collected fluids will be squeezed out of the foam pad 82 and discharged through the throat 81 into the graduated lower chamber 80 where the quantity thereof may be measured.

The negative pressure required to provide suction which is both gentle and effective has been found to be generally within the range of from about 15 to about 60 mm. of mercury. The fluid-collecting pump unit of the suction drainage device of the present invention is capable of developing and of maintaining, without reactivation, a negative pressure within this range for well in excess of the ordinary forty-eight hour post-operative draining period. Hence, once the device is operatively connected to the wound and the pump unit activated and attached to the patient's body, the device will reliably remain in efficient operation without attendance during the entire draining period without in any way interfering with the patient's ambulation.

It is often desirable, however, in order to insure maintenance of optimum aseptic conditions, to have the fluid-

collecting pump unit detached from the system and replaced with a new sterile pump unit at least every twenty-four hours. Since stagnant accumulations of blood and other body fluids afford the ideal environment for bacterial growth, such procedure serves to control bacterial population within the system and thus insures operation of the device under conditions minimizing the possibility of wound contamination. Moreover, by having the detached pump unit submitted to the laboratory for bacterial analysis of the collected wound exudate, such procedure can also serve to periodically monitor the development of any bacterial infection in the wound, thereby enabling early administration of suitable antibiotics. Due to the relatively low cost of the fluid-collecting pump unit employed with the suction drainage device of the present invention, such periodic replacement of the pump unit permits optimum aseptic conditions to be maintained without materially adding to the over-all cost of the device.

The components of the suction drainage device of the present invention are preferably packaged in easy-to-assemble, pre-sterilized kit form. Thus, one or more fluid-collecting pump units, together with all the necessary accessories, including tubing, needle, check valve and adaptors, may all be compactly packaged in a suitable wrapping, sterilized, and then stocked in sterile, ready-to-use form.

The suction drainage device of the present invention may also be used in conjunction with other suction means and/or other collector means, particularly during the early stages of the draining period immediately following the operation when the drainage is most heavy and the patient is not yet ready for ambulation. Thus, an intermediate collector sufficiently rigid to withstand being collapsed by the suction force, may be connected in the system, as for example, between the connecting tube and the drainage tube, in such a manner that the body fluids will be collected in the intermediate collector instead of passing into the pump unit. When the heavy drainage has subsided, the intermediate collector may be disconnected from the system and further drainage collected in the pump unit in the manner previously described. Furthermore, until the patient is ready for ambulation, a conventional suction pump may be connected to the system by means of suitable tubing connected to the tubular member at the outlet opening of the fluid-collecting pump unit. While so connected, the conventional suction pump may be operated as the primary source of suction, with the activated pump unit of this invention serving as a secondary source of suction in the event of mechanical failure of the conventional pump or the need for temporary disconnection of the conventional pump. When the patient is ready for ambulation, the conventional suction pump may be disconnected from the system and the device permitted to operate in the manner previously described.

Although the suction drainage device of the present invention has been described primarily with regard to its application in the post-operative drainage of serosanguineous fluids from closed surgical wounds, the device may also be employed in other surgical drainage applications. For example, the device may be used to provide suction drainage in connection with irrigation or closed circulation of antibiotics in the treatment of osteomyelitis or contaminated or potentially infected wounds. Furthermore, the device may be used in the surgical puncture or tapping of body cavities, such as, for example, in thoracentesis or abdominal paracentesis. In this latter application, a suitable rigid tubular needle, may be connected directly to the tubular connector member at the inlet opening of the container, without any flexible connecting tubing, and, after activation of the pump unit, the body cavity may then be punctured with the needle. The body fluids will then be drawn from the cavity through the tubular needle into the container.

From the foregoing, it is readily apparent that the present invention provides a highly efficient portable sterile suction drainage device including a fluid-collecting pump unit which is sufficiently lightweight and compact as to enable its convenient attachment to the patient's body so as not to interfere with the patient's ambulation, and which is sufficiently simple in construction and inexpensive to manufacture as to economically enable the device to be employed under optimum aseptic conditions and to be disposed of after a single use. While there is shown and described herein preferred forms of the invention for purposes of illustration, it will be understood by those skilled in the art that various changes and modifications might be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

We claim:

1. In a suction drainage device for extraction and collection of body fluids from wounds defined by a collapsible container having walls formed of air-impermeable material with an inlet opening in one of said walls and a conduit of tubing having its distal end adapted to be inserted into a body wound and its proximal end connected to said container in fluid-tight relation therewith and in operative communication with the interior of said container through said inlet opening, the improvement in combination therewith comprising a resiliently compressible open cell foam pad encased within said container and exerting a separating force on said container walls tending to maintain said container in a normally expanded position, said container being adapted to expel air and assume a collapsed position upon being subjected to external pressure compressing said foam pad and to develop an internal negative pressure while being expanded by the resilient force of said foam pad against said container walls after release of said external pressure, whereby when said foam pad is compressed and then allowed to expand with said distal end of the tubing inserted in a body wound, said negative pressure developed within said container will cause body fluids to be drawn from said wound through said tubing toward said container.

2. The suction drainage device of claim 1 wherein said inlet opening is one of two openings in the walls of said container, said container being air-tight except for said openings, the second of said openings being an outlet opening provided with releasable closure means.

3. The suction drainage device of claim 1 including at least one check valve disposed between said tubing and said inlet opening of said container to prevent fluid from flowing into said tubing toward said wound.

4. The suction drainage device of claim 3 wherein said check valve is detachably connected to said container.

5. The suction drainage device of claim 3 wherein said check valve is anchored to said container at said inlet opening to prevent fluid from flowing out of said container through said inlet opening, said container also having an outlet opening provided with releasable closure means.

6. The suction drainage device of claim 5 wherein said check valve anchored to said container is one of two check valves disposed between said tubing and said inlet opening of said container, the second of said check valves being detachably connected to said container.

7. The suction drainage device of claim 1 wherein said container is provided with means for attachment to a support for said container.

8. The suction drainage device of claim 7 wherein said means for attachment is a strap member secured to the outer surface of said container walls.

9. The suction drainage device of claim 1 wherein said tubing is provided with a plurality of apertures at its distal end.

10. The suction drainage device of claim 1 wherein said tubing is branched at its distal end so as to provide

a plurality of tubes adapted to be inserted into the body wound.

11. The suction drainage device of claim 1 wherein said conduit of tubing comprises a flexible connecting tube of larger diameter having its proximal end connected to said container, at least one flexible drainage tube of smaller diameter having its distal end adapted to be inserted into a body wound, and an adapter means connecting the distal end of said connecting tube to the proximal end of each of said drainage tubes.

12. The suction drainage device of claim 11 wherein said adapter means includes a main body portion adapted to engage the distal end of said connecting tube in fluid-tight relation, two branches each interconnecting with said main body portion and adapted to engage the proximal end of said drainage tube in fluid-tight relation, and releasable closure means integrally attached to said adapter means and adapted to close either one of said two branches.

13. A combination pump and fluid collector comprising a collapsible container having walls formed of an air-impermeable non-cellular flexible skin, one of said walls having an inlet opening with means at said inlet opening for enabling connection between the interior of said container and a source of fluid to be collected, and a resiliently compressible open-cell foam pad integral with said flexible skin encased within said container and exerting a separating force on said container walls tending to maintain said container in a normally expanded position, said container being adapted to expel air and assume a collapsed position upon being subjected to external pressure compressing said foam pad and to develop an internal negative pressure while being expanded by the resilient force of said foam pad against said container walls after release of said external pressure.

14. A combination pump and fluid collector comprising a collapsible container having walls formed of air-impermeable material and having an inlet opening in one of said walls, means at said inlet opening for enabling connection between the interior of said container and a source of fluid to be collected, and a resiliently compressible open-cell foam pad encased within said container and exerting a separating force on said container walls tending to maintain said container in a normally expanded position, said foam pad consisting of a composite structure comprising an open-cell foam material and a flexible absorbent filler material, said filler material being more highly absorbent than said foam material, said container being adapted to expel air and assume a collapsed position upon being subjected to external pressure compressing said foam pad and to develop an internal negative pressure while being expanded by the resilient force of said foam pad against said container walls after release of said external pressure.

15. A combination pump and fluid collector comprising a collapsible container having walls formed of air-impermeable material and having an inlet opening in one of said walls, means at said inlet opening for enabling connection between the interior of said container and a source of fluid to be collected, and a resiliently compressible open-cell foam pad encased within said container and exerting a separating force on said container walls tending to maintain said container in a normally expanded position, said foam pad being sealed within a fluid permeable flexible covering sheet within said container, said covering sheet presenting at least a partial barrier to direct contact between said foam pad and said container walls, said container being adapted to expel air and assume a collapsed position upon being subjected to external pressure compressing said foam pad and to develop an internal negative pressure while being expanded by the resilient force of said foam pad against said container walls after release of said external pressure.

16. A combination pump and fluid collector comprising a collapsible container having walls formed of air im-

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permeable material and having an inlet opening in one of said walls, means at said inlet opening for enabling connection between the interior of said container and a source of fluid to be collected, and a resiliently compressible open-cell foam pad encased within said container and exerting a separating force on said container walls tending to maintain said container in a normally expanded position, the interior of said container including two inter-connecting chambers, one of said chambers containing said foam pad and said inlet opening and being adapted to discharge the liquid contents thereof into the second of said chambers, the second of said chambers being provided with means for measuring the quantity of liquid discharged thereinto, said container being adapted to expel air and assume a collapsed position upon being subjected to external pressure compressing said foam pad and to develop an internal negative pressure while being ex-

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panded by the resilient force of said foam pad against said container walls after release of said external pressure.

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CHARLES F. ROSENBAUM, Primary Examiner

Notice of Adverse Decision in Interference

In Interference No. 97,872, involving Patent No. 3,572,340, J. K. Lloyd and P. H. Darling, SUCTION DRAINAGE DEVICE, final judgment adverse to the patentees was rendered May 16, 1974, as to claims 1, 2, 7, 8 and 9.
[*Official Gazette October 1, 1974.*]