



(51) International Patent Classification:
A61M 1/00 (2006.01)

(21) International Application Number:
PCT/US2009/046580

(22) International Filing Date:
8 June 2009 (08.06.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/475,954 1 June 2009 (01.06.2009) US

(71) Applicant (for all designated States except US): **TYCO HEALTHCARE GROUP LP** [US/US]; 15 Hampshire Street, Mansfield, MA 02048 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BRAGA, Richard, M.** [US/US]; 7 Parkview Circle, North Easton, MA 02356 (US). **VESS, Mark, A.** [US/US]; 303 High Street, Hanson, MA 02341 (US). **SWISHER, David, R.** [US/US]; 372 Clarendon Lane, St. Charles, MO 63301 (US). **SHAH, Chirag, B.** [US/US]; 71 Achilles Way, North Attleboro, MA 02763 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SYSTEM FOR PROVIDING CONTINUAL DRAINAGE IN NEGATIVE PRESSURE WOUND THERAPY

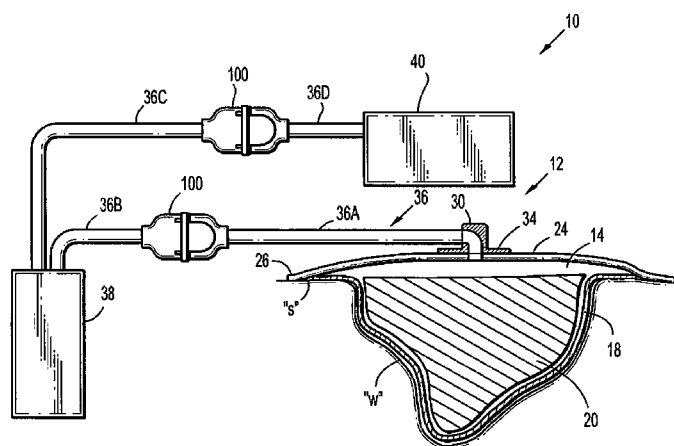


FIG. 1

(57) Abstract: A system for subatmospheric pressure therapy in connection with healing a wound is provided. The system includes a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system further includes an exudate conduit in fluid communication with the wound dressing and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum source and a vent conduit in fluid communication with the collection canister and the wound dressing for introducing air into the reservoir to facilitate flow of exudate through the exudate conduit.

**SYSTEM FOR PROVIDING CONTINUAL DRAINAGE
IN NEGATIVE PRESSURE WOUND THERAPY**

BACKGROUND

1. **Technical Field**

[0001] The present disclosure relates generally to treating a wound with negative or reduced pressure. In particular, the disclosure relates to a system for providing continual drainage of fluids from a wound site to a collection canister.

2. **Background of Related Art**

[0002] Various techniques to promote healing of a wound involve providing suction to the wound. For example, a vacuum source may serve to carry wound exudates away from the wound, which may otherwise harbor bacteria that inhibit the body's natural healing process. One particular technique for promoting the body's natural healing process may be described as negative pressure wound therapy (NPWT). This technique involves the application of a reduced pressure, e.g. sub-atmospheric, to a localized reservoir over a wound. Sub-atmospheric pressure has been found to assist in closing the wound by promoting blood flow to the area, thereby stimulating the formation of granulation tissue and the migration of healthy tissue over the wound. This technique has proven effective for chronic or non-healing wounds, but has also been used for other purposes such as post-operative wound care.

[0003] The general NPWT protocol provides for covering the wound with a flexible cover layer such as a polymeric film, for example, to establish a vacuum reservoir over the

wound where a reduced pressure may be applied by individual or cyclic evacuation procedures. To allow the reduced pressure to be maintained over time, the cover layer may include an adhesive periphery that forms a substantially fluid tight seal with the healthy skin surrounding the wound.

[0004] Although some procedures may employ a micro-pump contained within the vacuum reservoir, most NPWT treatments apply a reduced pressure using an external vacuum source. Fluid communication must therefore be established between the reservoir and the vacuum source. To this end, a fluid port is coupled to the cover layer to provide an interface for an exudate conduit extending from the external vacuum source. Fluid being drained from the reservoir through the exudate conduit tends to stagnate with slow fluid buildup. This stagnation results in interrupted and/or incomplete fluid drainage. Accordingly, it would be beneficial to have a negative pressure wound therapy system that included a controlled or fixed “leak” to provide for continuous and/or complete fluid drainage.

SUMMARY

[0005] A system for subatmospheric pressure therapy in connection with healing a wound is provided. The system includes a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system further includes an exudate conduit in fluid communication with the wound dressing and the collection canister for collecting exudate

removed from the reservoir and deposited in the collection canister under influence of the vacuum source and a vent conduit in fluid communication with the collection canister and the wound dressing for introducing air into the reservoir to facilitate flow of exudate through the exudate conduit.

[0006] The vent conduit may define an internal dimension less than a corresponding internal dimension of the exudate conduit. The exudate conduit and the vent conduit may include independent tube segments, or instead may include integral tube segments. A filter may be in fluid communication with the vent conduit. The filter includes a hydrophobic material. The filter may instead or additionally include a bacterial filter.

[0007] Also provided is a system for subatmospheric pressure therapy in connection with healing a wound including a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system further includes an exudate conduit in fluid communication with the wound dressing and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum source and a vent mounted to the wound dressing, the vent being selectively movable between a closed position and an open position, the vent permitting ingress of air within the reservoir when in the open position.

[0008] The vent may include a flap mounted to the wound dressing cover, the flap being movable between the closed position and the open position. The flap may be releasably securable in the closed position with an adhesive. A filter membrane may be mounted adjacent the flap. The filter membrane may include a hydrophobic material. The filter membrane may instead or additionally include a bacterial filter.

[0009] Additionally, provided is a system for subatmospheric pressure therapy in connection with healing a wound including a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system further includes an exudate conduit in fluid communication with the wound dressing and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum source and a filtered air vent mounted to the wound dressing cover, the filtered air vent adapted to permit ingress of air within the reservoir to facilitate flow of exudate through the exudate conduit.

[0010] Additionally, provided is a system for subatmospheric pressure therapy in connection with healing a wound including a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid

communication with the vacuum source. The system also includes a wound port operatively connected to the wound dressing in fluid communication with the reservoir. The wound port includes a vacuum port and at least one tube piercing through the wound port into the reservoir, the tube being operable to allow ambient air into the reservoir. The system further includes an exudate conduit in fluid communication with the wound port and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum.

[0011] Additionally, provided is a system for subatmospheric pressure therapy in connection with healing a wound including a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system also includes a wound port operatively connected to the wound dressing in fluid communication with the reservoir. The wound port includes a vacuum port and a plurality of holes arranged circumferentially around the wound port, the plurality of holes being operable to allow ambient air into the reservoir. The system further includes an exudate conduit in fluid communication with the wound port and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum.

[0012] Additionally, provided is a system for subatmospheric pressure therapy in connection with healing a wound including a wound dressing cover dimensioned for positioning

relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system also includes a wound port operatively connected to the wound dressing in fluid communication with the reservoir. The wound port includes a vacuum port and an orifice being operable to allow ambient air into the reservoir. The system further includes an exudate conduit in fluid communication with the wound port and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum.

[0013] Additionally, provided is a system for subatmospheric pressure therapy in connection with healing a wound including a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained, a subatmospheric pressure mechanism including, a housing, a vacuum source disposed in the housing, and a collection canister in fluid communication with the vacuum source. The system also includes a wound port operatively connected to the wound dressing in fluid communication with the reservoir. The system further includes an exudate conduit in fluid communication with the wound port and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum. The exudate conduit has a first conduit for providing a pathway for the exudate between the reservoir and the collection canister and a second conduit in fluid communication with ambient atmosphere and the wound dressing for introducing air into the reservoir to facilitate flow of exudate through the exudate conduit.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present disclosure and, together with the detailed description of the embodiments given below, serve to explain the principles of the disclosure.

[0015] FIG. 1 depicts an embodiment of a NPWT system in accordance with the present disclosure;

[0016] FIG. 2 depicts an embodiment of an NPWT treatment apparatus including a vent conduit;

[0017] FIG. 3A is a partial cross sectional view of the conduits of the NPWT treatment apparatus of FIGS. 1 and 2 connected in an alternate configuration;

[0018] FIG. 3B is a partial cross sectional view of an alternative embodiment of the fluid port of FIGS. 1 and 2;

[0019] FIG. 4 is a cross sectional view of an alternative embodiment of the wound dressing in accordance with the present disclosure;

[0020] FIGS. 5A and 5B depict alternative embodiments of the wound dressing in accordance with the present disclosure;

[0021] FIGS. 6A and 6B depict alternative embodiments of the wound dressing in accordance with the present disclosure;

[0022] FIGS. 7A and 7B depict alternative embodiments of the wound dressing in accordance with the present disclosure;

[0023] FIGS. 8A and 8B depict alternative embodiments of the wound dressing in accordance with the present disclosure;

[0024] FIG. 9 depicts an alternative embodiment of the wound port in accordance with the present disclosure;

[0025] FIGS. 10A and 10B depict alternative embodiments of the wound port in accordance with the present disclosure; and

[0026] FIGS. 11A-11D depict alternative embodiments of the wound port in accordance with the present disclosure.

DETAILED DESCRIPTION OF EMBODIMENTS

[0027] Various embodiments of the present disclosure provide negative pressure wound therapy systems (or apparatus) including a collection canister having a chamber to collect wound fluids. Embodiments of the presently disclosed negative pressure wound therapy systems are generally suitable for use in applying negative pressure to a wound to facilitate healing of the wound in accordance with various treatment modalities. Embodiments of the presently disclosed negative pressure wound therapy systems are entirely portable and may be worn or carried by the user such that the user may be completely ambulatory during the therapy period. Embodiments of the presently disclosed negative pressure wound therapy apparatus and components thereof may be entirely reusable or may be entirely disposable after a predetermined period of use or

may be individually disposable whereby some of the components are reused for a subsequent therapy application.

[0028] Hereinafter, embodiments of the presently disclosed negative pressure wound therapy systems and embodiments of the presently disclosed sensors for use in negative pressure wound therapy systems will be described with reference to the accompanying drawings. Like reference numerals may refer to similar or identical elements throughout the description of the figures. As used herein, "wound exudate", or, simply, "exudate", generally refers to any fluid output from a wound, e.g., blood, serum, and/or pus, etc. As used herein, "fluid" generally refers to a liquid, a gas or both.

[0029] Referring to FIG. 1, a NPWT apparatus according to an embodiment of the present disclosure is depicted generally as 10 for use on a wound bed "w" surrounded by healthy skin "s". Negative pressure wound therapy apparatus 10 includes a wound dressing 12 positioned relative to the wound bed "w" to define a vacuum chamber 14 about the wound bed "w" to maintain negative pressure at the wound area. Wound dressing 12 includes a contact layer 18, a wound filler 20 and a wound cover 24.

[0030] Contact layer 18 is intended for placement within the wound bed "w" and may be relatively non-supportive or flexible to substantially conform to the topography of the wound bed "w". A variety of materials may be used for the contact layer 18. Contact layer 18 selection may depend on various factors such as the patient's condition, the condition of the periwound skin, the amount of exudate and/or the condition of the wound bed "w". Contact layer 18 may be formed from perforated film material. The porous characteristic of the contact layer 18

permits exudate to pass from the wound bed “w” through the contact layer 18. Passage of wound exudate through the contact layer 18 may be substantially unidirectional such that exudate does not tend to flow back into the wound bed “w”. Unidirectional flow may be encouraged by directional apertures, e.g., apertures positioned at peaks of undulations or cone-shaped formations protruding from the contact layer 18. Unidirectional flow may also be encouraged by laminating the contact layer 18 with materials having absorption properties differing from those of the contact layer 18, or by selection of materials that promote directional flow. A non-adherent material may be selected for forming the contact layer 18 such that the contact layer 18 does not tend to cling to the wound bed “w” or surrounding tissue when it is removed. One example of a material that may be suitable for use as a contact layer 18 is commercially available under the trademark XEROFLOW® offered by Tyco Healthcare Group LP (d/b/a Covidien). Another example of a material that may be suitable for use as the contact layer 18 is the commercially available CURITY® non-adherent dressing offered by Tyco Healthcare Group LP (d/b/a Covidien).

[0031] Wound filler 20 is positioned in the wound bed “w” over the contact layer 18 and is intended to transfer wound exudate. Wound filler 20 is conformable to assume the shape of any wound bed “w” and may be packed up to any level, e.g., up to the level of healthy skin “s” or to overfill the wound such that wound filler 20 protrudes over healthy skin “s”. Wound filler 20 may be treated with agents such as polyhexamethylene biguanide (PHMB) to decrease the incidence of infection and/or other medicaments to promote wound healing. A variety of materials may be used for the wound filler 20. An example of a material that may be suitable for

use as the wound filler 20 is the antimicrobial dressing commercially available under the trademark KERLIX™ AMD™ offered by Tyco Healthcare Group LP (d/b/a Covidien).

[0032] Cover layer 24 may be formed of a flexible membrane, e.g., a polymeric or elastomeric film, which may include a biocompatible adhesive on at least a portion of the cover layer 24, e.g., at the periphery 26 of the cover layer 24. Alternately, the cover layer 24 may be a substantially rigid member. Cover layer 24 may be positioned over the wound bed “w” such that a substantially continuous band of a biocompatible adhesive at the periphery 26 of the cover layer 24 forms a substantially fluid-tight seal with the surrounding skin “s”. An example of a material that may be suitable for use as the cover layer 24 is commercially available under the trademark CURAFORM ISLAND® offered by Tyco Healthcare Group LP (d/b/a Covidien).

[0033] Cover layer 24 may act as both a microbial barrier and a fluid barrier to prevent contaminants from entering the wound bed “w” and to help maintain the integrity thereof.

[0034] In one embodiment, the cover layer 24 is formed from a moisture vapor permeable membrane, e.g., to promote the exchange of oxygen and moisture between the wound bed “w” and the atmosphere. An example of a membrane that may provide a suitable moisture vapor transmission rate (MVTR) is a transparent membrane commercially available under the trade name POLYSKIN® II offered by Tyco Healthcare Group LP (d/b/a Covidien). A transparent membrane may help to permit a visual assessment of wound conditions to be made without requiring removal of the cover layer 24.

[0035] Wound dressing 12 may include a vacuum port 30 having a flange 34 to facilitate connection of the vacuum chamber 14 to a vacuum system. Vacuum port 30 may be configured

as a rigid or flexible, low-profile component and may be adapted to receive a conduit 36 in a releasable and fluid-tight manner. An adhesive on at least a portion of the underside of the flange 34 may be used to provide a mechanism for affixing the vacuum port 30 to the cover layer 24. The relative positions, size and/or shape of the vacuum port 30 and the flange 34 may be varied from an embodiment depicted in FIG. 1. For example, the flange 34 may be positioned within the vacuum chamber 14 such that an adhesive on at least a portion of an upper side surface of the flange 34 affixes the vacuum port 30 to the cover layer 24. A hollow interior portion of the vacuum port 30 provides fluid communication between the conduit 36 and the vacuum chamber 14. Conduit 36 extends from the vacuum port 30 to provide fluid communication between the vacuum chamber 14 and the vacuum source 40. Alternately, the vacuum port 30 may not be included in the dressing 12 if other provisions are made for providing fluid communication with the conduit 36.

[0036] Any suitable conduit may be used for the conduit 36, including conduit fabricated from flexible elastomeric or polymeric materials. In the negative pressure wound therapy apparatus 10 illustrated in FIG. 1, the conduit 36 includes a first conduit section 36A, a second conduit section 36B, a third conduit section 36C and a fourth conduit section 36D. The first conduit section 36A extends from the vacuum port 30 and is coupled via a fluid line coupling 100 to the second conduit section 36B, which extends to the collection canister 38. The third conduit section 36C extends from the collection canister 38 and is coupled via another fluid line coupling 100 to the fourth conduit section 36D, which extends to the vacuum source 40. The shape, size and/or number of conduit sections of the conduit 36 may be varied from the first, second, third and fourth conduit sections 36A, 36B, 36C and 36D depicted in FIG. 1.

[0037] The first, second, third and fourth conduit sections 36A, 36B, 36C and 36D of the conduit 36 may be connected to components of the apparatus 10 by conventional air-tight means, such as, for example, friction fit, bayonet coupling, or barbed connectors. The connections may be made permanent. Alternately, a quick-disconnect or other releasable connection means may be used to provide some adjustment flexibility to the apparatus 10.

[0038] Collection canister 38 may be formed of any type of container that is suitable for containing wound fluids. For example, a semi-rigid plastic bottle may be used for the collection canister 38. A flexible polymeric pouch or other hollow container body may be used for the collection canister 38. Collection canister 38 may contain an absorbent material to consolidate or contain the wound fluids or debris. For example, super absorbent polymers (SAP), silica gel, sodium polyacrylate, potassium polyacrylamide or related compounds may be provided within collection canister 38. At least a portion of canister 38 may be transparent or semi-transparent, e.g., to permit a visual assessment of the wound exudate to assist in evaluating the color, quality and/or quantity of exudate. A transparent or semi-transparent portion of the collection canister 38 may permit a visual assessment to assist in determining the remaining capacity or open volume of the canister and/or may assist in determining whether to replace the collection canister 38.

[0039] The collection canister 38 is in fluid communication with the wound dressing 12 via the first and second conduit sections 36A, 36B. The third and fourth conduit sections 36C, 36D connect the collection canister 38 to the vacuum source 40 that generates or otherwise provides a negative pressure to the collection canister 38. Vacuum source 40 may include a

peristaltic pump, a diaphragmatic pump or other suitable mechanism. Vacuum source 40 may be a miniature pump or micropump that may be biocompatible and adapted to maintain or draw adequate and therapeutic vacuum levels. The vacuum level of subatmospheric pressure achieved may be in the range of about 20 mmHg to about 500 mmHg. In embodiments, the vacuum level may be about 75 mmHg to about 125 mmHg, or about 40 mmHg to about 80 mmHg. One example of a peristaltic pump that may be used as the vacuum source 40 is the commercially available Kangaroo PET Eternal Feeding Pump offered by Tyco Healthcare Group LP (d/b/a Covidien). Vacuum source 40 may be actuated by an actuator (not shown) which may be any means known by those skilled in the art, including, for example, alternating current (AC) motors, direct current (DC) motors, voice coil actuators, solenoids, and the like. The actuator may be incorporated within the vacuum source 40.

[0040] In embodiments, the negative pressure wound therapy apparatus 10 includes one or more fluid line couplings 100 that allow for selectable coupling and decoupling of conduit sections. For example, a fluid line coupling 100 may be used to maintain fluid communication between the first and second conduit sections 36A, 36B when engaged, and may interrupt fluid flow between the first and second conduit sections 36A, 36B when disengaged. Thus, fluid line coupling 100 may facilitate the connection, disconnection or maintenance of components of the negative pressure wound therapy apparatus 10, including the replacement of the collection canister 38. Additional or alternate placement of one or more fluid line couplings 100 at any location in line with the conduit 36 may facilitate other procedures. For example, the placement of a fluid line coupling 100 between the third and fourth conduit sections 36C, 36D, as depicted in FIG. 1, may facilitate servicing of the vacuum source 40.

[0041] Referring to FIG. 2, an NPWT apparatus similar to the NPWT apparatus of FIG. 1 is depicted generally as 10 for use on a wound “w” surrounded by healthy skin “s.” The NPWT apparatus 10 of FIG. 2 includes a vent conduit 37 that extends from between contact layer 18 and cover layer 22 of wound dressing 12 to collection canister 38. Vent conduit 37 may be integral formed with wound dressing 12. Alternatively, vent conduit 37 may be inserted between contact layer 18 and cover layer 22 by a clinician during application of the wound dressing 12, or may have been previously inserted therebetween prior to application. Vent conduit 37 may be releasably connected to the collection canister 38 by conventional air-tight means such as friction fit, bayonet coupling, or barbed connectors.

[0042] Vent conduit 37 is configured to provide a low flow of air from the reservoir 14 to the collection canister 38. Vent conduit 37 includes a smaller diameter than exudate conduit 36 and may be formed of any suitable conduit including those fabricated from flexible elastomeric or polymeric materials. An air filter 39 positioned along the air flow path filters the air flowing from collection canister 38 to remove any impurities, including bacteria and other infectious material. Filter 39 may include a hydrophobic material to prevent wetting.

[0043] In operation, wound dressing 12 is placed adjacent a wound “w” with the vent conduit 37 extending from between the contact layer 18 and the cover layer 22. If the vent conduit 37 is not integral formed with the wound dressing 12, the clinician may be required to position the vent conduit 37 between the layers during application of the wound dressing 12. Vacuum source 50 is then activated to produce a sub-atmospheric pressure in the reservoir 14 of the wound dressing 12. Fluid from the reservoir 14 is drawn through aperture 24 in cover layer

22, into fluid port 30 and along exudate conduit 36 to be deposited in collection canister 40. As fluid and other exudates are drawn through exudate conduit 36, filtered air is received within the reservoir 14 of the wound dressing 12 through the vent conduit 37. The low flow filtered air flowing from the collection canister 38 through the vent conduit 37, in combination with the high flow drainage occurring through exudate conduit 36, creates a sump action between the reservoir 14 and the collection canister 40. This sump action ensures continuous flow through exudate conduit 36, thereby preventing fluid stagnation and its complications. Because of capillary action, fluid from reservoir 14 only flows through the larger diameter exudate conduit 36.

[0044] With reference now to FIG. 3A, in an alternative embodiment of the present disclosure, a wound dressing 112 is substantially similar to wound dressing 12 described hereinabove, and will only be described as relates to the differences therebetween. Wound dressing 112 includes a cover layer 122 having a first or fluid aperture 124 and a second or vent aperture 125. A fluid port 130 is in fluid communication with fluid aperture 124 and is configured for operable engagement with exudate conduit 136. A vent port 131 is in fluid communication with vent aperture 125 and is configured for operable engagement with vent conduit 137. Fluid and vent ports 130, 131 may be affixed to cover layer 122 in any suitable manner. Each of fluid and vent port 130, 131 are in fluid communication with collection canister 38 (FIGS. 1 and 2).

[0045] Wound dressing 112 operates in substantially the same manner as wound dressing 12. When connected to collection canister 40 and the vacuum source 50 is activated, the sub-atmospheric pressure produced by the vacuum source 50 creates a suction that draws fluid from

the reservoir 114. Vent conduit 137 provides the reservoir 114 with a low flow of filtered air to ensure continuous fluid flow through the exudate conduit 136.

[0046] Turning now to FIG. 3B, in another embodiment, wound dressing 212 is substantially similar to the wound dressings 12, 112 described hereinabove. Wound dressing 212 includes a cover layer 222 having a first and second aperture 224, 225. Positioned adjacent first and second apertures 224, 225 is a fluid/vent port 230. Port 230 is configured to fluidly communicate first aperture 224 of wound dressing 212 with collection canister 38 (FIGS. 1 and 2) via exudate conduit 236. Port 230 is further configured to fluidly communicate second aperture 225 of wound dressing 212 with collection canister 40 via vent conduit 237. As discussed above, the difference in size between exudate conduit 236 and vent conduit 237 results in capillary action that causes fluid to flow only through the larger exudate conduit 36.

[0047] With reference now to FIG. 4, in yet another embodiment, a wound dressing 312 similar to those described above including a vent assembly 340 formed in a cover layer 322. Vent assembly 340 includes a filter member 342 and a flap or cover member 344. Filter member 342 may be integrally formed with, or otherwise affixed to, the cover layer 322. In one embodiment, filter member 342 is secured to the cover layer 322 with an adhesive. Filter member 342 is configured to provide reservoir 314 of wound dressing 312 with filtered air. To prevent wetting, the filter member 342 may be hydrophobic. Filter member 342 may be sized depending on the desired flow therethrough. A larger filter member 342 would provide a greater amount of airflow; however, if the filter member 342 is too large, it may reduce the effectiveness of the NWPT.

[0048] Flap 344 may be integrally formed with cover layer 322. Alternatively, flap 344 may be releasably secured over filter member 342. Flap 344 may be attached to or separable from cover member 322. Flap 344 may be configured to selectively partially or completely uncover filter member 342. In this manner, a clinician may affect the flow of air into the reservoir 314. Although shown including flap 344, it is envisioned that wound dressing 312 may be provided with filter member 342 exposed.

[0049] In use, wound dressing 312 is applied to a wound “w” in a conventional manner. Activation of the vacuum source 40 (FIGS. 1 and 2) initiates drainage from reservoir 314 of wound dressing 312. At any time prior to or during the drainage process, flap 344 may be partially or complete pulled back to expose filter member 342. As described above, the more of filter member 342 that is exposed, the greater the possible airflow into reservoir 14. The airflow provided to reservoir 14 through filter member 342 acts in a manner similar to the sump action described above. In this manner, vent assembly 340 permits continuous fluid flow through exudate conduit 336, thereby preventing fluid stagnation and its complications.

[0050] With reference to FIGS. 5A and 5B, in yet another embodiment, a wound port 500 is shown. Wound port 500 is suitable for use with the above described wound dressings. Wound port 500 has a plastic cover 510 which includes a vacuum port 512. In addition to the vacuum port 512, the plastic cover 510 has tube 520. Tube 520 may be made of a small-bore stainless steel or rigid plastic. Tube 520 is used to provide a controlled or fixed leak by admitting air into the wound dressing. Tube 520 can be arranged to allow the insertion of tube 520 into the wound port 500 so that depth adjustment and placement within the wound packing

material is possible as indicated by the arrows in FIGS. 5A and 5B. As such, air can be injected into the wound packing material to direct movement of excess exudate toward the vacuum port and out of the wound. Tube 520 may have a valve (not shown) to adjust the flow rate of air into the wound bed. The valve may be a small needle valve that can be attached to the tube 520 to allow for infinite adjustment of air flow into the wound dressing.

[0051] The end of tube 520 that may be exposed to ambient atmosphere or to a source of air may include a filter 522. Filter 522 may be a q-tip like air filter to prevent clogging of the tube and also prevent dirt and other contaminants from entering the wound site. Alternatively, filter 522 may include a charcoal filter to prevent odor, a hydrophobic filter, or any sintered or porous material. The tip of tube 520 that is inserted into the wound packing material may be equipped with a puncturing tip 524 to allow for easier insertion into the wound packing material.

[0052] With reference to FIGS. 6A and 6B, in yet another embodiment, a wound port 600 is shown. As shown in FIG. 6A, wound port 600 has tube 610 in separate locations around a circumference of the wound port 600. Each tube may include a punctured tip or a filter as described above. As shown in FIG. 6B, the distance "a" between tube 610 and tube 612 may be one distance and the distance "b" between tube 610 and 614 may be a distance different the distance "a". On the other hand, the difference between each tube may be similar as in the distance "c" between tube 620 and 622 and tube 620 and 624. Although FIGS. 6A and 6B show a specific number of tubes, any number of tubes may be arranged outside a circumference of the wound port 600.

[0053] With reference to FIGS. 7A and 7B, in yet another embodiment, a wound port 700 is shown having a tube 710 which is similar to the tubes described above. Tube 710 may be slightly larger in diameter to allow for fluids to enter the wound site. The fluids may include a solution to flush the wound such as saline or it may be an anesthetic to anesthetize the wound area. Tube 710 may be fitted with valve 712 to open and close the pathway into the wound site. Additionally, the end of tube 710 may be fitted with a luer connector 714 to create a fluid tight connection with additional tubing, syringes, or any other conduits. Alternatively, instead of a valve, a plug (not shown) could be used to close the luer connector. With reference to FIG. 7B, a hypodermic needle 716 may be inserted into tube 710. Hypodermic needle 716 could be used to deliver a solution to a specific area of the wound or it could be used to obtain a sample of blood, exudate or tissue from the wound site.

[0054] With reference to FIGS. 8A and 8B, in yet another embodiment, a wound port 800 is shown. Instead of using tubes as described above to allow a controlled or fixed leak, a number of small holes arranged in a circumference around the wound port 800 may be provided. The holes may take the form of a simple puncture 810 of a given size as shown in FIG. 8A. Alternatively, the holes 822 may be formed in a plate 820 that is radio frequency (RF) welded to the wound port 800.

[0055] With reference to FIG. 9, in yet another embodiment, a cross section of wound port 900 is shown. Wound port 900 is operatively connected to wound dressing 910 and includes a flange 912. Flange 912 may have a circular or any polygonal shape. A body 914 is connected to the flange 912 which is fluidly connected to conduit 916. Conduit 916 leads

directly or indirectly to the collection canister. Body **914** has as small orifice **920** used to provide a controlled leak into the wound site. The diameter of the orifice **920** and the pressure difference between the outside of the wound port **900** and the inside of the wound port **90** create a controllable air leak into the wound port **900** via the orifice. The small orifice **920** can be created in various ways. The orifice **920** can be integral to the port design, such as a molded in feature. It can be created via post molding micro-piercing into the port using a needle or syringe. Alternatively, assembly or insertion of a small tube that allows for communication of air from outside the wound port **900** to inside the wound port **900** can be used to create the orifice **920**.

[0056] With reference to FIGS. 10A and 10B, in yet another embodiment, a wound port **1000** is shown. Wound port **1000** is operatively connected to wound dressing **1010** and includes a flange **1012**. Flange **1012** may have a circular or any polygonal shape. A body **1014** is connected to the flange **1012** which is fluidly connected to conduit **1016**. Conduit **1016** leads directly or indirectly to the collection canister. Conduit **1016** includes a main lumen **1110** used to provide a pathway for exudate between the wound “w” and the collection canister. A secondary lumen or vent lumen is provided in conduit **1016** to provide a controlled leak to the wound site. Exudate enters lumen **1110** at area **1114** and air exits lumen **1112** at area **1116**. Secondary lumen **1112** is exposed to the ambient environment or to a source of air to provide a controlled leak in the wound port **1000**. Although FIG. 10B depicts lumens **1110** and **1112** in a single conduit **1016**, lumens **1110** and **1112** can be provided as separate conduits.

[0057] With reference to FIG. 11A, in yet another embodiment, a wound dressing **1200** is shown having a wound port **1210**. Wound dressing **1200** and wound port **1210** are similar to wound dressing **12**, **112**, and **212** and wound port **1210** are similar to wound port **30**, **130** and

230 described hereinabove. A vent conduit 1220 may be inserted into the top of wound port 1210 to provide a source of filtered air into the wound dressing 1200 through the vent conduit 1220. Vent conduit 1220 may be a stainless steel needle having a lumen extending through the needle. The end of vent conduit 1220 has filter 1225 to filter the air from the ambient atmosphere. The low flow filtered air flowing from the ambient atmosphere through the vent conduit 1220, in combination with the high flow drainage occurring through an exudate conduit, creates a sump action between the wound and a collection canister. This sump action ensures continuous flow through exudate conduit 36, thereby preventing fluid stagnation and its complications. As discussed above, the difference in size between exudate conduit and vent conduit 1220 results in capillary action that causes fluid to flow only through the larger exudate conduit. FIGS 11B-11D depict a wound port 1210 similar to the wound port in FIG. 11A. In FIGS 11B-11D, the vent conduit 1220 is placed on the side of the wound port 1210 rather than the top of the wound port 1210 as shown in FIG. 11A. FIG 11D depicts the end of vent conduit 1220 being located in the wound port 1210 above an exudate orifice 1230.

[0058] Although the foregoing disclosure has been described in some detail by way of illustration and example, for purposes of clarity or understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims. For example, the individual fluid and vent conduits may be substituted for by a conduit having a dual lumen. To ensure the capillary action, one lumen must be larger than the other; however, the lumens may be coaxial or parallel.

What is claimed is:

1. A system for subatmospheric pressure therapy in connection with healing a wound, which comprises:

a wound dressing cover dimensioned for positioning relative to a wound bed of a subject to establish a reservoir over the wound bed in which subatmospheric pressure may be maintained;

a subatmospheric pressure mechanism including:

a housing;

a vacuum source disposed in the housing; and

a collection canister in fluid communication with the vacuum source;

a wound port operatively connected to the wound dressing in fluid communication with the reservoir, the wound port including:

a vacuum port; and

a plurality of holes arranged circumferentially around the wound port, the plurality of holes being operable to allow ambient air into the reservoir; and

an exudate conduit in fluid communication with the wound port and the collection canister for collecting exudate removed from the reservoir and deposited in the collection canister under influence of the vacuum source.

2. The system according to claim 22, wherein the plurality of holes are formed in a plate.

3. The system according to claim 23, wherein the plate is radio frequency welded to the wound port.

1/11

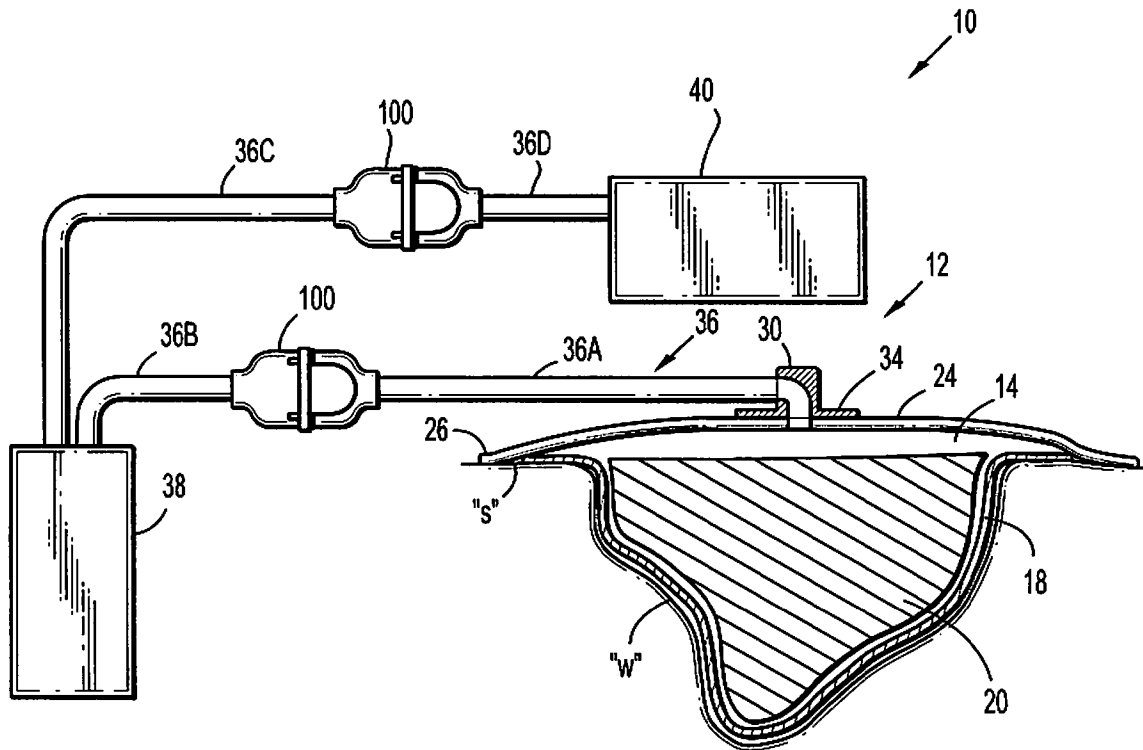


FIG. 1

2/11

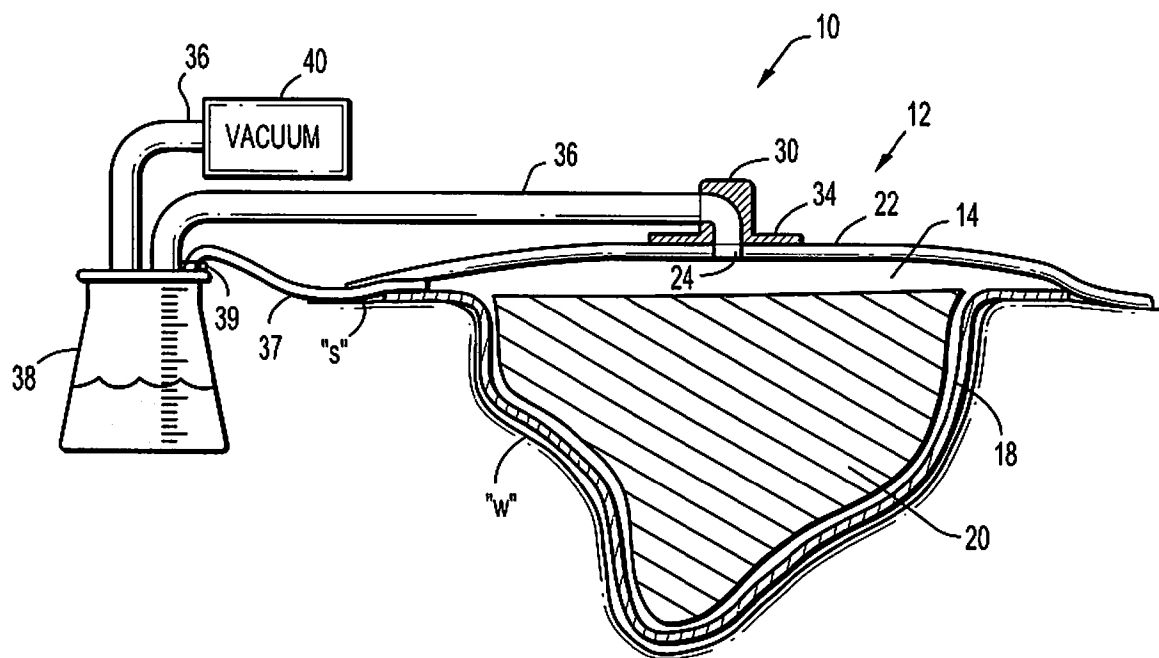


FIG. 2

3/11

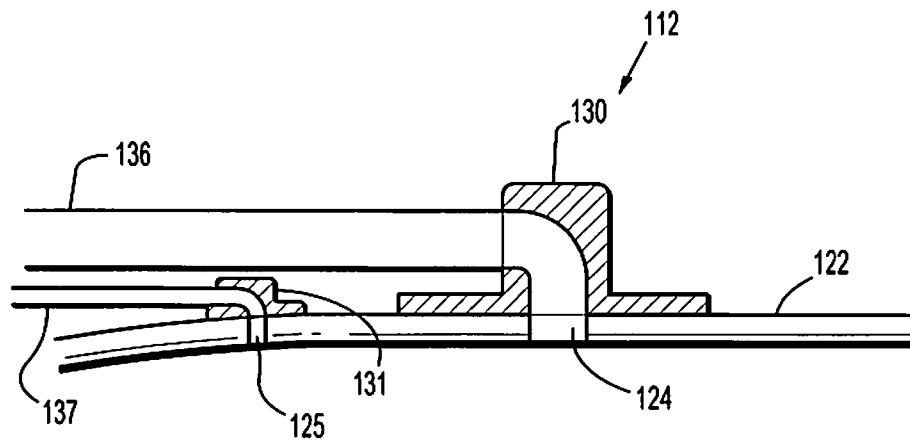


FIG. 3A

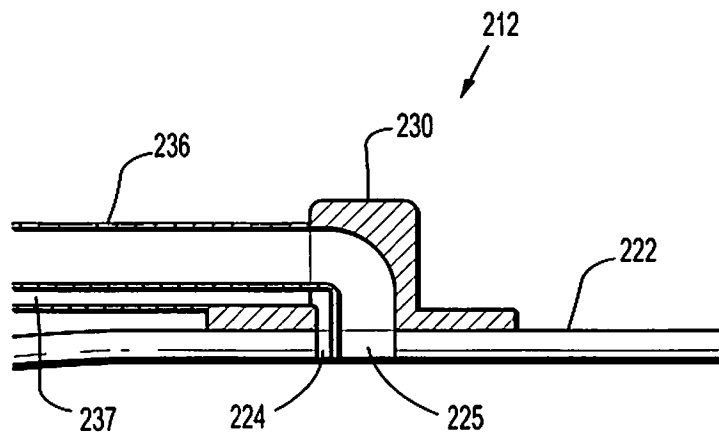


FIG. 3B

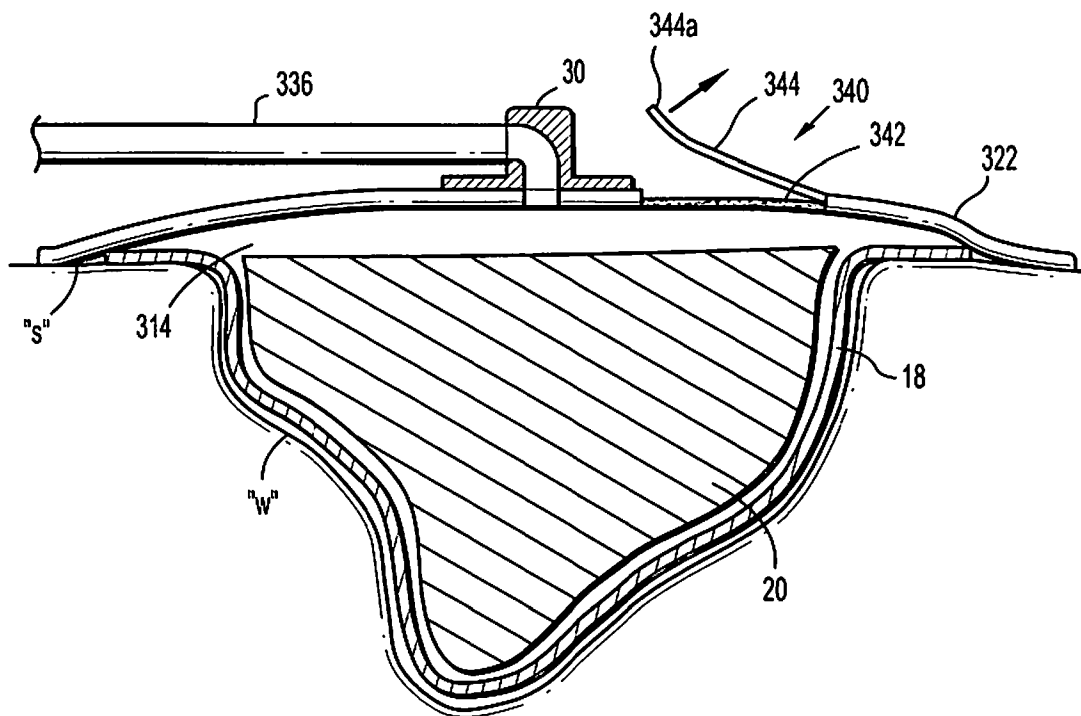
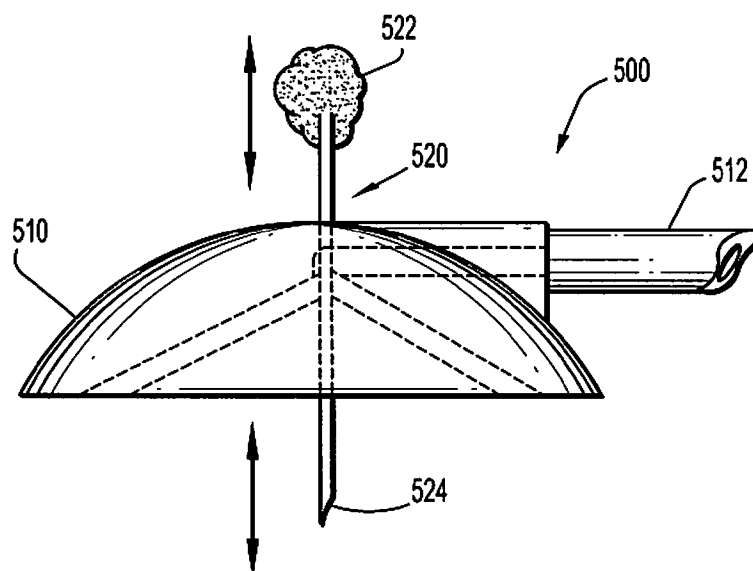
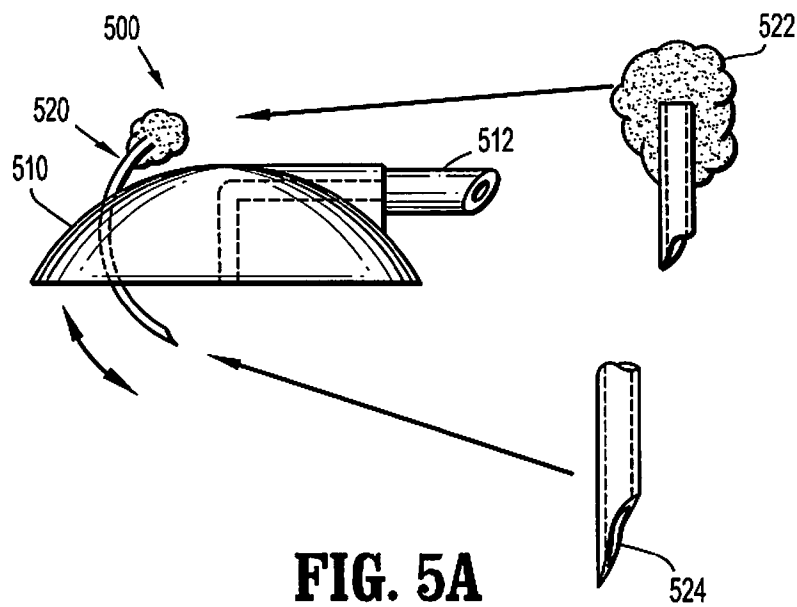


FIG. 4

5/11



6/11

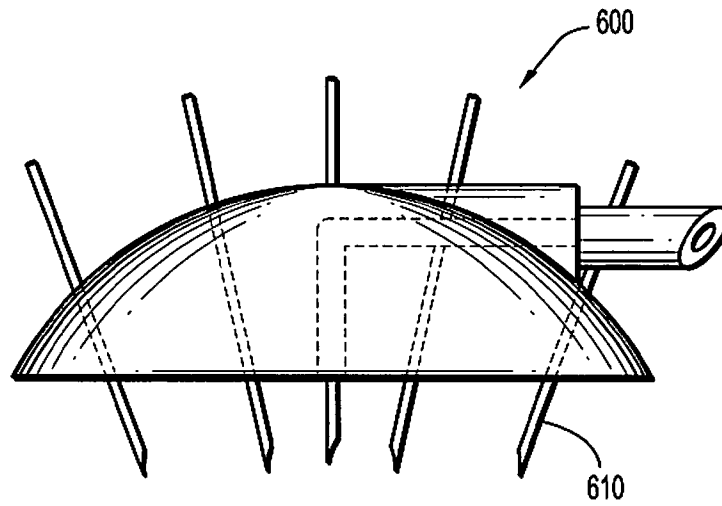


FIG. 6A

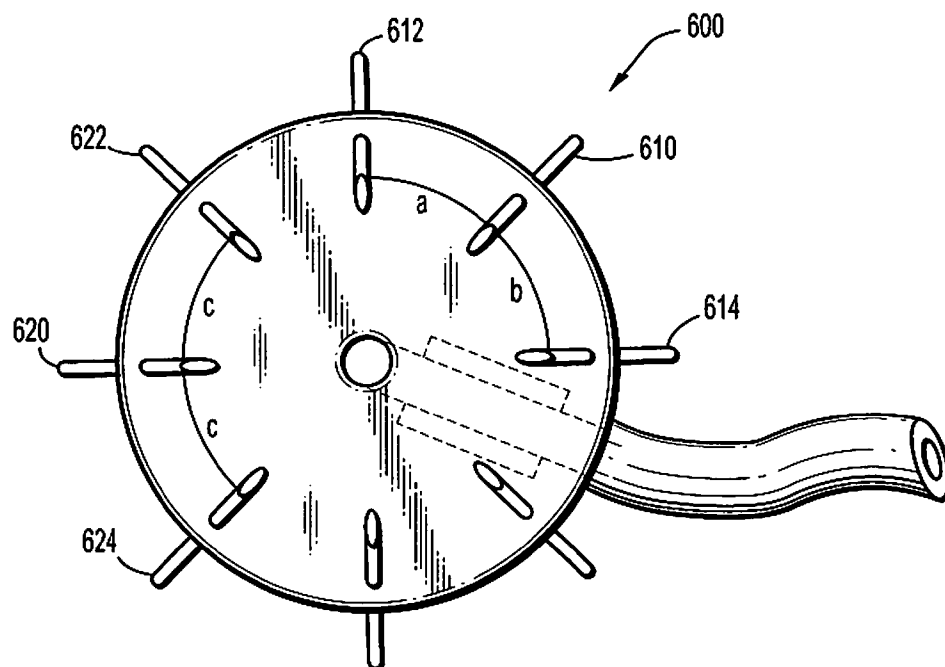


FIG. 6B

7/11

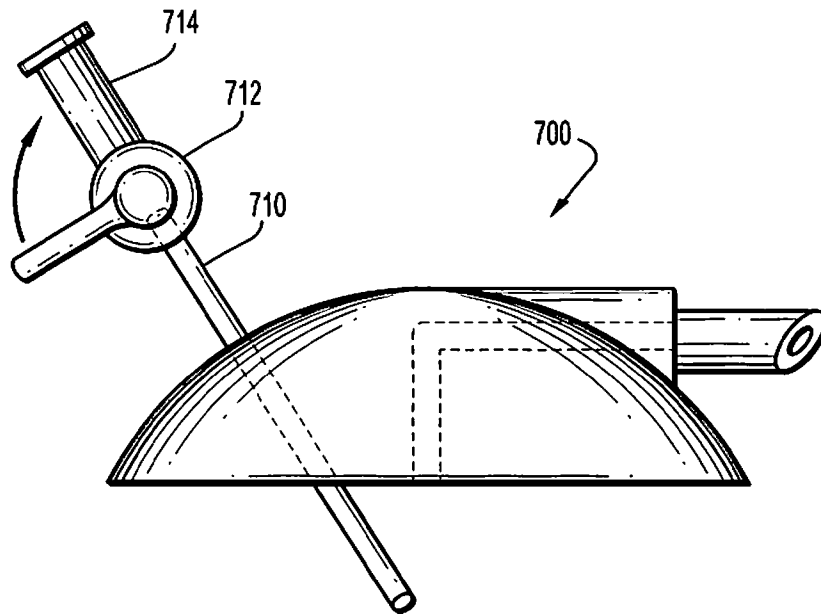


FIG. 7A

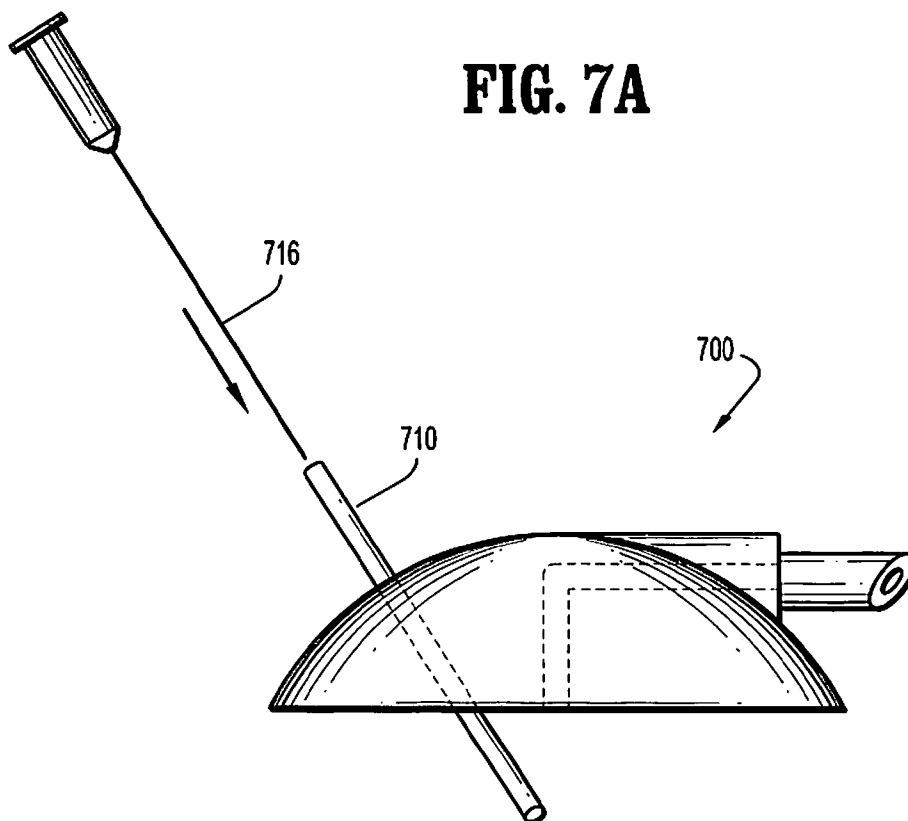


FIG. 7B

8/11

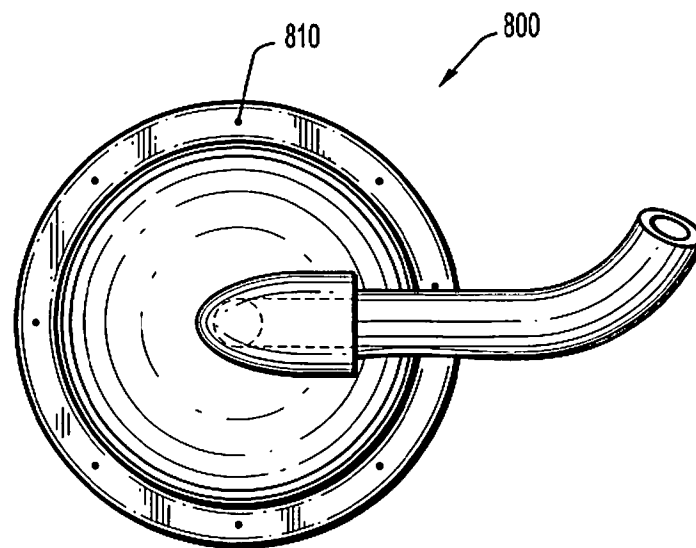


FIG. 8A

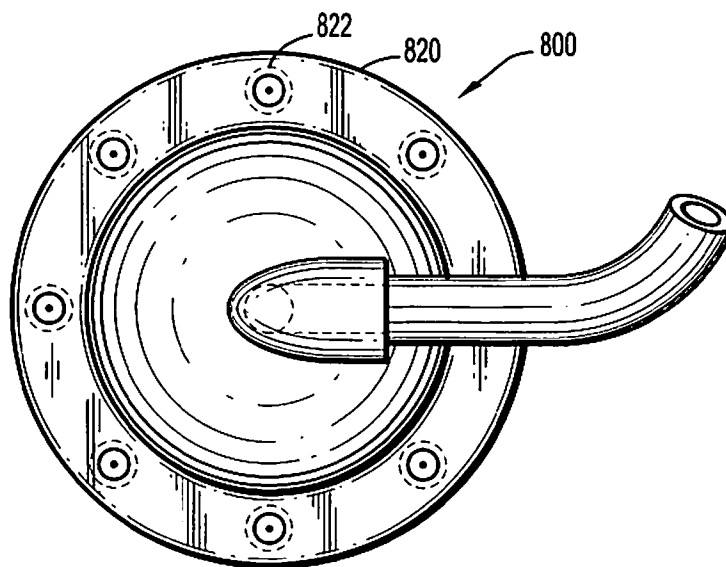


FIG. 8B

9/11

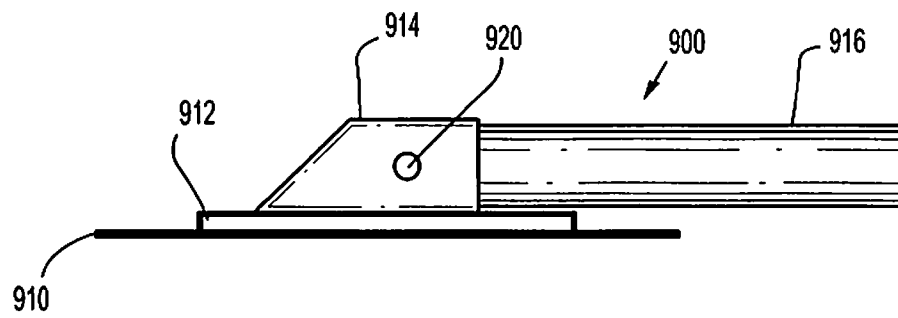


FIG. 9

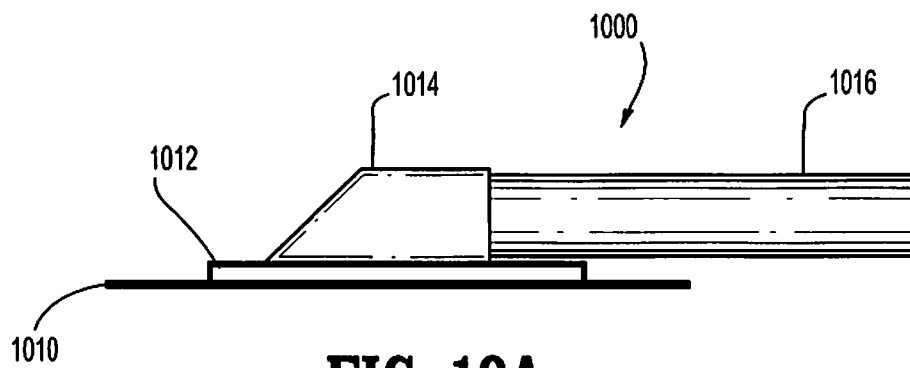


FIG. 10A

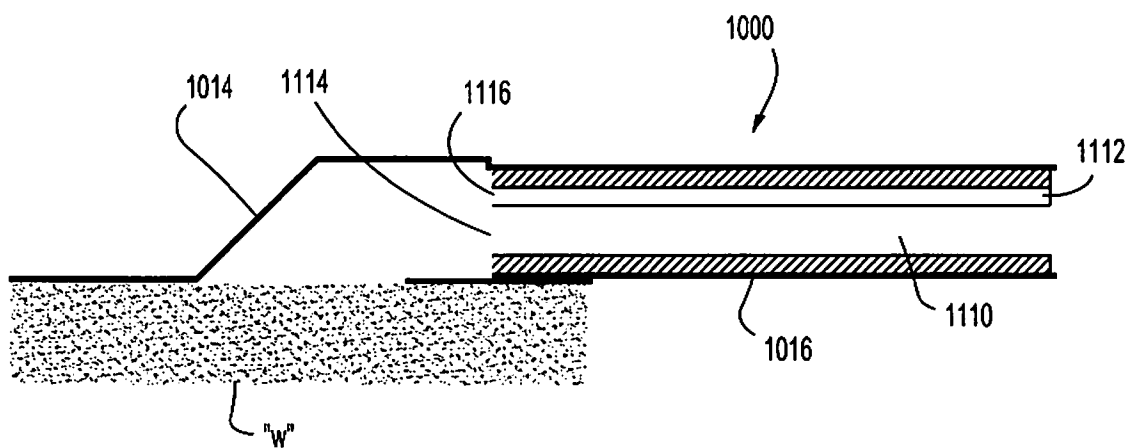


FIG. 10B

10/11

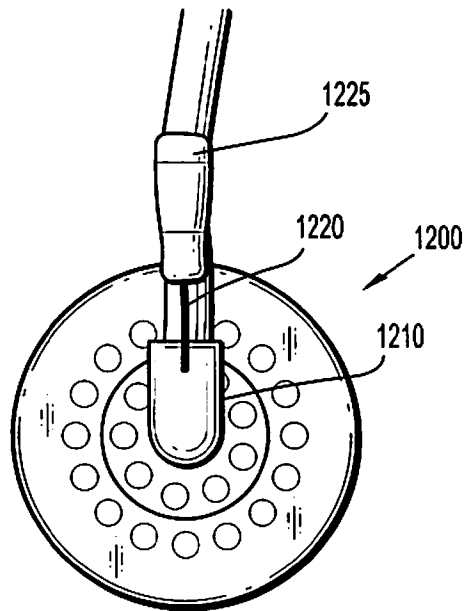


FIG. 11A

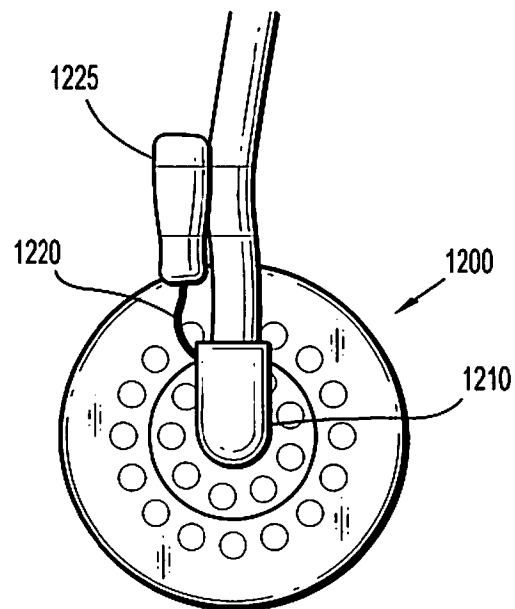


FIG. 11B

11/11

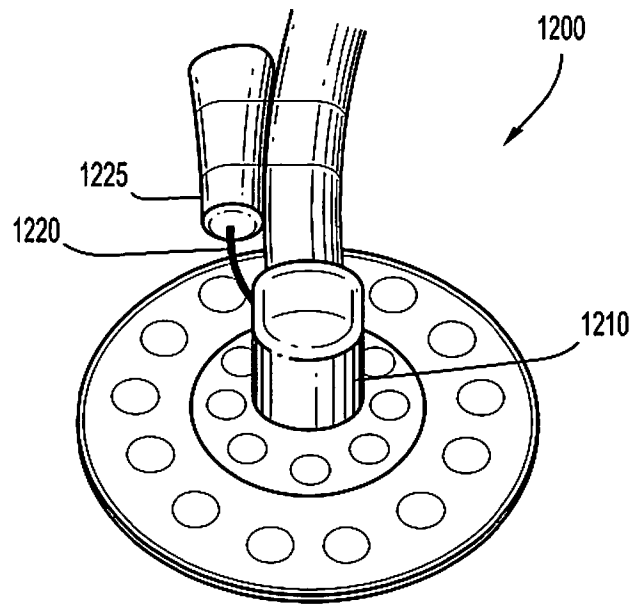


FIG. 11C

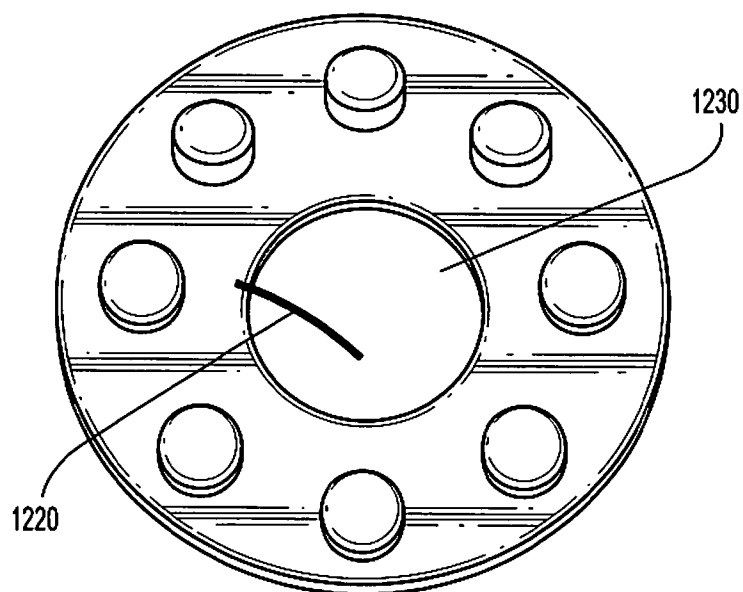


FIG. 11D

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/046580

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 1/00 (2009.01)

USPC - 604/313

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61M 1/00, 27/00 (2009.01)

USPC - 424/445; 604/43, 304, 313

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0066946 A1 (HAGGSTROM et al) 22 March 2007 (22.03.2007) entire document	1-3
Y	US 3,026,874 A (STEVENS) 27 March 1962 (27.03.1962) entire document	1-3
Y	WO 2008/020862 A1 (RICHMOND) 21 February 2008 (21.02.2008) entire document	3

☐ Further documents are listed in the continuation of Box C.


* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 July 2009

Date of mailing of the international search report

29 JUL 2009

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenhaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774