

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
16 August 2007 (16.08.2007)

PCT

(10) International Publication Number
WO 2007/092397 A2

(51) International Patent Classification: Not classified

(21) International Application Number: PCT/US2007/003065

(22) International Filing Date: 6 February 2007 (06.02.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/765,548 6 February 2006 (06.02.2006) US
11/702,822 6 February 2007 (06.02.2007) US

(71) Applicant (for all designated States except US): KCI LICENSING, INC. [US/US]; P.o. Box 659508, San Antonio, TX 78265 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HEATON, Keith, Patrick [GB/GB]; 24 Mansfield Road, Parkstone, Poole, Dorset, BH14 0DJ (GB). ROBINSON, Timothy, Mark [GB/GB]; 27 Wellington Terrace, Basingstoke, Hampshire, RG23 8HH (GB). LOCKE, Christopher, Brian [GB/GB]; 70 Stratton Road, Bournemouth, Dorset, BH9 3PT (GB).

(74) Agents: MASON, Robert, W. et al.; Kinetic Concepts, Inc., P.O. Box 659508, San Antonio, TX 78265 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, 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, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, 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, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

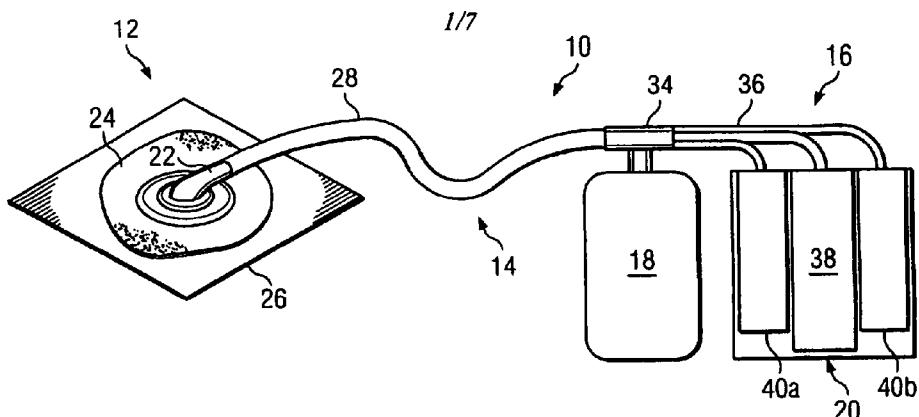
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

- without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEMS AND METHODS FOR IMPROVED CONNECTION TO WOUND DRESSINGS IN CONJUNCTION WITH REDUCED PRESSURE WOUND TREATMENT SYSTEMS



(57) Abstract: Described are improvements to the structure and functionality of a reduced pressure adapter used to connect a distribution manifold and a reduced pressure source instrumentation in a reduced pressure wound treatment (RPWT) system. The reduced pressure adapter reduces instances of unintentional liquid ingress into ancillary lumens of a reduced pressure delivery tube, while channeling the liquid to a primary lumen of the reduced pressure delivery tube.

Systems and Methods for Improved Connection to Wound Dressings in Conjunction with Reduced Pressure Wound Treatment Systems

Technical Field

5 The present invention relates to generally to systems and methods for providing reduced pressure treatment to tissue, particularly open wounds. The present invention relates more specifically to systems and methods for improving the connection between a tissue dressing and reduced pressure source instrumentation used in conjunction with reduced pressure wound treatment (RPWT).

10

Background Art

Various therapies have been developed over time to facilitate the process of wound closure and healing. Wound closure generally involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted by the inflammatory process, whereby blood flow is increased and various functional cell types are activated. As a result of the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such 15 wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and, thus, less able to naturally 20 close the wound. Additionally, some wounds harden and inflame to such a degree that closure by stapling or suturing is not feasible. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus 25 ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

30 As a result of the shortcomings of mechanical wound closure devices, methods and apparatus for draining wounds by applying continuous and/or periodic reduced pressures have been developed. When applied over a sufficient area of the

-2-

wound, such reduced pressures have been found to promote the migration of epithelial and subcutaneous tissues toward the wound. In practice, the application to a wound of reduced pressure typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, RPWT augments 5 the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

Vacuum or reduced pressure induced healing of open wounds has recently 10 been popularized by Kinetic Concepts, Inc. of San Antonio, Texas, through its commercially available RPWT systems product line. The reduced pressure induced healing process has been described in commonly assigned U.S. Patent No. 4,969,880, issued on November 13, 1990 to Zamierowski, as well as in its related 15 patents, including U.S. Patent No. 5,100,396, issued on March 31, 1992; U.S. Patent No. 5,261,893, issued on November 16, 1993; and U.S. Patent No. 5,527,293 issued June 18, 1996, the disclosures of which are each incorporated herein by reference. Further improvements and modifications of the RPWT process are also described in 20 U.S. Patent No. 6,071,267, issued on June 6, 2000 to Zamierowski and U.S. Patents Nos. 5,636,643 and 5,645,081 issued to Argenta et al. on June 10, 1997 and July 8, 1997 respectively, the disclosures of which are each incorporated by reference as 25 though fully set forth herein. Additional improvements have also been described in U.S. Patent No. 6,142,982, issued on May 13, 1998 to Hunt, et al.

One important component of a RPWT system is the device or structure that 30 connects the reduced pressure source (a vacuum pump, typically) to the components (a granular foam layer, typically) enclosed within the pad or wound dressing. This reduced pressure port structure must adhere to the wound dressing and be in fluid communication with the foam layer of the dressing. The port is preferably of low profile, in the nature of an attachment pad, in order to provide both comfort and safety to the patient. Various efforts have been made in the past to provide suitable adapter configurations to effectively connect the reduced pressure source (through tubing, typically) to a tissue site.

Commensurate with the application of continuous and/or periodic reduced pressures to a wound is a coordinated monitoring of the pressure present at the

-3-

tissue site as a result of the application of the RPWT system. It has become important, therefore, to provide systems that are capable of monitoring and responding to changes in the level of reduced pressure applied at the tissue site. Various regimens of RPWT that involve cycling the reduced pressure applied to the 5 wound have been found to be beneficial under certain circumstances. Other situations benefit from a constant but closely regulated application of reduced pressure. In any case, it becomes valuable to accurately monitor the level of reduced pressure applied at the tissue site.

Generally it is not possible to characterize the pressure level at the tissue site 10 by simply measuring the level of reduced pressure that the reduced pressure source is providing, either at the source or in the conduit lines connecting the source to the wound dressing. Fluid flow within the primary lumen of tubing associated with RPWT systems prevents using pressure level measurements at the instrumentation from being accurate indicators of the level or stability of the pressure at the tissue 15 site itself. Other methods for directly monitoring the wound pressure levels are therefore required.

Some efforts have been made in the past to provide a separate pressure sensing or measurement conduit to the wound site connected to monitoring instrumentation. These efforts have typically provided a separate lumen within the 20 RPWT tubing or have utilized a separate section of tubing altogether. The assumption being made with such systems, however, is that the ancillary measurement lumen or measurement tube is open and clear down to its port at the wound dressing. This is not always a valid assumption as, despite the fact that the measurement lumen is not forcibly drawing fluids in as is being done in the primary 25 flow lumen of the RPWT system, it still collects fluids and other materials that inhibit or altogether block its function. The typically smaller cross-section of such measurement lumens may reduce the port size, and therefore the chance of fluid or other matter entering the port, but the same smaller cross-section results in even minor blockages becoming significant.

Disclosure of Invention

Exemplary embodiments of the present invention provide improvements to the structure and use of the connector elements between the wound dressing and the reduced pressure source in a reduced pressure wound treatment (RPWT) system.

5 More specifically certain exemplary embodiments provide:

(A) A low profile reduced pressure adapter that improves the reliability of operation and prevents or reduces instances of unintentional fluid ingress into measurement lumens;

10 (B) An improved reduced pressure delivery tube comprising an oval tubing structure with a larger inner lumen and smaller outer lumens for supporting the dynamic pressure functionality described below;

(C) An improved and dynamic method of measuring wound pressure that overcomes certain problems with existing pressure control in RPWT systems;

15 (D) An improved reduced pressure adapter structure having rotational functionality to facilitate the comfort of the attachment to the patient; and

(E) A structure to provide indications of the presence of bacteria within the reduced pressure adapter and fluids transported therethrough.

The improved reduced pressure adapter includes a conduit housing with a primary conduit and at least one secondary conduit for fluid connection to a wound dressing. The reduced pressure adapter also may include a base with a substantially circular shape. The conduit housing includes a recessed region defining an entry surface. The primary conduit connects the entry surface to a primary lumen of a multi-lumen reduced pressure delivery tube, and ancillary conduits connect the entry surface to ancillary lumens of the multi-lumen reduced pressure delivery tube. Channels positioned on the entry surface preferentially route liquids and other fluids into the primary conduit in order to prevent the clogging of the ancillary conduits, which are generally utilized to measure pressure within the wound dressing.

30 The improved reduced pressure delivery tube incorporates a larger primary inner lumen to effect the conduction of reduced pressure to the tissue and fluids away from the tissue. Smaller outer ancillary lumens are provided to support the hereinafter described dynamic pressure functionality that insures the continuity of

5 accurate pressure measurements through the monitoring of the open or closed (clogged) state of each of the ancillary lumens. The reduced pressure delivery tube may be mated to the improved reduced pressure adapter described above, or may be used with other adapters to fluidly connect a reduced pressure source and pressure sensors to a porous pad or other distribution manifold.

10 The improved method of measuring pressure addresses certain problems with existing pressure control in RPWT systems that result from excessive fluid incursion into the measurement lumens of the system. Each of the ancillary lumens are monitored for their responsiveness to changes in the reduced pressure source (and thus in the wound dressing itself). A slow response in one of the ancillary lumens is indicative of clogging in that lumen, and as a result, the RPWT system considers the pressure measurement from the clear ancillary lumen as the accurate measurement. The system further allows for the introduction of elevated pressure into the clogged lumen in a manner that may serve to clear the lumen of fluid obstruction, all the while 15 the second of the two ancillary lumens may continue to function as a monitoring channel for measuring the pressure at the tissue site.

20 In other embodiments the improved reduced pressure adapter structure incorporates rotational functionality to improve the patient's convenience and comfort. The conduit housing is positioned on and rotatably attached to the perimeter base in a manner that allows the reduced pressure adapter and attached tubing to rotate with respect to the wound dressing thereby reducing strain on the dressing and the reduced pressure adapter.

25 Finally, in a yet further embodiments, the improved reduced pressure adapter incorporates an internal surface, preferably formed on the interior perimeter wall of the conduit housing of the adapter, to provide indications of the presence of bacteria within the adapter enclosure and therefore the fluids transported through the adapter. This indicator surface retains a layer of material sensitive to the volatile organic compounds (VOC) associated with various targeted microorganisms. The VOC sensitive surface develops a specific color pattern depending on the type of 30 VOC and therefore the type of microorganism present. The color pattern may be visually discerned through the clear material of the reduced pressure adapter

-6-

construction or may be automatically detected by photometric color analysis using one of a variety of such photometric sensor devices.

Finally, many other features, objects, and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the 5 foregoing discussions and the following drawings and exemplary detailed description.

Brief Description of Drawings

Although the scope of the present invention is much broader than any 10 particular embodiment, a detailed description of the preferred embodiment follows, together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

FIG. 1 is a partially schematic, perspective view of the general arrangement of the components of a reduced pressure wound treatment (RPWT) system 15 incorporating the improved elements of an exemplary embodiment of the present invention;

FIG. 2 is a perspective view of the underside (open side) of an improved reduced pressure adapter according to an embodiment of the present invention;

FIG. 3 is a plan view of the topside (closed side) of the improved reduced 20 pressure adapter of FIG. 2;

FIG. 4 is a first side view of the improved reduced pressure adapter of FIG. 2;

FIG. 5 is an end view of the improved reduced pressure adapter of FIG. 2;

FIG. 6 is a second side view of the improved reduced pressure adapter of 25 FIG. 2;

FIG. 7 is a plan view of the underside (open side) of the improved reduced pressure adapter of FIG. 2, the underside configured according to a first exemplary embodiment of the present invention;

FIG. 8 is a plan view of the underside (open side) of the improved reduced pressure adapter of FIG. 2, the underside configured according to another exemplary 30 embodiment of the present invention;

FIG. 9 is a detailed view of a recessed region of the reduced pressure adapter of FIGS. 7 and 8;

FIG. 10 is a perspective view of an open end of an improved reduced pressure delivery tube according to an exemplary embodiment of the present invention;

5 FIG. 11 is a longitudinal cross-sectional view of the improved reduced pressure delivery tube of FIG. 10;

FIG. 12 is a schematic block diagram illustrating the arrangement and functionality of a reduced pressure system according to an exemplary embodiment of the present invention;

10 FIG. 13 is an exploded perspective view of an improved reduced pressure adapter according to an exemplary embodiment of the present invention, the reduced pressure adapter incorporating elements that provide rotational functionality;

FIG. 14 is a cross-sectional view of the reduced pressure adapter of FIG. 13;

15 FIG. 15 is a bottom perspective view of a reduced pressure adapter having panels sensitive to the presence of microorganisms according to an exemplary embodiment of the present invention; and

FIG. 16 is a side view of the reduced pressure adapter of FIG. 15 in which the panels are visible through transparent or translucent side walls of the reduced pressure adapter.

20 **Best Mode for Carrying Out the Invention**

In the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific preferred embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable 25 those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the invention, the description may omit certain information known to those skilled in 30 the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

Reduced Pressure Adapter

Improvements in an RPWT system are disclosed that provide a reduced pressure adapter to improve the reliability of operation and prevent or reduce instances of unintentional liquid ingress into the measurement lumens of a reduced pressure delivery tube, particularly in conjunction with a low-profile dressing.

5 Traditional adapters typically include both a sensing lumen and a reduced pressure delivery lumen together an elbow-shaped housing. A common cause of failure for these reduced pressure adapters results from liquid ingress into the sensing lumen, which may cause the control of therapy to become unstable and, in extreme cases,

10 may contribute to the eventual shutdown of the device. Part of this problem is due to the location of the fluid conduction and the nature of wound fluid in general. Wound excretions and fluids are generally pseudoplastic in consistency and will splash and foam in the elbow of a reduced pressure apparatus under the influence of reduced pressure. One goal of certain exemplary embodiments of the present invention,

15 therefore, is to prevent the wound liquids and other non-gaseous fluids from entering the sensing lumen.

One concept of the improved reduced pressure adapter is for the lumens to be separate down to the distribution manifold of the wound dressing so that the distribution manifold becomes the barrier between the sensing lumens and the reduced pressure path. The underside of the reduced pressure adapter is provided with channel features that attract small droplets splashed inside the reduced pressure adapter during periods of high flow or after a large slug of liquid has been pulled into the tubing. This preferencing of the liquid and solid matter into the larger primary lumen, and away from the smaller ancillary measurement lumens, helps prevent the lumens from becoming blocked. The concept further includes providing offset outer measurement lumen ports in the pad, which are designed such that in most orientations one of the two should be above the flow level in the distribution manifold of the dressing. The reduced pressure adapter is further intended to operate in conjunction with the dynamic pressure control methodologies described in more detail below. The reduced pressure adapter may also include an adhesive drape or cover that secures the reduced pressure adapter within the wound. The profile of the reduced pressure adapter is low for increased patient comfort, and the

-9-

reduced pressure adapter is preferably elbow-shaped such that the connecting tubing is routed cleanly away from the tissue site.

Reference is made first to FIG. 1 for a general description of the components included in a reduced pressure wound treatment (RPWT) system incorporating the 5 improved elements of an exemplary embodiment of the present invention. The three primary components of RPWT system 10 include wound dressing 12, reduced pressure delivery tube 14, and remote fluid containment and instrumentation 16.

Wound dressing 12 is generally comprised of a distribution manifold 24 such as a porous pad or granular foam and a cover or drape 26 that secures the 10 distribution manifold at a tissue site. Dressing 12 also may include improved reduced pressure adapter 22, as shown positioned on distribution manifold 24 and adhered thereto by an adhesive positioned on the reduced pressure adapter 22, the wound drape 26, or a separate adhesive drape associated with reduced pressure adapter 22.

Reduced pressure delivery tube 14 is a multi-lumen tube, comprised of one or 15 more tubing sections 28 which, as an assembled structure, provide a continuous conduit between reduced pressure adapter 22 and container connector 34 positioned on fluid container 18. As described in more detail below, and as known in the art, liquid and other exudates drawn by RPWT system 10 are removed from the 20 tubing at this point and are retained within container 18. Sections of additional tubing in the form of instrumentation tubing 36a and 36b likewise extend from container connector 34 to instrumentation components 20. In certain embodiments of the present invention, instrumentation components 20 comprise a reduced pressure source 38 and pressure monitoring instrument components 40a and 40b. 25 Described in more detail below, each of these three instrument components 20 is individually associated with one of three isolated conduits (tubes or lumens) that extend from reduced pressure adapter 22 into remote fluid containment and instrumentation 16.

Reference is now made to FIGS. 2 – 9 for a more detailed description of the 30 reduced pressure adapter 22. FIG. 2 provides a perspective view of the underside of reduced pressure adapter 22 showing the various structural elements within the

-10-

opening of reduced pressure adapter 22 that are adapted to contact the distribution manifold 24 (not shown) of the wound dressing.

Reduced pressure adapter 22 generally comprises a base 50, which may be adhered to the distribution manifold, and a conduit housing 62 coupled to the base 5. Conduit housing 62 includes a primary conduit and a pair of ancillary conduits. The base 50 includes an aperture 53, which is positioned over the distribution manifold and through which the liquids and gases (collectively referred to as "fluids") are drawn from the tissue site. A significant feature of improved reduced pressure adapter 22 is the presence of channel elements positioned near and in fluid 10 communication with aperture 53 and the effective way in which the channel elements direct liquid into the primary conduit for drainage. The routing of liquids into the primary conduit maintains the ancillary conduits of the system open for pressure measurement purposes.

Referring to FIG. 2, the conduit housing 62 of reduced pressure adapter 22 15 includes a recessed region 54 defining an entry surface 55. The primary conduit terminates on the entry surface 55 at a primary port 60, which is centrally located at an apex of the recessed region 54. The ancillary conduits terminate on the entry surface 55 at ancillary ports 56 and 58. The ancillary ports are positioned near diametrically opposing edges of aperture 53.

20 A second end of the primary conduit terminates at a primary lumen interface 64. Primary lumen interface 64 is generally centrally positioned within aperture 66. Ancillary lumen interfaces 48, 49 (see FIG. 5) to the ancillary conduits also are located within aperture 66 and are described in more detail below.

FIG. 3 provides a plan view (from above) of reduced pressure adapter 22.

25 The conduit housing 62 is preferably "elbow" shaped; however, the conduit housing may be configured at any desired angle or may extend perpendicularly from base 50. In the elbow configuration illustrated in FIG. 3, reduced pressure adapter 22 is seen to comprise base 50 and a centrally positioned conduit housing 62. Conduit housing 62 includes an elbow region 68, and the conduit housing 62 internally comprises 30 conduits between the ports 56, 58, 60 and the ancillary and primary lumen interfaces 48, 49, 64.

FIGS. 4, 5 & 6 show side, and end views of the reduced pressure adapter 22. Reduced pressure adapter 22, as seen in the side view shown in FIG. 4, is of low profile construction with base 50 defining its lateral limits. As indicated above, base 50 may be directly adhered to the distribution manifold or may be positioned and 5 adhered using the drape of the wound dressing. The reduced pressure adapter 22 is positioned on distribution manifold such that the aperture 53 (not seen in this view) of base 50 is in direct contact with the distribution manifold. In the view shown in FIG. 4, primary lumen interface 64 extends centrally out from conduit housing 62 and is surrounded by aperture 66. Conduits extend through the material of reduced 10 pressure adapter 22 between the tubing interfaces and recessed region 54, as described above. The elbow region 68 redirects fluid flow from the wound dressing positioned beneath reduced pressure adapter 22 to an angle associated with interface 64 in a manner that allows the system to be placed on the wound dressing and be maintained close to the wound dressing surface.

15 FIG. 5 is an end view of the same structure shown in FIG. 4 with the configuration of elbow region 68 and the internal configuration of conduit housing 62 more clearly shown. In this view, the same components associated with adhering reduced pressure adapter 22 to the wound dressing are disclosed. Base 50 and aperture 54 are positioned as indicated in FIG. 4. Conduit housing 62 is shown as it 20 would be positioned to receive a section of tubing for connection to the balance of the system of the present invention.

Internal to conduit housing 62 are primary lumen interface 64 and ancillary lumen interfaces 48 and 49. Ancillary lumen interfaces 48 and 49 align with the corresponding lumens in the delivery tubing by placing the primary lumen in the 25 tubing over the primary lumen interface 64. The structure of one embodiment of multi-lumen tubing used in conjunction with the improved reduced pressure adapter structure of the present invention is described in more detail below.

FIG. 6 provides essentially the same view of reduced pressure adapter 22 as that of FIG. 4 but from the opposite side. Structurally, the elements shown are the 30 same as those shown and described with FIG. 4, which is indicative of the lateral (and to an extent, radial) symmetry of the connector. Unless otherwise indicated, the materials used to construct the improved connector of the present invention may be

-12-

selected from a number of materials known in the art that provide the necessary flexibility and comfort to the patient while maintaining sufficient rigidity or resilience to maintain the open lumens that are integral to the reduced pressure adapter function.

FIG. 7 provides a plan view (from below) of reduced pressure adapter 22 and clarifies the structure and function of the various features and elements within recessed region 54 that serve to preference liquids and other non-gaseous fluids away from the ancillary ports 56, 58. In this view, base 50 is shown surrounding the edge of recessed region 54. Ancillary ports 56 and 58 are shown positioned as indicated, with associated conduits extending internally from ports 56 and 58 to ancillary lumen interfaces (hidden and not shown in this view). Primary port 60 can be seen centrally located within aperture 54. The primary conduit extends (hidden and not shown in this view) from primary port 60 through primary lumen interface 64. The specific structures within recessed region 54 that serve to conduct liquid into the primary conduit, and thereby allow the ancillary conduits to remain unobstructed are described in more detail below with respect to FIG. 9.

FIG. 8 shows an alternate exemplary embodiment of the base associated with the reduced pressure adapter of the present invention. In this view (the same perspective as that of FIG. 7) added features to the underside surface of alternate base 52 are shown. These features, molded into the structure of base 52, include base serrated guide channels 70, perimeter collection channels 72, and intermediate collection channels 74. The objective of these channels is to direct liquid away from the two ancillary measurement ports 56, 58 and into the primary port 60. Base serrated guide channels 70 are positioned and oriented on base 50 to directly capture and channel at least half of the liquids being drawn into the reduced pressure adapter, and indirectly channel a major portion of the balance of the liquids being drawn in. The spaced, radially-oriented arrangement of base serrated guide channels 70 funnels liquids away from the ancillary ports and into the primary port. In addition, perimeter collection channels 72 and intermediate collection channels 74 redirect the flow of liquids that are being drawn in between the radially-oriented guide channels 70 into the guide channels 70 and away from the ancillary ports. An example of this redirected flow is shown in FIG. 8 with bolded flow indication arrows.

-13-

Reference is now made to FIG. 9 for a more detailed description of the features and elements contained within the recessed region of conduit housing 62. These features are positioned on the entry surface 55 of the recessed region 54 and are structured to preference liquids and other non-gaseous exudates away from the 5 ancillary ports 56, 58 and into the primary port 60. In this view, primary port 60 is shown centrally positioned within recessed region 54 and extending from the central location to one side of recessed region 54. Ancillary ports 56 and 58 are likewise disclosed in this view, positioned to either side of the central location of primary port 60. In this view, ancillary ports 56 and 58 are circular openings (each with raised 10 circumferential edges) that extend toward a drainage point that opens into an internal conduit extending to the associated ancillary lumen interface (not shown). The openings of the conduits can be seen within the confines of ancillary ports 56 and 58.

Four basic features within the structure shown in FIG. 9 are positioned to 15 preference liquid into the primary port 60 of the reduced pressure adapter 22. The first such structure is simply the placement of the ancillary ports 56 and 58 near the perimeter of the aperture 53 at a level that is close to the surface of the distribution manifold when the reduced pressure adapter 22 is positioned thereon. In other words, when the reduced pressure adapter 22 is positioned on the wound dressing, 20 the ancillary ports 56 and 58 are in contact, or are nearly in contact, with the surface of the distribution manifold. In this manner, the likelihood of splashed or agitated liquid being directed into these ports is minimized.

The remaining three features that direct liquids into the primary port are 25 structural serrated channels formed on various portions of the entry surface 55 of recessed region 54. A first linear serrated channel section 42 is positioned in association with the approximately half circle section of recessed region 54 that is associated with ancillary port 58. The material that comprises the ceiling of this section of recessed region 54 covers and contains the conduit that extends between ancillary port 58 and its interface (not shown). This ceiling or wall is configured with 30 an array of serrated channels or striations that directs liquids that fall upon this surface towards the primary port at the center of the recessed region 54. Any liquids that are drawn into the opening and fall upon this portion of the entry surface 55

-14-

would be channeled directly into primary port 60, rather than being directed into ancillary port 58.

A similar configuration is constructed in an approximately one-third circular radial serrated channel section 44. Insofar as no internal conduit is contained within 5 this section of the recessed region 54, the serrated channels in section 44 may extend deeper and more directly to the primary port 60. These radial serrated channels are directed from the perimeter of aperture 54 towards the apex of the recessed region 54 that drains into primary port 60. These radial striations or channels extend from a radius adjacent ancillary port 58 radially around 10 approximately one-third of the circle to a radius adjacent ancillary port 56. Any liquids that fall upon this portion of the recessed region 54 will be directed centrally to primary port 60, rather than being conducted to either of the ancillary ports.

Finally, the wall section that supports ancillary port 56 at the point at which the ancillary port 56 overhangs primary port 60 is structured with serrated or striated 15 channels 46 that extend downward (upward in the normal positioning of the connector) from the opening of ancillary port 56 towards the opening of primary port 60.

As described above, the various internal features and elements of the recessed region 54 are structured to draw liquid from most points within the 20 recessed region 54 towards the centrally located primary port 60. Only liquid that enters directly into ancillary port 56 or 58 would likely be drawing into an ancillary lumen. Insofar as little or no suction is occurring at these ports, this structure greatly reduces the likelihood of obstructions in the form of liquid or material blockages in an ancillary lumen.

25 **Reduced Pressure Delivery Tube**

Reference is now made to FIGS. 10 and 11 for a detailed description of the structure of an improved reduced pressure delivery tube 80 operable in association with the system of an exemplary embodiment of the present invention. The reduced pressure delivery tube 80 preferably includes a primary central lumen 82 and 30 ancillary lumens 84 and 86. Ancillary lumens 84 and 86 are generally used for taking pressure measurements. In FIG. 11, fluid flow designated by the block arrows is shown as it would be directed through primary lumen 82 while ancillary lumens 84

and 86 remain generally free of liquid or any non-gaseous matter. The cross-sectional perspectives shown in both FIGS. 10 and 11 disclose the relative cross-sectional diameters of the primary lumen 82 as compared with the ancillary lumens 84 and 86. Delivery device 80 has an oval cross-section, which optimizes flexibility without allowing for the collapse of any of the described lumens. This cross-sectional shape also orients the ancillary lumens 84 and 86 so that the lumens align appropriately with the interfaces on the improved reduced pressure adapter described above.

Dynamic Method of Measuring Wound Pressure

The system of the present invention also includes an improved and dynamic method of measuring the wound pressure that overcomes problems inherent with current reduced pressure wound treatment control systems. Various methods have been developed in the art to control the operation of reduced pressure wound treatment products and systems to insure that the wound pressure is maintained and that the therapy is safe by effective operation of the prescribed regimens. Currently, wound pressure is measured with the outer lumen or lumens of a multi-lumen tube that are commoned together and connected to one pressure sensor. This structure can suffer certain problems if liquid enters the lumens or they become blocked. If such liquid intrusion or blockages occur, the system can become unstable and alarms or indicators related to pressure become unreliable. Various mechanical remedies for these problems have been attempted and some have been partially successful. Ultimately, however, a system such as described in the prior art will be challenged with liquid in the control lumen unless there is a physical barrier placed against the ingress of liquid into the measurement lumen(s). One goal of the present invention is a system that is more reliable and more robust when challenged with extremes of therapy, as compared to current single sensor measurement lumen systems.

Reference is made to FIG. 12 wherein the system of an exemplary embodiment of the present invention and the functional relationship of its components are disclosed. The system incorporates two wound pressure sensors 40a and 40b in the system instrumentation that extend separately (through discrete lumens or conduits) from the instrumentation to the reduced pressure adapter and

-16-

are not commoned until the discrete lumens combine at the interface of the reduced pressure adapter and the distribution manifold. As indicated above, the reduced pressure adapter incorporates two separate pressure sensing ports as well as the fluid path through fluid chamber 18 to the reduced pressure pump 38 in the system 5 instrumentation. Inside the system instrumentation, each of the ancillary measurement lumen conduits is fitted with a solenoid valve 92 and 94 which will relieve pressure to the wound at the end of therapy, during intermittent therapy, or if required to clear blockages. These valves, as well as a similar valve associated with the reduced pressure source 38, are controlled by microprocessor/controller 90.

10 Microprocessor/controller 90 likewise controls the operation of reduced pressure pump 38 and receives data from first and second pressure measurement devices 40a and 40b. The microprocessor/controller 90 is programmed to monitor the wound pressure through the two readings associated with the two ancillary lumen paths. In instances where liquid enters one of the lumens, the liquid will cause a delay in the 15 pressure change response time of that lumen versus the clear lumen. As the blockage becomes more acute so will the delay. When a delay is detected, the system will control the wound pressure according to that of the open lumen and will try to clear the liquid from the blocked lumen by opening the appropriate valve to atmosphere. The preferred programming will try to clear the blockage in this manner 20 several times. If the system is not successful in clearing the blockage, the programming will, from that point on, ignore the affected lumen and control the system with the remaining clear lumen. The reduced pressure adapter design of the present invention, as described above, is such as to maximize the chances of having at least one clear ancillary measurement lumen at any given time.

25 **Reduced Pressure Adapter with Rotating Function**

Currently, reduced pressure adapters in RPWT systems typically allow for the effective connection of reduced pressure wound therapy to the wound, but do not allow for the tube connection point to be repositioned (for example, in the event that the patient is susceptible to skin breakdown) or for a situation where the user has 30 incorrectly positioned the reduced pressure adapter (for example, in the event that the reduced pressure adapter is facing in the wrong direction). In such instances, the user must remove and discard the reduced pressure adapter, and in some

-17-

instances the drape, which causes discomfort and is a nuisance to the patient and user as well as an additional cost. Providing a rotation or swivel function to the reduced pressure adapter enables repositioning the tube without having to remove and relocate the reduced pressure adapter. This ability assists in any situation 5 where the tubing requires relocation to avoid tissue damage. One goal of the present invention is to provide a reduced pressure adapter structure that allows for easy relocation of the tubing without removing and relocating the reduced pressure adapter or the wound dressing.

Reference is made to FIGS. 13 and 14 for a description of the configuration of 10 an alternate preferred embodiment of the reduced pressure adapter structure. The reduced pressure adapter 110 shown in FIG. 13 employs a hard plastic inner core that forms a bearing surface to enable a rubber o-ring to seal against it and also to enable the bearing surface to slide past with relatively low friction. Bonded to the hard plastic inner core is a soft thermoplastic or elastomeric polymer that acts as a 15 protective and cushioning cover. FIGS. 13 and 14 show the various circular ring components that go together to make up the swivel connection of the present invention. A top rotating PVC component 112 covers a top ABS insert ring 114 which itself is surrounded by a rubber o-ring 116. A bottom ABS insert ring 118 is shown that holds o-ring 116 captive between it and the top ABS insert 114. Each of 20 these rings is then fitted within the bottom PVC ring 120 which comes into contact with the base of the reduced pressure adapter and/or with the wound dressing itself.

The internal features and elements associated with the reduced pressure 25 adapter as described above in conjunction with a non-rotating embodiment are equally applicable here and may be integrated into the inside structure of top rotating PVC component 112 by direct molding of the component or by positioning a molded insert into a shell to for rotating component 112. In any event, the same benefits of the liquid preferencing structures surrounding the lumen ports described above are obtainable with the rotating functionality of the alternate embodiment described. [0001] FIG. 14 discloses the same components mentioned above as they would be 30 assembled and thereby shows in clearer detail the manner in which the components interlock and rotate with or against each other. In this view, the captive o-ring 116 is also shown to provide a proper seal for the internal reduced pressure chamber

-18-

formed by the reduced pressure adapter 110. In this view it is also clear how the internal features and elements in the port opening may be appropriately positioned on the underside of top PVC component 112 to serve the function of preferencing liquid to the primary conduit as described above.

5 Reduced Pressure Adapter with Microorganism Indication

10 Current reduced pressure treatment systems do not generally alert the caregiver to the presence of microorganisms in wound dressings. Many of these microorganisms can be significant factors in controlling infection at the wound site. One goal of the present invention is to provide a system that will alert the caregiver to significant levels of key microorganisms under the classification of aerobic, non-aerobic, gram positive and gram negative. The response or indication is in the form of color patterns discretely reflecting the four classifications mentioned above.

A volatile organic compound (VOC) sensitive strip mounted on the reduced pressure adapter or its associated drape is utilized in certain embodiments. When exposed to the targeted VOC known to form in the presence of certain microorganisms, a color pattern becomes apparent and thereby identifies the type of microorganism present in the wound fluid. Referencing FIGS. 15 and 16, a reduced pressure adapter 122 includes a base 124 and a conduit housing 130 similar to that described previously with reference to FIGS. 2-9. The positioning of a VOC sensitive panel 128 in a recessed region 126 of the conduit housing 130 is shown. In FIG. 16, it can be seen that given the translucent or transparent character of the material from which the reduced pressure adapter 122 is constructed, the VOC sensitive panel 128 can be visually inspected even from the exterior while the reduced pressure adapter 122 is in place with base 124 in position against the distribution manifold of the wound dressing. The preferable positioning of this VOC sensitive panel 128 is therefore within the recessed region 126 near the periphery of the recessed region 126 as shown. FIG. 15 shows more clearly the placement of this VOC sensitive panel within the recessed region 126 where it is constantly exposed to the fluid materials being drawn from the wound. Alternate placements of the panels are possible as long as sufficient exposure to wound fluids exists.

[0002] It should be apparent from the foregoing that an invention having significant advantages has been provided. While the invention is shown in only a few of its

-19-

forms, it is not just limited but is susceptible to various changes and modifications without departing from the spirit thereof.

-20-

Claims

1. A reduced pressure adapter for connecting a reduced pressure source to a porous pad, the adapter comprising:
5 a conduit housing having a recessed region defining an entry surface;
a primary conduit through the conduit housing in fluid communication with a primary port on the entry surface;
at least one ancillary conduit through the conduit housing in fluid communication with an ancillary port on the entry surface; and
channels positioned on the entry surface to direct liquid away from the ancillary port and into the primary port.
10
2. The adapter of claim 1, further comprising:
a base attached to the conduit housing such that an aperture of the base surrounds the recessed region.
15
3. The adapter of claim 2, wherein the conduit housing is rotatable about the base.
15
4. The adapter of claim 1, further comprising:
a base attached to the conduit housing such that an aperture of the base surrounds the recessed region; and
radial channels positioned on the base to direct liquid from a periphery of the base away from the ancillary conduit.
20
5. The adapter of claim 1, further comprising:
a base attached to the conduit housing such that an aperture of the base surrounds the recessed region;
radial channels positioned on the base to direct liquid from a periphery of the base away from the ancillary conduit; and
25

-21-

an intermediate collection channel positioned on the base to direct liquid into the radial guide channels.

6. The adapter of claim 1, wherein the channels comprise:
a linear channel section along approximately half of the entry surface; and
a radial channel section along approximately one-third of the entry surface.
7. The adapter of claim 1, further comprising an oval reduced pressure delivery tube having a primary lumen fluidly connected to the primary conduit and an ancillary lumen fluidly connected to the ancillary conduit.
8. The adapter of claim 1, further comprising a volatile organic compound sensitive strip mounted within the recessed region.
9. The adapter of claim 1, wherein there are at least two ancillary conduits having diametrically opposite ancillary ports on the entry surface.
10. The adapter of claim 1, further comprising a wall section supporting and surrounding the ancillary conduit, the wall section having an inside surface, an outside surface, and guide channels along the outside surface extending toward the primary port.
11. A system for applying reduced pressure to tissue, the system comprising:
a multi-lumen reduced pressure delivery tube having a proximate end, a distal end, a primary lumen extending through the conduit from the proximate end to the distal end, and an ancillary lumen extending through the conduit from the proximate end to the distal end;
a vacuum pump coupled to the proximate end of the primary lumen; and
a reduced pressure adapter coupled to the distal end of the reduced pressure delivery tube, the adapter having channels to direct liquid away from the ancillary lumens and into the primary lumen.

5

10

15

20

25

-22-

12. The system of claim 11, wherein the reduced pressure adapter comprises:
a conduit housing having an recessed region defining an entry surface;
a primary conduit through the conduit housing in fluid communication with the primary lumen and a primary port on the entry surface;
5 an ancillary conduit through the conduit housing in fluid communication with the ancillary lumen and an ancillary port on the entry surface; and
wherein the channels are positioned on the entry surface to direct liquid away from the ancillary port and to the primary port.

5

13. The system of claim 11, further comprising a base attached to the conduit 10 housing.

10

14. The system of claim 13, wherein the conduit housing is rotatable about the base.

15. The system of claim 13, wherein:

the conduit housing is rotatable about the base; and
the ancillary port is positioned substantially flush with the base.

15

16. The system of claim 12, further comprising:

a base attached to the conduit housing; and
radial guide channels positioned on the base to direct liquid from a periphery of the base away from the ancillary port.

20

17. The system of claim 12, further comprising:

a pressure sensor coupled to the proximate end of the ancillary lumen;
a valve coupled to the ancillary lumen; and
a controller coupled to the pressure sensor, the valve, and the vacuum pump,
the controller programmed to:
operate the vacuum pump to reduce pressure in the primary lumen;
receive pressure data from the pressure sensor,

25

-23-

monitor changes in the pressure data in response to associated changes to the vacuum pump operation; identify if the ancillary lumen has a delayed pressure response; and operate the valve coupled to the identified ancillary lumen.

5 18. A method for monitoring a pressure applied to a tissue site, the method comprising:
 measuring pressure through at least two pressure measurement conduits having openings near the tissue site, said measurement conduits isolated from each other and from a primary conduit;
10 monitoring a response time associated with changes in pressure measured through the pressure measurement conduits when changes in pressure are applied through the primary conduit; and
 opening one or more of the pressure measurement conduits to a pressure greater than the applied pressure if the response time associated with the pressure measurement conduits indicates a delayed response.
15

19. A rotatable reduced pressure adapter for connecting a reduced pressure source to a porous pad, the adapter comprising:
 a base;
 a perimeter ring attached to the base;
20 an first insert ring within the perimeter ring;
 an o-ring within the first insert ring;
 a second insert ring within the o-ring; and
 a housing covering the second insert ring.

25 20. The connector of claim 19, wherein the housing includes a recessed region defining an entry surface.

21. The connector of claim 20, further comprising:

-24-

a primary conduit through the housing in fluid communication with a primary port on the entry surface;
at least one ancillary conduit in fluid communication with an ancillary port on the entry surface; and
5 channels positioned on the entry surface to direct liquid away from the ancillary port and to the primary port.

22. A system for applying reduced pressure to a tissue site, the system comprising:

10 a multi-lumen reduced pressure delivery tube having an oval cross-section, a proximate end, a distal end, a primary lumen extending through the conduit from the proximate end to the distal end, and a plurality of ancillary lumens extending through the conduit from the proximate end to the distal end;
a vacuum pump coupled to the proximate end of the primary lumen; and
a reduced pressure adapter coupled to the distal end, the adapter comprising:
15 a conduit housing having a recessed region defining an entry surface;
a primary conduit positioned within the conduit housing and terminating at a primary port centrally positioned on the entry surface;
ancillary conduits positioned adjacent to the primary conduit and terminating at ancillary ports located on the entry surface;
a linear serrated channel section along approximately half of the entry surface;
20 a radial serrated channel section along approximately one-third of the entry surface;
a base attached to the conduit housing;
25 radial guide channels positioned on the base to direct liquid from a periphery of the base away from the ancillary ports;
an intermediate collection channel positioned on the base to direct liquid into the radial guide channels; and
30 a volatile organic compound sensitive strip mounted within the recessed region.

-25-

23. A reduced pressure adapter comprising:

a conduit housing having a recessed region for receiving a liquid from a tissue site;
means for fluidly connecting the recessed region to a primary lumen and an ancillary lumen; and
means for directing the liquid away from the ancillary lumen and to the primary lumen.

24. The adapter of claim 23, further comprising:

a base connected to the conduit housing; and
means for rotating the conduit housing about the base.

25. A system for applying reduced pressure to a tissue site, the system comprising:

a multi-lumen conduit having a proximate end, a distal end, a primary lumen extending through the conduit from the proximate end to the distal end, and ancillary lumens extending through the conduit from the proximate end to the distal end;
a vacuum pump coupled to the proximate end of the primary lumen;
a reduced pressure adapter coupled to the distal end, the adapter having channels to direct liquid into the primary lumen; and
means for operating the vacuum pump using feedback from at least two pressure sensors coupled to the ancillary lumens.

26. A multi-lumen reduced pressure delivery apparatus comprising:

a flexible tube having a first end, a second end, and an oval cross-section;
a primary conduit extending from the first end to the second end; and
an ancillary conduit extending from the first end to the second end adjacent to the primary conduit;
wherein the primary conduit has a first diameter and the ancillary conduit has a second diameter substantially smaller than the first diameter.

-26-

27. A dressing for applying reduced pressure to a tissue site, the dressing comprising:

5 a multi-lumen reduced pressure delivery tube having a proximate end, a distal end, a primary lumen extending through the conduit from the proximate end to the distal end, and ancillary lumens extending through the conduit from the proximate end to the distal end;

10 a reduced pressure adapter coupled to the distal end, the adapter having channels to direct liquid away from the ancillary lumens and into the primary lumen;

a porous pad attached to the reduced pressure adapter; and

a drape placed over the reduced pressure adapter and the porous pad, the drape having an adhesive surface for securing the reduced pressure adapter and the porous pad at the tissue site.

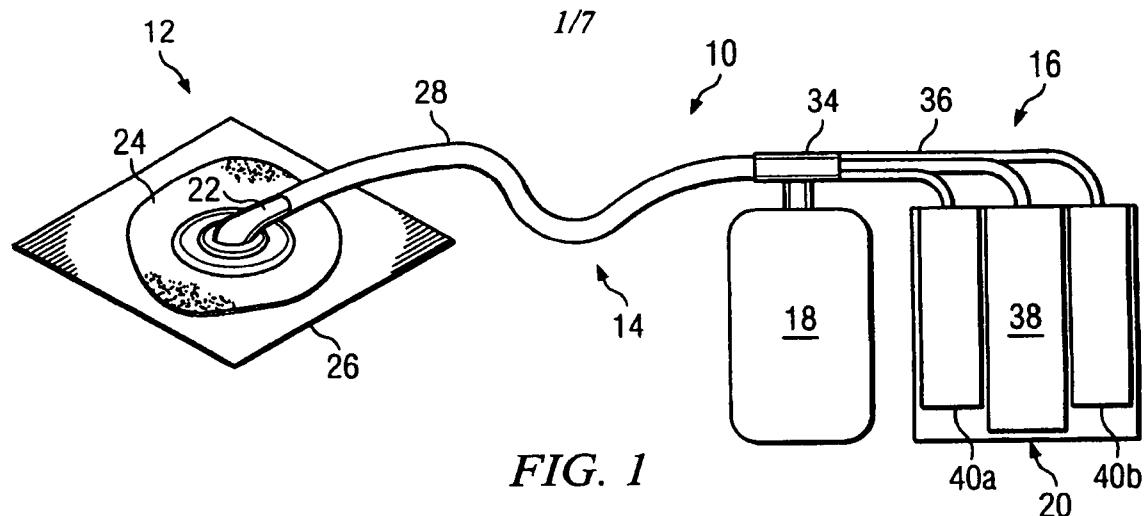


FIG. 1

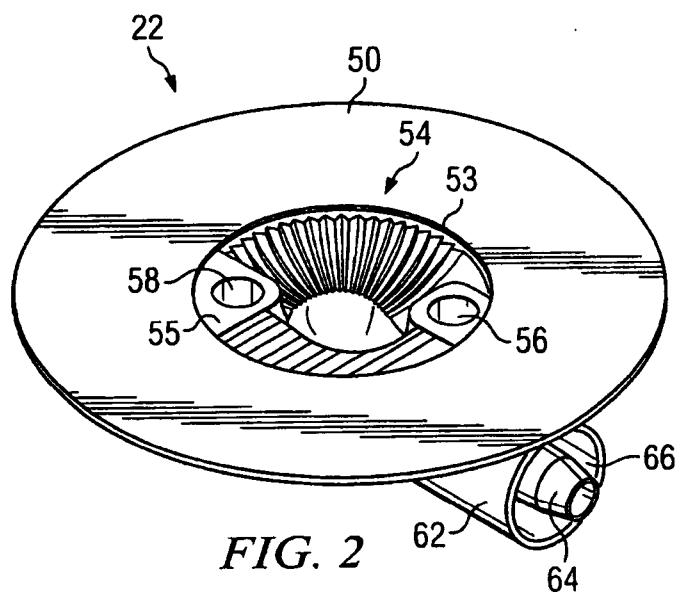


FIG. 2

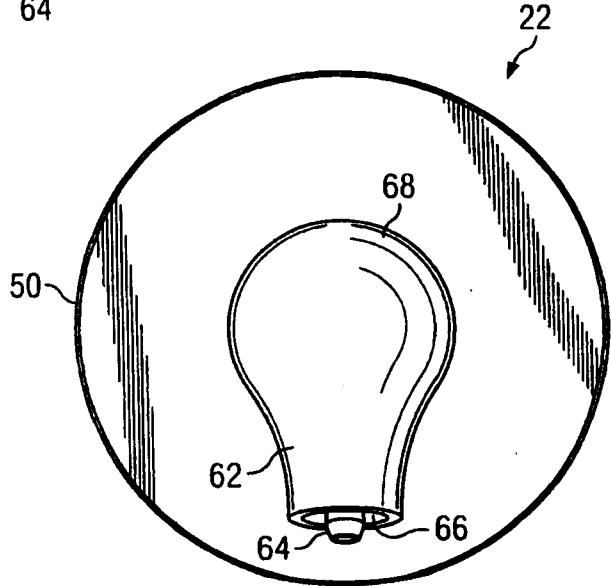
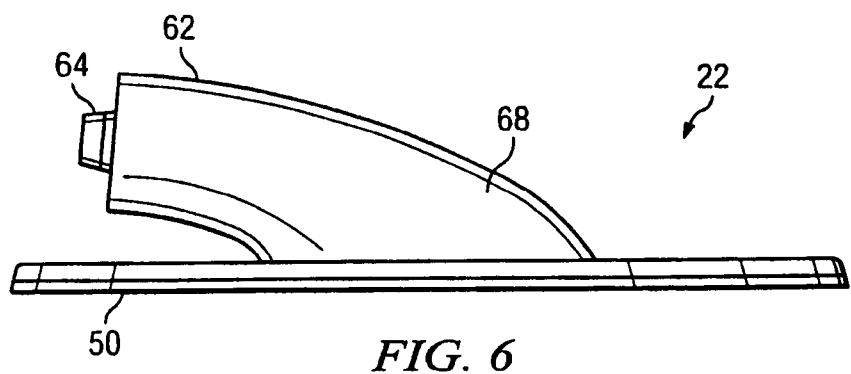
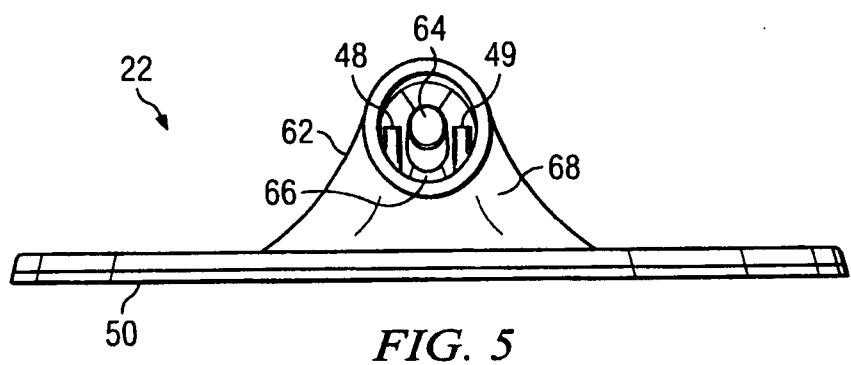
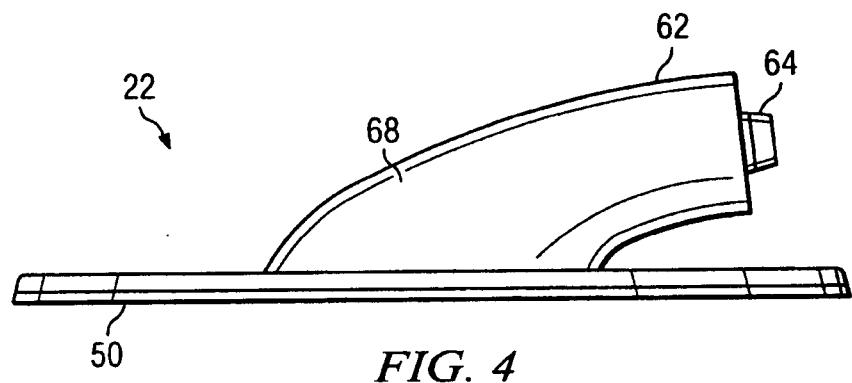


FIG. 3

2/7



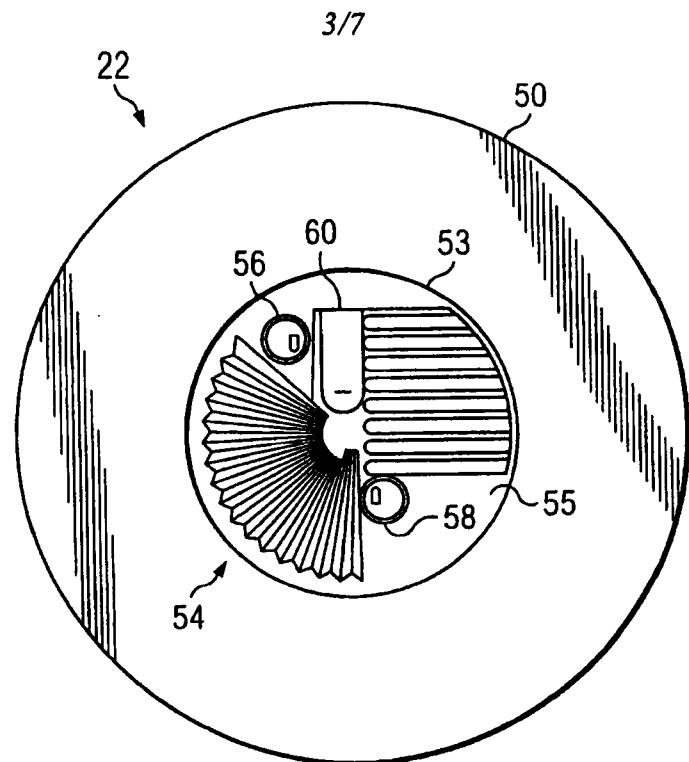


FIG. 7

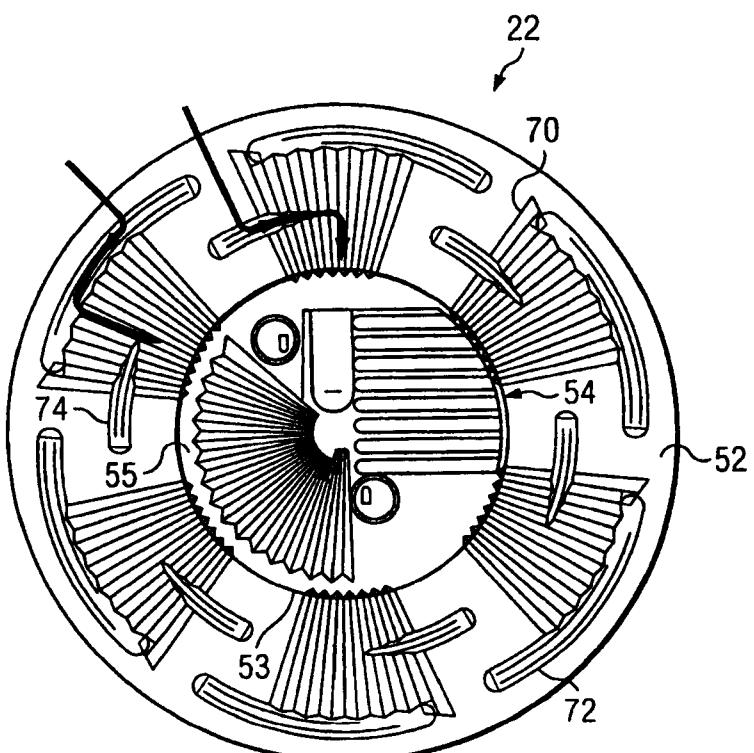
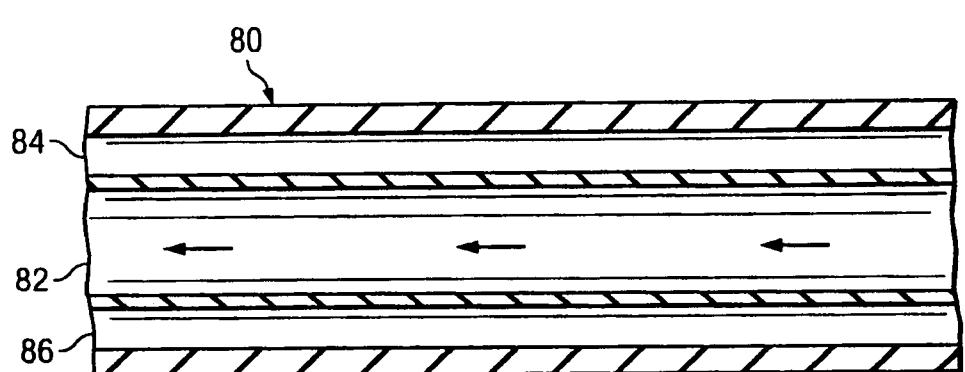
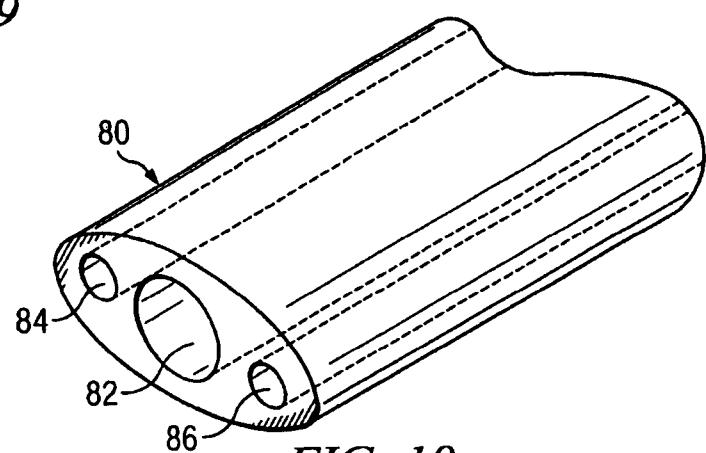
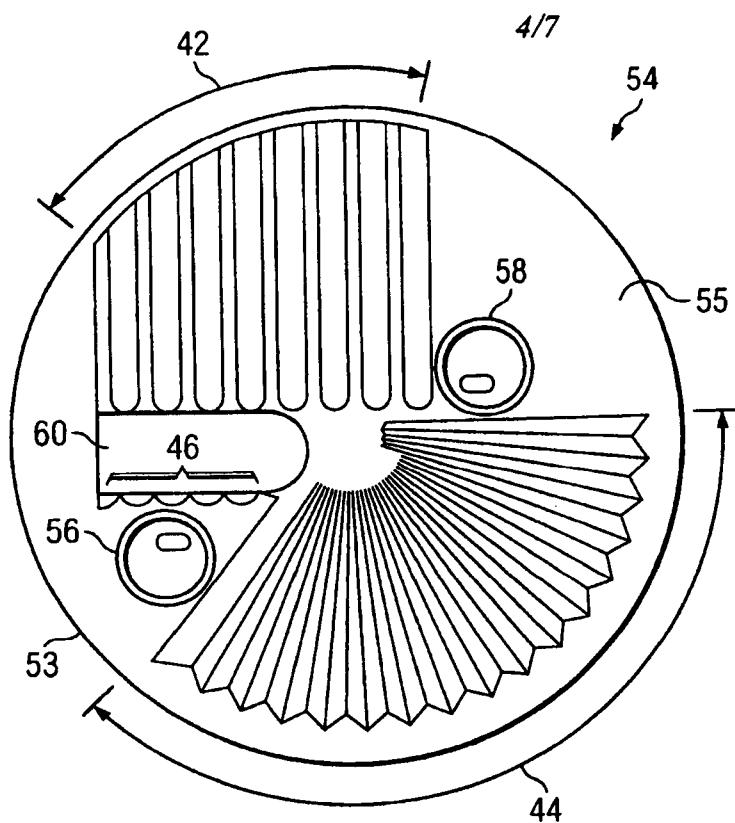


FIG. 8



5/7

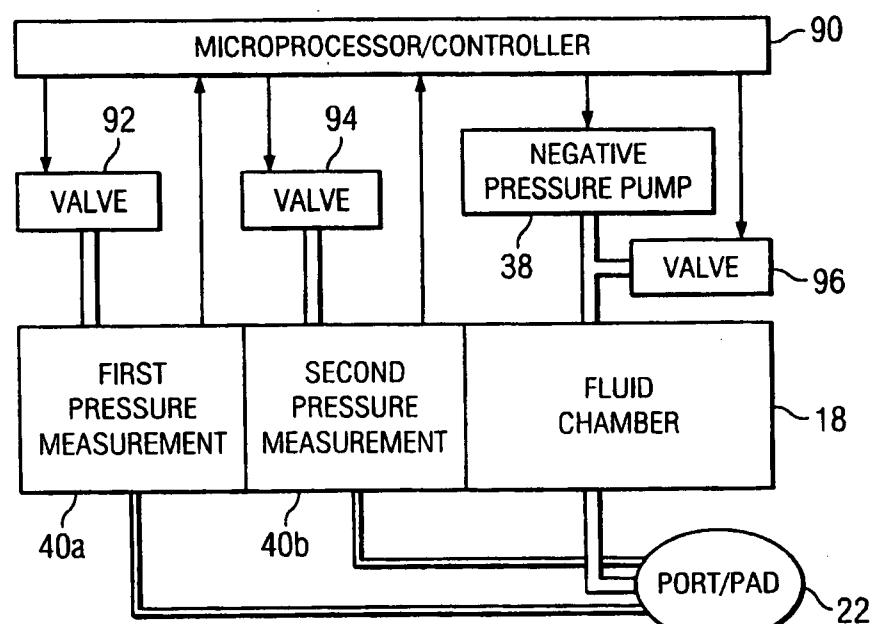


FIG. 12

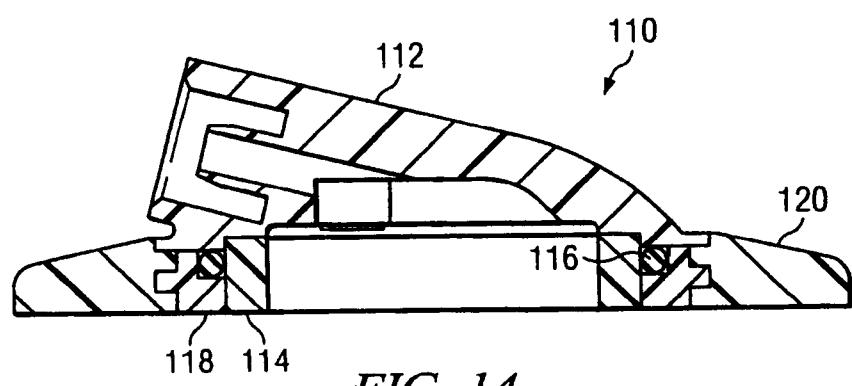


FIG. 14

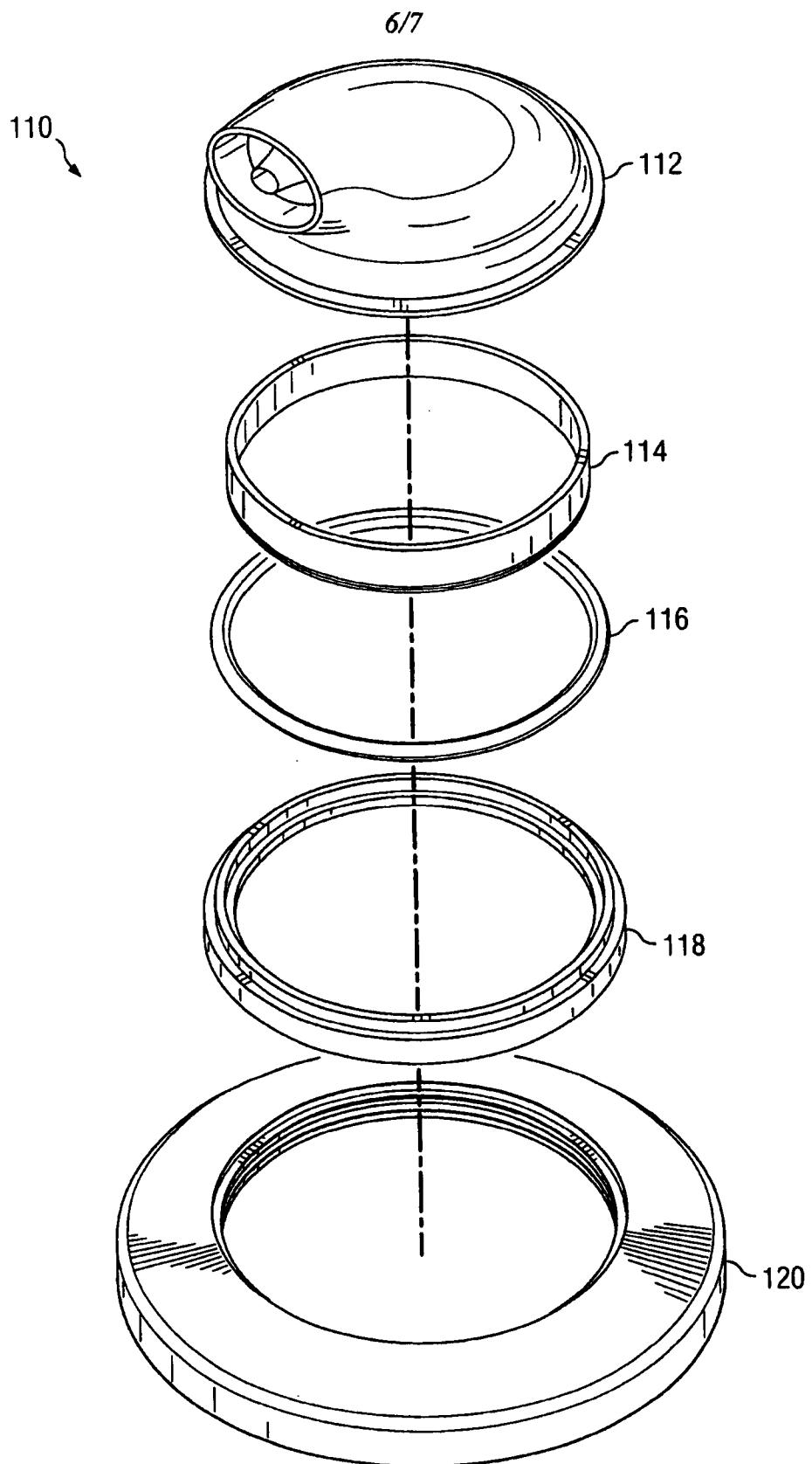


FIG. 13

SUBSTITUTE SHEET (RULE 26)

7/7

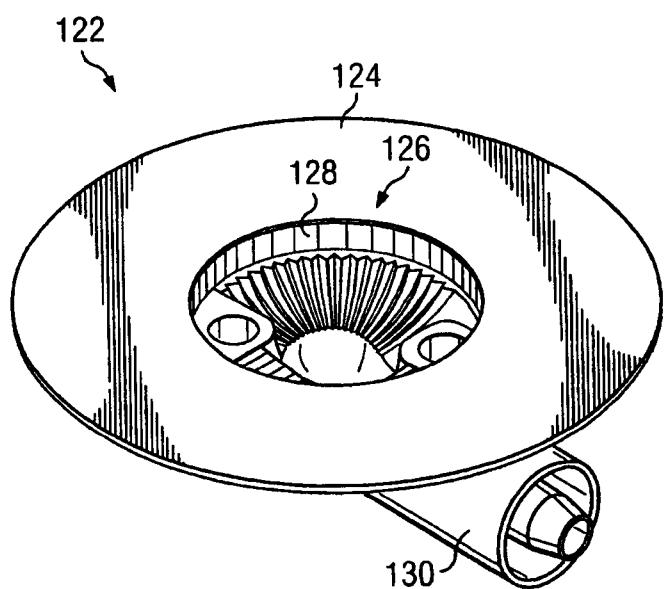


FIG. 15

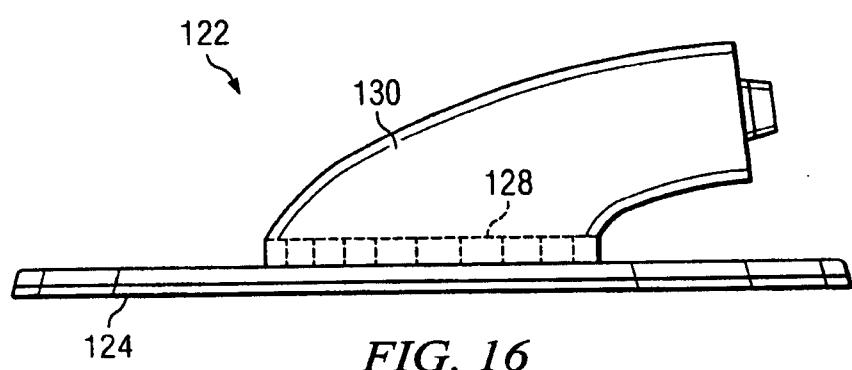


FIG. 16