TITLE OF THE INVENTION

OPEN-CAVITY, REDUCED-PRESSURE TREATMENT DEVICES AND SYSTEMS

RELATED APPLICATIONS

The present invention claims the benefit, under 35 USC § 119(e), of the filing of U.S. Provisional Patent Application serial number 61/109,410, entitled "Reduced-Pressure, Wound-Closure System and Method," filed October 29, 2008; U.S. Provisional Patent Application serial number 61/109,486, entitled "Reduced-Pressure, Abdominal Treatment System and Method," filed October 29, 2008; U.S. Provisional Patent Application serial number 61/109,390, entitled "Open-Cavity, Reduced-Pressure Wound Dressing and System," filed October 29, 2008; and U.S. Provisional Patent Application serial number 61/109,448, entitled "Reduced-Pressure, Deep-Tissue Closure System and Method," filed October 29, 2008.

BACKGROUND

The present invention relates generally to medical treatment systems and, more particularly, to open-cavity, reduced-pressure treatment devices and systems.

Whether the etiology of a wound, or damaged area of tissue, is trauma, surgery, or another cause, proper care of the wound, or wounds, is important to the outcome. Unique challenges exist when the wound involves locations that require reentry, for example, the peritoneal cavity and more generally the abdominal cavity. Often times when surgery or trauma involves the abdominal cavity, establishing a wound management system that facilitates reentry, allows for better and easier care, and helps to address such things as peritonitis, abdominal compartment syndrome, and infections that might inhibit final healing of the wound and the internal organs. In providing such care, it may be desirable to remove unwanted fluids from the cavity, help approximate the fascia and other tissues, and finally to help provide a closing force on the wound itself at the level of the epidermis.

Currently, an abdominal opening on the epidermis may be closed using sutures, staples, clips, and other mechanical devices to allow the skin, or epidermis, to be held and

pulled. Such devices cause wounds in and of themselves. Moreover, without more, if edema occurs, tremendous pressure may be placed on the closure device with potential harm resulting. For example, if pressure rises due to edema, sutures may tear out.

With respect to an overall system for allowing reentry into the abdominal cavity, a number of techniques have been developed. One approach is to place towels down into the cavity and then use clips, such as hemostats, to close the skin over the towels. While simple and fast, the results appear to have been regarded as suboptimal. Another approach is the "Bogota bag." With this approach, a bag is sutured into place to cover the open abdomen. Still another approach, sometimes called a "vac pack," has been to pack towels in the wound and then place a drain into the abdomen and cover the abdomen with a drape. Finally, a reduced pressure approach has been used. Such an approach is shown in U.S. Patent 7,381,859 to Hunt et al. and assigned to KCI Licensing, Inc. of San Antonio, Texas.

In addition to accessing the cavity for reentry, it may be desirable to remove fluids from the cavity. It may also be desirable to provide reduced-pressure therapy to the tissue or wound, including wounds that may be within the abdominal cavity. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") may provide a number of benefits, including faster healing and increased formulation of granulation tissue.

It would be desirable to provide a system and method that could remove excess fluids from an abdominal cavity, protect the interior of the abdominal cavity by providing a nonadherent barrier, and deliver reduced pressure. Further, it would be desirable to provide a system that can be readily placed in various locations in the abdominal cavity, such as paracolic gutters, is quickly installed, and that easily accommodates different size areas.

SUMMARY

Shortcomings with existing dressings and systems for open cavities, such as abdominal cavities, are addressed by the systems, apparatus, and methods of the illustrative embodiments described herein. According to one illustrative embodiment, a reduced-pressure treatment system for providing reduced-pressure treatment within a body cavity of a patient may include a treatment device having a plurality of encapsulated leg members, each encapsulated leg member having an interior portion with a leg manifold member and formed with fenestrations operable to allow fluid flow into the interior portion. The treatment device also includes a central connection member having a connection manifold member and wherein each leg manifold member is in fluid communication with the connection manifold member. The central connection member has a first side and a second, inward-facing side. The reduced-pressure treatment system further includes a manifold for disposing proximate the first side of the central connection member and operable to distribute reduced pressure to the central connection member; a sealing member for disposing on a portion of the patient's epidermis and operable to form a pneumatic seal over the body cavity; a reduced-pressure conduit; and a reduced-pressure source for producing reduced pressure. The reduced-pressure source is fluidly coupled to the reduced-pressure delivery conduit, which is fluidly coupled to a reduced-pressure interface.

According to another illustrative embodiment, an open-cavity, reduced-pressure treatment device for treating a tissue site in a body cavity includes a plurality of encapsulated leg members, each encapsulated leg member having an interior portion with a leg manifold member. The plurality of encapsulated leg members are formed with fenestrations operable to allow fluid flow into the interior portion. The open-cavity, reduced-pressure treatment device also includes a central connection member, which has a connection manifold member. The plurality of encapsulated leg members are in fluid communication with the connection manifold member.

According to another illustrative embodiment, a method of manufacturing a reduced-pressure treatment device for use in a body cavity of a patient includes the steps of: forming a plurality of encapsulated leg members, each encapsulated leg member having an interior portion with a leg manifold member and formed with fenestrations operable to allow fluid flow into the interior portion. The method of manufacturing a reduced-pressure treatment

device further includes forming a central connection member having a connection manifold member and fluidly coupling the central connection member to the plurality of encapsulated legs, wherein each leg manifold member is in fluid communication with the connection manifold member. The illustrative method may also include placing visual indicia on the non-adherent drape that indicates various sizes that might be cut.

According to another illustrative embodiment, a method of providing reduced-pressure treatment in an abdominal cavity of a patient may include the steps of: disposing a treatment device into the abdominal cavity, wherein the treatment device has a plurality of encapsulated leg members, each encapsulated leg member having an interior portion with a leg manifold member and formed with fenestrations operable to allow fluid flow into the interior portion, and a central connection member, wherein the central connection member has a connection manifold member and wherein each leg manifold member is in fluid communication with the connection manifold member. The central connection member has a first side and a second, inward-facing side. The method further includes placing at least one of the plurality of encapsulated leg members proximate a paracolic gutter in the abdominal cavity; disposing a manifold proximate the first side of the central connection member; placing a sealing member on a portion of the patient's epidermis to form a pneumatic seal over the body cavity; coupling a reduced-pressure interface to the sealing member; and coupling a reduced-pressure conduit to the reduced-pressure interface to deliver reduced pressure to the manifold. The illustrative method may further include the step of sizing the treatment device before disposing the treatment device into the body cavity.

Other objects, features, and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1A is a schematic diagram, with a portion in cross section, of an illustrative embodiment of an open-cavity, reduced-pressure treatment device and system;

FIGURE 1B is a schematic cross section of a portion of the treatment device of FIGURE 1A;

FIGURE 1C is a schematic cross section of a portion of the treatment device of FIGURE 1A taken along line 1C-1C;

FIGURE 1D is a schematic cross section of a portion of the system of FIGURE 1A;

FIGURE 2 is a schematic, perspective view of the illustrative embodiment of an open-cavity, reduced-pressure treatment device of FIGURES 1A-1D;

FIGURE 3A is a schematic, plan view of another illustrative embodiment of an open-cavity, reduced-pressure treatment device;

FIGURE 3B is a schematic, plan view of a portion of the treatment device of FIGURE 3A;

FIGURE 3C is a schematic cross section of a portion of the treatment device of FIGURE 3B taken along line 3C-3C;

FIGURE 4 is schematic, perspective view of another illustrative embodiment of an open-cavity, reduced-pressure treatment device; and

FIGURE 5 is a schematic, plan view of another illustrative embodiment of an open-cavity, reduced-pressure treatment device.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable 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 embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the illustrative embodiments are defined only by the appended claims.

Referring to FIGURES 1A-1D, an illustrative embodiment of an open-cavity, reduced-pressure system 100 and a treatment device 102 is presented. The open-cavity reduced-pressure system 100 and the treatment device 102 are for treating a tissue site 104 of a patient. The tissue site 104 may be the bodily tissue of any human, animal, or other organism, including bone tissue, adipose tissue, muscle tissue, dermal tissue, tissue, connective tissue, cartilage, tendons, ligaments, or any other tissue. In this illustrative embodiment, the tissue site 104 includes tissue in a body cavity, and in particular the abdominal cavity, and includes the abdominal contents or tissue that is proximate the abdominal cavity. Treatment of the tissue site 104 may include removal of fluids, e.g., ascites, protection of the abdominal cavity, or reduced-pressure therapy. Unless otherwise indicated, as used herein, "or" does not require mutual exclusivity.

As shown, the treatment device 102 is disposed within the abdominal cavity of the patient to treat the tissue site 104. The treatment device 102 includes a plurality of encapsulated leg members 106 that are supported by the abdominal contents, which make up a surface on which the plurality of leg members 106 are placed. One or more of the plurality of encapsulated leg members 106 may be placed in or proximate to a first paracolic gutter 108, and one or more of the plurality of encapsulated leg members 106 may be placed in or proximate to a second paracolic gutter 110. The plurality of encapsulated leg members 106 is coupled to a central connection member 112, and there is fluid communication between the plurality of encapsulated leg members 106 and the central connection member 112. The plurality of encapsulated leg members 106 and/or the central connection member 112 may be

formed with fenestrations 114, 116, 118, 120 that allow fluids in the abdominal cavity to pass through. The fenestrations 114, 116, 118, 120 may take any shape, e.g., circular apertures, rectangular openings, polygons, etc., but are presented in this illustrative embodiment as slits, or linear cuts. One or more fenestrations 114, 116, 118, 120 might be omitted in alternative embodiments.

A manifold 122, or manifold pad, distributes reduced pressure to the treatment device 102. A sealing member 124 provides a pneumatic seal over body-cavity opening 126. One or more skin closure devices may be placed on a patient's epidermis 134. Reduced pressure is delivered to the manifold 122 through a reduced-pressure interface 128, which is coupled to a reduced-pressure delivery conduit 130. A reduced-pressure source 132 delivers reduced pressure to the reduced-pressure delivery conduit 130.

The reduced pressure may be applied to the tissue site 104 to help promote removal of ascites, exudates, or other fluids from the tissue site 104. In some instances, reduced pressure may be applied to stimulate the growth of additional tissue. In some instances, only fluid removal may be desired. In the case of a wound at the tissue site 104, the growth of granulation tissue, removal of exudates, or removal of bacteria may help to promote healing of the wound. In the situation of a non-wounded or non-defective tissue, reduced pressure may be used in some instances to promote the growth of tissue that may be harvested and transplanted to another tissue site. As used herein, "reduced pressure" generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Alternatively, the reduced pressure may be less than a hydrostatic pressure at the tissue site. Reduced pressure may initially generate fluid flow in the manifold 122, the reduced-pressure conduit 130, and proximate the tissue site 104. As the hydrostatic pressure around the tissue site 104 approaches the desired reduced pressure, the flow may subside, and the reduced pressure may be maintained. Unless otherwise indicated, values of pressure stated herein are gauge pressures.

The manifold 122 is proximate the central connection member 112. The manifold 122 may take many forms. The term "manifold" as used herein generally refers to a substance or structure that is provided to assist in applying reduced pressure to, delivering fluids to, or removing fluids from the tissue site 104. The manifold 122 typically includes a plurality of flow channels or pathways that distribute the fluids provided to and removed from the tissue

site 104 around the manifold 122 and through the central connection member 112. In one illustrative embodiment, the flow channels or pathways are interconnected to improve distribution of fluids provided or removed from the tissue site 104. The manifold 122 may be a biocompatible material that is capable of being placed in contact with the tissue site 104 and distributing reduced pressure to the tissue site 104. Examples of manifold 122 may include, without limitation, devices that have structural elements arranged to form flow channels, cellular foam, such as open-cell foam, porous tissue collections, liquids, gels and foams that include or cure to include flow channels. The manifold 122 may be porous and may be made from foam, gauze, felted mat, or any other material suited to a particular biological application. In one embodiment, the manifold 122 is a porous foam and includes a plurality of interconnected cells or pores that act as flow channels. The porous foam may be a polyurethane, open-cell, reticulated foam, such as a GranuFoam® material manufactured by Kinetic Concepts, Incorporated of San Antonio, Texas. Other embodiments might include "closed cells." These closed-cell portions of the manifold may contain a plurality of cells, the majority of which are not fluidly connected to adjacent cells. The closed cells may be selectively disposed in the manifold 122 to prevent transmission of fluids through perimeter surfaces of the manifold 122. In some situations, the manifold 122 may also be used to distribute fluids such as medications, antibacterials, growth factors, and various solutions to the tissue site 104. Other layers may be included in or on the manifold 122, such as absorptive materials, wicking materials, hydrophobic materials, and hydrophilic materials.

The sealing member 124 is placed over the body-cavity opening 126 and provides a pneumatic seal adequate for the open-cavity, reduced-pressure system 100 to hold a reduced pressure at the tissue site 104. The sealing member 124 may be a cover that is used to secure the manifold 122 on the central connection member 112. The sealing member 124 may be impermeable or semi-permeable. The sealing member 124 is capable of maintaining reduced pressure at the tissue site 104 after installation of the sealing member 124 over the body-cavity opening 126. The sealing member 124 may be a flexible over-drape or film formed from a silicone-based compound, acrylic, hydrogel or hydrogel-forming material, or any other biocompatible material that includes the impermeability or permeability characteristics as desired for applying reduced pressure to the tissue site 104.

The sealing member 124 may further include an attachment means 131 to secure the sealing member 124 to the patient's epidermis 134. The attachment means 131 may take

many forms; for example, an adhesive layer 136 may be positioned along a perimeter of the sealing member 124 or any portion of the sealing member 124 to provide, directly or indirectly, the pneumatic seal with the patient's epidermis 134. The adhesive layer 136 might also be pre-applied to the sealing member 124 and covered with a releasable backing, or member (not shown), that is removed at the time of application.

The reduced-pressure interface 128 may be, as one example, a port or connector 138, which permits the passage of fluid from the manifold 122 to the reduced-pressure delivery conduit 130 and vice versa. For example, fluid collected from the tissue site 104 using the manifold 122 and the treatment device 102 may enter the reduced-pressure delivery conduit 130 via the connector 138. In another embodiment, the open-cavity, reduced-pressure system 100 may omit the connector 138 and the reduced-pressure delivery conduit 130 may be inserted directly into the sealing member 124 and into the manifold 122. The reduced-pressure delivery conduit 130 may be a medical conduit or tubing or any other means for transportating a reduced pressure and fluid. The reduced-pressure delivery conduit 130 may be a multi-lumen member for readily delivering reduced pressure and removing fluids. In one embodiment, the reduced-pressure delivery conduit 130 is a two-lumen conduit with one lumen for reduced pressure and liquid transport and one lumen for communicating pressure to a pressure sensor.

Reduced pressure is generated and supplied to the reduced-pressure delivery conduit 130 by the reduced-pressure source 132. A wide range of reduced pressures may be generated or supplied by the reduced-pressure source 132. In one embodiment, the range may include the range -50 to -300 mm Hg and in another embodiment, the range may include -100 mm Hg to -200 mm Hg. In one illustrative embodiment, the reduced-pressure source 132 includes preset selectors for -100 mm Hg, -125 mm Hg, and -150 mm Hg. The reduced-pressure source 132 may also include a number of alarms, such as a blockage alarm, a leakage alarm, or a battery-low alarm. The reduced-pressure source 132 could be a portable source, wall source, or other unit for abdominal cavities. The reduced-pressure source 132 may selectively deliver a constant pressure, varied pressure, intermittent pressure, or continuous pressure. The fluid removed from the cavity through the reduced-pressure delivery conduit 130 could be as much as 5L or more per day.

A number of different devices, e.g., device 140, may be added to a medial portion 142 of the reduced-pressure delivery conduit 130. For example, the device 140 might be a fluid

reservoir, or canister collection member, a pressure-feedback device, a volume detection system, a blood detection system, an infection detection system, a filter, a port with a filter, a flow monitoring system, a temperature monitoring system, etc. Multiple devices 140 might be included. Some of these devices, e.g., the fluid collection member, may be formed integral to the reduced-pressure source 132. For example, a reduced-pressure port 144 on the reduced-pressure source 132 may include a filter member (not shown) that includes one or more filters and may include a hydrophobic filter that prevents liquid from entering an interior space of the reduced-pressure source 132.

Referring now to FIGURES, 1C, 1D and 2, the treatment device 102 can include a non-adherent drape 148. The non-adherent drape 148 may be formed of a non-adherent material that inhibits tissue adhesion to the non-adherent drape 148. In one embodiment, the non-adherent drape 148 is formed from a breathable polyurethane film. The non-adherent drape 148 can include a plurality of openings, apertures, or fenestrations 150. The fenestrations can take a variety of shapes, such as circular openings, rectangular openings, polygon-shaped openings, etc., but are shown in FIGURE 2 as slits, or linear cuts. Depending on the particular application of device 102, the desired fluid flow and/or pressure delivery, or other system parameters, the fenestrations can different sizes.

The treatment device 102 includes the central connection member 112 to which the plurality of encapsulated leg members 106 are coupled. The central connection member 112 includes a manifold member 154 that is encapsulated by a first connection encapsulation member 186 and a second connection encapsulation member 192. However, a portion of the central connection member can fluidly couple at leg coupling areas 152 to permit fluid communication between the central connection member 112 and the plurality of encapsulated leg members 106. The first and second connection encapsulation members may be a defined by a single piece of material or, as illustrated, more than one sheet of material.

The central connection member 112, as discussed above, can fluidly communicate with manifold 122. In one aspect, fenestrations 118, similar to the fenestrations discussed above can permit fluid communication. Additionally, or alternatively, a portion or portions of the first connection encapsulation member can be exposed to manifold 112.

Referring again to FIGURES 1A-1D, each of the plurality of encapsulated leg members 106 can include a leg manifold member 160, which may be a single manifold member that runs between the leg modules 156 and/or central connection member 112, or

individual manifold components. The leg manifold member 160 is disposed within an interior portion 162 of each of the encapsulated leg members 106. Each leg manifold member 160 has a first side 164 and a second, inward-facing (patient-facing) side 166.

In one embodiment, one or more of the plurality of leg manifold members 160 can have different material properties or structures. For example, different flow rates may be desired in different encapsulated leg members 106. In one aspect, different manifold materials or manifold properties, different manifold sizes, manifold compression, the use flow restricting material structures, and/or or valves can provide different flow rates of fluid through the encapsulated leg members and/or central connection member.

In one aspect, a first leg encapsulating member 168, which can be formed with fenestrations 114, is disposed on the first side 164 of the leg manifold member 160. A second leg encapsulating member 170, which can include fenestrations 116, is disposed on the second, inward-facing side 166 of the leg manifold member 160. The second leg encapsulating member 170 may be a portion of the non-adherent drape 148. In one embodiment, the encapsulated leg members 106 can be mated with one another, for example, via drape 148. Alternatively, the leg members can be independently movable with respect to one another with the exception of their proximal end adjacent to the central connection member 112. For example, the leg members need not be connected to one another. In another embodiment, a portion of the material connecting the leg members, e.g., the non-adherent drape 148 between adjacent leg members 106, is expandable (e.g., a stretchable, flexible, deformable, and/or elastic material) and permits movement of individual leg members 106 with respect to one another.

As shown in the longitudinal cross section of FIGURE 1B by arrows 172, fluid can flow from leg modules 156 towards the central connection member 112. As shown by arrows 174, the fluid is able to enter fenestrations 114 and 116 and flow into the leg manifold member 160 and then flow toward the central connection member 112 as represented by arrows 172.

In plan view, the encapsulated leg members 106 may take a number of different shapes, such as elongate shapes, rectangular, elliptical, etc. In one aspect, the encapsulated leg members 106 may include leg modules 156. Adjacent leg modules 156 are fluidly coupled to each other and have a manipulation zone 158 between them. In one aspect, the manipulation zone includes a weakened or perforated area to facilitate sizing of the device. For example, a clinician can cut through a leg module to size the device. By pulling on the partially cut leg

module the manifold can be torn away at the next manipulation zone. In one aspect, the recessed shape of the manipulation zone 158 can inhibit accidental removal of additional leg modules. Additionally, or alternatively, the outer portion of the leg modules can be fixed to the device to inhibit unwanted manifold removal.

The encapsulated leg members 106 may also have various dimensions. If the longer dimension, e.g., lengthwise or longitudinal dimension, of the encapsulated leg 106 is $_{L1}$ and the width is $_{W1}$, then the aspect ratio is given by $_{L1}/_{W1}$. The aspect ratio may be 8.0, 7.0, 6.0, 5.0, 4.0, 3.0, 2.0 or any number in between. Moreover, other aspect ratios are possible. Generally, the width $_{W1}$ of the encapsulated leg member will be greater than a width $_{W2}$ of the central connection member 112, i.e., $_{W2} > _{W1}$. For example, in one illustrative embodiment, the encapsulated leg members 106 are approximately 270 mm long, 60 mm wide ($_{W1}$), and 10 mm thick, and the central connection member has a width parallel to the first width ($_{W1}$) of about 130 mm ($_{W2}$). Thus, in that illustrative example, the aspect ratio of the encapsulated leg 106 is approximately (270/60) or 4.5. In this same illustrative embodiment, the manipulation zones 158 have a width of about 10 mm.

Referring to FIGURE 1C, a lateral cross section of a portion of the encapsulated leg member 106 is presented. As before, it can be seen that the first side 164 of the leg manifold member 160 is covered with the first leg encapsulating member 168, and that the second, inward-facing side 166 of the leg manifold member 160 is covered by the second leg encapsulating member 170, which in this instance is a portion of the non-adherent drape 148. Thus, in this illustrative embodiment, the fenestrations 116 may be some of the plurality of fenestrations 150 in the non-adherent drape 148. In this illustrative embodiment, a peripheral edges 176 of the leg manifold member 160 are also covered by a portion of the first leg encapsulating member 168. The peripheral edges 176 include a first lateral edge 177 and a second lateral edge 179. The first leg encapsulating member 168 covers the first side 164 and the peripheral edges 176 and extends onto a first surface 178 of the non-adherent drape 148 and forms extensions 180. The extensions 180 have been coupled to the second leg encapsulating member 170 by welds 182. The first leg encapsulating member 168 may, however, be coupled to the second leg encapsulating member 170 using any known technique, including welding (e.g., ultrasonic or RF welding), bonding, adhesives, cements, etc.

Referring again to FIGURE 1D and FIGURE 2, the central connection member 112 includes the connection manifold member 154 that is encapsulated within the first connection

encapsulation member 186, which has fenestrations 118. The first connection encapsulation member 186 is disposed on a first side 188 of the connection manifold member 154. The second connection encapsulation member 192 is disposed on a second, inward-facing side 190 of the connection manifold member 154. The second connection encapsulation member 192 is formed with fenestrations 120. The first connection encapsulation member 186 has a peripheral zone or edge 194 as shown in FIGURE 2. In a similar fashion, the second connection encapsulation member 192 has a peripheral zone or edge (not explicitly shown) that lines up with the peripheral edge 194. The peripheral edge 194 of the first connection encapsulation member 186 is coupled to peripheral edge of the second connection encapsulation member 192, except at the leg coupling areas 152 in order to allow fluid within the plurality of encapsulated leg members 106 to flow into the connection manifold member 154 as suggested by arrows 196 in FIGURE 1D. Fluid may also enter directly into the connection manifold member 154 by flowing through fenestrations 120 as suggested by arrows 198. The manifold 122 is disposed proximate to the first connection encapsulation member 186, and when a reduced pressure is applied to the manifold 122, the reduced pressure causes fluid to flow from the connection manifold member 154 through fenestrations 118 and into the manifold 122 as suggested by arrows 200. The fluid continues to flow in the direction of the reduced-pressure interface 128 through which the fluid is removed to the reduced-pressure delivery conduit 130.

Referring to FIGURES 1A-1D and 2, in operation, the illustrative open-cavity, reduced-pressure system 100 may be used by first sizing the treatment device 102 as will be explained further below in connection with FIGURE 3A. The non-adherent drape 148 with the plurality of encapsulated leg members 106 is disposed within the abdominal cavity through the body-cavity opening 126 and is distributed against the abdominal contents; this may include placing at least one encapsulated leg member 106 in or proximate the first paracolic gutter 108, the second paracolic gutter 110, or behind the liver, etc. Once the treatment device 102 has been distributed, the manifold 122 is placed adjacent a first side 184 of the first connection encapsulation member 186. The sealing member 124 may then be applied over the body-cavity opening 126 to provide a pneumatic seal over the body-cavity opening 126.

In addition to the sealing member 124, the body-cavity opening 126 may be further closed or reinforced using mechanical closing means, e.g., staples, or using a reduced-pressure closure system. The sealing member 124 may be applied in a number of ways, but according

to one illustrative embodiment, the releasable backing member that is on the adhesive layer 136 of the sealing member 124 is removed and then the sealing member 124 is placed against the patient's epidermis 134 about the body-cavity opening 126. The reduced-pressure interface 128, such as port 138, is then attached to the sealing member 124 such that reduced pressure can be delivered by the interface 128, through the sealing member 124, and to the manifold 122. The reduced-pressure delivery conduit 130 is fluidly coupled to the reduced-pressure interface 128 and to the reduced-pressure port 144 on the reduced-pressure source 132.

The reduced-pressure source 132 is activated and thereby provides reduced pressure into the reduced-pressure delivery conduit 130, which delivers the reduced pressure to the reduced-pressure interface 128 and into the manifold 122. The manifold 122 distributes the reduced pressure and draws fluid through fenestrations 118 from the connection manifold member 154. The connection manifold member 154 draws fluid from the abdominal cavity through fenestrations 120 and pulls fluid from the plurality of encapsulated leg members 106 as suggested by arrows 196. Fluid from the abdominal cavity flows into the plurality of encapsulated leg members 106 through fenestrations 114 on the first leg encapsulating member 168 and through fenestrations 116 on the second leg encapsulating member 170 and then flows through the leg as suggested by arrows 172 towards the connection manifold member 154. The fluid then flows through the manifold 122, the reduced-pressure interface 128, and into the reduced-pressure delivery conduit 130.

Referring now to FIGURES 3A-3C, another illustrative embodiment of an open-cavity, reduced-pressure treatment device 302 is presented. The open-cavity, reduced-pressure treatment device 302 is analogous in most respects to the treatment device 102 of FIGURES 1A-1D. The open-cavity, reduced-pressure treatment device 302 has a non-adherent drape 304, a plurality of encapsulated leg members 306, and a central connection member 308. In this particular illustrative embodiment, the non-adherent drape 304 is formed generally with an oval or arcuate shape. The non-adherent drape 304 is formed with a plurality of fenestrations 305. The non-adherent drape 304 forms the second leg encapsulating member (see by analogy second leg encapsulating member 170 in FIGURE 1B) and the second connection encapsulation member (see by analogy 192 in FIGURE 1D). As such, the plurality of fenestrations 305 serves as flow channels for the plurality of encapsulated leg members 306 and the central connection member 308 on the second, inward-facing side. The non-adherent

drape 304 could also be used on the first side of the plurality of encapsulated leg members 306 and the central connection member 308.

Each of the encapsulated leg members 306 may be formed with a plurality of leg modules 310 with manipulation zones 312 between the plurality of leg modules 310. As with the manipulation zone 158 in FIGURES 1A-D, the manipulation zones 312 facilitate movement of the plurality of encapsulated leg members 306 within the body cavity and provide an easier location at which to cut the plurality of encapsulated leg members 306 when the open-cavity, reduced-pressure treatment device 302 is being sized for a particular application. In this regard, visual indicia 314 may be added on the non-adherent drape 304 to help the healthcare provider know where to cut the non-adherent drape 304 for different sizes of application within the cavity. The visual indicia 314 may comprise cut lines, or graduations, that preferably run through the manipulation zones 312. The manipulation zones 312 provide a convenient and easy location for cutting the open-cavity, reduced-pressure treatment device 302.

Referring to FIGURE 3C, a lateral cross section of a portion of an encapsulated leg member 306 is presented. The plurality of encapsulated leg members 306 are formed with a leg manifold member 318 having a first side 320 and a second, inward-facing (patient-facing) side 322. A first leg encapsulating member 324 covers the first side 320 of the leg manifold member 318 and covers a lateral zone or edge 326 of the leg manifold member 318. The second, inward-facing side 322 of the leg manifold member 318 is covered by a second leg encapsulating member 328, which in this embodiment is a portion of the non-adherent drape 304. The first leg encapsulating member 324 is coupled to the second leg encapsulating member 328 by any means known in the art, such as by welding (e.g., ultrasonic or RF), bonding, adhesives, cements, etc. In this illustrative embodiment, the first leg encapsulating member 324 and the second leg encapsulating member 328 are coupled by a weld 330. Referring to FIGURE 3B, the weld 330 is shown along the perimeter of the plurality of leg modules 310.

Referring again to FIGURE 3A, the central connection member 308 is formed analogously to the central connection member 112 in FIGURE 2. A first connection encapsulation member 334 and a second connection encapsulation member of the central connection member 308 are coupled along a peripheral edge 332 using a weld 333 or another coupling technique, such as those previously mentioned. The peripheral edge 332 is not

sealed, however, proximate each of the encapsulated leg members 306 in order to provide a channel for fluid to flow from the plurality of encapsulated leg members 306 into the central connection member 308.

According to one illustrative approach to constructing the open-cavity, reduced-pressure treatment device 302, the non-adherent drape 304, which is already formed with the plurality of fenestrations 305 and that has visual indicia 314 is provided. The leg manifold member 318 is disposed adjacent the non-adherent drape 304. The central connection manifold 308 is disposed adjacent to the leg manifold member 318 or may be formed integral with leg manifold member 318. The first connection encapsulation member 334 is placed on the central connection member 308, and the first leg encapsulating member 324 is placed over the leg manifold member 318. The first connection encapsulation member 334 and the first leg encapsulating member 324 may be formed from an integral sheet. Next, the welds 330 and 333 are applied.

In an alternative embodiment for manufacturing an open-cavity, reduced-pressure treatment device, a first non-adherent drape 304, which includes fenestrations, may be provided and the leg manifold member 318 and the central connection manifold 308 disposed on the first non-adherent drape 304. A second non-adherent drape, which has fenestrations, is placed over the first non-adherent drape 304, the leg manifold member 318, and the central connection manifold 308. Next, a plurality of welds (e.g., thermal or RF or another coupling techniques used) are made, such as with the welds 330. The first non-adherent drape 304 and the second non-adherent drape may be cut to size before or after assembly. By using two drapes, the first non-adherent drape 304 and the second non-adherent drape may provide better distribution of reduced pressure and may ease the manufacturing process.

The fenestrations may be formed before or after assembly. The perimeter of the first non-adherent drape 304 and the second non-adherent drape may be welded. Other points may be welded between the drapes to form a single unit. In another alternative embodiment, the drapes may initially be placed and welded without fenestrations, and then fenestrations added to the drapes so that the fenestrations align. The fenestrations might also be formed using an electrical member that cuts and seals at the same time to form aligned, "button hole" fenestrations through the two drapes.

Referring now to FIGURE 4, another illustrative embodiment of an open-cavity, reduced-pressure treatment device 402 is presented. The open-cavity, reduced-pressure

treatment device 402 is similar to the treatment device 102 shown in FIGURE 2, and to indicate analogous parts, reference numerals have been indexed by 300. The open-cavity, reduced-pressure treatment device 402 differs primarily in that a fluid delivery subsystem 445 is included. A plurality of encapsulated leg members 406 are shown without leg modules, and the fenestrations are shown with a circular shape. As noted before, the plurality of encapsulated leg members 406 may be formed with or without leg modules. The fluid delivery subsystem 445 allows various fluids, such as medicines or irrigation fluids, to be delivered into the cavity. The delivered fluids may then be removed by the open-cavity, reduced-pressure treatment device 402. The fluid delivery subsystem 445 includes a central port 447, which may be placed on or in a central connection member 412, for connecting to a conduit (not shown) that delivers the fluid from a location external to the central port 447. Fluidly coupled to the central port 447 is a plurality of fluid-delivery conduits 449. The plurality of fluid-delivery conduits 449 may be located anywhere on a non-adherent drape 448, but in this illustrative embodiment, are disposed in the plurality of encapsulated leg members 406. The plurality of fluid-delivery conduits 449 are opened on their distal ends 451 to allow the delivery of fluid therethrough. The flow of fluid through the distal ends 451 of the plurality of fluid-delivery conduits 449 is suggested by arrows 453.

In use, the open-cavity, reduced-pressure treatment device 402 may be used in a fashion analogous to that of the treatment devices 102 and 302, but at various times or even continuously, it may be desirable to deliver a fluid through the fluid delivery subsystem 445. For example, it may be desirable to flush the abdominal cavity with an irrigation fluid or to deliver periodic doses of medicine.

Another illustrative embodiment for using an open-cavity, reduced-pressure treatment device (e.g., cavity, reduced-pressure treatment device 102, 302, 402) or system will now be presented. The system is particularly suitable for temporary bridging of abdominal wall openings where primary closure may not be readily possible and or repeat abdominal entries are necessary. The illustrative system described here may be used with open abdominal wounds, with exposed viscera, including but not limited to abdominal compartment syndrome. Before applying the system, typically hemostasis should be achieved.

In deploying the open-cavity, reduced-pressure treatment system, the reduced-pressure treatment device preferably covers all exposed viscera and preferably separates completely the viscera from contact with the abdominal wall. For example, the lower surface of the reduced

pressure treatment device, such as drape 148, can be sized and shaped to permit coverage. The reduced-pressure treatment device may be placed over the omentum or exposed internal organs, and carefully tucked between the abdominal wall and internal organs. In doing so, the healthcare provider may use the reduced-pressure treatment device to completely separate the abdominal wall from the internal organs.

To prepare for deployment of the system, any sharp edges or bone fragments are eliminated from wound area or covered. The abdominal wound is irrigated and the periwound area cleaned. The periwound tissue at the epidermis is typically dried before further application.

The reduced-pressure treatment device is then sized by determining the appropriate size and cutting. The reduced-pressure treatment device is initially unfolded in a sterile field. Either side of the reduced-pressure treatment device may be placed on the omentum or viscera. The reduced-pressure treatment device is gently placed over the open abdominal cavity. The orientation of the reduced-pressure treatment device for the specific application is determined. If the reduced-pressure treatment device will be placed around tubes, drains or the falciform ligament, the reduced-pressure device is cut only between the plurality of encapsulated leg members. The reduced-pressure treatment device is placed in the proper orientation before cutting.

The reduced-pressure treatment device is then folded to size and used that way or may be cut. The healthcare provider holds the reduced-pressure treatment device by the edge and slightly lifts the reduced-pressure treatment device. The reduced-pressure treatment device is slowly lowered into the paracolic gutter with one hand and the other hand is used to gently and evenly work the reduced-pressure treatment device down. The healthcare provider folds any excess portions of the reduced-pressure treatment device up and over onto itself. The healthcare provider continues to placed the reduced-pressure treatment device between abdominal wall and internal organs throughout the abdominal compartment. The healthcare provider preferably provides full coverage of all viscera. The reduced-pressure treatment device may then be cut as needed for sizing outside of the wound.

To size the device, the reduced-pressure treatment device can be cut through center of one of the large manifold squares, or leg modules, using sterile scissors. In this illustrative embodiment, the cut is not made through the manipulation zone, but through the leg module. The healthcare provider then pinches the remaining half of the foam square, or leg module,

and the adjacent, inboard manipulation zone through the encapsulating member with one hand and pulls the manifold material. The manifold material in the leg module and the manipulation zone will separate at the next square, or leg module. This will ensure that edges of the reduced-pressure treatment device cover the otherwise exposed manifold edge. The manifold material, e.g., foam, preferably does not contact organs.

The manifold that is to be placed on top of the central connection member is next prepared. In this embodiment, the manifold may be a perforated foam manifold that has perforations to help tear the manifold to the desired size. The manifold preferably fits directly over the reduced-pressure treatment device while still being in contact with wound edges. The manifold should not contact intact skin. Two or more manifolds may be used in some instances. Then, the sized manifold is gently placed into the wound cavity over the reduced-pressure treatment device. The healthcare provider preferably takes care to avoid the manifold going below the level of the abdominal incision or wound.

A drape, or over-drape, is then applied. To apply the drape, a backing is removed from an adhesive layer on one side of the drape and the drape is applied. The drape covers the manifold and a portion of intact epidermis. Preferably the drape covers at least an 8-10 centimeter border of intact periwound tissue. Additional drape material may be added to seal any difficult areas.

The reduced-pressure interface, or interface pad, is then added. The healthcare provider chooses an application site. The site is chosen to optimize fluid flow as well as to facilitate easy tubing positioning. The healthcare provider pinches the drape and cuts a 2.5 cm hole (preferably not a slit) through the drape. The interface pad, which has a central disc and a surrounding outer adhesive skirt, is applied. The interface pad is applied by removing backing layers on an inward-facing surface of the interface pad to expose an adhesive. The interface pad opening in the central disc is placed directly over the hole in the drape. Pressure is gently applied on the central disc and the outer skirt to ensure complete adhesion of the interface pad. One or more stabilization layers may then be removed from a first side of the skirt. The system is now ready for the application of reduced pressure.

According to another illustrative embodiment, which is shown in FIGURE 5, an open-cavity, reduced-pressure treatment device 502 includes a central fluid hub 512 and a plurality of elongate members 506. The central fluid hub 512 has an upper surface 513 and a lower surface. The central fluid hub 512 includes a foam manifold 554, which defines at least a

portion of the upper surface 513, and a substantially fluid impermeable wall, which defines at least a portion of the lower surface. The fluid impermeable wall includes a plurality of apertures 518. The plurality of elongate members 506 have a proximal end 515, distal end 517, and upper 519 and lower surfaces. The elongate members 506 include a foam enclosed within substantially fluid impermeable walls. The proximal ends 515 of the plurality of elongate members 506 are in fluid communication with the central fluid hub 512. The elongate members 506 include apertures 514 extending through the fluid impermeable wall along at least a portion of the lower surface of the elongate members 506.

The plurality of elongate members 506 have a first length L_1 extending from the central fluid hub 512 and a first width (W_1) generally parallel to the upper surface and perpendicular to the first length. The central hub has a second width (W_2) between lateral edges on a portion between a first and second elongate member. The second width is greater than the first width ($W_2 > W_1$). The plurality of elongate members 506 are fluidly coupled to the central hub 512. The open-cavity, reduced-pressure treatment device 502 may have an aspect ratio of the plurality of elongate members 506 in the range of 3.0 to 10.0. The open-cavity, reduced-pressure treatment device 502 may have an aspect ratio of the plurality of elongate members 506 that is greater than 3.5. The open-cavity, reduced-pressure treatment device 502 may also include an elastic material 585 extending between the plurality of elongate members 506.

Although the present invention and its advantages have been disclosed in the context of certain illustrative, non-limiting embodiments, it should be understood that various changes, substitutions, permutations, and alterations can be made without departing from the scope of the invention as defined by the appended claims. It will be appreciated that any feature that is described in a connection to any one embodiment may also be applicable to any other embodiment.

CLAIMS

We claim:

Claim 1. An open-cavity, reduced-pressure treatment system for providing reduced-pressure treatment within a body cavity of a patient, the open-cavity, reduced-pressure treatment system comprising:

a treatment device comprising:

a plurality of encapsulated leg members, each encapsulated leg member having an interior portion a leg manifold member positioned therein, the leg members including fenestrations to allow fluid flow between an outer surface of the encapsulated leg members and the interior portion, and

a central connection member, wherein the central connection member has a connection manifold member and wherein the plurality of leg manifold members are in fluid communication with the connection manifold member, the central connection member having a first side and a second, inward-facing side;

a manifold for disposing proximate the first side of the central connection member and operable to distribute reduced pressure to the central connection member;

a sealing member for disposing on a portion of a patient's epidermis and operable to form a pneumatic seal over the body cavity;

a reduced-pressure delivery conduit;

a reduced-pressure source for producing reduced pressure, the reduced-pressure source fluidly coupled to the reduced-pressure delivery conduit; and

a reduced-pressure interface for coupling to the sealing member and operable to fluidly couple the reduced-pressure delivery conduit to the manifold.

Claim 2. The open-cavity, reduced-pressure treatment system of claim 1 wherein the plurality of encapsulated leg members comprises:

a first leg encapsulating member;

a second leg encapsulating member formed with fenestrations;

wherein the leg manifold member has a first side, a second, inward-facing side, a first lateral edge, and a second lateral edge; and

wherein the first leg encapsulating member is disposed proximate the first side of the leg manifold member, the second leg encapsulating member is disposed proximate

the second, inward-facing side of the leg manifold member, and the first leg encapsulating member and the second leg encapsulating member are coupled proximate the first lateral edge and the second lateral edge of the leg manifold member.

Claim 3. The open-cavity, reduced-pressure treatment system of claim 1 wherein the central connection member comprises:

a first connection encapsulation member formed with fenestrations and having a peripheral edge;

a second connection encapsulation member formed with fenestrations; and

wherein the peripheral edge of the first connection encapsulation member is coupled at least in part, to the second connection encapsulation member.

Claim 4. The open-cavity, reduced-pressure treatment system of claim 1, wherein each encapsulated leg member of the plurality of encapsulated leg members comprises:

a first leg encapsulating member formed with fenestrations,

a second leg encapsulating member formed with fenestrations,

wherein the leg manifold member has a first side, a second, inward-facing side, a first lateral edge, and a second lateral edge,

wherein the first leg encapsulating member is disposed proximate the first side of the leg manifold member, the second leg encapsulating member is disposed proximate the second, inward-facing side of the leg manifold member, and the first leg encapsulating member and the second leg encapsulating member are coupled proximate the first lateral edge and the second lateral edge of the leg manifold member; and

wherein the central connection member comprises:

a first connection encapsulation member formed with fenestrations and having a peripheral edge,

a second connection encapsulation member formed with fenestrations, and

wherein the peripheral edge of the first connection encapsulation member is coupled at least in part, to the second connection encapsulation member.

Claim 5. The system of claim 4 further comprising a non-adherent drape and wherein the second leg encapsulation member comprises at least a portion of the non-adherent drape.

Claim 6. An open-cavity, reduced-pressure treatment device for treating a tissue site in a body cavity, the treatment device comprising:

a plurality of encapsulated leg members, the encapsulated leg members having an interior portion with a leg manifold member disposed in the interior portions, the plurality of encapsulated leg members formed with fenestrations operable to allow fluid flow into the interior portion;

a central connection member, wherein the central connection member has a connection manifold member, and wherein the leg manifold members are in fluid communication with the connection manifold member; and

a lower surface extending below and between the plurality of encapsulated leg manifold members and the central connection member, wherein the fenestrations extend through the lower surface.

Claim 7. The open-cavity, reduced-pressure treatment device of claim 6 wherein each encapsulated leg member of the plurality of encapsulated leg members comprises:

a first leg encapsulating member;

a second leg encapsulating member formed with fenestrations;

wherein the leg manifold member has a first side, a second, inward-facing side, a first lateral edge, and a second lateral edge;

wherein the first leg encapsulating member is disposed proximate the first side of the leg manifold member, the second leg encapsulating member is disposed proximate the second, inward-facing side of the leg manifold member, and the first leg encapsulating member and the second leg encapsulating member are coupled proximate the first lateral edge and the second lateral edge of the leg manifold member.

Claim 8. The open-cavity, reduced-pressure treatment device of claim 6, wherein each encapsulated leg member of the plurality of encapsulated leg members comprises a plurality of leg modules.

Claim 9. The open-cavity, reduced-pressure treatment device of claim 6, further comprising a non-adherent drape defining the lower surface.

Claim 10. The open-cavity, reduced-pressure treatment device of claim 6 further comprising a non-adherent drape and wherein the second leg encapsulating member comprises at least a portion of the non-adherent drape.

Claim 11. The open-cavity, reduced-pressure treatment device of claim 10 wherein the non-adherent drape further comprises visual indicia indicating size graduation.

Claim 12. The open-cavity, reduced-pressure treatment device of claim 6 wherein the central connection member comprises:

a first connection encapsulation member formed with fenestrations and having a peripheral edge;

a second connection encapsulation member formed with fenestrations; and

wherein the peripheral edge of the first connection encapsulation member is coupled at least in part, to the second connection encapsulation member.

Claim 13. The open-cavity, reduced-pressure treatment device of claim 6, wherein each encapsulated leg member of the plurality of encapsulated leg members comprises:

a first leg encapsulating member formed with fenestrations,

a second leg encapsulating member formed with fenestrations,

wherein the leg manifold member has a first side, a second, inward-facing side, a first lateral edge, and a second lateral edge,

wherein the first leg encapsulating member is disposed proximate the first side of the leg manifold member, the second leg encapsulating member is disposed proximate the second, inward-facing side of the leg manifold member, and the first leg encapsulating member and the second leg encapsulating member are coupled proximate the first lateral edge and the second lateral edge of the leg manifold member; and

wherein the central connection member comprises:

a first connection encapsulation member formed with fenestrations and having a peripheral edge,

a second connection encapsulation member formed with fenestrations, and

wherein the peripheral edge of the first connection encapsulation member is coupled at least in part, to the second connection encapsulation member.

Claim 14. A method of manufacturing a reduced-pressure treatment device for use in a body cavity of a patient, the method comprising the steps of:

forming a plurality of encapsulated leg members, each encapsulated leg member having an interior portion with a leg manifold member and formed with fenestrations operable to allow fluid flow into the interior portion;

forming a central connection member having a connection manifold member; and

coupling the central connection member to the plurality of encapsulated leg members, wherein each leg manifold member is in fluid communication with the connection manifold member.

Claim 15. The method of manufacturing a reduced-pressure treatment device of claim 14, the method comprising the step of forming a non-adherent drape with fenestrations and wherein the step of forming a plurality of encapsulated leg members comprises using at least a portion of the non-adherent drape as a leg encapsulated member.

Claim 16. The method of manufacturing a reduced-pressure treatment device of claim 15 wherein the step of forming a non-adherent drape comprises forming an elastomeric drape, forming fenestrations through the elastomeric drape, and placing visual indicia on the elastomeric drape that indicates various sizes that might be cut.

Claim 17. The method of manufacturing a reduced-pressure treatment device of claim 14 wherein the steps of forming a plurality of encapsulated leg members, forming a central connection member having a connection manifold member, and coupling the central connection member to the plurality of encapsulated leg members comprise the steps of: providing a first non-adherent drape, placing a manifold unit, which has a plurality of leg manifold members and a connection manifold member, adjacent to a surface of the first non-adherent drape; placing a second non-adherent drape over the manifold unit; and coupling the first non-adherent drape and the second non-adherent drape to form the plurality of encapsulated leg members and the central connection member.

Claim 18. The method of manufacturing a reduced-pressure treatment device of claim 14 wherein the steps of forming a plurality of encapsulated leg members, forming a central connection member having a connection manifold member, and coupling the central connection member to the plurality of encapsulated leg members comprise the steps of: providing a first non-adherent drape, placing a manifold unit, which has a plurality of leg

manifold members and a connection manifold member, adjacent to a surface of the first non-adherent drape; placing a second non-adherent drape over the manifold unit; coupling the first non-adherent drape and the second non-adherent drape to form the plurality of encapsulated leg members and the central connection member; and cutting the first non-adherent drape and second non-adherent drape.

Claim 19. The method of manufacturing a reduced-pressure treatment device of claim 14 wherein the steps of forming a plurality of encapsulated leg members, forming a central connection member having a connection manifold member, and coupling the central connection member to the plurality of encapsulated leg members comprise the steps of: providing a first non-adherent drape, placing a manifold unit, which has a plurality of leg manifold members and a connection manifold member, adjacent to a surface of the first non-adherent drape; placing a second non-adherent drape over the manifold unit; coupling the first non-adherent drape and the second non-adherent drape to form the plurality of encapsulated leg members and the central connection member; wherein the step of coupling the first non-adherent drape and the second non-adherent drape comprises bonding the first non-adherent drape to the second-adherent drape; and further comprising cutting the first non-adherent drape and second non-adherent drape.

Claim 20. The method of manufacturing a reduced-pressure treatment device of claim 15 wherein the step of forming a plurality of encapsulated leg members comprises, for each encapsulated leg member, the steps of:

forming a first leg encapsulating member;

forming fenestrations in the first leg encapsulating member;

forming a second leg encapsulating member;

forming fenestrations in the second leg encapsulating member;

disposing the first leg encapsulating member proximate a first side of a leg manifold member;

wherein the leg manifold member has the first side, a second, inward-facing side, a first lateral edge, and a second lateral edge;

disposing the second leg encapsulating member proximate the second, inward-facing side of the leg manifold member; and

coupling the first leg encapsulating member and the second leg encapsulating member proximate the first lateral edge and the second lateral edge of the leg manifold member.

Claim 21. The method of manufacturing a reduced-pressure treatment device of claim 15 wherein the step of forming a central connection member comprises the steps of:

forming a first connection encapsulation member having a peripheral edge;

forming fenestrations in the first connection encapsulation member;

forming a second connection encapsulation member;

forming fenestrations in the second connection encapsulation member; and

coupling, at least in part, the peripheral edge of the first connection encapsulation member to the second connection encapsulation member.

Claim 22. The method of manufacturing a reduced-pressure treatment device of claim 15, wherein the step of forming a plurality of encapsulated leg members comprises, for each encapsulated leg member, the steps of:

providing a leg manifold member, wherein the leg manifold member has a first side, a second, inward-facing side, a first lateral edge, and a second lateral edge,

forming a first leg encapsulating member;

forming a second leg encapsulating member;

forming fenestrations in the second leg encapsulating member,

disposing the first leg encapsulating member proximate the first side of the leg manifold member,

disposing the second leg encapsulating member proximate the second, inward-facing side of the leg manifold member,

coupling the first leg encapsulating member and the second leg encapsulating member; and

wherein the step of forming a central connection member comprises the steps of:

providing a connection manifold member having a first side and a second, inward-facing side;

forming a first connection encapsulation member having a peripheral edge,

forming fenestrations in the first connection encapsulation member,

forming a second connection encapsulation member;

forming fenestrations in the second connection encapsulation member,

disposing the first connection encapsulation member on the first side of the connection manifold member;

disposing the second connection encapsulation member on the second, inward-facing side of the connection manifold member; and

coupling, at least in part, the peripheral edge of the first connection encapsulation member to the second connection encapsulation member.

Claim 23. An open-cavity, reduced-pressure treatment device comprising:

a central fluid hub having an upper surface and a lower surface, the fluid hub including a foam manifold defining at least a portion of the upper surface and a substantially fluid impermeable wall defining at least a portion of the lower surface, the fluid impermeable wall including a plurality of apertures,

a plurality of elongate members having a proximal and distal end and upper and lower surfaces, the elongate members including a foam enclosed within substantially fluid impermeable walls, the proximal ends of the plurality of elongate members in fluid communication with the central fluid hub, the elongate members including apertures extending through the fluid impermeable walls along at least a portion of the lower surface of the elongate members,

wherein the plurality of elongate members have a first length L_1 extending from the central fluid hub and a first width (W_1) generally parallel to the upper surface,

wherein the central hub has a second width (W_2) between a first and second elongate member ;

wherein the second width is greater than the first width ($W_2 > W_1$).

Claim 24. The open-cavity, reduced-pressure treatment device of claim 23 wherein an aspect ratio (L_1 to W_1) of the plurality of elongate members is in the range of 3.0 to 10.0.

Claim 25. The open-cavity, reduced-pressure treatment device of claim 23 wherein an aspect ratio of the plurality of elongate members is greater than 3.5.

Claim 26. The open-cavity, reduced-pressure treatment device of claim 23 further comprising a substantially fluid impermeable material extending between the plurality of elongate members.

Claim 27. The open-cavity, reduced-pressure treatment device of claim 23, further comprising an expandable material extending between the plurality of elongate members.