LOW-PROFILE REDUCED PRESSURE TREATMENT SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to tissue treatment systems and in particular to low-profile reduced pressure treatment systems.

2. Description of Related Art

Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, including faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a porous pad or other manifolding device. The porous pad contains cells or pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The porous pad often is incorporated into a dressing having other components that facilitate treatment.

Traditionally, dressings have been rather cumbersome and difficult to apply to small wounds. Simply sitting on or rolling onto a dressing may cause significant patient discomfort, or pressure-induced injury, particularly at contact with relatively stiff components such as tubing connections, elbows, and other components. Moreover, these actions may compress the dressing and interfere with the application of reduced pressure. Furthermore, the profile of these dressings and any protuberances present the likelihood of snagging on patient clothing or surroundings during normal activity, a risk associated with pain and possible re-injury of tissue.

Accordingly, there is much demand for improved dressings that alleviate the disadvantages of known dressings.

All references cited herein are incorporated by reference to the maximum extent allowable by law. To the extent a reference may not be fully incorporated herein, it is

incorporated by reference for background purposes and indicative of the knowledge of one of ordinary skill in the art.

BRIEF SUMMARY OF THE INVENTION

The problems presented in known reduced pressure treatment systems are solved by the systems and methods of the present invention. A low-profile reduced pressure treatment apparatus and system are provided in accordance with the principles of the present invention.

One embodiment of the low-profile reduced pressure treatment apparatus includes a moldable conduit holder, a conduit extending through the conduit holder, and a flexible base. The conduit holder has substantially parallel first and second bulkhead surfaces, a convex top surface, and a bottom surface adapted to substantially conform in shape to a tissue contact region adjacent to a tissue site. The conduit extends through the conduit holder such that an end of the conduit is substantially flush with the first bulkhead surface and a longitudinal axis of the conduit is substantially perpendicular to the first and second bulkhead surfaces. The flexible base has a first side connected to the bottom surface of the conduit holder, the flexible base extending beyond the first bulkhead surface to form an overlay zone adjacent the first bulkhead surface. An adhesive is disposed on a second side of the flexible base to secure the flexible base to the tissue contact region.

An embodiment of the low-profile reduced pressure treatment system includes a moldable conduit holder, a conduit received by the conduit holder, a base, a porous pad, a drape, and a reduced pressure source fluidly connected to the conduit to deliver reduced pressure through the conduit and the porous pad. The conduit holder has substantially parallel first and second bulkhead surfaces, a convex top surface, and a bottom surface adapted to substantially conform in shape to a tissue contact region adjacent to a tissue site. The conduit is received by the conduit holder such that an end of the conduit is substantially flush with the first bulkhead surface and a longitudinal axis of the conduit is substantially perpendicular to the first and second bulkhead surfaces. The base has a first side connected to the bottom surface of the conduit holder, the base extending beyond the first bulkhead surface to form an overlay zone adjacent the first bulkhead surface. An adhesive is disposed on a second side of the base to secure the base to the tissue contact region adjacent to the tissue site. The porous pad includes a primary delivery region configured to contact the tissue site and a bridge region configured to contact the overlay zone of the base and apply a flexible transition to the tissue

site. The drape is sized to cover and create a sealed space around the conduit holder and the porous pad.

Also in accordance with the principles of the present invention, a process for making and using a low-profile reduced pressure treatment apparatus and system is provided. One embodiment for making a low-profile reduced pressure treatment apparatus includes positioning a first flexible membrane on an arcuate form, positioning a conduit on the first flexible membrane, extruding silicone onto and around the conduit, positioning a second flexible membrane over the silicone and the conduit, securing edges of the second flexible membrane to edges of the first flexible membrane, and securing the first flexible membrane to a drape having dimensions greater than the first flexible membrane so that the drape extends beyond the edges of the first flexible membrane adjacent to an aperture of the conduit.

One process for using a low-profile reduced pressure treatment apparatus includes positioning a first flexible membrane so that an overlay zone is adjacent to the tissue site and a conduit holder is adjacent to the overlay zone opposite the tissue site; positioning a porous pad so that a bridge region is aligned with the overlay zone and a primary delivery region is aligned with the tissue site; connecting the porous pad to a reduced pressure source through a conduit in the conduit holder; positioning a second flexible membrane over the conduit holder and the porous pad; sealing the second flexible membrane to the tissue contact region; and applying reduced pressure from the reduced pressure source to the tissue site through the conduit and the porous pad.

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

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a schematic view of a reduced pressure treatment system according to the present invention;

FIG. 2 illustrates an exploded view of a low-profile adapter according to the present invention;

FIG. 3 illustrates a perspective view of the assembled low-profile adapter of FIG. 2 according to the present invention;

FIG. 4 illustrates a perspective view of the assembled low-profile adapter of FIG. 3 with a porous pad in position over a bridge overlay zone according to the present invention;

FIG. 5 illustrates a perspective view of the assembled low-profile adapter of FIG. 3 with an alternate embodiment of the porous pad according to the present invention;

FIG. 6 illustrates a perspective view of the assembled low-profile adapter and porous pad of FIG. 4 covered by a drape according to the present invention;

FIG. 7 illustrates a perspective view of an alternate embodiment of a low-profile adapter having multiple conduits according to the present invention; and

FIG. 8 illustrates a front view of an alternate embodiment of a low-profile adapter having a concave molded base according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

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 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 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.

In the context of this specification, the term "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 of the location at which the patient is located. Although the terms "vacuum" and "negative pressure" may be used to describe the pressure applied to the tissue site, the actual pressure applied to the tissue site may be significantly less than the pressure normally associated with a complete vacuum. Consistent with this nomenclature, an increase in reduced pressure or vacuum pressure refers to a relative reduction of absolute pressure, while a decrease in reduced pressure or vacuum pressure refers to a relative increase of absolute pressure.

Figure 1 is a schematic diagram of a reduced pressure treatment system 100 incorporating the novel features of the invention. The reduced pressure treatment system 100 comprises a dressing 110, which is applied to a tissue site 120 for treatment. Dressing 110 is fluidly connected to a reduced pressure source 125 by a conduit 130. In certain embodiments, the reduced pressure system 110 may also include a canister 140 for collecting liquid and other non-gaseous exudates extracted from a tissue site.

Figure 2 is an exploded view of an embodiment of a low-profile adapter 200. In this embodiment, the adapter 200 comprises a conduit holder 205, a first bulkhead surface 215, and a second bulkhead surface 220 that is substantially parallel to the first bulkhead surface 215. In this embodiment, the conduit holder 205 has a convex top surface 210 to minimize the profile of the conduit holder 205. The conduit holder 205 also includes a conduit 225 that

extends through the length of the conduit holder 205, having an aperture 230 on the first bulkhead surface 215 and an aperture 235 on the second bulkhead surface 220.

The conduit holder 205 is constructed from any material that may be extruded or injected into a mold, such as room temperature vulcanizing (RTV) silicone. The conduit 130 may be inserted into or connected to the conduit 225 to establish a fluid path between the aperture 230 and the reduced pressure source 125.

Depending on the composition of the conduit holder 205, the conduit holder 205 may optionally be enclosed between flexible membranes of a material more suitable for tissue contact, such as a nitrile film, as illustrated by the flexible membranes 240 and 245. In such an embodiment, the flexible membrane 245 is attached to the flexible membrane 250.

Alternatively, the flexible membrane 245 may be omitted and the flexible membrane 240 may be attached directly to the flexible membrane 250. The flexible membrane 250 is preferably a polyurethane material. A drape 255 having adhesive surface 256 is bonded to the flexible membrane 250 on one side. The drape 255 may include an optional biocompatible adhesive surface 257 on the side opposite the adhesive surface 256. The biocompatible adhesive surface 257 may consist of any suitable bonding agent, such as an acrylic adhesive or hydrogel. The biocompatible adhesive surface 257 may be applied to intact tissue to secure the low-profile adapter in position when applied to a tissue site. If the drape 255 includes the biocompatible adhesive surface 257, a protective liner 260 is applied to the biocompatible adhesive surface 257 to preserve the adhesive and facilitate handling. The protective liner 260 is removed to expose the underlying adhesive before application to the tissue site 120. The flexible membrane 250, the drape 255, and optionally, the protective liner 260 comprise a base 265. The drape 255 generally is constructed from any flexible material having a sufficiently high moisture vapor transmission rate (MTVR) to preclude tissue maceration, typically greater than 600 $mg/m^2/day$. Polyurethane is an example of a suitable material for the drape 255. Because of the flexibility of the flexible membrane 250 and the drape 255, the base 265 readily conforms to the contours of most tissue sites.

Figure 3 is a perspective view of the assembled low-profile adapter 200. The conduit holder 205 has a height h, as measured between the apex of the first bulkhead surface 215 and the base 265. As Figure 3 illustrates, the base 265 extends beyond the first bulkhead surface 215 to form a bridge overlay zone 300 adjacent to the first bulkhead surface 215 and the aperture 230.

Figure 4 is a perspective view of the assembled low-profile adapter 200 with a porous pad 400 in position over the bridge overlay zone 300 (not visible in Figure 4). The porous pad 400 generally includes a porous bridge 402 and a primary delivery region 404. Figure 4 also illustrates a section of the conduit 130, which is connected on one end to the aperture 235 (not shown in Figure 4). The porous pad 400 has a thickness, *t*, sufficient to cover the aperture 230 in the first bulkhead surface 215, which is typically the same dimension as the height *h* of the conduit holder 205. The porous pad 400 also has a depth *d* sufficient to extend from the first bulkhead surface 215 and overhang the bridge overlay zone 300 to cover a tissue site. Figure 4 also illustrates an optional porous extension 405, which may be inserted into a tissue site for deeper penetration. Although the porous extension 405 is depicted in Figure 4 as a separate component, the porous extension 405 may be an integral component of the porous pad 400 so that the porous pad 400 and the porous extension 405 form a single component. Likewise, the porous pad 400 and the porous extension 405 are illustrated as simple block pieces, but they may be adapted to any desired shape. For example, the porous pad 400 may be cut to conform to the profile of the conduit holder 205 or to the shape of an irregular tissue site.

The porous pad 400 and the porous extension 405 represent any material known in the art to be suitable for reduced pressure treatment, the size and shape of which may be varied to accommodate tissue sites of various size and shape. Preferably, the porous pad 400 and the porous extension 405 include a plurality of flow channels or pathways to facilitate the distribution of reduced pressure or fluids to or from the tissue site. In one embodiment, the porous pad 400 and the porous extension 405 are porous foam that includes interconnected cells or pores that act as flow channels and a pressure manifold. The porous foam may be polyurethane or any other type of open-cell, reticulated foam, such as GRANUFOAM manufactured by Kinetic Concepts, Inc. of San Antonio, Texas. If open-cell foam is used, the porosity may vary, but is preferably about 400 to 600 microns. Alternatively, gauze or any other material suited to a particular biological application may be used to construct the porous pad 400 and the porous extension 405.

Figure 5 is a perspective view of the low-profile adapter 200 with an alternative embodiment of a porous pad. As Figure 5 illustrates, a porous pad may be comprised of one or more discrete components, such as a porous bridge 502 and a primary delivery component 504. Such an alternative embodiment may be advantageous for packaging a universal bridge component with the low-profile adapter 200, while permitting additional components to be fit to a particular tissue site as needed.

Figure 6 is a perspective view of the low-profile adapter 200, a porous pad 400, and a drape 600. The drape 600 covers the low-profile adapter 200 and the porous pad 400, and includes an adhesive on the surface 605 that is applied to a tissue contact region adjacent to a subject tissue site (not shown). The adhesive may consist of any suitable bonding agent, such as an acrylic adhesive or hydrogel. The seal isolates the tissue site from the surrounding environment and assists in maintaining a reduced pressure at the tissue site when reduced pressure is applied. The convex top surface 210 provide tapered lateral edges, which minimize the risk of leaks between the drape 600 and the tissue contact region adjacent to the tissue site. The adhesive may also secure the low-profile adapter 200 and the porous pad 400 in position if the drape 255 does not include the optional biocompatible adhesive surface 257. Like the drape 255, the drape 600 generally is constructed from any flexible material having a sufficiently high moisture vapor transmission rate (MTVR) to preclude tissue maceration, typically greater than 600 $mg/m^2/day$.

In operation, the protective liner 260 (if present) is removed to expose the adhesive surface 257 (if present), and the low-profile adapter 200 is positioned so that the bridge overlay zone 300 is over intact tissue and immediately adjacent to a tissue site 120. A porous pad (such as porous pad 400) is positioned so that it extends from the first bulkhead surface 215 and overhangs the bridge overlay zone 300 to cover the tissue site 120, while one end covers the aperture 230 in the first bulkhead surface 215. The drape 600 is then placed over the low-profile adapter 200 and the porous pad 400, and the edges of the drape 600 are pressed against intact tissue surrounding the low-profile adapter 200 and the intact tissue surrounding the tissue site 120. The conduit 130 is then connected on one end to the conduit 225 through the aperture 235 in the second bulkhead surface 220, and on the other end to the collection canister 140 or the reduced pressure source 125. Reduced pressure may then be delivered to the tissue site 120 through the conduit 130, the conduit 225, and the pad 400.

Figure 7 is a perspective view of an alternate embodiment of a low-profile adapter 700. In this embodiment, the adapter 700 comprises a conduit holder 705 having a convex top surface 710, a first bulkhead surface 715, and a second bulkhead surface 720 that is substantially parallel to the first bulkhead surface 715. The conduit holder 705 also includes two conduits 725 and 730 that extend through the length of the conduit holder 705, having two apertures 735 and 740 on the first bulkhead surface 715, and two apertures 745 and 750 on the second bulkhead surface 720. Multiple conduits, such as those depicted in Figure 7, may be advantageous for applications such as pressure monitoring and fluid distribution in

conjunction with reduced pressure application. Alternatively, a multi-lumen conduit may be substituted for any pair of conduits.

Figure 8 is a front view of another alternate embodiment of a low-profile adapter 800. In this embodiment, the low-profile adapter 800 comprises a conduit holder 805 having a convex top surface 810, a first bulkhead surface 815, and a second bulkhead surface (not shown) that is substantially parallel to the first bulkhead surface 815. The conduit holder 805 also includes a conduit (not shown) that extends through the length of the conduit holder 805, having an aperture 830 on the first bulkhead surface 815 and an aperture (not shown) on the second bulkhead surface (not shown). The conduit holder 805 is attached to a base 835 that is molded to conform to the contours of a particular tissue site, such as on a finger or other limb. The base 835 in such an embodiment may be constructed from any material that may be extruded or injected into a mold, such as room temperature vulcanizing (RTV) silicone, or from any biocompatible material that is readily manipulated at room temperature.

A low-profile adapter embodying the principles and features described above may generally be constructed as follows, referring to the embodiment described above as the low-profile adapter 200 having the flexible membranes 240 and 245 for illustration. First, the flexible membranes 240 and 245 are cut into substantially equal shapes and sizes, and the flexible membrane 245 is anchored or placed onto a form of desired contour or shape. For the low-profile adapter 200, the form should be substantially flat, but the form may have a convex surface to form alternate embodiments such as the low-profile adapter 800. The conduit 225 is then positioned across the flexible membrane 245. The material of the conduit holder 205 is then extruded onto and around the conduit 225, forming the first bulkhead surface 215 and the second bulkhead surface 220 around each end of the conduit 225 so that the aperture 230 is substantially flush with the first bulkhead surface 215 and the aperture 235 is substantially flush with the second bulkhead surface 220. The material should be shaped to form the convex top surface 210. The flexible membrane 240 is then stretched across the conduit 225 and the surrounding material, and the edges of the flexible membrane 240 are secured to the edges of the flexible membrane 245 using any adhesive, bonding agent, thread, staples, or other suitable means. The drape 255 is prepared by sizing it so that a border of desired width extends laterally and in front of the conduit holder 205. For small tissue sites, the border width may be on the order of 1 cm. Allowing time for the material surrounding the conduit 225 to cure, if necessary, the flexible membrane 245 is placed on the adhesive surface 256 of the drape 255. The flexible membrane 250 is placed around the conduit holder 225 to cover

any exposed adhesive on the adhesive surface 256. Finally, the protective liner is applied to the adhesive surface 257, if desired.

One skilled in the art will see that the present invention can be applied in many areas where there is a need to provide tissue treatment. For example, the shape of the low-profile adapter may be changed to accommodate anatomical features, as well as flat, convex, or saddle-shaped skin contours. Likewise, the shape and dimensions of the porous bridge may be altered to accommodate various sizes and shapes of tissue sites. Additionally, multiple low-profile adapters may be used in series using small conduits and interconnecting ports, which may be advantageous for hardware penetration points of orthopedic external fixation.

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

CLAIMS

We claim:

1. A reduced pressure treatment system comprising:

a moldable conduit holder having substantially parallel first and second bulkhead surfaces, a bottom surface, and a convex top surface, the bottom surface adapted to substantially conform in shape to a tissue contact region adjacent to a tissue site;

a conduit having a first portion received by the second bulkhead surface and a second portion extending longitudinally through the conduit holder to the first bulkhead surface and substantially perpendicular to the first and second bulkhead surfaces;

a base having a side connected to the bottom surface of the conduit holder, the base extending beyond the first bulkhead surface to form a bridge overlay zone adjacent the first bulkhead surface;

a porous pad having a primary delivery region configured to contact the tissue site and a porous bridge region having a side surface configured to contact the first bulkhead surface in fluid communication with the conduit and a bottom surface connected to the bridge overlay zone of the base;

a drape sized to create a sealed space around and cover the first portion of the conduit, the conduit holder, and the porous pad, wherein the conduit is substantially parallel to the tissue contact region; and

a reduced pressure source fluidly connected to the conduit to deliver reduced pressure through the conduit and the porous bridge region to the primary delivery region of the porous pad.

2. The system of claim 1, wherein the conduit holder is formed from room-temperature-vulcanizing silicone.

3. The system of claim 1, wherein the base is adhesively connected to the bottom surface of the conduit holder.

4. The system of claim 1, further comprising a second conduit positioned adjacent the first conduit such that an end of the second conduit is substantially flush with the first bulkhead surface and a longitudinal axis of the second conduit is substantially perpendicular to the first and second bulkhead surfaces.

5. The system of claim 1, wherein the conduit holder further comprises:
a first flexible membrane forming the bottom surface;
a second flexible membrane forming the top surface; and
a moldable material disposed between the first and second flexible membranes to encase the conduit between the first and second flexible membranes.

6. The system of claim 5, wherein the first and second membranes are nitrile film.

7. The system of claim 1, further comprising a porous extension region oriented adjacent to the primary delivery region so that the porous extension region extends into the tissue site.

8. The system of claim 1, wherein the side surface of the porous bridge region has substantially the same cross-sectional shape as the first bulkhead surface.

9. The system of claim 1, wherein the porous pad has a thickness and the conduit holder has a height that are substantially equal.

10. The system of claim 1, wherein the porous pad has a top surface facing the drape which is substantially coplanar with the convex top surface of the conduct holder.

11. The system of claim 1, wherein the side surface of the porous bridge region is substantially perpendicular to the tissue site.

12. The system of claim 1, wherein the primary delivery region and the porous bridge region as separate components, each having a contact surface in fluid communication with each others contact surface.

13. The system of claim 12, wherein the porous bridge region and the primary delivery region each have a top surface facing the drape that are substantially coplanar.

14. The system of claim 12, wherein the porous bridge region has a top surface facing the drape which is substantially coplanar with the convex top surface of the conduit holder.

15. The system of claim 1, wherein:

the primary delivery region of the porous pad is a first manifold positioned in contact with the tissue site for distributing reduced pressure to the tissue site; and

the porous bridge region of the porous pad is a second manifold positioned in fluid communication with the first manifold for distributing reduced pressure to the tissue site.