REDUCED PRESSURE DELIVERY SYSTEM HAVING A MANUALLY-ACTIVATED PUMP FOR PROVIDING TREATMENT TO LOW-SEVERITY WOUNDS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to reduced pressure treatment systems and in particular to a reduced pressure treatment system having a manually-activated pump for providing treatment to low-severity wounds.

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 one particular application of reduced pressure has involved 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 migration of epithelial and subcutaneous tissues, improved blood flow, and micro-deformation of tissue at the wound site. Together these benefits result in increased development of granulation tissue and faster healing times.

While reduced pressure treatment is usually provided in a hospital or monitored-care setting, a great number of situations exist where it may be advantageous to provide reduced pressure therapy to ambulatory and other patients outside of these traditional settings. A conventional reduced pressure system includes an electrically-powered reduced pressure pump that requires a patient to remain relatively still during treatment. A need exists for a portable pump that is small in size and is capable of being manually-activated, and reactivated if necessary, by a patient receiving treatment.

BRIEF SUMMARY OF THE INVENTION

The problems presented in providing reduced pressure treatment to ambulatory patients and low-severity wounds are solved by the systems and methods of the present invention. A manually-activated reduced pressure treatment system is provided in accordance with an embodiment of the present invention. The system includes a substantially rigid housing, and an end cap slidingly received by the housing. An inner chamber is disposed between the end cap and housing, and a volume of the inner chamber is variable in amount depending on the position of the end cap within the housing. The end cap is slidingly movable between an uncompressed position at which the volume of the inner chamber is at a maximum value and a compressed position at which the volume of the inner chamber is at a minimum value. A position indicating member is associated with the end cap and housing to indicate the position of the end cap relative to the housing at predetermined positions between the uncompressed position and the compressed position.

In accordance with another embodiment of the present invention, a manually-activated reduced pressure system is provided and includes a reduced pressure manifold configured to be placed adjacent a tissue site. A manually-compressible pump in fluid communication with the reduced pressure manifold delivers a reduced pressure to the tissue site. The manually-compressible pump includes a flexible and compressible side wall and first and second end caps connected at opposite ends of the side wall. An inner chamber is defined by the side wall and the end caps, and the inner chamber includes a volume that varies from a maximum value when the side wall is in an uncompressed position to a minimum value when the side wall is in a compressed position. A connection port is disposed in one of the first and second end caps to allow fluid communication between the inner chamber and the reduced pressure manifold. A one-way valve is disposed in one of the first end cap, the second end cap, and the side wall to allow fluid expulsion from the inner chamber. A hydrophobic filter in communication with the one-way valve prevents liquids from exiting the inner chamber through the one-way valve, and an odor filter in communication with the one-way valve eliminates odors associated with gases expelled through the one-way valve.

In still another embodiment of the present invention, a method of activating a reduced pressure treatment pump is provided. The method includes manually compressing a flexible diaphragm to reduce a volume of a chamber fluidly connected to a tissue site. The method further includes audibly, visually, or tactilely indicating the positioning of the flexible

diaphragm at a position between an uncompressed position and a compressed position. An estimated reduced pressure provided by the compressed flexible diaphragm is determined based on the indicated position, and the reduced pressure is delivered to the tissue site.

In yet another embodiment of the present invention, a low-profile reduced pressure treatment system includes a reduced pressure source and a reduced pressure manifold configured to be placed adjacent a tissue site. A substantially flat reduced pressure delivery tube is fluidly connected between the reduced pressure source and the reduced pressure manifold. The tube includes a substantially rectangular cross-section and a plurality of corrugations within the tube to prevent collapse of the tube during delivery of reduced pressure.

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 cross-sectional front view of a reduced pressure treatment system having a manually-compressible pump according to an embodiment of the present invention, the manually compressible pump being fluidly connected by a reduced pressure delivery tube to a reduced pressure manifold;

FIG. 2 depicts a cross-sectional front view of a reduced pressure treatment system having a manually-compressible pump according to an embodiment of the present invention, the manually compressible pump being fluidly connected to a reduced pressure manifold;

FIG. 3 illustrates an exploded perspective view of a manually-compressible pump according to an embodiment of the present invention;

FIG. 4 depicts a perspective view of a manually-compressible pump according to an embodiment of the present invention;

FIG. 5 illustrates a cross-sectional perspective view of the pump of FIG. 4;

FIG. 6 depicts a perspective view of a position indicating member disposed on the manually-compressible pump of FIG. 4, the position indicating member having a plurality of teeth and a pawl;

FIG. 7 illustrates a front view of the position indicating member of FIG. 6;

FIG. 8 depicts a graph of test results measuring the pressure decay over time of various manually-compressed bellows pumps having flexible walls of different hardness values;

FIG. 9 illustrates a reduced pressure dressing having an adhesive film, a hydrogel, and a tube connector according to an embodiment of the present invention;

FIG. 10 depicts a top view of the reduced pressure dressing of FIG. 9 fluidly connected to a low-profile reduced pressure delivery tube;

FIG. 11 illustrates a side view of the reduced pressure dressing and reduced pressure delivery tube of FIG. 10; and

FIG. 12 depicts a cross-sectional view of the reduced pressure delivery tube of FIG. 10.

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.

Referring to FIGS. 1 and 3, a reduced pressure delivery system 11 according to an embodiment of the present invention is provided for administering a reduced pressure tissue treatment to a tissue site 13 of a patient. The reduced pressure delivery system includes a bellows pump 15 fluidly connected to a reduced pressure delivery tube 19, which is in turn fluidly connected to a low-profile wound dressing 25 (an integrated system that omits the reduced pressure delivery tube is illustrated in FIG. 2). The bellows pump 15 delivers a reduced pressure to the tissue site 13 through the reduced pressure delivery tube 19 and the dressing 25. The reduced pressure is maintained at the tissue site, which promotes micro-deformation of tissue at the tissue site and promotes growth of new tissue.

The bellows pump is preferably a cylindrically-shaped, manually operated pump that includes a corrugated side wall, or diaphragm 31. The corrugated side wall includes a

plurality of ridges 35 and grooves 37 that facilitate compression of the bellows pump along its longitudinal axis. The bellows pump further includes a first end wall 39 and a second end 41 wall integrally connected at opposite ends of the corrugated side wall. Alternatively, the bellows pump may include first and second end caps, or valve caps 43 that are sealingly connected at opposite ends of the corrugated side wall (see FIG. 3). Together, the corrugated side wall and the opposing first and second end walls form a flexible bladder, the boundaries of which define an inner chamber 51. The volume of the inner chamber 51 is variable. In an uncompressed position, the corrugated wall of the bellows pump is in its naturally extended state (i.e. the corrugations are still present) and the volume of the inner chamber is at a maximum value. In a compressed position, the bellows pump has been subjected to a compressive force, thereby causing the volume of the inner chamber to decrease and the linear density of the corrugations to increase. When the corrugated wall is compressed, a biasing force is exerted by the corrugations to attempt to return the corrugated wall to the uncompressed position. Instead of corrugations, an independent biasing member, such as a spring, or the elasticity of a non-corrugated side wall, may be used to bias the side wall toward the uncompressed position.

A connection port 53 is preferably disposed on one of the end walls of the bellows pump to allow fluid connection of the inner chamber with the reduced pressure delivery tube. An umbrella valve 55 and a duck bill valve 57 are operably connected to the connection port to selectively admit or expel fluids from the inner chamber. The duck bill valve provides one-way fluid communication from the reduced pressure delivery tube to the inner chamber. The umbrella valve provides one-way fluid communication from the inner chamber to the ambient atmosphere surrounding the bellows pump. A similar umbrella valve is disposed within the end wall opposite the end wall containing the connection port.

Referring more specifically to FIG. 3, a hydrophobic filter 61 and an odor filter 63 (e.g. charcoal filter) are positioned near the umbrella valves. The hydrophobic filter prevents any liquids within the inner chamber from being expelled through the umbrella valve. The odor filter eliminates odors associated within any gases that are expelled from the inner chamber through the umbrella valves.

The plurality of valves associated with the bellows pump selectively allows fluid exchange with the inner chamber. When the bellows pump is initially primed to the compressed position (caused by exerting a manual compressive force on the end walls), the gaseous fluids within the inner chamber are expelled through one or both of the umbrella

valves. The gaseous fluids pass through the odor filter prior to exiting the inner chamber. With the bellows in the compressed position, the corrugated wall, which has been elastically deformed, attempts to resume its uncompressed state. As the corrugated wall moves back toward its uncompressed state, the volume of the inner chamber increases, which results in a decrease in pressure within the inner chamber (the inner chamber acts as a closed system P1*V1 = P2*V2). The differential pressure between the inner chamber and the ambient atmosphere (i.e. pressure at the tissue site) results in gaseous and liquid fluids from the reduced pressure delivery tube and the wound dressing being drawn into the inner chamber. This then results in a reduced pressure at the tissue site. With a properly sealed wound dressing, this reduced pressure can be maintained at the tissue site. The fluids drawn from the tissue site enter the inner chamber through the duck bill valve. The duck bill valve prevents these fluids from exiting the inner chamber.

One goal of the bellows device is to deliver and maintain a reduced pressure at the tissue site until the inner chamber becomes completely filled with liquid wound exudate. In some instances, the bellows pump may reach the uncompressed position (following initial priming) without the inner chamber being fully filled with wound exudate and other liquids. In this case, the bellows pump may be re-primed by again exerting a compressive force on the end walls of the bellows pump. As the volume of the inner chamber again decreases, gaseous fluids within the inner chamber are expelled through the umbrella valves. The hydrophobic filters prevent liquids within the inner chamber from being expelled. Because the bellows pump includes more than one umbrella valve, the pump can be re-primed regardless of its orientation.

The bellows pump may include an absorbent foam disposed within the inner chamber to capture wound exudate and other fluids that are removed from the tissue site. Additionally, a one-way membrane may be provided within the bellows pump to prevent any fluids from backflowing out of the inner chamber.

Referring to FIGS. 4 and 5, in one embodiment of the present invention, the bellows pump may include a rigid housing 71 that contains the corrugated wall. An end cap 73 may be slidingly carried by the housing and positioned over the corrugated wall such that the corrugated wall is compressed by pressing on the end cap. A position indicating member having a detent 75 and tab 77 may be operably associated with the housing and end cap to provide an audible and tactile "click" when the corrugated wall reaches the compressed position. Alternatively, and referring to FIGS. 6-8, a plurality of teeth or detents and a pawl

may be operably associated with the housing and end cap to generate a ratcheting sound as the bellows pump is primed. Each individual "click" may be representative of a defined differential pressure that the bellows pump is capable of providing at that instant in time. The audible indicators may also be accompanied by a visual indicator 79 to convey to a user how much differential pressure will be provided.

Referring to FIG. 8, testing was performed to measure pressure decay associated with bellows pumps having corrugated walls made from materials of different hardness values. While the results indicate that a material having Shore 65 A experienced less decay, this is in part due to an improved seal at the wound dressing. The Shore 65 A material was found to be capable of providing between 125 and 150 mm Hg of differential pressure. These levels of pressure are capable of being maintained for at least six hours. For higher pressures, harder materials (such as the Shore 85A material) may be used. It is possible for pressures of 250 mm Hg, and possibly even above 400 mm Hg to be generated using this type of pump design.

It should be noted that while a bellows pump is described, any manually operated pump, including without limitation a diaphragm pump or a piston pump may be substituted for the bellows pump. In some situations, it may be desired to prime (or set) the pump using electrical power, but in most cases, the pump will be capable of manual operation by the user without electrical power.

Referring again to FIG. 1, the low-profile wound dressing includes a tube connector 81, a hydrogel ring 83, and a film 85. The tube connector is positioned above a reduced pressure manifold such that an aperture of the tube connector is in fluid communication with the manifold. The hydrogel ring is disposed between the tube connector and a tissue surface 89 of the patient adjacent the tissue site. The film, preferably made of polyurethane, is adhesively applied to the tube connector and the tissue surface of the patient to secure the dressing against the patient and provide a seal between the dressing and the patient. The sealing characteristics of the dressing are further enhanced by the hydrogel ring, which not only seals against the tissue surface of the patient, but also prevents the tissue surface from becoming damaged during use of the dressing.

The manifold is preferably a highly reticulated, open-cell foam. The manifold allows distribution of the reduced pressure provided by the bellows pump. It should be noted that any material capable of distributing reduced pressure could be used in place of the open-cell foam.

Referring to FIG. 9, an integrated wound dressing 111 may also be used with the reduced pressure delivery system. The integrated wound dressing includes a large island of a hydrogel 113 disposed on a film 115. The film preferably includes an adhesive 117 to serve as a backup seal to the hydrogel. An aperture 121 is disposed in the film and an aperture 123 is disposed in the hydrogel to allow through connection of a conformable tube connector 125.

Referring to FIGS. 10-12, in another embodiment of the wound dressing, an ultra-low-profile reduced pressure delivery tube 135 is directly connected to the dressing. The tube is fairly flat and rectangular in cross section, which significantly reduces the thickness of the overall dressing when connected to the tube. Preferably, corrugations 137 are provided within the tube (see FIG. 12) to resist collapse of the tube under pressure. The tube and corrugations may be extruded together in a single manufacturing process, or may be assembled following separate manufacturing processes. A plurality of flow channels 139 are defined between the corrugations. The tube is preferably connected to the film by pouring a hydrogel over the film and tube and causing it to gel.

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 just limited but is susceptible to various changes and modifications without departing from the spirit thereof.

CLAIMS

We claim:

1. A manually-activated reduced pressure treatment system comprising:
   a substantially rigid housing;
   an end cap slidingly received by the housing;
   an inner chamber disposed between the end cap and housing, a volume of the inner chamber being variable in amount depending on the position of the end cap within the housing, the end cap being slidingly movable between an uncompressed position at which the volume of the inner chamber is at a maximum value and a compressed position at which the volume of the inner chamber is at a minimum value;
   a position indicating member associated with the end cap and housing to indicate the position of the end cap relative to the housing at predetermined positions between the uncompressed position and the compressed position.

2. The system of claim 1, wherein the position indicating member further comprises:
   one of a plurality of teeth and a pawl disposed on the housing; and
   another of the plurality of teeth and the pawl disposed on the end cap, the plurality of teeth and the pawl being configured to mate with one another to indicate the position of the end cap relative to the housing at predetermined positions between the uncompressed position and the compressed position.

3. The system of claim 1, wherein the position indicating member provides audible indication of the end cap being moved from the uncompressed position toward the compressed position.

4. The system of claim 1 further comprising:
   a flexible bladder disposed within the housing and constrained by the end cap to form the inner chamber.

5. The system of claim 1 further comprising:
   a biasing member positioned between the end cap and the housing to bias the end cap toward the uncompressed position.

6. The system of claim 5 further comprising:

a flexible bladder disposed within the housing and constrained by the end cap to form the inner chamber;

wherein the flexible bladder includes a flexible side wall having a plurality of corrugations; and

wherein the corrugations, when compressed, serve as the biasing member to bias the end cap toward the uncompressed position.

7. A manually-activated reduced pressure treatment system comprising:

a reduced pressure manifold configured to be placed adjacent a tissue site; and

a manually-compressible pump in fluid communication with the reduced pressure manifold to deliver a reduced pressure to the tissue site, the manually-compressible pump comprising:

a flexible and compressible side wall;

first and second end caps connected at opposite ends of the side wall to form an inner chamber defined by the side wall and the end caps, the inner chamber having a volume that varies from a maximum value when the side wall is in an uncompressed position to a minimum value when the side wall is in a compressed position;

a connection port disposed in one of the first and second end caps to allow fluid communication between the inner chamber and the reduced pressure manifold;

a one-way valve disposed in one of the first end cap, the second end cap, and the side wall to allow fluid expulsion from the inner chamber;

a hydrophobic filter in communication with the one-way valve to prevent liquids from exiting the inner chamber through the one-way valve; and

an odor filter in communication with the one-way valve to eliminate odors associated with gases expelled through the one-way valve.

8. The system according to claim 7, wherein:

the side wall includes a plurality of corrugations; and

the corrugations, when compressed, exert a biasing force that biases the side wall toward the uncompressed position.

9. The system according to claim 7, wherein the one-way valve is disposed in the first end cap.

10. The system according to claim 9, wherein the manually compressible pump further comprises:

a second one-way valve disposed in the second end cap;

wherein the presence of a one-way valve in each end cap allows the side wall to be recompressed following collection of fluid within the inner chamber from the tissue site regardless of the orientation of the manually-compressible pump.

11. The system according to claim 7, wherein the manually compressible pump further comprises:

an absorbent foam disposed within the inner chamber to capture fluid drawn from the tissue site by the manually-compressible pump.

12. The system according to claim 7, wherein the manually compressible pump further comprises:

a housing configured to receive and positioned around the side wall;

a position indicating member associated with the housing and at least one of the end caps to indicate the position of the side wall at predetermined positions between the uncompressed position and the compressed position.

13. The system of claim 12, wherein the position indicating member further comprises:

one of a plurality of teeth and a pawl disposed on the housing; and

another of the plurality of teeth and the pawl disposed on the at least one of the end caps, the plurality of teeth and the pawl being configured to mate with one another to indicate the position of the side wall at predetermined positions between the uncompressed position and the compressed position.

14. The system of claim 12, wherein the position indicating member provides audible indication of the end cap being moved from the uncompressed position toward the compressed position.

15. A method of activating a reduced pressure treatment pump, the method comprising:

manually compressing a flexible diaphragm to reduce a volume of a chamber fluidly connected to a tissue site;

audibly, visually, or tactilely indicating the positioning of the flexible diaphragm at a position between an uncompressed position and a compressed position;

determining an estimated reduced pressure provided by the compressed flexible diaphragm based on the indicated position; and

delivering the reduced pressure to the tissue site.

16. The method of claim 15 further comprising:

manually recompressing the flexible diaphragm following the expansion of the flexible diaphragm.

17. The method of claim 15 further comprising:

collecting fluid drawn from the tissue site in the chamber.

18. The method of claim 17 further comprising:

manually recompressing the flexible diaphragm following partial filing of the chamber with fluid drawn from the tissue site.

19. A low-profile reduced pressure treatment system comprising:

a reduced pressure source;

a reduced pressure manifold configured to be placed adjacent a tissue site; and

a substantially flat reduced pressure delivery tube fluidly connected between the reduced pressure source and the reduced pressure manifold, the tube having a substantially rectangular cross-section and a plurality of corrugations within the tube to prevent collapse of the tube during delivery of reduced pressure.

20. The system of claim 19, wherein the reduced pressure source is a manually-compressible pump comprising:

a flexible and compressible side wall;

first and second end caps connected at opposite ends of the side wall to form an inner chamber defined by the side wall and the end caps, the inner chamber having a volume that varies from a maximum value when the side wall is in an uncompressed position to a minimum value when the side wall is in a compressed position;

a connection port disposed in one of the first and second end caps to allow fluid communication between the inner chamber and the reduced pressure manifold;

a one-way valve disposed in one of the first end cap, the second end cap, and the side wall to allow fluid expulsion from the inner chamber;

a hydrophobic filter in communication with the one-way valve to prevent liquids from exiting the inner chamber through the one-way valve; and

an odor filter in communication with the one-way valve to eliminate odors associated with any gases expelled through the one-way valve.