Rigidity of straws prevent filler collapsing in wound

Straw structures are cut to length and fill wound

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COMPRESSIBLE WOUND FILLERS AND SYSTEMS AND METHODS OF USE IN TREATING WOUNDS WITH NEGATIVE PRESSURE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/784,868, filed March 14, 2013, entitled COMPRESSIBLE WOUND FILLERS AND SYSTEMS AND METHODS OF USE IN TREATING WOUNDS WITH NEGATIVE PRESSURE. The content of the aforementioned application is hereby incorporated by reference in its entirety as if fully set forth herein. The benefit of priority to the foregoing applications is claimed under the appropriate legal basis, including, without limitation, under 35 U.S.C. §119(e).

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] Embodiments described herein relate to devices and methods that can be used to treat a wound with negative pressure. Particular embodiments can also be useful to aid in wound closure, for example in abdominal wounds.

SUMMARY OF THE INVENTION

[0003] Generally, the embodiments described herein can be used to assist in the treatment of wounds with negative pressure. The embodiments can be particularly useful in treating large wounds, such as abdominal wounds, where closure and approximation of the wound edges is challenging. Certain embodiments described herein are directed to the compressible wound fillers, their methods of use and systems incorporating the same, wherein the compressible wound filler is configured to compress or collapse, for example horizontally, as the wound closes under negative pressure.

[0004] In some embodiments, a method of treating a wound comprises:

placing a porous wound contacting layer, for example foam, in a wound;
positioning an inflatable wound filler over the porous wound contacting layer, wherein the inflatable wound filler may be semi-inflated, the inflatable wound filler comprising a plurality of pores configured to allow the passage of fluid;

positioning at least one wound cover over the inflatable wound filler to form a seal with skin surrounding the wound;

applying negative pressure to the wound, wherein the application of negative pressure causes the inflatable wound filler to further inflate; and

releasing fluid from the inflatable wound filler, wherein the release of fluid from the inflatable wound filler causes the inflatable wound filler to contract and draw the edges of the wound closer together.

[0005] In certain embodiments, a negative pressure treatment apparatus may comprise a porous wound contacting layer, an inflatable wound filler, a wound cover and a source of negative pressure configured to perform the method as described above.

[0006] In some embodiments, a wound treatment apparatus for use with negative pressure comprises any of a number of wound fillers, as described herein. In some embodiments, the wound treatment apparatus may further comprise a cover configured to be placed over the wound filler and seal to skin surrounding the wound. In certain embodiments, the wound treatment apparatus may further comprise a port configured to connect the wound cover to a source of negative pressure. In further embodiments, the wound treatment apparatus may comprise a source of negative pressure configured to provide negative pressure to the wound.

[0007] In some embodiments, a wound filler for use in treating a wound with negative pressure can comprise:

a porous wound filling material;

a plurality of vertically extending members configured to extend vertically when the wound filler is positioned within a wound bed, the vertically extending members being made of a more rigid material than the porous wound filling material; and
wherein upon application of negative pressure to the wound filler, the wound filler is configured to contract horizontally with the vertically extending members reducing vertical movement of the wound filler.

[0008] In some embodiments, a wound filler for use in treating a wound with negative pressure can comprise:

- a plurality of vertically extending straws configured to extend vertically when the wound filler is positioned within a wound bed;
- a plurality of joints connecting adjacent vertically extending straws; and

wherein upon application of negative pressure to the wound filler, the wound filler is configured to contract horizontally with the vertically extending straws reducing vertical movement of the wound filler.

[0009] In some embodiments, the vertically extending straws may be solid. In certain embodiments the straws can be hollow. Some embodiments may call for the joints to be flexible and/or rigid. In certain embodiments, the wound filler may be further configured to be placed in the wound bed in a spiral conformation. In particular embodiments, a wound treatment apparatus may further comprise at least one pressure sensor.

[0010] In some embodiments, a wound filler for use in treating a wound with negative pressure can comprise:

- a flexible hollow tube;

  a vertical strut positioned within the flexible hollow tube, the vertical strut configured to extend vertically when the wound filler is positioned within a wound bed, the vertical strut being made of a more rigid material than the flexible hollow tube; and

  wherein upon application of negative pressure to the wound filler, the wound filler is configured to contract horizontally with the vertically strut reducing vertical movement of the wound filler.

[0011] Certain embodiments of the wound treatment apparatus may call for the addition of gripping members located on the outside of the flexible hollow tube, the gripping members configured to grip the wound bed. In some embodiments, the flexible hollow tube
may be configured to be placed within the wound bed in a spiral conformation. In some embodiments, the flexible hollow tube comprises an extruded foam.

[0012] In some embodiments, a method of treating a wound may comprise:
  placing a porous wound contact layer in the wound;
  positioning a dissolvable material over the porous wound contact layer, the dissolvable material for example comprising a polyvinyl alcohol; and
  applying negative pressure to the wound, wherein the application of negative pressure draws moisture from the wound into the dissolvable material, causing the dissolvable material to dissolve.

[0013] In certain embodiments, a negative pressure treatment apparatus may comprise a dissolvable material as described above, a wound cover and a source of negative pressure configured to perform the method as described above.

[0014] In certain embodiments, a wound filler for use in treating a wound with negative pressure comprises:
  one or more rigid concentric rings surrounding a central portion of the wound filler, the concentric rings configured to resorb into a wound; and
  wherein the one or more rings comprises an outer ring configured to resorb more quickly than the remaining rings.

[0015] In some embodiments, a wound filler for use in treating a wound with negative pressure comprises:
  a plurality of elongate upper layers, wherein the upper layers are connected at an upper apex at a first angle;
  a plurality of elongate lower layers, wherein the lower layers are connected at a lower apex at a second angle;
  wherein the upper layers and the lower layers are connected to form a pattern of repeating, parallel rows;
  wherein the second angle is greater than the first angle; and
  wherein upon application of negative pressure to the wound filler, the wound filler is configured to collapse in a horizontal direction while remaining rigid in a vertical direction.
In certain embodiments, a wound filler for use in treating a wound with negative pressure may comprise:

- a layer comprising a plurality of variable size bubbles spread across a surface of the layer; and
- wherein the bubbles are configured to collapse under negative pressure.

In certain embodiments, a wound filler for use in treating a wound with negative pressure can comprise:

- a plurality of layers comprising bubbles, wherein the layers are configured such that the bubbles face one another; and
- wherein upon application of negative pressure to the wound filler, the bubbles are configured to collapse in a horizontal direction while remaining rigid in a vertical direction.

In some embodiments, a method of treating a wound comprises:

- placing a wound filler into the wound;
- applying a cover over the wound filler and sealing the cover to skin surrounding the wound;
- applying negative pressure to the wound through the cover; and
- controlling collapse of the wound filler as the wound closes under negative pressure.

Some embodiments may call for the addition of a pressure sensor to monitor an internal pressure. In certain embodiments, the internal pressure may be measured by monitoring at least one of a bladder pressure, an aortic pressure, a pressure within the colon, a pressure within the uterus, a limb pressure, and a blood flow rate. In certain embodiments, the wound filler may be an inflatable bladder, and controlling collapse of the wound filler comprises controlling the pressure within the bladder. Some embodiments may call for dynamically adjusting at least one of the volume, stiffness, pressure to collapse the wound filler as the wound closes. In particular embodiments, at least one of the volume, stiffness pressure and collapse of the wound packing member is dynamically adjusted based on internal pressure readings of the patient.
BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Embodiments of the present invention will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0021] Figure 1 illustrates an embodiment of a negative pressure wound therapy system.

[0022] Figure 2 illustrates an embodiment of a semi-inflated wound filler.

[0023] Figures 3A-B illustrate embodiments of a wound filler comprising pillars.

[0024] Figures 4A-B illustrate embodiments of a wound filler comprising pillars.

[0025] Figures 5A-B illustrate an embodiment of a wound filler comprising rigid straws.

[0026] Figures 6A-C illustrate and embodiment of a wound filler comprising an extruded foam.

[0027] Figures 7A-C illustrate an embodiment of a dissolvable wound filler.

[0028] Figures 8A-C illustrate an embodiment of a wound filler with various sections having various rates of dissolution.


[0031] Figures 11A-C illustrate an embodiment of a wound filler comprising bubbles that collapse in one direction.

[0032] Figure 12 is a schematic representation of an embodiment of an apparatus used to provide negative pressure wound therapy to a wound.

[0033] Figure 13 is a schematic representation of another embodiment of an apparatus used to provide negative pressure wound therapy to a wound, showing the wound in first state of contraction.

[0034] Figure 14 is a schematic representation of another embodiment of an apparatus used to provide negative pressure wound therapy to a wound, showing the wound in second state of contraction.
DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0035] Various embodiments that can be used for the treatment of wounds will now be described with references to the following figures and description which follow. It will be of course understood that various omissions, substitutions, and changes in the form and details of the embodiments illustrated can be made without departing from the spirit of the disclosure. Additionally, the various features and processes described above can be used independently of one another, or can be combined in various ways. All possible combinations and sub-combinations are intended to fall within the scope of this disclosure. Many of the embodiments described above include similar components, and as such, these similar components can be interchanged in different embodiments.

[0036] Embodiments disclosed herein relate to apparatuses and methods of treating a wound with reduced pressure, including pump and wound dressing components and apparatuses. Generally, the embodiments including the wound fillers described herein may be used in combination with a negative pressure system comprising a drape or wound cover placed over the filler. A vacuum source, such as a pump, may be connected to the cover, for example, through one or more tubes connected to an aperture or port made in or under the cover. The apparatuses and components comprising the wound overlay and packing materials, if any, are sometimes collectively referred to herein as dressings. Further details of methods and apparatuses that are usable with the embodiments described herein are found in the following applications, which are hereby incorporated by reference in their entireties: U.S. Application Serial No. 12/886,088, titled "SYSTEMS AND METHODS FOR USING NEGATIVE PRESSURE WOUND THERAPY TO MANAGE OPEN ABDOMINAL WOUNDS", published as US 2011/0213287 on September 1, 2011; U.S. Application Serial No. 13/092,042, titled "WOUND DRESSING AND METHOD OF USE", published as US 2011/0282309 on November 17, 2011.

[0037] It will be appreciated that throughout this specification reference is made to a wound or wounds. It is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured, or where trauma causes a contusion, or any other superficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus
broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, acute wounds, chronic wounds, surgical incisions and other incisions, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like. In some embodiments, the components of the negative pressure treatment system described herein can be particularly suited for incisional wounds that exude a small amount of wound exudate.

[0038] As is used herein, reduced or negative pressure levels, such as -X mmHg, represent pressure levels that are below standard atmospheric pressure, which corresponds to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of -X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760-X) mmHg. In addition, negative pressure that is "less" or "smaller" than -X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g., -40 mmHg is less than -60 mmHg). Negative pressure that is "more" or "greater" than -X mmHg corresponds to pressure that is further from atmospheric pressure (e.g., -80 mmHg is more than -60 mmHg).

[0039] The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric pressure. Thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively a pressure range of up to -75 mmHg, up to -80 mmHg or even -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively, a pressure range of over approximately -100 mmHg, or even -150 mmHg, can be supplied by the negative pressure apparatus.

[0040] Turning to Figure 1, treatment of a wound with negative pressure in certain embodiments uses a negative pressure treatment system 101 as illustrated schematically here. In this embodiment, a wound site 110, illustrated here as an abdominal wound site, may benefit from treatment with negative pressure. Such abdominal wound sites may be a result of, for example, an accident or due to surgical intervention. In some cases,
medical conditions such as abdominal compartment syndrome, abdominal hypertension, sepsis, or fluid edema may require decompression of the abdomen with a surgical incision through the abdominal wall to expose the peritoneal space, after which the opening may need to be maintained in an open, accessible state until the condition resolves. Other conditions may also necessitate that an opening—particularly in the abdominal cavity—remain open, for example if multiple surgical procedures are required (possibly incidental to trauma), or there is evidence of clinical conditions such as peritonitis or necrotizing fasciitis.

[0041] In cases where there is a wound, particularly in the abdomen, management of possible complications relating to the exposure of organs and the peritoneal space is desired, whether or not the wound is to remain open or if it will be closed. Therapy, preferably using the application of negative pressure, can be targeted to minimize the risk of infection, while promoting tissue viability and the removal of deleterious substances from the wound site. The application of reduced or negative pressure to a wound site has been found to generally promote faster healing, increased blood flow, decreased bacterial burden, increased rate of granulation tissue formation, to stimulate the proliferation of fibroblasts, stimulate the proliferation of endothelial cells, close chronic open wounds, inhibit burn penetration, and/or enhance flap and graft attachment, among other things. It has also been reported that wounds that have exhibited positive response to treatment by the application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached. Consequently, the application of negative pressure to a wound site 110 can be beneficial to a patient.

[0042] Accordingly, certain embodiments provide for a wound contact layer 105 to be placed over the wound site 110. Preferably, the wound contact layer 105 can be a thin, flexible material which will not adhere to the wound site or the exposed viscera in close proximity. For example, polymers such as polyurethane, polyethylene, polytetrafluoroethylene, or blends thereof may be used. In one embodiment, the wound contact layer is permeable. For example, the wound contact layer 105 can be provided with openings, such as holes, slits, or channels, to allow the removal of fluids from the wound site
110 or the transmittal of negative pressure to the wound site 110. Additional embodiments of the wound contact layer 105 are described in further detail below.

[0043] Certain embodiments of the negative pressure treatment system 101 may also use a porous wound filler 103, which can be disposed over the wound contact layer 105. This pad 103 can be constructed from a porous material, for example foam, that is soft, resiliently flexible, and generally conformable to the wound site 110. Such a foam can include an open-celled and reticulated foam made, for example, of a polymer. Suitable foams include foams composed of, for example, polyurethane, silicone, and polyvinyl alcohol. Preferably, this pad 103 can channel wound exudate and other fluids through itself when negative pressure is applied to the wound. Some pads 103 may include preformed channels or openings for such purposes. In certain embodiments, the pad 103 may have a thickness between about one inch and about two inches. The pad may also have a length of between about 16 and 17 inches, and a width of between about 11 and 12 inches. In other embodiments, the thickness, width, and/or length can have other suitable values. Other embodiments of wound fillers that may be used in place of or in addition to the pad 103 are discussed in further detail below.

[0044] Preferably, a drape 107 is used to seal the wound site 110. The drape 107 can be at least partially liquid impermeable, such that at least a partial negative pressure may be maintained at the wound site. Suitable materials for the drape 107 include, without limitation, synthetic polymeric materials that do not significantly absorb aqueous fluids, including polyolefins such as polyethylene and polypropylene, polyurethanes, polysiloxanes, polyamides, polyesters, and other copolymers and mixtures thereof. The materials used in the drape may be hydrophobic or hydrophilic. Examples of suitable materials include Transeal® available from DeRoyal and OpSite® available from Smith & Nephew. In order to aid patient comfort and avoid skin maceration, the drapes in certain embodiments are at least partly breathable, such that water vapor is able to pass through without remaining trapped under the dressing. An adhesive layer may be provided on at least a portion the underside of the drape 107 to secure the drape to the skin of the patient, although certain embodiments may instead use a separate adhesive or adhesive strip. Optionally, a release layer may be disposed over the
adhesive layer to protect it prior to use and to facilitate handling the drape 107; in some embodiments, the release layer may be composed of multiple sections.

[0045] The negative pressure system 101 can be connected to a source of negative pressure, for example a pump 114. One example of a suitable pump is the Renasys EZ pump available from Smith & Nephew. The drape 107 may be connected to the source of negative pressure 114 via a conduit 112. The conduit 112 may be connected to a port 113 situated over an aperture 109 in the drape 107, or else the conduit 112 may be connected directly through the aperture 109 without the use of a port. In a further alternative, the conduit may pass underneath the drape and extend from a side of the drape. U.S. Patent No. 7,524,315 discloses other similar aspects of negative pressure systems and is hereby incorporated by reference in its entirety and should be considered a part of this specification.

[0046] In many applications, a container or other storage unit 115 may be interposed between the source of negative pressure 114 and the conduit 112 so as to permit wound exudate and other fluids removed from the wound site to be stored without entering the source of negative pressure. Certain types of negative pressure sources—for example, peristaltic pumps—may also permit a container 115 to be placed after the pump 114. Some embodiments may also use a filter to prevent fluids, aerosols, and other microbial contaminants from leaving the container 115 and/or entering the source of negative pressure 114. Further embodiments may also include a shut-off valve or occluding hydrophobic and/or oleophobic filter in the container to prevent overflow; other embodiments may include sensing means, such as capacitive sensors or other fluid level detectors that act to stop or shut off the source of negative pressure should the level of fluid in the container be nearing capacity. At the pump exhaust, it may also be preferable to provide an odor filter, such as an activated charcoal canister.

The Wound Fillers and Wound Closure Devices of Figures 2A-1 1C

[0047] Figures 2A-2C illustrate one embodiment of a wound filler that may be used in the negative pressure systems and methods as described herein. As illustrated in Figure 2A, a layer of foam or other porous material may be placed in the wound. An inflatable wound filler such as a bag or other structure may be placed in the wound over the
porous material. The inflatable wound filler may be placed in the wound in a semi-inflated state. A wound cover may be placed over the wound filler that is sealed to skin surrounding the wound. A conduit may connect the wound cover to a source of negative pressure (not shown). When negative pressure is applied to the wound through the wound cover as shown in Figure 2B, the increase in vacuum level under the wound cover causes the bag to inflate further (due to the drop in the surrounding pressure). The inflation of the bag provides an upward force against the wound cover to prevent the wound cover from extending downward into the wound. As negative pressure is applied, wound exudate may travel through the porous material to a collection location which may be located either outside the wound cover (such as canister 115 described above) or even to a collection location located under the wound cover.

[0048] The inflatable wound filler may comprise at least a portion of porous material, and may for example have a plurality of pores or openings to allow air or other inflation fluid to leak from the inflatable filler. As shown in Figure 2B, inflation fluid can leak out of the wound filler, and as shown in Figure 2C, over time the filler contracts as the wound heals due to the leakage of the wound filler, and the inflatable filler will contract to allow the edges and sides of the wound to draw closer together.

[0049] Figures 3A-4B illustrate embodiments of a porous wound filler material, such as a felted foam wound filler, having a plurality of vertically extending pillars spaced throughout. The pillars may be arranged in parallel rows, and may be approximately equally spaced from each other. In the embodiment of Figures 3A-3B, the pillars may be made of a higher density material than that of the porous wound filler material. In some embodiments, the pillars may be arranged in a linear formation within the rows, thereby limiting the amount of collapse due to interaction between the pillars. In certain embodiments, the pillars may be arranged in a staggered formation within the rows, thereby allowing for greater collapse because the pillars will no longer block one another to the same extent. In certain embodiments, the pillars may alternate in their staggered formation one by one, while in other formations the pillars may alternate in two by twos, three by threes, etc.
[0050] In the embodiment of Figures 4A-4B, the pillars may be rigid cylindrical, hollow members through which fluid can flow. When placed in a wound under negative pressure, the pillars allow the filler to collapse horizontally, but prevent vertical collapse.

[0051] Figure 5A illustrates an embodiment of a wound filler comprising a plurality of vertical straws connected to each other in series side-by-side along the length of the straws to form an elongate strip of material. The straws may be solid or hollow. The elongate strip of material is preferably vertically rigid, but may be flexible about the joints connecting adjacent straws to allow the elongate material to be manipulated to fit into a wound. For example, as shown in Figure 5B (which shows a top view of a wound), the elongate strip of material can be cut to an appropriate length and may be placed in a wound in a spiral or other desired configuration, with the straws oriented vertically within the wound. The straws may also be compressible in a horizontal direction such that when the wound closes under negative pressure therapy, the straws will collapse horizontally within the wound but remain vertically rigid.

[0052] Figures 6A-6B illustrate an embodiment of a wound filler comprising an elongate, flexible hollow tube that may be placed in a wound in a desired configuration. As illustrated in Figure 6C, the hollow tube may be arranged in a spiral configuration into a wound, though other configurations are possible. The tube may be made of an extruded foam or other materials. As illustrated, the tube may include a vertical strut that extends through the middle of the tube to provide the tube with vertical rigidity. In certain embodiments, the wound filler does not contain a vertical strut but still retains vertical rigidity. Additionally, as shown in Figure 6B, the tube may be made of a material that is horizontally compressible. The tube may also have gripping members that may be used to connect the sides of the tube to other portions of the tube or to the edges of the wound. When the tube is arranged in a wound for negative pressure wound therapy, the vertical strut is preferably arranged vertically in the wound to provide vertical rigidity, while the sides of the tube are configured to horizontally collapse as the wound closes. In certain embodiments, the wound filler comprising an elongate, flexible hollow tube may be inflated.

[0053] Figures 7A-7C illustrate an embodiment comprises a wound filler made of dissolvable material, such as a dissolvable polyvinyl alcohol (PVA) filler. As illustrated in
Figure 7A, a dissolvable PVA material may be placed in a wound over a porous material (such as foam), where the porous material provides a fluid path. The dissolvable PVA material may be provided in any suitable form, including sheet, rolls, powder, or other configurations. During negative pressure wound treatment, moisture from the wound slowly dissolves the PVA over time, allowing the wound to close. In one embodiment, as illustrated in Figures 7B-7C, saline can be introduced to the filler as treatment is occurring to increase and/or control the dissolving of the PVA filler.

[0054] Figures 8A-8C illustrate an embodiment of a wound filler comprising one or more concentric rings around a central portion of wound filler. The central portion and one or more rings can be made of rigid material, but may have variable resorption rates. Under negative pressure wound therapy, an outer ring may be configured to dissolve more quickly than an inner ring, as shown in the transition from Figure 8B to 8C. Thus, as the wound closes, the amount of wound filler decreases to allow the edges of the wound to come closer together.

[0055] Figures 9A-9C illustrate an embodiment of a wound filler having an accordion or concertina configuration. The wound filler may comprise an upper layer and a lower layer that together form a pattern of repeating, parallel rows. The wound filler may be made of any suitable material, including silicone, rigid plastics, semi-rigid plastics, biocompatible materials, flexible plastic materials, composite materials, and foam. The upper layer of each row comprises a first face and a second face each comprising a generally flat, elongate and rectangular piece of material that are connected at an angle to each other at an upper apex. The lower layer of each row comprises a first face and a second face each comprising a generally flat, elongate and rectangular piece of material that are connected at an angle to each other at a lower apex. As illustrated, the upper apex is generally above the lower apex, and the angle formed between the first and second faces of the lower layer is greater than the angle formed between the first and second faces of the upper layer.

[0056] Foam inserts may optionally be provided between adjacent rows of the wound filler. As illustrated in Figure 9B, the foam inserts may have a triangular shape in cross-section to correspond with the triangular-shaped gap between the first and second faces of the upper layer.
[0057] The wound filler and foam inserts may be cut to an appropriate size as shown in Figure 9A for placement into a wound. A wound cover may be positioned over the wound filler and foam inserts as described above, and negative pressure may be provided to the wound through the wound cover. Under negative pressure, the wound filler may collapse preferably in only one horizontal direction, as shown in Figure 9C. As the wound filler collapses, the angle at the upper and lower apices decreases and the faces in each row come closer together. The foam inserts may be compressed between the first and second faces of the upper layer as negative pressure is applied, and desirably can be selected to control the amount of compression of the wound filler as the wound filler compresses when the wound closes under negative pressure.

[0058] Figures 10A-10B illustrate an embodiment of a wound filler that comprises a bubble wrap material. The material may include a layer having a plurality of variable sizes bubbles spread across a surface of the layer. As illustrated in Figure 10B, the layer may be wrapped or roller into a spiral or other configuration when placed in the wound. Figure 10B illustrates a top view of a wound showing how the bubble wrap would be placed in the wound in one embodiment, though the bubble wrap may be placed in the wound in any suitable configuration. When the wound filler is used in a negative pressure system as described above, the variable size bubbles will collapse under varying pressures in the wound.

[0059] Figures 11A-11C illustrate another embodiment of a wound filler comprising a bubble wrap material. In this embodiment, layers of bubble wrap material may be provided one on top of the other in the wound. For example, as shown in Figure 11B, adjacent layers may be provided where the bubbles face each other. As shown in Figure 11C, when used in a negative pressure system as described above and when under negative pressure, the bubbles may preferentially collapse in one direction (e.g., a horizontal direction) but remain vertically rigid.

[0060] In some embodiments, it may be desired to control the closure of a wound by controlling the volume, stiffness, pressure, and/or collapse of any of the wound fillers described herein this section or elsewhere in the specification. In some embodiments, the closure can be controlled based on measurement of internal pressure within the wound, for example by monitoring at least one of a bladder pressure, an aortic pressure, a pressure within
the colon, a pressure within the uterus, a limb pressure, and a blood flow rate. For example, as will be described in greater detail below, feedback from the internal pressure mechanism can be used to manually or automatically control the rate of collapse or the compression of the wound filler, thereby controlling the rate of closure of a wound. Further details regarding these and other embodiments are described below and in U.S. Provisional Application No. 61/782,026, filed March 14, 2013, entitled APPARATUSES AND METHODS FOR WOUND THERAPY, the entirety of which is hereby incorporated by reference.

The Apparatuses and Methods of Figures 12-14

[0061] Compartment syndrome can occur when excessive pressure builds up inside an enclosed space in the body. Excessive pressures in the abdominal compartment, for example, can impede the flow of blood to and from the affected tissues, bodily organs, or even the lower extremities if excessive pressure is exerted on the abdominal aorta. The pressure buildup within the abdominal compartment can be the result of excessive fluid buildup in the abdominal compartment, in addition to or alternatively as a result of the forces exerted on the abdominal region from the application of negative pressure wound therapy to the abdominal compartment.

[0062] Such excessive pressure can cause permanent injury or damage to the tissues, organs (such as the liver, bowels, kidneys, and other organs), and other body parts affected by the reduction of blood flow. Therefore, preventing the buildup of excessive pressures in the abdominal compartment is beneficial for the treatment of abdominal injuries.

[0063] Internal abdominal pressure may also be measured and/or monitored indirectly using intragastric, intracolonic, intravesical (bladder), inferior vena cava catheters, or by other suitable methods, such as via the uterus. In some arrangements, for example, the internal pressure may be measured by inserting a catheter into the patient's bladder. Aortic blood pressure can also be monitored using techniques known in the field. For limb-based compartment syndrome, the internal pressure can be measured by a needle inserted into the affected limb, and preferably, the pressure measured there should be within 20-30mmHg of the patient's diastolic blood pressure. The clinician can also monitor for a pulse distal of the affected extremity.
In addition to any of the foregoing methods or devices for measuring internal pressure, or any combination of such, in some embodiments, negative pressure wound therapy can be applied to the wound of a patient in a manner to minimize or prevent the build-up of excessive pressure that causes compartment syndrome. For example, any of the negative pressure wound therapy dressing components and/or fillers disclosed herein can be configured to support or contain one or more pressure sensors configured to permit a clinician to monitor the internal pressure within the compartment, wound cavity, or abdominal cavity. In some embodiments, the negative pressure dressing components may include a wound filler that may have an adjustable volume, such as an inflatable bladder or other wound fillers as described below, which when placed within a wound can control how much the wound can close. In one example, one or more pressure sensors can be added to the dressing components, including without limitation positioning one or more pressure sensors on the surface of and/or inside any inflatable bladder embodiment disclosed herein (such as described below with respect to Figure 12) that can be positioned in the abdominal cavity. The pressure sensors can be supported on, embedded within, or be integral with an outer and/or inner surface of any inflatable bladder embodiments disclosed herein, and can be used to monitor the pressure exerted on the inflatable bladder from the adjacent tissues and organs within the abdominal cavity to alert the patient or caregiver when a threshold or potentially harmful pressure is present within the abdominal cavity.

Additionally or alternatively, one or more pressure sensors can be positioned on or supported by a portion of any wound packing or wound filler components positioned within or adjacent to the wound cavity, or embedded within a portion of the wound filler and/or the dressing overlay or cover, including being supported by the overlay itself, and/or any conduit components of the dressing. The pressure sensors can therefore be positioned on, supported by, or embedded within any combination of the dressing components disclosed herein.

Furthermore, in addition or alternatively to any of the sensor positions located herein, one or more pressure sensors can also be positioned adjacent to one or more of the organs in the cavity being treated, for example the bladder, one or more kidneys, and/or any other organs or proximally located tissue surfaces.
Some embodiments can have one or more pressure sensors supported by or on or embedded within the wound packing layer or wound filler, one or more pressure sensors supported by or on or embedded within one or more of the organs (such as the bladder) or tissue layers in the cavity, and one or more pressure sensors supported by or on or embedded within one or more inflatable bladders positioned within the wound cavity.

Monitoring the pressure in one, some or all of these three locations can permit the caregiver to optimize or control the level of negative pressure applied to the wound cavity, optimize or control a level of inflation or pressure of an inflatable bladder placed within the wound, optimize or control the collapse, stiffness or volume of a wound filler placed within the wound, and/or monitor a level of pressure exerted on one or more organs, tissue layers, blood vessels, or other body parts affected by the closure pressures. A caregiver can then adjust a level of pressure in the inflatable bladder by either adding fluid to the bladder or releasing fluid from within the bladder to a receptacle or container positioned outside the body, adjust the collapse, stiffness or volume of the wound filler, adjust a level of negative pressure exerted on the wound cavity, and/or adjust any other closure forces applied to the wound to either increase or decrease the closure forces. In some embodiments, these adjustments can be made dynamically or automatically by a computer controller that receives one or more pressure readings or other data indicative of excessive pressure, and that sends a control signal to a pump or other device to make the adjustments.

In certain embodiments, when the computer controller receives a signal from a sensor, such as any sensor disclosed herein this section or elsewhere in the specification, the controller may trigger an alarm. Such an alarm may be an audible and/or visual alarm to alert a caregiver to a particular reading. However, any suitable alarm may be used. In some embodiments, the alarm may trigger when a pressure reading has crossed above or below a particular threshold, such as when the pressure on an organ is too high. In certain embodiments, the alarm may trigger when the level of negative pressure rises above or falls below a certain threshold. As will be appreciated by one of skill in the art, since there are many possible sensor configurations disclosed within this specification, there may also be any number of suitable corresponding alarms.
[0070] A clinician may monitor the internal pressure as vacuum is slowly increased to the wound dressing, or as air is slowly released from the inflatable member. In one embodiment, human bladder pressure is controlled below approximately 40 mmHg, or below approximately 30 mmHg, approximately 20 mmHg, or approximately 15 mmHg. In some embodiments, the measurement of internal pressure and control of the vacuum and air release can be controlled automatically. This way, as the oedema decreases the wound can be slowly closed further over, for example, a period of hours to days (e.g., closure by seven days). It will be appreciated that systems can be employed where the vacuum can be slowly applied with pressure feedback being provided based on vital signs of the patient or other monitoring described herein or in http://www.uptodate.com/contents/abdominal-compartment-syndrome.

[0071] Figure 12 is a schematic representation of an apparatus 120 used to provide negative pressure wound therapy to a wound and to control the level of therapy and/or closure of the wound based on pressure sensors positioned within the wound cavity to minimize the risk of compartment syndrome. For example and without limitation, in some embodiments, the apparatus 120 can have a backing layer 122 for providing a substantially air and liquid-tight seal over a wound. Under the overlay, the apparatus 120 can have a wound packing member or wound filler 124 that can have an adjustable volume and/or internal pressure. For example, some embodiments of the wound packing member 124 can have a sealed member 126 (such as a sealed bag) that can be controllably inflatable and deflatable from a pressure source such as a pump via a conduit 128 in communication with a sealed space within the sealed member 126. The sealed member 126 can be positioned in the wound in contact with the wound tissue interface. For example, in any embodiments used for abdominal wounds, the sealed member 126 can be configured and can be positioned in the wound cavity so as to engage all tissue layers above the organs in the body. For example, in some embodiments, the sealed member 126 can be positioned in the wound so as to contact any or all of the layers that can be present in an abdominal wound, such as (from deepest to most superficial) the peritoneum, extraperitoneal fascia (deep fascia), muscle, superficial fascia, subcutaneous tissue, and skin. However, the presence or absence of various layers is location dependent, so not all of these layers may be present in every abdominal wound treatable with the apparatuses of the present disclosure.
In some embodiments, an organ protection layer 127, such as any embodiments of the wound contact layer disclosed in U.S. Application Publication No. 2011/0213287, Serial No. 12/886,088, titled SYSTEMS AND METHODS FOR USING NEGATIVE PRESSURE WOUND THERAPY TO MANAGE OPEN ABDOMINAL WOUNDS, filed on September 20, 2010, which application is hereby incorporated by reference herein as if fully set forth herein, can be positioned between the sealed member 126 and the viscera or other organs. Embodiments of the apparatus 120 disclosed herein can comprise any of the other components, materials, features, or details of any of the embodiments or components of the negative pressure systems disclosed in U.S. Application No. 12/886,088. As mentioned, all embodiments or components of the negative pressure systems disclosed in U.S. Application No. 12/886,088 are hereby incorporated by reference as if fully set forth herein.

A pressure sensor 130 (also referred to herein as a first pressure sensor) can be used to monitor a pressure level within the sealed member 126. The pressure sensor 130 can provide a visual reading of the level of pressure within the sealed member 126, and/or can provide a signal to a controller 132 based on the level of pressure within the sealed member.

The level of pressure within the sealed member 126, as mentioned, can be controlled in part by the pump 127 (also referred to herein as the first pump) and can be adjusted to be a positive or a negative pressure. Additionally, in some embodiments, the pump 127 can be configured to cycle the pressure level between any desired positive or negative pressure levels or to apply intermittent pressure to the sealed member 126. Positive pressures within some embodiments of the sealed member 126 or any sealed member embodiment disclosed herein can range from 0 mmHg to 60 mmHg or more. Negative pressures within some embodiments of the sealed member 126 or any sealed member embodiment disclosed herein can range from 0 mmHg to -180 mmHg or more.

In any embodiments disclosed herein, the pressure level within the sealed member 126 can be controlled independently of the pressure in a space 134 beneath the backing layer 122. The pressure beneath the backing layer 122 can be detected by a pressure sensor (such as pressure sensor 138, which is also referred to herein as a second pressure
sensor) in communication with the space 134 beneath the backing layer 122. The second pressure sensor 138 can be configured to provide a signal to the controller 132. In any embodiments disclosed herein, a second pump, such as pump 136, can be used to provide a source of negative pressure to a space 134 beneath the backing layer 122. Alternatively, the apparatus can be configured to have only one pump (not illustrated) having multiple conduits and multiple valves to independently control a level of pressure within the sealed member 126 and the space 134 beneath the backing layer 122.

[0076] In some embodiments, the level of pressure within the sealed member 126 can be adjusted independent of the level of reduced pressure in the space 134 to increase or decrease a volume of the sealed member 126, which can be beneficial in terms of controlling a level of pressure exerted on one or more organs in the abdominal area and, hence, can be beneficial in terms of controlling or minimizing a risk of compartment syndrome. A pressure sensor 140 (which is also referred to herein as a third pressure sensor) can be placed in communication with a human organ, for example the human bladder to monitor pressure within the human bladder. The third pressure sensor 140 can also be configured to provide a signal to the controller based on the pressure reading detected by the third pressure sensor 140.

[0077] If a pressure detected in one or more organs, such as the human bladder, as detected by a pressure sensor 140, exceeds a threshold value, the controller 132 can adjust one or more pressure levels to reduce the pressure exerted on the organ or organs. In some embodiments, the threshold value of pressure measurements for organs in the abdominal region can be 10 mmHg (or approximately 10 mmHg), or 12 mmHg (or about approximately 12 mmHg), or 15 mmHg (or about 15 mmHg) but such values may be organ specific and/or patient specific. Additionally, in some applications, wherein any of the dressings disclosed herein are used to treat a wound on the thigh, for example, compartment pressures can reach as high as 120 mmHg, such that the threshold value of compartment pressure in that region may be much higher than for abdominal wounds, such as approximately 60 mmHg or less to approximately 80 mmHg, or approximately 100 mmHg. In the leg, generally, the threshold value of pressure which can trigger such pressure and dressing adjustments can be approximately 40 mmHg, or from approximately 40 mmHg to approximately 60 mmHg.
Some embodiments of the apparatus can be configured such that a medical practitioner can set the level of the threshold value, since a different value may be applicable to each patient. For younger patients or children, or patients that are at a higher risk for developing compartment syndrome, for example, a lower threshold value can be set. In some embodiments, the threshold value can be set at from approximately 8 mmHg to approximately 12 mmHg.

[0078] For example, in abdominal negative pressure wound therapy kits, to reduce the pressure buildup, the apparatus can be configured to decrease the level of closure forces applied to the wound. This can be achieved in some embodiments by increasing a level of pressure in the sealed member 126, thereby limiting the amount of closure in the walls of the wound interface even when an elevated level of reduced pressure applied to the space 134 in the wound is maintained to ensure an appropriate level of fluid removal. This can be done until the level of pressure in one or more of the organs, such as the bladder, or blood flow rate measurements, reach a safe or below-threshold value once again. In some embodiments, the pressure level within the sealed member 126 can be a positive value (i.e., above atmospheric) to exert a spreading force on the tissue interface, while the pressure level within the space 134 but outside of the sealed member 126 is at a negative pressure level. This arrangement wherein the sealed member 126 can independently control the level of closure of the wound interface, can also permit a medical practitioner to exceed the normal negative pressure levels in the space 134 beyond the typical therapeutic ranges that might otherwise have been limited by excessive interabdominal pressure levels.

[0079] In some embodiments or arrangements, a sealed member 126 can be sized and configured to contact the peritoneum, extraperitoneal fascia (deep fascia), muscle, superficial fascia, subcutaneous tissue, and skin when placed in the abdominal wound. When the level of closure of the wound interface is desired to be limited, such as when excessive levels of pressure are present in or adjacent to the wound area, a level of pressure within the sealed member 126 can be increased to limit the contraction in one or more of the peritoneum, extraperitoneal fascia (deep fascia), muscle, superficial fascia, subcutaneous tissue, and skin, thereby increasing the volume of space that the viscera can occupy and reducing the level of pressure exerted on the various organs and blood vessels. Again, because the level of pressure within the sealed member 126 can be adjusted independently of the level of pressure...
within the space 134 beneath the backing layer 122 but outside of the sealed member 126, a therapeutic level of reduced pressure can be applied to the wound to remove excessive liquid exuded in the abdominal compartment and improve the healing conditions.

[0080] In any of embodiments disclosed herein, the apparatus can gather pressure readings from one or more pressure sensors positioned throughout the body to monitor compartment pressures. For interabdominal compartment pressures, readings can be gathered in the abdominal region or adjacent thereto. For example, any apparatus disclosed herein can have one or more blood flow meters (such as a laser Doppler blood flow meter) configured to measure a flow rate of blood through target blood vessels, arteries, capillaries, and/or muscles. Any embodiments of the laser Doppler can be permanently mounted to the patient's skin near the wound cavity. In some embodiments, for example, one or more blood flow meters can be used to measure a flow rate of blood through the femoral arteries or through musculature at or near to the abdominal region and provide a feedback signal to the controller 132.

[0081] Additionally, in some embodiments, pressure levels in, for example, the abdominal compartment can be measured using the vesicular technique, which can involve the use of an indwelling urinary catheter, a pressure transducer, and a syringe or similar device capable of infusing fluid. Additionally, pressure levels in the abdominal compartment can be measured by catheterizing the inferior vena cava through either the left or right femoral artery. See F. Lui, A. Sangosanya, and L.J. Kaplan, "Abdominal Compartment Syndrome: Clinical Aspects and Monitoring," Critical Care Clinics, vol. 23, no. 3, pp. 415-433, 2007 for more information about monitoring techniques for suitable for monitoring abdominal compartment syndrome.

[0082] Further, any embodiments of the sealed member 126 disclosed herein can be formed from a substantially sealed impermeable membrane 148, that seals around or to the conduit 128 that provides the fluid (e.g., air, nitrogen, or argon, or saline, water, or other liquids) into and out of the impermeable membrane 148, which can be formed from any suitable, biocompatible polymer film, sheet, bag, pouch, chamber, or otherwise, similar to any of the inflatable membranes disclosed in U.S. Patent No. 7,753,894, which is Application No. 12/886,088, titled WOUND CLEANSING APPARATUS WITH STRESS, filed on December 17, 2007.
In some embodiments, the sealed member 126 can have a foam layer 150 around some or all of the outside surface of the impermeable membrane 148. In some embodiments, the foam layer 150 can surround the entire surface of the impermeable membrane 148. The foam 150 can help cushion any pressure points exerted on the tissue by the sealed member 126, and can assist with the distribution of negative pressure across the wound cavity.

Additionally, though not required, any embodiments disclosed herein can have a structural member 160 positioned inside the impermeable membrane 148. In some embodiments, the structural member 160 can be configured to be more rigid in a vertical direction (i.e., transverse to the backing layer, as indicated by arrow A1 in Figure 12), than in a lateral direction (i.e., in the direction of wound closure of the tissue interfaces, as indicated by arrow A2 in Figure 12). Examples of structural members that can be used are found in Application Serial No. 13/365,615, titled "Negative Pressure Wound Closure Device," filed February 3, 2012, published as US 2012/0209227, the entirety of which is hereby incorporated by reference.

In some embodiments, the sealed member 126 can have multiple, independently controllable (e.g., inflatable or deflatable) chambers. One or more manifolds can control the inflation and deflation of the various compartments or chambers to control the size and/or shape of the bladder member as desired to suit the particular wound size and application.

Additionally, in any embodiments disclosed herein, the sealed member 126 can be used with a vertically rigid but laterally collapsible structure positioned either inside or outside of the sealed member 126. For example, with reference to Figure 13, another embodiment of an apparatus 200 is illustrated. The apparatus 200 can have any of the same features, components, or details of any other embodiments disclosed herein, including any of the visualization elements and the pressure sensors disclosed above. Additionally, as shown in Figure 13, a sealed member 206 can be positioned in the wound cavity and have any of the same features, materials, or other details of the sealed member 126 disclosed herein, including but not limited to the foam layer or interface 208 surrounding the impermeable layer 210.
The apparatus 200 can also have a support member 216 positioned under a backing layer 218. Some embodiments of the support member 216 can have one or more legs (also referred to herein as a body portion) 220 attached to a top portion 226 (also referred to herein as a first portion) of the support member 216. In some embodiments, the top portion 226 of the support member 216 can be along an apex of the support member 216 and define a longitudinal axis A1 of the support structure. The legs 220 can be rotatably supported by the top portion 226 so that the legs 220 can rotate about axis A1 defined through the axial centerline of the top portion 226. The sealed member 206 can be coupled with, connected to, adhered to, or otherwise attached the legs 220 such that contracting or expanding the sealed member 206 will correspondingly contract or expand the legs 220 and support member 216. In some embodiments, the legs 220 can be positioned within molded pockets formed in the sealed member 206. In some embodiments, one or more foam pockets positioned at the bottom of the legs 220 can be adhered to the sealed member 206.

In this configuration, as the sealed member 206 is contracted from a first volume, such as volume V1 shown in Figure 13, to a second, larger volume, such as volume V2 shown in Figure 14, the support member 216 (or any other suitable support member having greater vertical than lateral rigidity) can also laterally contract. Additionally, the sealed member 206 can be configured to expand from a smaller volume, such as volume V2 shown in Figure 14, to a larger volume, such as volume V1 shown in Figure 13, the so as to urge the support member 216 and the legs 220 thereof, laterally outward against the walls of the wound interface, thereby potentially reducing the pressure on the organs within the abdominal compartment. As the wound closes during the course of healing, the legs 220 can rotate closer together so that the closure of the wound is not inhibited by the dressing backing layer 218.

Further, some embodiments of the wound closure apparatuses, such as embodiments 120 and 200, can have one or more tissue engaging elements supported by the sealed member or the support member in communication with the sealed member. The tissue engaging elements can be configured to engage one or more layers of the wound interface, including any one or combination of the peritoneum, extraperitoneal fascia (deep fascia), muscle, superficial fascia, subcutaneous tissue, and skin. The tissue engaging elements 164
(schematically represented in Figure 12) of the embodiment of the apparatus 120 shown in Figure 12, or the tissue engaging elements 264 of the embodiment of the apparatus 200 can comprise any one or combination of tissue connectors, tissue anchors, hook shaped members, balls on the ends of rods, and/or any other suitable engaging mechanisms available for use with the various layers of tissue. Some embodiments of the sealed member 126 can have any combination of different tissue engaging elements desired to engage the various different tissue layers in the wound site.

[0090] In any embodiments of the sealed member disclosed herein, a level of the volume of fluid within the sealed member can be controlled automatically by the control system, as discussed. Additionally, in any embodiments, the level of the volume of fluid within the sealed member can be changed manually by adding or removing fluid into the sealed member through a tube and a hand operated pump system, or through a syringe and cannula device inserted into a sealed receptacle such as one or more syringe ports on the sealed member, in response to pressure readings acquired by any of the plurality of pressure sensors in the apparatus.

[0091] In some embodiments, the sealed member can itself be more rigid in a vertical direction than in a lateral direction. For example, any embodiments of the sealed member can have corrugations or an undulating surface that causes the sealed member to be more flexible in a lateral direction than in a vertical direction. In some embodiments, the sealed member can have, for example, an accordion-like shape.

[0092] It will be appreciated that in some embodiments, it is not necessary to take any measurements indicative of excessive pressure within the patient. Rather, it may simply be desired to control the closure of a wound by controlling the volume, stiffness, pressure, and/or collapse of any of the wound fillers described above. Such closure can be controlled based on visual inspection, use of the wound visualization methods and apparatus described above, or can be controlled based on a desired predetermined schedule. The control over such closure can be performed manually by a health practitioner, or may be performed automatically or based on inputs by a controller as described above. For example, where an inflatable bladder is placed in the wound, the pressure in the bladder may be manually or automatically controlled to limit and/or allow a certain amount of wound closure for a given
period of time. This concept may similarly be applied to wound fillers such as described in Figure 13 by including a mechanism (such as the adjustable bladder between the legs) where the angle between the legs can be controlled over time. Other embodiments of wound fillers whose volume, stiffness, pressure and/or collapse may be controlled, can be used with any of the components of any of the embodiments disclosed herein. Examples of such additional wound fillers that can be used with any of the components of any of the embodiments disclosed herein are found in Application Serial No. 13/365,615, titled "Negative Pressure Wound Closure Device," filed February 3, 2012, published as US 2012/0209227, incorporated by reference herein, the entirety of which is hereby incorporated by reference and should be considered a part of this specification. It will be appreciated that any of these embodiments of wound fillers may also be used in combination with or instead of the inflatable bladder in the system and method of Figure 12.

[0093] In other embodiments, such closure can be controlled based on visual inspection, the use of the wound visualization methods and apparatus as described herein this section or elsewhere in the specification, or based on a desired predetermined schedule. The control over such closure can be performed manually by a health practitioner, or may be performed automatically or based on inputs by a controller as described herein this section or elsewhere in the specification. For example, where an inflatable member such as described herein this section or elsewhere in the specification is placed in the wound, the pressure in the inflatable member may be manually or automatically controlled to limit and/or allow a certain amount of wound closure for a given period of time. This concept may similarly be applied to other wound fillers described herein this section or elsewhere in the specification, for example as described in Figure 13, by including a mechanism (such as the adjustable bladder between the legs) where the angle between the legs can be controlled over time. Other mechanisms can also be employed to control the change in volume, stiffness, pressure, and/or collapse of any of the wound fillers described herein, either manually by a user or automatically based on control for a controller. It will further be appreciated that any of the embodiments of wound fillers as described above may also be used in combination with or instead of the inflatable bladder in the system and method of Figure 12.
[0094] Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0095] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

[0096] Although the present disclosure includes certain embodiments, examples and applications, it will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof, including embodiments which do not provide all of the features and advantages set forth herein. Accordingly, the scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments herein, and may be defined by claims as presented herein or as presented in the future.
WHAT IS CLAIMED IS:

1. A wound treatment apparatus for use with negative pressure, comprising:
   a wound filler for use in treating a wound with negative pressure, comprising:
   a plurality of vertically extending straws configured to extend vertically when the wound filler is positioned within a wound bed;
   a plurality of joints connecting adjacent vertically extending straws; and
   wherein upon application of negative pressure to the wound filler, the wound filler is configured to contract horizontally with the vertically extending straws reducing vertical movement of the wound filler.

2. The wound treatment apparatus of claim 1, wherein the vertically extending straws are solid.

3. The wound treatment apparatus of claim 1, wherein the vertically extending straws are hollow.

4. The wound treatment apparatus of claim 1, wherein the joints are flexible.

5. The wound treatment apparatus of claim 1, wherein the joints are rigid.

6. The wound treatment apparatus of claim 1, wherein the wound filler is further configured to be placed in the wound bed in a spiral conformation.

7. The wound treatment apparatus of claim 1, further comprising at least one pressure sensor.

8. A wound treatment apparatus for use with negative pressure, comprising:
   a wound filler for use in treating a wound with negative pressure, comprising:
   a flexible hollow tube;
   a vertical strut positioned within the flexible hollow tube, the vertical strut configured to extend vertically when the wound filler is positioned within a wound bed, the vertical strut being made of a more rigid material than the flexible hollow tube; and
   wherein upon application of negative pressure to the wound filler, the wound filler is configured to contract horizontally with the vertically strut reducing vertical movement of the wound filler.
9. The wound treatment apparatus of claim 8, further comprising gripping members located on the outside of the flexible hollow tube, the gripping members configured to grip the wound bed.

10. The wound treatment apparatus of claim 8, wherein the flexible hollow tube is configured to be placed within the wound bed in a spiral conformation.

11. The wound treatment apparatus of claim 8, wherein the flexible hollow tube comprises an extruded foam.

12. The wound treatment apparatus of any one of the preceding claims, further comprising a cover configured to be placed over the wound filler and seal to skin surrounding the wound.

13. The wound treatment apparatus of Claim 12, further comprising a port configured to connect the wound cover to a source of negative pressure.

14. The wound treatment apparatus of Claim 13, further comprising a source of negative pressure configured to provide negative pressure to the wound.
FIG. 6A

Extruded foam filler

Profile of foam prevents filler collapsing

Outer features grip to edge of wound

FIG. 6B

Rigidity of straws prevent filler collapsing in wound

Straw structures are cut to length and fill wound

FIG. 5A

FIG. 5B

FIG. 6C
Variable resorption rates allow filler to dissolve as wound heals.

Rigid foam wound filler.

FIG. 8C

FIG. 8B

FIG. 8A
FIG. 9B

FIG. 9C

FIG. 9A

Under vacuum concertina will only collapse in one direction.

Foam inserts

Upper apex

First face

Lower apex

Second face

Lower layer

First face

Upper layer
Variable sized bubbles will collapse under varying pressures in wound

FIG. 10A

Bubble wrap

FIG. 10B

Wrap is pulled up and inserted in wound
FIG. 11B

Under vacuum, bubble wrap will collapse in one direction

FIG. 11C

Bubble wrap is layered in wound

FIG. 11A
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F13/00 A61M1/00 A61M27/00 A61F13/02

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>A</td>
<td>paragraphs [0042] - [0043], [0054] - [0055], [0057] - [0059]; figure 10</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

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

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Date of the actual completion of the international search

13 June 2014

Date of mailing of the international search report

24/06/2014

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Mangin, Sophie
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