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(54) Title: APPARATUSES AND METHODS FOR WOUND THERAPY

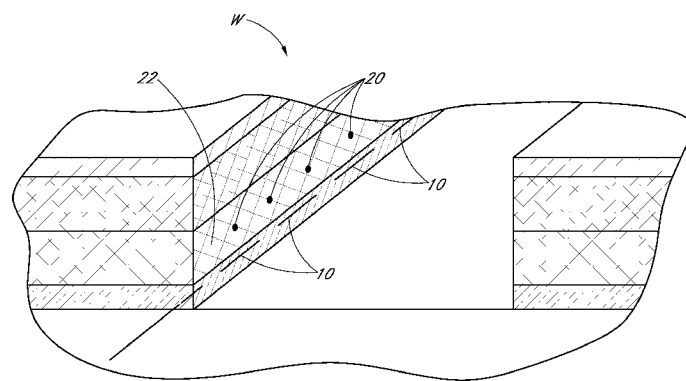


FIG. 1

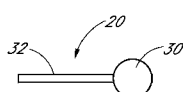


FIG. 1A

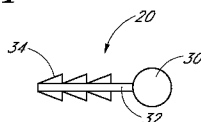


FIG. 1B

(57) Abstract: Some arrangements disclosed herein relate to devices and methods for treating a wound, comprising applying negative pressure to the wound through a cover applied over a wound, monitoring the internal pressure in the wound, and controlling the closure of the wound by controlling the amount that a wound packing material positioned under the cover collapses within the wound based on the monitored internal pressure. The wound packing material collapse can be controlled to ensure that the monitored internal pressure does not exceed a threshold value. Additionally, some embodiments or arrangements disclosed herein relate to a visualization element to visualize a location of a wound surface. The visualization element can comprise a radiopaque member that is configured to be positioned on or adjacent to a surface of an open wound.



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APPARATUSES AND METHODS FOR WOUND THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application Nos. 61/650,391, filed May 22, 2012, entitled WOUND CLOSURE DEVICE, 61/663,405, filed June 22, 2012, entitled APPARATUSES AND METHODS FOR VISUALIZATION OF TISSUE INTERFACE, 61/681,037, filed August 8, 2012, entitled WOUND CLOSURE DEVICE, and 61/782,026, filed March 14, 2013, entitled WOUND CLOSURE DEVICE, the contents of which are hereby incorporated by reference in their entireties 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 DISCLOSURE

Field of the Disclosure

[0002] Embodiments or arrangements disclosed herein relate to methods and apparatuses for visualizing a position of a wound interface or a degree of closure of a wound. Such apparatuses and methods can be applied to a wide range of wounds, for example an abdominal wound or following fasciotomy procedures. The methods and apparatuses for visualizing a position of a wound interface or a degree of closure of a wound may be used with topical negative pressure (TNP) therapy dressings or kits, but are not required to be. Other embodiments disclosed herein relate to methods and apparatuses for treating a wound with negative pressure, and for detecting excessive compartment pressures and adjusting treatment to reduce such excessive pressures.

Description of the Related Art

[0003] A number of techniques have been developed for treatment (e.g., closure) of wounds, including wounds resulting from accident and wounds resulting from surgery.

Often, for deeper wounds in the abdominal region, fasciotomy procedures on deep tissue, deep trauma wounds, or pressure ulcers, it is difficult or impossible to determine whether the deeper layers of tissue are being drawn together by the surgical or wound therapy treatment methods. It is particularly difficult to determine if the deeper layers of tissue, such as the subcutaneous, muscle and fascial layer, are closing or have closed during wound closure treatment after an open abdominal surgical procedure or fasciotomy.

[0004] 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 can be beneficial to a patient.

[0005] 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. 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.

SUMMARY OF SOME EMBODIMENTS

[0006] Some embodiments of the present disclosure relate to visualization apparatuses and methods for visualizing a position of a wound interface during negative

pressure wound therapy. Some embodiments of the present disclosure relate to pressure sensing, feedback, and control systems for preventing compartment syndrome during application of negative pressure wound therapy or any therapeutic treatment of wounds. Other embodiments of the present disclosure relate to methods and apparatuses for controlling the rate of closure of a wound.

[0007] Any of the features, components, or details of any of the arrangements or embodiments disclosed in this application, including those disclosed below, are interchangeably combinable with any other features, components, or details of any of the arrangements or embodiments disclosed herein to form new arrangements and embodiments. With that, the following are examples of arrangements disclosed herein.

1. A visualization element to visualize a location of a wound surface, comprising:

a radiopaque member that is configured to be positioned on or adjacent to a surface of an open wound.

2. The visualization element of arrangement 1, wherein the visualization element comprises a radiopaque marker, the radiopaque marker being configured to be attached to an edge or the surface of the wound.

3. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a radiopaque marker configured to be attached to the surface of the wound along at least one of subdermal layer, a fat layer, a muscle layer, and a fascia layer.

4. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a radiopaque marker configured to be attached to the surface of the wound along the fascia layer and at least one of subdermal layer, a fat layer, and a muscle layer.

5. The visualization element of any one of the previous arrangements, comprising a plurality of radiopaque markers configured to be attached to the surface of the wound.

6. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a gold wire that is configured to be advanced through tissue at the surface of the wound.

7. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a suture wire that is configured to be advanced through tissue at the surface of the wound, the suture wire comprising at least one of barium sulfate, zirconium, gold, titanium, and tungsten oxide.

8. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a suture wire that is configured to be stitched through tissue at the surface of the wound in a running stitch and/or a loop stitch.

9. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a gold wire that is configured to be advanced through the peritoneum tissue at and/or adjacent to the surface of the wound.

10. The visualization element of any one of the previous arrangements, wherein the visualization element comprises a bioabsorbable material.

11. The visualization element of any one of the previous arrangements, wherein the visualization element comprises an adhesive configured to be applied to a surface of the wound, the adhesive comprising a radiopaque material.

12. The visualization element of arrangement 11, wherein the radiopaque material comprises at least one of least one of barium sulfate, zirconium, gold, titanium, and tungsten oxide.

13. A kit for use in the treatment of a wound using negative pressure wound therapy, the kit comprising:

the visualization element of any one of the previous arrangements configured to be positioned on or adjacent to a surface of an open wound;

a dressing configured to sealably cover the wound; and

a source of negative pressure configured to apply negative pressure to a space between the dressing and the wound.

14. The kit of arrangements 13, further comprising a wound packing element positioned in the wound.

15. A method of visualizing a position of a tissue interface in a wound, comprising:

positioning one or more visualization elements of any one of the previous arrangements in or on a first side of the wound, the visualization element or elements being configured to contrast with tissue in the wound;

positioning one or more visualization elements of any one of the previous arrangements on a second side of the wound, the visualization element being configured to contrast with tissue in the wound; and

monitoring a position of the visualization element or elements on the first side of the wound relative to a position of the visualization element or elements on the second side of the wound to determine the distance between the first and second sides of the wound.

16. A method of visualizing a position of a tissue interface in a wound, comprising:

positioning a first visualization element in or on a first side of a wound interface, the visualization element being configured to contrast with a tissue in the wound;

positioning a second visualization element in or on a second side of a wound interface, the visualization element being configured to contrast with a tissue in the wound; and

monitoring a position of the first visualization element relative to a position of the second visualization element to determine the distance between the first and second sides of the wound.

17. The method of visualizing a position of a tissue interface in a wound of arrangement 16, wherein positioning a first visualization element in or on a first side of the wound interface comprises advancing a suture comprising a radiopaque material through at least a portion of the tissue on the first side of the wound.

18. The method of visualizing a position of a tissue interface in a wound of any one of arrangements 16-17, wherein positioning a first visualization element in or on a first side of the wound interface comprises advancing a suture comprising a radiopaque material through at least a portion of a peritoneum layer of tissue on the first side of the wound.

19. The method of visualizing a position of a tissue interface in a wound of any one of arrangements 16-18, wherein positioning a first visualization element in or on a first

side of the wound interface comprises applying an adhesive comprising a radiopaque on at least a portion of a peritoneum layer of tissue on the first side of the wound.

20. The method of visualizing a position of a tissue interface in a wound of any one of arrangements 16-19, further comprising removing the first visualization element and/or the second visualization element when the distance between the first side of the wound and the second side of the wound meets or exceeds a threshold distance.

21. A method of treating a wound, comprising:

placing a wound packing member into the wound;

applying a cover over the wound packing member and sealing the cover to skin surrounding the wound;

applying negative pressure to the wound through the cover;

monitoring the internal pressure in the wound; and

controlling the closure of the wound by controlling the amount that the wound packing material collapses within the wound based on the monitored internal pressure, wherein the wound packing material collapse is controlled to ensure that the monitored internal pressure does not exceed a threshold value.

22. The method of treating a wound of arrangement 21, wherein the internal pressure is 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.

23. The method of treating a wound of any one of arrangements 21-22, wherein the wound is an abdominal wound.

24. The method of treating a wound of any one of arrangements 21-22, wherein the wound is a wound on a limb.

25. The method of treating a wound of any one of arrangements 21-24, wherein the wound packing member comprises an adjustable volume wound filler.

26. The method of treating a wound of any one of arrangements 21-25, wherein the wound packing member comprises an inflatable sealed member and controlling the closure of the wound comprises controllably removing fluid or air from the inflatable member

27. The method of treating a wound of any one of arrangements 21-26, comprising detecting blood flow rate adjacent to the treated region using Laser Doppler velocimetry.

28. The method of treating a wound of any one of arrangements 21-27, further comprising positioning one or more wound visualization elements in a wound interface.

29. A method of treating a wound, comprising:

placing a wound packing member into the wound;

applying a cover over the wound packing member and sealing the cover to skin surrounding the wound;

applying negative pressure to the wound through the cover; and

controlling collapse of the wound packing member as the wound closes under negative pressure.

30. The method of treating a wound of arrangement 29, wherein the wound packing member is an inflatable bladder, and controlling collapse of the wound packing member comprises controlling the pressure within the bladder.

31. The method of treating a wound of any one of arrangements 29-30, comprising dynamically adjusting at least one of the volume, stiffness, pressure and collapse the wound packing member as the wound closes.

32. The method of treating a wound of arrangement 31, wherein the 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.

[0008] Other apparatuses, systems, methods and arrangements are also contemplated, which may or may not include some or all of the features described above. For example, wound treatment systems are contemplated that may utilize or perform one or more of the elements, kits or methods described above.

[0009] For example, in another embodiment, an apparatus for providing negative pressure wound therapy to a wound is provided. The apparatus may comprise a wound packing member or wound filler that has an adjustable volume, a backing layer for providing a substantially air and liquid-tight seal over a wound when the wound packing member or wound filler is positioned in the wound, and a source of negative pressure for providing

negative pressure to a space beneath the backing layer. In some embodiments, a pressure sensor for measuring internal pressure is provided. Closure of the wound can be controlled by controlling the amount that the wound packing member or wound filler collapses based on the measured internal pressure.

[0010] In some embodiments, the pressure sensor for measuring internal pressure is configured to be placed in communication with a human organ. The wound packing member or wound filler may comprise a sealed member that can be controllably inflatable and deflatable from a pressure source. The apparatus may further comprise an organ protection layer configured to be positioned between the wound packing member or wound filler and the viscera or other organs. A further pressure sensor may be provided configured to monitor a pressure level within the sealed member. A pump may be configured to control a level of pressure within the sealed member. In further embodiments, a pressure sensor may also be provided for detecting pressure beneath the backing layer. A controller may be configured to adjust negative pressure based on one or more of the aforementioned pressure sensors.

[0011] In some embodiments, an apparatus may comprise at least three pressure sensors, the first pressure sensor configured to monitor a pressure level within the sealed member, the second pressure sensor being for detecting pressure beneath the backing layer, and the third pressure sensor being for measuring internal pressure within or on an organ. A controller may be configured to adjust one or more pressure levels under the backing layer and/or within the sealed member to reduced pressure exerted on the organ.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Embodiments of the present disclosure will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0013] Figure 1 is a schematic illustration of an embodiment of a wound interface visualization apparatus.

[0014] Figures 1A and 1B illustrate embodiments of visualization elements.

[0015] Figure 2 is an image of an experimental setup of a wound having an embodiment or arrangement of a wound interface visualization apparatus, looking vertically down through the wound wherein no negative pressure has been applied to the wound.

[0016] Figure 3 is an image of the experimental setup of the wound having the embodiment or arrangement of a wound interface visualization element shown in Figure 2, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -120 mmHg.

[0017] Figure 4 is an image of an experimental setup of a wound having the embodiment or arrangement of the wound interface visualization element shown in Figure 2, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -200 mmHg.

[0018] Figure 5 is an image of an experimental setup of a wound having another embodiment or arrangement of a wound interface visualization element, looking vertically down through the wound wherein no negative pressure has been applied to the wound.

[0019] Figure 6 is an image of an experimental setup of a wound having the embodiment or arrangement of a wound interface visualization element shown in Figure 5, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -120 mmHg.

[0020] Figure 7 is an image of an experimental setup of a wound having the embodiment or arrangement of a wound interface visualization element shown in Figure 5, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -200 mmHg.

[0021] Figure 8 is an image of an experimental setup of a wound having the embodiment or arrangement of a wound interface visualization element shown in Figure 5, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -200 mmHg, then released to -120 mmHg and held at -120 mmHg for the image.

[0022] Figure 9 is an image of an experimental setup of a wound having another embodiment or arrangement of a wound interface visualization element, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -120 mmHg.

[0023] Figure 10 is an image of an experimental setup of a wound having the embodiment or arrangement of a wound interface visualization element shown in Figure 9, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -200 mmHg.

[0024] Figure 11 is a split image showing, on the left hand side, an experimental setup of a wound having an embodiment or arrangement of a wound interface visualization element without application of negative pressure and looking vertically down through the wound, and on the right hand side, the same experimental setup of a wound shown in the left side, having the embodiment or arrangement of the wound interface visualization element shown in the left hand side of Figure 11, having a vacuum applied to the wound at a level of -200 mmHg, and looking vertically down through the wound.

[0025] Figure 12 is a schematic representation of an embodiment of an apparatus used to provide negative pressure wound therapy to a wound.

[0026] 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.

[0027] 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.

[0028] Figures 15A-15F illustrate further embodiments of wound fillers.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0029] Some of the 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, such as dressing components and inflatable bladders, 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. Patent No. 8,235,955, titled “Wound treatment apparatus and method,” issued August 7, 2012; U.S. Patent No. 7,753,894, titled “Wound cleansing apparatus with stress,” issued July 13, 2010; Application Serial No. 12/886,088, titled “Systems And Methods For Using Negative Pressure Wound Therapy To Manage Open Abdominal Wounds,” filed September 20, 2010, published as US 2011/0213287; Application Serial No. 13/092,042, titled “Wound Dressing And Method Of Use,” filed April 21, 2011, published as US 2011/0282309; and Application Serial No. 13/365,615, titled “Negative Pressure Wound Closure Device,” filed February 3, 2012, published as US 2012/0209227.

[0030] 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 dehiscent 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. Thus, while some embodiments and methods disclosed herein are described in the context of treating abdominal wounds, the apparatuses and methods disclosed herein are applicable to any wound in a body.

[0031] 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).

[0032] 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 over -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. Unless stated otherwise, the term approximately is meant to represent a range of +/- 10% of the stated value.

[0033] Figure 1 is a schematic illustration of an embodiment of a wound interface visualization element. As illustrated in Figure 1, in some embodiments and methods for the visualization of a surface of a wound interface, one or more first visualization elements 10 and/or second visualization elements 20 can be positioned along a surface of a wound W. The visualization elements can be positioned in fascia, peritoneum, fat, muscle, and/or any other tissue in the body.

[0034] In some embodiments, the first visualization elements 10 and/or second visualization elements 20 can comprise any suitable and biocompatible radiopaque material or a radiopaque marker for visualization during any suitable procedure, including, for example and without limitation, fluoroscopy, computerized tomography (CT) scan, x-ray, magnetic resonance imaging (MRI), or any other suitable visualization procedures or techniques applied during or after wound treatment, including without limitation negative pressure wound treatment. Any number or variety of radiopaque markers or visualization elements can be used.

[0035] The visualization element(s) can be sutures, a powder or solid material (such as a barium sulfate powder), or an adhesive comprising a radiopaque or contrasting material or element that can be applied at or adjacent to a surface of a wound. For example,

in some arrangements, the visualization element(s) can be applied at or adjacent to an interface or wound surface of a fascia layer of tissue, the peritoneum, and/or any other suitable tissue layer.

[0036] As illustrated in Figure 1, the visualization elements 10 can be radiopaque sutures (such as, without limitation, gold wire) applied in running or loopstitch along the length of a particular tissue layer in a wound interface. In the embodiment illustrated in Figure 1, the tissue layer through which the visualization elements 10 are passed can be a fascia layer 12. However, any of the visualization element embodiments disclosed herein can be positioned in any desired tissue or tissue layer during surgery.

[0037] The sutures can comprise a radiopaque material. Additionally, though not required, the sutures can comprise a bioabsorbable material so that the sutures need not be removed from the wound after the target layer of tissue has progressed to a threshold or sufficient level of closure.

[0038] Additionally, in some embodiments, the visualization element can be an adhesive material, such as cyanoacrylate, or a powder comprising a radiopaque material such as barium sulfate, zirconium, gold, titanium, iodine, isohexol, iodixanol and tungsten oxide (any one or combination of which can be used with any other material or substance disclosed herein), can be applied to the surface of the subject layer of tissue to provide the contrast desired for visualization under fluoroscopy, computerized tomography (CT) scan, x-ray, magnetic resonance imaging (MRI), or during any other suitable visualization procedure or technique described herein or otherwise. The chosen materials for the visualization element should be biocompatible and also compatible with the chosen medical and visualization procedures and equipment.

[0039] Further, with reference to Figure 1, any disclosed embodiments of the visualization elements, such as without limitation visualization elements 20, can be positioned in a fatty layer 22. In any embodiments, as illustrated in Figures 1A and 1B, the visualization elements can have a body portion 30 and a shaft portion 32. In some embodiments, the body portion can comprise one or more radiopaque studs, balls, or other radiopaque objects 30, which can be positioned on an end portion of a shaft portion 32. Additionally, in any embodiments, the visualization elements 20 can have one or more barbs

or protrusions 34 extending in a transverse direction away from the shaft portion 32 for more secure engagement with the target tissue.

[0040] In the embodiment illustrated in Figure 1, the tissue layer through which the visualization elements 20 are passed can be a fatty layer 22. However, any of the visualization element embodiments disclosed herein can be positioned in any desired tissue or tissue layer during surgery.

[0041] Any of the embodiments or details of the visualization elements described herein can be used with, or adapted for use with, negative pressure wound therapy dressings or components, surgical dressings or components used for closing wounds, or any other dressings or dressing components.

[0042] A number of experiments were conducted, using as the visualization element a gold wire used for jewellery making. The gold wire was very flexible, making it easy to position and pull through the tissue thus minimising trauma to the tissue. A further advantage of the being flexible is the fact that it does not impact on or hinder the contraction of the wound. Thus, in any embodiments disclosed herein, the visualization element can be flexible.

[0043] Other materials that may be suitable are titanium, tantalum, stainless steels, and corrosive resistant alloys, for example and without limitation Inconel, monel, hastelloy. Other materials that can be used include polymers filled with powdered radiopaque materials e.g. Barium Sulphate, titanium, zirconium oxide, iodine, iohexol, iodixanol. Additionally, the following non-resorbable polymers that can be used in conjunction with a contrast agent include, without limitation, nylon and polypropylene. Further improvements of some embodiments disclosed herein may be made by making the visualization elements from bioresorbable polymers. Suitable bioresorbable materials include polyglycolic acid, polylactic acid and caprolactan. Other suitable radiopaque materials may be so called radiopaque dyes e.g. low-osmolality contrast agents or less preferably high osmolality contrast agents. Use of bioresorbable polymers allows the visualization elements to be left within the tissue such that they will slowly dissolve over time without trace or substantially no trace.

[0044] Monofilaments of the above polymers may be produced by extrusion of the polymer premixed with a desired contrast agent. This will ensure the contrasting agent is

spread uniformly throughout the visualization element and remain in contact with the substrate or other materials of the visualization element. Alternatively a master batch of the polymer containing the contrast agent may be made and then extruded or molded into the desired visualization element.

[0045] In further improvements, it may be desirable to utilize two or more visualization elements that include contrast agents of different contrast levels to show the movement of different layers of tissue in the body or different areas of the same tissue in the body. Closure of the fascial layer is one of the primary objectives of open abdominal treatments. So, monitoring the closure of the fascial layer is very important to ensuring a successful abdominal wound treatment. For example and without limitation, a metal may be used to give a contrast close to black whereas an inorganic salt (e.g., barium sulphate) may be used to give a contrast closer to white. Additionally, for example and without limitation, two or more visualization elements that define a different shape or which are similar in all regards but which are stitched in a different pattern can be used to show the movement of different layers of tissue in the body or different areas of the same tissue in the body. In this way the movement of different layers of tissue or different areas of the same tissue can be visualized and easily distinguished by a user in a 2-dimensional or other image.

[0046] Alternatively the contrasting agent maybe printed, sprayed, sputtered or coated onto the visualization element. In this way it may be possible to apply the contrasting agents at different spacings along the length or patterns on the visualization element thus allowing for differentiation of 2 or more different visualization elements in the body.

[0047] In the examples, the wire was looped through the fascia tissue in a running stitch format right around the wound such that the majority of the wire was not imbedded in the tissue, but ran along the surface of the tissue. This was achieved by threading the wire onto a standard curved surgical suture needle and passing through the tissue to create a running stitch.

[0048] The fluoroscope was positioned vertically over the centre of the wound. The contraction of the wound was watched in real time on the screen of the fluoroscope and still images were captured once movement had stopped. Using the fluoroscope in real time video mode, it is possible to see the tissue move and therefore visually determine the degree of closure being achieved in the deep tissue

[0049] Other embodiments may include staples comprising a radiopaque material but minimising the number of parts used, which reduces the risk of any devices being left in the body after closure, unless the parts are bioresorbable. An alternative embodiment may include sprinkling radiopaque powder on the wound edge. In a further embodiment a radiopaque liquid or gel maybe painted or sprayed or spread on to the wound edge. Suitable liquids/gels may preferably be glues, advantageously their adherence to tissue prevents their movement after application. E.g. cyanoacrylate or fibrin glues filled with radiopaque powder. Such glues may also be used to help attach the main tissue closure device to the tissue.

[0050] In some embodiments, there can be a separate device attached to the tissue rather than the main closure device in case the main closure devices movement does not follow the movement of the tissue. Making the main closure device radiopaque also would help show differential movement.

[0051] Additionally, a surgeon or medical practitioner can place one or more visualization elements in a patient's dermis to detect a position of the dermis during the course of treatment. The one or more visualization elements in a patient's dermis can have a different level of contrast or a different shape as compared to the visualization elements that can be positioned in other layers of tissue. Or, the visualization elements can be positioned in the various tissue layers following a different pattern. For example, a radiopaque wire sutured through a first layer or fascial layer can have a first shape, a first pattern, and/or a first contrast level, and a radiopaque wire sutured through second layer or dermal layer can have a second shape, a second pattern, and/or a second contrast level. A first stitch pattern can have a wave-like stitch pattern having a first frequency and amplitude. A second stitch pattern can have a wave-like stitch pattern having a second frequency and amplitude so as to be discernible from the first stitch pattern.

[0052] A series of images were taken during experiments conducted having different embodiments of visualization element or arrangements, as shown in Figures 2-11.

[0053] Figure 2 is an image of an experimental setup of a wound having an embodiment or arrangement of a wound interface visualization element, looking vertically down through the wound wherein no negative pressure has been applied to the wound. The wound shown in Figure 2 is packed with foam and covered with a drape. The visualization element 50 is a gold wire sewn through the fascia in a wave form pattern or path.

[0054] Figure 3 is an image of the experimental setup of the wound having the embodiment or arrangement of a wound interface visualization element shown in Figure 2, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -120 mmHg. In this experimental setup, as mentioned above, the wound is packed with foam and covered with a drape. Again, the visualization element 50 is a gold wire sewn through the fascia in a wave form pattern or path. In Figure 3, a negative pressure of -120 mmHg. has been applied to the wound. The visualization element 50 provides a clear image and identification of the location of the interface of the fascia layer to a surgeon or medical practitioner. Figure 4 has the same experimental setup and visualization element embodiment as shown in Figure 3, with a negative pressure level of -200 mmHg applied to the wound.

[0055] Figures 5-7 are images of an experimental setup of a wound having another embodiment or arrangement of a wound interface visualization element 60, which again is a gold wire, sewn through the fascia in a wave form. In Figure 5, the wound is subject only to atmospheric pressure. In Figure 6, the level of negative pressure applied to the wound is -120 mmHg. In Figure 7, the level of negative pressure applied to the wound is -200 mmHg. Figure 8 is an image of the experimental setup of the wound having the embodiment or arrangement of the wound interface visualization element 60 shown in Figure 5, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -200 mmHg, then released to -120 mmHg and held at -120 mmHg for the image.

[0056] Figure 9 is an image of an experimental setup of a wound having another embodiment or arrangement of a wound interface visualization element 70, looking vertically down through the wound wherein negative pressure has been applied to the wound at a level of -120 mmHg. In this experimental setup, the wound has been packed with wound packing and foam inserts in cells and covered with drape. The visualization element 70, which was a gold wire in this experimental setup, is sewn through the fascia in a wave form. Figure 10 is an image of the same experimental setup as shown in Figure 9, showing the wound with negative pressure level of -200 mmHg applied to the wound.

[0057] Figure 11 is a split image showing, on the left hand side, an experimental setup of a wound having an embodiment or arrangement of a wound interface visualization

element 80 without application of negative pressure and looking vertically down through the wound, and on the right hand side, the same experimental setup of a wound shown in the left side, having the embodiment or arrangement of the wound interface visualization element 80 shown in the left hand side of Figure 11, having a vacuum applied to the wound at a level of -200 mmHg, and looking vertically down through the wound. Split image comparing the wound packing closure device at rest and after application of 200 mmHg of reduced pressure.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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 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 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.

[0062] 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.

[0063] 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.

[0064] 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.

[0065] 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.

[0066] 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>.

[0067] 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.

[0068] 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 09/20/2010, 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.

[0069] 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.

[0070] 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.

[0071] 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.

[0072] 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.

[0073] 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.

[0074] 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.

[0075] 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.

[0076] 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.

[0077] 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.

[0078] 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 12/17/2007.

[0079] 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.

[0080] 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.

[0081] 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.

[0082] 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.

[0083] 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 22 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.

[0084] 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.

[0085] 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.

[0086] 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.

[0087] 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.

[0088] 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.

[0089] 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. Figures 15A-F illustrate further embodiments of suitable wound fillers, and examples of these and other suitable wound fillers may be found in U.S. Patent No. 7,754,937, titled “WOUND PACKING MATERIAL FOR USE WITH SUCTION,” the entirety of which is hereby incorporated by reference. Other embodiments of negative pressure therapy apparatuses, dressings, wound fillers and methods of using the same that may also be utilized alone or in combination with the embodiments described herein, and further description of the embodiments found above, for example with respect to Figures 13 and 14 above, are found in U.S. Provisional Application No. 61/681,037, filed August 8, 2012, entitled WOUND CLOSURE DEVICE, and PCT Application No. PCT/US13/42064 filed May 21, 2013, entitled WOUND CLOSURE

DEVICE, the entireties of which are hereby incorporated by reference. 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.

[0090] Figure 15A illustrates a wound filler comprising a corrugated unit 450 comprising two sheets. A first sheet layer 410 is provided, and a second sheet-like layer 420 having an essentially sinusoidal cross section, for example, is coupled to the surface of the first sheet layer at locations 430. The coupling can be achieved by use of an adhesive or heat sealing. A two part silicone adhesive has been found suitable to provide coupling between sheet 410 and sheet 420. A bead of silicone material 440 may be optionally added to adjust the resiliency of the corrugated unit 450. A suitable sheet material is polyester or polyester fibers. Although sheet layer 420 is illustrated as having a sinusoidal cross-section, it is also contemplated that other cross-sections, such as pleated, may be used.

[0091] Corrugated unit 450 can be used as a wound packing without further modification. It can also be used to form more complex three-dimensional structures. Spiral wound packing 500 illustrated in Figures. 15B and 15C is formed by rolling corrugated unit 450 to expose a portion of the first flat sheet 410 along the circumference. More elaborate structures can also be formed from a plurality of corrugated units. For example, individual corrugated units may be coupled to each other by adhesive or heat sealing means to form multi-corrugated wound packing 550, as shown in Figure 15D. One or more beads of silicone material 552 can serve dual purposes of coupling the corrugated units 450, and improving the resiliency of the structure. It should be noted that, while FIG. 15D illustrates this embodiment with the peaks of each adjacent corrugation unit in alignment, a staggered configuration is also contemplated. Multi-corrugated wound packing 550 can also be sliced along a cross section at a suitable thickness to produce cut corrugated wound packing. Alternatively, wound packing 550 can be sliced at a bias to produce biased-cut corrugated wound packing.

[0092] Spiral wound packing 500, cut corrugated wound packing, and biased-cut corrugated wound packing have the benefit of being highly compressible and highly resilient. Preferably, these wound packing structures are sufficiently compressible to reduce to less than 50% of their original volume when subjected to the approximately 2 psi (pounds per square inch) compression force commonly encountered with the application of suction. More

preferably, the wound packing is sufficiently compressible to reduce to less than 25% of its original volume. Most preferably, the wound packing is sufficiently compressible to reduce to less than 10% of its original volume.

[0093] Figures 15D-15F illustrate another embodiment of a wound filler. As shown in Figure 15D, wound packing material 1000 has a generally spiral shape exhibiting open areas 1020 along the longitudinal axis of the fiber spiral and open areas 1040 between adjacent segments of a particular spiral. Wound packing material 1000 is generally constructed from polymer fibers 1060, such as spandex.

[0094] To form wound packing material 1000, fibers 1060 are wrapped around mandrels, such as a steel tube (not shown). The steel tubes with the spandex wrap are stacked in rows and a polyurethane film (not shown) is placed between each row. Desirably, the polyurethane film is about 0.003 inch thick. The stack of tubes is then clamped together and heated to about 320 degrees F. The polyurethane film melts and adheres to the spandex fibers, thus coupling the adjacent spirals to one another. After cooling, the steel tubes are removed. Wound packing material 1000, as illustrated in Figures 15D-15F, remains.

[0095] 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.

[0096] 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.

[0097] 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 visualization element to visualize a location of a wound surface, comprising:
a radiopaque member that is configured to be positioned on or adjacent to a surface of an open wound.
2. The visualization element of Claim 1, wherein the visualization element comprises a radiopaque marker, the radiopaque marker being configured to be attached to an edge or the surface of the wound.
3. The visualization element of any one of the previous claims, wherein the visualization element comprises a radiopaque marker configured to be attached to the surface of the wound along at least one of subdermal layer, a fat layer, a muscle layer, and a fascia layer.
4. The visualization element of any one of the previous claims, wherein the visualization element comprises a radiopaque marker configured to be attached to the surface of the wound along the fascia layer and at least one of subdermal layer, a fat layer, and a muscle layer.
5. The visualization element of any one of the previous claims, comprising a plurality of radiopaque markers configured to be attached to the surface of the wound.
6. The visualization element of any one of the previous claims, wherein the visualization element comprises a gold wire that is configured to be advanced through tissue at the surface of the wound.
7. The visualization element of any one of the previous claims, wherein the visualization element comprises a suture wire that is configured to be advanced through tissue at the surface of the wound, the suture wire comprising at least one of barium sulfate, zirconium, gold, titanium, and tungsten oxide.
8. The visualization element of any one of the previous claims, wherein the visualization element comprises a suture wire that is configured to be stitched through tissue at the surface of the wound in a running stitch and/or a loop stitch.
9. The visualization element of any one of the previous claims, wherein the visualization element comprises a gold wire that is configured to be advanced through the peritoneum tissue at and/or adjacent to the surface of the wound.

10. The visualization element of any one of the previous claims, wherein the visualization element comprises a bioabsorbable material.

11. The visualization element of any one of the previous claims, wherein the visualization element comprises an adhesive configured to be applied to a surface of the wound, the adhesive comprising a radiopaque material.

12. The visualization element of Claim 11, wherein the radiopaque material comprises at least one of least one of barium sulfate, zirconium, gold, titanium, and tungsten oxide.

13. A kit for use in the treatment of a wound using negative pressure wound therapy, the kit comprising:

the visualization element of any one of the previous claims configured to be positioned on or adjacent to a surface of an open wound;

a dressing configured to sealably cover the wound; and

a source of negative pressure configured to apply negative pressure to a space between the dressing and the wound.

14. The kit of Claim 13, further comprising a wound packing element positioned in the wound.

15. A method of visualizing a position of a tissue interface in a wound, comprising:

positioning one or more visualization elements of any one of the previous claims in or on a first side of the wound, the visualization element or elements being configured to contrast with tissue in the wound;

positioning one or more visualization elements of any one of the previous claims on a second side of the wound, the visualization element being configured to contrast with tissue in the wound; and

monitoring a position of the visualization element or elements on the first side of the wound relative to a position of the visualization element or elements on the second side of the wound to determine the distance between the first and second sides of the wound.

16. A method of visualizing a position of a tissue interface in a wound, comprising:

positioning a first visualization element in or on a first side of a wound interface, the visualization element being configured to contrast with a tissue in the wound;

positioning a second visualization element in or on a second side of a wound interface, the visualization element being configured to contrast with a tissue in the wound; and

monitoring a position of the first visualization element relative to a position of the second visualization element to determine the distance between the first and second sides of the wound.

17. The method of visualizing a position of a tissue interface in a wound of Claim 16, wherein positioning a first visualization element in or on a first side of the wound interface comprises advancing a suture comprising a radiopaque material through at least a portion of the tissue on the first side of the wound.

18. The method of visualizing a position of a tissue interface in a wound of any one of Claims 16-17, wherein positioning a first visualization element in or on a first side of the wound interface comprises advancing a suture comprising a radiopaque material through at least a portion of a peritoneum layer of tissue on the first side of the wound.

19. The method of visualizing a position of a tissue interface in a wound of any one of Claims 16-18, wherein positioning a first visualization element in or on a first side of the wound interface comprises applying an adhesive comprising a radiopaque on at least a portion of a peritoneum layer of tissue on the first side of the wound.

20. The method of visualizing a position of a tissue interface in a wound of any one of Claims 16-19, further comprising removing the first visualization element and/or the second visualization element when the distance between the first side of the wound and the second side of the wound meets or exceeds a threshold distance.

21. A method of treating a wound, comprising:

- placing a wound packing member into the wound;
- applying a cover over the wound packing member and sealing the cover to skin surrounding the wound;
- applying negative pressure to the wound through the cover;
- monitoring the internal pressure in the wound; and

controlling the closure of the wound by controlling the amount that the wound packing material collapses within the wound based on the monitored internal pressure, wherein the wound packing material collapse is controlled to ensure that the monitored internal pressure does not exceed a threshold value.

22. The method of treating a wound of Claim 21, wherein the internal pressure is 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.

23. The method of treating a wound of any one of Claims 21-22, wherein the wound is an abdominal wound.

24. The method of treating a wound of any one of Claims 21-22, wherein the wound is a wound on a limb.

25. The method of treating a wound of any one of Claims 21-24, wherein the wound packing member comprises an adjustable volume wound filler.

26. The method of treating a wound of any one of Claims 21-25, wherein the wound packing member comprises an inflatable sealed member and controlling the closure of the wound comprises controllably removing fluid or air from the inflatable member

27. The method of treating a wound of any one of Claims 21-26, comprising detecting blood flow rate adjacent to the treated region using Laser Doppler velocimetry.

28. The method of treating a wound of any one of Claims 21-27, further comprising positioning one or more wound visualization elements in a wound interface.

29. A method of treating a wound, comprising:

placing a wound packing member into the wound;

applying a cover over the wound packing member and sealing the cover to skin surrounding the wound;

applying negative pressure to the wound through the cover; and

controlling collapse of the wound packing member as the wound closes under negative pressure.

30. The method of treating a wound of Claim 29, wherein the wound packing member is an inflatable bladder, and controlling collapse of the wound packing member comprises controlling the pressure within the bladder.

31. The method of treating a wound of any one of Claims 29-30, comprising dynamically adjusting at least one of the volume, stiffness, pressure and collapse the wound packing member as the wound closes.

32. The method of treating a wound of Claim 31, wherein the 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.

33. An apparatus for providing negative pressure wound therapy to a wound, comprising:

a wound packing member or wound filler that has an adjustable volume;

a backing layer for providing a substantially air and liquid-tight seal over a wound when the wound packing member or wound filler is positioned in the wound;

a source of negative pressure for providing negative pressure to a space beneath the backing layer; and

a pressure sensor for measuring internal pressure, wherein closure of the wound can be controlled by controlling the amount that the wound packing member or wound filler collapses based on the measured internal pressure.

34. The apparatus of Claim 33, wherein the wound packing member or wound filler comprises a sealed member that can be controllably inflatable and deflatable from a pressure source.

35. The apparatus of Claim 33 or 34, further comprising an organ protection layer configured to be positioned between the wound packing member or wound filler and the viscera or other organs.

36. The apparatus of Claim 34, further comprising a pressure sensor configured to monitor a pressure level within the sealed member.

37. The apparatus of Claim 36, further comprising a pump configured to control a level of pressure within the sealed member.

38. The apparatus of any one of Claims 33-37, further comprising a pressure sensor for detecting pressure beneath the backing layer.

39. The apparatus of any one of Claims 33-38, further comprising a controller configured to adjust negative pressure based on one or more pressure sensors.

40. The apparatus of any one of Claims 33-39, wherein the pressure sensor for measuring internal pressure is configured to be placed in communication with a human organ.

41. The apparatus of Claim 34, comprising:

at least three pressure sensors, the first pressure sensor configured to monitor a pressure level within the sealed member, the second pressure sensor being for detecting pressure beneath the backing layer, and the third pressure sensor comprising a pressure sensor for measuring internal pressure within or on an organ; and

a controller configured to adjust one or more pressure levels under the backing layer and/or within the sealed member to reduced pressure exerted on the organ.

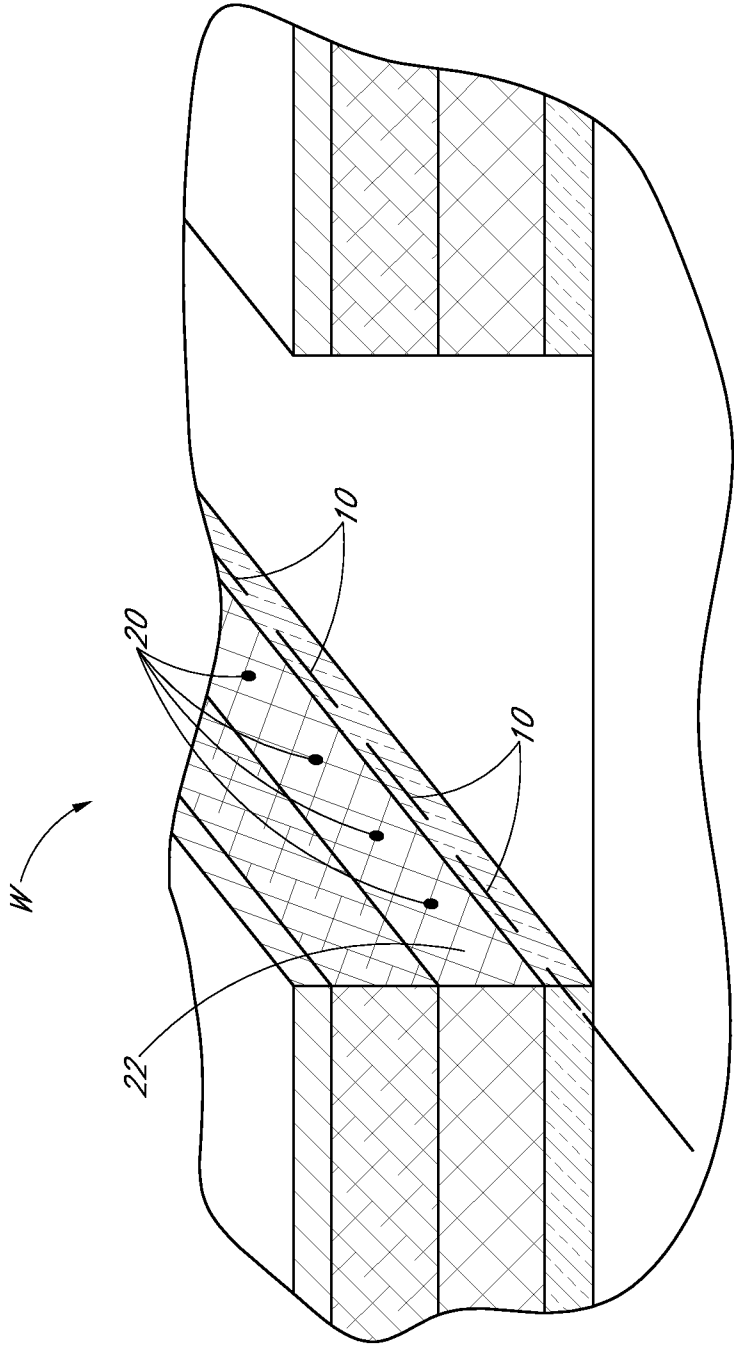


FIG. 1

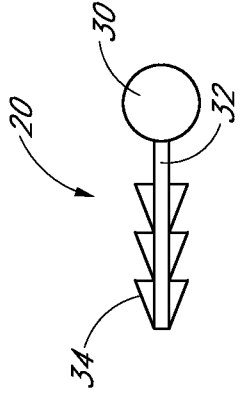


FIG. 1B

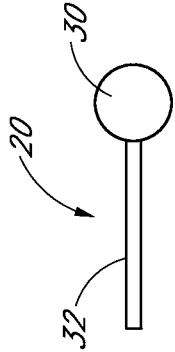


FIG. 1A

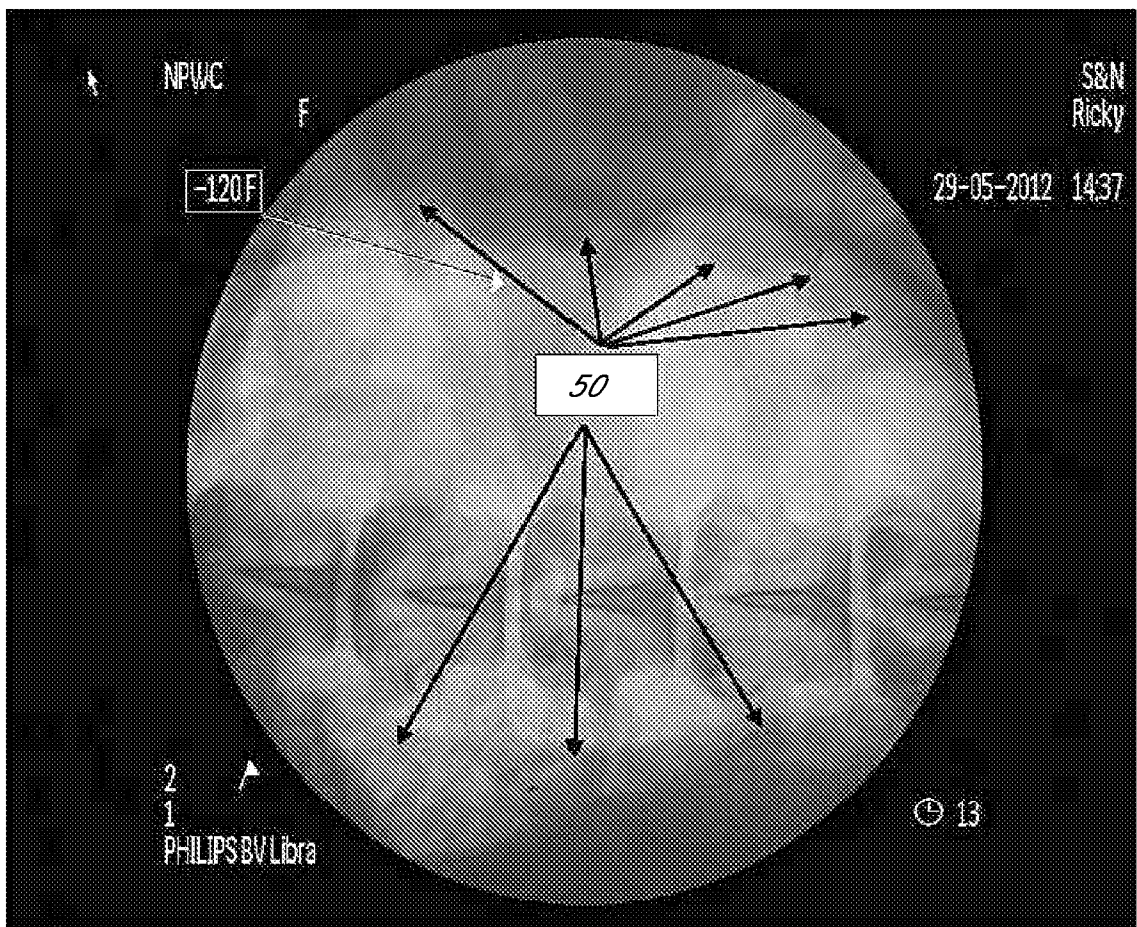


FIG. 2

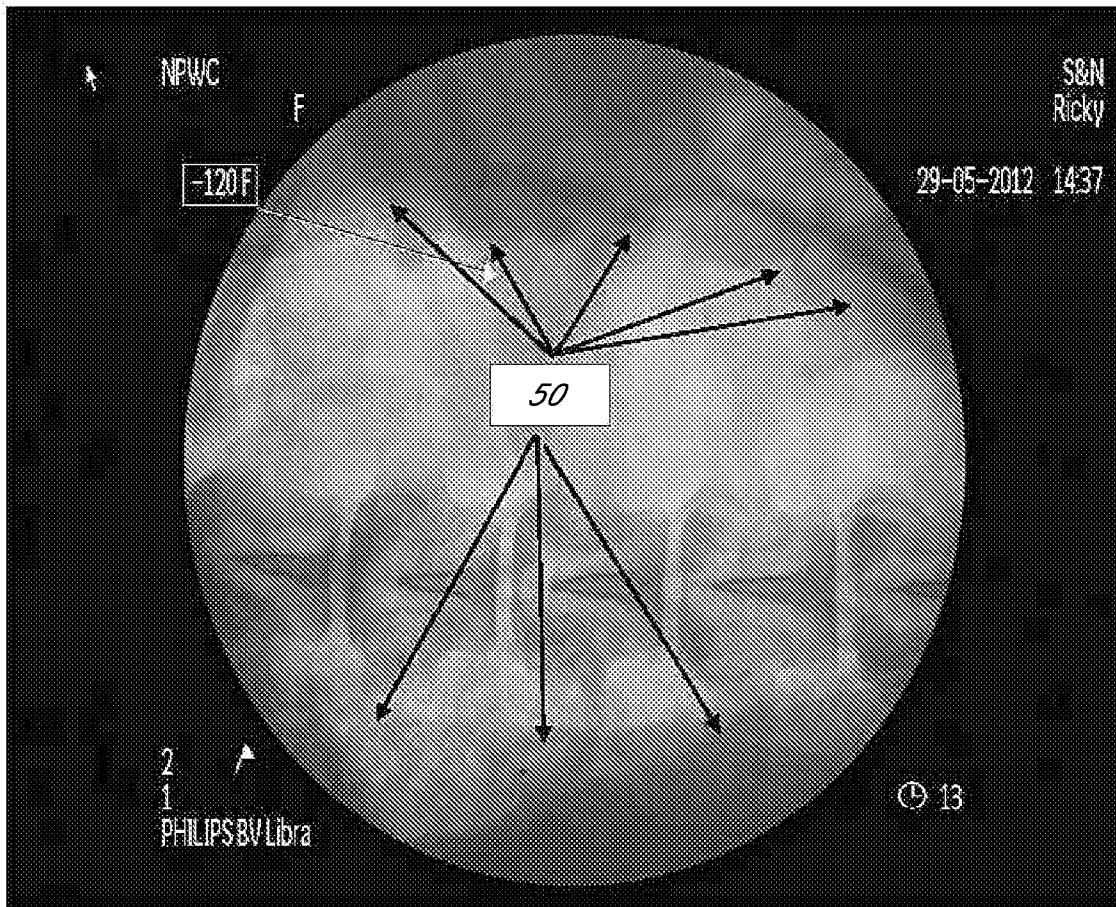


FIG. 3

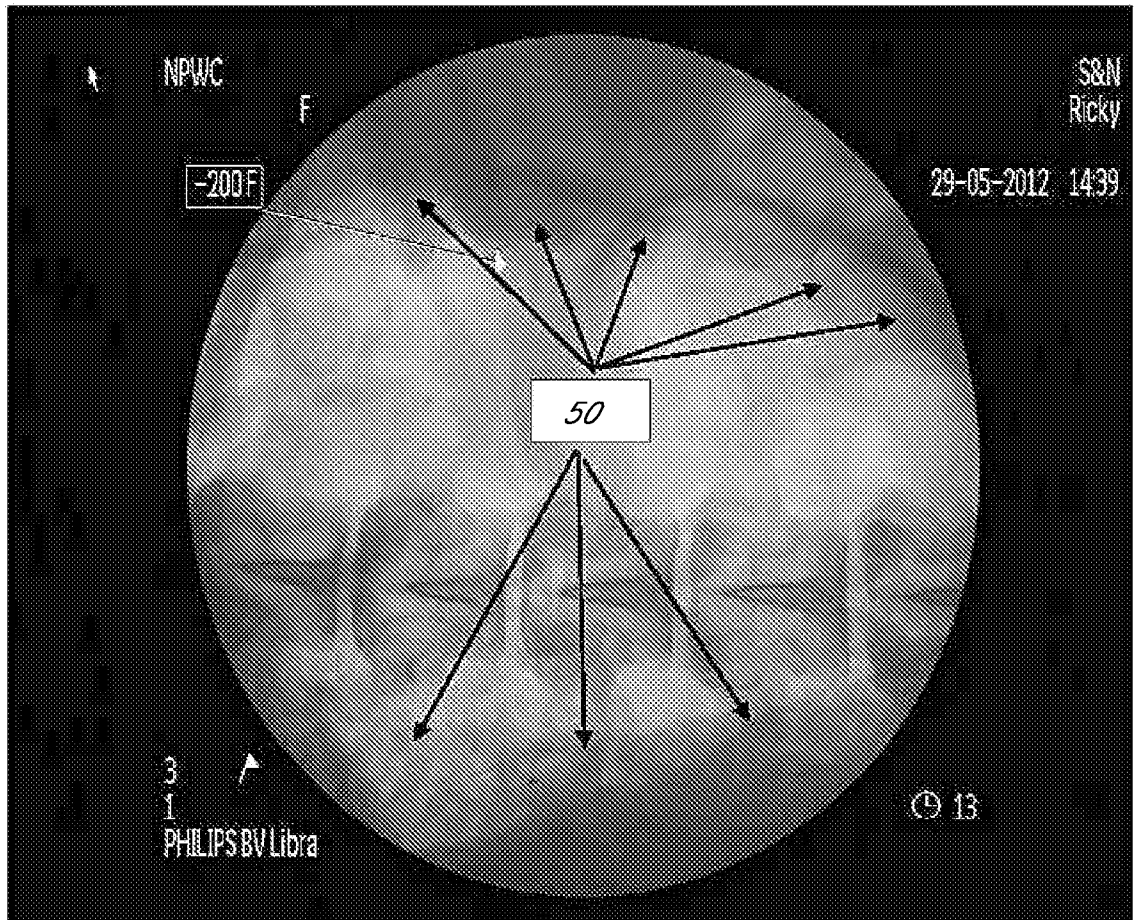


FIG. 4

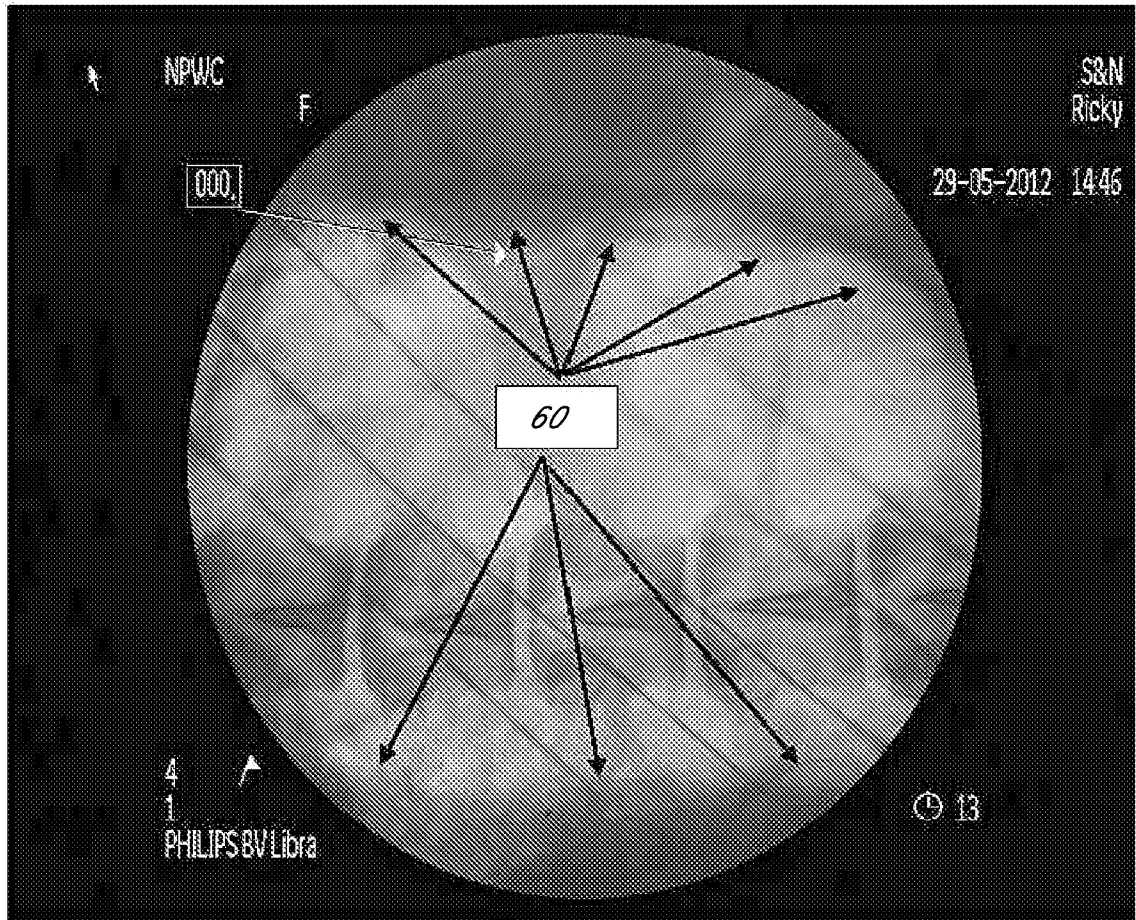


FIG. 5

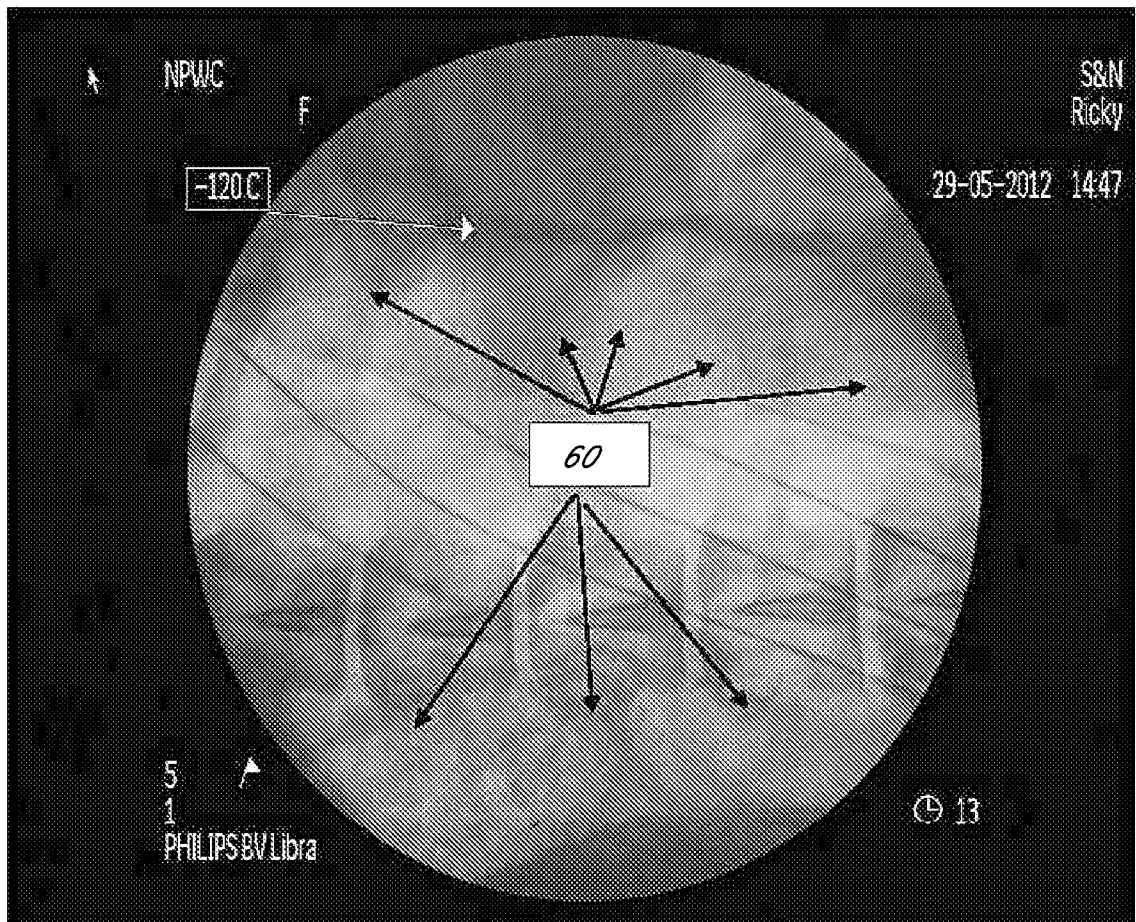


FIG. 6

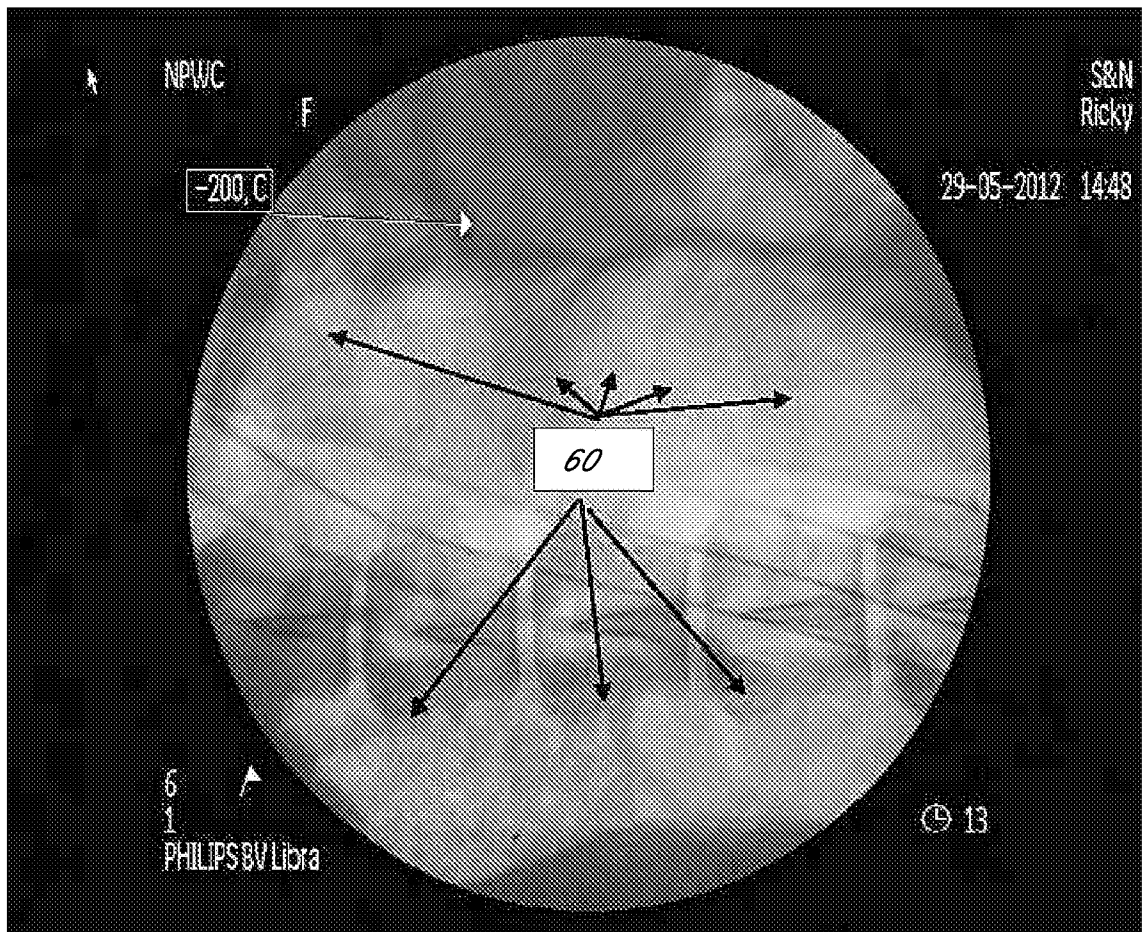


FIG. 7

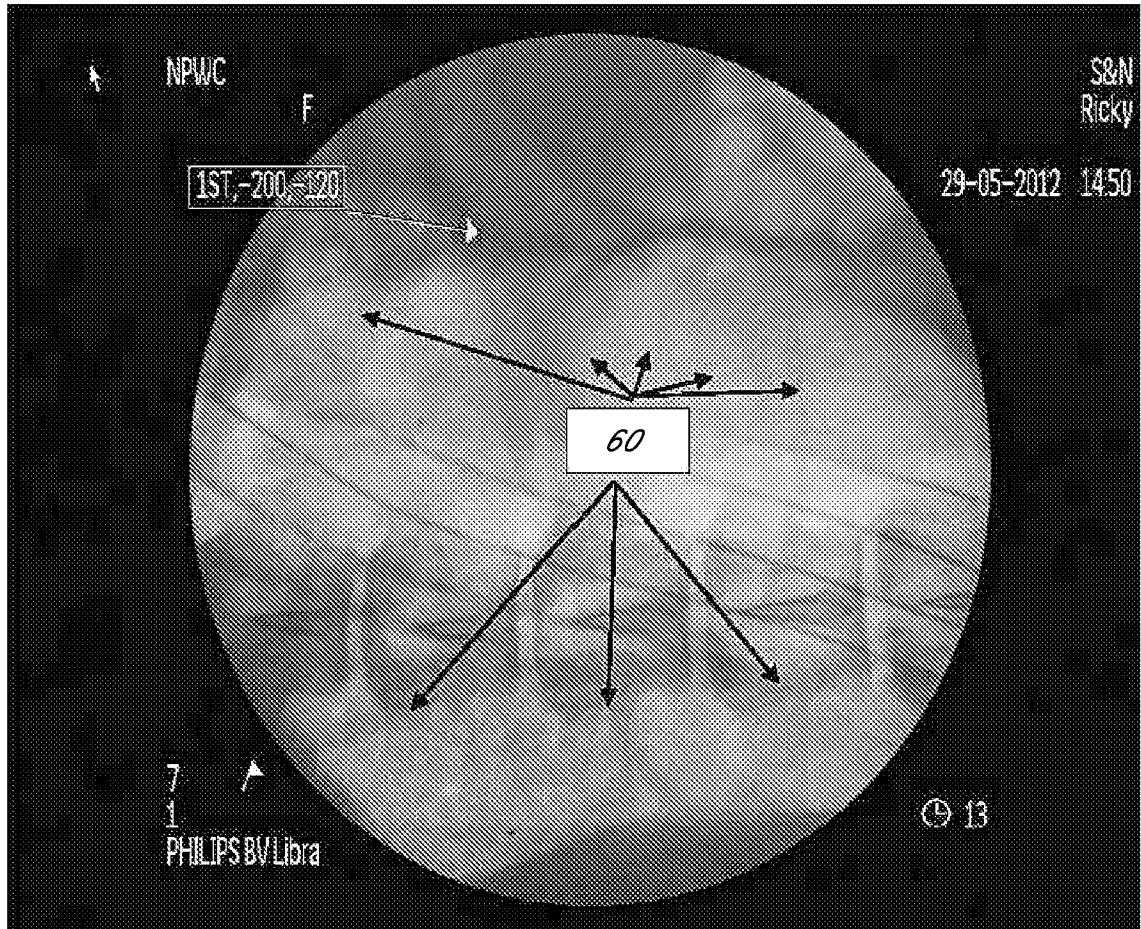


FIG. 8

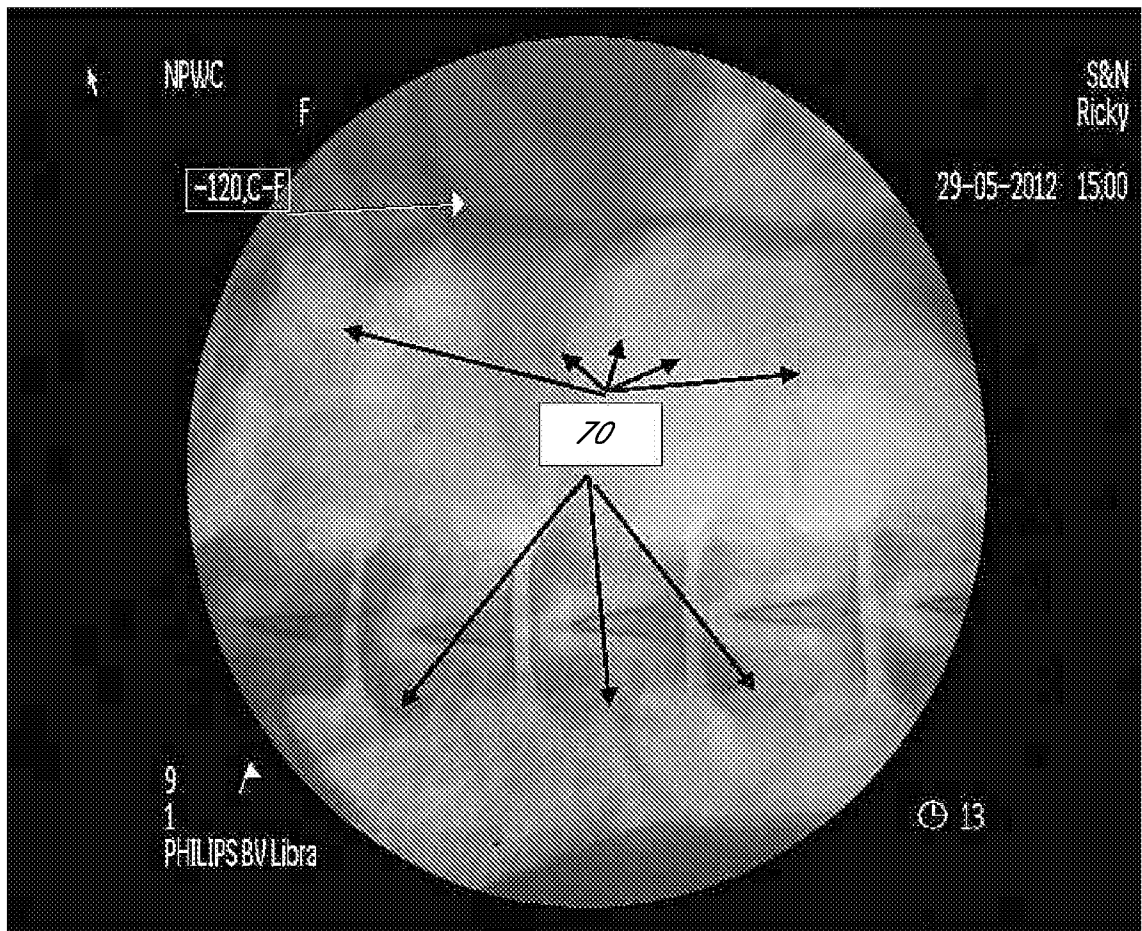


FIG. 9

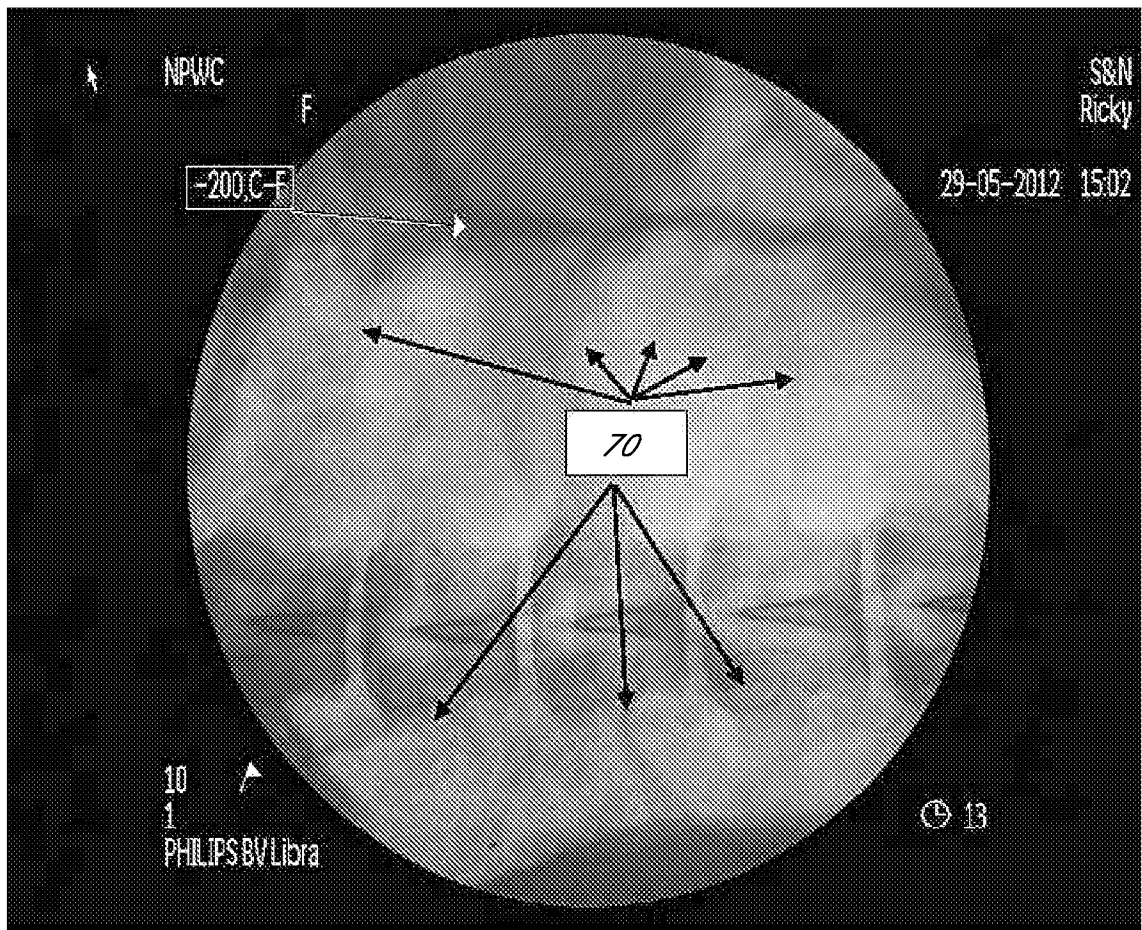


FIG. 10

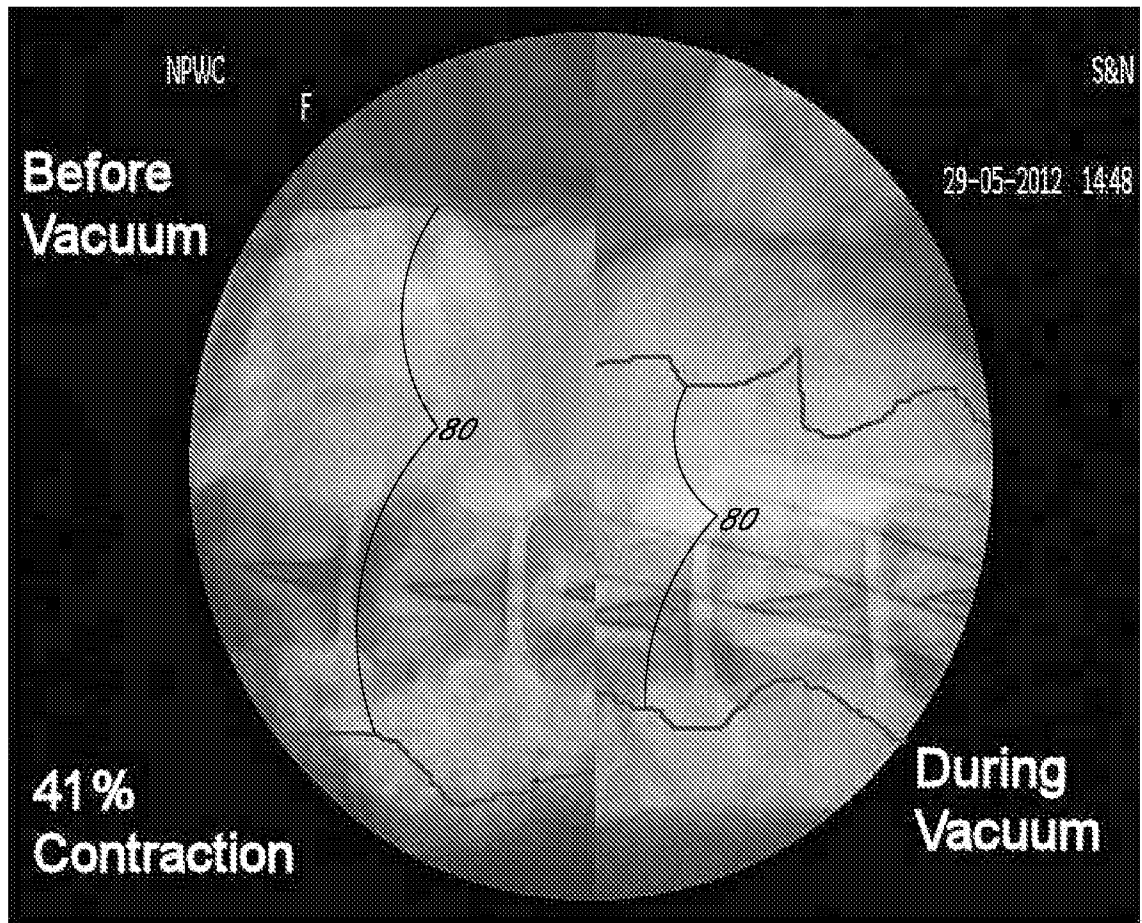


FIG. 11

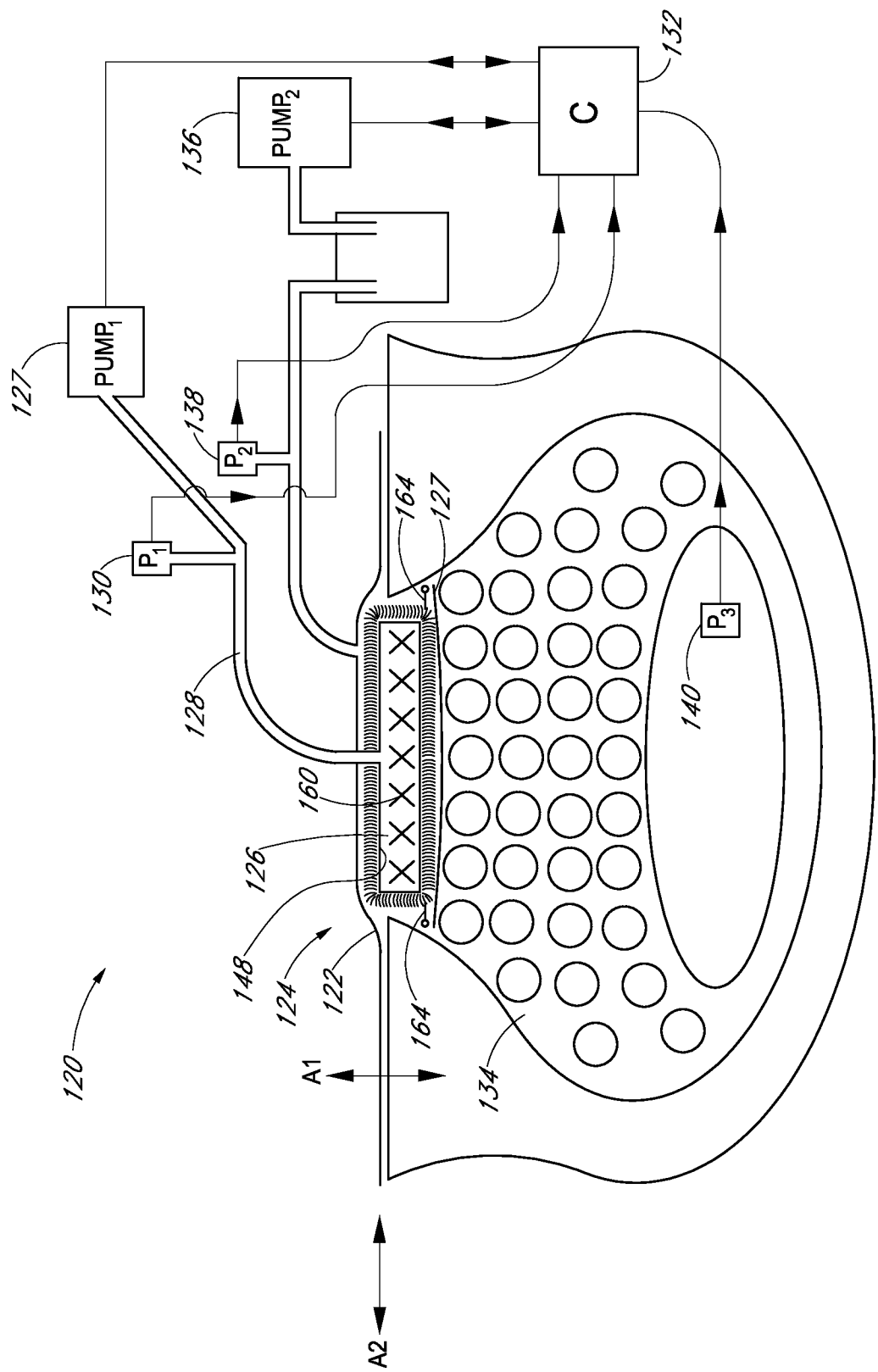


FIG. 12

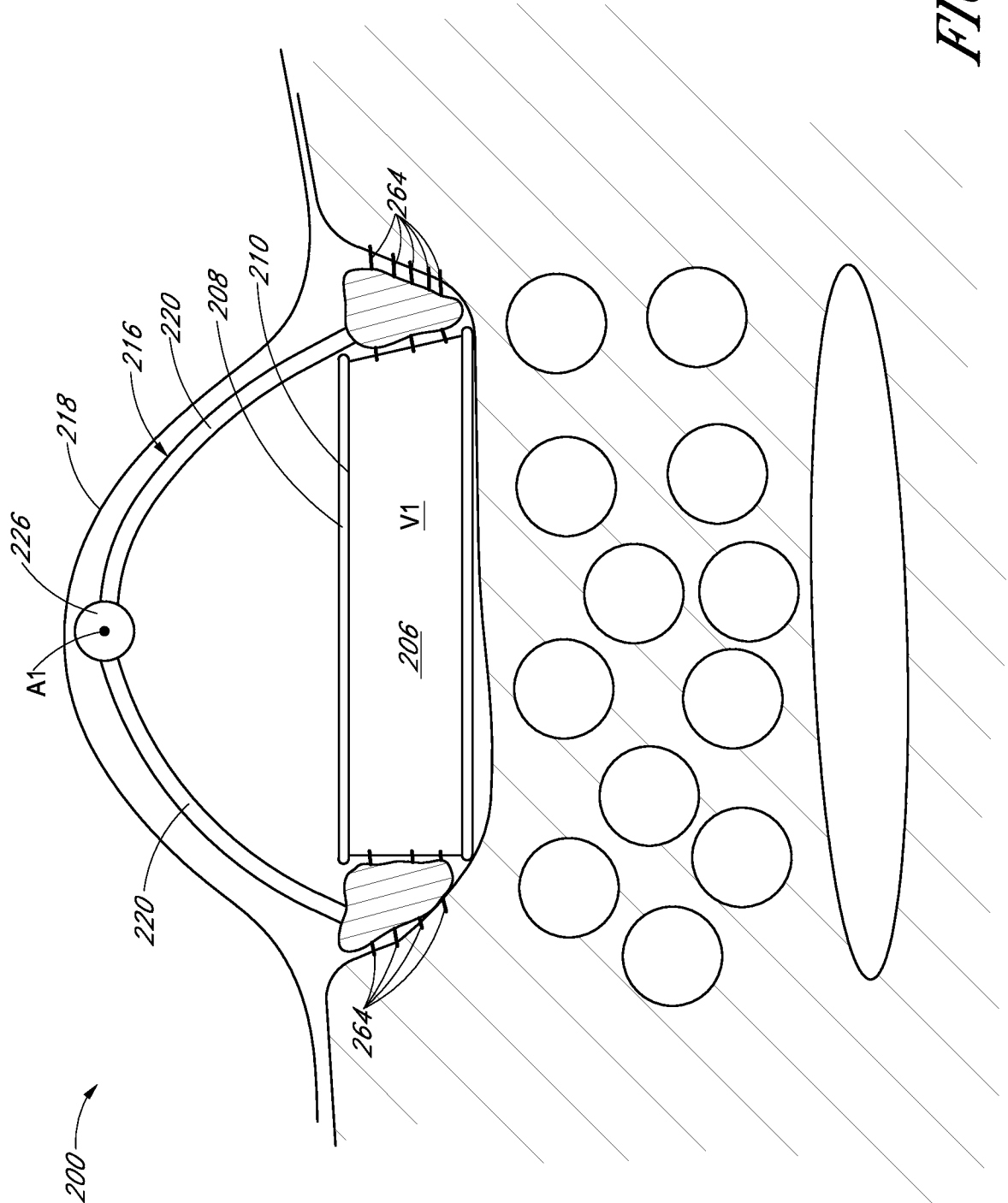


FIG. 13

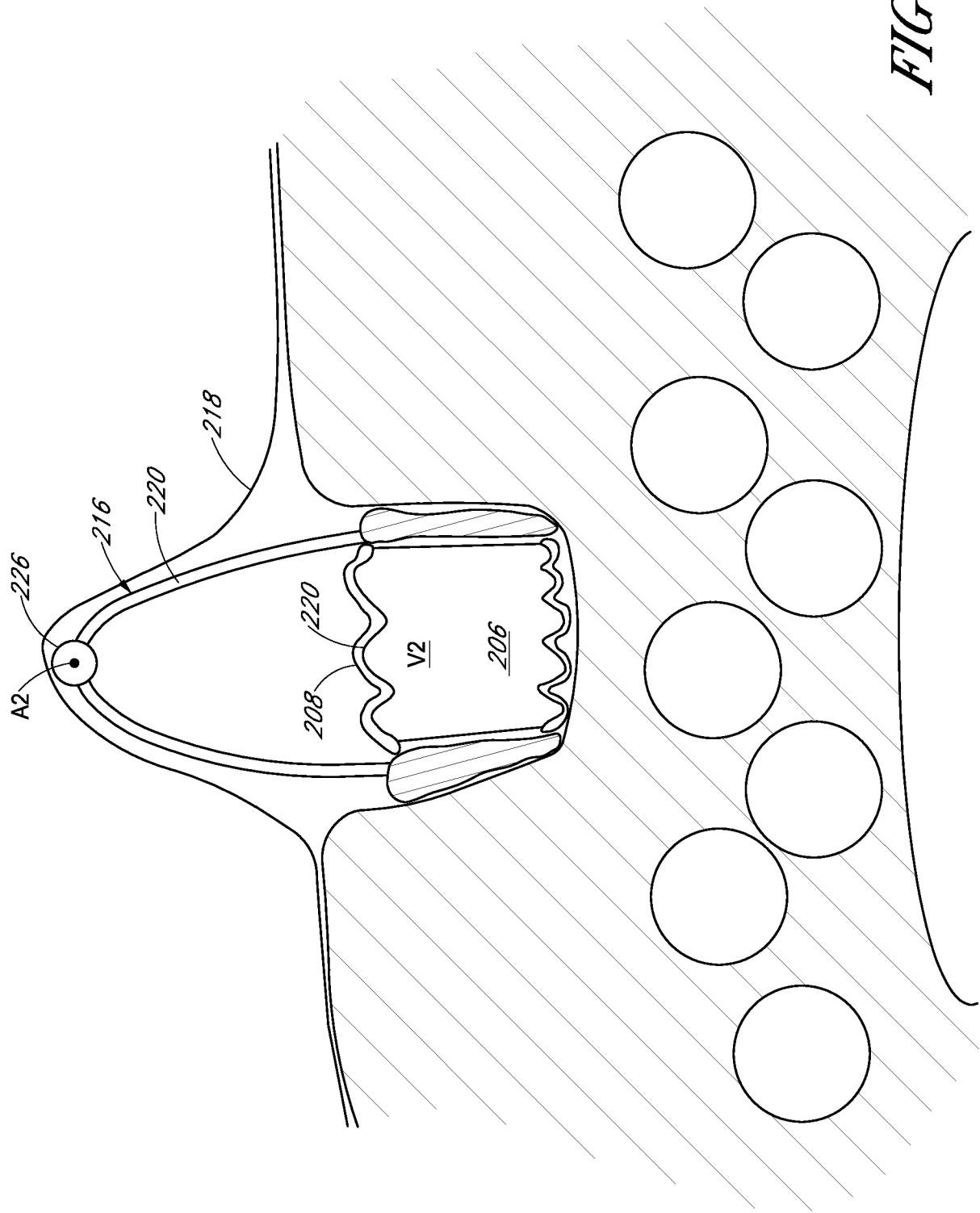


FIG. 14

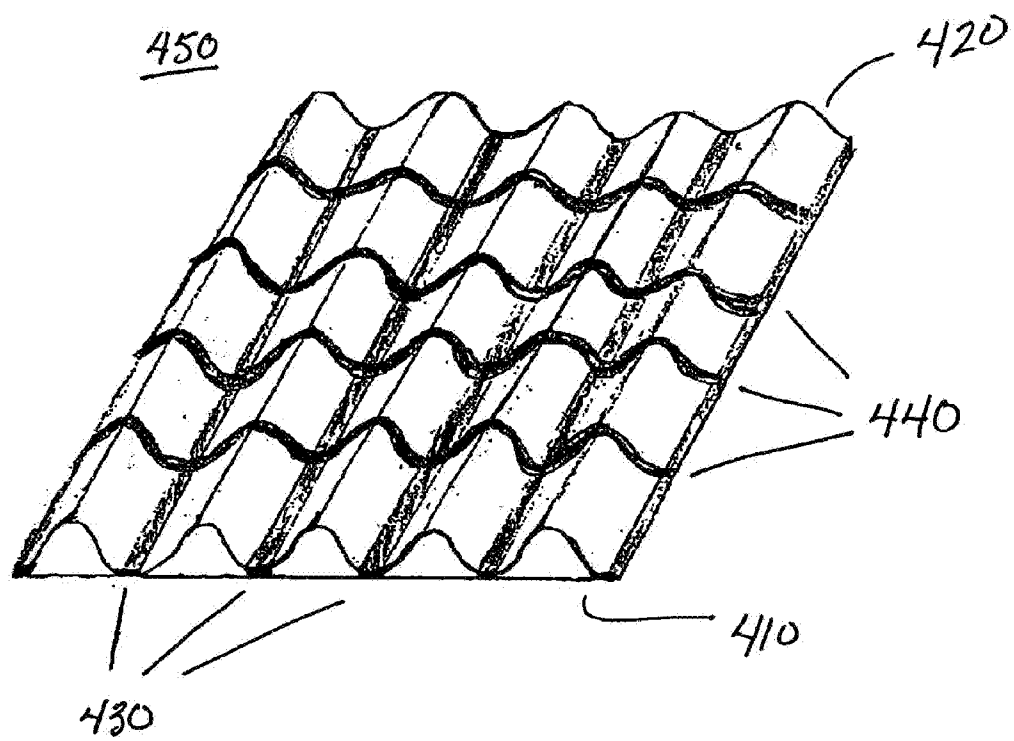


FIG. 15A

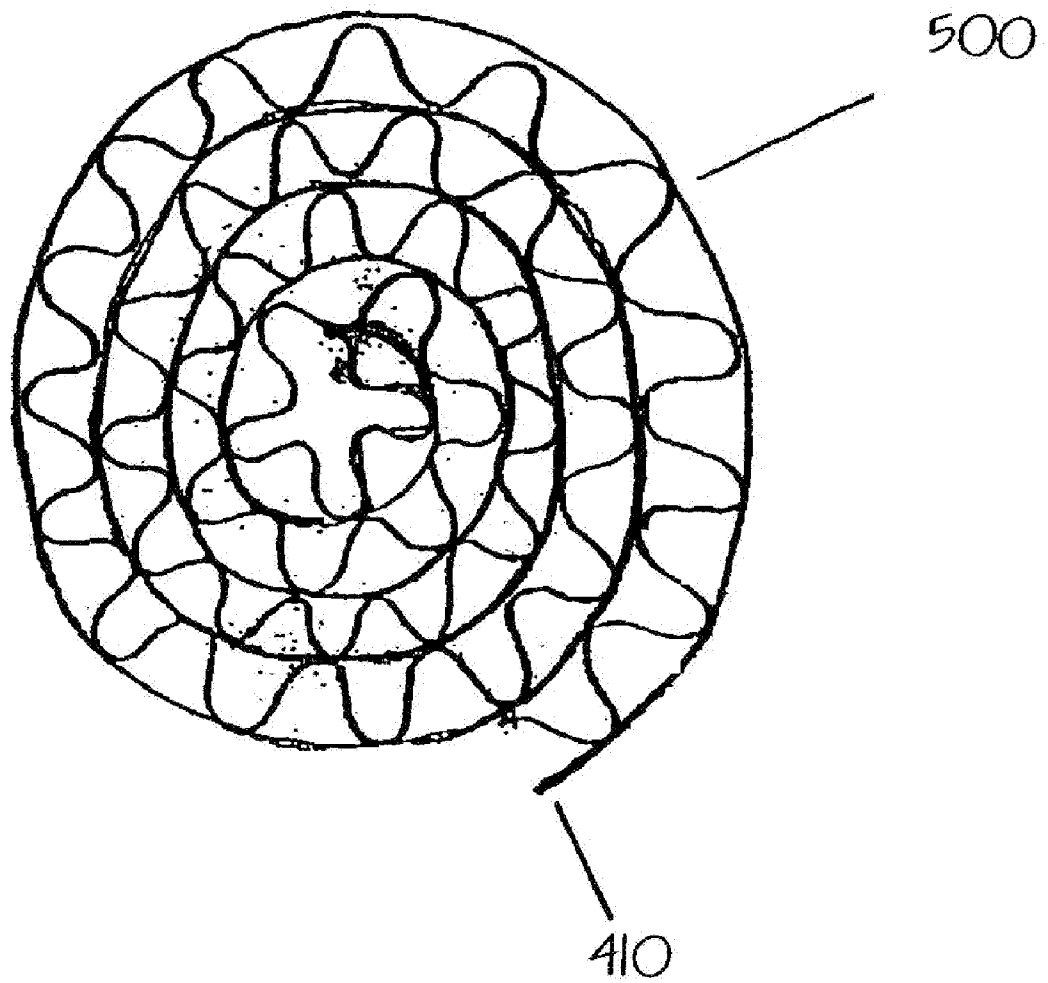


FIG. 15B

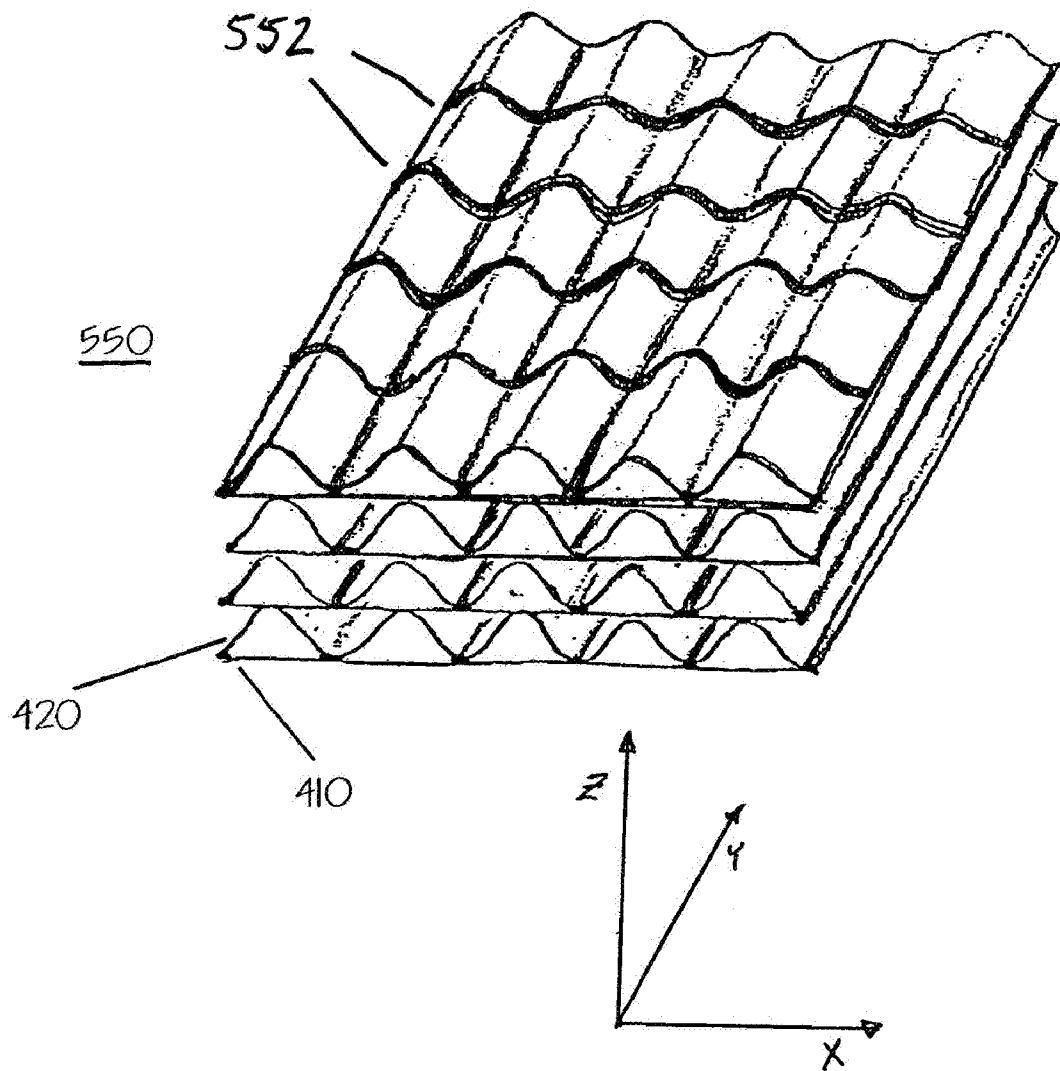


FIG. 15C

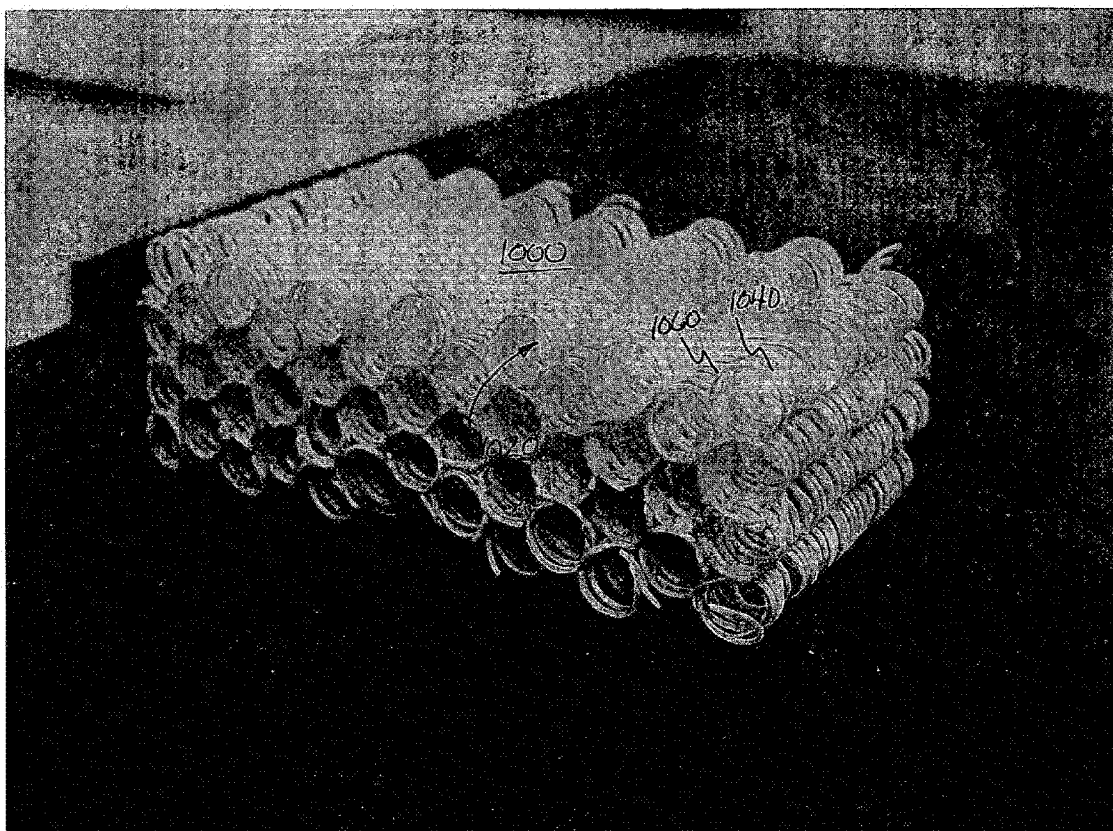


FIG. 15D

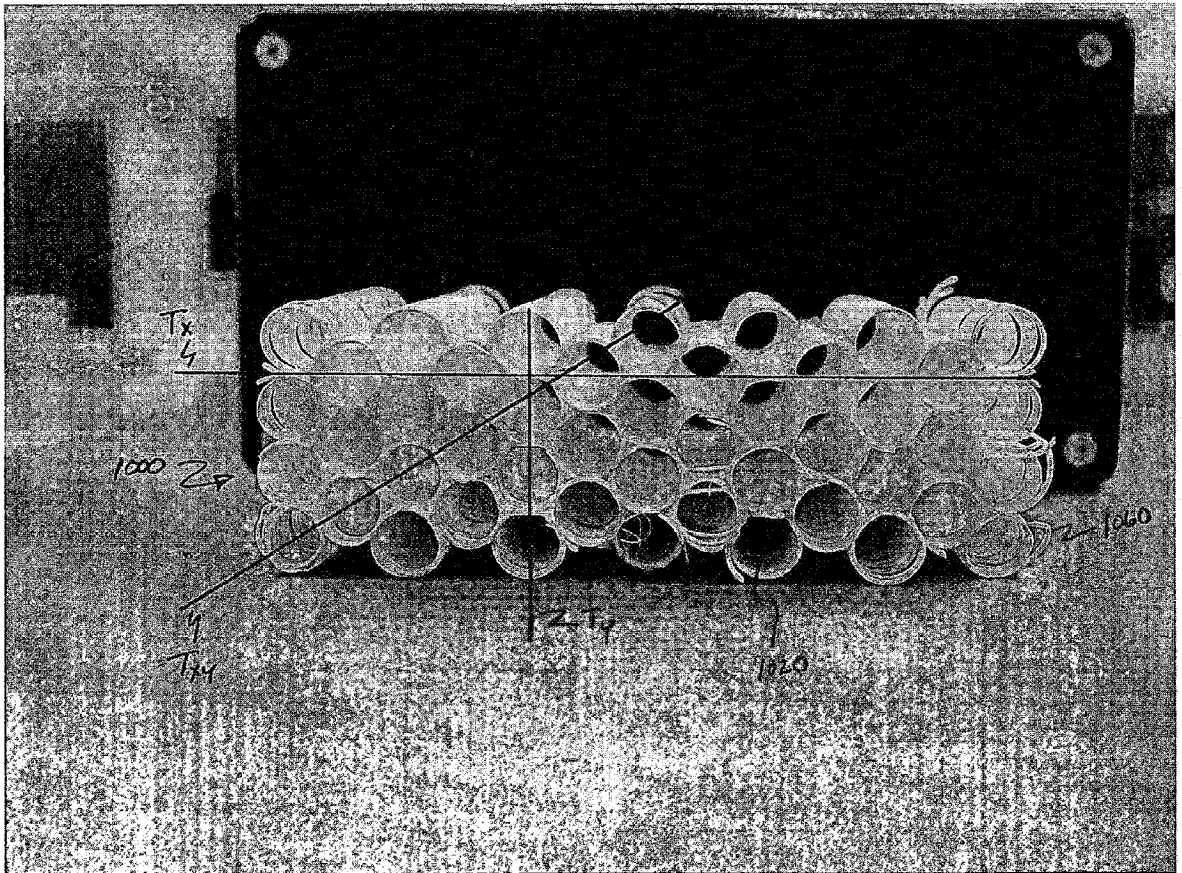


FIG. 15E

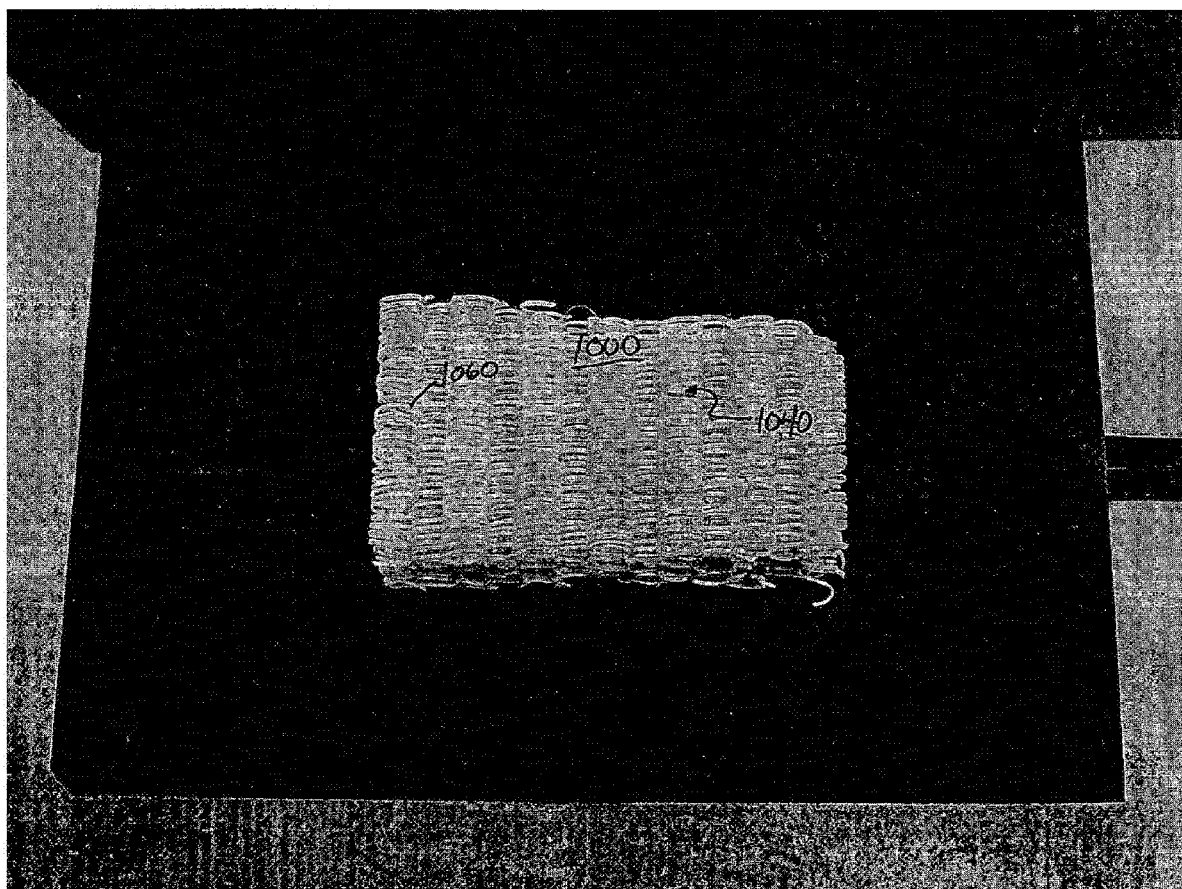


FIG. 15F