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(54) Title: REUSABLE ELASTIC WOUND CARE DRESSING COVER

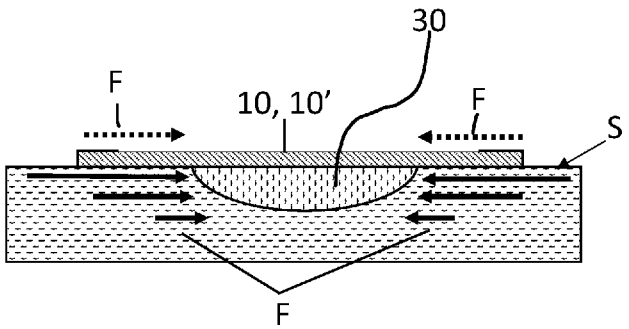


FIG. 7A

(57) Abstract: A wound care device comprises a cover layer having formed from a stretchable material which has an elastic memory such that upon stretching the first layer will tend to retract to an at-rest position; a layer of adherent on the bottom surface of the cover layer; and a removable release liner removably adhered to the adherent. In use, the wound care device is applied over or adjacent the wound in a stretched/elongated condition extending to be adhered to skin beyond the margins of the wound. The wound care device retracts under its elastic member along lines of tension towards a focal point of lines of tension, thereby drawing the margins of the wound together to stabilize and compress the skin about the wound. The wound care device reduces and absorbs sheer forces directed to the wound that would otherwise disrupt connective tissue of the wound, the device comprising:

WO 2021/173801 A1

REUSABLE ELASTIC WOUND CARE DRESSING COVER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to US App. No. 62/981377 filed 25 February 2020 and entitled "Convertible Tissue Retractor/Wound Cover." The contents of said application (including drawings and claims) are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable.

BACKGROUND

[0003] This application relates to a wound care device which can be used to compress and stabilize tissue about a wound into a desired position and shape to aid and facilitate the healing of the wound and to a new material from which the wound care device is made and which can also be used for negative wound pressure therapy drapes.

[0004] Mammalian, and in particular, human, skin comprises two layers. The epidermis and dermis. The epidermis is the outer layer of skin and forms a protective barrier; the dermis is below the epidermis and contains connective tissues which cushion the body from stress and strain. Below the dermis is subcutaneous tissue (or hypodermis) which connects the skin to underlying bone and muscle and supplies the skin (the dermis and epidermis) with blood and nerve cells. When a wound occurs in the dermis of human skin (such as by incision, biopsy, sores, etc.), the wound begins to heal by a complex process where the tissue surrounding the wound site ensues with the formation of a collagen foundation, upon which new connective tissue fibers, called fibroblasts, can begin to grow. As healing continues, the fibroblasts attach to the surrounding tissue, the edges of the

open wound shrink to begin a wound closure phase. As the fibroblasts continue to form, they continue shrinking or reducing the margins (edges) of the wound thereby closing (and healing) the wound.

[0005] As healing continues, the fibroblasts that form on the collagen foundation eventually draw the wound to complete closure, at which point, the wound margins come into contact. The fibroblasts mature at this point, as the collagen transforms into permanent scar tissue in which the wound is closed and sealed.

[0006] Throughout the healing process, the open wound continues to be susceptible, and remains sensitive, to natural movement in the surrounding skin. Excessive natural movements may disrupt the connective tissue that is formed by fibroblasts during wound healing and closure. In some cases, the formation of fibroblasts may be completely prevented, thereby causing delays in the healing process. The breakdown of the connective tissue will delay the healing process. Furthermore, the open wound remains susceptible to infection, which can further delay, or complicate, the healing process.

[0007] During healing, as the margins of the wound shrink, the surrounding dermis begins to revert to its original position. Current wound covers cannot adapt to this retraction, and thus will need to be adjusted, or a new wound cover will need to be applied. Further, typically the adhesive used on current wound covers is composed of an acrylate adhesive, which is known to bond to skin, including new skin, as it is formed. When the wound cover needs to be removed and replaced, the adhesive may have bonded to the skin which can cause dermal stripping, impeding healing of the wound. Additionally, during removal of typical wound covers, the adhesive can simply cause irritation to both the healing tissue and the existing skin surrounding the wound. This causes pain and may delay the healing

process. Further, multiple dressing changes enhance the likelihood of complications.

[0008] In negative wound pressure therapy, a negative wound pressure therapy drape is applied to the skin about the wound or wound dressing. The drape is connected to a vacuum source which can then draw a vacuum on the wound. This therapy aids healing by removing gasses and excess exudate from the wound. However, as with conventional wound covers, conventional wound pressure therapy drapes adhere to the skin, and when they are removed, they can cause dermal stripping. As can be appreciated, such dermal stripping can negatively impact healing, especially for wounds such as skin grafts and in burn victims.

BRIEF SUMMARY

[0009] In view of the above-noted shortcomings, it would be desirable to provide a new wound care device that can be used not only to cover a wound but to enhance the wound healing process and to provide a material from which the wound care device can be made. Such a wound care device has a memory, is flexible and is adequately sized to affect the dermis surrounding a wound as the wound heals. The wound care device is adhered to skin using an adherent material that is gentle to the skin during both long-term use and which allows for atraumatic removal of the device, or which does not irritate the skin surrounding the wound or otherwise interrupt the healing process. The objective is to provide a device intended for long-term wear that is easily applied, which facilitates uninterrupted wound healing (UWH) and greatly reduces the need for dressing changes.

[0010] Briefly stated, a wound care device is disclosed that can be used to aid in the wound healing process. Once applied to the wound, the wound care device provides support to the dermis and epidermis to preserve fibroblast structures. By reducing the potential for movement of the tissue surrounding the wound and wound margins, the wound care device will

protect and stabilize the wound and the periwound, thus allowing healing to commence.

[0011] In accordance with another aspect, a tissue stabilizing wound care device is provided that adds compression to a wound while minimizing movement of the wound and wound margins to improve healing. This tissue stabilizing wound care device can be adapted to be applied directly over the wound, or it can be applied over a dressing which covers the wound.

[0012] In another mode, the wound care device can be used as a negative wound pressure therapy (NWPT) cover. A port or valve may be placed within the body area of the wound care device, which permits attachment of tubing. The device will cover a NWPT dressing while allowing a complete seal to produce a more secure vacuum. This stabilizes the area around the wound, thereby enhancing wound healing and preventing excessive scarring.

[0013] Briefly stated, wound care device is provided to aid in the healing of a wound by providing stability to tissue of both the wound and periwound while reducing and absorbing sheer forces directed to the wound that would otherwise disrupt connective tissue of the wound. The wound care device comprises a cover layer having a bottom surface. The cover layer is made from a flexible ply that is stretchable in at least one direction along an axis and which has an elastic memory such that upon stretching the first layer will tend to retract to an at-rest position. A layer of adherent which is selected to adhere to a person's skin and to be removable form the skin atraumatically is applied to the bottom surface of the cover layer. Lastly, a removable release liner is positioned adjacent the layer of adherent to protect the adherent prior to application of the cover layer to a patient.

[0014] In use, the wound care device is applied to a person's skin over or adjacent the wound or wound dressing in a stretched/elongated condition with a first portion of the device adhered to the periwound at a first site proximate the wound and a second portion of the device is adhered to the

periwound at a second site proximate to the wound, the second site being a side of the wound opposite of the first site, wherein, upon application of the wound care device, the energy stored in the wound care device from stretching the wound care device causes the first layer to retract along lines of tension towards a center or focal point of the lines of tension, thereby drawing the margins of the wound together to stabilize and compress the skin about the wound.

[0015] The wound care device can have the following characteristics, which can be combined in any desired manner:

- The adherent comprises a gel adhesive, such as a silicone gel, a hydrogel, or the adherent comprises a co-adhesive. Preferably, the adherent is a heavy coat weight silicone gel.
- The adherent covers substantially the entire bottom surface of the top layer.
- The adherent defines a window such that the wound care device defines an adherent free area, the window preferably being sized to define an area at least as large as an area of the wound.
- The cover layer is comprised of a polymer or a blend of man-made and natural fibers, and which are preferably formed as a knit fabric, a woven fabric, a fleece, or a combination thereof. For example, the cover layer can include nylon.
- The wound care device can include an adhesive or binder, such as an acrylate adhesive, which bonds to the adherent to adhere the adherent to the cover layer.
- The first layer can comprise fibers which extend from the bottom surface thereof, and which fibers extend into the adhesive such that the adhesive binds to the fibers such that the adhesive being securely adheres the adherent to the cover layer.
- The gel adhesive adherent can include an integrated medicant.

- The elastic memory of the cover layer has a dynamic value, such that forces generated by the device upon stretching of the device are linear.
- The cover layer is stretchable in multiple directions along multiple axes.
- The wound care device is fluid impermeable and/or hydrophobic.
- The wound care device is vapor and gas permeable, and preferably has a moisture vapor transmissive rate of approximately 100-400 gm/m2/24 hours.
- The material of the cover layer can be fluid permeable when subjected to a vacuum such as used in negative wound pressure therapy, such as between –200 and –40 mmHg.
- The wound care device can include means for monitoring selected physiological effects.
- Either or both of the cover layer and adherent are conductive or semi-conductive, and for example, can contain conductive or semi-conductive fibers or elements.
- The wound care device is shaped such that upon application of the wound care device, the center point of the lines of tension is under the first layer and within the tissue being compressed.
- The wound care device is capable of being removed and cleaned, and then reapplied to the patient, whereby, after removal and cleaning, the device retains substantially the same amount of adhesion, tack, and elastic memory.

[0016] In accordance with one aspect of the wound care device, the adherent is adapted to transfer tensions in tissue surrounding the wound caused by natural movement of the skin proximate the wound to the cover layer, thereby diverting sheer forces to the cover layer that would interrupt the healing process or that otherwise would be transferred directly to the wound promoting uninterrupted wound healing. The gel adhesive works in

conjunction with the cover ply to elongate and accumulate sheer forces to absorb destructive forces which might otherwise be transferred to the wound. In doing so, the wound care device limits the tangential force applied to the skin.

[0017] In accordance with an aspect of the wound care device, the adherent has an adhesive strength such that when sheer forces accumulated in the adherent exceed engineered design limitations of the adherent (such as the adhesive strength of the adherent), the wound care device will release from the skin before injury can occur to the skin, limiting the tangential forces applied to the skin of the patient.

[0018] In accordance with another aspect, a sheet material is provided which is useable for wound care devices or negative pressure wound therapy. The sheet material comprises a cover or top layer formed from a woven or knit fabric comprised of fibers such that the sheet material is stretchable and has an elastic memory. The cover layer comprises a plurality of fibers extending from a bottom surface thereof. A binder, such as an acrylate adhesive, is applied to the bottom surface of the cover layer, and the fibers extend into the binder, whereby the binder adheres to the fibers along lengths of the fibers. This increases the surface area of the cover layer to which the adhesive can adhere. Lastly, the material has a bottom layer comprised of a gel adhesive, such as silicone gel (preferably a heavy coat weight silicone gel) or a hydrogel. The adhesive is an adhesive which will bond to the gel adhesive to securely adhere the gel adhesive to the top layer.

[0019] In an aspect of the sheet material, the sheet material can be provided with a release liner removably adhered to the gel adhesive to protect the gel adhesive until the sheet material is ready to be used.

[0020] The sheet material can have the following characteristics, which can be combined in any desired manner:

- The sheet material is gas and vapor permeable.
- The cover layer may be liquid permeable under pressure, such that when a vacuum such as between –200 and –40 mmHg, Is drawn on the cover layer, liquids can be pulled through the cover layer.
- The gel adhesive substantially covers the bottom surface of the top layer.
- The gel adhesive may have one or more openings formed therein to define one or more areas of the sheet material which are free of the gel adhesive.

[0021] A method for producing the sheet material is disclosed. The method comprises brushing or abrading a surface of the cover layer to cause the fibers to extend from said surface area available for bonding; applying the binder to the surface of the cover layer such that said fibers extend into the adhesive to enable the adhesive to bind to surfaces of the fibers; and applying the layer of gel adhesive over the binder whereby said layer of gel adhesive binds to said binder to be securely affixed to said cover layer.

[0022] In accordance with an aspect, a method of stabilizing and compressing dermis tissue proximate a wound is provided using either the wound care device or the sheet material as described above. The method comprises:

[0023] stretching the wound care device /sheet material a sufficient amount such that the wound care device /sheet material will extend beyond margins of the wound;

[0024] adhering the elongated wound care device /sheet material to a patient over or adjacent a wound site of the patient, such that the wound care device /sheet material is adhered to the skin of the patient proximate the wound on opposite sides of the wound;

[0025] whereby, the memory of the cover layer causes the cover layer to retract along lines of tension toward a center focal point of the lines of tension, thereby drawing the margins of the wound together such that the tissue adjacent the wound is compressed and stabilized.

[0026] Application of the wound care device /sheet material to the patient places the tissue immediately under the wound care device /sheet material in compression, and places the tissue of the periwound surrounding the wound care device /sheet material is in tension. As such, the method relieves tension on the wound and the wound margins.

[0027] Further, the wound care device /sheet material transfers stresses in the tissue caused by natural movement of the skin proximate to the wound through the adherent layer to the cover layer, thereby diverting and absorbing sheer forces that would interrupt the healing process or otherwise be transferred directly to the wound.

[0028] In accordance with an aspect of the method the step of applying the wound care device to the patient comprises applying the cover layer over the wound, whereby the cover layer forms a protective barrier over the wound.

[0029] In accordance with an aspect of the method, application of the cover layer to the patient comprises an initial step removing a backing layer to expose the adherent/gel adhesive. In an aspect of the method, the release layer comprises a first portion and a second portion; and the steps of removing the release liner and adhering the stretched wound care device to the patient comprise: removing a first portion of a release layer of the device to expose a first portion of an adherent/gel adhesive and adhering the first portion of the adherent/gel adhesive to skin adjacent the wound; then removing a second portion of the release layer to expose a second portion of the gel adhesive, stretching/elongating the cover layer, and adhering the

second portion of the gel adhesive to the skin on a side of the wound opposite the first portion of the device.

[0030] In a variation of the method, the cover layer is elongated prior to application to the patient and then attached, both sides at the same time, to the periwound.

[0031] Preferably the cover layer is larger than the wound in at least one dimension; wherein the retraction forces generated by the memory of the cover layer decrease with distance from the margin of the device.

[0032] Even more preferably, the cover layer is larger than the wound in all directions, is stretchable in multiple directions, such that the memory of the material of the cover layer retracts along multiple axes toward the center point. In this instance, the cover layer is deemed to be omnidirectional.

[0033] In accordance with an aspect of the method, the cover layer can be selectively stretched in desired directions to accommodate variations of the wound site and to selectively vary the forces exerted by the cover layer on selected areas of the wound, whereby, the forces can be greater in one area of the wound than in another area of the wound.

[0034] Similarly, the method can include a step of selectively shaping the cover layer, such as by cutting, to shape the cover layer so that it will be uniquely loaded to accommodate the needs of the wound and to selectively control the forces applied by the wound care device to various portions of the wound.

[0035] In accordance with an aspect of the method, once adhered to the skin of a person, the memory of the cover layer remains under a continuous tension for the duration that it is worn. Preferably, the wound care device remains in place on the epidermis as a cover of a wound for extended periods of time, and preferably until the wound heals.

[0036] In accordance with an aspect of the method, the wound care device can be adapted for use in as negative wound pressure therapy. This involves (1) connecting the cover layer to a vacuum source to place the wound under negative pressure, or (2) applying a negative wound pressure therapy drape over the wound care device, with the wound care device being applied to the patient. In this alternative, the cover layer is between the patient and the negative would pressure therapy drape, such that the negative wound pressure therapy drape does not contact the patient's skin.

[0037] When used for negative wound pressure therapy, it is preferably that the wound care device has adherent free areas. The step of applying the wound care device to the patient thus comprises positioning the wound care device such that the adherent free area is over the wound or wound dressing. Preferably, the window defines an area generally equal to, or greater than, an area of the wound.

[0038] In accordance with an aspect of the method, application of the cover layer substantially seals the wound from the ambient atmosphere, thereby reducing the need for dressing changes and promoting uninterrupted wound healing.

[0039] In accordance with a different aspect, a method of conducting negative pressure is disclosed, this method comprising: applying a wound cover over a wound to be treated; the wound cover comprising a wound care device or a sheet material as described above, and subjecting the wound to a vacuum pressure. In one aspect, the wound cover is directly connected to a source of vacuum. In another aspect, the method includes a step of applying a negative would pressure drape over the wound cover; and connecting the negative wound pressure drape to a source of vacuum.

[0040] Finally, also disclosed are uses of the wound cover device and the sheet material as (1) a scar therapy or scar-reduction device and (2) as a negative wound pressure therapy drape.

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] FIG. 1A is a bottom plan view of an illustrative embodiment of a wound care device;

[0042] FIG. 1B is a bottom plan view of a variation of the wound care device;

[0043] FIG. 1C is a bottom plan view of a wound care device having an adherent free area;

[0044] FIG. 2 shows a cross sectional view of the wound care device taken along line A-A of FIG. 1A;

[0045] FIG. 3A is a schematic perspective sectional view of a preferred embodiment of the wound care device;

[0046] FIG. 3B is an enlarged sectional view taken at the circle B of FIG. 3A;

[0047] FIG. 4A shows an exemplary wound care device applied to a patient over a wound dressing;

[0048] FIG. 4B shows an exemplary wound care device that has been cut and configured to be applied adjacent (and between) wounds to customize the application of forces applied by the wound care device to the wound(s);

[0049] FIGS. 5A-D are illustrative bottom plan views of an alternatively configured wound care device schematically showing the steps of application of the wound care device;

[0050] FIG. 5E is a schematic view illustratively showing the retraction forces generated by the wound care device on the wound and the skin surrounding the wound care device;

[0051] FIGS. 6A-D schematically demonstrate a first method for applying the wound care device to a wound;

[0052] FIGS. 6E-G schematically demonstrate a second method for applying the wound care device to a wound;

[0053] FIG. 7A is a schematic cross-section of the wound care device applied over a wound and schematically showing lines of force generated by the wound care device after application of the wound care device;

[0054] FIG. 7B is a schematic force diagram demonstrating tangential sheer forces absorbed in the adherent of the wound care device when the device is applied to a patient;

[0055] FIGS. 8A-C schematically show the forces of the applied wound care device retracting the wound care device towards a center or focal point for square, rectangular, and circular wound care devices and schematically showing direction of the compressive forces applied to the tissue under the wound care device and the tension forces applied to the tissue surrounding the wound care device;

[0056] FIG. 9A is a schematic drawing showing the wound care device adapted for use as a negative pressure wound therapy drape;

[0057] FIG. 9B is a schematic drawing showing the wound care device in use with a (traditional) negative pressure wound therapy drape;

[0058] FIG. 9C is a schematic view showing the wound care device in an exploded form applied to a wound and in use with a (traditional) negative pressure wound therapy drape; and

[0059] FIG. 10 shows a progression of healing of a wound facilitated by a prototype wound care device.

[0060] Corresponding reference numerals will be used throughout the several figures of the drawings.

DETAILED DESCRIPTION

[0061] The following detailed description illustrates the claimed invention by way of example and not by way of limitation. This description will clearly enable one skilled in the art to make and use the claimed invention, and describes several embodiments, adaptations, variations, alternatives and uses of the claimed invention, including what we presently believe is the best mode of carrying out the claimed invention. Additionally, it is to be understood that the claimed invention is not limited in its application to the details of construction and the arrangements of components set forth in the following description or illustrated in the drawings. The claimed invention is capable of other embodiments and of being practiced or being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting.

[0062] In the case of an open wound, a wound care device 10 can be placed over or adjacent the wound to aid in the healing process. Whether the wound care device is placed over or adjacent the wound depends on the type of wound and the needs of the particular patient. As is known, some wounds (such as, for example, incisions) are closed, and some wounds are allowed to heal as an open wound (in which dressings are changed). The wound care device 10 can be used with either type of wound. For wounds that are closed, the wound care device supports or can be used with any type of closure method (i.e., sutures, staples, skin glue, Steri-Strip® closures, etc.).

[0063] A wound care device 10 is illustratively shown in FIGS. 1A,B as being rectangular and having opposed end edges 13a,b and opposed top and bottom edges 13c,d, which in combination define an outer perimeter of

the wound care device 10. The wound care device has first and second end portions 25a,b at the end edges 13a,b, respectively which can be grasped during positioning of the wound care device during application of the device. Although the wound care device is shown to be generally rectangular in FIGS 1A,B, the wound care device can be square, oval, circular, hourglass shaped, or any other shape that may be needed by the practitioner based on the needs of the patient's wound. At a minimum, the wound care device is sized to have at least one dimension that is greater than at least one dimension of the wound.

[0064] With reference to FIG. 2, the wound care device 10 comprises at least three layers 16, 19, and 22. The first, top, layer 16 is a top ply having a top surface and a bottom surface and which is comprised of a flexible material that is capable of being stretched along at least one axis. The first layer 16 may hereafter be referred to the as the top or cover ply 16. The second, middle, layer 19 comprises an adherent material. An optional binding layer 17 may be used to aid in adhesion of the adherent 19 to the top layer 16. The third, bottom, layer 22 is a bottom ply having a top surface and a bottom surface. The bottom ply 22 is removably connected to the adherent 19 to protect the adherent until the device is put in to use. The third layer 22 may herein be referred to as a backing liner 22 or a release liner 22. During application of the wound care device 10, the release liner 22 is configured to be removed to expose the adherent 19 for application to the skin of a person.

[0065] The cover layer 16 is composed of a, preferably polymer or polymer containing, material that is capable of flexing and stretching. The material is preferably a polymer (such as nylon) or a polymer containing material (i.e., a blend of natural and man-made fibers). This material can be knit fabric, a woven fabric, or fleece. The material can have an elongation factor of at least 50% and up to 500%. For example, the material can have an elongation factor of 150%. In one variation, the material is stretchable

along just one direction or axis; and in another variation, the material is stretchable in many directions or axes (i.e., it stretches omni-directionally). Preferably, the material of the top ply is generally fluid impermeable, but has a moisture vapor transmission rate (MVTR). For example, the top ply can have an MVTR of approximately 100-400 gm/m^2/24 hours or greater. As will be described more fully below, despite the liquid impermeability, liquid can be drawn through the cover layer 16 under vacuum pressure. For example, the material of the cover layer is fluid permeable when subjected to a vacuum such as between –200 and –40 mmHg or greater. The material from which the top layer is made can also be hydrophobic. The material from which the top layer 16 is made preferably has an elastic memory such that it has an original at-rest shape and size and upon stretching, the material will tend to revert back to the at-rest shape and size. The elasticity of the top layer is dynamic, such that the forces applied by the top layer due to its elastic memory are linear. The cover layer 16 can, for example be made from a woven nylon, such as is described in US Pat. No. 9439808, which is incorporated herein by reference. Alternatively, the fabric layer can be made from a warp knit fabric, such as a tricot knit fabric, preferably of nylon.

[0066] The adherent 19 may be comprised of a silicone gel material, a hydrogel adhesive, or a co-adhesive. As is known, silicone gels and hydrogels do not bond to the skin and are gentle on the skin during removal. They are typically composed of a very lightly cross-linked silicone elastomer whose polymer network has been swollen with silicone fluids. In a variant, the adherent can have an integrated medicant.

[0067] In an alternative, as seen in FIG. 1C, the adherent 19 can define a window 19a or opening to form an adherent free area of the wound care device. This window can be sized to approximate the size of the wound or wound dressing, such that the adherent does not directly contact the wound or wound dressing, should that be desired. The adherent 19 will interfere with the liquid permeability of the material which forms the cover layer 16.

By providing the window 19c in the adherent, liquid, along with vapor and gasses, will more easily pass through the wound care device.

[0068] An optional binder agent 17, such as an acrylate adhesive, can be used to adhere the adherent 19 to the cover layer 16. The adherent 19 extends substantially over the entire lower surface of the cover layer 16. If an acrylate adhesive binder is used, the silicone gel or hydrogel will cover the acrylate adhesive, such that the acrylate adhesive will not come into contact with the patient's skin. As seen, the release liner 22 does not directly contact the cover layer 16. Thus, the release liner 22 is removably adhered to the bottom of the cover layer by the adherent 19.

[0069] The release layer 22 is preferably made from a generally non-stretchable material. The release liner 22, as shown in FIGS. 1A,B and 2 can be split into two portions by a full cut FC with a tab 27 associated with each portion. The tabs 27 are configured to be grasped and peeled away from the adherent 19 to expose the adherent. In FIG. 1A, the release liner 22 is split into an upper portion and a lower portion by a full cut FC extending between the end edges 13a,b, and the tabs 27 are positioned at one end of the device to extend from one of the edges 13a,b. As shown, the tabs extend from the edge 13a, but could alternatively extend from the edge 13b or one of the edges 13c,d. Alternatively, as shown in FIG. 1B, the release liner can be split into right and left portions by a face cut FC which extends between the top and bottom edges 13c,d of the release liner. In this instance, the tabs 27 can be shown to extend from the inner edges of the two portions at the face cut FC. The tabs could alternatively extend from one or both of the end edges 13a,b or one or both of the elongated top and bottom edges 13c,d. In FIG. 2, an adhesive 15 is shown to adhere the tabs 27 to the release layer 22. Although the release liner 22 is shown to be divided into two portions, depending on the size of the wound care device 10, the release liner can be a single piece, or it can be divided into three or more portions (as shown in FIG 4A and described below) . In any configuration, each

portion of the release liner will preferably have an associated tab to can be grasped to remove the release liner to expose the adherent 19. Although tabs are preferable, the wound care device can be provided without tabs. Instead, the wound care device can rely on a crack back, wherein the release liner is divided into at least two portions. Alternatively, the practitioner can simply peel the release liner from the adherent without the benefit of a crack back or the tabs.

[0070] For purposes of manufacturing the device 10, the cover layer 16 and the adherent 19 can be provided as a sheet assembly which is then combined with the release layer 22. The cover layer 16 with the adherent 19 is more pliable and more stretchable than the release layer 22. In production, a single multi-ply sheet is formed by positioning the cover layer 16 with the adherent 19 on the release liner 22 to removably adhere the release liner 22 to the adherent 19. The application of the release liner 22 to the combined cover layer and adherent can be accomplish by any desired technology. The device 10 can then be die cut from the sheet so formed.

[0071] We have found that release liner adheres to the silicone gel 19 better than the silicone gel adheres to the top layer. Thus, when the release liner was removed, it could pull the silicone gel with it. The use of the binder 17 improved this situation. The binder can be, for example, an acrylate adhesive which will bond to the silicone gel. However, we have found that using an assembly, such as shown schematically in FIGS. 3A,B overcomes this problem even better. In this preferred embodiment, the top layer 16 is made from an omnidirectional material having fibers 16a extending at least the bottom surface of the material 16. As an omnidirectional material, the material 16 can stretch or expand in any desired direction, as shown by the arrows 18 in FIG 3A. Because the silicone gel 19 is stretchable, the silicone gel will stretch with the material 16. These fibers 16a can be made to extend from the bottom surface of the material 16 by brushing or abrading the surface of the material. When modified to extend from the bottom of material

16, the fibers 16a can be straight, curved, twisted, etc. Further, the fibers may not be uniformly shaped. These fibers extending from the bottom of the material 16 greatly increases the surface area to which the adhesive 17 can adhere, as compared to a "smooth" material. The adhesive 17 (which bonds to the silicone) will then adhere to the fibers 16a. Stated differently, the fibers will extend into the layer of adhesive 17, as seen in FIG. 3B. Because the adhesive 17 is adhered to the surfaces of the fibers, and not just a smooth undersurface of the material 16, the grip of the adhesive 17 to the top layer 16 is much stronger, and thus is it much more difficult to separate the silicone gel 19 from the top ply 16. In fact, this embodiment of the wound care device has withstood repeated washings of the device without significant loss of function. That is, even after multiple washings, the device maintains is adhesion, tack, and elastic memory, and continues to adhere well to skin and to function as a wound care device, as described below.

[0072] In use, the wound care device is applied in a stretched/elongated condition or state to cover the wound or a wound dressing (as shown in FIG. 4A) or be adjacent the wound (as shown in FIG. 4B). In FIG. 4A, it can be assumed that the wound is a generally circular or irregularly shaped wound (i.e., it is not necessarily an incision). When covering a wound in this way, as will be described below, the wound care device will compress the wound from all directions. The wound shown in FIG. 4B, on the other hand, requires compression laterally. The wound care device 10 allows the practitioner to modify the shape of material, in this case to an hour-glass shape, used to bridge the wound. In the case of FIG. 4B, the patient's abdomen is distended and is exerting lateral pressure causing the wound to expand. The wound care device 10 counteracts these lateral forces by applying compression to the wound. The manner in which the wound care device was cut allows for the wound care device to exert horizontal compression C required from the 9 o'clock to 3 o'clock position, with reference to FIG. 4B, that is much greater than the vertical compression from the 6 o'clock to 12 o'clock position, again, with reference to FIG. 4B. Thus, as can be appreciated, the wound care

device 10 allows the practitioner to customize the shape of the device to customize the areas of compression for all types of wounds. After application of the device, the periwound is subject to tension T caused by the device. This tension T is illustrated in FIG. 4B by the white arrows. Tension on the periwound mirrors the compression C exerted by the wound care device.

[0073] This application of the device is shown illustratively in FIGS. 5A-D. These figures show a generally square wound care device 10'. The wound care device 10' is shown to include a center cut down the backing layer to divide the backing layer into right and left halves 22a, with additional cut lines at the four corners to define corner portions 22b. Across the bottom, the wound care device includes two sets of tabs 27a,b labeled as "1" and "2" respectively. The "1" tabs remove the center portions 22a of the release liner, and the "2" tabs remove the corner portions 22b of the release liner. Although the upper and lower corner portions are shown to be separate or independent of each other, they can be connected, so that "2" tabs will remove both the upper and lower corner portions from their respective sides of the wound care device.

[0074] In FIG 5B, the right central portion of the release liner has been removed to expose a first portion of the adherent 19. The release liner remains on at the upper and lower right corners to provide grasping or hand hold areas, so that practitioners can grasp the wound care device without contacting the adherent. In addition, these corners portions can be held when elongating and positioning the device over the wound. This exposed portion of the adherent is applied to the patient adjacent the wound, but without covering or crossing the wound. With the first half of the wound care device adhered to the patient, the left half of the wound care device 10' is lifted and the left central portion of the release liner is removed to expose additional adherent 19, as shown in FIG. 5C. With the left half extending over the wound, the wound care device is stretched, as indicated by the arrows A,B, and once stretched to a desired amount, the left half is adhered

to the patient. In this state, the wound care device will cover the wound and will be in a stretched (dynamic) condition. FIG. 5D shows the resulting omni-directional stretching of the device as applied to the patient and with the release liner corners still in place, the stretching being shown schematically by the arrows in FIG. 5D. At this point, corner sections 22b of the release liner can be removed, and the corner sections of the cover layer 16 can be adhered to the patient. The arrows demonstrate tension being applied to the wound care device; equal and opposite arrows can be shown to illustrate the lines of compression under the wound care device.

[0075] FIG. 5E shows the device applied to periwound or skin S surrounding the perimeter of the wound care device. With the wound care device 10' positioned on the patient in a stretched condition, the spring or elastic memory of the fibers of the wound care device will be in tension (as demonstrated by the arrows in FIG. 5D) and will draw the material toward its at-rest position. That is, the wound care device will tend to retract, which will bring the wound to a compressed and stabilized state, under which fibroblast formation and connective tissue growth can more readily be supported, thereby aiding and facilitating in the wound care and healing process. The retraction or reversion of the wound care device towards its at-rest position will generate forces traveling along force lines or vectors shown by the arrows in FIG. 5E.

[0076] The application of the wound care device is also shown cross-sectionally in FIGS. 6A-D and 6E-G. These figures also show a wound margin reference line MRL and a skin tension reference line STL, as dotted lines on the right and left sides, respectively, of the figures. FIG. 6A shows an illustrative wound 30 having a wound bed 39, a distal wound margin 33 and a proximal wound margin 34, with a periwound 31 surrounding the wound and wound margins. In FIG. 6B, an end 25a of the wound care device is adhered to the periwound 31 a distance from distal margin 33 of the wound by means of the silicone gel. The device is extended over the wound in a

static (unstretched) state. In FIG. 6C, the wound care device 10 is elongated to cover at least the margins of the wound, and preferably to extend over and onto the periwound. The device should be extended well beyond the proximal margin 34. The device is now in a stretched or dynamic state. FIG. 6D shows the opposite end portion 25b of the wound care device is adhered periwound 31 opposite the distal margin 33. The device will thus begin from its elongated state due to its elastic memory to generate compression forces in the tissues under the wound care device (including the wound 30 and the wound margins 33,34) and tension or stress forces in the periwound 31 surrounding the wound care device.

[0077] The effect of the forces on the wound 30 can be seen by comparing position of the wound margin reference line MRL and the skin tension line with respect to the wound 30. As can especially be seen by comparing FIGS. 6A and 6D, the wound in FIG. 6D is compressed compared to the wound in FIG. 6A. This compression stabilizes the wound and is believed to facilitate healing of the wound.

[0078] The images of FIGS. 6E-F show an alternative method of adhering the wound care device to a patient. In these figures, the wound care device is initially positioned over (but not in contact with) the wound, as shown in FIG. 6E. In FIG. 6F, the wound care device is stretched; and then in FIG. 6G, the wound care device is adhered to the patient to extend well beyond the margins of the wound. Unlike in the method of FIGS. 6B-D, in the method of FIGS. 6E-G, the wound care device is stretched before application of the wound care device to the patient.

[0079] With reference to FIG. 5E, the spring memory exerts compressive forces on the tissues under the wound care device to compress the tissues of the wound and wound margins. Additionally, the spring memory exerts tension forces (stresses) that pull on the skin surrounding the wound care device, placing this surrounding skin in tension. Thus, while the device is

placing the tissue immediately under the wound care device in compression (as it pulls inwardly), the wound care device is placing the periwound S surrounding the wound care device in tension. This creates tangential forces on the adherent 19, as schematically demonstrated in FIG. 7B. While the device is applying a force to the top of the adherent which pulls inwardly (i.e., a compressive force), the skin surrounding the device is applying a force to the bottom of the adherent which effectively pulls outwardly (a tensile force), or otherwise counters the compressive force (a tensile force). These opposing forces accumulate in the adherent (represented by the rectangle in FIG. 7B), and the adherent (which in a preferred embodiment is a heavy coat silicone gel) limits the opposing forces from impacting the tissue at and around the wound. As such, the wound care device relieves tension on the wound and the wound margins. Stated differently, the adherent works in conjunction with the elongated top layer 16 of the device to accumulate sheer stresses to relieve destructive sheer forces which might otherwise be transferred to the wound. If the sheer forces accumulated in the gel exceed a predetermined threshold (the engineered design limits of the adherent), such as the adhesive strength of the adherent, the wound care device will release from the skin before injury to the skin can occur, thereby limiting the forces applied to the skin of the patient. As is known, stresses are shown by the below equation, and are measured in units of force per area.

$$\sigma = \text{Stress} = \frac{\text{Resistive Force}}{\text{Unit Area}} = \frac{R}{A}$$

[0080] These lines of force are further shown in FIG. 7A. As schematically shown therein, the wound care device 10, 10' covers the wound 30 and at least a portion of the periwound (skin S surrounding the wound). The lines of force F are shown to pull inwardly, toward the center of the wound care device. As shown, the lines of force penetrate or extend

down into the dermis. That is, the force does not exist only at the surface of the skin. Rather, the inwardly directed forces act below the surface of the skin as well. The forces F in the dermis are shown as vectors of decreasing length. This demonstrates that the magnitude of the force F decreases as it penetrates deeper into the skin. These inwardly directed (with respect to the wound) forces, are shown to extend to a depth as deep as the wound, and these counteracting inwardly directed forces are believed to stabilize the wound and place the wound in compression and the periwound in tension.

[0081] FIGS. 8A-C are further schematic examples of our understanding of the flow of compressive and stabilizing forces generated by the wound care device after application to the skin. FIG. 8A shows the expected lines of force for a generally square wound care device, and FIGS. 8B and 8C show the expected lines of force for rectangular or circular wound care devices. As shown schematically, the forces are directed to a central point (shown as a "+" in FIGS. 8A-C) that lies within the perimeter of the wound care device. Depending on the shape of the wound care device used, and the configuration of the surface of the skin (i.e., whether the skin is relatively flat or if it curves), this central point could be beneath the device and in the dermis. Further, as demonstrated by the varying shading, the forces define a gradient, which is believed to be linear, with the magnitude of the force on the skin decreasing with distance from the central point. As seen, for the generally square and circular devices (FIGS. 8A and 8C), the lines of force define generally concentric and coaxial circles; whereas in the elongated device (FIG. 8B) the lines of forces define generally concentric and coaxial ovals.

[0082] Initially, it is believed that by compressing and stabilizing the wound and the periwound, the fibroblasts and connective tissues formed during wound healing can form generally unimpeded. Further, it is believed that the forces, such as tension and sheer forces, that would normally be transferred to the wound are instead transferred to, and absorbed in, the

wound care device, such that these forces are directed away from the wound. This further allows for the unimpeded growth of fibroblasts and connective tissue, which leads to healing of the wound.

[0083] As noted above, the wound care device is highly stretchable, and can be elongated in at least one axis, and preferably along multiple axes. When the device is stretched along just one axis, it is adapted for use with acute wounds, such as incisions resulting from surgery. However, when the device is omni-directional, and can stretch along multiple axes, the wound care device can be used with irregularly shaped wounds, such as might occur from fistulas, abscesses, biopsies, etc. Because the omni-directional wound care device is stretchable along multiple axes, it can be uniquely loaded to accommodate the requirements of the wound site. That is, by selectively shaping the wound care device, it can be made to vary the stresses placed on the wound and the periwound, and the forces can be limited in some areas and increased in others.

[0084] The wound care device can be applied directly over the wound or wound dressing (as shown in FIG. 4A), or adjacent the wound (as shown in FIG. 4B). Once applied, it is intended that the wound care device will remain in place for an extended period of time sufficient to allow for the wound to heal. Depending on the severity (size and depth) of the wound, the device can remain in place for up to two weeks, or a month, two months, or longer. The wound care device, as noted above, is fluid impermeable, but has a moisture vapor transmission rate. Thus, when placed over the wound (or over a wound dressing) the device will seal the wound from the ambient atmosphere, which will reduce the need for dressing changes, and will therefore promote uninterrupted wound healing. We believe that the compression and stabilization generated by the wound care device may effectively reduce the overall healing time by reducing the probability of the newly formed fibroblasts and connective tissue from being damaged.

[0085] Once the wound is healed or sealed, the wound care device 10, 10' can be repurposed for use as a scar therapy or scar-reduction device to minimize the effects of scarring at the wound site. Scar therapy requires that the device be placed directly over the wound site (i.e., applied directly to the skin around the wound), or over an existing wound dressing. This scar therapy function of the device reduces and minimizes hypertrophic, keloid and other scars resulting in a better cosmetic effect. If desired, prior to repositioning the wound care device, the wound care device can be removed from the patient, sterilized, cleaned, and then reapplied to the wound or incision for scar therapy. As noted above, the preferred embodiment of the wound care device (shown in FIGS. 3A-B) can be cleaned and washed multiple times (i.e., up to at least five times) without losing its adhesive, tackiness, and stretchability, and without significantly affecting its functionality.

[0086] Additionally, the wound care device can be used for negative wound pressure treatment (NWPT), in a similar manner as discussed in our US Pat. No. 10849704, which is incorporated herein by reference. For negative wound pressure treatment, a vacuum port 43 is formed in the wound care device. The wound care device can then be provided with a connector or tube 32, as seen in FIG. 9A, to place the vacuum port 43, and hence the wound in communication with a vacuum source V. This connector can be any type of connector, so that the vacuum port 43 can be connected to the vacuum source, in any desired manner. Preferably, if the wound care cover is to be used for negative pressure wound therapy, the wound care cover will be provided with an adherent free area that preferably defines an area as large of the area of the wound. The adherent would then form a seal about the wound. Because the wound care device is vapor permeable, and because the cover layer 16 is sufficiently porous to allow for liquid to be drawn through the cover layer 16 under pressure, vapor, gasses, and exudate can be removed from the wound site under the negative pressure generated by the vacuum. As can be appreciated, in this manner of use, the

wound care cover is, in effect, a negative pressure wound therapy drape. As described above, because the adherent is gentle to the skin, if necessary, the wound care cover/negative pressure wound therapy drape can be removed, cleaned, and reapplied.

[0087] In some instances, it may not be desirable to remove and reapply a wound care cover/negative pressure wound therapy drape. In this instance, a (traditional) negative wound pressure therapy drape 54, as shown in FIGS. 9B and 9C, can be applied over the wound care device while the wound care device is applied to the patient. In this instance, the tube 32 would be connected to the drape 3454 This would avoid the need to disturb the wound care device. Further, it would avoid the (traditional) negative pressure wound therapy drape from contacting the patient's skin. Instead, the negative wound pressure therapy drape would be applied directly to the wound care device. Therefore, when the negative pressure wound therapy drape can be removed, it can simply be lifted off the wound cover device 10, 10' without disturbing the healing wound.

[0088] In certain situations, it may not be desirable to place the wound tissue in compression when using negative pressure wound treatment. In this instances, the wound care device 10, 10' can be applied to cover the wound in a relaxed or static state (i.e., the cover layer 16 will not be stretched during application of the device). Although the cover layer will be applied in a relaxed or static condition, the gel adhesive (the silicone gel) will still form a seal about the wound so that a vacuum can be applied to the wound.

[0089] Additionally, the wound care device can be adapted and configured to monitor the healing of the wound. To monitor the wound, the device 10 is provided with monitoring means 40 (FIG. 1B) to monitor physiological conditions in the area of the wound. The monitoring means includes at a minimum, a sensor array 42. It can also include a transmitter 44 to transmit signals from the sensor array to a monitoring

device (such as a smart phone, tablet, computer, etc.) and/or a recording device 46 which can record the sensor signals for subsequent upload to a monitoring device (such as a smart phone, tablet, computer, etc.). The sensor array which measures physiological effects of the wound can include sensors which detect temperature, humidity, pH of the skin, static/charge of the device and/or skin, motion, stress to both the patient's skin and the device, tension/stretching of the device, spectroscopic data indicative of, for example, temperature, blood oxidation, pulse rate, etc. The sensor array can include any combination of these sensors. The cover layer 16 can include electrically conductive or semi-conductive fibers. Thus, the circuitry for the monitoring means can be woven into or applied directly to the cover layer. Alternatively, the circuitry can be printed on the cover layer. In the latter instance, the circuitry would be printed using known printing techniques.

[0090] We have found that the materials from which the device 10 is made has surprising results during use. A prototype device was worn by a patient having a large fistula that had remained unhealed for fourteen (14) months prior to application of the prototype device. The prototype device was applied over the wound. Rows 1-5 of FIG. 10 show a series of photographs of the healing of the wound over a period of 301 days. As seen, the abscess healed from what might have been a mortal issue to a position in which the wound is nearly healed. In the left column of rows 6 and 7, the wound care device 10 is shown over the wound when treated with negative pressure wound therapy (NWPT). The right column of row 6 (cell 6,3) shows the patient with a Mepilex-brand dressing applied to the wound two-and-a-half months after the photograph in cell 6,1 was taken. The photograph on the right of row 7 shows the wound care device 10 applied to a patient's abdomen.

[0091] The prototype device used, as is device 10, was comprised of a woven nylon fabric layer with a LDPE release layer releasably adhered to a

bottom surface of the nylon fabric layer by means of an adherent (such as a gel silicone and a binder and/or an acrylate adhesive).

[0092] As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is Claimed Is:

1. A wound care device configured to aid in the healing of a wound by providing stability to tissue of both the wound and periwound while reducing and absorbing sheer forces directed to the wound that would otherwise disrupt connective tissue of the wound, the wound care device comprising:

a cover layer having a bottom surface; said cover layer comprising a flexible ply that is stretchable in at least one direction along an axis and which has an elastic memory such that upon stretching the first layer will tend to retract to an at-rest position;

a layer of adherent on said bottom surface of said cover layer; said adherent being adapted to adhere to a person's skin and to be removable from the skin atraumatically; and

a removable release liner having a top surface positioned adjacent the layer of adherent to protect the adherent prior to application of the cover layer to a patient;

wherein in use, the wound care device is applied to a person's skin over or adjacent the wound or wound dressing in a stretched/elongated condition with a first portion of the device adhered to the periwound at a first site proximate the wound and a second portion of the device is adhered to the periwound at a second site proximate to the wound, said second site being a side of the wound opposite of the first site, wherein, upon application of the wound care device, the energy stored in the wound care device from stretching the wound care device causes the first layer to retract along lines of tension towards a center or focal point of the lines of tension, thereby drawing the margins of the wound together to stabilize and compress the skin about the wound.

2. The wound care device of Claim 1, wherein the adherent is adapted to transfer tensions in tissue surrounding the wound caused by natural movement of the skin proximate the wound to the cover layer, thereby diverting sheer forces to the cover layer that would interrupt the healing process or that otherwise would be transferred directly to the wound.

3. The wound care device of Claim 2, wherein the adherent comprises a gel adhesive, such as a silicone gel, a hydrogel, or said adherent comprises a co-adhesive.

4. The wound care device of Claim 3, wherein the adherent comprises a heavy coat weight silicone gel; wherein, in use, said heavy coat weight silicone gel works in conjunction with the cover layer to elongate and accumulate sheer forces to absorb destructive forces which might otherwise be transferred to the wound.

5. The wound care device of any of Claims 1-4 wherein the wound care device is adapted to, in use, limit the tangential force applied to the skin.

6. The wound care device of Claim 5 wherein the adherent has an adhesive strength such that when sheer forces accumulated in the gel exceed engineered design limitations of the adherent (such as the adhesive strength of said adherent), the wound care device will release from the skin before injury can occur to the skin, limiting the tangential forces applied to the skin of the patient.

7. The wound care device of any of Claims 1-6 wherein the adherent covers substantially the entire bottom surface of the top layer.

8. The wound care device of any of Claims 1-6 wherein the adherent defines a window such that the wound care device defines an adherent free area, said window preferably being sized to define an area at least as large as an area of the wound.

9. The wound care device of any one of Claims 1-8 wherein the cover layer is comprised of a polymer or a blend of man-made and natural fibers, and wherein the cover layer is preferably formed as a knit fabric, a woven fabric, a fleece, or a combination thereof.

10. The wound care device of any of Claims 1-9 further including an adhesive or binder, such as an acrylate adhesive, which bonds to the adherent to adhere the adherent to the cover layer.

11. The wound care device of Claim 10 wherein the first layer comprises fibers extending from the bottom surface thereof, said fibers extending into said adhesive such that said adhesive binds to said fibers such that said adhesive being securely adheres said adherent to said cover layer.

12. The wound care device of any of Claims 1-11, wherein the adherent comprises an integrated medicant.

13. The wound care device of any of Claims 1-12 wherein the elastic memory of the cover layer has a dynamic value, such that forces generated by the device upon stretching of the device are linear.

14. The wound care device of any one of Claims 1-13, wherein the cover layer is stretchable in multiple directions along multiple axes.

15. The wound care device of any one of Claims 1-14, wherein wound care device is shaped such that upon application of the wound care device, the center point of the lines tension is under the first layer and within the tissue being compressed.

16. The wound care device of any of Claims 1-15 wherein the wound care device is fluid impermeable and/or hydrophobic.

17. The wound care device of any of Claims 1-16 wherein the wound care device has a moisture vapor transmissive rate of approximately 100-400 gm/m^2/24 hours or greater.

18. The wound care device of any of Claims 1-17 wherein the material of the cover layer is fluid permeable when subjected to a vacuum such as used in negative wound pressure therapy, such as between –200 and –40 mmHg or greater.

19. The wound care device of any one of Claims 1-18, wherein the wound care device is capable of being removed and cleaned, and then reapplied to the patient, whereby, after removal and cleaning, the device retains substantially the same amount of adhesion, tack, and elastic memory.

20. The wound care device of any one of Claims 1-19 wherein the wound care device includes means for monitoring selected physiological effects.

21. The wound care device of any of Claims 1-20 wherein one or both of the cover layer and adherent are conductive or semi-conductive, and for example, contain conductive or semi-conductive fibers or elements.

22. A sheet material useable for wound care devices or negative pressure wound therapy, said sheet material comprising;

the cover layer formed from a woven or knit fabric comprised of fibers such that the sheet material is stretchable and has an elastic memory; said cover layer including a plurality of fibers extending from a bottom surface thereof;

a binder, such as an acrylate adhesive, adjacent said bottom surface of said top layer, said fibers extending into said binder, whereby said binder adheres to said fibers along lengths of said fibers; and

bottom layer of a gel adhesive, such as silicone gel (preferably a heavy coat weight silicone gel) or a hydrogel; said adhesive being an adhesive which will bond to said gel adhesive to securely adhere said gel adhesive to said top layer.

23. The sheet material of Claim 22 further including a release liner removably adhered to said gel adhesive.

24. The sheet material of any of Claims 22-23 wherein said sheet material is gas and vapor permeable.

25. The sheet material of any of Claims 22-24 wherein said cover layer is liquid permeable under pressure, such as a pressure of between –200 and –40 mmHg or greater.

26. The sheet material of any of Claims 22-25 wherein said gel adhesive substantially covers the bottom surface of said top layer, or wherein said layer of gel adhesive has openings formed therein to define areas of said sheet material which are free of said gel adhesive.

27. A method of stabilizing and compressing dermis tissue proximate a wound using the wound care device of any of Claims 1-20 or Claims 21-25, the method comprising:

stretching the wound care device a sufficient amount such that the wound care device will extend beyond margins of the wound;

adhering the elongated wound care device to a patient over or adjacent a wound site of the patient, such that the wound care device is adhered to skin of the patient proximate the wound on opposite sides of the wound;

whereby, the memory of the cover layer causes the cover layer to retract along lines of tension toward a center focal point of the lines of

tension, thereby drawing the margins of the wound together such that the tissue adjacent the wound is compressed and stabilized.

28. The method of Claim 27 wherein when the wound care device is applied to the patient, the wound care device places the tissue immediately under the wound care device in compression, and places the tissue of the periwound surrounding the wound care device is in tension.

29. The method of Claim 27, wherein the wound care device transfers stresses in the tissue caused by natural movement of the skin proximate to the wound through the gel adhesive to the cover layer, thereby diverting and absorbing sheer forces that would interrupt the healing process or otherwise be transferred directly to the wound.

30. The method of Claim 27 wherein the step of applying the wound care device to the patient comprises applying the cover layer over the wound, whereby the cover layer forms a protective barrier over the wound.

31. The method of Claim 27 wherein the wound care device comprises a backing layer removably adhered to the adhesive; the method applying the wound care device comprising a first step of removing the backing layer to expose the adherent.

32. The method of Claim 27, wherein the release layer comprises a first portion and a second portion; the steps of removing the release layer and adhering the stretched wound care device to the patient comprising:

removing a first portion of a release layer of the device to expose a first portion of the gel adhesive of the device and adhering the first portion of the gel adhesive to skin adjacent the wound;

removing a second portion of the release layer of the device to exposing a second portion of the adhesive layer of the device, stretching the

cover layer and adhering the second portion of the cover layer of the device to the skin on a side of the wound opposite the first portion of the device.

33. The method of Claim 27 wherein the cover layer is elongated prior to application to the patient and then attached, both sides at the same time, to the periwound.

34. The method of Claim 27 wherein the cover layer is larger than the wound in at least one dimension; wherein the retraction forces generated by the memory of the cover layer decrease with distance from the margin of the device.

35. The method of Claim 27 wherein the cover layer is larger than the wound in all directions, and wherein the cover layer is stretchable in multiple directions, such that the memory of the material of the cover layer retracts along multiple axes toward said center point.

36. The method of Claim 27 including a step of selectively stretching the cover layer in desired directions to accommodate variations of the wound site and to selectively vary the forces exerted by the cover layer on selected areas of the wound, whereby, the forces can be greater in one area of the wound than in another area of the wound.

37. The method of Claim 27 comprising, prior to application of the wound care device to the patient, a step of selectively shaping the cover layer, such as by cutting, to shape the cover layer so that it will be uniquely loaded to accommodate the needs of the wound and to selectively control the forces applied by the wound care device to various portions of the wound.

38. The method of Claim 27 wherein once adhered to the skin of a person, the memory of the cover layer remains under a continuous tension for the duration that it is worn.

39. The method of Claim 38 wherein the wound care device remains in place on the epidermis as a cover of a wound for extended periods of time, and preferably until the wound heals.

40 The method of Claim 27 wherein said method relieves tension on the wound and the wound margins.

41. The method of Claim 27 comprising a step of adapting the wound care device for use in as negative wound pressure therapy.

42. The method of Claim 41 wherein said step of adapting the wound care device for negative wound pressure therapy comprises connecting said cover layer to a vacuum source to place said wound under negative pressure.

43. The method of Claim 41 wherein the step of adapting the wound care device for use in negative would pressure therapy comprises applying a negative wound pressure therapy drape over the cover layer, with the cover layer device being applied to the patient and wherein the negative wound pressure therapy drape does not contact the patient's skin.

44 The method of either Claim 42 or 43 wherein the layer of adherent defines windows, such that the wound care device has adherent free areas; said step of applying the wound care device to the patient comprising positioning the wound care device such that said adherent free area is over the wound or wound dressing.

45. The method of Claim 43 wherein said window defines an area generally equal to, or greater than, an area of said wound.

46. The method of Claim 27 wherein the wound care device substantially seals the wound from the ambient atmosphere, thereby reducing the need for dressing changes and promoting uninterrupted wound healing.

47. A method of conducting negative pressure wound therapy comprising

applying a wound cover over a wound to be treated; said wound cover comprising a wound care device of any of Claims 1-21 or a sheet material of any of Claims 22-26; and

subjecting the wound to a vacuum pressure.

48. The method of Claim 47 including a step of connecting said wound cover to a source of vacuum.

49. The method of Claim 47 including a step of applying a negative wound pressure drape over said wound cover; and connecting said negative wound pressure drape to a source of vacuum.

50. Use of the device of any of Claims 1-21 or Claims 22-26 as a scar therapy or scar-reduction device.

51. Use of the device of any of Claims 1-21 or Claims 22-26 as a negative wound pressure therapy drape.

52. A negative wound pressure assembly comprising wound cover and a negative pressure wound therapy drape; said wound cover comprising the wound care device of any of Claims 1-21 or the sheet material of any of Claims 22-26; wherein said wound cover is larger in area than said negative pressure wound therapy drape; wherein in use, said wound cover is applied over a wound or wound dressing and said negative pressure wound therapy drape is adhered only to said wound cover, such that said negative pressure wound therapy drape does not contact skin of a patient.

53. A method of making the sheet material of any of Claims 22-26 comprising:

brushing or abrading a surface of the cover layer to cause the fibers to extend from said surface area available for bonding;

applying said binder to said surface of said cover layer such that said fibers extend into said binder to enable the binder to adhere to surfaces of the fibers;

applying said layer of gel adhesive over said binder whereby said layer of gel adhesive binds to said binder to be securely affixed to said cover layer.

SHEET 1 OF 9

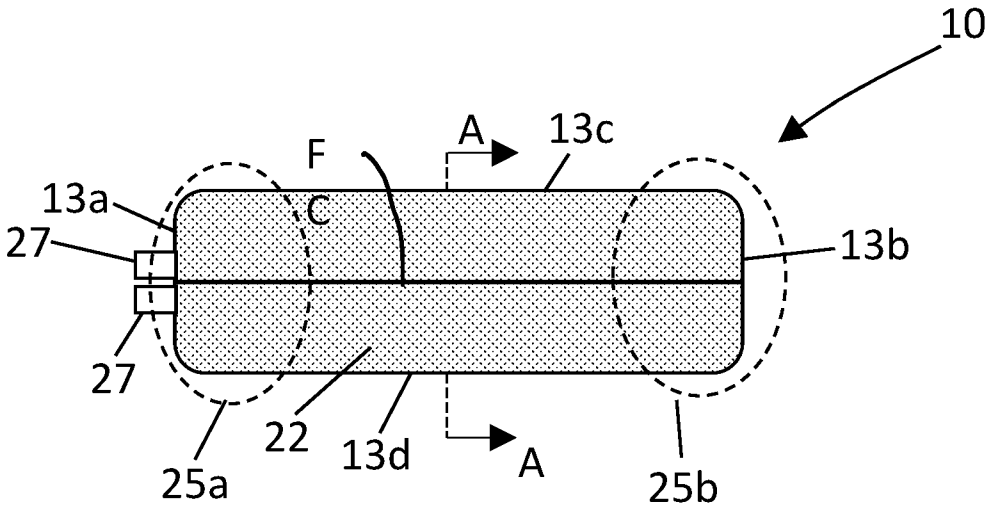


FIG. 1A

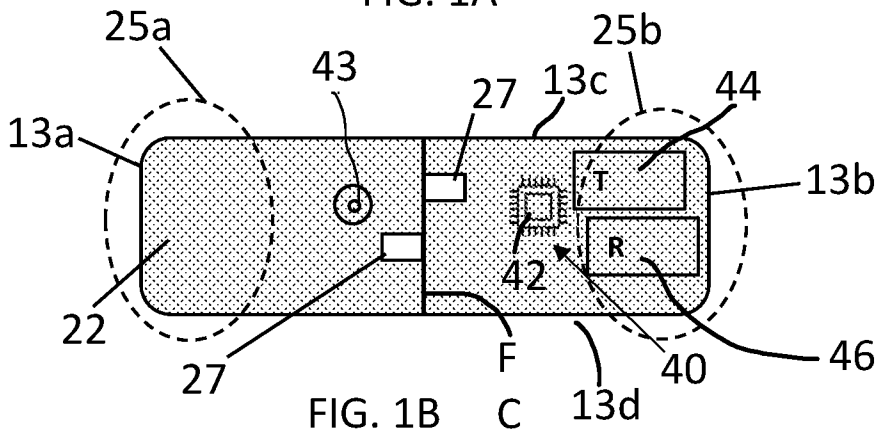


FIG. 1B

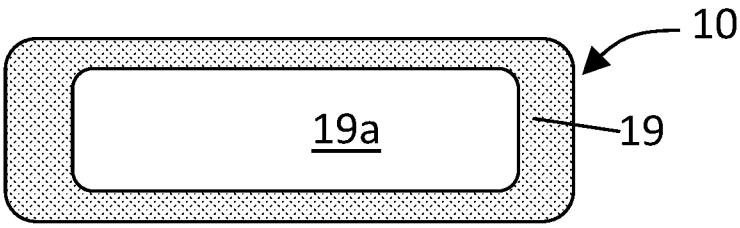


FIG. 1C

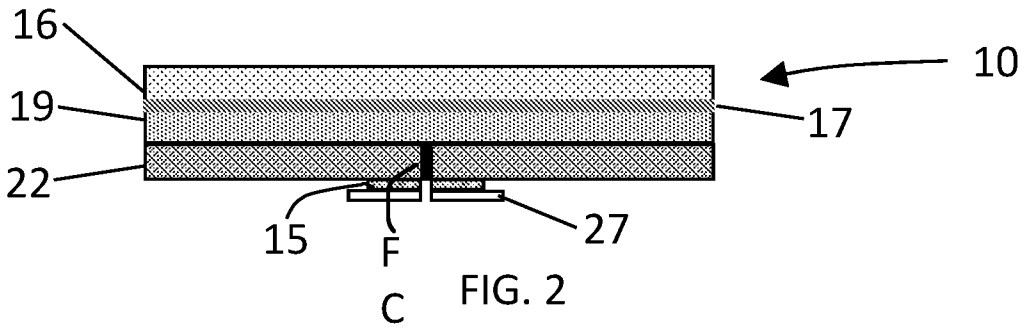


FIG. 2

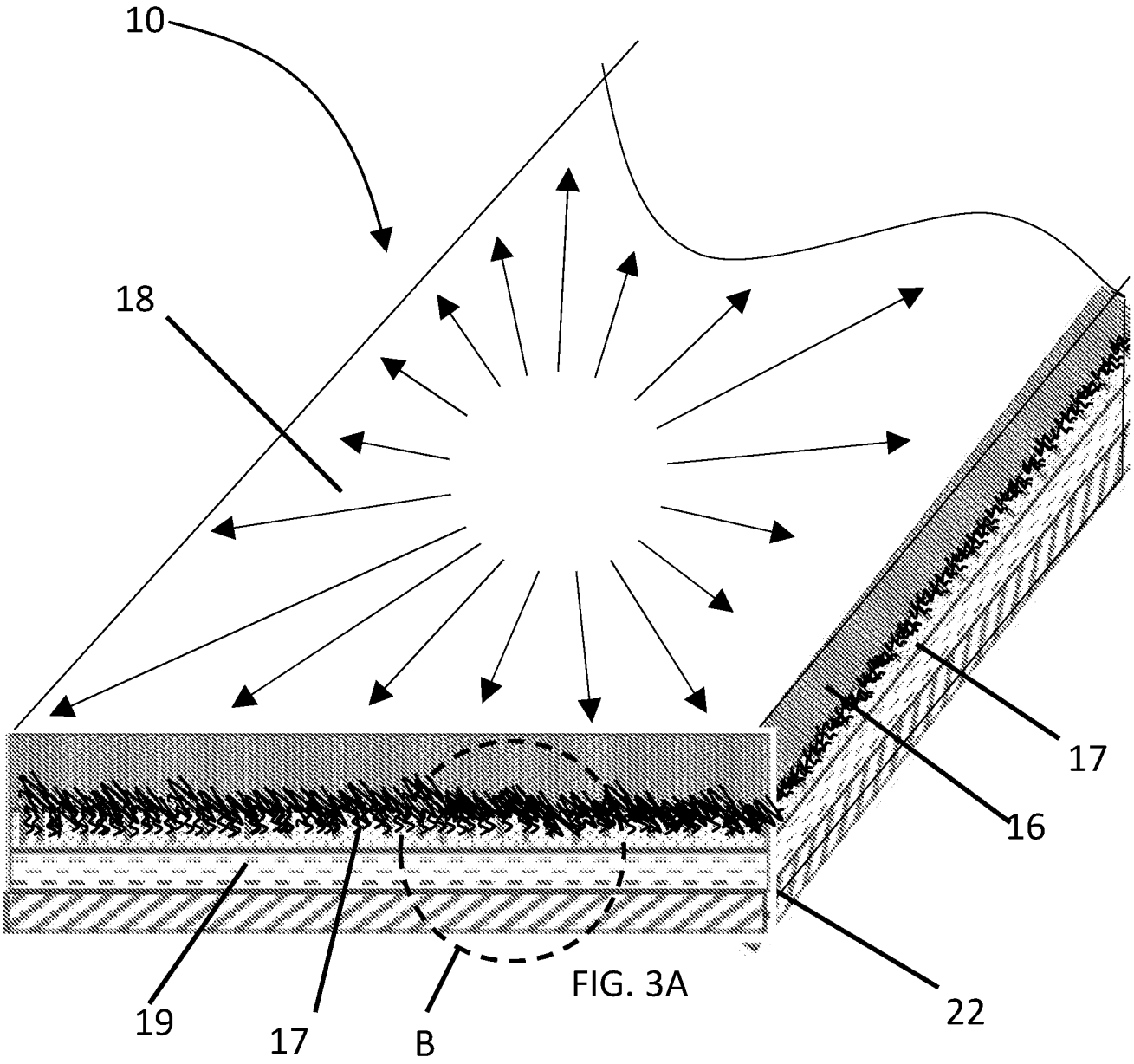


FIG. 3A

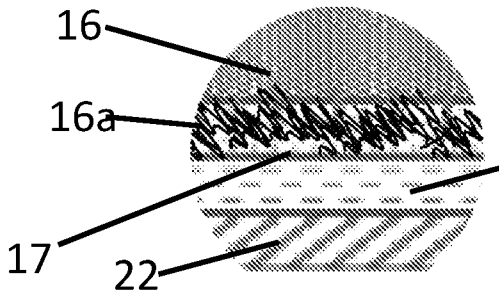


FIG. 3B

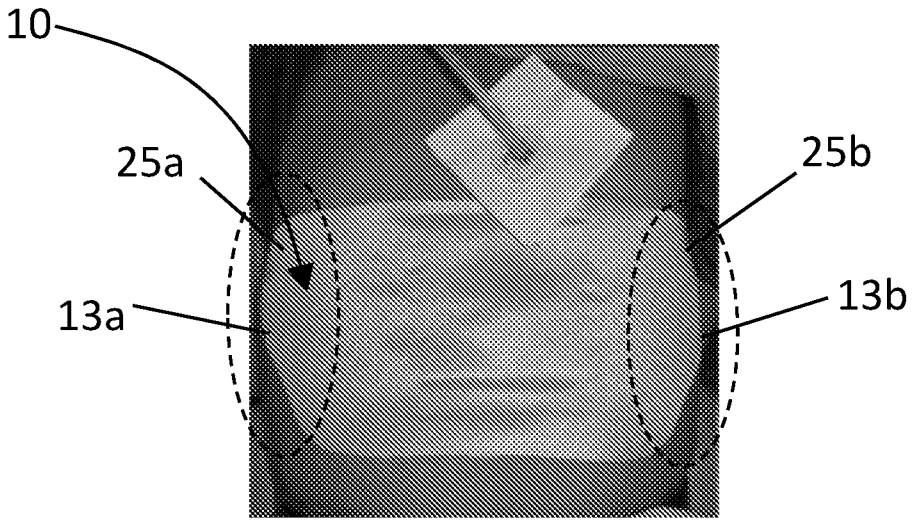


FIG. 4A

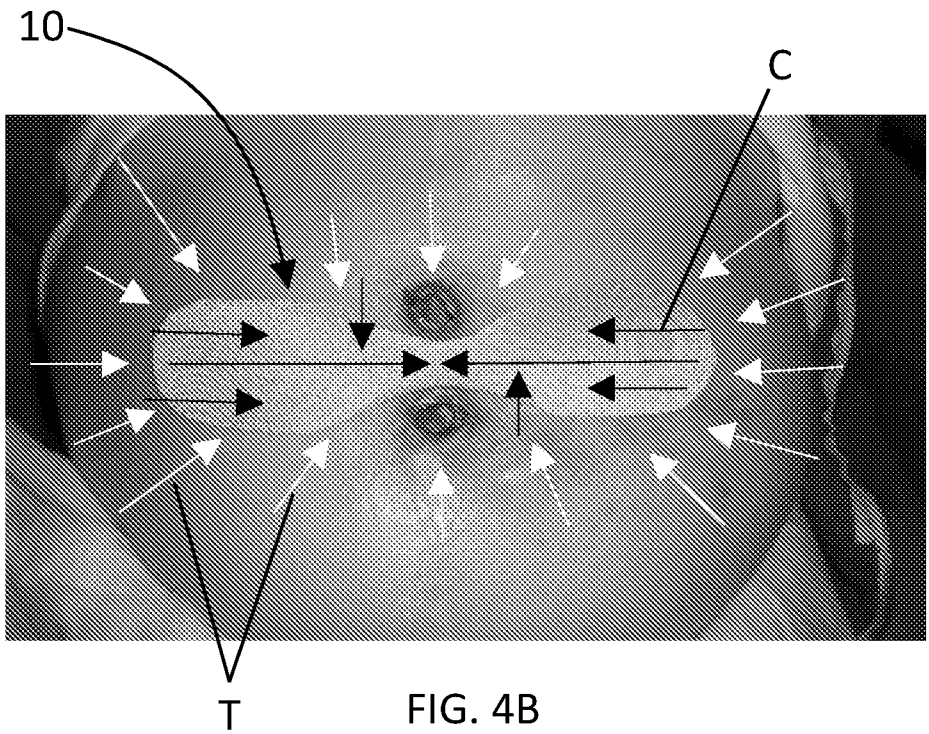


FIG. 4B

SHEET 4 OF 9

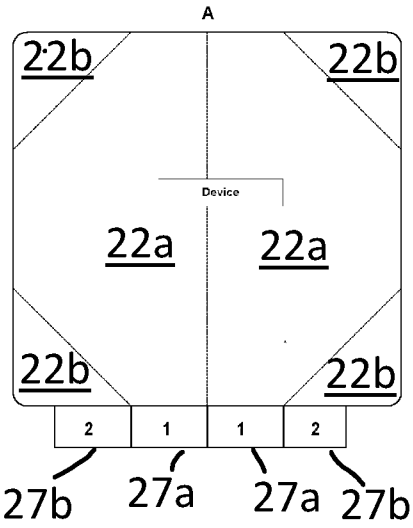


FIG. 5A

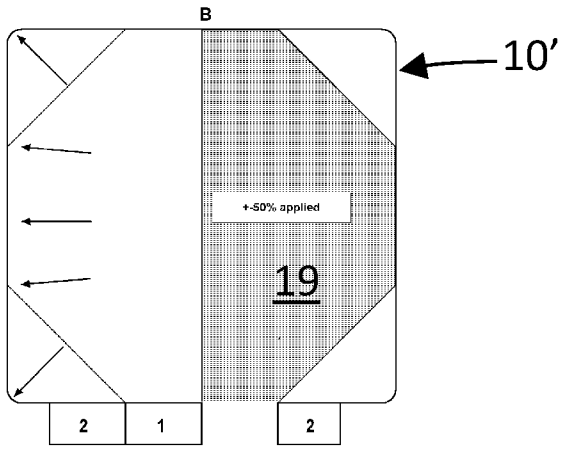


FIG. 5B

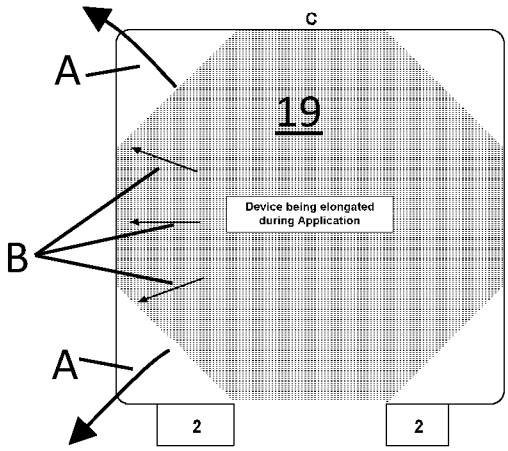


FIG. 5C

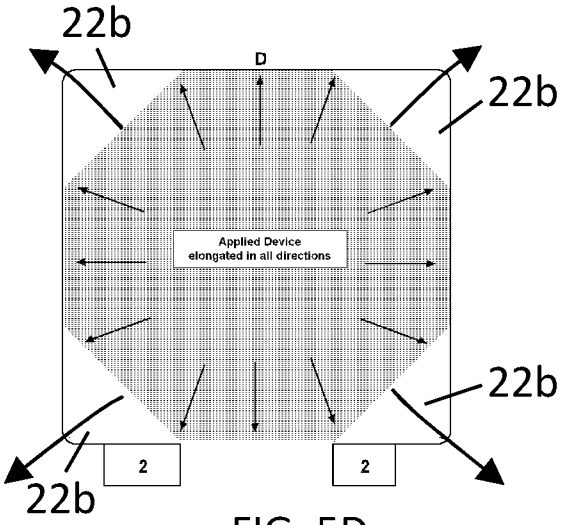


FIG. 5D

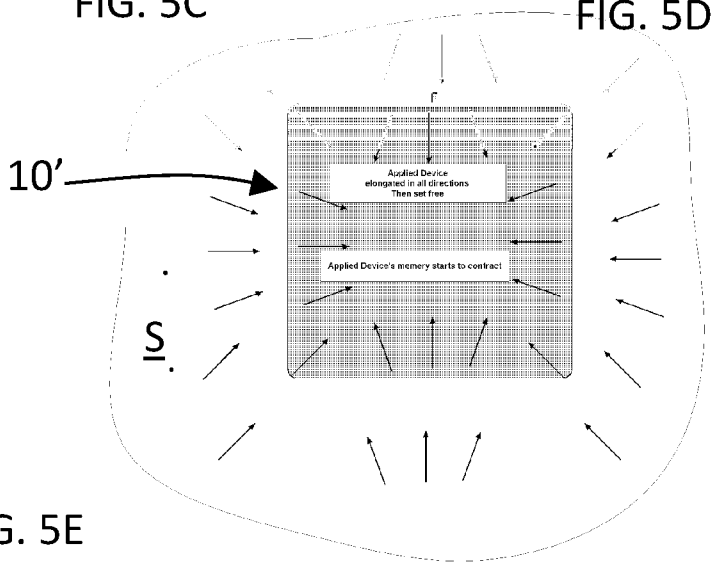


FIG. 5E

SHEET 5 OF 9

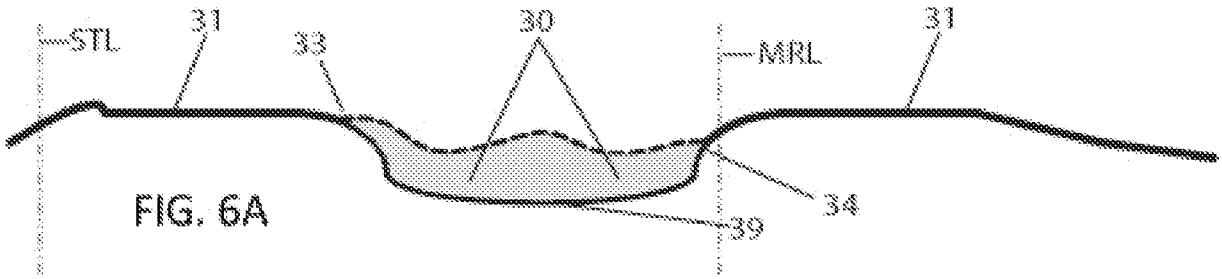


FIG. 6A

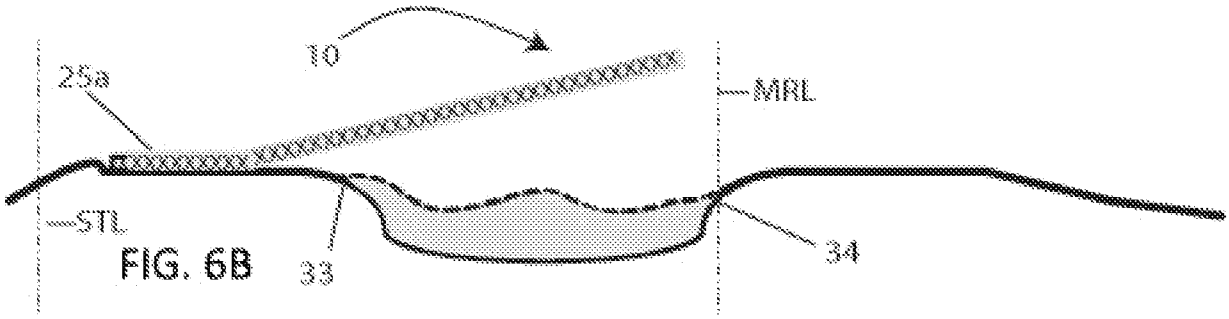


FIG. 6B

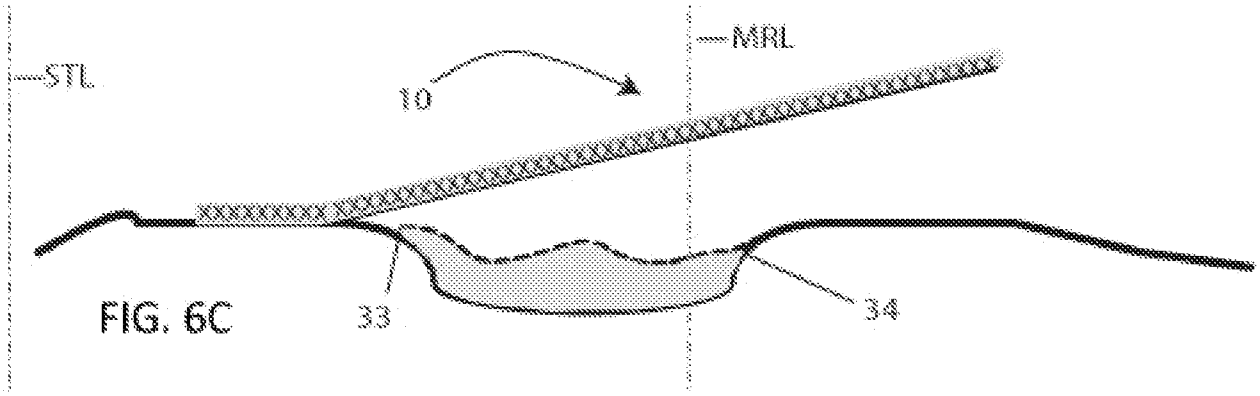


FIG. 6C

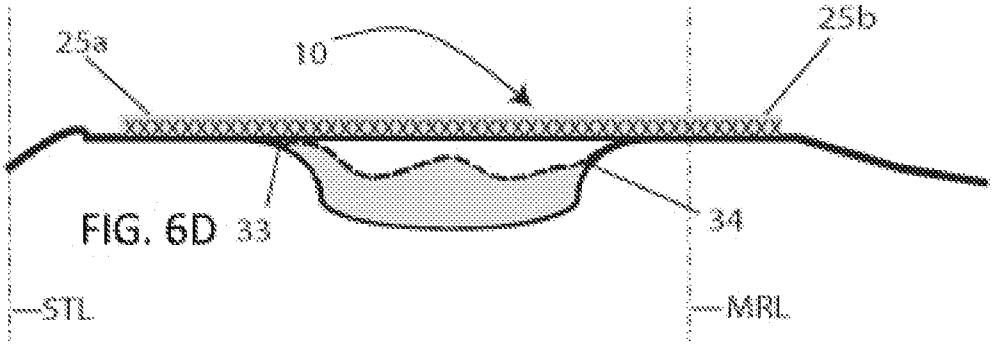


FIG. 6D

SHEET 6 OF 9

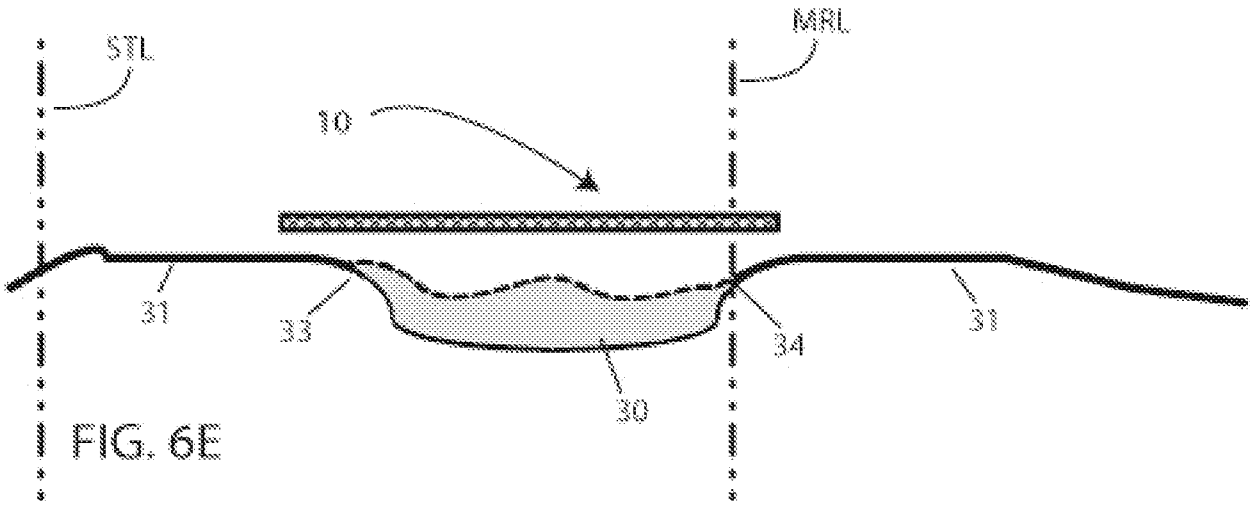


FIG. 6E

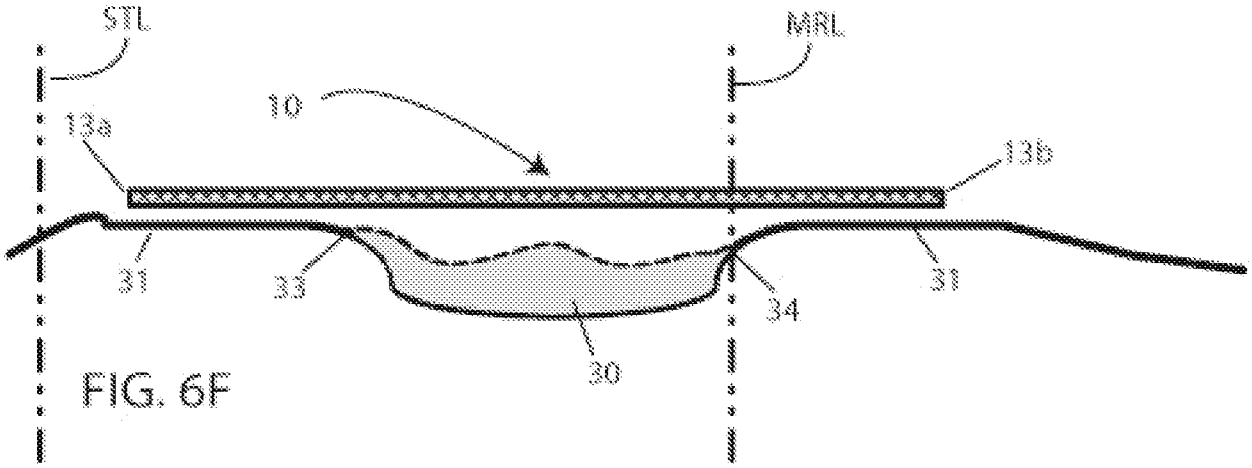


FIG. 6F

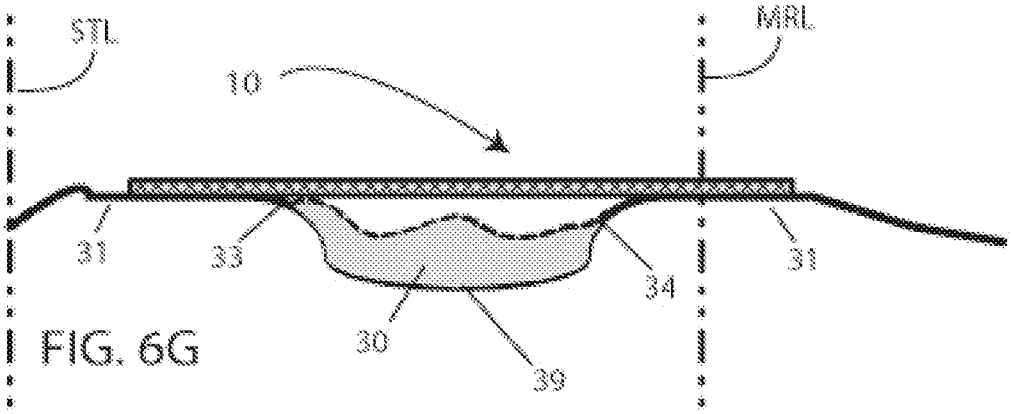
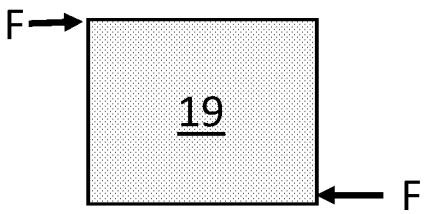


FIG. 6G

SHEET 7 OF 9



F=Tangential Force

FIG. 7B

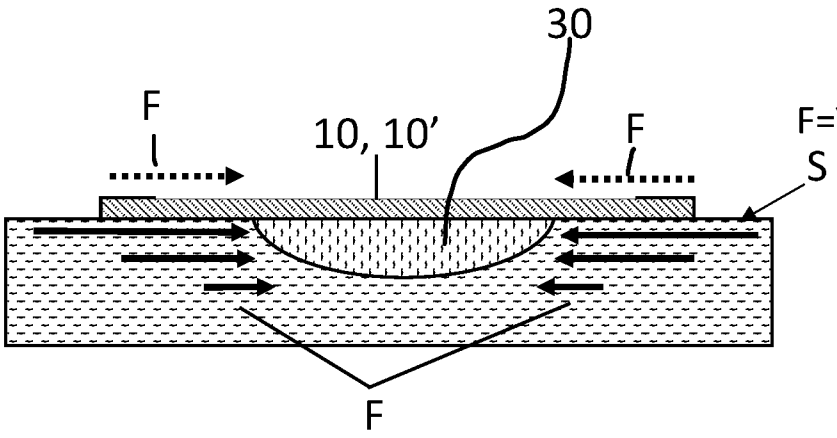


FIG. 7A

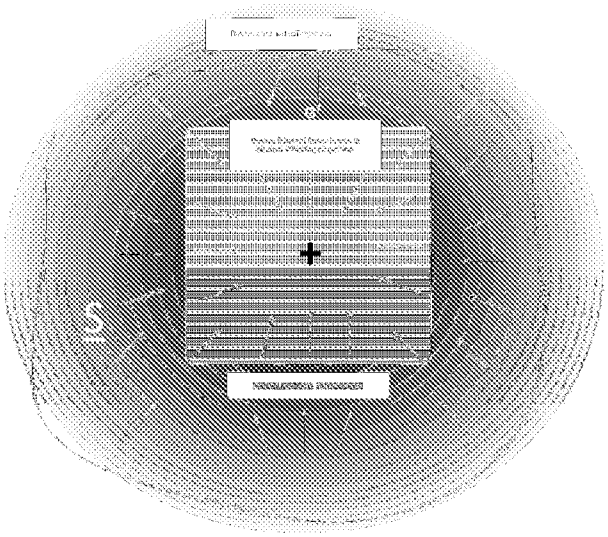


FIG. 8A

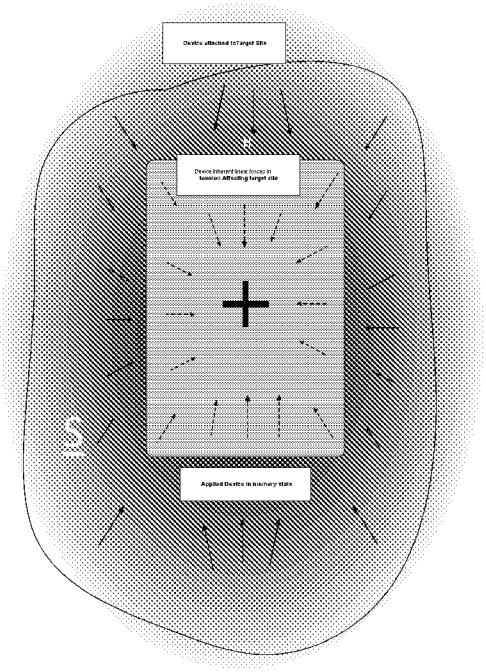


FIG. 8B

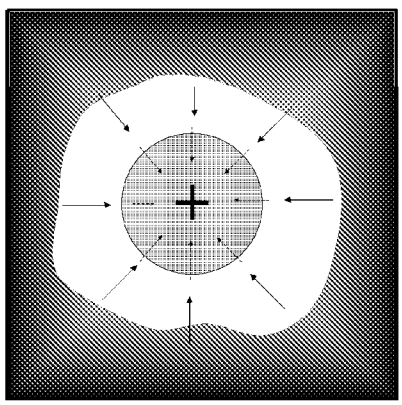


FIG. 8C

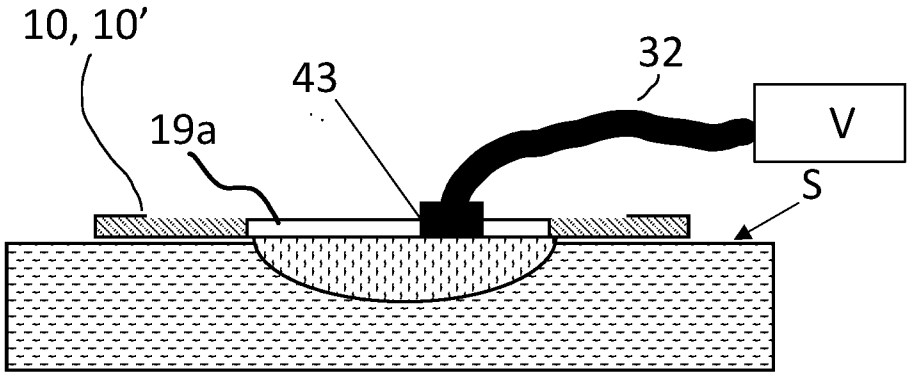


FIG. 9A

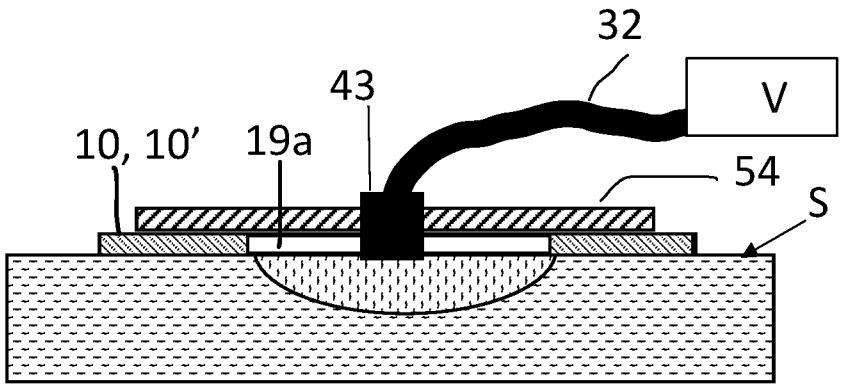


FIG. 9B

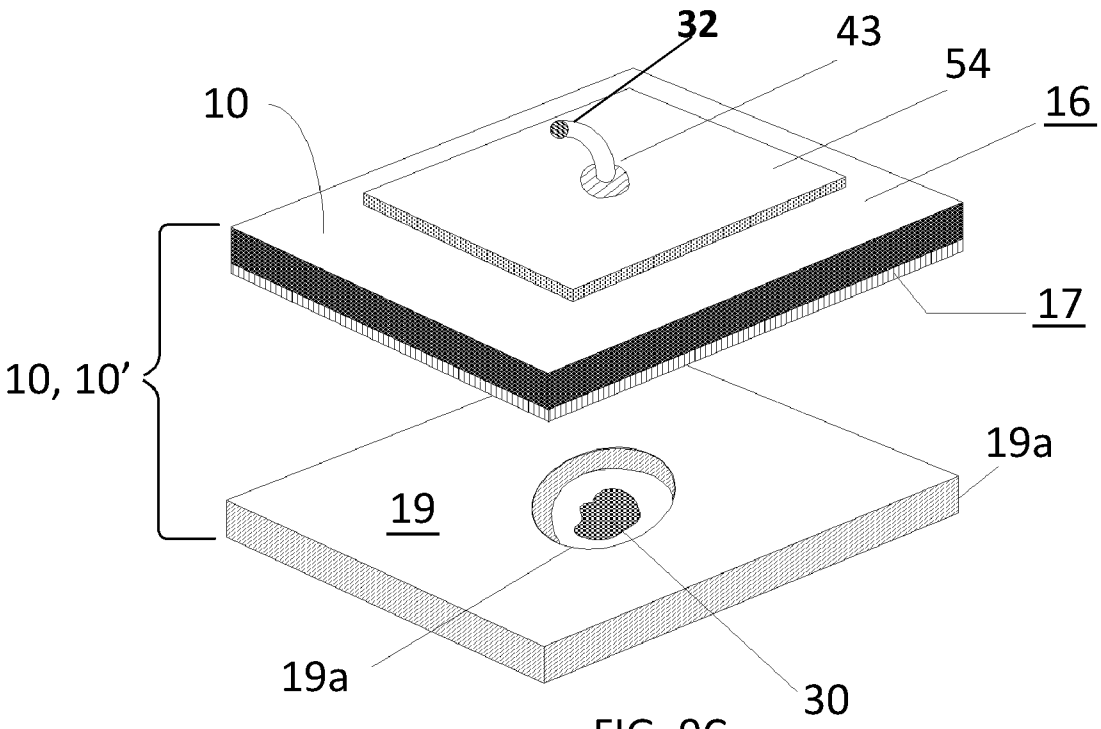


FIG. 9C

SHEET 9 OF 9

Cell	Day
1,1	1
1,2	26
1,3	29
2,1	70
2,2	70
2,3	75
3,1	96
3,2	99
3,3	120
4,1	152
4,2	180
4,3	215
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5,2	278
5,3	301
6,1	26
6,3	75
7,1	26
7,3	75

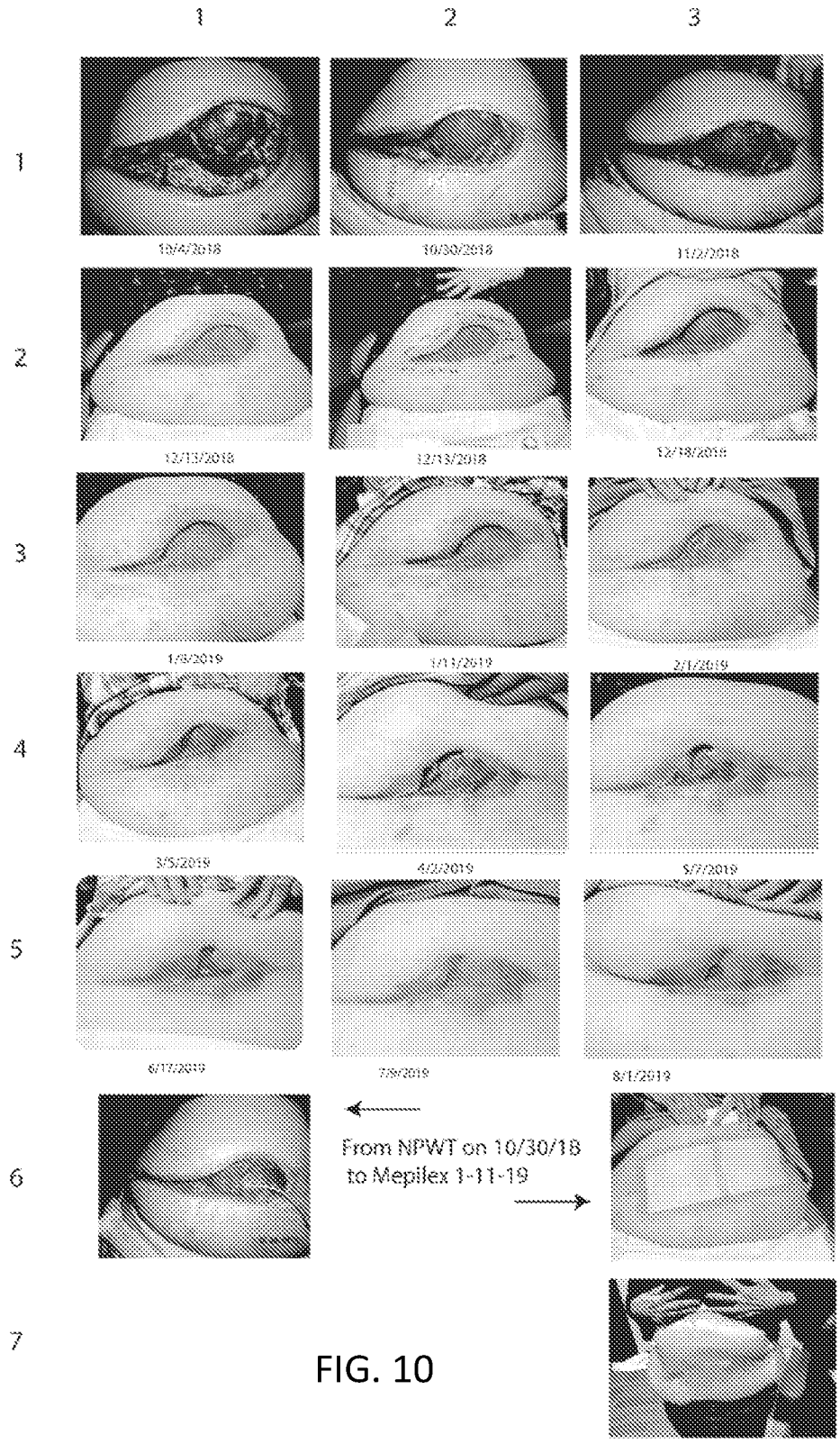

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/19615

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 13/02 (2021.01)

CPC - A61F 13/02, A61F 2013/00119, A61F 2013/00127, A61F 2013/00165, A61F 2013/00238, A61F 2013/00246, A61F 2013/0028, A61F 13/023, A61F 13/0243, A61F 13/0253

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)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2018/0008476 A1 (MOLNLYCKE HEALTH CARE AB) 11 January 2018 (11.01.2018) Entire document.	1-6 --- 22-24
X	US 2016/0015569 A1 (KCI LICENSING, INC) 21 January 2016 (21.01.2016) Entire document.	1-3, 5/(1-3)
Y	US 2013/0226062 A1 (KLOEPPELS et al.) 29 August 2013 (29.08.2013) Entire document.	22-24
A	US 4,034,751 A (HUNG) 12 July 1977 (12.07.1977) Entire document.	1-6
A	US 9,271,877 B2 (MOUTON) 01 March 2016 (01.03.2016) Entire document.	1-6
A	US 7,834,232 B2 (RASTEGAR et al.) 16 November 2010 (16.11.2010) Entire document.	1-6
A	US 2019/0030226 A1 (LIN) 31 January 2019 (31.01.2019) Entire document.	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"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
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 June 2021 (22.06.2021)	JUL 23 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/19615

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 7-21, 25-53
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-6, directed a wound care device configured to aid in the healing of a wound by providing stability to tissue of both the wound and periwound while reducing and absorbing sheer forces directed to the wound that would otherwise disrupt connective tissue of the wound

Group II: Claims 22-24, directed towards a sheet material useable for wound care devices or negative pressure wound therapy

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

---------- see extra sheet ----------

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/19615

---------- Continuation of Box No. III Observations where unity of invention is lacking (Continuation of item 3 of fi rst sheet) ----------

Special Technical Features

Group I includes the special technical features a [wound care device] configured to aid in the healing of a wound by providing stability to tissue of both the wound and periwound while reducing and absorbing sheer forces directed to the wound that would otherwise disrupt connective tissue of the wound, comprising a flexible ply, that upon stretching the first layer will tend to retract to an at-rest position; [adherent] being adapted to adhere to a person's skin and to be removable from the skin atraumatically; a removable release liner having a top surface positioned adjacent the layer of adherent to protect the adherent prior to application of the cover layer to a patient; wherein in use, is applied to a person's skin over or adjacent the wound or wound dressing in a stretched/elongated condition with a first portion of the device adhered to the periwound at a first site proximate the wound and a second portion of the device is adhered to the periwound at a second site proximate to the wound, said second site being a side of the wound opposite of the first site, wherein, upon application, the energy stored from stretching causes the first layer to retract along lines of tension towards a center or focal point of the lines of tension, thereby drawing the margins of the wound together to stabilize and compress the skin about the wound, not required in any other group.

Group II includes the special technical features [sheet material useable for wound care devices] or negative pressure wound therapy; formed from a woven or knit fabric comprised of fibers; [said cover layer] including a plurality of fibers extending from a bottom surface thereof; a binder, such as an acrylate adhesive, adjacent said bottom surface of said top layer, said fibers extending into said binder, whereby said binder adheres to said fibers along lengths of said fibers; and bottom layer of a gel [adhesive], such as silicone gel (preferably a heavy coat weight silicone gel) or a hydrogel; said adhesive being an adhesive which will bond to said gel adhesive to securely adhere said gel adhesive to said top layer, not required in any other group.

Common Technical Features

Groups I-II share the technical features of a wound care device comprising sheet material/cover layer useable for wound care devices that is stretchable and has an elastic memory; and a bottom layer of adhesive. However, these common technical features are anticipated by US 4,034,751 A to Hung. Hung describes a wound care device comprising sheet material/cover layer (polymeric sheet 33, FIG, 1, Abstract, col 5, ln 25-47) useable for wound care devices (col 8, ln 1-15) that is stretchable and has an elastic memory (col 2, ln 48-52; col 22, ln 4-10); and a bottom layer of adhesive (col 22, ln 4-5).

Accordingly, Groups I-II lack unity under PCT Rule 13.

**Note: Claims 7-21, 25-53 are unsearchable because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).