

ELASTIC WOUND COVER/SKIN CLOSURE MATERIAL AND ASSEMBLY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to US App. No. 63/498141 filed 25 April 2023, which is incorporated herein by reference.

5 BACKGROUND

[0002] This application relates to wound care, and in particular to a material which can be applied directly over a wound and periwound to be used as a wound dressing or a wound closure, over wound dressings to be used as a wound dressing cover, or to complement existing technology.

- 10 **[0003]** In US20230046036, which is incorporated herein by reference, we disclosed a wound care dressing cover comprised of a top fabric ply, a silicone gel layer below the top layer, and a release liner below the silicone gel layer. The silicone gel is adhered to the top fabric ply by a binder, such as an acrylate adhesive which bonds to the silicone gel and the release liner which is removably
- 15 adhered to the silicone gel by means of the natural adhesive property of the silicone gel. In a preferred embodiment, fibers extend from the underside of the top layer into the binder to further enhance the attachment of the silicone layer to the top layer.

SUMMARY

- 20 **[0004]** The wound dressing cover disclosed in the above-noted application works well. However, we have found that the selection of specialized materials and the order of assembly of the material can be improved upon. In particular, we have developed a new material which can be used for the top ply of the assembly. In one embodiment, the new material, which has high elastic memory in all planer
- 25 radial directions, has the ability for attachment of other materials (i.e., hook members and adhesives) to engage and/or adhere to itself, and which can be used to cover a wound or a wound dressing. In another embodiment, the new material can be used as a wound closure (e.g., to hold incisions closed), or a combination of all three (i.e., as a wound cover, a wound dressing, and a wound closure).

[0005] Briefly stated, an elastic, flexible, conformable material is disclosed which comprises a top layer and an adherent layer. The top layer comprises a base material, an upper pile extending from an upper surface of the base material, and a lower pile extending from a lower surface of the base material, with the base material being flexible and stretchable. The adherent layer comprises a silicone gel which is operatively bound to the lower pile by a binder; the binder being selected to be a binder which will bond to the silicone gel.

[0006] The material can include a reinforcing layer between the top layer and the silicone gel layer. The reinforcing layer is preferably formed from a polyurethane film or a polyethylene film and is secured to the top layer by a second binder. The binder of the adherent layer binds the silicone gel layer to a lower surface of the reinforcing layer. Preferably, the reinforcing layer is coextensive with the top layer.

[0007] In accordance with an aspect of the material, the material can be provided with a plurality of perforations or holes extending through at least the silicone gel and the reinforcing layer (if present). The perforations can have diameters between about 0.5mm - 3mm, preferably about 1mm-2.8mm, and preferably about 2mm; and wherein the perforations are preferably spaced on center apart by about 3-8mm, and preferably by about 5mm. The perforations can be arranged in rows, wherein the rows are spaced apart by about 3-8mm, and preferably by about 5mm. The perforations of the rows can be arranged in columns or the perforations of one row can be offset relative to the perforations of an adjacent row.

[0008] In accordance with an aspect of the material, the upper pile and the lower pile each comprise loops or fibers extending from the upper and lower surface, respectively, of the base material.

[0009] In accordance with an aspect of the material, the base material is composed of natural fibers, or man-made/synthetic fibers, such as nylon, Spandex, Lycra, carbon fibers, expanded polytetrafluoroethylene (i.e., Gore-Tex®), polyurethane, polyethylene, and combinations thereof. If the base material is made from, or includes, nylon, the nylon can comprise 50/17 SD nylon and/or 20/1 SD Nylon. For example, the base material can have a composition of, but not limited

to, about 69% of 50/17 SD nylon and about 21% 20/1 SD Nylon, and about 10% 40 denier Spandex. Preferably, the upper and lower piles have the same composition as the base material.

[0010] In accordance with an aspect of the material, the adherent layer can include antimicrobial and/or antibacterial agents such that these agents can be applied to and around an incision or wound by application of device formed from the material.

[0011] In accordance with an aspect of the material, the adherent layer can comprise a series of dots, lines or patterns defining regions with coatings of adhesive of equal or different coat weights and tack.

[0012] In accordance with an aspect of the material, the material, in use, will generate a triboelectric static charge and/or an electromagnetic field when worn. The electrostatic or electromagnetic field is created by induction, and affected by friction and conduction between the material and the wearer. In a device formed from the material, the silicone gel layer is neutral or near neutral in static charge; and the upper pile is capable of creating and accumulating in a device formed from the material and transferring the static charge so formed to the wound site. The pattern of the adherent layer, and in particular pattern of the silicone gel can affect the flow pattern of the static charge to the wound sound. The silicone gel is neutral (i.e., has virtually no charge), and when applied to the top layer, acts as an insulator. When a device made from the material is applied to the skin, which has its own electrical charge/field, the static charge of the device again changes when it comes in contact with the wearer. The charges want to balance, but continually vary as the environment and the wearer's electrical charges change, producing the induction of the above-noted electrical charge.

[0013] In accordance with an aspect of the material, the material can be part of an assembly which includes a release liner removably adhered to the adherent layer of the material.

[0014] In accordance with an aspect of the material, the material has an elastic memory after being elongated, such that upon removal from a surface, the material

will revert substantially back to its original shape and such that the material can be applied to a protective sheet, such as a release liner.

[0015] In accordance with an aspect of the material, the material can include two or more layers above the adherent layer.

- 5 **[0016]** In accordance with an aspect of the material, the material can be transparent to ultrasound energy, whereby the material is adapted for use with ultrasound technology.

[0017] In accordance with an aspect of the material, the silicone gel layer, the binder layer, and the top layer all move collinearly when the material is stretched.

- 10 **[0018]** In accordance with an aspect of the material, the material, or a device formed from the material, can be formed by 3D printing.

[0019] A device formed from the material is also disclosed. The device can be a wound cover or wound closure, a protective barrier, a wound dressing cover, a compression wrap, a wearable anchor point, a barrier, or an insulator.

- 15 **[0020]** In accordance with an aspect of the device, the device can be worn at for at least one day, preferably for at least 3 days, preferably at least one week, or preferably at least two weeks.

- [0021]** In accordance with an aspect of the device, the device can be stretched, elongated, and applied between at least two points on a surface, such as a patient's
20 skin, to apply a desired amount of tension/compression to margins of the incision/wound and periwound.

- [0022]** In accordance with an aspect of the device, wherein when the device is a wrap; wherein adhesive layer of a first portion of the wrap will engage with the upper pile of a second portion of the wrap, such that the wrap will connect to itself,
25 whereby, the wrap can be applied without the need for external connectors, snaps, etc.

[0023] In accordance with an aspect of the device, the device is designed to be elongated and applied to a patient.

[0024] In accordance with an aspect of the device, the device can be provided with include graduated markings which provide an indication of the amount of elongation of the material when the material of the device is stretched.

[0025] In accordance with an aspect of the device, when worn, the electrostatic charge from the material of the device charges the surface of the stratum corneum (the top layer of the skin) beneath the device and in the perimeter around the material of the device when positioned on the stratum corneum.

[0026] A tensioning assembly for use with the device is also disclosed. The tensioning assembly comprises a tensioning member selectively adherable to the upper pile of the device. The tensioning member comprises (1) an elongate elastic flexible, elastic strip and (2) a pair of non-stretchable pads secured to bottom surfaces of opposite ends of the elastic strip. The pads each have a bottom surface having hooks extending therefrom. The pads can be made from medical grade hook material. The hooks of the pads are sized and shaped to engage and grip the upper pile of the material, whereby, by securing a first end of the tensioning member to the material at a selected anchor point on the material, stretching the tensioning member, and securing a second end of the tensioning member to a second anchor point on the material spaced from the first anchor point a distance greater than the length of the tensioning member prior to stretching of the tensioning member, the tensioning member will exert a desired amount of compressive forces to the material and the surface underlying the material. When used, the tensioning member provides variable compression to tissue below the skin to which the device has been applied. Lastly, the elongate strip of the tensioning member is elastic and has elastic memory, whereby attachment of the tensioner to the device allows for adjustable tension/compression to a selected area of the material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] FIG. 1A is a schematic perspective sectional view of a preferred embodiment of a flexible material assembly;

- [0028]** FIG. 1B is an enlarged fragmentary schematic sectional view of the flexible material assembly taken at the circle B of FIG. 1A, but with an added reinforcing layer;
- [0029]** FIG. 1C is an enlarged schematic fragmentary cross-sectional view of the flexible material assembly similar to FIG. 1B, taken at the circle 1C of FIG. 1B, but with a release liner removed from the material;
- [0030]** FIG. 1D is a photomicrograph of a cross-section of the material assembly of FIG 1A;
- [0031]** FIGS. 1E and 1F are schematic drawings of the material assembly with (FIG. 1F) and without (FIG. 1D) the reinforcing layer, showing the various layers/components of the material assembly;
- [0032]** FIG. 2A is a schematic plan view of a device formed from the material assembly having a central portion surrounded by an adhesive free boarder, and a plurality of holes or pores in the adherent layer and reinforcing layer.
- [0033]** FIG. 2B is a schematic cross-sectional view of the device of FIG. 2A
- [0034]** FIG. 3A is a schematic cross-sectional view of a strip of the flexible material formed into a wrap, demonstrating the material adhering to itself;
- [0035]** FIG. 3B is an enlarged view of FIG. 2A taken along the Circle 2B of FIG. 2A;
- [0036]** FIG. 3C is a photomicrograph of the material adhering to itself taken at the circle 2B in FIG. 2A;
- [0037]** FIG. 4A is a plan view of a flexible tensioning member for use with the flexible material; and
- [0038]** FIG. 4B is a side view of the tensioning member.
- [0039]** Corresponding reference numerals will be used throughout the several figures of the drawings.

DETAILED DESCRIPTION

- [0040]** 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
- 5 embodiments, adaptations, variations, alternatives and uses of the claimed invention, including what is presently believed to be 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.
- 10 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.
- [0041]** A flexible material assembly 10 usable, for example, as a wound cover, wound dressing, wound dressing cover, or pressure wrap is illustratively shown in
- 15 FIGS. 1A-C, E, and F. As described below, the material assembly 10 comprises a flexible material 12 having an adhesive lower surface and a release liner 14 which is removably adhered to the lower surface of the material 12. The material 12 is preferably elastic and stretchable in all directions. Like the material shown and
- 20 described in our US Pub. No. 20230046036, the material 12 can be used to close a wound or can be applied directly over/above the wound or periwound, to the wound or periwound, or over a wound dressing. However, as described below, the material disclosed herein has additional functionality. In particular, the material may be utilized as a stand-alone or as a complement to traditional closure methods.
- 25 **[0042]** The flexible material assembly 10 (FIGS. 1A,B) is a multi-ply assembly comprising the flexible material 12 and the release liner 14 removably secured to the lower surface of the flexible material 12. As described below, the flexible material 12 can be used to close a wound or can be applied over and/or adjacent
- 30 a wound (i.e., over the periwound) or over a wound dressing (and thus can be used as a wound cover) or can be used to wrap, for example, a joint or limb or portion of a torso. The material 12 is flexible and is elastic such that it can be elongated

along at least one axis. Preferably, the flexible material 12 is elastically stretchable in multiple axes, and is thus elastically stretchable in any direction and tends to return to its natural state due to memory in the material when released from an elongated condition.

5 **[0043]** The flexible material 12 comprises a top layer 16 (which is described in more detail below) and an adherent layer 18 having viscoelastic properties. The top layer 16 may hereafter be referred to as the top ply or cover ply 16. The release liner (or bottom ply) 14 is removably attached to the viscoelastic adherent layer 18 to protect the adherent layer until the flexible material 12 is deployed, for example,
10 to cover a wound or wound dressing, or to be used as wound closure or as a wrap (including a compression wrap). When the release liner 14 is removed, the viscoelastic adherent layer 18 will affix to, and as described below, will conform to and removably adhere the material 12 to a surface, such as a patient's skin, such that the material can be removed from the surface (e.g., skin). Because the top
15 layer 16 and the adherent layer 18 are highly flexible and conformable, the viscoelastic properties enhance the adhesion of the material to the skin.

[0044] In one embodiment of the material 12, the top layer 16 comprises a base material 16a which, in a preferred embodiment, is formed from a knit material, a woven material, or a tricot material. The material which forms the base material
20 16a can comprise man-made fibers, natural fibers, or a combination thereof. Preferably, the base material 16a is formed from a combination of fibers, at least a portion of which are elastic fibers, such as spandex (a polyether-polyurea copolymer), such as, for example, Lycra®. If formed from a combination of fibers, the elastic fibers can be combined, intertwined, or formed with, for example, natural
25 fibers, such as cotton fibers, or man-made fibers, such as Nylon or Spandex, to form the thread or yarn from which the material for the top layer 16 is formed. The elastic fibers provide the stretchability and elasticity, as described above, of the top layer 16. The base material can, for example, be about 5% to about 95% Nylon and about 95% to about 5% Spandex. In a preferred embodiment, the base
30 material is about 90% Nylon and about 10% Spandex. Illustratively, the nylon can be SD Nylon and the Spandex can be 40 Denier Spandex. Further, the material can comprise different types of Nylon, such as "50/17 SD" Nylon and "20/1 SD"

Nylon. The two types of nylon can be combined in ratios of about 4:1 "50/17 SD" Nylon:"20/1 SD" Nylon to about 1:4 "50/17 SD" Nylon:"20/1 SD" Nylon, and preferably about 3.2:1 "50/17 SD" Nylon:"20/1 SD" Nylon. In a preferred embodiment, the material comprises about 69% "50/17 SD" nylon, about 21% "20/1 SD" nylon, and about 10% 40 denier Spandex®. In this embodiment (i.e., containing nylon), the material 12 may not be opaque; however, it may not be clear enough to visualize a wound when the wound is covered by the material 12. Further, in this embodiment, the base material 16a is composed of all inorganic material, and in particular materials which are generally inert and generally biocompatible. Fibers other than Nylon and spandex can be used. For example, the stretchable (spandex) component of the flexible material could comprise silicone and/or natural rubber; and the nylon could be replaced with polyethylene and/or polyurethane. The base material can be made of other types of natural fibers or man-made/industry-made fibers (or combinations thereof). For example, the other man-made/industry-made fibers can include carbon fibers, expanded polytetrafluoroethylene (commonly known by the brand name, Gore-Tex®), or other synthetic and/or conductive fibers. The top layer 16 can be made, as noted above, by weaving or knitting the fabric top layer. If the top layer is made from man-made materials, the top layer can be formed by 3D printing.

[0045] The top layer 16 further comprises an upper pile 16b and a lower pile 16c, each comprised of fibers, napping, or loops which extend from the upper and lower surfaces, respectively, of the base material 16a to define upper and lower napped or plush surfaces 16b,c of the top layer 16. The upper and lower piles 16b,c can be formed by brushing or abrading the surfaces of the base material 16a. As such, the upper and lower piles 16b,c have the same composition as the base material 16a. The upper and lower fibers/pile/napping 16b,c, depending on how they are formed, can be straight, curved, twisted, etc. Further, the piles 16b,c may not be uniformly shaped. The lower pile 16c extending from the bottom of the base material 16a greatly increases the surface area of the bottom of the top layer 16 as compared to a "smooth" (i.e., un-napped) material. The fibers 16b are formed to have a density of about 6.44 oz/yd² to 7.12 oz/yd² and preferably about 6.78 oz/yd².

[0046] The material from which the top layer is formed is absorbent. In particular, the material can absorb fluids, such as exudate, blood, etc. which may leak or ooze from a wound. The top layer 16, whether brushed or unbrushed, also enhances fluid wicking. The upper and lower pile 16b,c increases the absorbency of the top layer 16, as the upper and lower pile create areas which can trap the fluids which may leak or ooze from a wound.

[0047] In a preferred embodiment, the top layer 16 can have the following qualities/properties (individually or in combination):

- 10 • The top layer 16 (or main substrate) defines a thin and breathable membrane, capable of being elongated and stretched. Elongating the top layer material adds energy into the material. This energy provides compressive forces to the patient's wound and periwound when the material is used as a wound cover, wound dressing, or wound closure.
- 15 • The substrate or membrane is a semi-occlusive material, and thus protects the skin against moisture loss. This allows for an optimal healing environment to the epidermal layer below the device after the material has been placed on the patient.
- 20 • The top layer 16, inclusive of the base layer 16a and the upper and lower fibers 16b,c can have a base weight of about 6.78 to about 7.12 oz./yd² (+/- 5%) as determined in accordance with ASTM D3776.
- The top layer 16 has an elongation (as determined by a stretch test performed on a CRE Tester (Zwick) 3rd Cycle ASTM D4964:
 - warp stretch: about 47-67% and preferably about 57% and
 - side (or weft) stretch about 40-60% and preferably about 50%
- 25 • The top layer stretchable has an elastic memory. Thus, when released from a stretched or elongated position, it will tend to revert to its relaxed position.

- The upper pile 16b and/or lower pile 16c can be formed as 3-bar nap UBL (unbroken loop).
- The top layer 16 is die-cuttable, printable, and has excellent converting properties (i.e., it is easily formed into assemblies with other plies)
- 5 • The top layer 16 can be sterilized, such as by autoclaving, using ethylene oxide (EtO, (CH₂)₂O), or electron-beam radiation (using gas or photon exposure)
- The top layer 16 is inert and thus resistant to bacteria growth.
- The top layer 16 is gas and vapor permeable.
- 10 • The top layer 16 is highly flexible and thus will conform to the shape of the surface (i.e., the patient's skin) to which it is applied.
- The top layer 16 is preferably seamless.
- Acrylates, acrylics and/or other adhesives will adhere to the top side of the brushed or abraded surface of the top layer 16 enabling a bond
- 15 between the nylon and the adhesive(s).

[0048] The adherent layer 18, as noted, is secured to the bottom surface of the top layer 16, and in particular, to the bottom pile 16c. The adherent layer comprises at least an adherent 18a which adheres to, but does not aggressively bond to, skin and is gentle on the skin during long term wear as well as during removal. Thus,

20 the material 12 is removably attached to a patient's skin, and damage to the skin during removal of the material 12 is minimized by the use of the silicone gel adhesive. The silicone gel is near normal in static charge. The adherent 18a is preferably a silicone gel or a hydrogel adhesive, and has viscoelastic and/or high co-adhesive properties. It can be applied to the bottom surface of the material 16

25 at a heavy (high) coat weight thickness of about 100-350 g/m², and preferably about 250 g/m² (~7.3 oz/yd²). Such adhesives are typically composed of a very lightly cross-linked silicone elastomer whose polymer network has been swollen with silicone fluids. The silicone gel 18a has elastic characteristics, is stretchable

in any direction, and will elongate with the top layer 16. That is, as the silicone gel elongates, the silicone gel layer becomes thinner. The thinning of the silicone gel layer is constant, and thus, the silicone gel layer does not get thinner in just one area, but rather thins uniformly. The same is true for the top layer 16. Thus, the
5 silicone gel layer is collinear with the top layer 16, and remains collinear with the top layer 16 as the material 12 is stretched.

[0049] Because the top layer 16 and the adherent layer 18 (inclusive of the gel silicone gel layer 18b) are highly flexible and conformable, the viscoelastic properties of the silicone layer enhance the adhesion of the material to the skin.

10 **[0050]** If desired, the adherent (silicone gel) 18a can be coated and/or include, contain, or be impregnated with, an integrated medicant (such as an antimicrobial, an anti-bacterial agent, and/or an anti-fungal agent).

[0051] The adherent (silicone gel) layer 18a (FIG 1A) can be applied directly to the lower surface of the top layer 16. However, the adherent layer 18 preferably
15 includes a binder 18b that helps secure the adherent 18a to the bottom surface of the top ply 16 (i.e., to the lower pile 16c). The binder 18b can be, for example, an acrylic or acrylate adhesive which will bond to the adherent 18a and which will secure the adherent 18a to the cover layer 16. The binder 18b is covered by the adherent 18a, such that the acrylate adhesive binder 18b will not come into contact
20 with the patient's skin during use. The binder 18b (which bonds to the silicone) will adhere to the lower pile 16c. Stated differently, the lower pile 16c will extend into the binder 18b, as shown schematically by the shading in FIG. 1E, and as shown in a photomicrograph in FIG. 1D.

[0052] FIG. 1B shows a variant of the material 12 in which it is provided with a
25 reinforcing layer 19 between the lower pile 16c and the adherent layer 18. The reinforcing layer 19 can be adhered to the lower pile 16c by means of an adhesive 19a, such as an acrylate binder, applied to the top side of the reinforcing layer 19. The reinforcing layer 19 will be adhered to the silicone gel 18a of the adherent layer 18 either directly (or preferably) with the acrylate binder 18b on the bottom side of
30 the reinforcing layer (as seen in FIGS. 1B,F). The acrylate binder 19a can be the same as the acrylate binder 118b. In this instance, the reinforcing layer 19 is

adhered to the lower pile 16c by means of the acrylate binder 19a and to the silicone gel 18a by means of the acrylate binder 18b. The reinforcing layer 19 is preferably coextensive with at least the adherent layer 18, and more preferably coextensive with the top layer 16. This reinforcing layer 19 can be made from a polyurethane film or a polyethylene film and can add some slight rigidity to the material 12, which will make the material less “floppy” and a bit easier to handle, especially when wearing gloves. Although the reinforcing agent will add some rigidity to the material 12, the reinforcing layer 19 is stretchable, and preferably, elastic, in all directions, such that use of the reinforcing layer 19 will not diminish the stretchability or elasticity of the material 12, as described above.

[0053] The acrylate binder 18b (for the embodiment of FIG. 1A) or 19a (for the embodiment of FIG. 1B) is adhered to the surfaces of the lower pile 16c, and not just a smooth undersurface of the base material 16a, thus increasing contact surface area between the acrylate binder 18b/19a and the lower pile fibers 16c. In the material 12 of Fig. 1A, the acrylate binder 18b bonds the silicone gel 18a to the lower pile 16c; and in the material 12 of FIG. 1B, the acrylate binder 18b binds the silicone gel 18a to the reinforcing layer 19 and the acrylate binder 19a binds the reinforcing layer 19 to the lower pile 16c. The increased contact area generated by the engagement of the acrylate binder 18b/19a with the lower pile 16c significantly reduces the likelihood that the silicone gel adherent 18a will separate the top ply 16. In fact, this feature of the material (as shown in FIGS. 1A and E) has withstood repeated washings without significant loss of function. That is, even after multiple washings, the material 12 maintains its adhesion, tack, flexibility, and elastic memory, and continues to adhere well to skin and to function, for example, as a wound care device (i.e., as a closure and/or a cover).

[0054] In one embodiment, the adherent layer 18 can substantially cover the entire lower surface of the top layer 16. This embodiment can include the reinforcing layer 19 or the reinforcing layer can be absent. If the reinforcing layer is present, then the adherent layer 18 covers the entire lower surface of the reinforcing layer 19. In an alternative embodiment, the adherent layer 18 can comprise a series of dots, lines or patterns containing regions with coatings of equal or different coat weights and tack. This embodiment provides areas which

are free of the adherent layer. The change in coat weights allows for variations in lateral friction and the accumulation of sheer forces by the material when worn, as described in our above noted US Pub No. 20230046036. The thicker the coat weight of the adherent layer, the more sheer forces are absorbed. Also, an
5 adherent layer having a thicker coat weight will protect the patient from unwanted and potentially damaging vertical compression and sheer forces. In another alternative, the adherent 18 can be applied to the lower surface of the top layer 16 or the reinforcing layer 19 (if present) to define one or more areas which are devoid of adherent 18.

10 **[0055]** Although the material 12 is shown and described with a single ply top layer 16, the material 12 could be provided with two or more plies 16 above the adherent layer 18 or reinforcing layer 19. The additional ply or plies could be formed of the same material as the base layer 16a, or could be made from other materials. For example, the first layer above the adherent layer (or reinforcing
15 layer) could be made from the same material as the base layer 16. The second layer, and any successive layers, could be made from a different polymeric material, natural fibers, or a combination thereof. Further the second, third, etc. layers could be woven, knit, tri-cot, or even 3D printed. Additionally, these additional layers could be selected to enhance the performance, characteristics,
20 and/or functionality of the material 12. Preferably, at least the top layer will have upper pile 16b. If all the layers have both upper and lower pile, then the napping of adjacent layers will engage to help hold the layers together. To ensure that the layers do not separate, an adhesive, such as an acrylate binder, is used between adjacent layers which will then bind to the fibers of the adjacent layers.

25 **[0056]** As shown in FIGS. 2A,B, the material 12 can be provided with holes or perforations 26 which pass through at least the adherent layer 18 (including the silicone gel 18a), the reinforcing layer 19 (if provided), and the binder(s) 18b and 19a. If desired, the holes can also pass through the top layer 16. As seen in FIG. 2A, the holes/perforations can be formed in an array which covers the entirety of a
30 device formed from the material 12. The holes, for example, can have diameters between about 0.5mm - 3mm, preferably about 1mm - 2.8mm, and preferably about 2mm. The centers of the holes 26 are spaced apart by about 3 - 8mm, and

preferably by about 5mm. The holes 26 can be formed in an array with the holes of one row offset from the holes of the adjacent rows. Alternatively, the holes of all the rows can be aligned, to define columns of the array. In an alternative embodiment, the perforations can be provided in a desired pattern. When provided
5 with such holes or perforations, the breathability of the material is significantly enhanced. Further, the perforated material has a very high moisture transmission rate, and exudate, blood, and other fluids that may be emitted by the wound, will readily pass through adherent layer 18 and reinforcing layer 19 to be absorbed by the top layer 16 by capillary action. The perforated material will thus help maintain
10 these fluids away from the wound, to further facilitate healing of the wound. Further, we have found that when provided with perforations, a device made from the material is cooler to wear than a similar device that lacks perforations. This benefit is believed to be due to the increased breathability from the perforations. This adds to the comfort provided by a device formed from the material.

15 **[0057]** The release liner 14 is preferably made from a generally non-stretchable material, which can be transparent or opaque; and is held to the adherent 18 by the natural adhesive qualities of the silicone adherent 18a. The adhesive force of the silicone gel 18a is substantially less than the adhesive force of the binder 18b, and thus, removal of the release liner 14 from the silicone gel 18a will not pull the
20 silicone gel 18a from the top layer 16 (or reinforcing layer 19). The material for the release liner 14 or coating is chosen by design to be a material which has low adhesion force with respect to the silicone gel 18a. As seen, the release liner 14 does not directly contact the top layer 16 or the reinforcing layer 19. Thus, the release liner 14 is removably adhered to the bottom of the material 12 by the
25 silicone adherent layer 18. The release liner 14 could have a coating, for example, of fluorosilicone applied to the side of the release liner which is in contact with the silicone gel 18a. This will facilitate removal of the release liner 14 from the material 12. Additionally, the release liner could be slit or perforated and/or extend beyond the perimeter of the material 12 for ease of removal and parking a device when not
30 in use.

Manufacture and Use of the Material Assembly

- [0058]** For purposes of manufacturing the material assembly 10, the flexible material 12 (comprised of the cover/top layer 16, the adherent layer 18, and optional reinforcing layer 19) can be provided as a sheet assembly or in a roll form which is then combined with the release liner 14. The material 12 is more stretchable than the release liner 14. Thus, the release liner 14 will substantially stabilize the material 12 enabling the converting process. The release liner 14 can be coextensive with the material 16. In this instance, to facilitate removal of the release liner from the material 12, the release liner can be provided with tabs. Alternatively, the release liner can be perforated, such that as the material 12 can be stretched, the release liner will peel and detach from the material 12. Alternatively, the release liner 14 can extend beyond one or more edges of the material 12 to define a gripping area to facilitate removal of the release liner from the material 12.
- [0059]** In production, a single multi-ply sheet is formed by positioning the cover layer 16, the optional reinforcing layer 19, and the adherent layer 18 on the release liner 14 to removably adhere the release liner 14 to the silicone gel 18a of the adherent layer 18. The application of the release liner 14 to the flexible material 12 can be accomplished by any desired technology. The material assembly 10 can then be cut to the desired shape (as discussed above), such as by die cutting, or formed into strips which can then be formed into a roll.
- [0060]** In an alternative, the adherent layer 18 (with its binder) can be positioned over the release liner 14. The (optional) reinforcing layer 19 (with its binder) can be applied over the adherent layer 18. At this point, the holes/perforations 26 (if desired) can be formed, by punching holes through the release liner 14, adherent layer 18, and (optional) reinforcing layer 16. The cover layer 16 is then applied over the adherent layer 18 (or, if present, the reinforcing layer 19). The various layers can be laminated, one over the other. This process can be carried out on a system of rollers and conveyors, with the resultant material assembly 10 being rolled onto a collection roller.

[0061] Alternatively, the material assembly 10 can be 3-D printed. In this last instance, a 3D printer can print the silicone adherent layer 18a, the binder 18b, the optional reinforcing layer 19, the lower pile 16c, the base material 16a, and the upper pile 16b all to a specifically designed configuration as may be necessary for a particular wound. This would be beneficial when a non-standard size device is required, or the required device has a configuration that is difficult to cut from standard sized device. This would also allow for a practitioner to design the shape of the device needed for a particular application, and 3D print the material 12 including adherent layer 18 (including the silicone gel and binder), the (optional) reinforcing layer 19 and associated binder 19a, and the upper layer 16 (including the lower pile 16c, the base material 16a, and the upper pile 16b). The material 12 can be printed on a piece of the release liner material, or the release liner 14 can be 3D printed with the material 12.

[0062] The flexible material 12 is highly conformable, and thus can conform to the 3-dimensional shape of most any contoured surface. Its light weight (13.3-15.3 oz/yd²) in combination with a high degree of conformability allows a device formed from the material 12 (such as a wound cover/closure) to be worn for an extended period of time (i.e., several days, one week, two weeks, or longer). The silicone gel 18a enables such a device to be removed and reapplied with minimal to no damage to the wound or wound site. Thus, the device formed from the material 12 can be repositioned if the need arises. Further, the device formed from the material 12 can be removed, washed, and then reapplied without loss of its tackiness and function. To better ensure that the device formed from the material 12 can be reapplied, the surface (i.e., the patient's skin) to which the device is applied should be dried and cleaned prior to reapplication of the device so that the skin is free of lotions, oils, creams, and powder which can impact the device's tackiness. Alternatively, if the material 12 is not to be immediately reapplied, the material 12 can be placed back on the release liner 14, and then the release liner will protect the adherent layer 18 until the material 12 is reapplied. To facilitate reapplication, or returning, of the material 12 to the release liner, the release liner preferably is slightly larger (has a greater periphery) than the material 12. This slightly larger release liner also facilitates separation of the release liner from the material 12. To facilitate removal of the release liner and to aid in the material positioning, the

assembly 10 can be provided with tabs, as described in our Pat. No. 9427222, which is incorporated herein by reference.

[0063] The adhesive surface of the material 12 (i.e., the silicone gel adherent 18a) can be cleaned, for example, using a mild soap and water which will reinstitute
5 or reinstate the original tackiness of the silicone gel adherent. The device formed from the material has the ability to provide tension and controlled compression, as a continuous and even compressive force.

[0064] The material 12 can be made in different colors or levels of opacity. In one example, the top ply 16 can be formed to be clear or transparent. Here, it is
10 noted that the adherent layer 18 is itself clear or transparent. The surface of this material can be treated to affect protection of the skin from temperature extremes and pH variations. The top layer 16 of the material can be constructed or treated with a fire retardant or other coatings. Additionally, components/compounds can be included in the solution/resin from which the material 16 is made which can
15 react under certain conditions (such as a change in pH, temperature, etc.) to enable monitoring of the healing of the wound. That is, the material, for example, changes color in response to a change in pH, that could be an adverse indication, indicating that, perhaps, some form of medicament is needed at the wound site.

[0065] Further, the material 12 can generate a charge of static electricity on the
20 material 12. During use, the extent of this static charge may fluctuate. The construction of the top layer 16 provides the elements needed to create the triboelectric static charge which originates and accumulates in the top layer 16, and is transferred to the wearer. Static charge may be enhanced by the brushing which forms the pile 16a. Further, the material 12 acts as an electron accumulator as the
25 static electrical charge is accumulated in the top layer 16 of the material. The static charge in the top layer is believed to be constantly changing, and it is believed that the change in the static electrical charge will affect changes in the pH of the skin by an ionization process. The relationship of the static charge and its relation through ionization to the change in the pH of the skin are directly proportional. It is
30 believed that this change in pH due to the changes in the static charge promote healing by increasing oxygenation at the wound site. Additionally, the change in

static electrical charge may boost the immune system and may increase pathway communication between cells

[0066] The material 12 can also be transparent to ultraviolet (UV) light or radiation as well as to sonic energy. Thus, a device made from the material 12 would not need to be removed for UV radiation therapy/treatment or for ultrasonic examination. In an alternative, the material 12 could be designed to filter out UV or other undesired frequencies or wave lengths.

[0067] In other variations, the flexible material 12:

- is suitable for long term wear (i.e., at least for 3 days or at least one week or at least two weeks, or a month or more).
- is reusable and multi-configurable.
- can be provided with sensors and indicators, such as gas sensors, temperature sensors, pressure sensors, moisture sensors, sensors to detect physiological data, or any combination of the foregoing. Such sensors can be in the form of nanotechnology sensors, spectrophotometric, chemical, thermal, and/or electrical.
- The upper and lower pile 16b,c of the top layer 16 provides a number of advantages, whether the top layer material is used by itself, or as part of an assembly, as shown in FIGS. 1A,B.

20 APPLICATION OF DEVICES FORMED FROM THE MATERIAL

[0068] Prior to application, a device formed from the flexible material 12 (which is planar when lying on a flat surface) is elongated to energize the material. When the (elongated) flexible material 12 is applied directly over a wound, the material 12, due to its elasticity, is placed in tension. Applying the (elongated) material 12 to the superior and inferior aspects of the wound simultaneously approximates the margins at the moment of release of the material, closing the wound, and adds linear compression to the wound due to the elasticity of the material. Additionally, applying the material to the superior aspect of the incision creates an anchor.

Elongating the material, after anchoring it to (or adjacent) the superior aspect of the incision, and applying it to the inferior aspect of the incision creates a second anchor point for the material which upon release of the material approximates the margins of the wound together thereby resulting in the closing of the incision in a linear fashion.

[0069] In an alternative way of applying the material 12 to a wound or incision, the material is first elongated to be placed in tension and then applied in tension simultaneously to the inferior and superior aspects of the incision. This provides linear compression to the incision. Because a device formed from the material can be removed and reapplied, these applications allow for readjustment and alignment of wound margins to accomplish customized compression by manipulating the material to achieve the desired closure.

[0070] In yet a further application method, a device formed from the material can be applied statically to or over the wound (i.e., in a relaxed state without being elongated). In this application, the device will operate as a wound cover, bandage cover, or wound closure. However, it will not apply forces to the wound to actively close the wound.

[0071] The material, when applied, stabilizes the wound and the periwound, enhancing exudation and oxygenation of the wound, while reducing unwanted tension and relieving pressure on the wound and periwound thereby improving blood flow to the wound, and reducing pain. If the material 12 is perforated, as discussed above, the material will allow compression to the wound (when applied as a wrap) while the wound is exudating or bleeding. In this instance, any seepage from the wound would pass through the material to the upper surface of the material, and could be removed and cleaned.

USES AND DEVICES FORMED FROM THE MATERIAL

[0072] In one manner of use, the material assembly 10 can be shaped and sized to form a device which can be used as a wound cover, wound closure, or wound dressing cover, in a manner similar to the device disclosed in our above noted US20230046036, which is incorporated herein by reference. In such a device, the

material 12 can be formed in any desired peripheral shape, with the release liner 14 being at least coextensive with the flexible material 12. That is, the peripheral edge(s) of the material assembly 10 can define a circle, oval, rectangle, square, crescent, X-shape, or other desired (regular or irregular) shape, or combination of shapes. Further, the material assembly can be cut to a desired size or dimension. When such a wound or dressing cover formed from the material assembly 10 is applied to a patient to help hold a wound closed (or to prevent separation of wound edges), the undesired shear forces applied by retracted excess tissue around the wound are transferred to the wound cover.

10 **[0073]** If the flexible material 12 is to be used as a wound cover, a wound dressing cover, a wound closure, or a combination thereof, then the material assembly 10 can be provided as pads formed in distinct sizes that are, for example, rectangular or square (i.e., 1"x2", 2"x2", 2"x4", 4"x4", 4"x8", etc. or that are round, oval, or any other desired shape. The pads could be positioned and connected and/or assembled to form anchor sites. These anchor sites allow the distinct panels of the material to be interconnected one to another device or another anchor. This allows a methodology of covering wounds that are intended to be left open, such as healing delayed wounds or for secondary intention healing .

[0074] An illustrative device 20 comprised of the material 12 is shown in FIGS. 20 2A,B. This device 20 comprises a pad or central area 22 formed from the material 12 with perforations 26 extending through the adherent layer 18 and the reinforcing layer 19. The pad 22 is then surrounded by a non-perforated border or frame 24. In this device, there are multiple options as to where the adhesive can be applied to enable the device to adhere to skin. For example, the central area can have an adhesive layer, and the frame 24 can be adhesive free. Alternatively, the central area 22 can be adhesive free, and the frame 24 can have an adhesive layer. Finally, both the central area and the frame can be provided with an adhesive layer. In this device, the top layer 16 is covered by an absorbent material 28, such as gauze, cotton, or the like. A film 30, made for example, from polyethylene or polyurethane, then covers the gauze 28 and extends out from the pad 22 to form the boarder 24. The absorbent material 28 can be secured to the top cover 16 in part by the interaction to the top pile 16b with the absorbent material 28. The film

30 can be provided with an adhesive, such as a silicone or acrylate, which can be positioned only over the absorbent material 28 (to facilitate adhering the film to the central pad 20), only over the border area 24, or over the full extent of the film 30. Preferably, the border area 24 is provided with adhesive. In use, the device 20
5 can be adhered to a first anchor point on a patient (or initially stretched and then adhered to the first anchor point) on one side of a wound or incision, and then further stretched from that first anchor point in any desired direction to be adhered at a second anchor point on the patient at another side of the wound or incision. Because the border 24 fully surrounds the central area 22, the device can be
10 stretched in several different axes, as may be necessary. As can be appreciated, in the device 20 of FIGS. 2A,B, the absorbent material will absorb fluids which pass through the holes 26 and penetrate through the material 16.

[0075] In another example, the material assembly 10 can be shaped and sized to form a drape such as disclosed in our US Pat. No. 10849704, which is
15 incorporated herein by reference. The stretchability and elasticity of the material 12, comprised of a fabric, typically nylon, with stretchable fibers, such as Lycra®, and with an adherent layer 18 having a thick coat-weight copolymer, absorbs the sheer forces by accumulating the undesirable sheer forces in a gel (such as the silicone gel 18a) and transfers the energy to the base material 16a. If the sheer
20 forces accumulated in the gel exceed the designed limitations, the device formed from the material 12 will release or peel from the epidermis before injury can occur, limiting the sheer forces applied to the skin of the patient.

[0076] In a further example, the material assembly 10 can be provided to be used as a compression wrap 25. In this instance, a roll of the material assembly
25 12 can be provided having a width of, for example, 2" or 4" and a length of several (or more) feet, such that pieces or strips of the material assembly 10 of a desired length can be cut from the roll. In this latter example, a roll of the material assembly could also be used to provide wound closures of desired length. In this instance, the roll might have a width of ½", 1", or 2" in any desired lengths. If provided as a
30 roll, longer lengths of the flexible material 12 can be used as a compression wrap.

[0077] When used as a compression wrap 25, the flexible material 12 can adhere or secure to itself, as shown schematically in FIGS. 3A-B. Thus, for example, a desired length of the material 12 can be cut from the roll and used by itself to compression wrap an appendage. In this instance, a first portion or end E1 of the wrap 25 will overlie a second portion or end E2 of the wrap. The silicone gel 18a of the first portion E1 will engage and connect with the upper pile 16b of the top layer where a strip of the material 12 overlies itself (i.e., where portion E1 overlies portion E2). The fibers of the upper pile 16b of the lower portion E2 will extend into the silicone gel 18a of the first, upper portion E1 to hold the two portions of the material 12 together, and to thus hold the wrap in place about, for example, an appendage. FIG. 3C is a photomicrograph showing this connection or engagement of the overlying section E1 and the underlying section E2. As seen, the upper pile 16b of the underlying section E2 extends into, or otherwise adheres, to the lower surface of the silicone gel 18a of the overlying section E1 of the material.

[0078] When used as a compression wrap, the material 12 would be provided as a strip (as noted above) to be used to wrap, for example, a joint or limb, or it can be used to hold a dressing in place over a wound by wrapping about the dressing on a limb or torso. In this example, the material 12 can be used by itself to apply pressure to a wound or puncture, thereby applying a compressive force to the wound or puncture, all without the need for additional securing devices (i.e., hook and loop fasteners, pins, tape, ties, etc.). When used in this fashion (i.e., to wrap a limb, joint, or torso), the material 12 can be unwrapped, for example to inspect a wound, and then rewrapped. That is, the silicone gel layer 18a of the first, upper portion E1 can be separated from the upper fibers 16b of the second, lower portion E2 without affecting the functionality of either the silicone gel or the fibers of the upper pile 16b. As such, the material can be reapplied after it has been removed. Further, the material assembly 10 can be washed or sterilized repeatedly.

[0079] In these instances, a device formed from the material 12 can have the following properties:

- Memory and elasticity
 - long-term wearability.
- 5 • The device can be a wound dressing/closure device that is applied to, and/or around, a surgical incision or wound by straddling the incision or other wound types, i.e., punctures.
- 10 • When used as a closure, the device can typically be stretched or elongated perpendicularly to the incision thereby supplying compression to the margins of the wound.
- 15 • The device can be a wound dressing or wound closure device that contains an antimicrobial and/or antibacterial chemistry in the silicone gel adhesive.
- 20 • The device can be a wound dressing/closure device that provides continuous and even amounts of compression throughout the length of the incision/wound, as described in US20230046036, which is incorporated herein by reference. In particular, the stretchability of the top layer 16 is generally constant throughout the top layer 16. Thus, as long as there is no substantial variation in the thickness of adherent layer 18, the retraction force of the device formed from the material 12, and thus the compression force applied by the material 12 to the wound, will be substantially constant. The thickness (weight) of the adherent layer can be modified (or even be varied) to produce a different result.
- 25 • The device can be a wound dressing or wound closure device that can be left in place for extended periods of time.
- The device can be a wound dressing device that can be removed, cleaned and/or sterilized and reapplied.

- The device can be a wound dressing or wound closure device, which, when applied, will generate tension in the device to add compression to the tissue below and approximate the margins of the wound, as described in the aforementioned US20230046036.

- 5 • The device is adaptable and can conform to, can accommodate, and can be applied to any portion or area of the human anatomy.

[0080] In another example, the napped upper surface allows for attachment of certain devices or instruments to the material proximate the surgical site. For example, a device, such as a tensioner, can be used to secure instruments or
10 devices for tubing/lines, ostomy appliances, etc. to the upper pile 16b. Alternatively, a piece of the material can be adhered to a portion of the device, and the device can be held against the material by the interaction of the two pieces of material (similarly to a hook-and-loop (Velcro®) connection). In this latter instance, the upper pile of one portion of material will be pressed against the upper pile of a
15 second portion of the material. The upper piles 16b of the two portions will engage with and hold each other to hold the two pieces of material together.

[0081] In some instances, it may be desirable to enhance the forces generated by a wound cover, dressing, or closure device formed from the material 12 or to secure devices (such as, catheters, tubing, ports, etc.) to the wound cover,
20 dressing, or closure. In these instances, the device can be used with a tensioner 30, such as is shown schematically in FIGS. 4A,B. The tensioner 30 comprises a, typically, elongate (having a length longer than its width) and thin flexible elastic member 32 having upper and lower surfaces. A medical grade hook pad 34 is secured at each end of the elastic member 32. The medical grade hooks are
25 formed as hook members 34a on their bottom surfaces. These hook members are sized and shaped to engage and hold to the fibers of the upper pile 16b of the device formed from the material 12. The hook pads 34 can, for example, be sewn or bonded to the elastic member 32. The adjustable tensioner 30 thus comprises three portions, a central flexible, stretchable, elastic portion 30a having memory
30 and hook portions 30b on opposite ends of the central portion 30a.

[0082] The tensioner 30 is applied to a device formed from the material 12 by engaging the hook members 34a into the upper pile 16b of the material 12. When the hook member 34 is applied directly to the upper surface of the material 12, the hook members 34a will "grab" the upper pile 16b, such that the hook members will interlock with the upper pile 16b. As can be appreciated in the examples given, any point of the upper pile 16b of the material 12 can act as an anchor point for the hook pads 34 of the tensioner 30. By initially securing one end of the tensioner to the material 12, stretching the tensioner 30, and then securing the other end to the material 12 at an alternate location remote from the first end of the tensioner, the tensioner 30 will apply a controlled amount of compression to the site. In this use, the tensioner 30 is preferably applied to the device formed from the material 12 after the device has been applied to a patient. In this manner, the tensioner 30 can also be used to apply localized force to the surface of the material 16. Alternatively, the tensioner can be used to secure a device, such as tubing, to the material 12. In this instance, the tensioner 30 acts in the manner of a bracket to secure the tubing to the material 12. The tensioner 30 can be provided in different widths, lengths and forces. Further, the elastic material of the tensioner can be selected and adjusted to have a desired elasticity and elastic memory, such that the tensioner 30 will provide a desired effect to the localized site and the surrounding area.

[0083] In an alternative use, two separate devices formed from the material 12 can be adhered to the patient at distinct locations (such as opposite sides of a wound) to form anchor points for the tensioner 30. These anchor points are used to add compression by utilizing tensioners to engage the upper pile of the material. That is, tensioners 30 would extend between two discrete anchor points. Two anchors of various sizes and shapes can be added to and/or around the wound and connected via a tensioner member. This configuration will hold the tissue firmly in compression.

[0084] In another example, the material can be a device that can be used as a surgical stage/platform with an orifice through which the surgeon operates. The surgical wound site is held open via retractors anchored to the platform formed from the material 12. The platform is anchored to the patient, creating a seal. At

the same time, the device will also act as platform to anchor retractors and other equipment, in a manner as described above, to facilitate the procedure. That is, the device formed from the material can operate as a retractor and as a platform to which medical devices, such as cannulas, catheters, IV ports, etc., are secured.

5 BENEFITS FROM USE OF THE DEVICE

[0085] The application of devices made from the material creates a complete seal about the wound from moisture and protects from pH variation to all the tissue below it.

10 **[0086]** Devices made from the material 12 also enable manipulation of the relationship between the Trans Epidermal Water Loss (TEWL) and the moisture vapor transmission rate (MVTR) of the device, thereby keeping the proper amount of moisture below the device at the epidermis.

15 **[0087]** In other aspects, we have found that when a device formed from the material 12 is applied to a patient, an exchange of electrons take place, and either a slight static charge or a slight electromagnetic field is generated about the stratum corneum by induction (the outer layer of the epidermis) at the wound site and the device. When the material is worn, the human body generates low intensity electromagnetic fields, and that these electromagnetic fields can be measured, for example, with MEG (magnetoencephalography) and MCG (magnetocardiography)
20 devices, or even a simple electrostatic meter. The charge or field varies slightly depending on where on the body the measurement is taken and the surrounding environmental conditions.

25 **[0088]** The silicone gel is neutral (i.e., has virtually no charge), and when applied to the top layer, acts as an insulator. Thus, any charge from the top layer must pass around the insulating silicone. The skin, as is known, has an electrical charge, which can vary. The static charge of the device made from the material changes when it is applied to the skin, due to the fact that the charges want to balance. However, the charges from the skin and the charges from the device continually vary. This produces the induction of the above-noted electrical charge.

The charge is extremely small. Hence, the device, when applied to the skin, can be deemed to be a triboelectric nanogenerator.

[0089] Devices made or formed from the material may or may not utilize the electron transfer and accumulation feature of this material. When there is a charge, it is believed that the reinforcing layer 19 typically has a negative charge and the silicone gel layer 18a is neutral or near neutral in static charge. The static charge or electromagnetic field generated by the device when applied over a wound penetrates or passes around the adherent layer 18 of the device and beneficially affects the healing of the wound. There are several theories as to what is occurring in the wound and how the static charge or electromagnetic field affects the healing of the wound. Without being bound to any particular theory, the theories include the possibility that the charge or EMF affects microbes, oxygenation of blood at the wound site, and/or enhances granularization of the wound. It is also believed that these actions then affect the pH at the wound site, and in particular the pH of the stratum corneum at and surrounding the wound. Further, it is believed that the static charge or magnetic field does not substantially dissipate (or it recharges as the device is worn). Regardless as to mechanism by which the static charge or electromagnetic field enhances healing, and regardless of how the charge/filled is maintained, enhanced healing has been observed. We have observed that when the margins of the wound are pulled together by the material this electrostatic charge is generated, and that there is a change in pH at the wound site. It is believed that by pulling the wound margins together, preserving fibroblasts that are created in the healing matrix are better preserved, thus reducing the microbial load within the wound. This then is believed to affect the pH at the wound site, which in turn reduces chances of infection and the severity of infection.

[0090] Upon belief, the static charge or electromagnetic field is generated in the upper pile 16b of the top layer 16. Here, it is important that the material 16, and more importantly, the upper pile 16b be substantially formed from a component that will generate a static charge or electromagnetic field, such as nylon. Depending upon the combination of materials selected to assemble the top ply, the result may produce a positive or negative charge in the material assembly. For example, brushing or abrading the fibers will produce a negative charge or increase

the amount of negative charge until the point of saturation. Additionally, it is believed that forming the material 12 substantially from carbon fibers or polytetrafluoroethylene (i.e., Gore-Tex®) fibers will also enable a device formed from the material 12 to generate the static charge or electromagnetic field. It is
5 believed that this charge will be generated if the device is made from wool and silicone or other natural or man-made fibers.

[0091] 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
10 as illustrative and not in a limiting sense. For example, the silicone layer 18a can be made thinner, thicker, heavier, or lighter, higher or lower tack, the elongation percent can be increased or decreased, the base material from which the cover layer 16 is made can incorporate other, or different, materials, such as polyurethanes or polyethylenes.

15

CLAIMS:

1. An elastic, flexible, conformable material (12), comprising:

a top layer (16); the top layer comprising a base material (16a), an upper
5 pile (16b) extending from an upper surface of said base material, and a lower pile
(16c) extending from a lower surface of said base material; said base material
being flexible and stretchable; and

an adherent layer (18) comprising a silicone gel (18a), said silicone gel
being operatively bound to said lower pile (16c) by a binder (18b, 19a); said binder
10 being selected to be a binder which will bond to the silicone gel.
2. The material of Claim 1 further comprising a reinforcing layer (19)
between said top layer (16) and said silicone gel layer (18a); said reinforcing layer
preferably being formed from a polyurethane film or a polyethylene film, said
reinforcing layer (19) being secured to said top layer (16) by a second binder (19a);
15 said binder (18b) of said adherent layer (18) binding said silicone gel layer (18a) to
a lower surface of said reinforcing layer (19), said top layer and silicone gel layer
being collinear when stretched.
3. The material of claim 2 wherein said reinforcing layer is coextensive
with said top layer.
- 20 4. The material of any of Claims 1-3 wherein said material includes a
plurality of perforations extending through at least said silicone gel and said
reinforcing layer (if present).
- 25 5. The material of Claim 4 wherein said perforations have diameters
between about 0.5mm – 3mm, preferably about 1mm-2.8mm, and preferably about
2mm; and wherein said perforations are preferably spaced on center apart by
about 3-8mm, and preferably by about 5mm. said perforations being capable of
providing ventilation to a device formed from the material and/or for providing

capillary action to enable fluids to pass through at least said silicone gel and said reinforcing layer (if present).

6. The material of either Claim 4 or Claim 5 wherein said perforations are arranged in rows, wherein said rows are spaced apart by about 3-8mm, and
5 preferably by about 5mm.

7. The material of Claim 6 wherein the perforations of said rows are arranged in columns or wherein the perforations of one row are offset relative to the perforations of an adjacent row.

8. The elastic flexible material of any of Claims 1-7 wherein the upper
10 pile (16b) comprises loops or fibers extending from the upper surface of said base material (16a) and the lower pile (16c) comprises loops or fibers extending from the lower surface of said base material.

9. The elastic, flexible material of any of Claims 1-8 wherein said base material is composed of natural fibers, or man-made/synthetic fibers, such as
15 nylon, Spandex, Lycra, carbon fibers, expanded polytetrafluoroethylene (i.e., Gore-Tex®), polyurethane, polyethylene, and combinations thereof.

10. The elastic flexible material of Claim 9 wherein said base material comprises a nylon; said nylon preferably comprising 50/17 SD nylon and 20/1 SD Nylon, preferably wherein said base material has a composition of but not limited
20 to about 69% of 50/17 SD nylon and about 21% 20/1 SD Nylon;

11. The elastic flexible material of any of Claims 1-10 wherein said upper and lower piles (16b,c) have the same composition as the base material (16a).

12. The elastic flexible material of any of Claims 1-11 wherein said adherent layer (18) may contain antimicrobial and/or antibacterial agents such that
25 these agents can be applied to and around the incision or wound by application of a device formed from the material.

13. The material of any of the Claims 1-12 wherein said adherent layer (18) comprises a series of dots, lines or patterns defining regions with coatings of adhesive of equal or different coat weights and tack.

14. The material of any of Claims 1-13 wherein the said material (12) is adapted to generate a triboelectric charge in the top layer 16 which can be accumulated and transferred to the wound site during use of a device formed from the material.

15. The material of Claim 14 wherein the silicone gel (18a) is neutral or near neutral in static charge; and the static charge must pass around the silicone gel of the adhesive layer to reach and impact the wound.

16. The material of Claim 14 or 15, wherein a device formed from the material 12, when applied to the skin, acts as a triboelectric nanogenerator

17. The elastic flexible material of any of Claims 1-16 wherein said flexible material (12) is part of an assembly (10), said assembly including a release liner (14) removably adhered to the adherent layer (18) of said material (12).

18. The elastic flexible material of any of Claims 1-17 wherein said material has an elastic memory after elongation, such that upon removal from a surface, said material will revert substantially back to its original shape and such that said material can be applied to a protective sheet, such as a release liner.

19. The elastic flexible material of any of Claims 1-18 wherein said material includes two or more layers above the adherent layer.

20. The material of any of Claims 1-19 wherein said material is transparent to ultrasound energy, such that the material is adapted for use with ultrasound technology.

21. The elastic, flexible material of any of Claims 1-20 wherein said silicone gel layer (18a), the binder layer (18b, 19a), and the top layer (16) all move collinearly when said material is stretched.

22. The material of any of Claims 1-21 wherein said material is formed by 3D printing.

23 A device formed from the material of any of Claims 1-22 wherein said device is a wound cover or wound closure, a protective barrier, a wound dressing
5 cover, a compression wrap, a wearable anchor point, a barrier, or an insulator.

24. The device of Claim 23 wherein said device can be worn for at least one day, , preferably at least one week, or preferably at least two weeks.

25. The device of any of Claims 23-24 wherein said device can be stretched, elongated, and applied between at least two points on a surface, such
10 as a patient's skin, to apply a desired amount of tension/compression to margins of the incision/wound and periwound.

26. The device of any of Claims 23-24, wherein said device is a wrap; wherein adhesive layer of a first portion of said wrap will engage with the upper pile of a second portion of said wrap, such that said wrap will connect to itself, whereby,
15 said wrap can be applied without the need for external connectors, snaps, etc.

27 A device formed from the material of any of Claims 1-21 wherein said device is designed to be elongated and applied to a patient.

28. The device of any of Claims 26-27 wherein said device includes graduated markings which provide an indication of the amount of elongation of the
20 material when said material (12) of the device is stretched.

29. The device of any of Claims 21-28 wherein said device is formed by 3D printing.

30. The device of any of Claims 23-29 and Claim 14 wherein when worn, the electrostatic charge from the material (12) of the device (20) charges the
25 surface of the skin beneath and in the perimeter around the material of the device when positioned on the skin of a wearer.

31. A tensioning assembly for use with the device of any of Claims 20-25, the tensioning assembly (30) comprising a tensioning member selectively adherable to the upper pile of said device; said tensioning member comprising:

(1) an elongate elastic flexible, elastic strip (32), and

5 (2) a pair of pads (34) secured to bottom surfaces of opposite ends of said elastic strip; said pads each having a bottom surface having hooks (34a) extending therefrom, said pads preferably being non-stretchable and preferably being formed from medical grade hook material;

said hooks (34a) being sized and shaped to engage and grip said upper pile (16b),
10 whereby, by securing a first end of said tensioning member to said material (12) at a selected anchor point on said material, stretching said tensioning member, and securing a second end of the tensioning member to a second anchor point on said material spaced from said first anchor point a distance greater than the length of said tensioning member prior to stretching of said tensioning member, said
15 tensioning member will exert a desired amount of compressive forces to said material (12) and the surface underlying said material (12).

32. The tensioning assembly of claim 31 whereby, said tensioning member provides variable compression to tissue below the skin to which the device has been applied.

20 33 The tensioning assembly of any of Claims 31-32 wherein said elongate strip (32) is elastic and has elastic memory, whereby attachment of the tensioner to the device allows for adjustable tension/compression to a selected area of said material.