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(54) **DEVICES AND METHODS FOR SKIN
TIGHTENING**

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3, 2011, provisional application No. 61/476,163, filed
on Apr. 15, 2011, provisional application No. 61/605,
717, filed on Mar. 1, 2012.

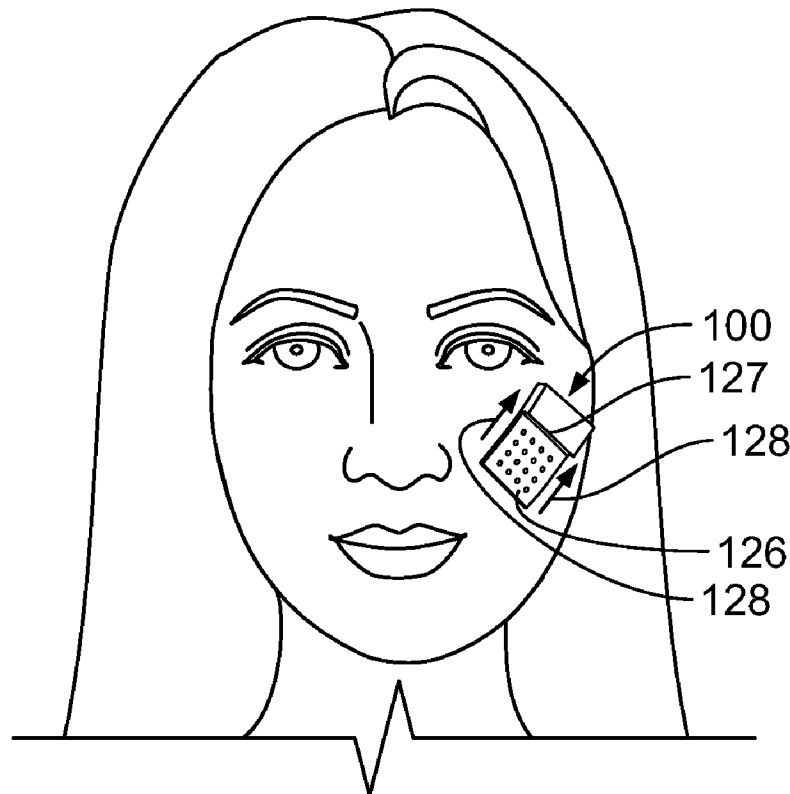
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(52) **U.S. Cl.**
CPC **A61F 13/00** (2013.01)
USPC **602/53**

(57) **ABSTRACT**

The methods, procedures, kits, and devices described herein assist with the healing process of tissue that was previously or simultaneously treated for a therapeutic or cosmetic effect. The methods, procedures, kits, and devices described herein can also provide temporary simulated results of a cosmetic procedure to allow for visual assessment to select the type of procedure or for treatment planning in advance of the surgical procedure.



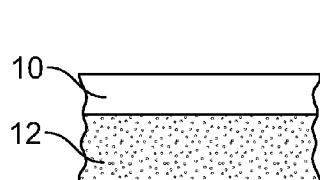


FIG. 1A

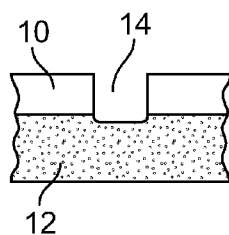


FIG. 1B

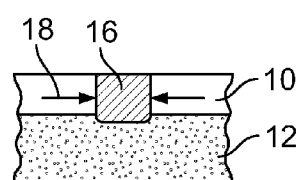


FIG. 1C

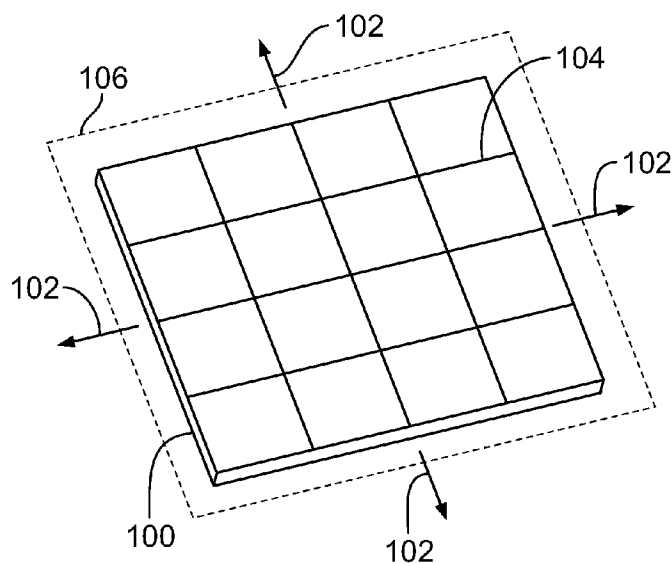


FIG. 2A

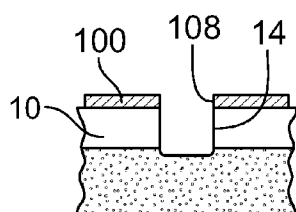


FIG. 2B

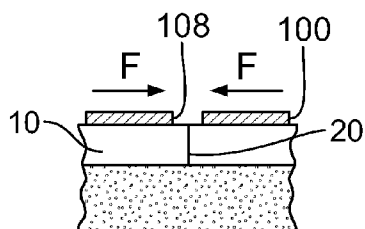


FIG. 2C

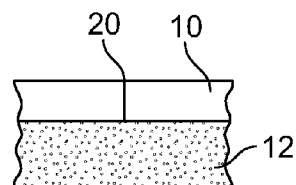


FIG. 2D

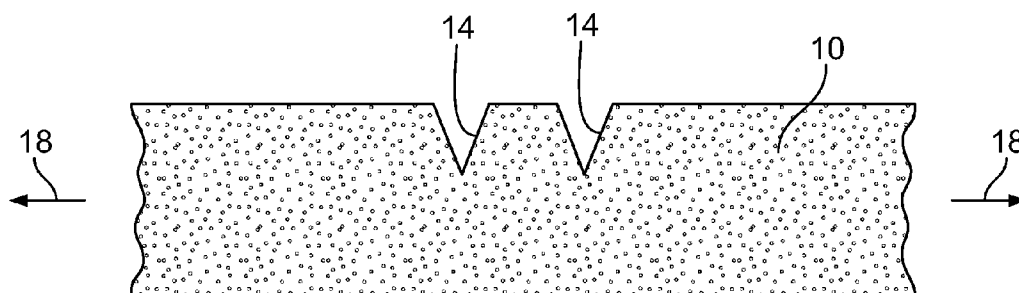


FIG. 2E

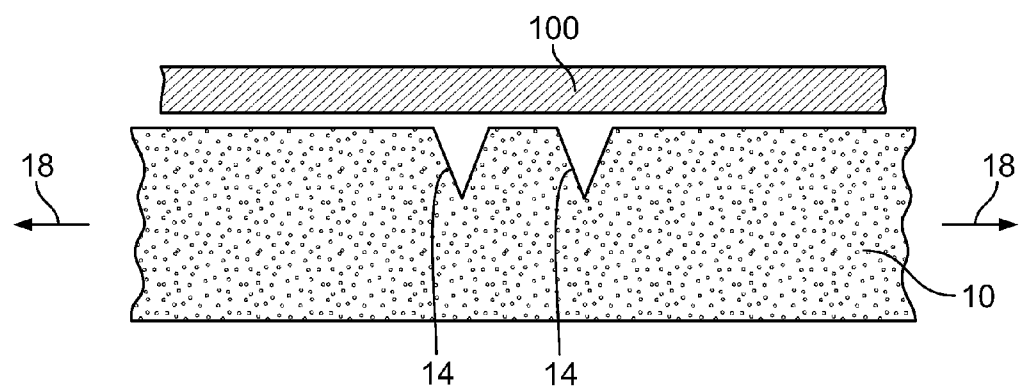


FIG. 2F

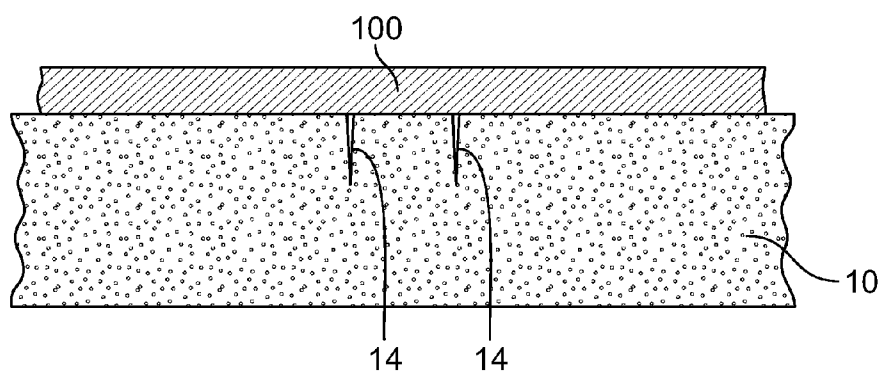


FIG. 2G

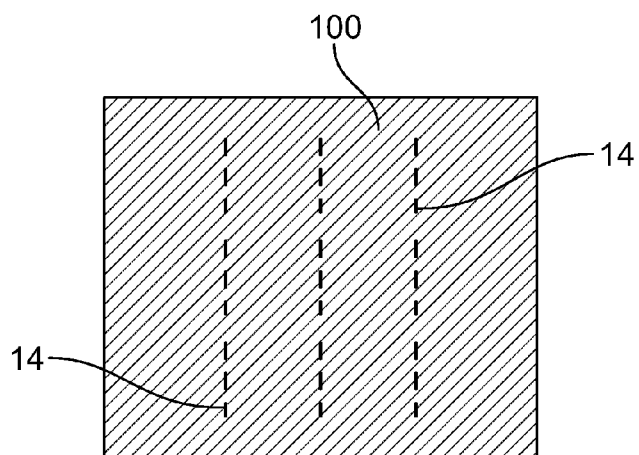


FIG. 2H

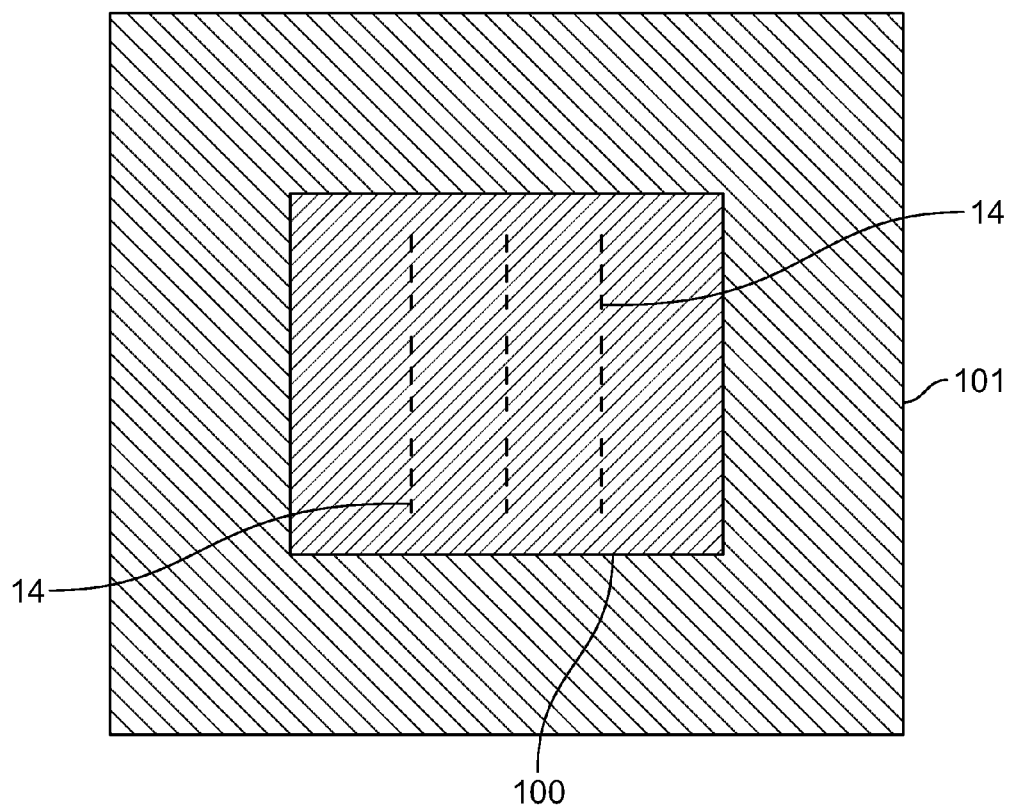


FIG. 2I

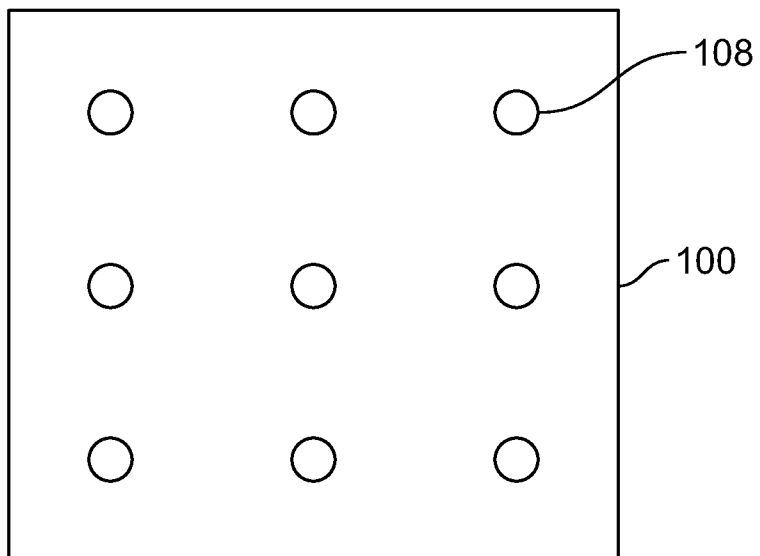


FIG. 3A

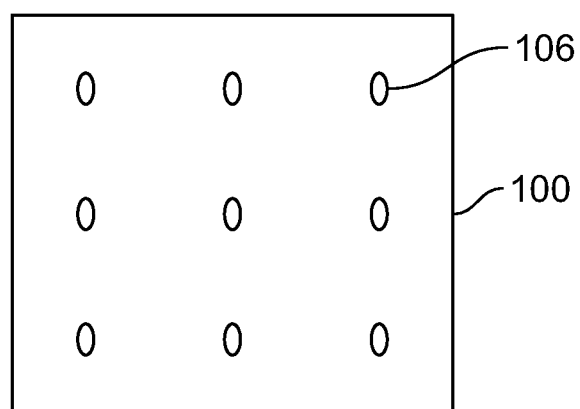


FIG. 3B

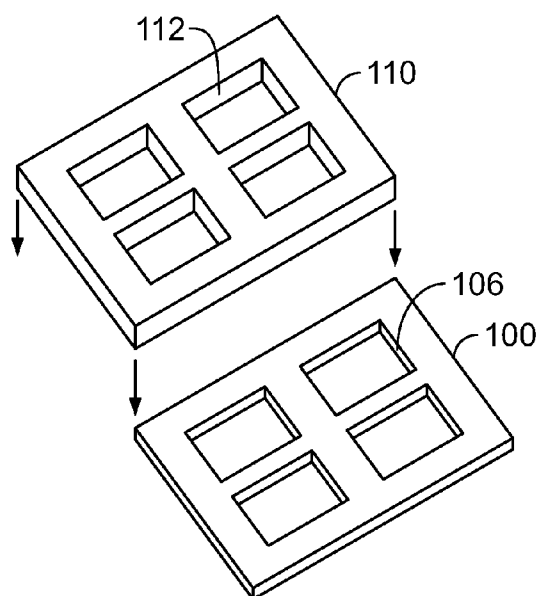


FIG. 3C

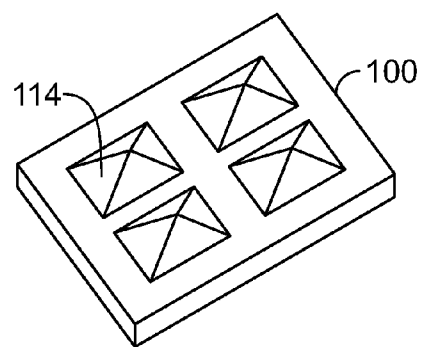


FIG. 3D

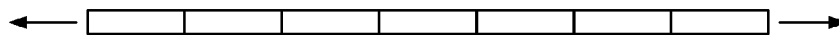


FIG. 3E



FIG. 3F

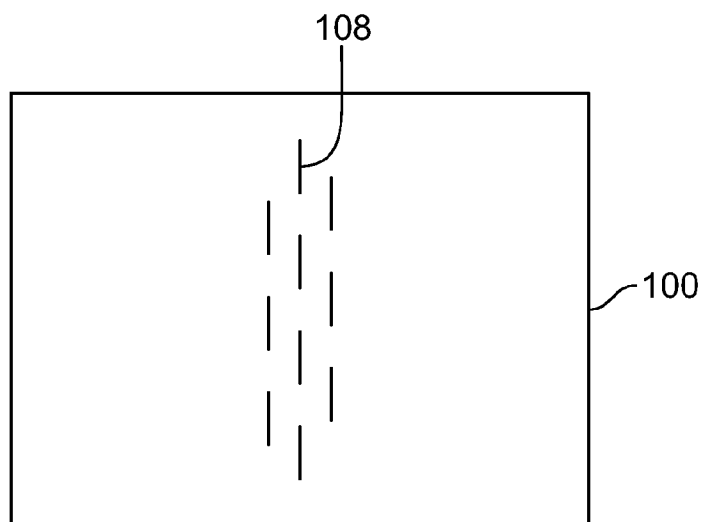


FIG. 3G

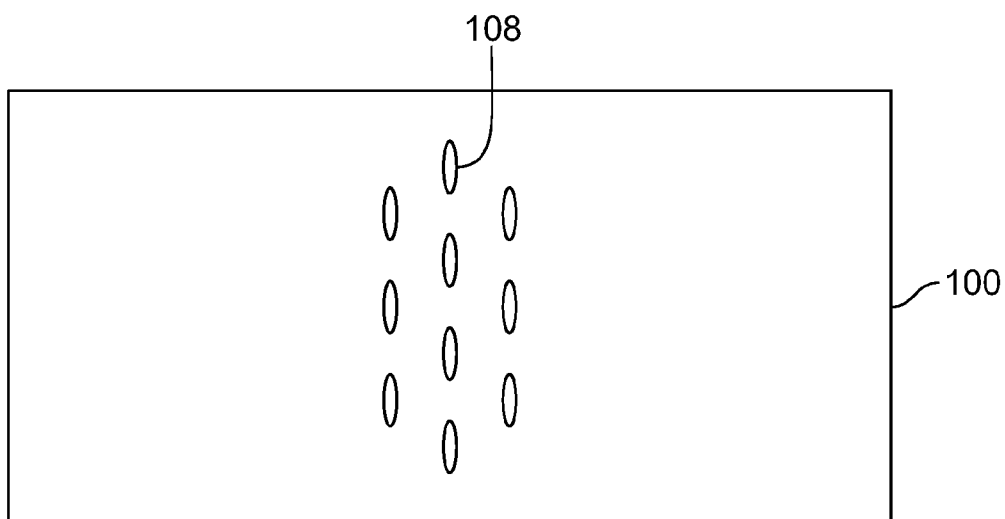


FIG. 3H

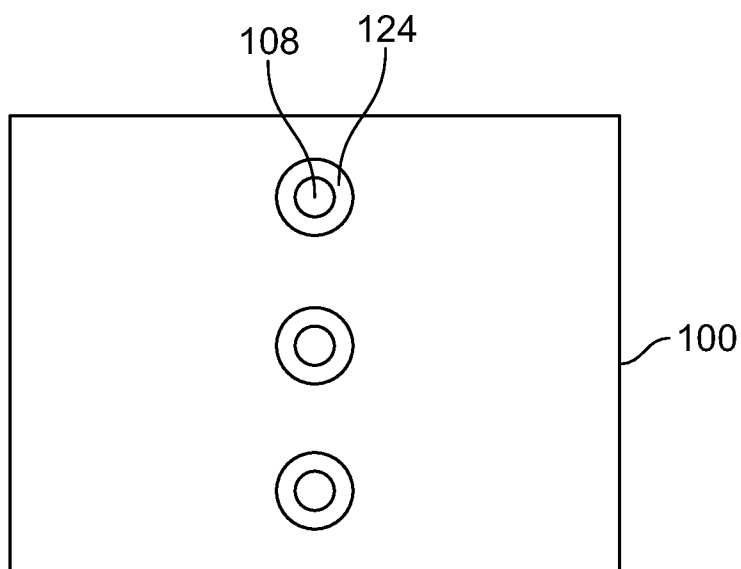


FIG. 3I

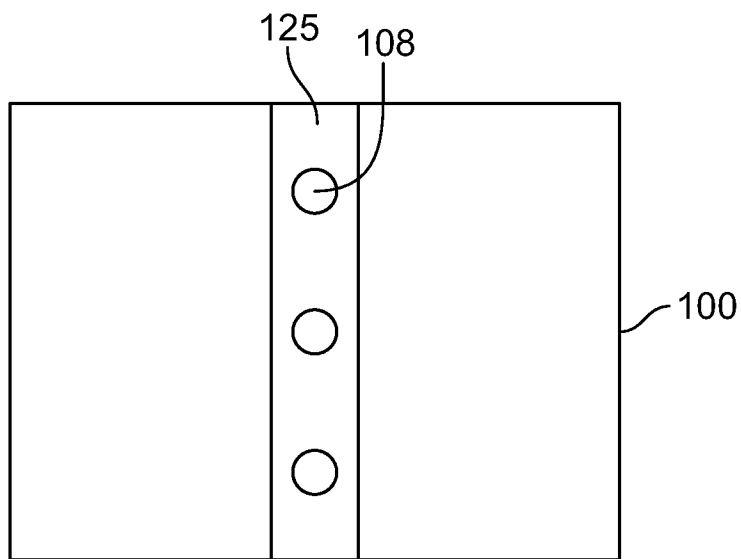


FIG. 3J

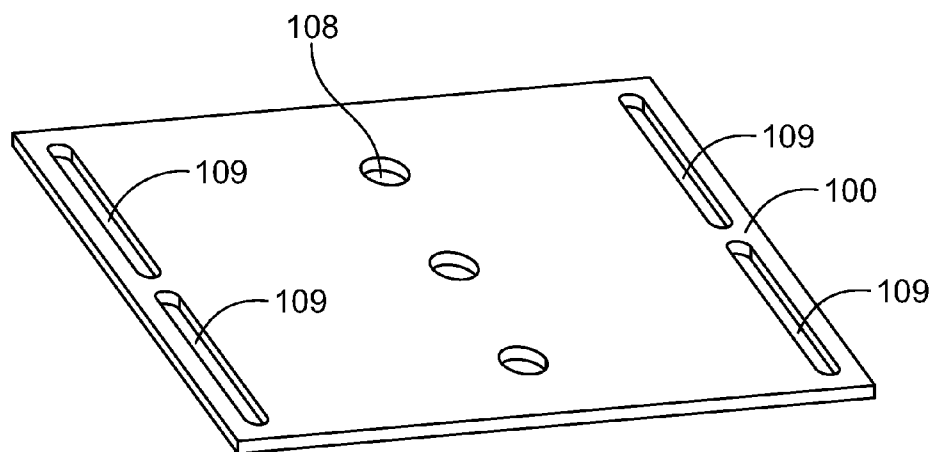


FIG. 4A

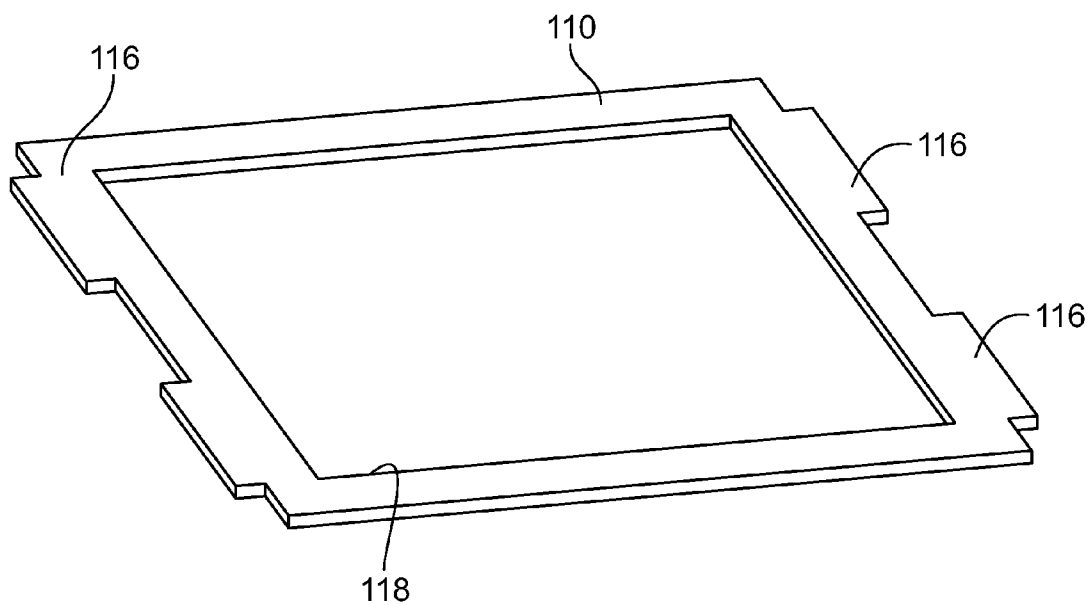


FIG. 4B

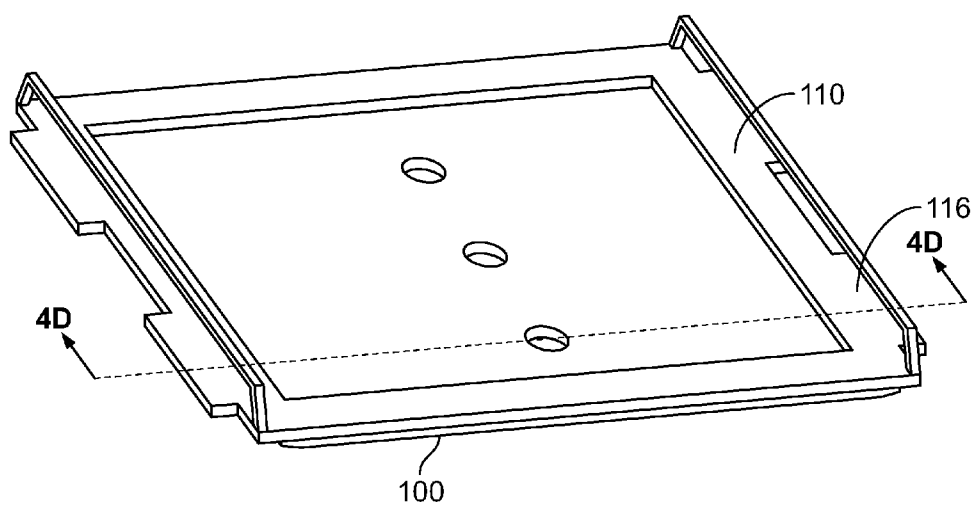


FIG. 4C

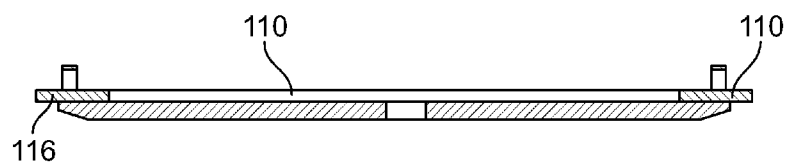


FIG. 4D

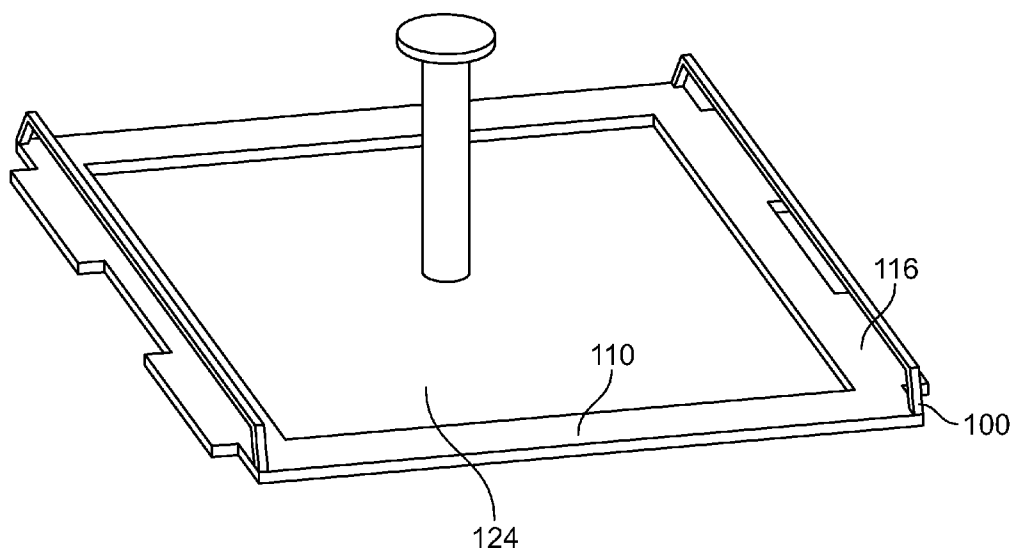


FIG. 4E

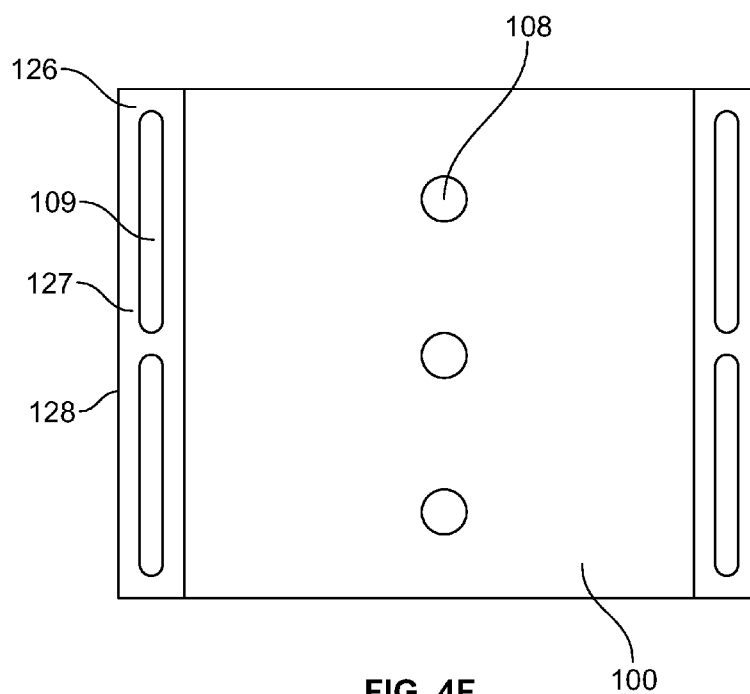


FIG. 4F

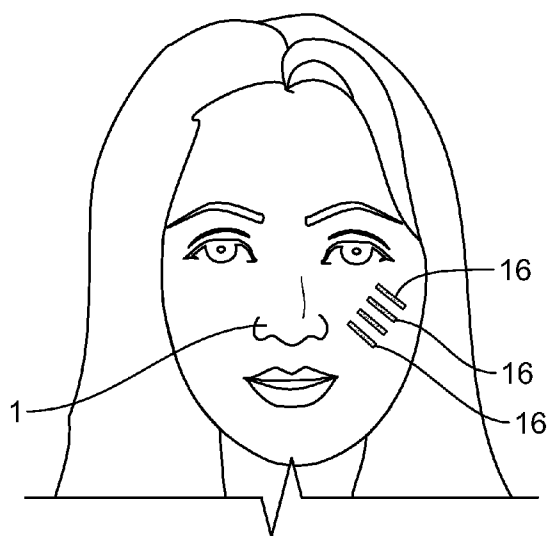


FIG. 5A

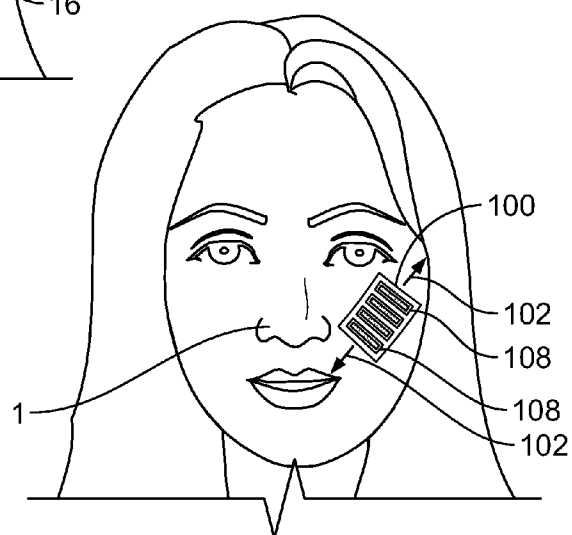


FIG. 5B

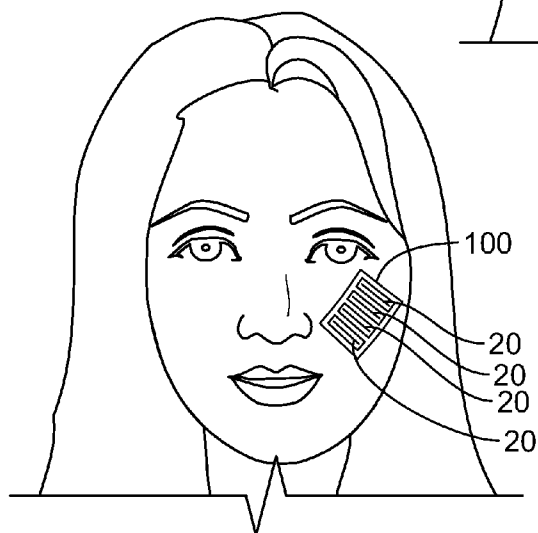


FIG. 5C

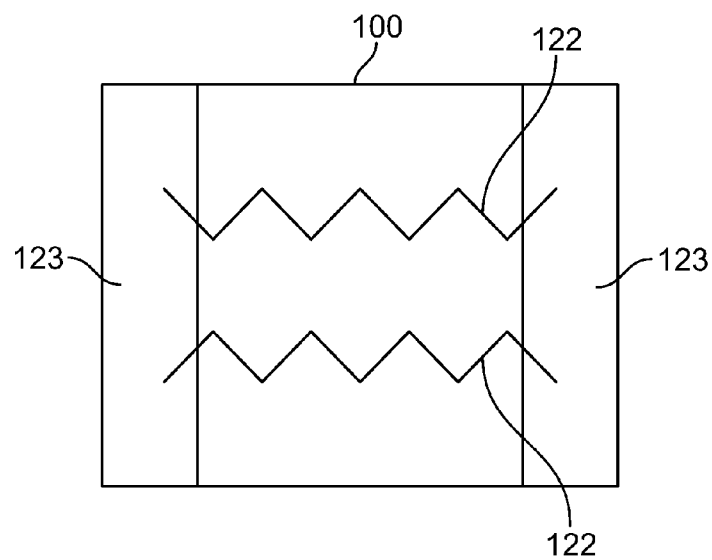


FIG. 6A

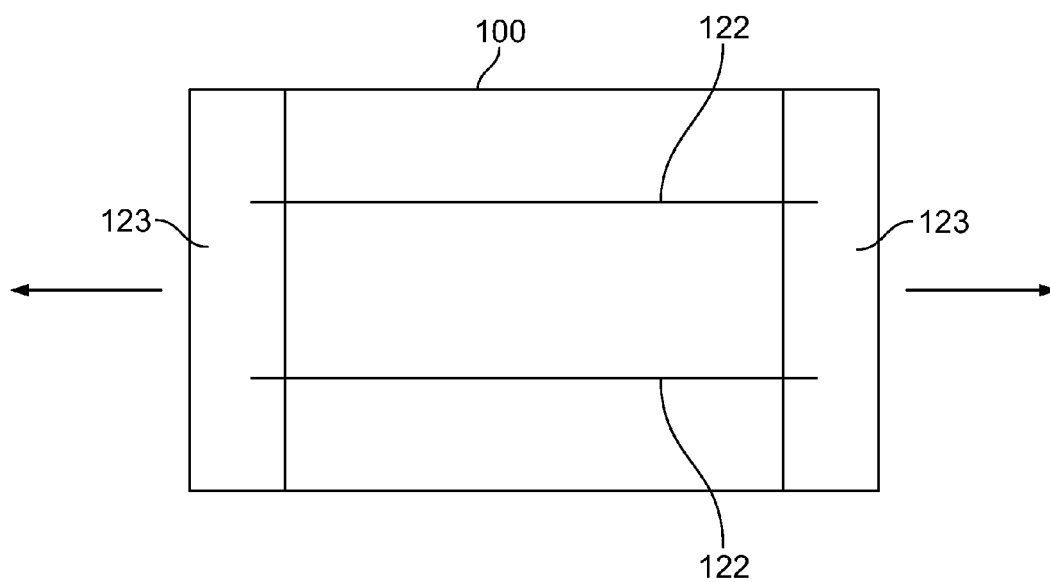


FIG. 6B

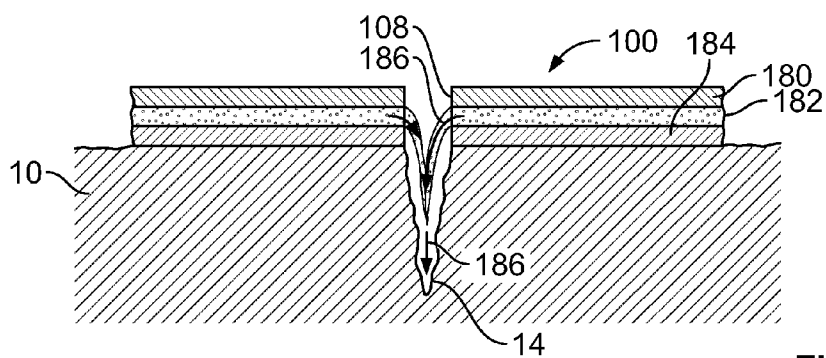
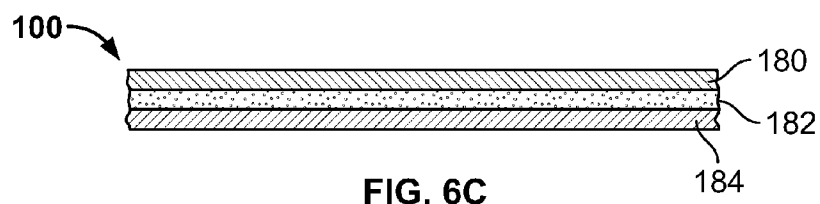


FIG. 6D

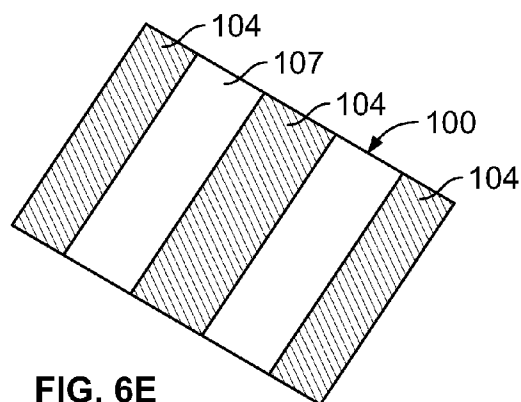


FIG. 6E

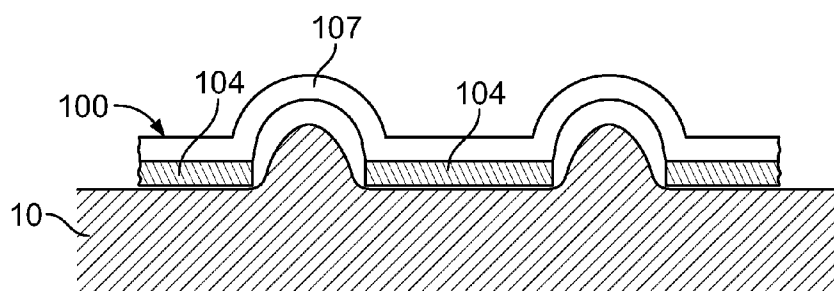


FIG. 6F

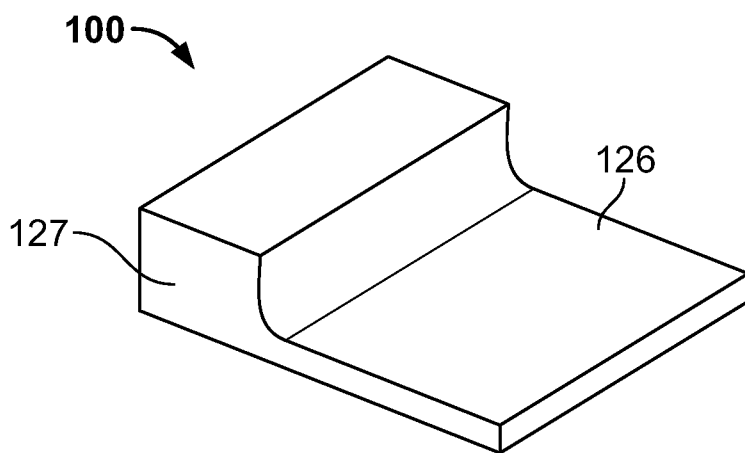


FIG. 6G

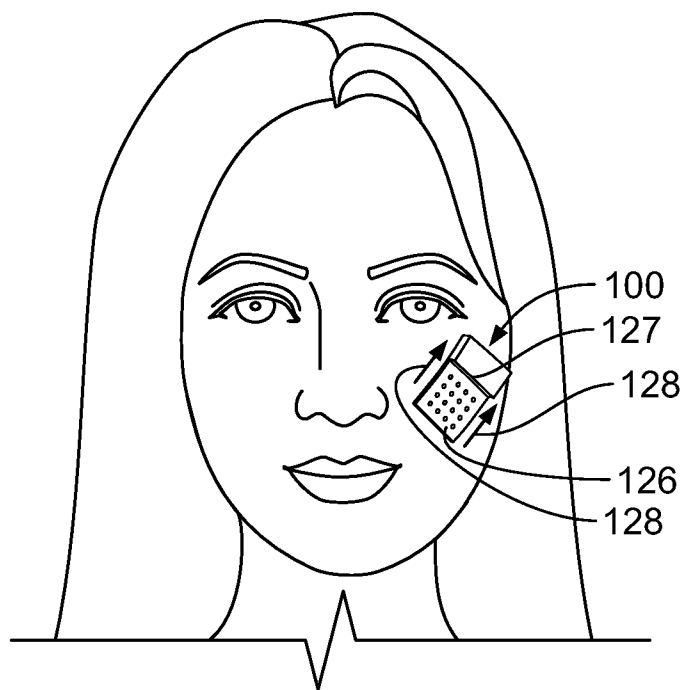


FIG. 6H

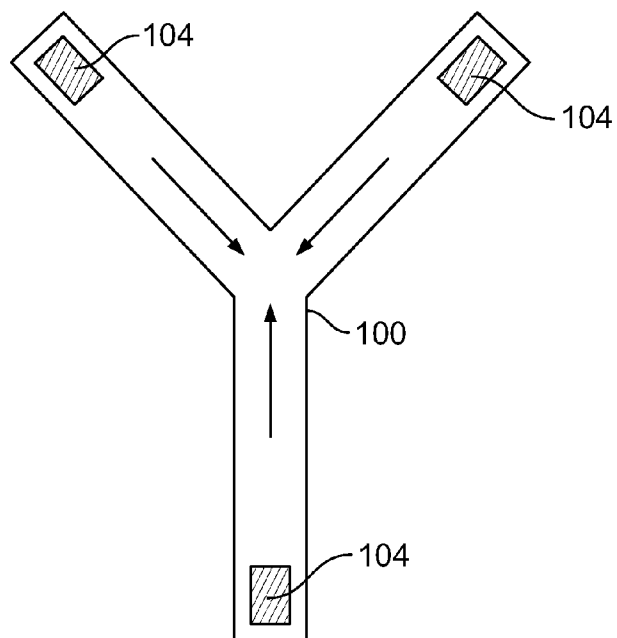


FIG. 6I

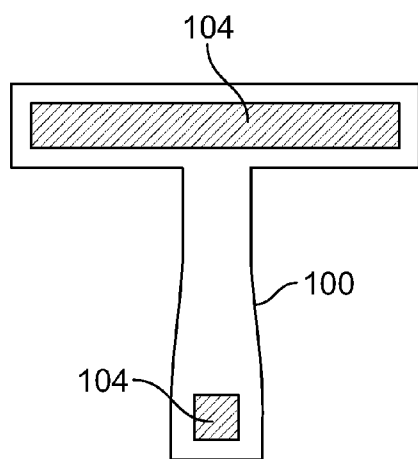


FIG. 6J

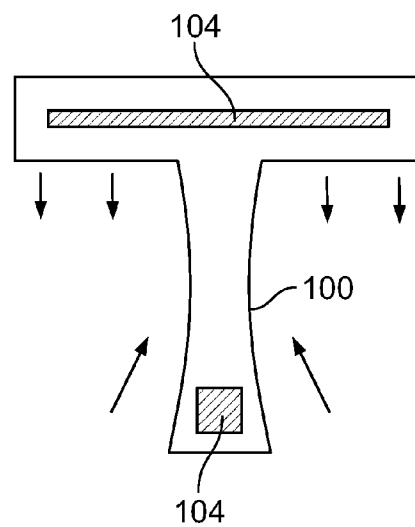


FIG. 6K

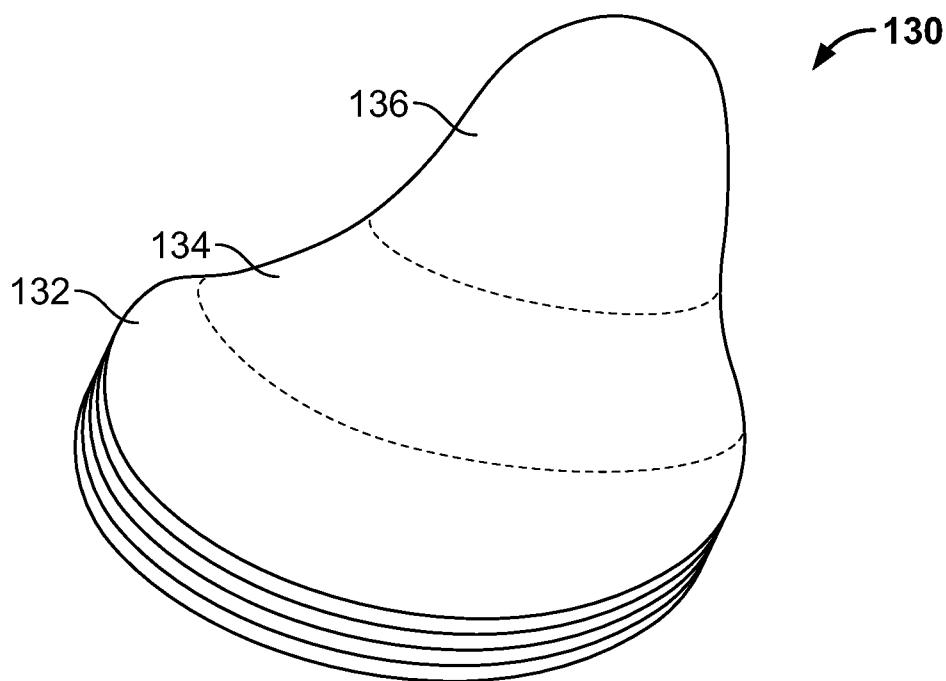


FIG. 7A

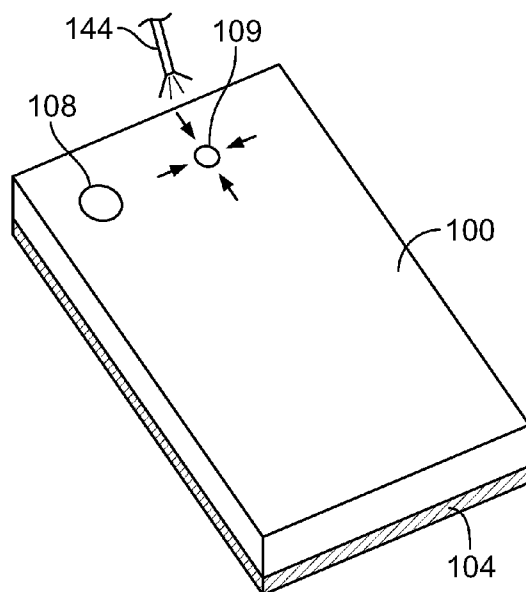


FIG. 7B

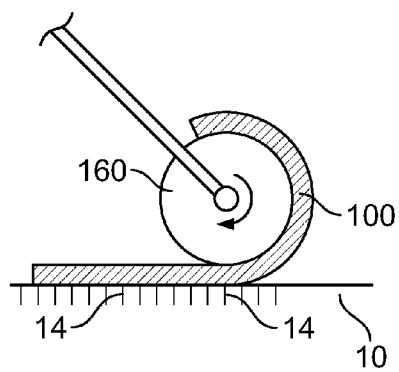


FIG. 7C

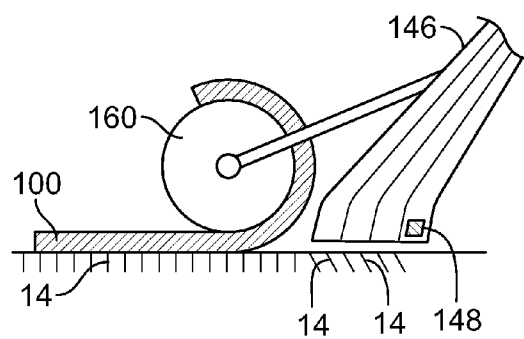


FIG. 7D

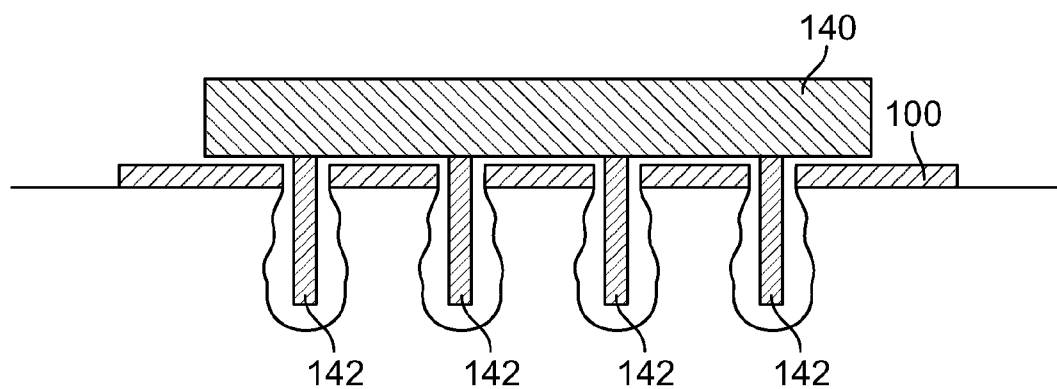


FIG. 8A

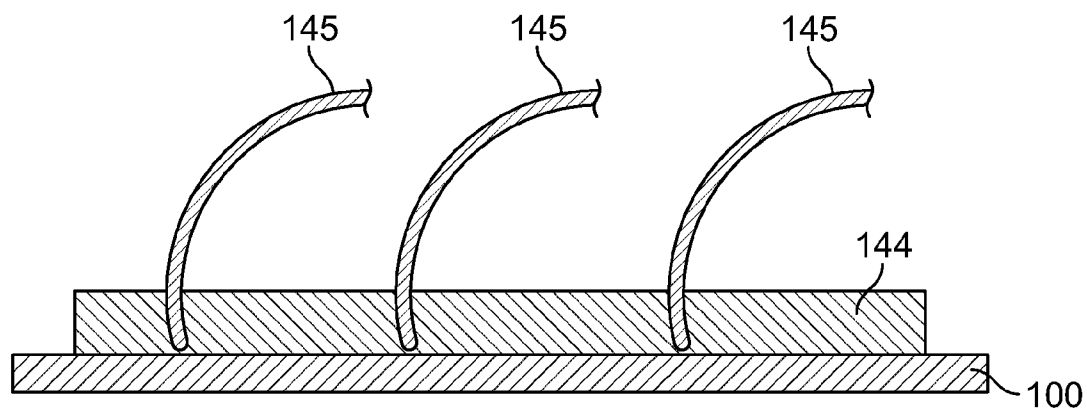


FIG. 8B

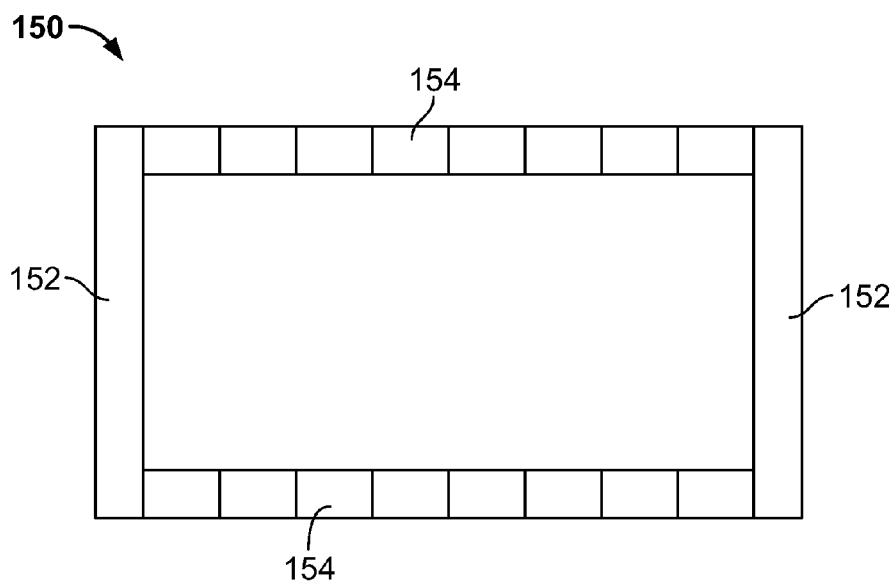


FIG. 9A

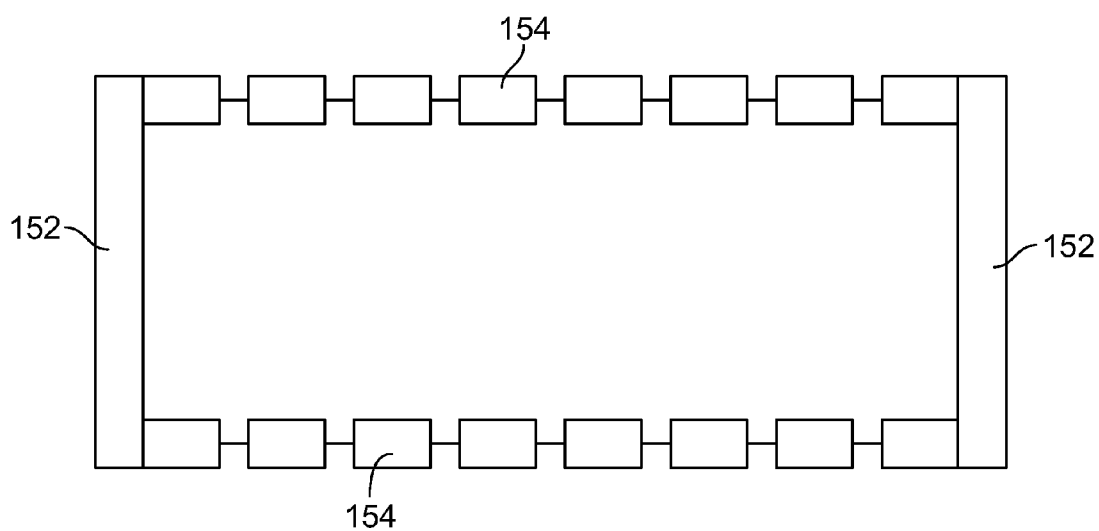


FIG. 9B

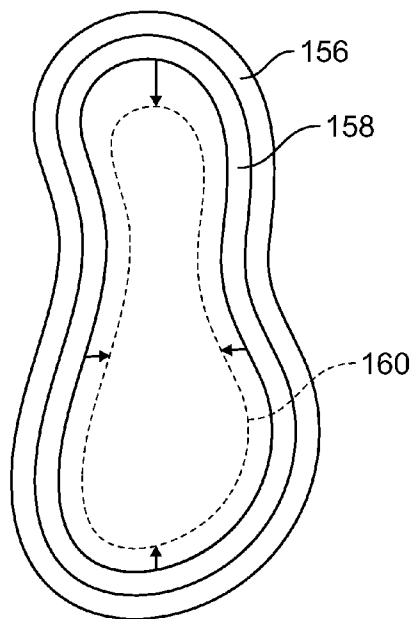


FIG. 9C

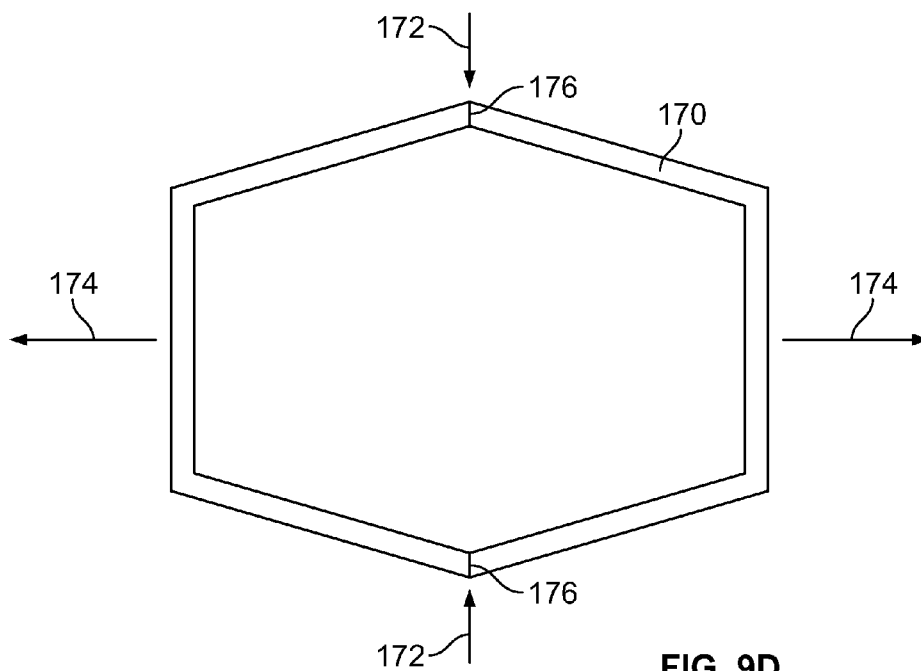


FIG. 9D

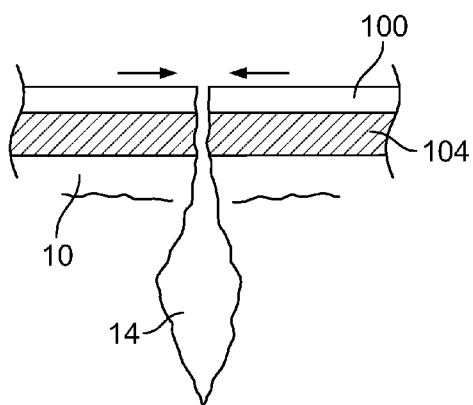


FIG. 10A

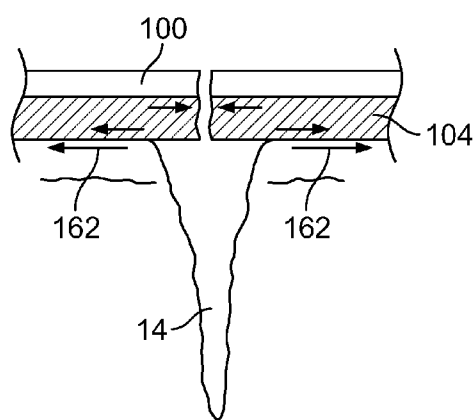


FIG. 10B

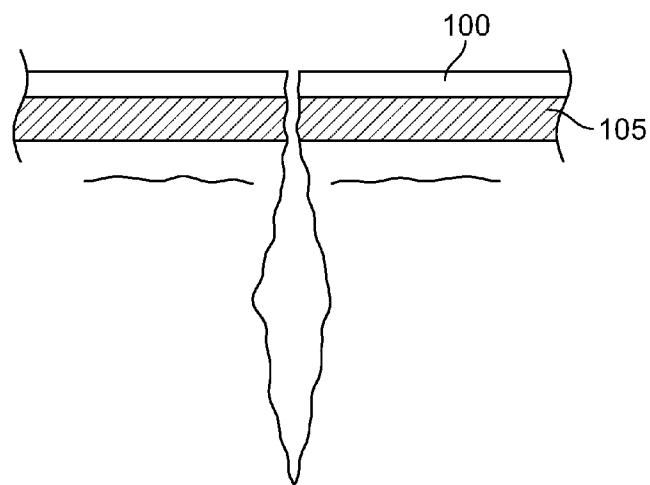


FIG. 10C

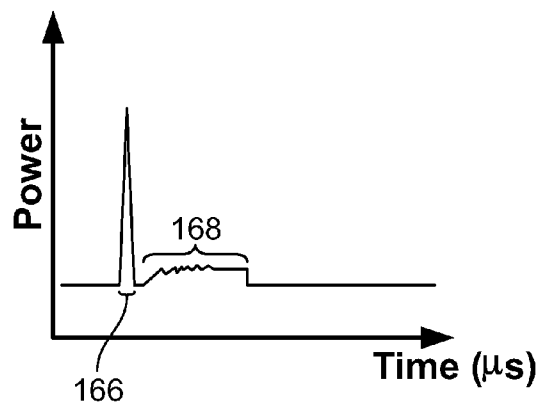


FIG. 11A

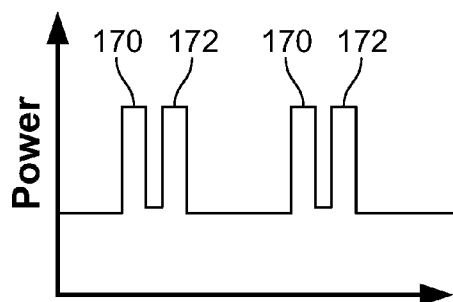


FIG. 11B

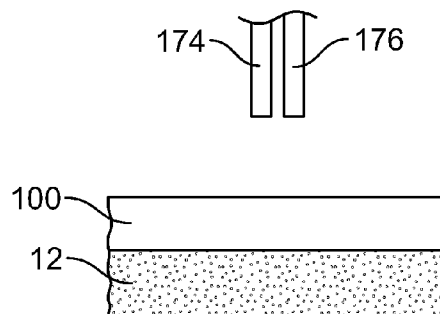


FIG. 11C

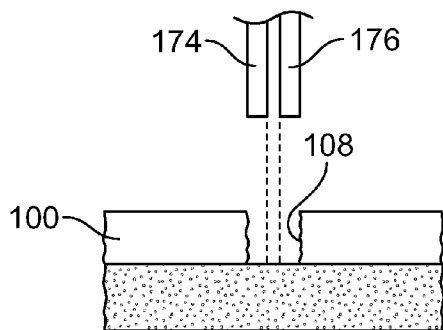


FIG. 11D

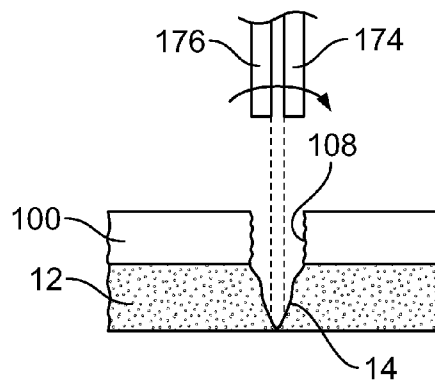


FIG. 11E

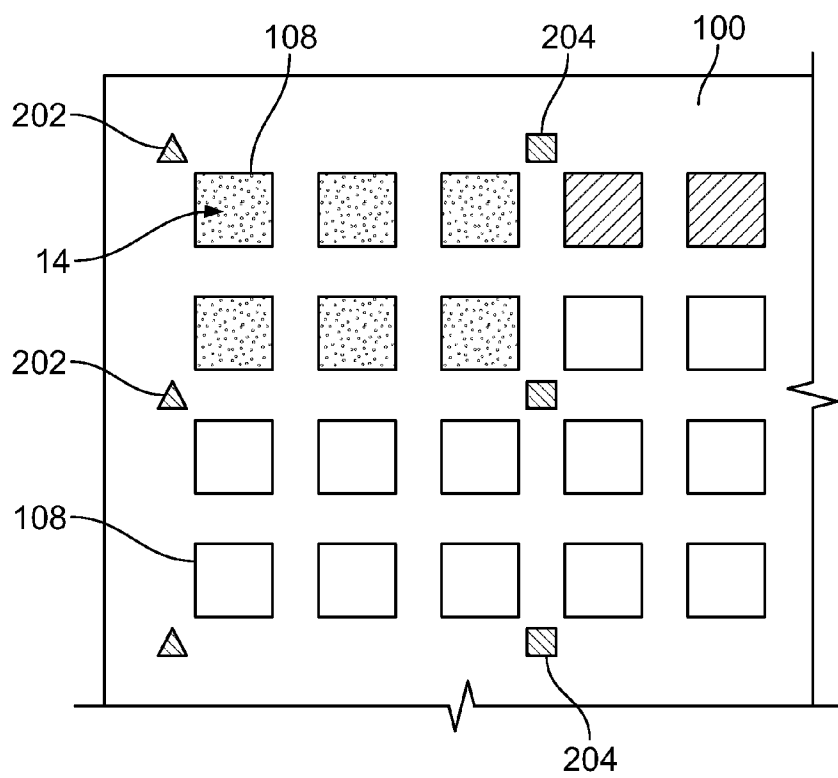


FIG. 12A

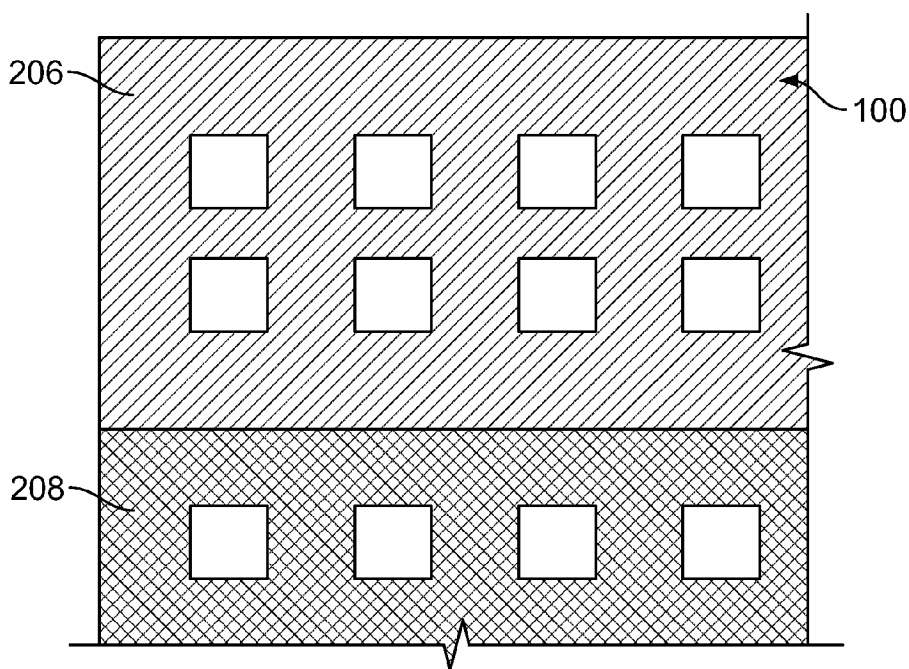


FIG. 12B

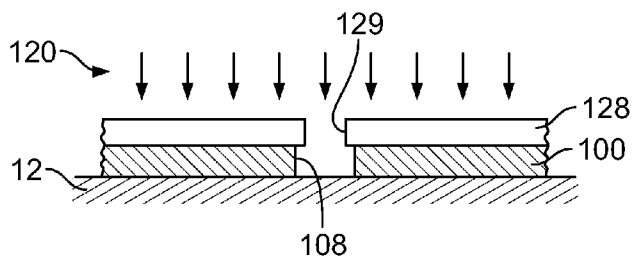


FIG. 13A

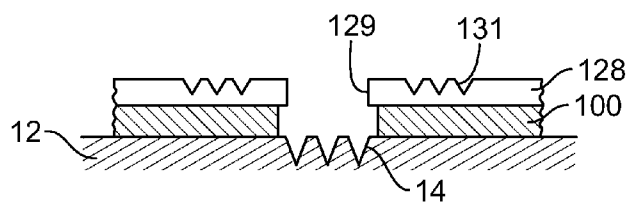


FIG. 13B

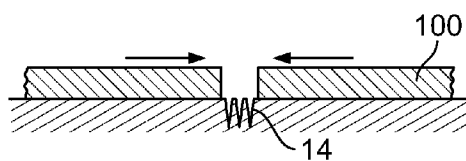


FIG. 13C

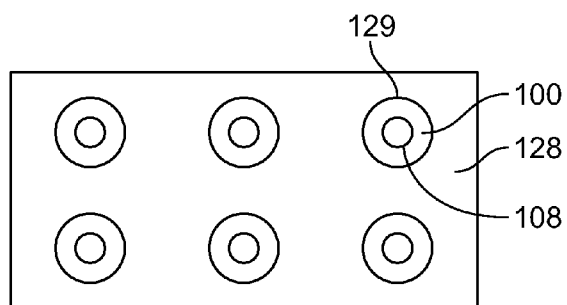


FIG. 13D

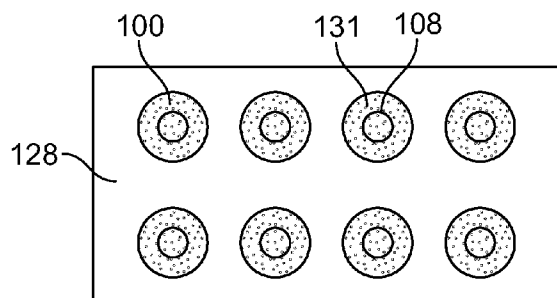


FIG. 13E

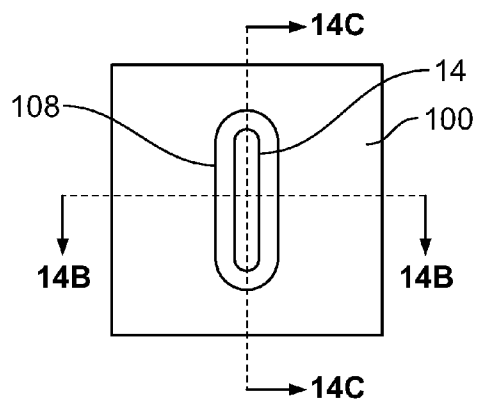


FIG. 14A

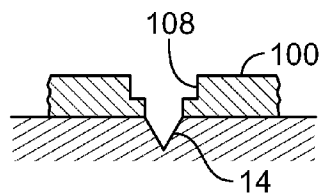


FIG. 14B

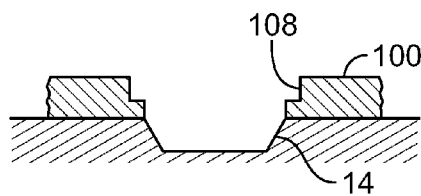


FIG. 14C

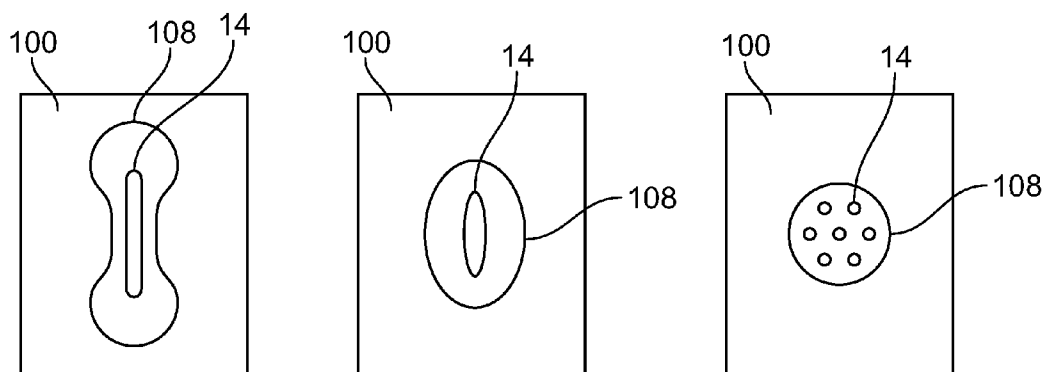


FIG. 14D

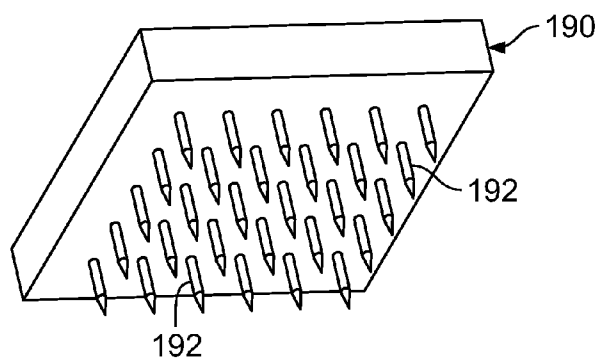


FIG. 15A

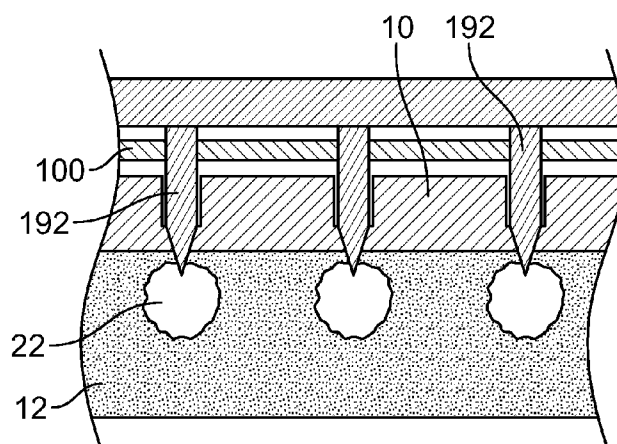


FIG. 15B

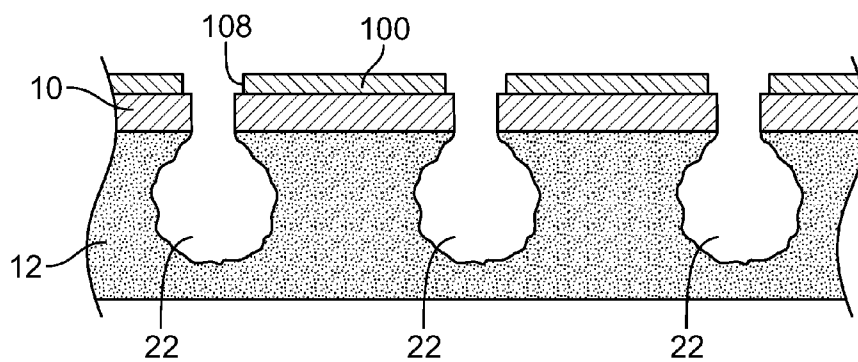


FIG. 15C

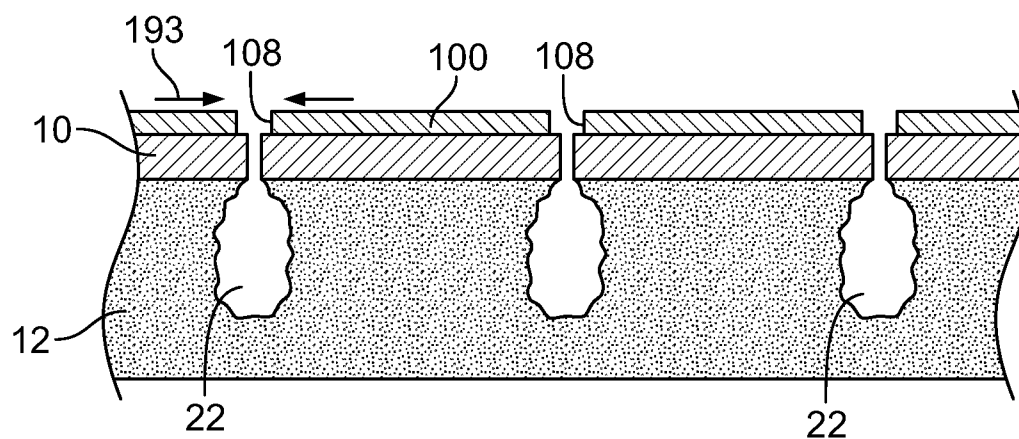


FIG. 15D

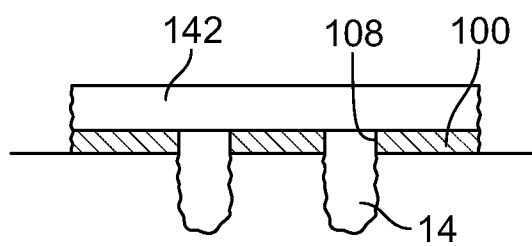


FIG. 16

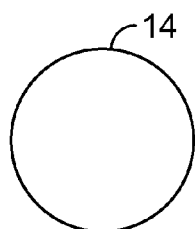


FIG. 17A

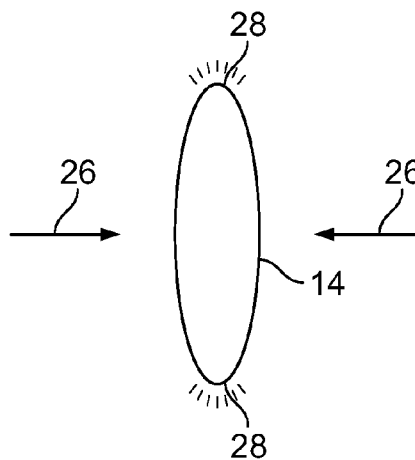


FIG. 17B

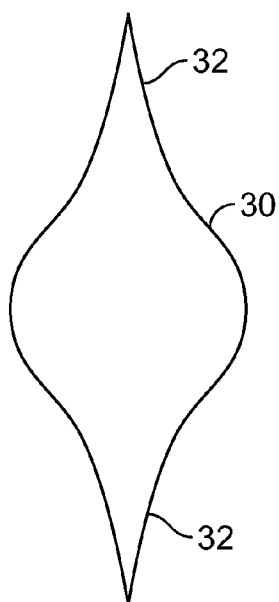


FIG. 18A

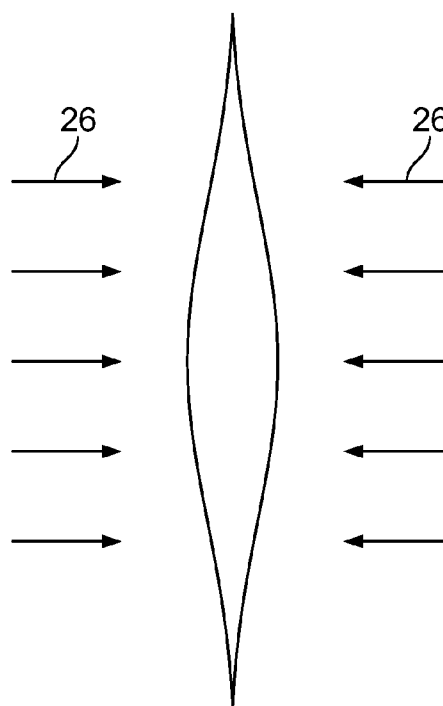


FIG. 18B

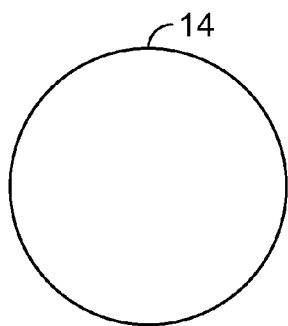


FIG. 18C

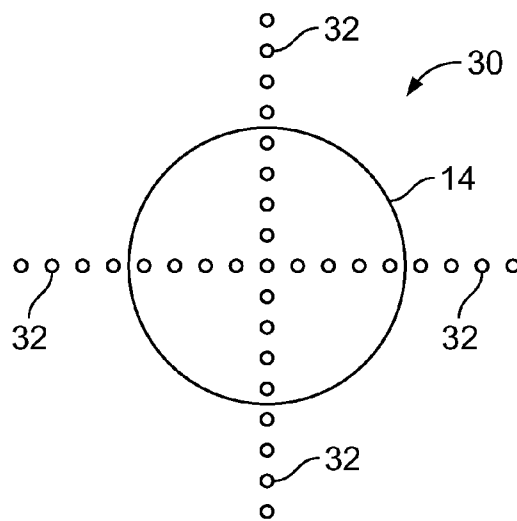


FIG. 18D

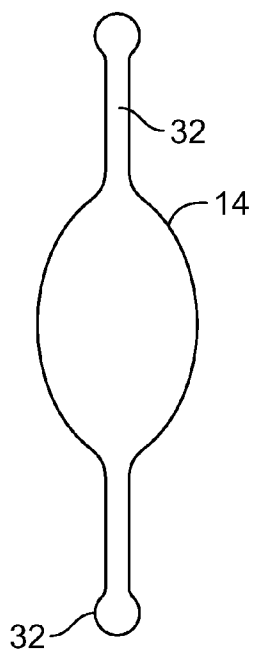


FIG. 18E

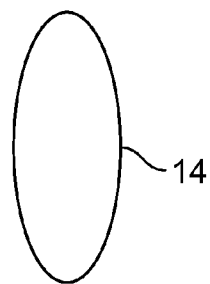


FIG. 18F

DEVICES AND METHODS FOR SKIN TIGHTENING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 13/411,443, filed Mar. 2, 2012, which claims benefit under 35 U.S.C. §119(e) to a) U.S. Provisional Application Ser. No. 61/448,809, filed on Mar. 3, 2011, b) U.S. Provisional Application Ser. No. 61/476,163, filed on Apr. 15, 2011, and c) U.S. Provisional Application Ser. No. 61/605,717, filed on Mar. 1, 2012, all of which are hereby incorporated by reference in their entirety. This application is also related to U.S. application Ser. No. 11/888,978, filed on Aug. 3, 2007, U.S. application Ser. No. 12/854,859, filed on Aug. 11, 2010, and U.S. application Ser. No. 13/345,524, filed Jan. 6, 2012, all of which are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] The present invention relates generally to medical devices, kits and methods used for improved healing of skin after a therapeutic injury. For example, such devices, kits and methods can be used to produce improved tightening of skin after a therapeutic treatment. The devices, kits and methods can also be used to produce a temporary cosmetic effect by displacing skin to stimulate a clinical effect.

BACKGROUND OF THE INVENTION

[0003] Many procedures involve producing a therapeutic injury to tissue to produce an improved therapeutic or cosmetic effect in the tissue. Skin tightening is one such therapy that involves creating an injury to produce an improved cosmetic appearance of the skin near or around the site of the therapeutic injury. Skin tightening can be performed many different ways ranging from invasive treatments to less invasive procedures such as IPL (intense pulsed light). Typically invasive procedures appear to be the most effective but require significant recuperative periods, while less invasive procedures are less effective than invasive procedures but the recuperative periods are shorter. In any case, the healing process that occurs subsequent to the therapeutic injury can determine the effectiveness of the procedure.

[0004] Again, in referring to skin tightening as one example, during the procedure a physician or medical practitioner induces a controlled trauma in the skin. This is typically performed by applying energy to the tissue to either ablate (vaporize) or non-ablatively heat the skin to create either patterns of lesions or a localized area of treatment. There are limits when creating therapeutic injury to tissue, if there is variability in the lesion or hole created in the tissue the healing process may not produce the optimal effect. For example, if the therapeutic treatment creates openings in the tissue that are too large, the tissue may not heal as desired.

[0005] In one variation, a skin treatment system is provided, comprising an dressing with a load per millimeter width of at least 0.1 Newtons at a strain of at least 0.01, 0.05, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9 or higher, and a limiting member coupled to the dressing and configured to resist straining of the dressing beyond a predetermined strain. The limiting member may comprise a first handle at a first end of the at least one limiting member, and a second handle at a second end of the at least one limiting member. The skin

treatment system may comprise at least two elongate strain limiting structures. The first handle may be contiguously or non-contiguously coupled to the dressing between the first ends of the at least two elongate strain limiting structures. The second handle may also be contiguously or non-contiguously coupled to the dressing between the second ends of the at least two elongate strain limiting structures. The predetermined strain may be at least 0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9 or higher. The limiting member may be releasably coupled to the dressing. The limiting member may be adhered to the dressing using an adhesive. The adhesive may comprise a shear-resistance to a force level that is greater than the T-peel resistance to the force level. The first handle and the second handle may comprise a substantially inelastic material relative to the dressing, which may optionally be a semi-rigid or rigid material. The limiting member may comprise at least one flexible, inelastic elongate element. The dressing may comprise an unstrained configuration in which a distance between a first attachment region of the limiting member and a second attachment region of the limiting member is less than a length of the limiting member between the first attachment region and the second attachment region, and may comprise a strained configuration at the predetermined strain wherein the distance between the first attachment region of the limiting member and a second attachment region of the limiting member is substantially equal to the a length of the limiting member between the first attachment region and the second attachment region. The limiting member may comprise a folded board with at least three two folds, or a ratchet and pawl mechanism. The limiting member may be selectively configured to resist straining of the dressing beyond a plurality of predetermined strains. The plurality of predetermined strains may comprise graphical indicia on the limiting member.

[0006] In another variation, the skin treatment system comprises an dressing, comprising a tensioning axis, and a limiting member coupled to the dressing and configured to resist straining of the dressing beyond a predetermined strain, wherein the attachment of a first end of the limiting member to the dressing is contiguous across a dimension of the dressing transverse to the tensioning axis. The dressing may have a load per millimeter width of at least 0.1 Newtons at a strain of at least 0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, or higher. The limiting member may comprise a first handle at a first end of the at least one limiting member, and a second handle at a second end of the at least one limiting member. The skin treatment system may comprise at least two elongate strain limiting structures. The first handle may be contiguously coupled to the dressing between the first ends of the at least two elongate strain limiting structures. The second handle may also be contiguously coupled to the dressing between the second ends of the at least two elongate strain limiting structures. The predetermined strain may be at least 0.01, 0.05, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, or higher. The limiting member may be releasably coupled to the dressing. The limiting member may be adhered to the dressing using an adhesive. The adhesive may comprise a shear-resistance to a force level that is greater than the T-peel resistance to the force level. The first handle and the second handle may comprise a substantially inelastic material relative to the dressing, which may optionally be a semi-rigid or rigid material. The limiting member may comprise at least one flexible, inelastic elongate element. The dressing may comprise an unstrained configuration in

which a distance between a first attachment region of the limiting member and a second attachment region of the limiting member is less than a length of the limiting member between the first attachment region and the second attachment region, and may comprise a strained configuration at the predetermined strain wherein the distance between the first attachment region of the limiting member and a second attachment region of the limiting member is substantially equal to the a length of the limiting member between the first attachment region and the second attachment region. The limiting member may comprise a folded board with at least three two folds, or a ratchet and pawl mechanism. The limiting member may be selectively configured to resist straining of the dressing beyond a plurality of predetermined strains. The plurality of predetermined strains may comprise graphical indicia on the limiting member.

[0007] In another variation, a skin treatment system is provided, comprising an elastic structure, first and second handles attached to opposite regions of the elastic structure, wherein the first and second handles are coupled to the elastic structure and configured to provide a substantially uniform tensile force across the elastic structure; and a strain indicator. The strain indicator may comprises graphical or numerical indicia of the degree of strain.

[0008] In one variation, a skin treatment device is provided, comprising a first layer comprising an elastic material pre-stretched to a predetermined strain level and a second layer coupled to the first layer and comprising a brace configured to maintain the first layer at the predetermined strain level while the device is attached to a skin layer of a subject; and comprising at least one second layer opening positionable for treatment of skin therethrough, and a securing element configured to secure the device to skin of a subject during treatment through said at least one second layer opening. The first layer may comprise at least one elastic material opening through the elastic material configured to be aligned with the at least one opening of the second layer for treatment through the aligned openings. The brace may further comprise a mating element configured to secure the first layer in a strained configuration on the brace. The brace may be rigid. The brace may comprise a plurality of segments bendable with respect to another of the plurality of segments to provide a variable contour of the brace. The brace may be configured to be bendable in a plurality of directions. Each of the plurality of segments may be configured to be bent in a plurality of directions. The second layer may comprise a mask having a pattern of openings. The pattern of openings comprises a treatment pattern. The skin treatment device may further comprise a connection element configured to connect the device to an energy emitting skin treatment device. Each second layer opening may correspond to at least one individual treatment zone. The second layer may be removable from the first layer after treatment is provided through the at least one second layer opening.

[0009] In another variation, a multilayered elastic dressing is provided, comprising a plurality of elastic layers, wherein each layer removably coupled to another layer of said plurality of elastic layers; wherein said plurality of elastic layers comprises a base layer having a skin adhesive layer on a skin adhesive side of the base layer and at least one additional layer. Each said at least one additional elastic layer may be removable from the base layer after the dressing has been strained and adhered to skin of a subject to thereby selectively alter the stresses placed on the skin through the base layer.

[0010] In another variation, a method of treating a subject is provided, comprising creating a plurality of lesions on a subject's skin and placing a dressing over the lesions on the subject's skin.

[0011] In another variation, a method treating a subject is provided, comprising placing a dressing over a skin region and creating lesions in the skin region through the dressing. Creating lesions in the skin regions may be performed using an energy-based modality. The dressing may comprise a mask region configured to selectively block the energy-based modality and a treatment region configured to selectively permit energy from the energy-based modality to pass through the dressing. The treatment region comprises an uninterrupted structure configured to selectively permit energy to pass through the uninterrupted structure. The uninterrupted structure may be an optically clear structure. The method may further comprise aligning a treatment device to indicia located on the dressing. The method may further comprise aligning a treatment device to pre-existing openings in the dressing. The pre-existing openings may be pre-existing potential openings in the dressing. The pre-existing potential openings may comprise slits. The method may further comprise creating a plurality of openings in the dressing using a treatment device.

[0012] In another variation, a method of treating a subject is provided, comprising maintaining a strain in an elastic dressing, placing the strained dressing over skin of a subject, creating at least one lesion on the skin of the subject through the dressing; and then releasing the dressing so that compressive forces from the dressing are applied to the skin of the subject.

[0013] A need remains for devices, kits and/or procedures to improve the outcome of such medical procedures by improving the healing process of the tissue subsequent to the treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIGS. 1A to 1C illustrate the process of a conventional skin tightening procedure performed on a section of skin.

[0015] FIG. 2A illustrates an example of a wound dressing that assists in the healing process to improve the outcome of a cosmetic procedure or provides temporary movement of tissue.

[0016] FIGS. 2B to 2D show an example of a dressing assisting in a wound healing process.

[0017] FIGS. 2E to 2G show another example of application of a dressing to assist in the wound healing process.

[0018] FIGS. 2H and 2I illustrate an example of a second dressing or frame placed upon an initial dressing.

[0019] FIGS. 3A and 3B respectively show an expanded or strained dressing and a dressing in an unstrained or relaxed profile.

[0020] FIGS. 3C to 3F show additional variations of dressings.

[0021] FIGS. 3G and 3H respectively depicted a dressing with slit openings in an unstrained and strained profile.

[0022] FIGS. 3I and 3J depict additional variations of dressings with reinforced openings.

[0023] FIGS. 4A and 4B illustrates a dressing and frame respectively, where the frame maintains the dressing in a strained configuration for eventual placement on tissue.

[0024] FIG. 4C shows the dressing of FIG. 4A positioned on the frame of FIG. 4B.

[0025] FIG. 4D shows a cross sectional view taken along the line 4D-4D of FIG. 4C.

[0026] FIG. 4E illustrates an optional applicator used to assist in positioning the dressing of FIG. 4A from a frame to tissue.

[0027] FIG. 4F depicts a dressing with reinforced retention openings.

[0028] FIGS. 5A to 5C illustrate another variation of a dressing according to the present disclosure.

[0029] FIGS. 6A and 6B shows a dressing having one or more limiting members to pre-determine a strain capacity of the dressing.

[0030] FIGS. 6C and 6D illustrate a variation of a dressing that incorporates a bio-active substance that is intended for delivery to or near the site of the lesion.

[0031] FIGS. 6E and 6F show a variation of a dressing having a varying adhesive pattern on the dressing.

[0032] FIGS. 6G and 6H show a dressing that has regions of varying elasticity or stretchability.

[0033] FIGS. 6I to 6K show additional variations of dressings that provide directional or vectored application of force.

[0034] FIG. 7A illustrates a contoured shape multi-layer dressing having regions of varying thickness to allow for customization of a strain amount of the dressing.

[0035] FIG. 7B illustrates a further variation of a dressing that includes a thermally responsive material.

[0036] FIGS. 7C and 7D illustrate various mechanisms for application of a dressing.

[0037] FIGS. 8A and 8B show a dressing positioned adjacent to treatment devices that are used to create lesions within tissue.

[0038] FIGS. 9A and 9B show an adjustable frame that permits shaping of the frame to adjust to a contour of a surface of tissue.

[0039] FIG. 9C shows a variation of a frame employing an expandable member or bladder to compress tissue within the perimeter of the bladder.

[0040] FIG. 9D illustrates another example of an adjustable frame that is used to compress tissue or expand a dressing.

[0041] FIGS. 10A to 10C illustrate a settable adhesive for use with dressings of the present disclosure.

[0042] FIG. 11A illustrates an exemplary plot of power versus time for a laser treatment application so that a single laser can create an opening in a dressing and a subsequent lesion at the site of the opening.

[0043] FIGS. 11B to 11E illustrate another variation of using multiple laser sources to create lesions in solid dressing.

[0044] FIGS. 12A and 12B shows an example of a dressing having registration features that allow for detection by the treatment device.

[0045] FIGS. 13A to 13E show another variation of a dressing covered by a mask that directs laser energy to openings within the dressing to control placement of lesions.

[0046] FIGS. 14A to 14D illustrate various types of lesions that can be created in situ with a solid dressing.

[0047] FIGS. 15A to 15D illustrate another use for dressings of the present disclosure.

[0048] FIG. 16 depicts an additional use of a dressing as a mask to direct creation of a lesion.

[0049] FIGS. 17A and 17B provides a top view to demonstrate compression or application of force to a lesion.

[0050] FIGS. 18A to 18F show variations of shaped lesions having geometries to prevent high stress areas when compressed.

DETAILED DESCRIPTION OF THE INVENTION

[0051] The methods, procedures, kits, and devices described herein are intended to assist with the healing process of tissue that was previously or simultaneously treated for a therapeutic or cosmetic effect. Assisting in the healing process can produce an improved outcome and in some cases can eliminate or reduce variability with the healing process. The combined therapeutic process of treating tissue and assisting the ensuing healing process can produce a consistent skin tightening procedure and improve the outcome of the procedure. It is noted that combinations of variations of the methods, kits, and/or procedures as well as combination of specific aspects of methods, kits, and/or procedures are within the scope of this disclosure even though such embodiments may not be specifically shown.

[0052] U.S. Pat. No. 7,683,234 to Gurtner et al describes devices and methods intended for the amelioration of scar and/or keloid formation and include a discussion of wound healing as well other information that can be combined with the novel methods, devices, and kits of the present invention. Accordingly, the entirety of this reference is incorporated by reference herein.

[0053] The present disclosure describes the methods, procedures, kits, and devices for use with skin tightening, treatment of skin laxity, skin contraction, skin shrinkage, and maybe even body sculpting procedures for purposes of illustration. However, the invention is not limited to skin tightening unless specifically noted otherwise. The benefits of the present disclosure can be applied in any number of medical procedures requiring providing augmentation of the healing process of a therapeutic or cosmetic treatment. For example, the devices herein may be used for sutureless wound closure, skin splinting or other supportive uses. Other uses for these skin treatment devices may or may not include without limitation, for example, amelioration or prevention of scar formation, treating skin related conditions such as acne, blemishes, rosacea, warts, rashes (including but not limited to erythematous, macular, papular and/or bullous conditions), psoriasis, skin irritation/sensitivity, allodynia, telangiectasia, port wine stains and other arterio-venous malformations, and ectopic dermatitis; treating or improving existing scars, wrinkles, stretch marks, loose or sagging skin or other skin irregularities; lifting, pinning, holding, moving skin for various purposes such as during pre-operative preparation, during surgical procedures for example as a low-profile tissue retractor, to stabilize blood vessels during needle or catheter insertion, postoperatively, pre or post operatively for pre-treating or preconditioning skin for example, prior to scar revision, wound incision, body contouring, in mastectomy skin expansion, during weight loss, or for aesthetic purposes; hair removal or hair loss; treating and/or closing skin injuries for example, incisions, wounds, chronic wounds, bed sores, ulcers (including venous stasis ulcers), preventing or reducing the incidence of wound dehiscence, diabetic skin or wound conditions, burn healing and/or relief; acting as an occlusive or negative-pressure wound dressing; protecting incisions or wounds, e.g. prevention of splitting or opening, protecting newborn belly buttons after cutting umbilical cord. Such treatments may include use of a drug or other therapeutic agent that may be applied to the skin with such device. The agents may include but are not limited to antibiotics, antifungals, immune modulators including corticosteroids and non-steroidal immune modulators. The agents may be provided in any of a variety of formulations, including but not

limited powders, gels, lotions, creams, pastes, suspensions, etc. The devices may also be used for purposes of delivering a drug to the skin or through the skin, for example by stretching the skin and applying a drug thereto. Different configurations of the device may be amenable to the size or geometry of different body regions. The treatments may be applied to regions of any shape (e.g. linear, curved, stellate), size or depth, and to one or more regions of the body, including but not limited to the scalp, forehead, face (e.g. nose, eyelid, cheeks, lips, chin), ears, neck, shoulder, upper arm, lower arm, palm, dorsum of the hand, fingers, nailbed, axilla, chest, nipple, areola, back, abdomen, inguinal region, buttocks, perineal region, labia, penis, scrotum, thigh, lower leg, plantar surface of the foot, dorsal surface of the foot, and/or toes.

[0054] A number of procedures for tightening of skin are commonly known. One non-invasive approach involves the use of laser energy to ablate (vaporize) or non-ablatively heat the skin. Ablative procedures are generally more invasive (i.e. longer down time) and effective. These types of lasers do not produce consistent skin tightening, and presently none of these lasers are FDA indicated for skin tightening. In general, the procedure relies on a lesion (if an area is treated) or a number of lesions to heal after the injury to produce a tightened appearance in or around the skin that was treated. However, if the holes or lesion made by the treatment device are too large, the skin surface will not heal well. In addition, the procedure might not produce an optimal outcome if the healing process is not consistent between the lesions. Furthermore, care must be taken to prevent environmental factors from interfering with the healing process. Additionally many non-ablative tightening procedures rely on collagen contraction to produce volume changes in the collagen by a thermal denaturation process that produces dimensional changes in skin in one or more axes. See, for example, the RF product THERMAGE® (Solta Corp., Hayward, Calif.) or the IR product TITAN® (Cuteri, Inc., Brisbane, Calif.). The devices herein may also be used with other skin treatments (aesthetic or not) or resurfacing procedures whether topical or subdermal, whether or not using an energy modality such as, for example, microwave, radio-frequency ablation, high-intensity focused ultrasound, laser, infrared, incoherent light, thermal (heat and/or cold, ablative or non-ablative), use of vacuum or suction, vibration or massage (e.g. ENDERMOLÓGIE®, LPG Systems, France). The methods, kits, and devices described herein can optionally be used with such non-ablative tightening procedures as well. For example, a water jet can be used to create lesions by directing water or other liquid, and/or a mix of liquid and particles to create the lesions. Furthermore, the water or fluid can be used to swell or expand tissue. Once expanded the tissue can be treated such that upon reversion to a normal non-swelled state, the tissue engages in natural compression.

[0055] FIGS. 1A to 1C illustrate the process of a conventional skin tightening procedure performed on a section of skin. As illustrated in FIG. 1A, the dermis **10** is located over a region of subcutaneous fat **12**. During a skin tightening procedure, as shown in FIG. 1B, a physician creates one or more lesions **14** (i.e., areas of treated tissue or actual openings in tissue) in the dermal region **10**. The skin tightening procedure relies on the adjacent healthy tissue to produce a healing response **16** or scar tissue that contracts the adjacent regions of the dermis layer **10** as shown by arrows **18**. The purpose of the scar tissue **16** is to create a state of traction for the adjacent region of tissue to produce a tissue tightening effect. The

single lesion shown in the figures is for illustrative purposes only. Clearly, the number of lesions **14** created during the procedure will vary. Moreover, the location of the treatment depends upon the particular procedure and region of skin to be cosmetically treated.

[0056] In conventional skin tightening procedures, there is variability in the healing phase of the dermis **10**. This variability can lessen the desired cosmetic effect. The dressings described herein are intended to reduce this variability and provide an improved effect as a result of the healing process. FIG. 2A illustrates one example of a wound dressing **100** according to the present disclosure that assists in the healing process to improve the outcome of the procedure. The dressing **100** can have any number of shapes as desired by the intended application. For example, the dressing shown in FIG. 2A has a rectangular shape. However, variations include dressings **100** having contoured shapes to accommodate placement of the dressing around or near various anatomic features. Moreover, the dressing can be cut to fit to a desired anatomic region or to alter the characteristics of the dressing as described below. Alternatively, the dressing can be fit to the desired anatomic region and cut or shaped after it is placed on the region. Exemplary construction and/or material(s) used for the dressing may include those disclosed in U.S. application Ser. No. 12/854,859, filed on Aug. 11, 2010, which was already hereby incorporated by reference in its entirety herein. In some variations, the dressing comprises an elastic material configured with a load per width of at least 0.35 Newtons per mm at an engineering strain of 60% or a load per width of at least 0.25 Newtons per mm at an engineering strain of 45%. The elastic material may have a load per width of no greater than about 2 Newtons per mm at the engineering strain of about 45% to 60%, about 1 Newtons per mm at the engineering strain of about 45% to 60%, about 0.7 Newtons per mm at the engineering strain of about 45% to 60%, or no greater than about 0.5 Newtons per mm at the engineering strain of about 45% to 60%. The elastic material may have a load per width that does not decrease from an engineering strain of 0% to 60%, a load per width plot that increases linearly from an engineering strain of 0% to 60%, or a load per width plot that is not convex from an engineering strain of 0% to 60%. The elastic material may comprise an adhesive configured to maintain a substantially constant stress in the range of 200 kPa to about 500 kPa for at least 8 hours when strained to an engineering strain of about 20% to 30% and attached to a surface. The elastic material may comprise an adhesive configured to maintain a substantially constant stress in the range of 200 kPa to about 400 kPa for at least 8 hours when strained to an engineering strain of about 20% to 30% and attached to a surface. The substantially constant stress may vary by less than 10% over at least 8 hours, or by less than 5% over at least 8 hours.

[0057] FIG. 2A shows one variation of a dressing **100**. In this example, the dressing can comprise an elastomeric dressing (e.g. fabricated from silicone) that can optionally stretch as shown in directions **102** to expand the dressing **100** to an expanded profile **106**. The dressing device **100** can further optionally include any configuration of adhesive **104** to adhere to skin. The adhesive should not prevent the skin and/or the lesions from compressing as described herein. Alternatively, variations of dressings can allow for adhesive to be applied prior to or during application of the dressing on tissue.

[0058] The device can be placed on the dermis **10** as shown in FIG. 2B. As discussed below, the dressing **100** can be placed on the dermis **10** either prior to, during, or subsequent to creation of the lesion **14**. Once the lesion **14** is created (or during creation of the lesion **14**), the dressing **100** applies a closure force **F** to contract the lesion **14** so that the dressing **100** causes the opening **14** in tissue to close as illustrated in FIG. 2C. The tissue formed **20** as a result of the healing response then maintains the dermis **10** in a state of traction even after removal of the dressing **100** as shown in FIG. 2D. The closure force **F** can be applied in a single direction/axis or in a planar direction (e.g., X-Y axes). Stretching of the dressing **100** can be uniform or non-uniform depending upon the area of placement. As described below, variations of the dressing **100** can be configured to provide for stretching in pre-determined directions or amounts.

[0059] In those variations where the dressing **100** is elastomeric and pre-stretched, the release of the dressing **100** from the stretching force creates the closure force **F** that is applied on tissue. In alternate variations, the dressing **100** can provide a closure force via thermal, electrical, chemical or other activation of an appropriately configured dressing **100**. In such cases, the dressing applies little or no force unless activated.

[0060] As shown above, the dressing **100** can have openings adjacent to the lesion **14**. FIG. 3A illustrates these openings **108** in a dressing **100** where the dressing is strained or expanded. The openings **108** can be pre-made in the dressing **100** or can be created during the application of energy to the tissue. As shown in FIG. 3B, the openings **108** reduce in size or can close when the dressing **100** returns to the compressed or reduced state. The openings **108** can serve an additional purpose of allowing moisture to pass through the dressing **100**. Accordingly, variations of the dressing **100** can include additional openings **108** solely allow for passing of moisture through the dressing **100**.

[0061] The openings may have any of a variety of shapes, including circles, ovals, triangles, square, rectangular, star-shaped, etc. Each of the In some variations, the openings (or a portion of the openings) may comprise potential openings which appear to be slits or cuts in the dressing, which then open or spread apart upon tensioning. FIGS. 3G and 3H depict one example of a dressing **100** in a unstrained and strained configuration, respectively, with openings **108** comprising slits which are transversely oriented to the direction of tensioning, which form double-tapered openings upon strain. The slits or cuts may be linear or curved, isolated or branching, etc.

[0062] In some further variations, one or more of the openings may be reinforced with a thicker or non-elastic material to reduce or control excessive strain in the dressing material about the openings, in comparison to regions without openings. In some variations, the reinforcement may comprise open or closed perimeter, ring-like structures surrounding the openings. Materials that may be used for the reinforcement structures include but are not limited to low-density polyethylene (LDPE), fluorinated ethylene propylene (FEP) or nylon. The openings **108** of the dressing **100** may comprise individual reinforcement structures **124**, as depicted in FIG. 3I, or a regional reinforcement structure **125** that reinforced multiple openings **108**, as depicted in FIG. 3J. In other variations, the reinforcement structure may comprise a layer of material embedded or attached to a surface of the dressing, the layer of material comprising an inelastic material or a material with reduced elasticity relative to the dressing. The

layer of material may comprise identical openings, slits or cuts as the dressing, or may have a different configuration. In still other variations, no openings, cuts, or slits are provided in the dressing, but indicia may be provided on the dressing to facilitate the formation of a skin lesion pattern through the dressing. In some variations, the indicia may comprise a uniform graphical grid depicted on the dressing, but in other variations, a non-uniform grid or other non-uniform pattern is provided.

[0063] FIGS. 2E to 2G show another variation of application of a dressing **100** for use in the methods and devices described herein. In this variation, as shown in FIG. 2E, the tissue is placed under a state of traction or is strained as shown by application of a straining force **18** and the lesions **14** (or a single lesion) are created. Next, as shown in FIG. 2F, a physician positions a dressing **100** adjacent to or on the region of tissue **10** and over the lesions **14**. The dressing **100** can have openings over the site of the lesions **14** or the dressing **100** can be continuous. FIG. 2G shows removal of the strain from the tissue **10** which causes closure of the lesion **14**. Once the strain is removed and the tissue relaxes is the dressing adhered to the tissue **10**. Adhering of the dressing can occur via an adhesive on the dressing, activation of the dressing, or application of an adhesive between the dressing and tissue.

[0064] FIGS. 2H and 2I illustrate another aspect of a use of dressings **100** that can be combined with the methods and devices described herein. In this variation, a dressing **100** is placed upon one or more lesions **14** as described herein. However, a second dressing or frame **101** is positioned to overlap the first dressing **100**.

[0065] The dressing **100** can be retained on the skin by any number of mechanisms. For example, some variations include an adhesive located between the skin and dressing. Alternate variations include the use of a tape or other sealing means placed around or at edges of the dressing **100**. The use of mechanical fasteners, e.g., staples, sutures, etc. is also within the scope of this disclosures.

[0066] FIG. 3C illustrates another variation of a dressing **100** under the present disclosure. In this variation, the dressing comprises a stretchable layer as discussed above with any number of optional window or openings **106**. Once the dressing **100** is stretched, a frame or brace **110** can be applied to the dressing **100** to maintain the dressing **100** in the stretched configuration. This may be accomplished through a fastening system (e.g., clamps or teeth) or via a temporary adhesive. The brace **110** can include any number of windows or openings to provide an unobstructed path to the tissue to create the lesions. Once the treatment occurs, the brace **110** can be removed from the dressing **110** to permit the dressing **100** to compress the lesions. In some variations, the brace **110** comprises a flexible but inelastic or incompressible material configured to resist a compression load per millimeter width of at least about 0.1 Newtons, about 0.2 Newtons, about 0.3 Newtons, about 0.4 Newtons, or about 0.5 Newtons, or more. In still other variations, the brace **110** may comprise a malleable material or a substantially inflexible or rigid material. In further variations, in the brace **110** may be pre-shaped with a generally planar shape, but in other variations, may be pre-shaped to a semi-cylindrical or other arcuate shape along one dimension of the brace **110**.

[0067] FIGS. 3D to 3F show another variation of a dressing **100**. In this variation, instead of openings, the dressing **114** includes any number of raised surfaces **114**. Prior to application on tissue, this variation of the dressing **100** is stretched

out, as shown in FIG. 3E. When applied to tissue the dressing **100** reverts to its pre-stretched shape so that the raised surfaces **114** separate from the surface of the tissue as shown in FIG. 3F. In such a variation, adhesive can be applied to the planar portion of the dressing **100** around the raised areas **114**.

[0068] Any of the dressings **100** shown above (and/or braces) can be mated or aligned with the lesion-creating device so that the dressing can be applied with a single device. Alternatively, a number of dressings **100** can be fitted to the treatment device in a cartridge-like form so that the physician can position a dressing onto the treatment device prior to application of the device to tissue.

[0069] FIG. 4A illustrates another variation of a dressing **100** for use as described herein. In this variation, the dressing **100** includes any number of openings **108** that allow for creation of the lesions. In additional variations, the dressing **100** may not have any lesion-openings **108**. In such a case, the treatment could take place through the dressing **100** or the openings **108** could be created after the treatment. In any case, this dressing variation includes one or more retention openings **109**. The retention openings **109** are designed so that the dressing can be stretched over a mask or brace **110** as shown in FIG. 4B. The brace **110** will include a number of mating retention tabs **116** so that the dressing can be stretched across the brace **110** and retained on the tabs **116**. In this variation, the brace **110** includes a single central opening **118**. However, as described above, the brace **110** can include any number of openings (i.e., to match the openings on the dressing, or to provide structural rigidity to allow for stretching.) Typically, the brace **110** is stiff or inflexible when compared to the dressing **100**. However, variations can include a brace **110** that is stiff when compared to the dressing **100** but is malleable so that the brace can conform to the contours of a targeted region of tissue. As mentioned previously, the lesion-openings **108** (or other drainage or access openings of the dressing) may be individually reinforced or regionally reinforced to reduce or control any relative greater strain that may occur in regions with openings **108** in comparison to regions of the dressing **100** without opening. As depicted in FIG. 4F, the retention openings **109** of the dressing **100** may also be reinforced with a reinforcement structure **126**, which may facilitate manual stretching and attachment of the dressing **100** to the brace **110** by the user. Reinforcement of the retention openings **109** may be beneficial reducing excessive straining of the dressing region **127** between the retention opening **109** and the closest adjacent edge **128** of the dressing **100**.

[0070] FIG. 4C illustrates the dressing **110** stretched across the brace **110** with the retention tabs **116** inserted into the retention openings **109** of the dressing **100**. FIG. 4D illustrates a cross sectional view taken along the line 4D-4D from FIG. 4C. To release the dressing **100** from the brace **110**, the ends of the dressing **100** can be pulled away from the brace when the dressing engages tissue. As discussed herein, the dressing **100** can include an adhesive to secure the dressing onto tissue. Alternatively, an adhesive or other fastening means can be applied to the dressing when the physician places the dressing on tissue. FIG. 4E illustrates a variation of a dressing **100** located on a frame **116** with an applicator that can be used to secure the dressing **100** against tissue as the dressing **100** is released from the retention tabs **116**.

[0071] FIGS. 5A to 5C illustrate another variation of a dressing **100** according to the present disclosure. In this variation, the dressing can be configured to provide a uni-axial

compression (compression along one axis) where required or a unidirectional compression (i.e., movement of the dressing occurs in a pre-determined direction). FIG. 5A shows a series of lesions **16** created on a face **1** of a patient. In this example, the therapeutic procedure creates the lesions **16** in a line array type pattern as opposed to a plurality of points or dots, where the lines of lesions **16** are arranged or aligned in a pre-determined direction. For example, the pattern can be made in alignment with, against, and/or orthogonal to Langer's lines, also referred to as cleavage lines. Langer's lines are topological lines drawn on a map of the human body. These lines correspond to the natural orientation of collagen fibers in the dermis and epidermis and can be defined by the direction in which the skin of a human cadaver splits when struck with a sharp point. In practice, a series of dressing can be applied with differing orientations corresponding to typical or mapped Langer's Lines.

[0072] For example, the physician can create lesions aligned to a directional path that is similar to sutures that could be used to tighten the tissue. FIG. 5B illustrates a dressing **100** stretched in direction **102** and having a plurality of openings **108** that open along the stretched direction. As discussed above, the dressing **100** can include an adhesive for securing to tissue. Alternatively, the adhesive can be applied between the skin and dressing or another mode of fixation can be employed. FIG. 5C shows the dressing **100** upon reaching a pre-stretched or relaxed state. As shown, the openings **108** reduce in thickness to compress the lesions when forming the tissue **20** generated as a result of the healing process.

[0073] In another variation, a dressing **100** can be adhered to tissue or skin without significantly stretching and then is stretched. Stretching the tissue in this manner uniformly and gently stretches the skin underlying the dressing in a direction along Langer's lines along with the dressing.

[0074] When the skin is then treated through the dressing in a stretched condition, releasing the stretch as well as removing the dressing will allow a gentle closure force due to the skin's own natural elasticity. Presently, physicians stretch tissue using their fingers to stretch the tissue area as they treat. However, this process increases overall procedure time since the physician is only able to treat small areas at any given time. A variation of present invention includes a dressing that is stretched after being applied to the skin to stretch the skin along Langer's lines. Once the tissue is treated, the dressing is removed. This permits the natural resiliency of the skin to provide a gentle closure force without having to leave the dressing in place.

[0075] FIGS. 6A and 6B illustrate an aspect of dressings **100** described herein. In this example, the dressing **100** includes one or more limiting members **122** to pre-determine a strain capacity of the dressing **100**. For example, as shown in FIG. 6A, the limiting members **122** are shown in a compressed configuration. When the dressing is stretched, as shown in FIG. 6B, the limiting members **122** approach their predetermined length to limit the maximum strain of the dressing **100**. Accordingly, a physician can be provided with a number of dressings **100** each having a varying amount of maximum strain. Although FIGS. 6A and 6B illustrate a dressing having uni-directional strain or deflection, variations of the invention contemplate limiting members that limit strain in a bi-axial direction. The limiting members **122** can be comprised of a shape memory alloy such as a super-elastic alloy or a heat activated alloy that extends or contracts in response to a temperature shift. Although a zig-zag shape is

depicted for the limiting member **122** in FIG. 6A, in other variations, the limiting member may comprise an undulating configuration or other curved configuration, or any non-linear configuration. The limiting member may comprise any of a variety of relaxed threads, strings, wires or other elongate, elongatable, straightenable or stretchable members that straighten, lengthen and/or stretch to a desired amount, degree, and/or preset limit. The limiting members may be configured with a sufficient tensile strength to prevent, resist or otherwise control over-stretching of the dressing. The skin treatment device may be constructed of multiple layers of an elastic material such as silicone with an adhesive between layers to which the members are attached initially in the relaxed, undulating, sinusoidal, unstraightened or other unstretched configuration. According to a variation, the shape limiting strings or other devices may prevent straining in regions where straining or less strain is desired. For example, the threads may be straight at the edges of the skin treatment device to prevent straining at the edges. In some variations with multiple limiting members, the limiting members may be equally spaced apart and have uniform lengths and uniform attachment points across a transverse dimension to the tensioning axis of the dressing. In other variations, the limiting members may have a variable or non-uniform spacing, may have non-uniform lengths, non-uniform attachment points, and may also be serially arranged along the tensioning axis. The opposing ends of the limiting members **122** may also optionally have removable (or non-removable) manipulation elements **123** attached to the ends to provide for a more even or uniform strain, and may comprise an inelastic material which is the same or different as the limiting members **122**. The manipulation elements **123** may span the entire transverse dimension of the device **100** to the axis of tensioning, as depicted in FIGS. 6A and 6B, but in other variations may be less than the entire transverse dimension (e.g. having a transverse dimension sufficient to span a plurality of limiting member **122**, but less than the full transverse dimension of the dressing **100**). Such elements may comprise planar members, handle members, flexible members and/or inflexible members. They may be attached and removed in a variety of manners, for example as described herein.

[0076] FIG. 6C illustrates another variation of a dressing **100** that incorporates a bio-active substance that is intended for delivery to or near the site of the lesion. In one example, the dressing **100** includes a polymer layer (e.g., silicone) and an adhesive layer **184**. The dressing **100** can also include a bio-active substance **182**. Although the bio-active substance is shown as a separate layer **182**, variations of the dressings can include a bio-active substance that is infused with the polymer layer **180** and/or adhesive layer **184**. Alternatively, the bio-active substance can be a separate layer. FIG. 6D illustrates the dressing **100** of FIG. 6C after an opening **108** is made in the dressing **100** during creation of a lesion **14**. As shown, creation of the opening causes the bio-active substance to enter the lesion **14** as represented by arrows **186**. The bioactive substance can be an activated substance, such as a Rose Bengal dye (a photosensitive dye typically used to cross-link collagen and is activated by light having wavelengths of 514 nm, 532 nm or 458 nm). Alternatively, the bioactive substance can be any drug or pharmaceutical substance delivered for a particular effect on the lesion or tissue. In further examples, the substance can be a material that causes cross-linking of collagen, such as riboflavin and/or glucose. Examples of other bio-active agents that may be used

include hemostatic or coagulative agents to help reduce bleeding. Such agents include chitosan, calcium-loaded zeolite, microfibrillar collagen, cellulose, anhydrous aluminum sulfate, silver nitrate, potassium alum, titanium oxide, fibrinogen, epinephrine, calcium alginate, poly-N-acetyl glucosamine, thrombin, coagulation factor(s) (e.g. II, VII, VII, X, XIII, Von Willebrand factor), procoagulants (e.g. propyl gallate), antifibrinolytics (e.g. epsilon aminocaproic acid), and the like. In some variations, the agents may be freeze-dried and integrated into the dressing and activated upon contact with blood or other fluid. In some further variations, an activating agent may be applied to the dressing or the treatment site before the dressing is used on the subject. In still other examples, the hemostatic agent may be applied separately and directly to the wound before application of the dressing, or after application to the dressing via a catheter or tube. The devices may also comprise one or more other active agents that may be useful in aiding in some aspect of the wound healing process. For example, the active agent may be a pharmaceutical compound, a protein (e.g., a growth factor), a vitamin (e.g., vitamin E), or combinations thereof. A further example of such medicament may include, but is not limited to various antibiotics (including but not limited to cephalosporins, bacitracin, polyxyxin B sulfate, neomycin, polysporin), antiseptics (such as iodine solutions, silver sulfadiazine, chlorhexidine), antifungals (such as nystatin), anti-proliferative agents (sirolimus, tacrolimus, zotarolimus, brolimus, paclitaxel), grow factors (such as VEGF) and other treatments (e.g. botulism toxin. Of course, the devices may comprise more than one medicament or agent, and the devices may deliver one or more medicaments or agents.

[0077] FIGS. 6E and 6F show another variation of a dressing **100** having an adhesive pattern **104** that varies on the dressing **100** as opposed to being located on the entire surface of the dressing **100**. FIG. 6E shows one example of a varying adhesive pattern **104** where the adhesive layers alternate with uncovered sections **107**. When applied to tissue **10** and released from the strained condition, the dressing **100** contracts at the uncovered regions **107** causing the tissue **10** to buckle at the uncovered regions **107** as shown in FIG. 6F. Other examples of variable adhesive patterns on the dressing are described in U.S. Pub. No. 2011/0152738, filed on Aug. 11, 2010, which was already incorporated by reference in its entirety herein.

[0078] FIG. 6G shows another variation of a dressing **100** for use as described herein. In this variation, the dressing comprises a varying elasticity across different sections. For example, as shown, a dressing can have an elastic section **126** coupled to a relatively less-elastic section **127**. The illustrated variation shows the elastic section **126** as being thinner than the less-elastic section **127**. However, any number of configurations can provide varying stretch or elasticity. For example, the different sections can have different reinforcements, different materials with varying durometers. One such use of the varying dressing **100** is shown in FIG. 6H, which shows the less elastic section **127** placed in an area where stretching of the skin is not desired and the elastic section **126** being used to produce a pulling force in a desired direction as shown by arrows **128**. Other examples of dressings with variable elasticity regions are described in U.S. Pub. No. 2011/0152738, which was already incorporated by reference in its entirety herein. In one particular example, a dressings may be tapered near its edges to reduce thickness. A tapered edge may also ameliorate peak tensile forces acting on skin tissue adjacent

to the adhesive edges of the dressing. This may or may not reduce the risk of skin blistering or other tension-related skin trauma. In other variations, the edges of the dressing may be thicker than the middle of the dressing. It is hypothesized that in some configurations, a thicker dressing edge may provide a relative inward shift of the location of the peak tensile forces acting near the dressing edge, compared to dressings of uniform thickness.

[0079] FIGS. 6I to 6K show additional variations of dressings **100** that provide directional or vectored application of force. As shown, the dressings **100** can include adhesive **104** such that when applied to tissue the dressing is pulled to provide a strain in tissue in a desired direction. Benefits of such a variation include providing the physician with control over the degree of strain. Furthermore, the dressings can be treated with, for example, a chromophore to monitor the degree of strain in the dressing. Other examples of a color change material or structure that may be used or incorporated into the dressing are described in U.S. Pub. No. 2006/0246802 to Hughes et al, which is herein incorporated by reference in its entirety.

[0080] FIG. 7A illustrates another variation of a dressing **130** that includes a contoured shape for suited for placement on specific anatomy (for example, the illustrated dressing **130** can be placed on a face of a patient having a larger area at a lower region to accommodate placement along the jaw-line and a smaller surface area at a top region to accommodate placement close to the ear). FIG. 7A also illustrates the dressing **130** as having a varying thickness across the length of the dressing **130**. The varying thickness allows for a physician to adjust the amount of strain that the dressing **130** applies to tissue. For example, section **132** can include the greatest number of layers, which translates into the highest strain rate. To reduce the strain rate, the physician or medical practitioner would cut or remove section **132** from the dressing **130**. Removing section **132** leaves sections having fewer layers and as a result, lower strain rates. Although the figure illustrates three sections **132**, **134**, **136**, any number of sections is within the scope of this disclosure.

[0081] FIG. 7B illustrates a further variation of a dressing **100** that includes a thermally responsive material. In this variation the dressing **100** can include one or more openings **108** but the construction of the dressing **100** allows for customization of the location as well as degree of strain that the dressing **100** will apply on tissue. The dressing can be adjusted using visible or UV light, or it can be activated using a chemical response or via heat. The dressing can also include a separate layer that drives shrinkage of the dressing upon activation (e.g., via a laser, heat, other irradiation). In any case, use of a shrinkable dressing permits customization to create tension or strain in a desired direction during the treatment procedure.

[0082] FIGS. 7C and 7D illustrate another mechanism for application of a dressing **100**. As shown, a dressing **100** can be applied using a roller applicator **160**. The roller applicator **160** can strain the dressing **100** as it applies the dressing **100** to tissue **10** over the lesions **14**. Alternatively, the roller applicator **160** can apply a pre-strained dressing **100** that compresses tissue **10** and the lesions **14** upon positioning on the tissue **10**. FIG. 7D illustrates a roller applicator **160** that is coupled to a lesion creating device **146**, which creates the lesion **14** and where movement of the device **146** causes the roller **160** to apply the dressing **100**. The device **146** can also include one or more sensors **148** to provide feedback of

location to the system or can be used to detect movement of the device **146**. In some variations, the roller applicator **160** may comprise a ribbon spring (or other spring mechanism or tension control mechanism) to resist rotation of the roller until a specific tension threshold is achieved.

[0083] FIG. 8A shows another application of a dressing **100** as described herein. In this variation, the dressing **100** is coupled to a treatment device **140**. The treatment device **140** can create a lesion through any variety of treatment modes where the active elements **142** of the treatment members pass through openings in the dressing. For example, the treatment device **140** can create the therapeutic lesion using RF energy, plasma, cryogenic energy, microwave energy, laser, optical energy (non-laser) chemical, resistive heat, ultrasound energy, or via mechanical energy. As shown, a dressing **100** can be coupled to the treatment device **140** so that after creation of the lesions, the treatment device **140** can be removed leaving the dressing in place to apply compression to the lesions. Alternatively, the treatment device **140** can be directly applied over a dressing **100** that was previously positioned. In some variations, the dressing **100** may comprise a pattern of treatment openings with predetermined size, spacing or location, and the treatment device **140** may comprise a matched pattern or array of treatment elements **142** with the same spacing or location. In some variations, the pattern of treatment openings in the dressing **100** may comprise a repeating sub-pattern, and the treatment device **140** may comprise a matched pattern or array of treatment elements **142** to the dressing subpattern of openings. In these variations, the dressing **100** may comprise indicia to delineate the locations of the subpatterns. Thus, the treatment device **140** may be used at multiple regions of the dressing **100**. The pattern or array of treatment elements **142** of the device **140** may comprise at least 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, or 20 treatment elements.

[0084] FIG. 8B illustrates another variation of a dressing **100** in combination with a treatment device **144**. In this variation, the treatment device **144** creates openings within the dressing **100** before or during the actual treatment. For example, the treatment device can employ a laser, optical/light, chemical, ultrasound or electrical energy to create an opening through the dressing while creating the therapeutic lesion in tissue beneath the dressing. Moreover, device **144** can apply energy to a dressing **100** to activate the dressing **100** induce or adjust strain. In such a case, the dressing can be in an unstrained condition prior to activation by the device **144**. Alternatively, or in combination, the device **144** can reduce or increase a strain in the dressing depending upon the desired application. FIG. 8B illustrates lesion creating elements **145** positioned adjacent to the dressing **100**. In the event that the device **144** employs a laser to create lesions, the laser is emitted from the elements **145** and can either pass through the dressing **100** or can create openings in the dressing. In those variations where the lesion creating elements **145** comprise electrodes or mechanical members, the elements **145** can pass through the dressing when advanced from the device **144**.

[0085] In many cases, the dressings described herein are intended for positioning on contoured tissue surfaces rather than planar surface. Accordingly, there may be a need to provide a dressing that can approximate the contoured shape prior to affixing to the tissue surface. FIGS. 9A and 9B show one possible solution to adjust a contour of a dressing described herein. FIG. 9A shows a variation of an adjustable frame **150**. In this example, the frame **150** includes a plurality

of adjustable links **154** coupled between two end-pieces **152**. However, variations of the frame **150** include adjustable links **154** forming the entire periphery of the frame. As discussed above, the frame **150** can include one or more fixtures to permit retention of the dressing. FIG. 9B illustrates the adjustable frame **150** where one or more of the plurality of links **154** can be adjusted or extended to permit a portion or all of the frame **150** to form a contoured shape. Although not illustrated, a dressing attached to the frame **150** will then be in a better configuration when being secured to a contoured tissue surface.

[0086] In additional variations, a frame can be used without a dressing to apply strain to the tissue in a similar manner as a dressing. For example, a deformable frame can apply a compression force to the tissue and then can be affixed to the tissue in a manner as described herein (e.g., adhesive, mechanical fasteners, sutures, etc.) Doing so allows the frame itself to compress tissue to assist healing of the treated region.

[0087] FIG. 9C shows another variation of a frame **156**. In this variation, the frame **156** employs an expandable member or bladder **158**. When affixed to tissue the bladder can be inflated or expanded to position **160** to provide compression within the area bounded by the frame **156** and bladder **158**. In other variations, a foam (open cell or closed cell) may be provided within the bladder to maintain the bladder in an expanded state, and negative pressure may be applied to reduce the bladder/foam size. In still other variations, the frame may comprise a foam member in lieu of a bladder member to provide a resilient or contouring surface or structure for the frame.

[0088] FIG. 9D illustrates another example of an adjustable frame that is used to compress tissue. In this example, the frame **170** can have hinges or joints **176** that transmit a force **172** applied at the joints to result in an expansion force **174** at the edges of the frame. In some variations, the frame is biased to return to its initial shape upon application of a force. In such a case, after force **172** is applied to the frame, the frame **170** provides compression within the area bounded by the perimeter of the frame **170**. In use, a physician could apply the activation force **172** to the frame, then adhere portions of the frame **170** to tissue. As the frame **170** attempts to return to its initial shape, the return force compresses tissue within the frame. In an alternate variation, the frame **170** is not biased. Instead, the frame **170** can be affixed to an elastic dressing (not shown) as described above. In this example, application of force **172** causes expansion or straining of the elastic dressing in direction **174**. A physician or medical practitioner can then affix the strained dressing **170** to tissue where the resiliency of the tissue compresses the tissue.

[0089] The dressings of the present invention can also provide temporary results to simulate a clinical effect. These temporary results can allow a patient or physician to determine the type or amount of treatment desired. For example, a physician can position pre-strained dressings on a patient to show the patient the results of a procedure given a pre-determined amount of shrinkage or lift. Such a feature allows a physician to position dressings having a pre-determined amount of strain on a patient so that the patient can visually see the results of the given reduction. For example, a physician can position dressings that lift the skin by a given amount so that the patient can determine whether more or less lift is desired. The goal is to simulate clinical results and allow a patient to see a real time simulated clinical result via the application of the dressings. Such pre-strained dressings can

be provided as a kit having varying ranges of displacement with corresponding templates to assist the physician in applying therapeutic treatments to match the temporary state of the tissue. In this way, a patient can observe the simulated clinical result, once a desired result is achieved; the physician can select treatment templates based on the dressings that are used to produce the temporary effect. Use of the dressings to simulate a clinical effect can be used in any number of cosmetic procedures outside of skin tightening. In additional variations, the simulated clinical effect can be used to establish a treatment plan. Such a treatment plan can include the amount of or location where the therapeutic treatment. The simulated clinical effect can be processed through a computer analysis to provide the physician with a treatment plan based on the type of dressing used or amount of lift used to produce acceptable or desired results.

[0090] FIGS. 10A to 10C illustrate another aspect for use with dressings of the present invention. As shown in FIG. 10A, a dressing **100** that is placed over a lesion **14** when used to apply compression to the dermal layer **10** of skin. In this variation, the dressing **100** includes an adhesive layer **104**. In some variations, the adhesive layer **104** is sufficient to prevent creeping or movement of the tissue **10** subsequent to placement of the dressing **100**. However, in certain circumstances, as shown in FIG. 10B, the tissue **10** contacting the adhesive layer **104** can begin to creep causing the lesion to move in the direction shown by arrows **162** resulting in opening of the lesion **14**. The creep of the tissue **10** can occur due to the restoring force of the skin, which may be higher in a particular target location. Alternatively, creeping of tissue can occur due to the thickness of the elastic layer or when the adhesive layer is non-rigid and/or deformable and takes time to secure the dressing to the tissue.

[0091] FIG. 10C provides a representation of an alternate variation of a dressing **100** having an adhesive material **105** that can be activated or set. In some variations the settable adhesive material **105** is set from a liquid or viscous phase to a solid phase via UV or IR irradiation or even oxidative curing. In some variations, use of oxidative curing allows for securing of the dressing without heating of the tissue and/or dressing. As shown in FIG. 10C, the adhesive material **105** solidifies to keep the lesion closed but also remains pliable to allow the dressing **100** to remain pliable and conform to the curvature of the tissue.

[0092] In additional variations a dressing can be used to limit the lesion size or to minimize collateral damage to tissue. For example, a solid dressing can be applied to tissue as described above. Next, a laser can then be used to create openings in the dressing as well as to create the lesion. For instance, an Er:YAG laser or an Er:YsGG may be used with a Cr²⁺: or Cr²⁺:ZnSe Q-switching device, or a Cr²⁺:Cr²⁺:ZnS Q-switching device to apply a pulse in a Q switched mode followed by a free running mode or normal mode. The pulse could be used to remove a portion of the dressing since the pulse produces a plasma initiation and expansion to photo-mechanically remove the layer of the dressing (e.g., a silicone layer). The free running mode operation creates a micro lesion via photothermal ablation of the tissue.

[0093] FIG. 11A illustrates an exemplary plot of power versus time for a laser treatment application so that a single laser can create an opening in a dressing and a subsequent lesion at the site of the opening. As shown, the first applied pulse **166** reaches a power level much greater than that of the subsequent free running mode pulse **168**. One benefit of

creating openings in the dressing simultaneously or immediately prior to creating the lesions is to eliminate alignment of the openings and lesions.

[0094] FIGS. 11B and 11C illustrate another variation of using a solid dressing and creating openings in the dressing once the dressing contacts the tissue. As illustrated in FIG. 11C, the treatment can include two or more different types of lasers 174, 176, where one of the lasers 174 can be selected such that it is highly absorbed by the dressing 10. While the second laser 176 can be selected such that it is highly absorbed in tissue. For example, a CO₂ and Er:YAG laser can be used together. The wavelength of the CO₂ laser is highly absorbed by silicone and the wavelength of the Er:YAG laser is highly absorbed in skin. In one example, the wavelength required to create openings in the dressing is 10.6 μ m while the wavelength for creating lesions could range from 1.9 to 3.3 μ m. The lasers can be arranged so that they are either co-axial or confocal (e.g., the laser elements in FIG. 11C can be rotated or moved so that each laser targets the same region.) Alternatively, the lasers can be configured to deliver light in a concentric manner. In use, the lasers are time-delayed as shown in FIG. 11B, which illustrates a graph of power versus time. As shown, the first laser 174 delivers a first pulse 170 to create the opening in the dressing 10. The pulse 172 from the second laser 176 can be staggered or delayed to allow for ejection and/or removal of debris. While any variation of lasers can be used in this configuration, one desirable variation can include the use of two low power lasers to provide each source of light. Alternatively, a more complicated dual wavelength system can be used. Such a system could deliver multiple wavelengths of light as described above.

[0095] FIG. 11D shows the system of FIG. 11C, where the first laser 174 creates an opening 108 in the dressing 100 but not the skin since the laser is not absorbed by the skin. FIG. 11E shows the second laser 174 creating the lesion 14 through the previously created opening 14.

[0096] The above system or configuration allows for a skin tightening therapy with an adhesive patch applied to skin with the skin and patch ablated in situ. The patch is applied to untreated skin under tension with an adhesive. The patch initially does not have holes over the areas where lesions are to be formed. The entire patch may be solid or may have holes or other features to position and/or stretch the patch. An initial laser beam ablates holes or other features in the patch to expose certain areas of the skin. The exposed areas can then be treated through holes in the patch. The laser parameters are such that the patch material is cleanly ablated with a minimum of thermal damage to the underlying skin. A second laser beam of possibly different character is then used to ablate a controlled amount of skin. An additional benefit of creating openings in the dressing and subsequently creating lesions is that the lesion pattern and/or openings in the dressing can be customized during a procedure rather than needing to follow the pattern of a pre-configured dressing.

[0097] One benefit of creating openings in the dressing in situ is that there is no need for orienting a dressing having pre-made openings with previously created lesions. Yet another benefit of creating openings in-situ is that the pattern or features of the holes in the dressing are customized to match the lesions.

[0098] FIG. 12A shows an example of a dressing 100 having one or more registration features 202, 204 allowing for detection and/or recognition regarding characteristics of the

dressing. For example, FIG. 12A shows registration features 202 and 204, which allow for optical scanning or reflecting light that can be used to confirm alignment of the treatment device. Alternatively, or in combination, the presence or relative position of the registration features 202 and 204 can provide any range of information regarding the pattern of openings 108 or even the location where treatment should occur. For example, in FIG. 12A, lesions are created in the openings that are within specific registration features 202 and 204.

[0099] Once the system obtains feedback regarding the registration features, the system can confirm that the treatment device is in the correct position. Subsequently, image analysis hardware and software can be used to recognize the patterns or openings 108 in the dressing 100 to either control the treatment parameters, to maintain a database of treatment areas, or to perform some other custom treatment depending upon type of dressing or orientation of the dressing.

[0100] One approach is to position a handheld scanning handpiece directed at the approximate location of the treatment. The system can determine whether positioning of the handpiece is within an acceptable tolerance using an optical detection of one or more registration features 202, 204. Once the system confirms correct or acceptable positioning, the system can then permit or trigger a treatment cycle. For example, a laser scan pattern can be released on a time scale sufficiently rapid enough (<50 msec) such that inadvertent motion of the handheld scanning handpiece does not appreciably affect the pattern. The handheld scanning handpiece can be repositioned to treat the next zone, and the optical detection of registration features at the correction positioning of the dressing with respect to the handpiece will again trigger the release of a laser scan pattern.

[0101] Alternatively, a handpiece with either scanning patterns or fixed patterns (including a single shot) can be manually positioned laterally to the dressing, with optical detection of the registration features 202, 204 triggering individual firing events. One example involves the use of an optical mouse-type arrangement in which a light source such as an LED projects onto the dressing surface and the reflected or scattered light from the dressing is re-imaged into an optical detector as the handheld device is manually moved laterally across the dressing.

[0102] Alternatively, a complete image may be acquired by an imaging system, and image-processing software may be used to create a custom scan pattern to be delivered. The positioning of the dressing with respect to the laser delivery system, the particular configuration of the dressing, the desired pattern of lesions may all be processed to determine a customized laser scanning pattern appropriate for a particular dressing and patient. In this realization, a relatively large area may be treated by a scanned laser pattern, which may require a duration that is long enough that movements of the patient with respect to the laser delivery device may occur. The invention may interrupt delivery of laser pulses if motion of the registration features 202, 204 is detected. The positioning may be restored and laser firing resumed. Alternatively, a new image may be acquired and a new laser delivery pattern computed and delivered.

[0103] FIG. 12B provides a partial illustration of another variation of a dressing 100. In this variation, a dressing 100 can include a surface that provides a particular optical or other identifiable property that can be recognized by the treatment device to alter treatment parameters or lesion location based

upon pre-determined parameters. For example, the dressing **100** can include a particular, reflective, absorptive, or scattering characteristic that is recognized by the treatment device. In addition, as shown, a dressing can include a first region **206** having a first set of characteristics, and a second region **208** having a second set of characteristics.

[0104] FIGS. **13A** to **13E** show another variation of a dressing **100** covered by a mask **128** where the dressing **100** and mask **128** allow for a treatment device to create lesions at specific areas, thereby eliminating the need to align the dressing with the lesion. As shown, the mask **128** can include openings **129** that are in alignment with opening **108** in the dressing. Optionally, the mask **128** can apply strain to the dressing **100**. FIG. **13A** illustrates the dressing **100** in a strained configuration to place the tissue **12** in a state of traction. The dressing **100** and mask **128** are exposed to the treatment energy **120** (e.g., a laser or other treatment modality). The therapeutic energy **120** creates ablation patterns **14** and **131** in the tissue **12** and the mask **128** respectively. FIG. **13C** shows removal of the mask **128** and eventual compression/closure of the lesions **14** as the dressing **100** contracts. FIGS. **13D** and **13E** illustrate top planer view of a dressing **100** and mask **128** having respective openings **108** and **129**. FIG. **13D** shows the dressing **100** and mask **128** pre-treatment. FIG. **13E** shows the dressing **100** and mask **128** after the ablation process. As shown, the ablation pattern **14** and **131** can be created over a wider area than the opening **14** in the dressing **108** but only forms lesions **14** in the tissue in a limited manner at the exposed areas.

[0105] FIG. **14A** illustrates another advantage of creating a lesion **14** in situ with the dressing **100**. As shown in FIG. **14A**, the lesion **14** as well as the opening **108** in the dressing **100** can be made to have a unique shape that can be made or modified during the procedure. For example, FIG. **14A** shows a dressing **100** with a lesion **14** in tissue, where both the lesion **14** and opening **108** are made to have a longer dimension when viewed along **14C-14C** (as shown in FIG. **14C**), when compared to direction **14-B-14B** (and as shown in FIG. **14D**). Furthermore, the lesion pattern can be a non-linear design. An additional example of such patterns is shown in FIG. **14D**.

[0106] FIGS. **15A** to **15D** illustrate another use for dressings of the present disclosure.

[0107] FIG. **15A** illustrates an array **190** of electrodes **192** adapted to penetrate subdermal tissue, such as subcutaneous layers **12**. FIG. **15B** illustrates a dressing **100** as described herein, where the dressing is strained and placed over the electrodes **192** as shown in FIG. **15B**. The electrodes **192** (e.g., RF electrodes or any other energy modality described herein) applies energy to the subcutaneous fat layer **12** to lyse, burn, or otherwise breakdown the fat to create a lesion **22** or cavity **22**. FIG. **15C** illustrates removal of the electrode array **190** leaving the dressing **100** in place against the dermal region **10** of tissue. Because the dressing **100** is in a strained configuration, removal of the dressing **100** from the electrode array causes movement of the dressing **100** to close the openings **108** as described above.

[0108] FIG. **16** depicts an additional use of a dressing **100** as a mask to direct creation of the lesion **14**. As illustrated, an electrode **142** or other lesion creation element is placed against a dressing **100** such that activation of the element **142** creates lesions **14** through openings **108** in the dressing **100**. As discussed above, creating lesions **14** through openings **108** in the dressing **100** eliminates the need to match openings in

the dressing to lesions. The use of the dressing **100** as a mask type element eliminates the need for electrodes penetrating into tissue.

[0109] Elastomeric dressings of the present disclosure can also be used by affixing to the tissue, stretching or straining once placed on tissue. Then creating the lesions in the tissue. The dressing can then be released to compress the lesion. The dressing can also be removed so that the natural elasticity of the skin or tissue helps appose the lesion openings. Accordingly, the dressing can be removed.

[0110] In additional variations, the dressings or frames described herein can be affixed to external structures placed on a patient to provide the degree of lift or tissue movement required for an acceptable clinical effect. For example, a cap or similar structure can be placed on a patient's head and serve an anchoring type device that allows the dressings or frames to displace tissue for an acceptable simulated visual result.

[0111] The devices, methods and kits described herein can be used for applying force to any portion of tissue to compress, reposition, or lift tissue as required by the intended cosmetic application (e.g., lifting of the breast, stretching scalp tissue to increase a density of implanted, underarm, abdominal procedures, etc. The dressing described herein can be fabricated from any biocompatible material that can provide the compressive force necessary to achieve

[0112] the intended result. For example, the dressings can comprise a polymer, a shape memory polymer (e.g., acrylate-based, styrene-based and epoxy-based shape memory polymers), or biocompatible polymer (e.g., silicone). The dressings and/or frame can be transparent or opaque or have other features as required by the intended application. The strain rates of the dressings and frames described herein can range from 1% to 100% either uni-directional, uni-axial, or bi-axial.

[0113] The fixation means described above can include any conventionally known means to secure similar dressings or frames to tissue. For example, the devices can be secured to tissue in a variety of ways (either temporarily affixed or affixed until the fixation means is removed). For example, the devices can be removably secured to the tissue with an adhesive, with a skin piercing device, or the like. Suitable adhesives include pressure sensitive adhesives, such as polyacrylate-based, polyisobutylene-based, temperature activated adhesives, chemically activated adhesives and silicone-based pressure sensitive adhesives. Suitable skin-piercing devices include clamps, needles, microneedles, sutures, anchors, staples, microtines and the like.

[0114] The devices may have any suitable or desirable shape or size. In some examples, the shape of the dressings or frames can be adjusted before, during or after the procedure. For example, the devices may have a shape selected from the group consisting of rectangles, circles, squares, trapezoids, toroids, ovals, or segments and combinations thereof. For example, some devices may be substantially circular, others may be substantially toroidal, and still others may be substantially rectangular.

[0115] In another aspect, altering the geometry of a lesion to assist in wound healing can be combined with methods and devices described herein to improve the outcome of a treatment. For example, FIG. **17A** provides a representative illustration of a top view of a lesion **14** without application of any compressive force. FIG. **17B** illustrates the lesion **14** of FIG. **17A**, where a compressive force, as described above and

illustrated by arrows 26, attempts to close the lesion 14. However, the lesions 14 circular geometry creates regions of increased stress 28. The high stress regions 28 are not desirable for a number of reasons. For example, the high stress regions 28 can impede the healing process. Moreover, the high stress regions 28 caused increased resistance when attempting to close the lesion 14. For example, the high stress regions 28 can provide an opposing force to the dressing and ultimately render the procedure less effective. FIG. 18A shows a variation of a shaped lesion 30 intended to reduce areas of high stress when the lesion 30 is compressed as discussed herein. The lesion 30 can be created via a single treatment or can comprise a number of treatments to produce a desired shape. For example, in FIG. 18A the lesion 30 can be created to be asymmetrical so that portions 32 of the lesion 30 do not generate high areas of stress when the lesion is compressed (see e.g., FIG. 18B). In one example, a shaped lesion 30 is created via a slit in tissue and superimposing a circular lesion on the slit portion. Alternatively, as shown in FIG. 18C, a standard lesion 14 is created and then a secondary process creates one or more additional lesions 32 to create a shaped lesion 30 as shown in FIG. 18D. The creation of the base lesion 14 can be made by any conventional means (e.g. a CO₂

laser) that creates a lesion of the desired size. The additional lesions 32 can be created using a means that allows creation of smaller lesions.

[0116] FIG. 18E illustrates another variation of a lesion 14 with features 32 to prevent high stress areas upon compression of the tissue. Such complex lesions can be created using a masking approach or creating series of therapeutic treatment lesions similar to that shown in FIG. 18D. FIG. 18F illustrates another lesion geometry conducive to avoiding high stress areas upon compression of tissue. In this variation, the lesion 14 includes a relatively simple geometric configuration (oval as opposed to circular).

[0117] The applications of the disclosed invention discussed above are not limited to certain treatments or regions of the body, but may include any number of other treatments and areas of the body. Modification of the above-described methods and devices for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the arts are intended to be within the scope of this disclosure. Moreover, various combinations of aspects between examples are also contemplated and are considered to be within the scope of this disclosure as well.

1. A skin treatment device.

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