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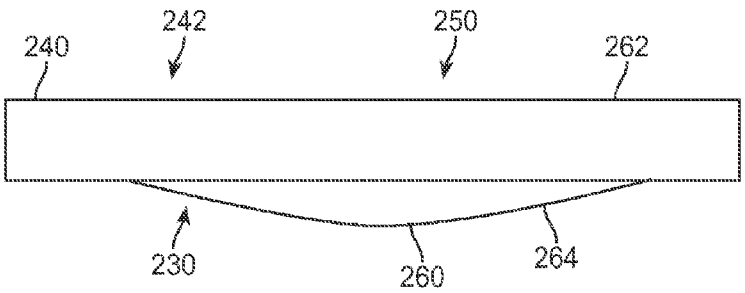

FIG. 19B

(57) Abstract: Oxygen diffusive wound dressings and methods of manufacturing and use are described herein. The wound dressing may generally provide a ready supply of oxygen to a wound being treated via one or more oxygen conduits which are designed to pass oxygen from ambient air or other oxygen reservoirs into proximity to the wound, and may also provide for exudate removal through transecting channels in fluid communication with both the wound surface and a hydrophilic absorbent material.

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OXYGEN DIFFUSIVE WOUND DRESSINGS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Pat. App. 13/692,343 filed December 3, 2012 which is a continuation-in-part of U.S. Pat. App. 13/650,003 filed October 11, 2012, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to wound dressing apparatus and methods of their manufacturing and use. More particularly, the present invention relates to wound dressings that allow for the oxygenation and prevention of dehydration of wounds while removing exudate from the wounds and methods of their use.

BACKGROUND OF THE INVENTION

[0003] To facilitate the healing of wounds, the wound environment needs to be conducive to cell survival and proliferation. If the wound becomes dehydrated or if a pool of exudate develops above or within the wound, oxygen diffusion to or through the wound becomes impeded and the cells become hypoxic, which impairs their function (for example, the antimicrobial activity of neutrophils or the production of collagen by fibroblasts). Under sustained hypoxic or anoxic conditions the cells may die. This is especially true if the wound has impaired vascular delivery of oxygen from the native blood vessels. Dressings which are used to simply cover wounds typically absorb at least a thin layer of exudate (e.g., more than a couple hundred microns of exudate within the dressing). If the exudate and/or if the dressing material itself limits oxygen permeation to the wound, the covered cells may die and impede wound healing. As the cells die, they release cytotoxic factors which cause additional cells to die, potentially leading to a downward spiral of cell death.

[0004] Wound dressings generally cover a wound and limit dehydration but also restrict oxygen availability to the wound, which leads to cells becoming anoxic and dying due to the limited oxygen supply. Cellular preparations such as platelet rich plasma gels improve wound healing, and providing oxygen from outside the wound may improve their effectiveness.

[0005] For aggressively weeping wounds, dressings used sometimes rely on evaporation to remove excess water from the exudate and wound site; however, this has the undesirable effect of concentrating toxic factors (e.g., metalloproteases) in the exudate and may worsen conditions. Moreover, excess evaporation may also lead to wound dehydration which may further worsen the environment for wound healing. Dried exudate can form a crust with abrasive properties, further impeding healing.

[0006] In some treatments, wet gauze or hydrogel dressings are used to maintain a moist wound environment. In other situations hyperbaric oxygen treatments are used to oxygenate wounds. Other treatments for oxygenating wounds have used glucose and glucose oxidase to generate oxygen *in situ* or electrolysis of water *in situ* to generate oxygen. Other designs have actively delivered oxygen gas via a cannula under conventional dressings.

[0007] Yet other treatments have delivered peroxide rather than oxygen to wound sites where the peroxide is converted to oxygen *in situ* by native catalase or by, e.g., manganese dioxide.

[0008] Additional treatments have utilized films as dressings, e.g., polyurethane films, which include a stored reservoir of oxygen for application to the wound. Such reservoirs require replenishment. Absorbent materials such as polyHEMA hydrogel beads are sometimes poured directly into a wound. Foreign materials poured into a wound may trap layers of exudate, water, or debris after becoming saturated, limiting oxygen diffusion through the interstitial spaces. Moreover, depending on the molecular weight exclusion profile of the absorbent material, debris and toxic high molecular weight constituents of the exudate may become concentrated as water is absorbed into the material.

[0009] Accordingly, there is a need for a wound dressing which is able to maintain consistent high levels of oxygen permeability, prevent dehydration, and accommodate potentially copious volumes of exudate.

SUMMARY OF THE INVENTION

[0010] Wound dressings which maintain a high availability of oxygen to a wound and which also provide for uninterrupted exudate removal may utilize one or more oxygen conduits which are designed to pass oxygen from ambient air or other oxygen source into proximity to the wound where the oxygen may diffuse directly to the wound.

[0011] Generally, such a wound dressing may comprise a hydrophilic absorbent material (e.g., sponge, foam, absorbent hydrogel, etc.) a hydrophilic absorbent material envelope which defines an open area for contacting a wound site and which at least partially encloses the hydrophilic absorbent material, and at least one oxygen conductive conduit with an oxygen-diffusive coating, wherein the at least one conduit is positioned to extend exposed along the open area and adjacent to the hydrophilic absorbent material, and wherein the at least one conduit has at least one portion further exposed to a reservoir or source of oxygen to serve as a conduit for oxygen to the wound surface. Such a reservoir may be ambient air, compressed gas mixtures containing oxygen, oxygen generating chemical cells or highly oxygenated fluids such as perfluorocarbons. The hydrophilic absorbent material may be surrounded by an envelope which at least partially encloses the hydrophilic absorbent material, and defines an open area for contacting a wound site and which may impede evaporation of fluid from said hydrophilic absorbent material. Such a wound dressing may be applied to a wound site by placing the open area upon the wound site such that the at least one conduit is in contact against the wound site, and oxygen can diffuse from the at least one conduit and through the oxygen-diffusive coating to the wound site.

[0012] Additionally, the wound dressing may be formed through various manufacturing processes. One variation may generally comprise passing a length of multifilament fiber through a coating solution such that the fiber is coated via the solution while maintaining the openness of the internal interfilament spaces, arranging lengths of the coated fiber to align in parallel, woven, knit or otherwise arranged such that a coated fiber array is formed, securing the coated fiber array via one or more space-filling adhesive stripes placed transversely relative to a length of the coated fiber, positioning the coated fiber array over the open area of a hydrophilic absorbent material envelope and a hydrophilic absorbent material such that the hydrophilic absorbent material is positioned at a distance from the open area, and securing the hydrophilic absorbent material envelope such that the coated fiber array and hydrophilic absorbent material are sealed therein. The coating material and filament material may be hydrophobic to minimize condensation of water vapor diffusing through the coating, which could result in occlusion of the open interfilament spaces and a diminution of lateral oxygen diffusion along the length of the fiber.

[0013] The wound dressing may comprise a plurality of coated fibers, e.g., multifilament fibers or threads made from materials such as polypropylene or polyethersulfone, which may be coated with an oxygen diffusive material which may also be hydrophobic such as a thin silicone coating (e.g., low-viscosity acetoxy-cure silicone) or a microperforated hydrophobic coating whereby surface tension effects prevent aqueous liquid from traversing the perforations over the exterior of the fibers. In coating the fiber exterior, the fibers may be optionally first wetted with a liquid such as water or ethanol or isopropanol or mixtures thereof (such as 30% to 70% isopropanol) to prevent the coating solution from wicking into and between the filaments. Once the coating has been placed over the fiber, the liquid may evaporate ensuring that the conduits between the filaments are open for oxygen passage.

[0014] The coated fibers may also range in size and construction, e.g., about 40 to 2000 micron diameter threads or more particularly about 80 to 260 micron diameter threads with anywhere from 2 to several thousand filaments or more particularly a few to several filaments per fiber (such as 6 to 8 filaments). These fibers may be aligned adjacent and parallel to one another along the wound dressing and a hydrophilic absorbent material may be positioned over at least a portion of the fibers such that the hydrophilic absorbent material is optionally positioned at a distance from the wound when in use. Because the hydrophilic absorbent material is separated from the wound by the fibers and optionally the hydrophilic absorbent material envelope the hydrophilic absorbent material does not directly contact the wound and hence will not irritate or become engrafted into the wound.

[0015] The hydrophilic absorbent material may comprise any number of hydrophilic absorbent materials that freely allows for the absorption of large molecules and particulates such that there are no concentration effects on particulates or macromolecular toxic factors. For particular applications, where the benefit of increased concentration of beneficial factors present in the exudate (e.g., wound healing promoters) may outweigh the deleterious impact of toxic factor concentration, it may be desirable to optionally choose a hydrophilic absorbent material (e.g., a hydrogel such as polyacrylamide or dextranomer hydrogels) which will lead to an increase in concentration of macromolecular constituents of the exudate. The hydrophilic absorbent material may also inhibit or prevent gel polarization or fouling at the surface of the hydrophilic absorbent material. The hydrophilic absorbent material may be

coated or otherwise covered by a film or membrane envelope (e.g., silicone, PVC, polyester, polyamide, or any other material which exhibits a low water vapor permeability) which coats or covers the faces of the hydrophilic absorbent material contiguous with the ambient environment . The hydrophilic absorbent material envelope may be hermetically sealed to help maintain a sterile environment at the wound site. While the hydrophilic absorbent material envelope may help to prevent excessive evaporation, the hydrophilic absorbent material envelope may be optionally removed or breached to encourage evaporation or removal of accumulated wound exudate, if so desired. One or more openings or ports in the hydrophilic absorbent material envelope may allow for the removal of accumulated exudate when the hydrophilic absorbent material becomes saturated and for the addition of fluids (optionally with drugs or other additives). The optional feature of being able to remove excess accumulated exudate through an access port permits the dressing to function indefinitely, obviating the need to periodically remove and replace the dressing when it becomes saturated with fluid, thereby saving labor and expense and limiting trauma to the wound site. Alternatively the hydrophilic absorbent material may be reversibly affixed to the dressing allowing removal and replacement when it becomes saturated with exudate.

[0016] The hydrophilic absorbent material and hydrophobic material envelope may be comprised of an absorbent wound dressing applied over an oxygen conductive assembly in contact with the wound, wherein a portion of the oxygen conductive assembly is in contact with air.

[0017] The hydrophilic absorbent material may be pre-moistened with saline solution or any number of agents (e.g., colloidal silver or other antimicrobial solutions, epinephrine, coagulants, anticoagulants, wound-healing promoters, inflammation inhibitors, wetting agents, etc.) either in the original package or added directly to the hydrophilic absorbent material prior to or after application of the dressing to the wound. Prior to application of the dressing to the wound, the wound site may be debrided (if necessary or desired) and an antimicrobial agent, such as colloidal silver or iodine preparations), may be applied directly to the wound. The dressing may then be placed upon the wound. The dressing may also be applied to wounds to enhance the benefits of, e.g., platelet gel, plasma concentrate, white cells, stem cells, skin grafts, growth factors, etc. which may be administered to the wound

prior to application of the dressing. Preventing dehydration and maintaining high oxygen availability may be advantageous for such treatments.

[0018] With the hydrophilic absorbent material situated, the coated fibers (or other air conduits) may extend beyond the hydrophilic absorbent material longitudinally and/or laterally to form a border surrounding the hydrophilic absorbent material or they may be wrapped over the top of the dressing. The portion of the coated fibers extending beyond the open, wound contacting area may form an antenna for absorbing oxygen from the ambient air and may be coated or the gaps between adjacent coated fibers may be otherwise filled with an oxygen permeable material, e.g., silicone, and the underside of the border may have an adhesive formed thereupon such that when the dressing is placed over the wound, an open area exposing the coated fibers may be placed into direct contact against the wound. The adhesive border may encircle the wound such that any exudate from the wound is prevented or inhibited from wicking laterally. Instead, the exudate may wick between and through the gaps defined between the coated fibers along the open area within the coated fiber array and directly into the hydrophilic absorbent material where it may be retained by the hydrophilic absorbent material envelope.

[0019] With the coated fibers extending beyond the enveloped hydrophilic absorbent material, at least one of the terminal ends of the fibers may be left with open terminal ends along either or both ends of the dressing extending through the border. The open terminal ends of the fibers may provide openings for the additional entry of ambient air for passage through the length of the fibers. Thus, while the coated fibers form oxygen conduits where oxygen in the ambient air or other oxygen source may pass or conduct through the coated fibers (from the coated fiber terminal ends as well as through diffusion through the oxygen permeable coating) and further diffuse directly through the silicone coating and into the wound site, exudate may be prevented from entering into and fouling the coated fibers by their coating as the exudate passes into the hydrophilic absorbent material. In alternative variations, the conduits may be formed as hollow conduits or passages for allowing the passage of air or other oxygen source through with no multifilament fibers or threads. Such hollow conduits or passages may be used within any of the embodiments described herein.

[0020] Gaps between the coated fibers may allow conduction of wound exudate away from the wound surface into the hydrophilic absorbent material. The coated fibers may be

bonded to one another by space-filling or adhering (e.g., silicone) stripes which are formed transversely to the coated fibers and which also provide for a smooth wound contacting surface and also prevent fluid accumulation between the coated fibers adjacent to the wound within the stripe coated areas. These transversely coated areas may be sufficiently wide while still allowing for sufficient removal of exudate through the intervening spaces to prevent any excessive exudate pooling as the width and spacing of these transversely stripes may affect how far the exudate travels to find a path from the wound surface and to the hydrophilic absorbent material.

[0021] While the coated fibers may directly contact the underlying wound, an optional membrane, e.g., track-etched polycarbonate or microperforated polymer film, may be interposed over the open area for contacting the wound. In the event that a membrane is used, such a membrane may be relatively thin and may further prevent adherence to the wound. Optional hydrophilic channels may extend from the membrane and through the coated fibers to the overlying hydrophilic absorbent material to allow for the conduction of exudate or infusion of various agents or drugs. The membrane may resist adhering to or integrating with the wound.

[0022] Optionally, an array of vertically oriented conduits (e.g., hollow air-filled tubes or channels, sealed at their termini to exclude exudate or fluid from the ambient environment from entering and flooding) may extend through the hydrophilic absorbent material to bring oxygen from above to the underlying wound-contacting membrane surface. The inner walls of said tubes or conduits may be hydrophobic to prevent water vapor condensation. To maximize uniformity of oxygen supply to the tissue, the conduits may be small and closely spaced. The hydrophilic absorbent material and dressing may be varied in size depending upon the size of the wound to be treated. Alternatively, the dressing may be formed into any number of standard uniform sizes.

[0023] One or more hydrophilic fibers or wicking material may be interspersed between the coated fibers within the open area of the coated fiber array to conduct exudate away from the wound. The number or amount and positioning of the hydrophilic fibers or material may be varied in various patterns, e.g., oxygen-conducting coated fibers may be interspersed between every two wicking fibers or so on, or they may be omitted completely. Moreover, the diameter of the wicking fibers, e.g., 700 microns, may be similar or identical to

the diameter of the coated fibers although the diameters may also be varied depending upon the desired wicking properties. The outer surfaces of the coated fibers may be rendered hydrophobic, e.g., by surface modification chemistry, to promote conduction of exudate from the wound site to the hydrophilic absorbent material.

[0024] Another alternative may use individual fibers positioned in a transverse orientation relative to one another. A first set of fibers oriented parallel to one another may be laid atop a second set of fibers which are also parallel to one another such that the first and second set are transverse to one another. Alternatively, the crossing fibers may be interwoven with respect to one another and in other alternatives the crossing fibers may be orientated at some other angle rather than being orthogonal, e.g., 45 degrees relative to one another. The combined thickness of the crossing fibers may still be less than 1 mm.

[0025] Yet another variation may utilize a silicone contact film having one or more ridges or notches formed over its surface on the opposite side of the wound contact surface and including an upper film adhered and sealed to the ridges, forming an array of open conduits within a sealed envelope. These ridges or notches may be formed as ridges, undulations, tapered protrusions, or any other projections which extend between the two films to form lateral conduits for oxygen diffusion to the wound contact surface. One or more through-holes may be defined to extend in a direction normal to the surface for allowing any exudate to flow from the wound and to the hydrophilic absorbent material positioned above the contact film. A second film may be laid atop the contact film where the second film may define one or more through-holes that correspond to first film through-holes. With the second film positioned atop contact film, the open channels formed by the ridges or notches between the upper and lower films may function as the oxygen conduits where the oxygen may then diffuse through the contact film and into the underlying wound. Through-channels for wound exudate may be formed in the ridges between the conduits.

[0026] Yet another variation may have a contact film with one or more columnar through-holes which extend from the surface of the contact film. A second film having one or more through-holes corresponding to respective through-holes may be placed atop and sealed to the contact film with the respective holes aligned. The channels formed by the columns of through-holes allow for wicking of wound exudate to the hydrophilic absorbent material,

while the spaces between the films may accordingly allow for the passage of oxygen therethrough for diffusion through the contact film and into the underlying wound.

[0027] Yet another variation would be the substitution of extruded small silicone tubes or multilumen silicone extrusions for the coated multifilament fibers.

[0028] Another variation may include the substitution of a planar array of hydrophobic multifilament fibers embedded in and completely encapsulated by a thin slab of, e.g., silicone, for the coated multifilament fibers where channels for exudate flow from the wound to the hydrophilic absorbent material may have interruptions in the encapsulating silicone slab. For example, several multifilament hydrophobic fibers may be embedded in each of a number of narrow thin slabs arranged in parallel, the gaps between the narrow thin slabs serving as such channels.

[0029] Any of the wound dressing variations may optionally utilize mechanisms for increasing the oxygen availability to the wound while still allowing for exudate to pass into the hydrophilic absorbent material. For example, a flattened silicone bag or a plurality of defined conduits may be formed through the dressing to circulate an oxygen enriched gas mixture, or an oxygen-carrying fluid such as oxygenated water or oxygenated perfluorocarbon solutions through the dressing to increase the oxygenation to the wound and to also prevent the formation of an oxygen gradient. A pump may be optionally integrated either with the dressing or it may be fluidly coupled to the dressing and worn or carried separately by the patient. In yet another variation, introduction or flow of a fluid or gas (such as air) through the one or more ports or septa may be introduced not only for the infusion of an inflation fluid for inflating balloons, but also for the expansion of one or more encapsulated pads as well which may be used, e.g., for providing a compressive force.

[0030] Another variation may have a wound dressing with an oxygen reservoir integrated with the dressing. A pump may be optionally coupled fluidly to the reservoir and the reservoir may also be accessible for re-filling or for filling with other agents or fluids, as described herein, or it may alternatively be removed entirely from the dressing and replaced with a substitute reservoir.

[0031] Another variation may comprise an oxygen conductive assembly such as an array of coated fibers with gaps or through-holes between to permit fluid to pass through from the wound and a removable, replaceable hydrophilic absorbent material partially enveloped in

a hydrophilic absorbent material envelope affixed reversibly thereto, permitting replacement of the hydrophilic absorbent material when it becomes saturated with exudate without the need to detach the oxygen conductive assembly from the patient.

[0032] In manufacturing a wound dressing with the features described, various methods may be used for forming the dressing. One variation would be the substitution of extruded small silicone tubes or multilumen silicone extrusions for the coated multifilament fibers. Another variation may involve several rods each having, e.g., a rectangular cross-section, aligned adjacent to one another along a planar surface. With the rods aligned, spacing rails may be secured along one or both ends of the rods to at least temporarily secure the position of the rods relative to one another. A silicone resin film may be swept out upon the rods and the spacing rails may be removed and the rods may be separated individually before the resin film cures and then be positioned upon a cylindrical spool. Because of the rectangular cross-sectional shape of the rods, parallel gaps may be formed between each adjacent rod.

[0033] One or more lengths of fibers may be dragged or passed through an oxygen permeable hydrophobic solution, e.g., silicone resin, and then wound onto the spool by rotating the spool such that the coated fibers are wound adjacent along the length of the spool. Once the resin has cured, one or more longitudinal cuts may be made through the spooled coated fibers and the completed coated fiber array may be removed from the spool.

[0034] Yet another variation may have a common length of coated fiber wound in an alternating manner with a common length of coated fiber upon a supporting frame. The width of the frame may correspond to the desired width or length of the coated fiber array which contacts the wound region. With the coated fibers wound parallel to one another and secured, one or more adhesive stripes may be laid transversely across the width of the coated fiber array such that formed gaps are defined between the respective stripes. Once the adhesive stripes have cured, the secured coated fiber array may be removed from the supporting frame. The coated fiber array may then have a film applied to the coated fiber array such that an open area formed in the film is positioned over the coated fiber array. The hydrophilic absorbent material may then be laid atop the open area of the film, in contact with the coated fiber array and the film and optionally secured with an adhesive.

[0035] With the coated fiber array and hydrophilic absorbent material so arranged, the film may be wrapped to cover and completely envelope the assembly while leaving the coated fiber array exposed within the open area for contacting the wound. The terminal ends of the coated fibers may make contact with an oxygen source, such as ambient air for passive diffusion into an antenna area or other oxygen source as described above. To complete the wound dressing, a border of adhesive may be framed around the coated fiber array and hydrophilic absorbent material so as to leave the open area exposed for contact against the wound. The coated fiber array and hydrophilic absorbent material assembly may be adhered or otherwise secured to the adhesive border, which may be trimmed to form the border. The border may thus allow for the dressing to be secured over a wound such that the exposed coated fibers along the open area directly contact the wound while border prohibits or inhibits any exudate from wicking laterally along the dressing and maintaining a hermetic seal.

[0036] However, in other alternative variations, the dressing assembly may be configured to facilitate the lateral flow of exudate towards the sides of the dressing. Generally, the wound dressing may comprise an oxygen diffusive substrate defining a contact surface and a hydrophilic absorbent material in fluid communication with at least one portion of a periphery of the oxygen-diffusive substrate, wherein at least one portion of the substrate is configured to protrude from the dressing for pressing the contact surface against a wound surface. In use, the wound dressing may press at least a portion of the substrate against the wound such that exudate from the wound is urged to flow laterally along the substrate and into the absorbent material and diffuse oxygen through the oxygen-diffusive substrate and into the wound.

[0037] In one variation, an oxygen diffusive substrate may be optionally formed to have one or more channels or grooves which face towards the underlying wound. An optional compressible pad may be layered atop the substrate such that a protrusion defined along the pad is positioned to face towards and into contact against the substrate. An absorbent material may be placed into contact around the substrate as well as the pad such that the absorbent material is in fluid communication with the channels or grooves of the substrate.

[0038] With the substrate and pad layered and with the absorbent material placed around at least the substrate, the assembly may present a low-profile dressing having a protruding portion of the substrate extending in conformance with the protrusion defined

along the pad. The entire dressing assembly may be optionally encased or sealed by a fluid-permeable coating or covering while the absorbent material may be at least partially encased or sealed by a fluid-tight coating or covering which may prevent any exudate from leaking or seeping out of the material or impede evaporation of water from accumulated exudate. The absorbent material may remain in fluid communication along its contact surfaces with the substrate. Additionally, the absorbent material may also be sealed to the enveloped pad to prevent any exudate from wicking between the pad and the absorbent material.

[0039] The contact surface of the substrate may protrude from the dressing for contact against the wound. Hence, when the dressing is placed against the wound, the contact surface may apply a gentle pressure or force against the wound to urge exudate from the wound to flow laterally, e.g., through the channels or grooves of substrate if defined, and towards the absorbent material which may absorb and retain the exudate within. While the dressing assembly may have a central portion of the substrate bowed outward from the dressing, the pad as well as the substrate may be configured in alternative variations to curve or extend along other portions. For instance, a portion of the pad and the substrate may be shaped to urge exudate in the contacted wound to flow along a single direction towards the absorbent material.

[0040] The dressing assembly may be shaped into any number of configurations which may be uniform or customized for a particular wound or patient anatomy. For instance, the dressing assembly may be shaped into a circular configuration. Additionally and/or alternatively, the absorbent material may be omitted entirely and instead replaced by a bag or expandable reservoir chamber which may be shaped in a corresponding manner, e.g., toroidal or washer-shaped.

[0041] In yet other variations, one or more ports or septum regions may be optionally incorporated into the dressing assembly for allowing gases or other agents to be introduced into the dressing or for allowing exudate to be removed. Additionally and/or alternatively, a regulated source such as a pump may be fluidly coupled through one or more of the ports. Moreover, adhesives may also be incorporated along the dressing assembly for facilitate attachment of the dressing to the skin surface surrounding a wound to be treated.

[0042] In additional variations, fluid permeable skirts may also be incorporated around a periphery of the dressing as well as compressible pads which may have portions

removed. These variations as well as any of the other features may be optionally incorporated in various combinations between different dressing variations.

BRIEF DESCRIPTION OF THE DRAWINGS

[0043] Figs. 1A to 1C illustrate perspective, side, and bottom views, respectively, of one variation of a wound dressing which comprises a plurality of oxygen conducting fibers or conduits and a hydrophilic absorbent material in communication with an underlying wound.

[0044] Fig. 1D illustrates a bottom view of another variation of a wound dressing which incorporates an optional membrane for contact against the wound.

[0045] Fig. 1E illustrates a detail partial cross-sectional side view a variation of a contacting membrane having a plurality of exudate channels interspersed between the oxygen conductive conduits.

[0046] Figs. 2A and 2B illustrate top and bottom views of another variation of a wound dressing having a circular configuration.

[0047] Fig. 3A illustrates a detail bottom view of the oxygen conduits and fibers aligned adjacent to one another.

[0048] Fig. 3B illustrates a detail bottom view of another variation of coated oxygen conductive fibers aligned with hydrophilic fibers.

[0049] Fig. 3C illustrates a detail bottom view of yet another variation of coated fibers which are transversely aligned relative to one another.

[0050] Figs. 4A and 4B illustrate bottom and top views of another variation where the fiber array may be secured by adhesive stripes transversely aligned relative to the fibers.

[0051] Figs. 5A and 5B illustrate perspective and partial cross-sectional side views of another variation of a wound dressing having orthogonal channels.

[0052] Fig. 6 illustrates a cross-sectional perspective view of yet another variation of a wound dressing having a port.

[0053] Figs. 7A and 7B illustrate perspective views of yet another variation of a wound dressing assembly having ridges or undulations which define the oxygen conduits.

[0054] Fig. 7C illustrates a perspective assembly view of another variation where protruding orthogonal channels define the oxygen conduction passages.

[0055] Fig. 8 illustrates a perspective view of a composite fiber array which may be used alone or in combination with other dressings.

[0056] Fig. 9 illustrates a perspective view of yet another variation of a wound dressing incorporating a pumping mechanism.

[0057] Fig. 10 illustrates a perspective view of yet another variation of a wound dressing incorporating a reservoir.

[0058] Figs. 11A to 11F illustrate one variation for manufacturing a wound dressing fiber assembly.

[0059] Figs. 12A to 12P illustrate another variation for manufacturing a wound dressing.

[0060] Figs. 13A illustrates an example of an array having members of alternating length for forming oxygen conduits.

[0061] Figs. 13B and 13C illustrate top views of oxygen conduits which may be formed utilizing the array of Fig. 13A.

[0062] Figs. 14A to 14C illustrate another variation for manufacturing a composite fiber array in combination with a fluid absorbent material.

[0063] Figs. 14D and 14E illustrate alternative variations for utilizing a composite fiber array with various dressings.

[0064] Figs. 15A and 15B illustrate alternative variations of a simplified wound dressing.

[0065] Fig. 16 illustrates a perspective view of a substrate variation having one or more channels or grooves defined along a wound contact surface.

[0066] Fig. 17 illustrates a perspective view of an absorbent material shaped to define an opening for receiving a substrate within.

[0067] Fig. 18 illustrates a perspective view of a compressible material or pad which may be optionally layered atop the substrate.

[0068] Figs. 19A and 19B illustrate an exploded assembly view and assembly side view of a wound dressing assembly having a protrusion positioned to face towards and into contact against the wound.

[0069] Figs. 20A and 20B illustrate side and perspective views of another variation where the dressing assembly may be shaped into a circular configuration.

[0070] Fig. 21A illustrates a perspective view of another variation which may incorporate one or more access ports.

[0071] Fig. 21B illustrates a perspective view of yet another variation which may incorporate a pump in fluid communication with the dressing assembly.

[0072] Fig. 22 illustrates a perspective view of yet another variation which may incorporate an adhesive around a periphery of the dressing.

[0073] Fig. 23 illustrates a side view of yet another variation of a dressing assembly incorporating a permeable membrane spanning an annular gap around the assembly.

[0074] Fig. 24 illustrates a side view of yet another variation of a dressing assembly which may have a portion of the compressible pad removed to form an opening which encircles the underlying wound.

[0075] Figs. 25A to 25C illustrate side and perspective views of yet another variation of a dressing assembly having a border which extends circumferentially.

[0076] Figs. 26A and 26B illustrate top and side views of another dressing assembly variation having a substrate and optional compressible pad contained within a coating or covering.

[0077] Figs. 27A to 27D illustrate side, bottom, and perspective views of the dressing assembly having a replaceable absorbent material positionable upon a supporting portion of the dressing assembly.

[0078] Fig. 28 illustrates an example of how the dressing assembly and absorbent material may be placed upon an underlying wound.

DETAILED DESCRIPTION OF THE INVENTION

[0079] In covering wounds to facilitate healing, wound dressings are provided which maintain a high availability of oxygen, provide for removal of exudate, prevent toxin accumulation, minimize evaporation, and maintain a moist environment. Furthermore, all wound dressings should prevent contamination, inhibit infection and prevent re-injury of the healing wound. Such a wound dressing may also optionally allow for the administration of various agents or medicines directly to the wound site. Healing may thus be enhanced by providing conditions at the wound site with dressings which are conducive to cell survival and growth in the underlying tissue while preventing cells from dying. Because the wound

dressing is sealed to prevent dehydration of the wound, the dressing may be entirely waterproof while preventing adhesion to the wound allowing for normal lifestyle activities including bathing and accelerating healing time.

[0080] One variation for a wound dressing which provides for oxygenation of the underlying wound may utilize a hydrophobic fiber mat or other hydrophobic structure interposed between an optional wound-contacting membrane and a sponge or other absorbent material to provide gas-filled conduits for oxygen conduction. The wound dressing may be flexible to enable conformance against the wound anatomy. In the body, cells are typically no more than about 200 microns from the capillaries supplying oxygen and the air conducting conduits in the wound dressing may similarly present an equivalent of an oxygen diffusion barrier of a 200 micron water barrier or less between the wound and the air conducting conduit.

[0081] WOUND DRESSINGS

[0082] Fig. 1A shows a perspective view of such a variation in wound dressing **10** which generally comprises a plurality of fibers **12**, e.g., multifilament fibers or threads made from materials such as polypropylene or polyethersulfone, which may be coated with an oxygen diffusive hydrophobic material such as a thin silicone coating over the exterior of the fibers **12** such as a low-viscosity acetoxy-cure silicone. In coating the fiber exterior, the fibers may be optionally first permeated with a fluid such as water, ethanol, isopropanol or mixtures thereof (such as 30% to 70% isopropanol) to prevent the hydrophobic solution from wicking into and between the filaments. Once the coating has been placed over the fiber, the fluid may evaporate ensuring that the spaces between the filaments are open for oxygen passage. Alternatively, the fibers **12** may be permeated with fluid and then embedded in silicone. Before the silicone resin cures, the fibers **12** and silicone resin may be embedded between thin cured films or pre-formed and uncured films. In yet another alternative, the external surfaces of the coated fibers **12** may be treated to improve wettability.

[0083] In yet other variations, the hydrophobic coated fibers **12** may be micro-perforated to facilitate the oxygen diffusion through the coating but which may also exclude any aqueous fluid permeation via surface tension effects. In some other variations, various surface treatments, e.g., plasma treatment, chemical modification, etc., may be applied to the

coating over the fibers to make the external surfaces of the oxygen conduits hydrophilic to facilitate exudate removal from the underlying wound.

[0084] The fibers **12** may also range in size and construction, e.g., about 40 to 2000 micron diameter threads or more particularly about 80 to 260 micron diameter threads with anywhere from 2 to several thousand filaments or more particularly 6 to 8 filaments per fiber. These fibers may be entwinded, twisted, woven, or lie parallel. These coated fibers **12** may be aligned adjacent and parallel to one another along the wound surface **10** and a hydrophilic absorbent material **16** may be positioned over at least a portion of the coated fibers **12** such that the hydrophilic absorbent material **16** is optionally positioned at a distance from the wound surface when in use. Because the hydrophilic absorbent material **16** is separated from the wound by the coated fibers **12** the hydrophilic absorbent material **16** does not directly contact the wound and hence will not irritate or become engrafted into the wound.

[0085] The hydrophilic absorbent material **16** may comprise any number of hydrophilic absorbent materials that freely allow for the absorption of large molecules and particulates. The hydrophilic absorbent material may also inhibit or prevent gel polarization or fouling within the hydrophilic absorbent material. For example, in one variation, the hydrophilic absorbent material **16** may be comprised of an open-cell foam, hygroscopic sheets, films, or beads which attract and hold water may also be used as hydrophilic absorbent materials. Examples of hygroscopic materials which may be used may include, for instance, dextranomer, polyacrylamide, etc. Use of such hygroscopic materials may prevent any exudate from being inadvertently squeezed back into the wound site by external massaging and they may also provide a force for pulling or drawing exudate from the wound.

[0086] The hydrophilic absorbent material **16** may be coated or otherwise covered by a hydrophilic absorbent material envelope **18** (e.g., silicone, PVC, polyester, polyamide, or any other material which exhibits a low water vapor permeability) and which coats or covers the hydrophilic absorbent material **16** above the coated fibers **12**, as shown in the side view of Fig. 1B. The hydrophilic absorbent material envelope **18** may be hermetically sealed to help maintain a sterile environment at the wound site. Any fluids or exudate from the wound may wick between the gaps formed by the adjacent coated fibers **12** and into the hydrophilic absorbent material **16** while the hydrophilic absorbent material envelope **18** may prevent or inhibit evaporation from the hydrophilic absorbent material **16** so that solutes in the exudate

do not become concentrated through evaporation of water from the exudate in the hydrophilic absorbent material **16**.

[0087] While the hydrophilic absorbent material envelope **18** may help to prevent excessive evaporation, the hydrophilic absorbent material envelope **18** may be optionally removed or breached to encourage evaporation, if so desired. One or more openings or ports in the hydrophilic absorbent material envelope **18** may allow the addition of fluids or liquids (optionally with drugs or other agents) or removal of accumulated wound exudate.

[0088] The hydrophilic absorbent material **16**, if wet, may lessen wound dehydration and allow drug administration while the conduits may continue to provide rapid oxygen diffusion to the wound. Alternatively, the hydrophilic absorbent material **16** may be pre-moistened with any number of agents (e.g., colloidal silver or other antimicrobial solutions, coagulants, anticoagulants, epinephrine, wound-healing promoters, inflammation inhibitors, wetting agents, etc.) either in the original package or added directly to the hydrophilic absorbent material **16** prior to or after application of the dressing to the wound. Prior to application of the dressing **10** to the wound, the wound site may be debrided (if necessary or desired) and an antimicrobial agent such as, e.g., colloidal silver, or a cell containing preparation e.g. platelet rich plasma, stem cells, or skin grafts may be applied directly to the wound. The dressing **10** may then be placed upon the wound. The dressing **10** may also be applied to wounds to enhance the benefits of, e.g., platelet gel, plasma concentrate, white cells, stem cells, skin grafts, etc.

[0089] With the hydrophilic absorbent material **16** situated, the coated fibers **12** may extend beyond the hydrophilic absorbent material **16** longitudinally and/or laterally to form a border **20** surrounding the hydrophilic absorbent material **16**, as shown. The portion of the coated fibers **12** forming the border **20** may be coated or the gaps between adjacent coated fibers **12** may be otherwise filled with oxygen permeable materials, e.g., silicone, and the underside of the border **20** may have an adhesive **24** formed thereupon such that when the dressing **10** is placed over the wound, an open area **22** exposing the coated fibers **12**, as shown in the perspective view of Fig. 1C, may be placed into direct contact against the wound. With the coated fibers **12** placed against the wound, the barrier between the wound and the coated fibers **12** may range anywhere from, e.g., 50 to 300 micron or less, to facilitate the diffusion of oxygen from the coated fibers **12** to the underlying wound. The adhesive **24** along border

20 may encircle the wound such that any exudate from the wound is prevented or inhibited from wicking laterally by the border 20. Instead, the exudate may wick between and through the gaps defined between the coated fibers 12 along the open area 22 and directly into the hydrophilic absorbent material 16 where it may be retained by the hydrophilic absorbent material envelope 18. In other variations, rather than using an adhesive 24 along border 20 (or in addition to), the dressing 10 may be secured to the wound with a separate bandage, e.g., an elastic bandage such as an ACE bandage, which may be wrapped about the patient rather than adhered directly to the surrounding skin.

[0090] With the coated fibers 12 extending through the dressing 10, at least one of the terminal ends of the coated fibers 12 may be left with open terminal ends 26 along either or both ends of the dressing 10 extending through the border 20. The open terminal ends 26 of the coated fibers 12 may provide openings for the additional entry of ambient air or other oxygen source for passage through the length of the coated fibers 12. Thus, while the coated fibers 12 form oxygen conduits 14 where oxygen in the ambient air or other oxygen source may pass or conduct through the coated fibers 12 (from the fiber terminal ends 26 as well as through diffusion through the coating) and further diffuse directly through the coating and into the wound site, exudate may be prevented from entering into and fouling the coated fibers 12 by their coating as the exudate passes into the hydrophilic absorbent material 16. The external surfaces of the coating may be rendered hydrophilic to facilitate wicking of exudate from the wound site to the hydrophilic absorbent material.

[0091] In alternative variations, rather than having the coated fibers 12 forming the airway passages, oxygen conduits or channels 14 may be formed as hollow channels or passages with no multifilament fibers or threads for allowing the passage of the air or other fluids through. Such hollow oxygen conduits or channels 14 may be used within any of the embodiments described herein in place of the coated fibers 12.

[0092] The coated fibers 12 (particularly along the open area 22 where the fibers 12 are coated but not supported by additional silicone filler) may be bonded to one another by silicone stripes which are formed transversely to the coated fibers 12 and which also provide for a smooth wound contacting surface and also prevent fluid accumulation between the coated fibers, as described below in further detail. These transversely coated areas may be sufficiently wide while still allowing for sufficient removal of exudate through the intervening

spaces to prevent any excessive exudate pooling as the width and spacing of these transversely stripes may affect how far the exudate travels to find a path from the wound surface and to the hydrophilic absorbent material **16**.

[0093] While the coated fibers **12** may directly contact the underlying wound, an optional membrane **27** (e.g., perforated silicone) may be interposed over the open area **22** for contacting the wound **W** instead, as shown in the perspective view of Fig. 1D. In the event that a membrane **27** is used, such a membrane may be relatively thin and may further prevent adhesion to the wound. Other examples of membranes **27** may include thin, highly perforated non-stick materials utilized as the wound contacting surface, such as the Telfa® "Ouchless" non-adherent dressing (Kendall Co., Boston, MA). Optional hydrophilic channels **28** may extend from the membrane and through the coated fibers **12** to the overlying hydrophilic absorbent material **16** to allow for the conduction of exudate or infusion of various agents or drugs (e.g., epinephrine, antibiotics, wound healing promoters, coagulants, anticoagulants, anti-inflammatories, analgesics, etc.). The membrane **27** may resist adhering to or integrating with the wound.

[0094] In some instances, proteins and other factors in the wound exudate may prove beneficial to wound healing, and therefore removal of bulk wound exudate may be disadvantageous or contraindicated. Rather, the suspending fluid of the wound exudate may be removed while leaving the protein and other macromolecular solutes *in situ*. The underlying membrane **27** which contacts the wound may be alternatively comprised of an ultrafiltration membrane that prevents macromolecular or cellular constituents of the exudate from escaping the wound site. The membrane **27** may have a structure that allows lateral diffusion so that fluid is readily conducted between the entire wound surface and the hydrophilic channels.

[0095] Osmotic pressure developed across the membrane **27** by solutes to which the membrane **27** is impermeable may tend to drive water across the membrane **27**. By adjusting the concentration of solutes to which the membrane **27** is impermeable on the side of the membrane facing the hydrophilic absorbent material **16**, the flux can be directed in either direction. For example, a high concentration of albumin in the hydrophilic absorbent material **16** would drive water away from the wound while pure saline would drive water toward the wound. If a reverse osmosis (RO) membrane were used, adjusting salt concentration in the

hydrophilic absorbent material **16** would have a similar effect. Other forces which can be used to drive the direction of fluid flow include capillary force and hygroscopic polymer swelling. Removal of water from the wound may offer the additional advantage of concentrating healing and growth-promoting factors at the wound site.

[0096] Optionally, an array of vertically oriented conduits (e.g., open, hollow air-filled tubes such as conduits **28**) may extend through hydrophilic absorbent material **16** to bring oxygen from above to the underlying wound-contacting membrane **27** surface, as shown in the detail cross-sectional side view of Fig. 1E. To maximize uniformity of oxygen supply to the tissue, the conduits may be small and closely spaced. The conduit termini may be sealed to liquids by a thin oxygen permeable film to prevent flooding of the conduit by exudate, water or other liquids (e.g. medicants) from the external environment.

[0097] The hydrophilic absorbent material **16** and dressing **10** may be varied in size depending upon the size of the wound to be treated. Alternatively, the dressing **10** may be formed into any number of standard uniform sizes. Moreover, while the variation shown in Fig. 1A illustrates a rectangular-shaped dressing **10**, the dressing may be formed into alternative configurations as well, e.g., circular, square, etc. In the instance where the oxygen conducting conduits are oriented vertically the dressing can be cut to conform to the wound anatomy.

[0098] Another variation of wound dressing **30** is illustrated in the respective top and bottom views of Figs. 2A and 2B which show a circularly-shaped dressing **30**. In this variation, the dressing diameter may be, e.g., 3 inches, while the hydrophilic absorbent material **36** may have a diameter of, e.g., 2 inches. The hydrophilic absorbent material **36** may be covered or encased by hydrophilic absorbent material envelope **38** which may also form a border **40** around the hydrophilic absorbent material for contact against the patient's skin. As above, border **40** may be secured to the skin surface surrounding the wound via adhesive **44** and prevent any exudate from wicking laterally of the open area **42** (e.g., having a size of 1.5 in by 1.25 in.) which exposes the coated fibers **32** for contact against the wound. The open terminal ends **46** of the coated fibers **32** may allow for the surrounding air or other oxygen source to enter into and through the coated fibers **32** such that the coated fibers function as oxygen conduits **34** to provide oxygen from the air or other oxygen source directly into proximity to the wound. As described above, the oxygen may diffuse directly from

passages in the coated fibers **32** and pass through the surrounding film and into the wound. Alternatively, as previously described, the oxygen conduits or channels **34** may remain hollow rather than having a fiber within.

[0099] The open area **42** may have, e.g., about 50 coated fibers **32**, aligned parallel to one another and the adjacent fibers may have thread diameters of about 700 microns which are bonded to one another with, e.g., two or more spaced strips of silicone having a width of about 3.175 mm and aligned transversely relative to the lengths of the coated fibers **32**. The number of fibers **32** may, of course, be varied depending upon the diameter of the fibers used as well as the dimensions of the open area **42** and size or configuration of the dressing. Moreover, the hydrophilic absorbent material **36** may have a thickness of about, e.g., 2 mm to 2 cm, with an exudate absorbing capacity of about, e.g., 1.5 cc to 15 cc.

[0100] As discussed, although specific dimensions are presented they are intended to be illustrative and the size and configuration of the wound dressings may be varied depending upon the wound to be treated. Moreover, the dimensions such as thread diameters, thicknesses of coating and films or the number of fibers used may be used in any of the different variations or embodiments described herein.

[0101] Fig. 3A shows a detail bottom view of a dressing illustrating an example of threads or multifilament threads which may be covered or coated to form individual coated fibers **12** which may then be aligned parallel to one another to form the oxygen passageways. Alternatively, oxygen conduits or channels **14** may be formed as hollow passageways, as previously described. The gaps between the individual adjacent coated fibers **12** may be left open to allow for any exudate to wick through to the hydrophilic absorbent material. Alternatively, the gaps may have an interrupted, discontinuous filler **50** material interspersed or formed such that the gaps between the fibers are mostly filled leaving gaps for transit of wound exudate from below and optionally medicants from above. Such fillers **50** may include any of the materials described herein, e.g., silicone, and may be used to contact against the wound along with the fibers. In yet another alternative, Fig. 3B shows another detail bottom view where one or more hydrophilic fibers **52** or wicking fiber (e.g., absorbent fibers such as cotton) may be interspersed between the coated fibers **12** to conduct exudate away from the wound or medicants to the wound surface. Although the variation shows hydrophilic fibers **52** alternated with the coated hydrophobic fibers **12**, the number and

positioning of the hydrophilic fibers **52** may be varied in various other patterns, e.g., hydrophobic fibers **52** may be interspersed between every two fibers **12** or so on, or they may be omitted completely as well. Moreover, the diameter of the coated fibers **12**, e.g., 700 microns, may be similar or identical to the diameter of the hydrophobic fibers **52** although the diameters may also be varied depending upon the desired wicking properties.

[0102] Another alternative is shown in the detail bottom view of Fig. 3C. In this variation, the individual fibers **12** may be positioned in a transverse orientation relative to one another. A first set of fibers **12** oriented parallel to one another may be laid atop a second set of fibers **12** which are also parallel to one another such that the first and second set are transverse to one another. Alternatively, the crossing fibers **12** may be interwoven with respect to one another and in other alternatives the crossing fibers may be orientated at some other angle rather than being orthogonal, e.g., 45 degrees relative to one another. The combined thickness of the crossing fibers may still be less than 1 mm. The coated fibersand hydrophilic fibers may be arranged relative to one another in any fashion, including woven, intertwined or knit.

[0103] As described above, the coated fibers **12** may be secured to one another via one or more adhesive stripes **60** (e.g., silicone) which are placed across the width of the dressing so as to align perpendicularly relative to the direction of the coated fibers **12**. These stripes may take any orientation, including an interrupted flat film that allows passage of fluid from the wound surface to the hydrophilic absorbing material. A detail example is illustrated in the bottom view of Fig. 4A, which shows a plurality of coated fibers **12** which are aligned adjacent to one another and several adhesive stripes **60** placed over and between the fibers. The open gaps **62** left between adhesive stripes **60** may allow for the exudate to pass through and wick into the hydrophilic absorbent material **16**, which is positioned atop and in contact with the fibers **12**, as shown in the top view of Fig. 4B.

[0104] In yet another variation, Fig. 5A illustrates a perspective view of a wound dressing **70** which shows an embodiment having a hydrophilic absorbent material **72** positioned and encased between a contacting bottom layer **74** and a sealing top layer **76** where each of the layers **74**, **76** may have a thickness, e.g., of less than 2 mm. An additional layer of silicone film (e.g., 50-100 micron) may be applied over one or both layers **74**, **76** to modify the surface and further inhibit any leakage through the layers **74**, **76**. A bondable skirt **78** may

be formed to surround the periphery of the dressing **70**. While the wound-contacting bottom layer **74** and sealing top layer **76** may be formed of any of the materials described herein, it may be comprised of a material such as medical grade platinum cure silicone. The layers **74**, **76** may be formed with the bondable skirt **78** to provide an area for bonding and sealing the layers to one another around the hydrophilic absorbent material **72**.

[0105] The dressing **70** may also be formed with one or more bondable wings **80** formed into the dressing, as shown in the partial cross-sectional end view of Fig. 5B. The bondable wings **80** may be incorporated during the molding process for forming the layers **74**, **76** and may be comprised of a material such as felt or fabric which may be mechanically trapped in the silicone to leave the exposed surfaces silicone-free for bonding. The portion of the dressing **70** which contacts the wound may be defined along a wound-contact area **82** which may define one or more through-holes **86**, e.g., conical through-holes, which extend from the wound to wick any exudate through the holes **86** and into the hydrophilic absorbent material **72**. Also shown are the oxygen conduit **84** which may be formed into the contacting bottom layer **74** for direct contact with the wound surface for facilitating the delivery of oxygen to the wound.

[0106] In yet another variation, Fig. 6 illustrates a perspective view of another wound dressing **90** which is sectioned for illustrative purposes. In this variation, the layers may surround the hydrophilic absorbent material **72** but the dressing **90** may optionally incorporate a port **92** for exudate evacuation or agent introduction, e.g., along sealing top layer **76**. Because hydrophilic absorbent material **72** is sealed for preventing dehydration of the wound, port **92** may provide an opening which can be opened or closed to provide access to the interior of hydrophilic absorbent material **72** and dressing **90**. For instance, port **92** may be configured as a Luer attachment for facilitating the suction or removal of any excess exudate from the hydrophilic absorbent material **72**. Port **92** may also provide an opening through which any number of medicaments or agents may be introduced into the interior of dressing **90** and hydrophilic absorbent material **72** to provide for the infusion of any additional treatments to the wound. Such a port **92** feature may be incorporated into any of the embodiments described herein as practicable.

[0107] Additionally and/or alternatively, the hydrophilic absorbent material **72** may be removed from the wound dressing and optionally replaced with a new absorbent material if

excess exudate is absorbed into the material **72**. The remainder of the wound dressing **90** may be left upon the wound site while the hydrophilic absorbent material is replaced or removed. Alternatively, the wound dressing **90** may be removed from the wound site for replacement of the absorbent material and then replaced upon the wound site. In this variation and others disclosed herein, the absorbent material may be optionally removed and/or replaced in such a manner as described.

[0108] Yet another variation is shown in the perspective view of Fig. 7A which illustrates a silicone contact film **100** having one or more ridges or notches **102** formed over its surface on the opposite side of the wound contact surface **106**. These ridges or notches **102** may be formed as ridges, undulations, tapered protrusions, or any other projections which extend from the surface to form lateral conduits for oxygen diffusion through the wound contact surface **106**. One or more through-holes **104** may be defined to extend in a direction normal to the surface **106** for allowing any exudate to flow from the wound and to the sponge positioned above the contact film **100**.

[0109] Fig. 7B illustrates a perspective view of a second film **108** which may be laid atop contact film **100** where the second film **108** may define one or more through-holes **110** which correspond to through-holes **104**. With the second film **108** positioned atop contact film **106**, the open channels formed by the ridges or notches **102** between the upper and lower films may function as the oxygen conduits where the oxygen may then diffuse through the contact film **100** and into the underlying wound.

[0110] Fig. 7C shows a perspective assembly view of yet another variation where contact film **112** may incorporate one or more columnar through-holes **114** which extend from the surface of the contact film **112**. A second film **118** having one or more through-holes **120** corresponding to through-holes **114** may be placed atop and sealed to the contact film **112** with the respective holes aligned. The resulting channels **116** formed by the columns of through-holes **114** and between the films **112**, **118** may accordingly allow for the passage of oxygen therethrough for diffusion through the contact film **112** and into the underlying tissue. The aligned through-holes **114**, **120** may also allow for the passage of the exudate from the wound to the sponge which may be positioned atop the second film **118**. The through-holes **114**, **120** may also allow for the infusion of various medicaments or agents into the wound.

[0111] Fig. 8 shows a perspective view of yet another variation where a fiber array assembly may be formed by one or more fiber array sub-assemblies **121A**, **121B**, **121C**, **121D**. The sub-assemblies may be formed by utilizing any of the methods described herein for creating the oxygen conduits or channels where several conduits may be formed into an individual ribbon. Each of the ribbons forming the sub-assemblies **121A**, **121B**, **121C**, **121D** may then be aligned adjacent and adhered or other attached relative to one another. The variation shown illustrates four fiber array sub-assemblies although fewer than four or more than four sub-assembly ribbons may be formed and attached to one another. Moreover, the lengths and widths of each of the sub-assemblies may be adjusted according the size of the wound to be treated or they may be standardized in any number of suitable dimensions.

[0112] With the individual sub-assemblies **121A**, **121B**, **121C**, **121D** formed and aligned, they may be attached to one another via attachment **123A**, **123B**, **123C** which may comprise any number of suitable attachment methods. For instance, silicone may be applied for maintaining the relative positioning of each sub-assembly along the entire length of the assembly or each individual sub-assembly may be adhered to another layer such as a silicone layer or directly to a hydrophilic fluid absorbent material such as gauze, sponge, or any of the materials described herein.

[0113] Regardless of the attachment mechanism, each of the sub-assemblies **121A**, **121B**, **121C**, **121D** may be formed with a gap, space, or channel formed between adjacent sub-assemblies to provide a channel or pathway for exudate to pass between the sub-assemblies and the hydrophilic fluid absorbent material which may optionally be placed adjacent to the fiber array. Alternatively, any number of hydrophilic wicking materials or channels **127** may be formed along the gap or channel between the sub-assemblies **121A**, **121B**, **121C**, **121D** to facilitate the wicking away of exudate from the underlying wound.

[0114] Additionally and/or alternatively, portions of the fiber array may be applied with an adhesive, e.g., adhesive silicone film, for securement to the patient over the wound surface.

[0115] As shown, the wound contact region **125** may be formed by the composite fiber array such that the wicking materials or channels **127**, if present, may be situated directly over the wound surface. The portions of the fiber array adjacent to one or both sides of the wound contact region **125** may form the oxygen absorption region (antenna region) **129** where

oxygen may diffuse into the channels for further diffusion into the underlying wound over the wound contact region **125**, as described herein. The ends **131** of the oxygen absorption region **129** may be optionally sealed to prevent exudate from entering into the channels.

[0116] As previously described, any of the features of this variation may be combined with the features of other variations. For instance, dressing incorporating the ridges or notches **102** may be used with the port **92** as previously described, if so desired.

[0117] ACTUATED WOUND DRESSINGS

[0118] In yet another variation, any of the wound dressing variations may optionally utilize mechanisms for increasing the oxygen availability to the wound while still allowing for exudate to pass into the hydrophilic absorbent material. Fig. 9 shows an illustrative variation of a dressing having an either a flattened silicone bag or a plurality of defined conduits **122** formed through the dressing. Either the bag or conduits **122** may circulate fluid such as oxygenated water, perfluorocarbons, or gaseous mixtures through the dressing to increase the oxygenation to the wound and to also prevent the formation of an oxygen gradient. Circulating the fluid may allow for the oxygen to diffuse into the conduits **122** and through the silicone membrane into the underlying wound. A pump **120** may be optionally integrated either with the dressing or it may be fluidly coupled to the dressing and worn or carried separately by the patient. Alternatively, rather than circulating the oxygenated fluid, pump **120** may be used to simply pulse the air and/or oxygen or mixtures thereof through the conduits **122**.

[0119] Another variation is shown in the perspective view of Fig. 10 which illustrates a dressing having an oxygen reservoir **124** integrated with the dressing. Reservoir **124** may contain oxygen for diffusion into and through the hydrophilic absorbent material **16** and for passage either directly into the wound or via the coated fibers **12** and subsequently into the wound. Pump **120** may optionally be a fluid connection to the reservoir **124** and the reservoir **124** may also be accessible for re-filling or for filling with other agents or fluids, where any of the agents or fluids as described herein may be used, or it may alternatively be removed entirely from the dressing and replaced with a substitute reservoir.

[0120] METHODS OF MANUFACTURING

[0121] In manufacturing a wound dressing with the features described, various methods may be used for forming the dressing. One variation is illustrated in Figs. 11A to

11F where hollow or coated fiber oxygen conduits are formed directly onto substrate rods, the latter coated with a bonding polymer e.g. silicone. The several substrates or rods **130** each having, e.g., a rectangular cross-section, may be aligned adjacent to one another along a planar surface, as shown in the perspective view of Fig. 11A. The length and width of the substrates or rods **130** may be varied depending upon the desired size and configuration of the final wound dressing, but one example may utilize the rods having a surface width of, e.g., 0.5 to 1.0 cm. With the substrates or rods **130** aligned, spacing rails **132** may be secured along one or both ends of the rods **130** to at least temporarily secure the position of the substrates or rods **130** relative to one another, as shown in Fig. 11B, as well as to provide a guide for a silicone resin film **134** to be laid atop the substrates or rods **130** and between spacing rails **132**, as shown in Fig. 11C. Thus, the spacing rails **132** may have a height which corresponds to the height of the resin film **134** to be laid atop the substrates or rods **130** such that the resin film **134** may be swept out with a straight edge using the rails **132** as a guide. For example, the spacing rails **132** may have a thickness of about 115 microns.

[0122] With the silicone resin film **134** swept out upon the substrates or rods **130**, the spacing rails **132** may be removed and the substrates or rods **130** may be separated individually before the resin film **134** cures, as shown in Fig. 11D. The substrates or rods **130** may then be positioned upon a cylindrical spool **136** (e.g., having a 1 to 2 in. diameter) and attached via securing members **138**, e.g., rubber bands, such that the surface of the substrates or rods **130** opposite to the resin film **134** are placed against the spool surface and the resin film **134** is positioned to face outwardly relative to the spool **136**. Because of the rectangular cross-sectional shape of the substrates or rods **130**, parallel gaps **140** (e.g., about 1 to 2 mm) may be formed between each adjacent rod **130**, as shown in Fig. 11E.

[0123] One or more lengths of fibers **142** may then be dragged or passed through a coating solution, e.g., silicone resin, and then wound onto the spool **136** by rotating the spool **136** either automatically or manually such that the coated fibers **142** are wound adjacent along the length of the spool **136**, as shown in Fig. 11F. The rotational speed of the spool **136** may be varied, e.g., at 0.1 to 1.0 RPM to yield a pull-rate of about 0.6 in/min. Because the rods **130** with the silicone resin film **134** are spaced apart from one another with gaps **140**, the substrates or fibers **142** may be secured to one another with the corresponding gaps **140** formed transversely to the lengths of the fibers **142**. Once the film **134** has cured, one or

more longitudinal cuts may optionally be made through the spooled fibers **142** and the completed fiber array may be removed from the spool **136**.

[0124] In dragging or passing the fibers through the hydrophobic solution, the fibers may be first wetted with a fluid such as water or alcohol such as ethanol, isopropanol or mixtures thereof (such as 30% to 70% isopropanol) to prevent the hydrophobic solution from wicking into and between the filaments, as described above. Once the coating has been placed over the fiber, the fluid may evaporate ensuring that the conduits between the filaments are open for oxygen passage. The coating or covering of these fibers as well as the pre-wetting with fluid may be utilized with any of the variations described herein.

[0125] Although the spool **136** variation is illustrated with a single common length of fiber **142**, other variations may incorporate hydrophilic fibers or other wicking fibers interspersed between the coated hydrophobic fibers **142**, as discussed above, or hollow tubes of oxygen permeable material rather than coated threads.

[0126] Yet another variation is shown in the top view of Fig. 12A which illustrates a manufacturing method where a common length of fiber **12** may be wound in an alternating manner with a common length of hydrophobic fiber **52** upon a supporting frame **150**, e.g., a planar support. The width of the frame **150** may correspond to the desired width of length of the fiber array which contacts the wound region.

[0127] With the fibers wound parallel to one another and secured, one or more adhesive stripes **152**, e.g., silicone resin, may be laid transversely across the width of the fiber array such that formed gaps **154** are defined between the respective stripes **152**, as shown in the perspective view of Fig. 12B. Once the adhesive stripes **152** have cured, the secured fiber array may be removed from the supporting frame **150**, as shown in the perspective view of Fig. 12C. Fig. 12D illustrates a detail bottom view showing how the hydrophobic coated fibers **12** are aligned in parallel in an alternating manner with hydrophilic fibers **52**. The adhesive stripes **152** may be seen with the formed gap **154** between exposing the respective fibers **12**, **52** for contact against the wound. Alternatively, these materials can be woven, knit, or otherwise entwined in any fashion, providing the oxygen conduction from outside the wound surface is unimpeded and fluid connection between the wound surface and the hydrophilic absorbent material is preserved.

[0128] The fiber array may then have an oxygen permeable film **156**, e.g., silicone film which may be temporarily backed by polyethylene for handling, may be aligned with the fiber array such that an open area **158** formed in the film **156** is aligned with the fiber array, as shown in the perspective view of Fig. 12E. The fiber array may be adhered to the film **156** with an adhesive such that the adhesive stripes **152** face away from the open area **158** of film **156**. The hydrophilic absorbent material **16** may then be laid atop the fiber array and film **156** and optionally secured with an adhesive, as shown in the respective bottom and top views of Figs. 12F and 12G.

[0129] With the fiber array and foam so arranged, the film **156** may be wrapped to cover and completely envelope the assembly while leaving the fiber array exposed within the open area **158** for contacting the wound, keeping the ends accessible to an oxygen reservoir as shown in the respective top and bottom views of Figs. 12H and 12I. The exposed terminal ends of the fibers may be optionally wrapped over the top portion of the hydrophilic absorbent material **16**, if desired, and secured (e.g., via RTV paste) as shown in respective bottom and top views of Figs. 12J and 12K.

[0130] To complete the wound dressing, a frame of adhesive tape **160**, e.g., medical adhesive tape, may be arranged around the fiber array and hydrophilic absorbent material so as to leave the open area **158** exposed for contact against the wound. Figs. 12L and 12M show bottom and top views of an example where the adhesive tape **160** may be arranged about the assembly. The fiber array and hydrophilic absorbent material assembly may be adhered to or otherwise secured to the tape, which may be trimmed to form border **162**, as shown in the respective bottom, top, and perspective views of Figs. 12N-12P. The border **162** may thus allow for the dressing to be secured over a wound such that the exposed fibers **12**, **52** along open area **158** directly contact the wound while border **162** prohibits or inhibits any exudate from wicking laterally along the dressing.

[0131] Yet another variation for manufacturing a fiber array assembly is shown in Figs. 13A to 13C. In this variation, an array **170** of tines or elongate members may be used to comb or rake a thin layer of any of the oxygen diffusive materials described herein, such as RTV silicone paste, onto a cured silicone film. Such an array **170** may generally comprise a base **176** having a first set of aligned members **172** having a first length and a second set of aligned members **174** having a second length which is shorter than the first length. Each of

the members **172**, **174** may be alternated such that regions may be framed between the members **172** and **174**, as shown in Fig. 13A. The difference between the lengths of **172** and **174** may form the barriers between each adjacent oxygen diffusive channel.

[0132] A layer of the silicone paste may be laid upon the cured silicone film **178** and array **170** may be combed or raked over the film such that parallel channels **182** (where members **172** are raked) are formed between silicone barriers **180** (where members **174** are raked), as shown in Fig. 13B. A second thin film of silicone **184** may be laid upon the raked silicone paste prior to curing such that the channels **182** are enclosed and separated between films **178**, **184** and silicone barriers **180**, as shown in Fig. 13C.

[0133] Once the silicone has cured, the array may be cut or otherwise separated longitudinally between every few channels **182** to produce relatively thinner multi-lumen ribbons. The separated ribbons may be attached to adhered to one another (e.g., via bonding with orthogonally positioned silicone strips, as described herein) to form a composite fiber array such as the variation shown above in Fig. 8. An example is shown in the Fig. 14A which illustrates a fiber array which has been formed and cured and then cut longitudinally into individual sub-assemblies **121A**, **121B**, **121C**, **121D**. Although four sub-assemblies are shown, any number of sub-assemblies may be formed as desired. Each of the sub-assemblies may have one or several oxygen conduits formed through the ribbons.

[0134] Each of the sub-assemblies **121A**, **121B**, **121C**, **121D** may be aligned with respect to one another to form a composite fiber array **190** having longitudinally aligned gaps, spaces, or channels **196** between each adjacent sub-assembly, as shown in Fig. 14B. The composite fiber array **190** may then be either adhered directly to one another (e.g., via orthogonally aligned silicone adhesive, as described herein) and/or directly to another substrate such as a hydrophobic absorbent material **194** such as gauze, sponge, etc. Each of the oxygen conduits may be optionally filled at least partially with silicone to seal the channels to prevent or inhibit any exudate from wicking laterally through the channels.

[0135] Fig. 14C shows a top view of the absorbent material **194** having the composite fiber array **190** attached on the opposing side. A hydrophilic absorbent material may also be placed or situated along one or portions of the gaps or channels **196** to facilitate exudate wicking from the wound surface to the absorbent material **194**. For instance, one or more

absorbent threads (such as cotton threads) may be aligned longitudinally along the gaps or channels **196** between adjacent sub-assemblies **121A**, **121B**, **121C**, **121D**.

[0136] The oxygen channels of the composite fiber array **190** may be formed in any of the variations described above, if desired. For instance, fibers may be placed along each of the channels or the channels may be alternated with hydrophilic materials as well, as previously described.

[0137] With the composite fiber array **190** formed, it may be applied directly upon the wound for treatment. Alternatively, the fiber array **190** may be adhered or placed upon an adhesive border **196**, as shown in Fig. 14D. In yet another variation, the composite fiber array **190** may be used without any hydrophilic absorbent material for application directly upon a wound surface. In yet another variation, the composite fiber array **190** may be used in conjunction with a conventional dressing such as an adhesive bandage **200**. The composite fiber array **190** may be placed directly into contact against a wound surface between the gauze **202** of adhesive bandage **200**, as shown in Fig. 14E. The oxygen antenna **129** may be placed to extend beyond the bandage to ensure oxygen absorption and diffusion through the channels while the assembly may be held against the wound surface via the adhesive **204** of bandage **200**.

[0138] COMPRESSIBLE DESIGNS

[0139] In alternative designs, the wound dressing assembly may be modified to conform more closely to wound topography while still allowing for control of gas composition and cycling of different compositions and even of compression pressure against the wound. Such dressings may optionally also allow for visualization of the wound.

[0140] One variation is shown in the bottom views of Figs. 15A and 15B which illustrate a simplified wound dressing which may omit the hydrophilic absorbent material positioned above the substrate. The substrate **210** (e.g., comprised of any of the suitable materials described herein) may have its one or more oxygen conduits or channels **14** (as described herein) extending through the substrate **210**. The substrate **210** may optionally further define exudate drainage regions **212** where the substrate **210** may be narrowed relative to the rest of the substrate **210**, e.g., hourglass shaped, such that the oxygen conduits or channels **14** are positioned to extend orthogonally relative to the direction of exudate flow while remaining exposed to the air.

[0141] An absorbent material may be optionally positioned in proximity to the exudate drainage regions **212** (e.g., above, around, at least partially around, or adjacent to the regions **212**) where it may absorb any exudate flowing laterally. If the lateral exudate flow is insufficient, the substrate **210** may be bulged or otherwise pressed against the wound **W** slightly to facilitate exudate flow towards the sides of the substrate **210** by squeezing or urging the exudate towards the less compressed sides of the substrate **210** (also described in further detail below). Additionally and/or alternatively, the substrate **210** may have one or more grooves defined along the wound contacting surface to facilitate channeling the exudate flow. Moreover, the substrate **210** may optionally be made with a wide ribbon covering the entire wound **W** and overlaid with an absorbent material which is relatively wider than the ribbon while maintaining exposure of the ends of the oxygen conduits or channels **14** to air.

[0142] Fig. 15B shows another variation of the substrate **214** which may define one or more tubes or channels **216** which are filled with air and which also function to support the substrate **214**. In this variation, the ends **220** of the tubes or channels **216** may be sealed. Air may also be trapped in adjacent air channels **218**. In this variation, the exudate may be urged to flow laterally towards the sides of the substrate **214** relative to the direction of the tubes or channels **216**. As with the variation of Fig. 15A, an optional absorbent material may be placed above or adjacent to the substrate **214** and/or relative to the exudate drainage region where the substrate **214** is narrowed although in other variations the narrowed region may be omitted entirely.

[0143] In yet another variation, a simple substrate **230** (e.g., any of the suitable materials described herein such as silicone) may optionally have one or more channels or grooves **232** defined along a lower wound contact surface **234** while its upper surface remains exposed to air, as shown in the perspective view of Fig. 16. While the substrate **230** may optionally define the channels or grooves **232** to encourage lateral flow of exudate from the underlying contact wound through the channels, oxygen may be diffused from the air and through the substrate **230** directly to the underlying wound rather than through oxygen conduits.

[0144] In order to maintain the substrate **230** in a dry condition when exposed to air, a hydrophilic absorbent material **240** (e.g., any of the absorbent materials described herein) may be placed into proximity or adjacent to the sides of the substrate **230** rather than positioned

atop the substrate surface. In one alternative, a thin film of non-foaming silicone may be coated upon a mold and then filled with foam within the mold. The mold may be configured into any desired such that the silicone coated material is thus formed with the foam within. One example is illustrated in the perspective view of Fig. 17 which shows absorbent material **240** shaped to define an opening **242** for receiving the substrate **230** within. While the absorbent material **240** is shown in a rectangular configuration, the material **240** may be shaped to receive any number of other substrate configurations which may be uniform or customized for a particular wound or patient anatomy. Because the absorbent material **240** is designed to receive and surround the substrate **230** within, the absorbent material **240** may define one or several substrate contact surfaces **244** which may abut or be positioned into proximity to the substrate **230** for fluidly receiving any exudate.

[0145] By locating the absorbent material **240** away from above the substrate **230** and from the central portion of the dressing, the exudate may accumulate around the substrate **230** rather than above the oxygen diffusive portion. Moreover, because only the substrate **230** may contact the wound, adherence of the dressing to the wound may be minimized and the substrate **230** may more closely conform to the wound topography due to its relative flexibility.

[0146] In addition to the absorbent material **240**, an additional compressible material or pad may be optionally layered atop the substrate **230**. Such a compressible pad **250**, as shown in the perspective view of Fig. 18, may be comprised of a material (e.g., an open cell foam, cotton, etc.) which allows for the unhindered diffusion of oxygen through the pad **250** and to the underlying substrate **230**. The pad **250** may be encapsulated in a waterproof oxygen permeable film or coating, such as silicone, to prevent exudate or other fluids from soaking the pad **250**. The pad **250** may have a substrate contact surface **252** which defines a protrusion **254** such as a curved or wedged portion which extends from the contact surface **252**. In use, the protrusion **254** may be placed against the substrate **230** to gently press or compress a portion (such as the central portion) of the substrate **230** against the underlying wound to force or urge any exudate to flow laterally from under the substrate **230** for absorption into the absorbent material.

[0147] One variation of such an assembly is shown in the exploded assembly view of Fig. 19A which illustrates how the substrate **230** may be positioned with the channels or

grooves **232** to face towards an underlying wound. The compressible pad **250** may be layered atop the substrate **230** such that the protrusion **254** is positioned to face towards and into contact against the substrate **230**. The absorbent material **240** may be placed into contact around the substrate **230** as well as the pad **250** such that the absorbent material **240** is in fluid communication with the channels or grooves **232** of the substrate **230**. As previously described, the channels or grooves **232** may be omitted in this variation as well as any of the variations described herein since the exudate may be urged via the protrusion **254** to flow laterally.

[0148] With the substrate **230** and pad **250** layered and with the absorbent material **240** placed around at least the substrate **230**, the assembly may present a low-profile dressing having a protruding portion **260** of substrate **230** extending in conformance with the protrusion **254** defined along pad **250**, as shown in the side view of the assembly in Fig. 19B. The entire dressing assembly may be optionally encased or sealed by a fluid-permeable coating or covering **262** while the absorbent material **240** may be at least partially encased or sealed by a fluid-tight coating or covering which may prevent any exudate from leaking or seeping out of the material **240** or impede evaporation of water from accumulated exudate. The absorbent material **240** may remain in fluid communication along its contact surfaces **244** with the substrate **230**. Additionally, the absorbent material **240** may also be sealed to the enveloped pad **250** to prevent any exudate from wicking between the pad **250** and absorbent material **240**.

[0149] The side view of Fig. 19B illustrates how the contact surface **264** of substrate **230** may protrude from the dressing for contact against the wound. Hence, when the dressing is placed against the wound, the contact surface **264** may apply a gentle pressure or force against the wound to urge exudate from the wound to flow laterally, e.g., through the channels or grooves **232** of substrate **230**, and towards the absorbent material **240** which may absorb and retain the exudate within. While the dressing assembly is illustrated as having a central portion of the substrate **230** bowing outward from the dressing, the pad **250** as well as the substrate **230**, may be configured in alternative variations to curve or extend along other portions. For instance, a side portion of the pad **250** and substrate **230** may be curved to urge exudate in the contacted wound to flow along a single direction away from the curved side portion.

[0150] As previously described, the material **240** may be shaped to receive any number of other substrate configurations which may be uniform or customized for a particular wound or patient anatomy. Additionally and/or alternatively, rather than incorporating a protrusion along the pad **250**, the protrusion may be formed along another portion of the dressing assembly (e.g., along a top surface of the pad, a separately incorporated layer having a protrusion, etc.) or it may be formed by another mechanism such as an external compress or bandage having some protrusion pressing against the dressing assembly. Any of the features may be utilized in combination to produce the protrusion for contact against the wound, if so desired.

[0151] Figs. 20A and 20B show side and perspective views of another variation where the dressing assembly **270** may be shaped into a circular configuration. The hydrophilic absorbent material **272** may be circularly shaped (or any other suitable shape) to receive a compressible pad or inflatable balloon **274** which is correspondingly configured. For instance, in one variation, the absorbent material **272** may be formed as a simple washer configuration. In yet other variations, the absorbent material **272** may be configured to be removable from the dressing assembly **270** allowing for replacement of the material **272**, for example when full of exudate, without having to remove the dressing from the wound or skin surface.

[0152] The protruding portion **276** of the encased substrate (which may or may not omit the channels or grooves therealong) may be seen having a protruding contact surface **280** while the dressing may be encased in a coating or covering **278**, as previously described. Because the dressing assembly **270** may be circularly configured, the exudate from the contacted wound may be forced to flow out radially rather than laterally towards the absorbent material **272**.

[0153] In alternative variations, the absorbent material **272** may be omitted entirely and instead replaced by a bag or expandable reservoir chamber which may be shaped in a corresponding manner, e.g., toroidal or washer-shaped. In this variation as well as any of the variations described, the underlying portion of the absorbent material **272** may include an adhesive or incorporate an adhesive skirt emanating radially for securing the dressing upon the skin surrounding the wound. In yet other variations, an elastic bandage (e.g., commercially available bandage) may be optionally applied over the dressing assembly **270** to

further secure the dressing to the patient as well as to provide additional compression of the dressing against the wound.

[0154] In yet another variation, one or more ports may be optionally incorporated into the dressing assembly, as shown in the perspective view of Fig. 21A. An optional exudate access port **294** may be incorporated along the absorbent material **272** to provide access for removing any excess exudate. Additionally and/or alternatively, one or more optional ports may be provided along the pad or substrate for introducing and/or flow gas mixtures through the either the inflatable balloon or encapsulated compression pad. For instance, a gas inlet port **290** and/or gas outlet port **292** may be provided. Alternatively, any number of agents or medicaments may be introduced through the ports for application to the underlying wound.

[0155] In other variations, rather than incorporation of ports, one or more regions of the dressing may incorporate septum (e.g., urethane or polymeric portions) through which agents or medicaments may be introduced or fluids removed via the insertion of needles through the septum. A contact region **296** between the pad and absorbent material may be seen around the periphery of the pad.

[0156] As described above, a compressible pad or inflatable balloon **274** may be used to bulge out the substrate into compressive contact against the wound. The use of a balloon with a port may allow for the introduction of air, e.g., from an air-filled syringe, to enable the adjustment of the pressure to accommodate different needs. Such an inflatable balloon **274** may be inflated with oxygen rather than air to increase the oxygen concentration in contact with the wound. This may also allow for the cycling of different concentrations of oxygen.

[0157] Additionally and/or alternatively, the inflatable balloon **274** may be coupled to a regulated source such as a pump **298** through one or more of the ports **290**, as shown in the perspective view of Fig. 21B. A second opening or port **292** in the balloon **274** may allow the oxygen to flow through the balloon **274** continuously to also prevent equilibration with air. In yet another variation, introduction or flow of a fluid or gas (such as air) through the one or more ports **290** or septa may be introduced not only for the infusion of an inflation fluid for inflating balloons, but also for the expansion of one or more encapsulated pads as well which may be used, e.g., for providing a compressive force.

[0158] In yet another variation shown in the perspective view of Fig. 22, a dressing assembly **300** may incorporate a hydrophilic absorbent material **302** and a compressible pad

or inflatable balloon **304** which may form the protruding portion **306** of the encased substrate extending from the contact surface **312**, as described above. The dressing may also incorporate coating or covering **310**. However, the dressing may incorporate an open annular gap **308** which may be perforated to receive any exudate for absorption by the absorbent material **302**. Moreover, the contact surface **312** may also optionally include an adhesive **314**, e.g., around the periphery of the dressing, to secure the dressing **300** upon the skin surrounding the wound to be treated.

[0159] As described previously, this variation (as well as any of the other variations described) may optionally incorporate one or more ports or inflatable balloons or variously configured pads or balloons.

[0160] Fig. 23 shows a side view of yet another dressing assembly **320** formed as previously described. However, an additional permeable membrane **322** (e.g. perforated silicone) may be formed to span the annular gap between the protruding portion **276** and the absorbent material **272** along the contact surface that is pressed against the wound. The inclusion of membrane **322** may prevent any exudate from collecting within the annular gap.

[0161] Yet another variation of the dressing assembly **330** is shown in the side view of Fig. 24, which illustrates a portion of the compressible pad **274** removed to form an opening **322**. The portion removed from the pad may be sized to match a size of the underlying wound such that the opened portion is placed directly over and encircles the wound. The substrate **230** may extend a distance from the wound to facilitate oxygen diffusion as well as diffusion directly through the substrate **230** covering the wound.

[0162] In any of the embodiments described above which utilize the absorbent material, rather than using a hydrophilic material a hygroscopic materials (e.g., polyacrylamide, etc.) may be used instead to avoid any exudate from being squeezed out, particularly where the adhesive may fail to seal the periphery of the dressing to the skin. For instance, hygroscopic beads may be used in place of the hydrophilic material by containing the beads within a mesh, fabric or perforated film. If such a hygroscopic material is used, a material having a relatively high molecular weight exclusion to minimize concentration of toxic factors and fouling may be utilized.

[0163] Yet another variation is shown in the side and perspective views of Figs. 25A to 25C which show a dressing assembly **340** formed to have the substrate and optional

compressible pad enveloped within a coating or covering **342**, as previously described. The contact surface **344** as well as the enveloped compressible pad may be both formed as dome-shaped or curved structures which intersect with one another along a border **346** which may extend circumferentially, e.g., around the periphery of the dressing, to adhesively secure the dressing assembly **340** upon the skin surrounding the wound to be treated. Alternatively, the circumferential border **346** may extend around the dressing and function as a structural member for supporting an absorbent material which may be placed upon or into contact against the border **346** such that the contact surface **344** (when compressed into contact against the underlying wound) may urge any exudate to flow laterally for absorption into the absorbent material which may be integrated with or alternatively positioned upon the border **346**.

[0164] In yet another variation, Figs. 26A and 26B show top and side views of a dressing assembly **350** also having a substrate and optional compressible pad contained within a coating or covering **354**. A circumferential border **352** may also be formed around the dressing such that the border **352** is supported by one or more radially extending supports **356**. These supports **356** may extend away from the dressing and form a plurality of annular openings **358** between the border **352** and the dressing. Moreover, while the contact surface **360** may extend below the border **352** in a curved manner for contacting the underlying wound, as shown in the side view of Fig. 26B, the supporting portion **362** of the dressing extending above the border **352** may curve and terminate in a flattened surface for presenting a relatively low profile when the dressing assembly **350** is placed upon the skin of the patient.

[0165] With the contact surface **360** containing the substrate and optionally compressible pad within, the border **352** extending circumferentially may function as a support for positioning an absorbent material **364** upon the dressing. As illustrated in the side, bottom, and perspective views of Figs. 27A to 27D, the absorbent material **364** may be comprised of any of the suitable materials described herein although in this variation, the absorbent material **364** is shaped into a disc or washer configuration which defines an opening **366** which may be sized to receive the supporting portion **362** of the dressing. Hence, the dressing assembly **350** may have the absorbent material **364** placed upon the border **352**, as shown in Fig. 27B, such that the assembly still presents a low-profile. The absorbent material **364** may remain attached to the supporting portion **362** via attachment between the opening

366 and supporting portion 362 (e.g., via an interference fit, adhesive, etc.) such that the absorbent material 364 remains exposed through the annular openings 358, as shown in the bottom view of Fig. 27C. Accordingly, with the contact surface 360 of the dressing placed upon the wound, the exudate may be urged laterally via the compressive force placed against the wound by the dressing assembly 350 such that the exudate may flow through the annular openings 358 for absorption by the absorbent material 364.

[0166] Additionally, because the absorbent material 364 may be removed from the dressing while the dressing assembly 350 remains upon the wound and in contact against the patient's skin surface, the absorbent material 364 may be removed and changed periodically without disturbing the wound or dressing. The absorbent material 364 may also be placed into proximity to the wound W either with the dressing assembly 350 or after placement of the assembly 350 upon the skin surface, as shown in the perspective assembly view of Fig. 28.

[0167] The apparatus and methods disclosed above are not limited to the individual embodiments which are shown or described but may include combinations to wound dressings which incorporate individual features between the different variations. Modification of the above-described assemblies and methods for carrying out the invention, combinations between different variations as practicable, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

CLAIMS

What is claimed is:

1. A wound dressing, comprising:

an oxygen-diffusive substrate defining a contact surface; and,

a hydrophilic absorbent material in fluid communication with at least one portion of a periphery of the oxygen-diffusive substrate,

wherein at least one portion of the substrate is configured to press the contact surface against a wound surface.

2. The dressing of claim 1 wherein the oxygen-diffusive substrate is comprised of silicone.

3. The dressing of claim 1 wherein the oxygen-diffusive substrate defines one or more channels or grooves along the contact surface.

4. The dressing of claim 3 wherein the channels transect the contact surface.

5. The dressing of claim 1 wherein the oxygen-diffusive substrate is water resistant.

6. The dressing of claim 1 wherein at least one portion of the substrate is configured to protrude from the dressing for pressing the contact surface.

7. The dressing of claim 1 wherein the hydrophilic absorbent material defines an opening sized to receive the substrate therein such that the hydrophilic absorbent material is in communication with the at least one portion of the periphery.

8. The dressing of claim 7 wherein the hydrophilic absorbent material is in fluid communication with one or more channels or grooves along the contact surface.

9. The dressing of claim 1 wherein the hydrophilic absorbent material is removable and/or replaceable from the wound dressing.

10. The dressing of claim 9 wherein the absorbent material is removable and/or replaceable without removing the contact surface from the wound surface.

11. The dressing of claim 1 further comprising a compressible pad which defines at least one protrusion, wherein the at least one protrusion contacts and conforms the substrate to the wound surface.

12. The dressing of claim 11 wherein the at least one protrusion is aligned with a central portion of the substrate.

13. The dressing of claim 11 wherein a portion of the compressible pad defines an area which is sized to cover the wound surface.

14. The dressing of claim 11 wherein a portion of the compressible pad is configured to conform to or in proximity to the wound surface.

15. The dressing of claim 1 further comprising at least one access port upon the dressing.

16. The dressing of claim 15 further comprising a pump or reservoir fluidly coupled to the at least one access port.

17. The dressing of claim 16 further comprising at least one pad encapsulated within the dressing fluidly coupled to the pump.

18. The dressing of claim 1 further comprising an adhesive border formed around a periphery of the wound dressing.

19. The dressing of claim 1 further comprising a drug, medicant or agent infused into the dressing.

20. The dressing of claim 1 further comprising a border supported around a periphery of the dressing.

21. The dressing of claim 20 further comprising a hydrophilic absorbent material configured to be removable and/or replaceable upon the border of the dressing.

22. The dressing of claim 21 wherein the absorbent material is removable and/or replaceable without removing the contact surface from the wound surface.

23. The dressing of claim 20 wherein the border and dressing define one or more openings therebetween.

24. A method of treating a wound, comprising:

providing a wound dressing having an oxygen-diffusive substrate defining a contact surface and a hydrophilic absorbent material in fluid communication with at least one portion of a periphery of the oxygen-diffusive substrate;

pressing at least a portion of the substrate against the wound such that exudate from the wound is urged to flow laterally along the substrate and into the absorbent material; and,

diffusing oxygen through the oxygen-diffusive substrate and into the wound.

25. The method of claim 24 wherein the oxygen-diffusive substrate is comprised of silicone.

26. The method of claim 24 wherein the oxygen-diffusive substrate is water resistant.

27. The method of claim 24 further removing excess exudate from the wound via at least one access port upon the wound dressing.

28. The method of claim 24 further comprising infusing a drug, medicant or agent into the wound dressing.

29. The method of claim 24 wherein the wound dressing further comprises a compressible pad which defines at least one protrusion, wherein the at least one protrusion contacts and conforms the substrate to the wound surface.

30. The method of claim 29 wherein pressing at least a portion comprises pressing against the wound via the at least one protrusion.

31. The method of claim 24 wherein pressing at least a portion comprises adhering the wound dressing around a periphery of the wound via an adhesive border.

32. The method of claim 24 further comprising wicking the exudate across the substrate via one or more channels or grooves defined along the contact surface.

33. The method of claim 32 wherein the channels or grooves transect the contact surface.

34. The method of claim 24 wherein pressing at least a portion comprises introducing a fluid or gas via a reservoir fluidly coupled to the substrate.

35. The method of claim 34 further comprising cycling the fluid or gas through the wound dressing via one or more ports.

36. The method of claim 24 further comprising removing and/or replacing the absorbent material without removing the oxygen-diffusive substrate from the wound.

37. A wound dressing, comprising:

a hydrophilic absorbent material;

a hydrophilic absorbent material envelope which defines an open area for contacting a wound site and which at least partially encloses the hydrophilic absorbent material; and

at least one conduit having an oxygen-diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length,

wherein the at least one area of the conduit is positioned to extend exposed along the open area in contact with the wound surface and adjacent to the fluid absorbent material such that the wound surface and hydrophilic absorbent material are in fluid communication, and wherein the at least one channel has at least one portion further exposed to ambient air.

38. The dressing of claim 37 wherein the hydrophilic absorbent material envelope impedes water vapor transmission.

39. The dressing of claim 37 further comprising at least one multifilament fiber positioned through the at least one conduit.

40. The dressing of claim 37 further comprising at least one hydrophilic element interspersed with the at least one conduit.

41. The dressing of claim 37 wherein the hydrophilic absorbent material is removable and/or replaceable from the hydrophilic absorbent material envelope.

42. The dressing of claim 37 wherein the at least one conduit comprises a diameter range from 40 to 2000 micron.

43. The dressing of claim 42 wherein the at least one conduit comprises a diameter range from 80 to 260 micron.

44. The dressing of claim 37 wherein the oxygen-diffusive coating has a thickness of about 50 to 300 micron.

45. The dressing of claim 37 wherein the oxygen-diffusive coating is comprised of silicone.

46. The dressing of claim 37 wherein the oxygen-diffusive coating defines one or more micro-perforations which are sized to exclude aqueous fluid permeation via surface tension effects.

47. The dressing of claim 37 wherein the oxygen-diffusive coating has an external surface which is modified to be hydrophilic.

48. The dressing of claim 37 wherein the hydrophilic absorbent material envelope comprises an oxygen permeable material.

49. The dressing of claim 37 further comprising an access port upon the hydrophilic absorbent material envelope which is in fluid communication with the hydrophilic absorbent material.

50. The dressing of claim 49 further comprising a vacuum apparatus fluidly coupled to the access port for removing exudate from the wound dressing.

51. The dressing of claim 49 wherein the access port can be reversibly opened to permit evaporation of water from the hydrophilic absorbent material.

52. The dressing of claim 37 further comprising an adhesive border formed around a periphery of the wound dressing.

53. The dressing of claim 37 further comprising a drug, medicant or agent infused into the hydrophilic absorbent material.

54. The dressing of claim 37 further comprising a plurality of additional conduits each having an oxygen-diffusive covering.

55. The dressing of claim 54 wherein the plurality of additional conduits are formed transversely relative to one another.

56. The dressing of claim 54 further comprising one or more oxygen permeable adhesive stripes formed transversely relative to lengths of the conduits.

57. The dressing of claim 37 further comprising a perforated or semi-permeable membrane over the open area for contacting the wound site.

58. The dressing of claim 57 further comprising one or more channels formed through the perforated or semi-permeable membrane and positioned to fluidly couple the wound site and the hydrophilic absorbent material.

59. The dressing of claim 57 wherein the perforated or semi-permeable membrane defines one or more ridges or notches to form the at least one conduit.

60. The dressing of claim 37 further comprising a pump in fluid communication with the at least one conduit.

61. The dressing of claim 37 further comprising a treatment applied to the wound site selected from the group consisting of platelet gel, plasma concentrate, white cells, stem cells, skin grafts, and growth factors.

62. A wound dressing, comprising:

a hydrophilic absorbent material;

at least one conduit having an oxygen-diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length,

wherein at least one area of the conduit is positioned to extend in contact with a wound surface and adjacent to the hydrophilic absorbent material such that the wound surface and hydrophilic absorbent material are in fluid communication, and wherein the at least one conduit has at least one portion further exposed to ambient air.

63. The dressing of claim 62 further comprising a hydrophilic absorbent material envelope which defines an open area for contacting the wound site and which at least partially encloses the hydrophilic absorbent material, wherein the at least one area of the conducit is exposed along the open area for contact with the wound surface.

64. The dressing of claim 62 wherein the hydrophilic absorbent material envelope impedes water vapor transmission.

65. The dressing of claim 62 further comprising at least one multifilament fiber positioned through the at least one conduit.

66. The dressing of claim 62 further comprising at least one hydrophilic element interspersed with the at least one conduit.

67. The dressing of claim 62 wherein the hydrophilic absorbent material is removable and/or replaceable from the hydrophilic absorbent material envelope.

68. The dressing of claim 62 wherein the at least one conduit comprises a diameter range from 40 to 2000 micron.

69. The dressing of claim 68 wherein the at least one conduit comprises a diameter range from 80 to 260 micron.

70. The dressing of claim 62 wherein the oxygen-diffusive coating has a thickness of about 50 to 300 micron.

71. The dressing of claim 62 wherein the oxygen-diffusive coating is comprised of silicone.

72. The dressing of claim 62 wherein the oxygen-diffusive coating defines one or more micro-perforations which are sized to exclude aqueous fluid permeation via surface tension effects.

73. The dressing of claim 62 wherein the oxygen-diffusive coating has an external surface which is modified to be hydrophilic.

74. The dressing of claim 62 wherein the hydrophilic absorbent material envelope comprises an oxygen permeable material.

75. The dressing of claim 62 further comprising an access port upon the hydrophilic absorbent material envelope which is in fluid communication with the hydrophilic absorbent material.

76. The dressing of claim 75 further comprising a vacuum apparatus fluidly coupled to the access port for removing exudate from the wound dressing.

77. The dressing of claim 75 wherein the access port can be reversibly opened to permit evaporation of water from the hydrophilic absorbent material.

78. The dressing of claim 62 further comprising an adhesive border formed around a periphery of the wound dressing.

79. The dressing of claim 62 further comprising a drug, medicant or agent infused into the hydrophilic absorbent material.

80. The dressing of claim 62 further comprising a plurality of additional conduits each having an oxygen-diffusive covering.

81. The dressing of claim 80 wherein the plurality of additional conduits are formed transversely relative to one another.

82. The dressing of claim 80 further comprising one or more oxygen permeable adhesive stripes formed transversely relative to lengths of the conduits.

83. The dressing of claim 62 further comprising a perforated or semi-permeable membrane over the open area for contacting the wound site.

84. The dressing of claim 83 further comprising one or more channels formed through the perforated or semi-permeable membrane and positioned to fluidly couple the wound site and the hydrophilic absorbent material.

85. The dressing of claim 83 wherein the perforated or semi-permeable membrane defines one or more ridges or notches to form the at least one conduit.

86. The dressing of claim 62 further comprising a pump in fluid communication with the at least one conduit.

87. The dressing of claim 62 further comprising a treatment applied to the wound site selected from the group consisting of platelet gel, plasma concentrate, white cells, stem cells, skin grafts, and growth factors.

88. A wound dressing, comprising:

a hydrophilic absorbent material;

a vapor barrier envelope which defines an open area for contacting a wound site and which at least partially encloses the hydrophilic absorbent material; and

at least one conduit having an oxygen-diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length,

wherein the at least one area of the conduit is positioned to extend exposed along the open area in contact with the wound surface and adjacent to the fluid absorbent material such that the wound surface and hydrophilic absorbent material are in fluid communication, and wherein the at least one channel is in fluid communication with an oxygen reservoir.

89. The dressing of claim 88 wherein the reservoir is filled with an oxygenated fluid or oxygen-containing gas.

90. The dressing of claim 88 wherein the reservoir produces oxygen via a chemical reaction.

91. The dressing of claim 88 wherein the reservoir is pressurized.

92. The dressing of claim 88 further comprising at least one multifilament fiber positioned through the at least one conduit.

93. The dressing of claim 88 further comprising at least one hydrophilic element interspersed with the at least one conduit.

94. The dressing of claim 88 wherein the hydrophilic absorbent material is removable and/or replaceable from the hydrophilic absorbent material envelope.

95. The dressing of claim 88 wherein the at least one conduit comprises a diameter range from 40 to 2000 micron.

96. The dressing of claim 95 wherein the at least one conduit comprises a diameter range from 80 to 260 micron.

97. The dressing of claim 88 wherein the oxygen-diffusive coating has a thickness of about 50 to 300 micron.

98. The dressing of claim 88 wherein the oxygen-diffusive coating is comprised of silicone.

99. The dressing of claim 88 wherein the oxygen-diffusive coating defines one or more micro-perforations which are sized to exclude aqueous fluid permeation via surface tension effects.

100. The dressing of claim 88 wherein the oxygen-diffusive coating has an external surface which is modified to be hydrophilic.

101. The dressing of claim 88 wherein the hydrophilic absorbent material envelope comprises an oxygen permeable material.

102. The dressing of claim 88 further comprising an access port upon the hydrophilic absorbent material envelope which is in fluid communication with the hydrophilic absorbent material.

103. The dressing of claim 102 further comprising a vacuum apparatus fluidly coupled to the access port for removing exudate from the wound dressing.

104. The dressing of claim 88 further comprising an adhesive border formed around a periphery of the wound dressing.

105. The dressing of claim 88 further comprising a drug, medicant or agent infused into the hydrophilic absorbent material.

106. The dressing of claim 88 further comprising a plurality of additional conduits each having an oxygen-diffusive covering.

107. The dressing of claim 106 wherein the plurality of additional conduits are formed transversely relative to one another.

108. The dressing of claim 106 further comprising one or more oxygen permeable adhesive stripes formed transversely relative to lengths of the conduits.

109. The dressing of claim 88 further comprising a perforated or semi-permeable membrane over the open area for contacting the wound site.

110. The dressing of claim 109 further comprising one or more channels formed through the perforated or semi-permeable membrane and positioned to fluidly couple the wound site and the hydrophilic absorbent material.

111. The dressing of claim 109 wherein the perforated or semi-permeable membrane defines one or more ridges or notches to form the at least one conduit.

112. The dressing of claim 88 further comprising a pump in fluid communication with the at least one conduit.

113. The dressing of claim 88 further comprising a treatment applied to the wound site selected from the group consisting of platelet gel, plasma concentrate, white cells, stem cells, skin grafts, and growth factors.

114. A wound dressing, comprising:

a hydrophilic absorbent material;

at least one oxygen conductive hydrophobic conduit extending therethrough or adjacent therealong; and

a hydrophilic absorbent material envelope which defines an open area for contacting a wound site and which at least partially encloses the hydrophilic absorbent material,

wherein at least a portion of the at least one oxygen conductive hydrophobic conduit is positioned to extend exposed along the open area in contact with the wound surface and adjacent to the hydrophilic absorbent material such that the wound surface and hydrophilic absorbent material are in fluid communication, and

wherein the at least one area of the at least one oxygen conductive conduit is in contact with ambient air and is permeable to oxygen.

115. The dressing of claim 114 further comprising at least one multifilament fiber positioned through the at least one oxygen conductive hydrophobic conduit.

116. The dressing of claim 114 further comprising at least one hydrophilic element interspersed with the at least one oxygen conductive hydrophobic conduit.

117. The dressing of claim 114 wherein the hydrophilic absorbent material is removable and/or replaceable from the hydrophilic absorbent material envelope.

118. The dressing of claim 114 wherein the at least one oxygen conductive hydrophobic conduit comprises a diameter range from 40 to 2000 micron.

119. The dressing of claim 118 wherein the at least one conduit comprises a diameter range from 80 to 260 micron.

120. The dressing of claim 114 wherein the oxygen conductive hydrophobic conduit has a thickness of about 50 to 300 micron.

121. The dressing of claim 114 wherein the oxygen conductive hydrophobic conduit is comprised of silicone.

122. The dressing of claim 114 wherein the oxygen conductive hydrophobic conduit defines one or more micro-perforations which are sized to exclude aqueous fluid permeation via surface tension effects.

123. The dressing of claim 114 wherein the oxygen-diffusive coating has an external surface which is modified to be hydrophilic.

124. The dressing of claim 114 wherein the hydrophilic absorbent material envelope comprises an oxygen permeable material.

125. The dressing of claim 114 further comprising an access port upon the hydrophilic absorbent material envelope which is in fluid communication with the hydrophilic absorbent material.

126. The dressing of claim 125 further comprising a vacuum apparatus fluidly coupled to the access port for removing exudate from the wound dressing.

127. The dressing of claim 114 further comprising an adhesive border formed around a periphery of the wound dressing.

128. The dressing of claim 114 further comprising a drug, medicant or agent infused into the hydrophilic absorbent material.

129. The dressing of claim 114 further comprising a plurality of additional conduits each having an oxygen-diffusive covering.

130. The dressing of claim 129 wherein the plurality of additional conduits are formed transversely relative to one another.

131. The dressing of claim 129 further comprising one or more oxygen permeable adhesive stripes formed transversely relative to lengths of the conduits.

132. The dressing of claim 114 further comprising a perforated or semi-permeable membrane over the open area for contacting the wound site.

133. The dressing of claim 132 further comprising one or more channels formed through the perforated or semi-permeable membrane and positioned to fluidly couple the wound site and the hydrophilic absorbent material.

134. The dressing of claim 132 wherein the perforated or semi-permeable membrane defines one or more ridges or notches to form the at least one conduit.

135. The dressing of claim 114 further comprising a pump in fluid communication with the at least one conduit.

136. The dressing of claim 114 further comprising a treatment applied to the wound site selected from the group consisting of platelet gel, plasma concentrate, white cells, stem cells, skin grafts, and growth factors.

137. A wound dressing, comprising:

a hydrophilic absorbent material;

at least one oxygen conductive hydrophobic conduit extending therethrough or adjacent therealong; and

a hydrophilic absorbent material envelope which defines an open area for contacting a wound site and which at least partially encloses the hydrophilic absorbent material,

wherein the at least one oxygen conductive hydrophobic conduit is positioned to extend exposed along the open area in contact with the wound surface and adjacent to the fluid absorbent material such that the wound surface and hydrophilic absorbent material are in fluid communication, and

wherein the at least one oxygen conductive conduit is fluidly coupled to an oxygen reservoir.

138. The dressing of claim 137 further comprising at least one multifilament fiber positioned through the at least one oxygen conductive hydrophobic conduit.

139. The dressing of claim 137 further comprising at least one hydrophilic element interspersed with the at least one oxygen conductive hydrophobic conduit.

140. The dressing of claim 137 wherein the hydrophilic absorbent material is removable and/or replaceable from the hydrophilic absorbent material envelope.

141. The dressing of claim 137 wherein the at least one oxygen conductive hydrophobic conduit comprises a diameter range from 40 to 2000 micron.

142. The dressing of claim 141 wherein the at least one conduit comprises a diameter range from 80 to 260 micron.

143. The dressing of claim 137 wherein the oxygen conductive hydrophobic conduit has a thickness of about 50 to 300 micron.

144. The dressing of claim 137 wherein the oxygen conductive hydrophobic conduit is comprised of silicone.

145. The dressing of claim 137 wherein the oxygen conductive hydrophobic conduit defines one or more micro-perforations which are sized to exclude aqueous fluid permeation via surface tension effects.

146. The dressing of claim 137 wherein the oxygen-diffusive coating has an external surface which is modified to be hydrophilic.

147. The dressing of claim 137 wherein the hydrophilic absorbent material envelope comprises an oxygen permeable material.

148. The dressing of claim 137 further comprising an access port upon the hydrophilic absorbent material envelope which is in fluid communication with the hydrophilic absorbent material.

149. The dressing of claim 148 further comprising a vacuum apparatus fluidly coupled to the access port for removing exudate from the wound dressing.

150. The dressing of claim 137 further comprising an adhesive border formed around a periphery of the wound dressing.

151. The dressing of claim 137 further comprising a drug, medicant or agent infused into the hydrophilic absorbent material.

152. The dressing of claim 137 further comprising a plurality of additional conduits each having an oxygen-diffusive covering.

153. The dressing of claim 152 wherein the plurality of additional conduits are formed transversely relative to one another.

154. The dressing of claim 152 further comprising one or more oxygen permeable adhesive stripes formed transversely relative to lengths of the conduits.

155. The dressing of claim 137 further comprising a perforated or semi-permeable membrane over the open area for contacting the wound site.

156. The dressing of claim 155 further comprising one or more channels formed through the perforated or semi-permeable membrane and positioned to fluidly couple the wound site and the hydrophilic absorbent material.

157. The dressing of claim 155 wherein the perforated or semi-permeable membrane defines one or more ridges or notches to form the at least one conduit.

158. The dressing of claim 137 further comprising a pump in fluid communication with the at least one conduit.

159. The dressing of claim 137 further comprising a treatment applied to the wound site selected from the group consisting of platelet gel, plasma concentrate, white cells, stem cells, skin grafts, and growth factors.

160. The dressing of claim 137 wherein the reservoir is filled with an oxygenated fluid or oxygen-containing gas.

161. The dressing of claim 137 wherein the reservoir produces oxygen via a chemical reaction.

162. The dressing of claim 137 wherein the reservoir is pressurized.

163. A wound dressing, comprising:

at least one conduit having an oxygen-diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length,

wherein the conduit defines a wound contact region for contact with a wound surface and an oxygen absorption region which extends beyond the wound surface and is exposed to ambient air.

164. The dressing of claim 163 further comprising:

a hydrophilic absorbent material which is in fluid communication with the wound surface; and

a hydrophilic absorbent material envelope which defines an open area for contacting the wound site and which at least partially encloses the hydrophilic absorbent material.

165. The dressing of claim 164 wherein the hydrophilic absorbent material envelope impedes water vapor transmission.

166. The dressing of claim 164 wherein the hydrophilic absorbent material is removable and/or replaceable from the hydrophilic absorbent material envelope.

167. The dressing of claim 163 wherein the oxygen-diffusive coating is comprised of silicone.

168. The dressing of claim 163 further comprising an adhesive border formed around a periphery of the wound dressing.

169. A method of treating a wound, comprising:

providing a wound dressing having a hydrophilic absorbent material, a hydrophilic absorbent material envelope which defines an open area for contacting a wound site and which at least partially encloses the hydrophilic absorbent material, and at least one conduit having an oxygen-diffusive coating;

placing the open area upon the wound site such that the at least one conduit is in contact against the wound site and the wound site and hydrophilic absorbent material are in fluid communication; and

diffusing oxygen from the at least one conduit and through the oxygen-diffusive coating to the wound site.

170. The method of claim 169 wherein the at least one conduit is positioned to extend exposed along the open area and adjacent to the hydrophilic absorbent material.

171. The method of claim 169 further wicking exudate from the wound site to the hydrophilic absorbent material.

172. The method of claim 169 wherein placing the open area upon the wound site comprises maintaining a separation between the hydrophilic absorbent material and the wound site.

173. The method of claim 169 wherein the at least one conduit comprises at least one coated multifilament fiber positioned through the at least one conduit.

174. The method of claim 173 wherein prior to providing a wound dressing, permeating the multifilament fiber with a fluid to transiently obstruct the open inter-filament spaces before applying the oxygen diffusive coating.

175. The method of claim 169 wherein the wound dressing further comprises at least one hydrophilic element interspersed with the at least one conduit.

176. The method of claim 169 wherein the oxygen-diffusive coating is comprised of silicone.

177. The method of claim 169 further removing excess exudate from the wound site via an access port upon the hydrophilic absorbent material envelope which is in fluid communication with the hydrophilic absorbent material.

178. The method of claim 177 wherein removing excess exudate comprises suctioning the exudate from the wound site.

179. The method of claim 169 wherein placing the open area upon the wound site comprises adhering the wound dressing around a periphery of the wound site via an adhesive border.

180. The method of claim 169 further comprising infusing a drug, medicant or agent into the hydrophilic absorbent material.

181. The method of claim 169 further comprising inhibiting evaporation from the hydrophilic absorbent material via the hydrophilic absorbent material envelope.

182. The method of claim 169 comprising an oxygen delivery system comprising pumping an oxygen-rich fluid through the at least one conduit via a pump or pressurized reservoir.

183. The method of claim 169 further comprising applying a treatment to the wound site selected from the group consisting of platelet gel, plasma concentrate, white cells, stem cells, skin grafts, and growth factors.

184. The method of claim 183 wherein the treatment is applied prior to, during, or after placing the open area upon the wound site.

185. The method of claim 169 further comprising removing the hydrophilic absorbent material from the hydrophilic absorbent material envelope.

186. The method of claim 185 wherein the hydrophilic absorbent material is removed from the hydrophilic absorbent material envelope while maintaining the open area upon the wound site.

187. A method of forming a wound dressing, comprising:

passing a length of multi-filament fiber through a coating solution such that the fiber is coated via the solution while maintaining continuous inter-filament spaces through the fiber;

arranging the length of coated fiber to align in parallel upon a supporting frame such that a coated fiber array is formed;

securing the coated fiber array via one or more adhesive stripes placed transversely relative to a length of the coated fiber;

removing the coated fiber array from the supporting frame;

positioning the coated fiber array between an open area of a hydrophilic absorbent material envelope and a hydrophilic absorbent material such that the hydrophilic absorbent material is positioned at a distance from the open area; and

securing the hydrophilic absorbent material envelope such that the hydrophilic absorbent material is sealed therein while the coated fiber array remains exposed.

188. The method of claim 187 wherein the coating solution comprises a silicone solution.

189. The method of claim 187 wherein arranging the length of coated fiber comprises arranging the coated fiber upon a plurality of substrates having a resin film thereupon.

190. The method of claim 189 wherein arranging the length of coated fiber comprises arranging positioning the coated fiber upon a rotatable spool.

191. The method of claim 190 wherein positioning the coated fiber comprises forming a gap between each adhesive stripe when positioned upon the rotatable spool.

192. The method of claim 187 wherein removing the coated fiber array comprises cutting a length of the coated fiber array.

193. The method of claim 187 wherein arranging the length of coated fiber further comprises aligning a length of hydrophilic multi-filament fiber adjacent to the length of coated fiber.

194. The method of claim 193 wherein the coated fibers and hydrophilic fibers are intertwined, woven, or knit.

195. The method of claim 187 further comprising wetting the length of filament prior to passing a length of filament through an oxygen permeable coating solution.

196. The method of claim 187 further comprising introducing a drug or agent into the hydrophilic absorbent material prior to securing vapor barrier.

197. The method of claim 187 further comprising introducing a drug or agent into the hydrophilic absorbent material through a port defined along the vapor barrier.

198. The method of claim 187 further comprising forming a border around a periphery of the wound dressing.

199. The method of claim 187 further comprising micro-perforating the coated fiber array prior to positioning the coated fiber array.

200. The method of claim 187 further comprising modifying an external surface of the coated fiber array such that the external surface is hydrophilic.

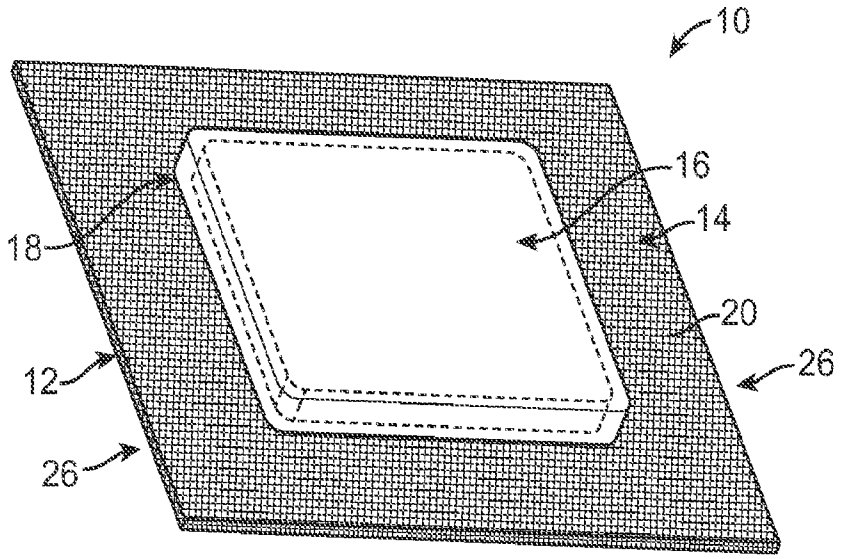

FIG. 1A

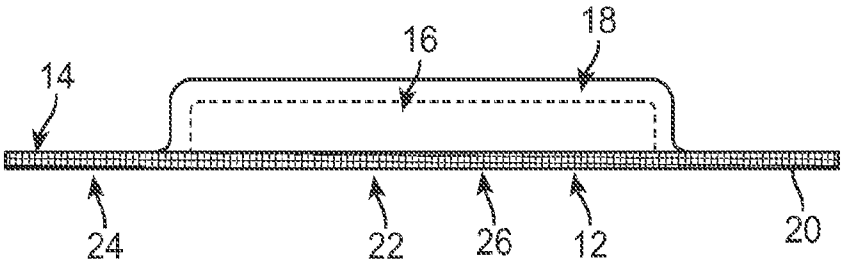

FIG. 1B

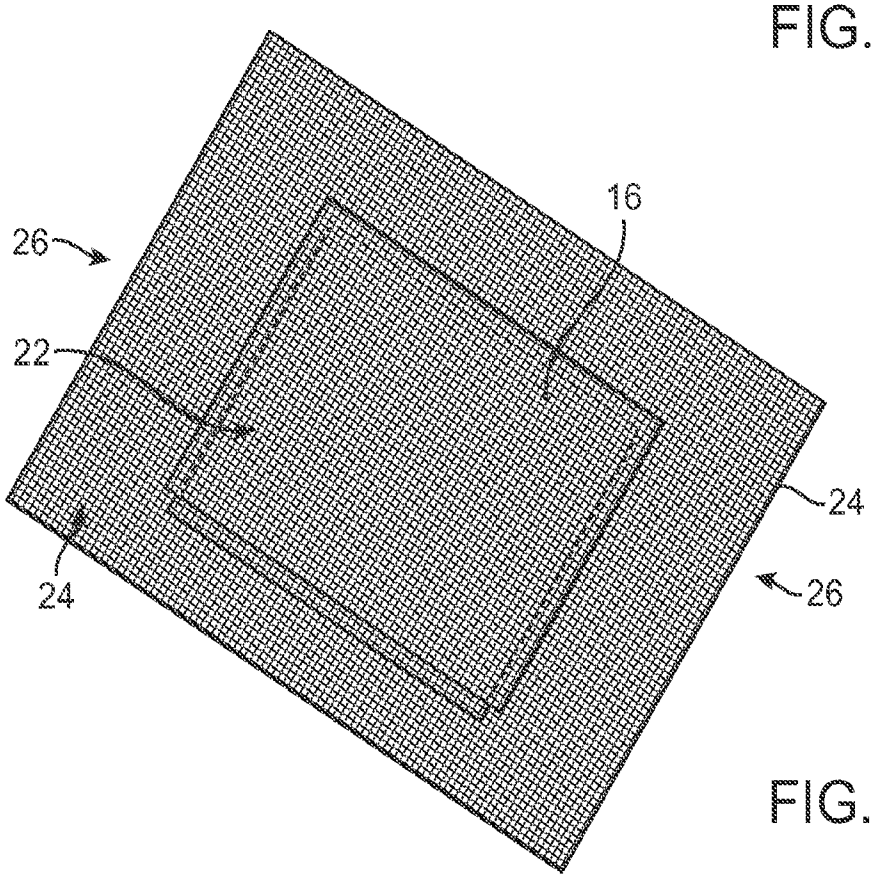

FIG. 1C

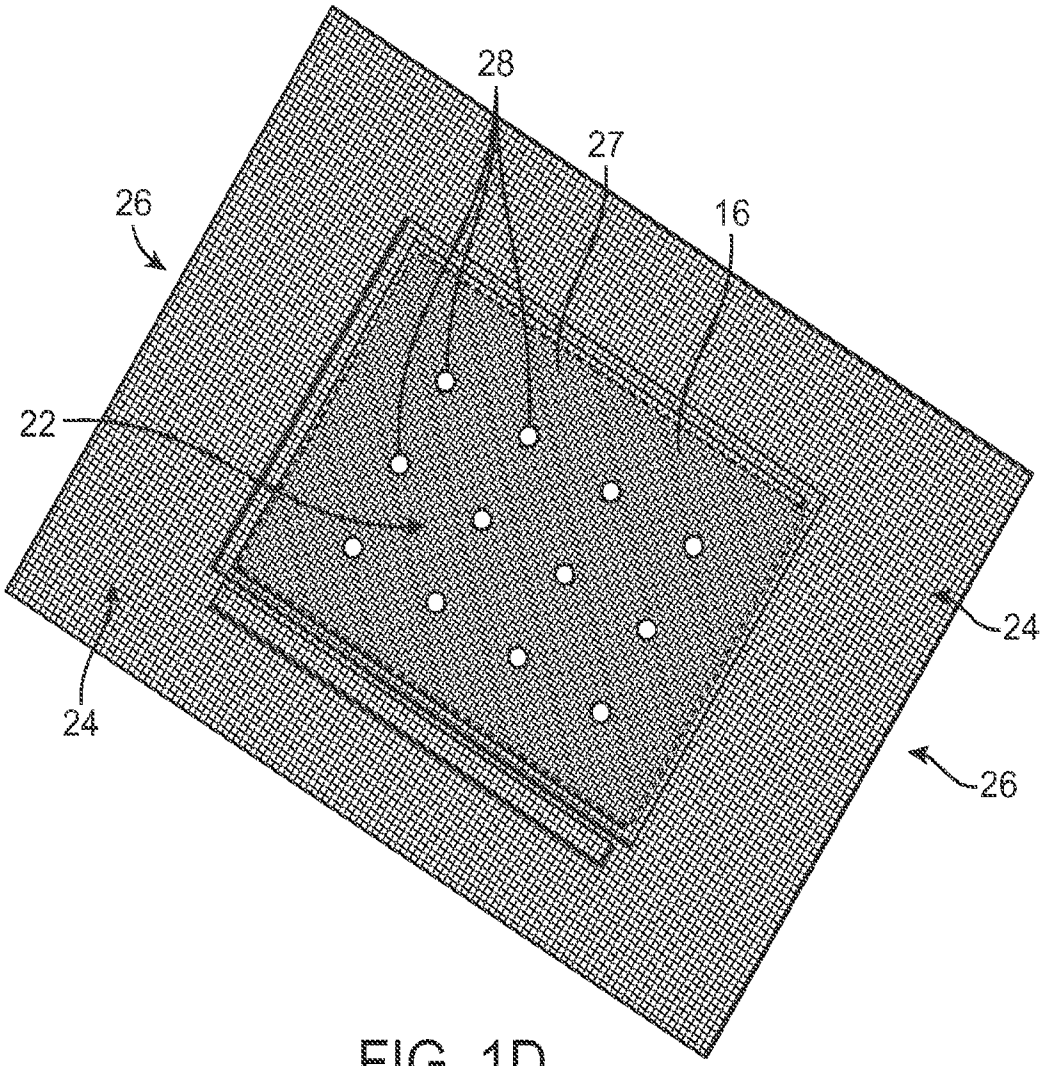

FIG. 1D

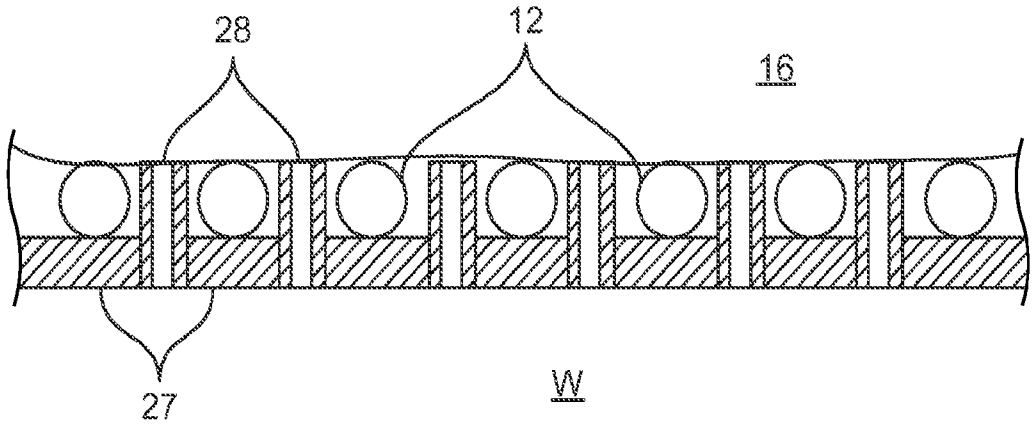

FIG. 1E

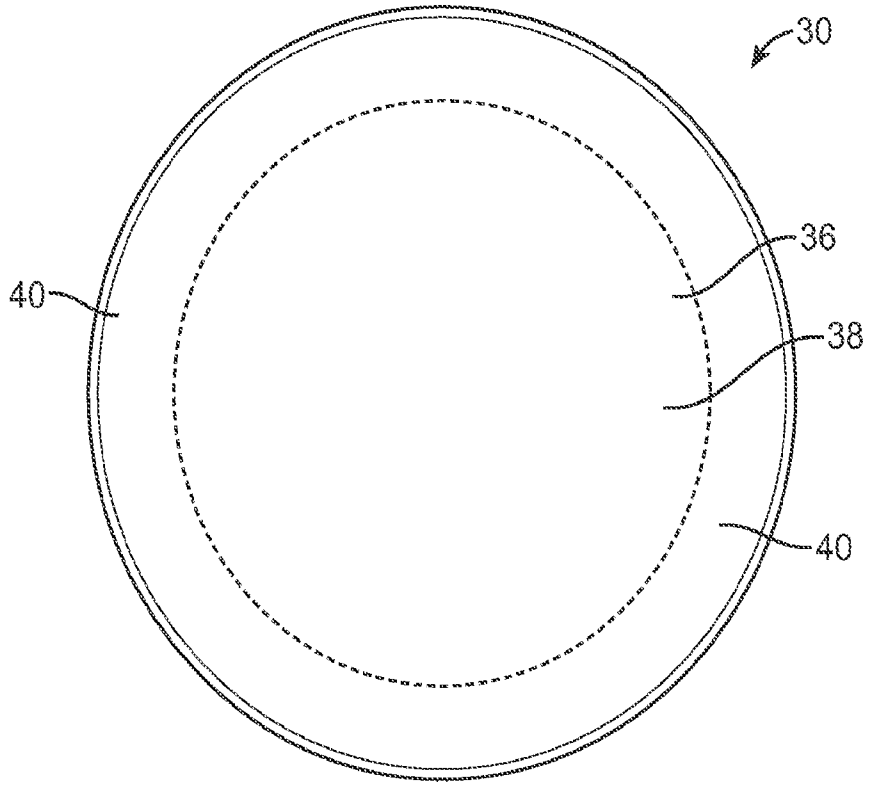

FIG. 2A

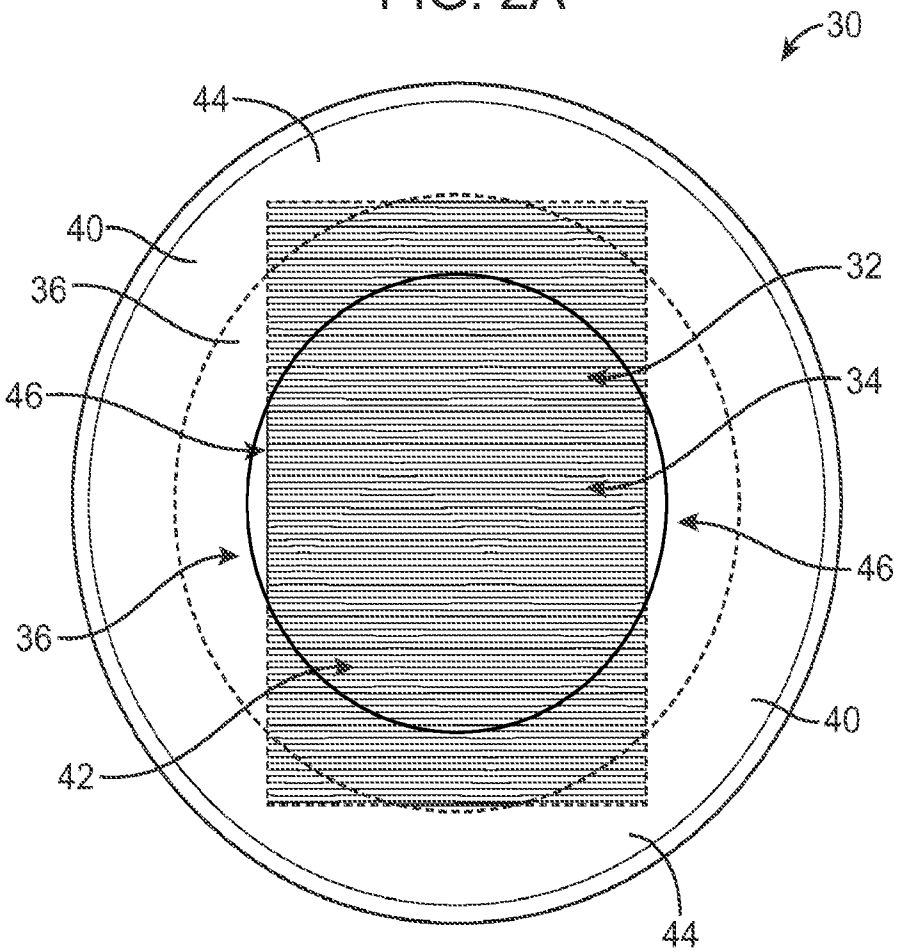

FIG. 2B

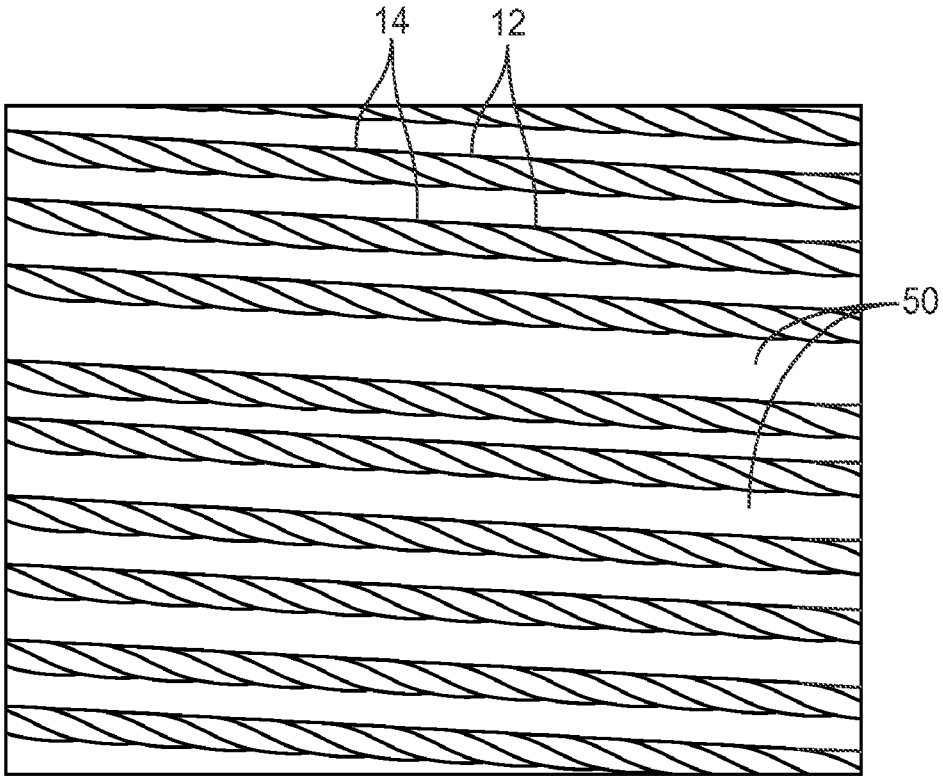

FIG. 3A

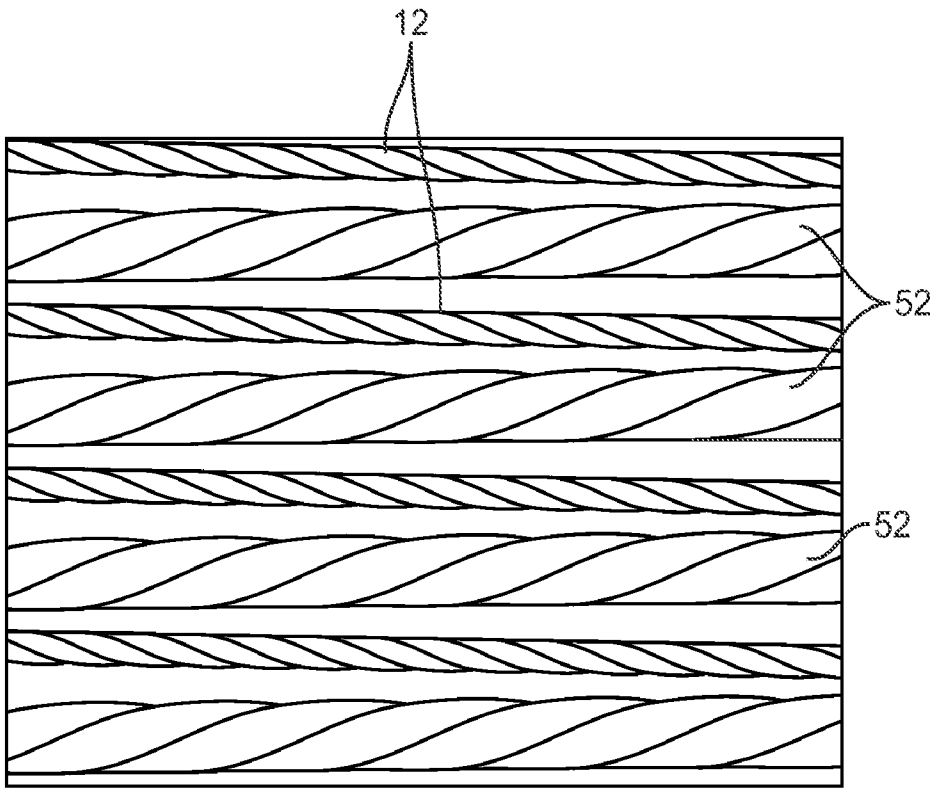

FIG. 3B

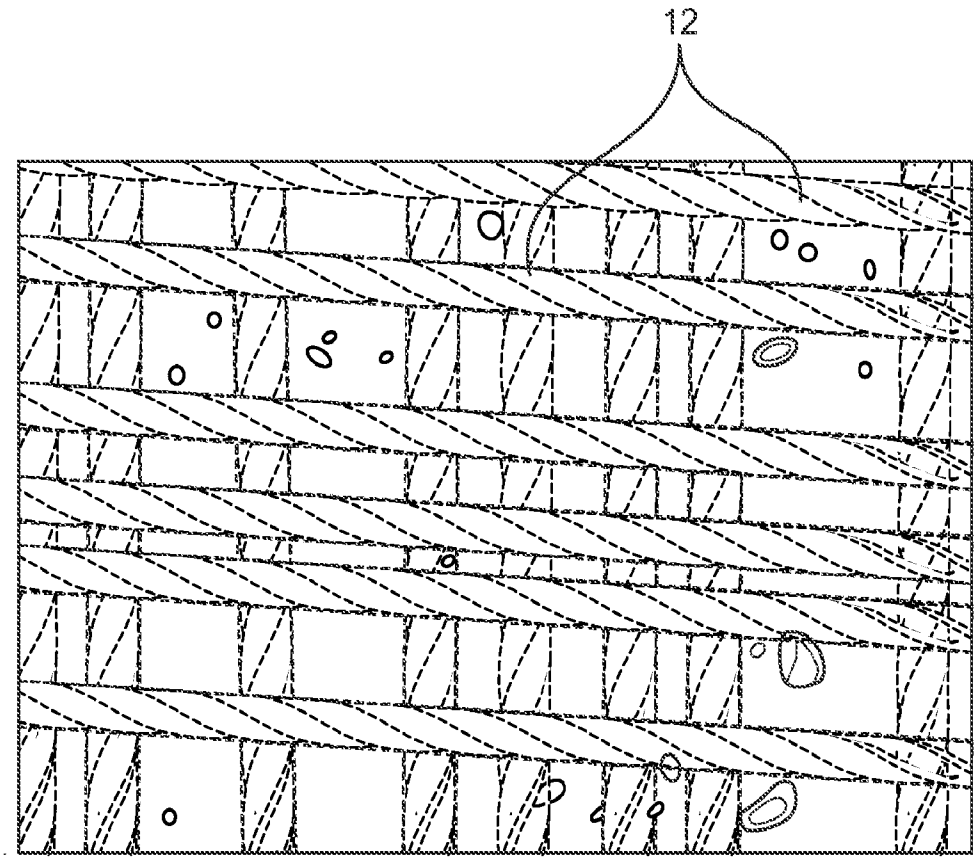

FIG. 3C

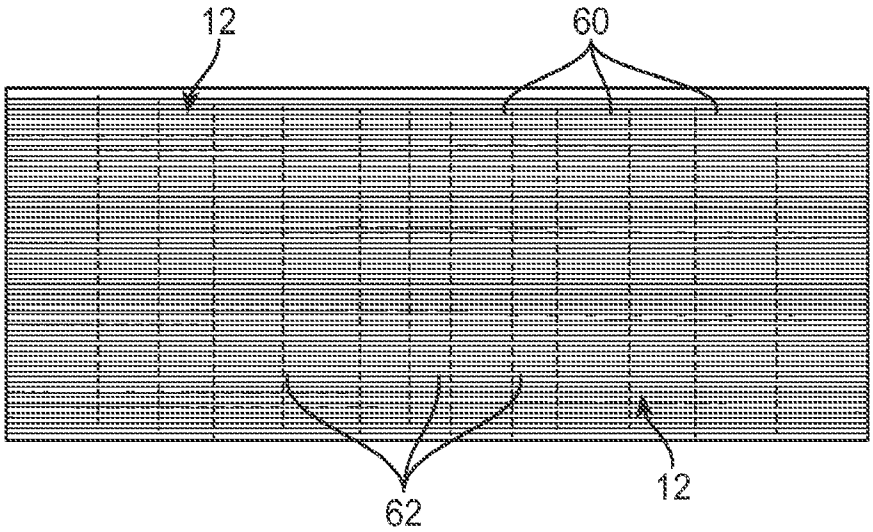

FIG. 4A

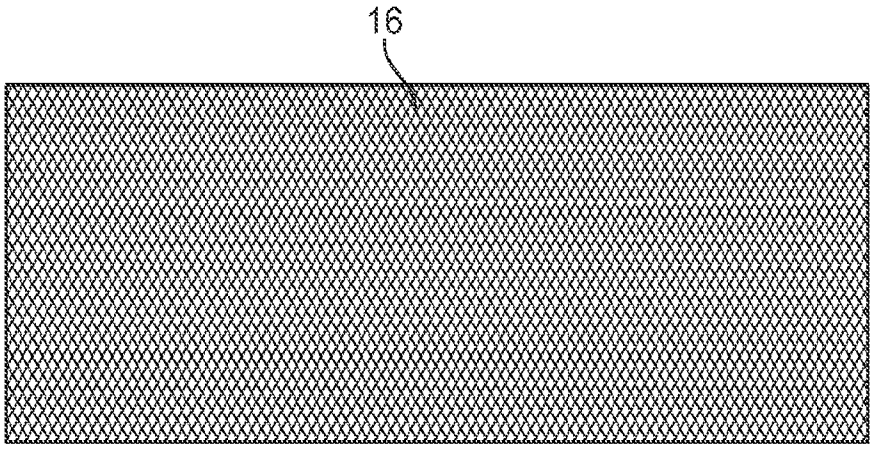

FIG. 4B

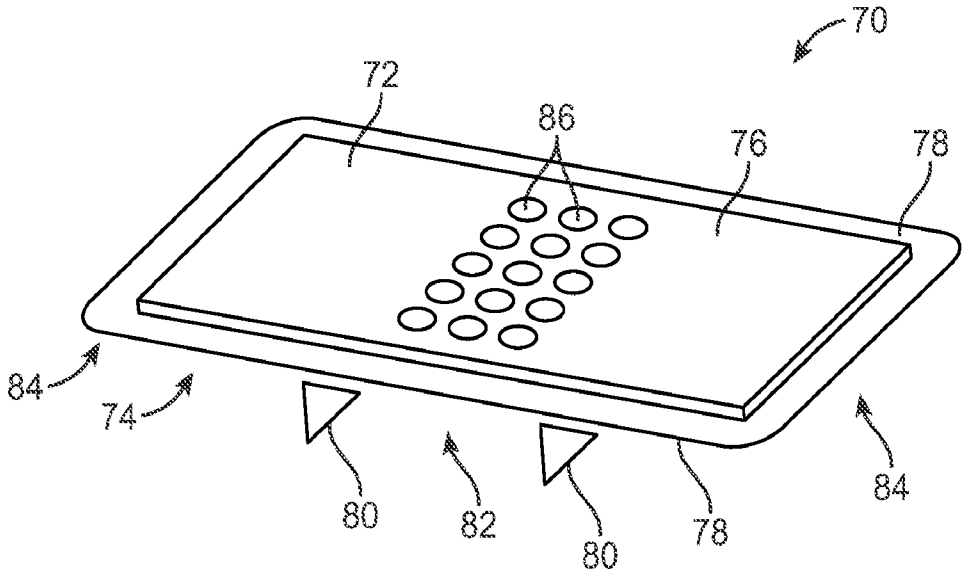

FIG. 5A

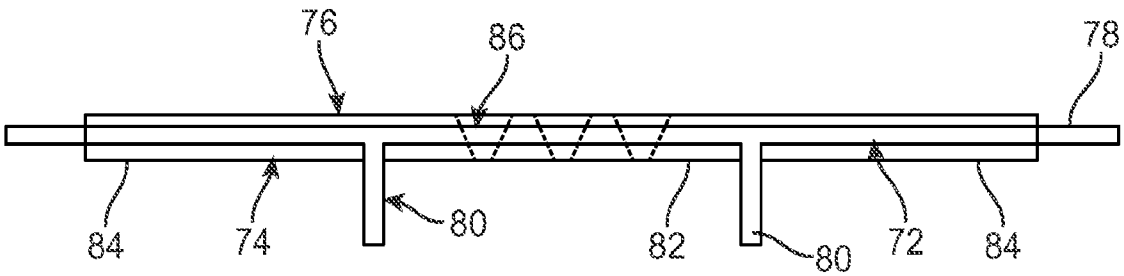

FIG. 5B

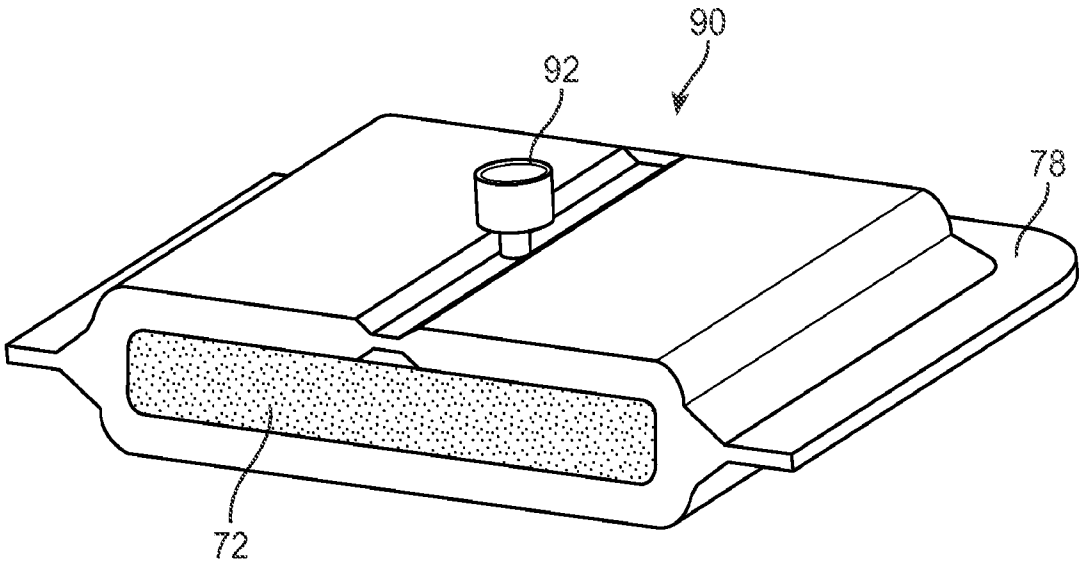

FIG. 6

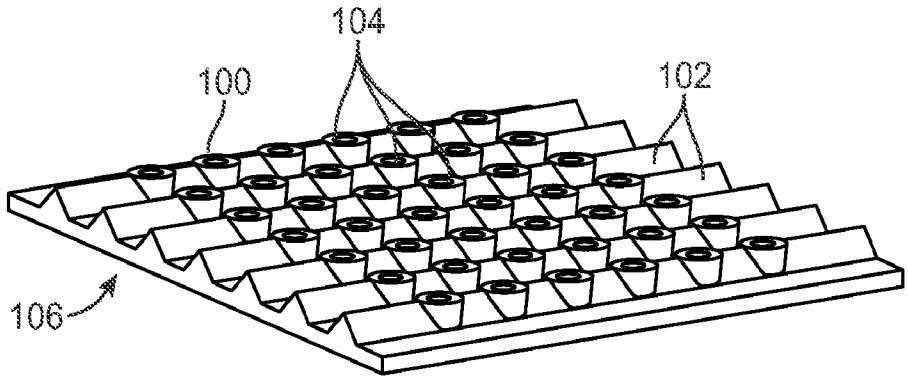

FIG. 7A

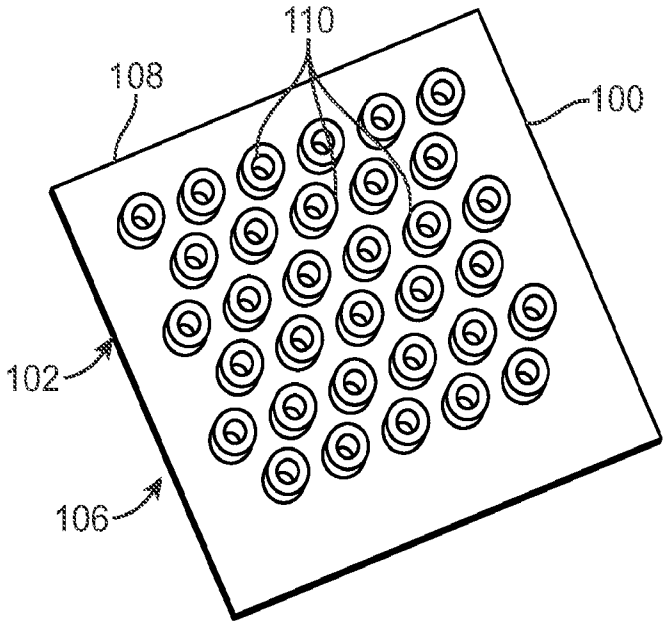

FIG. 7B

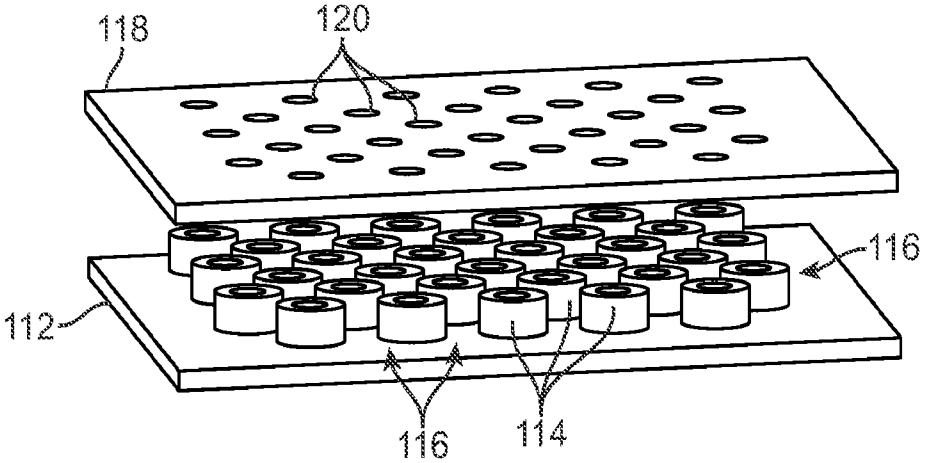

FIG. 7C

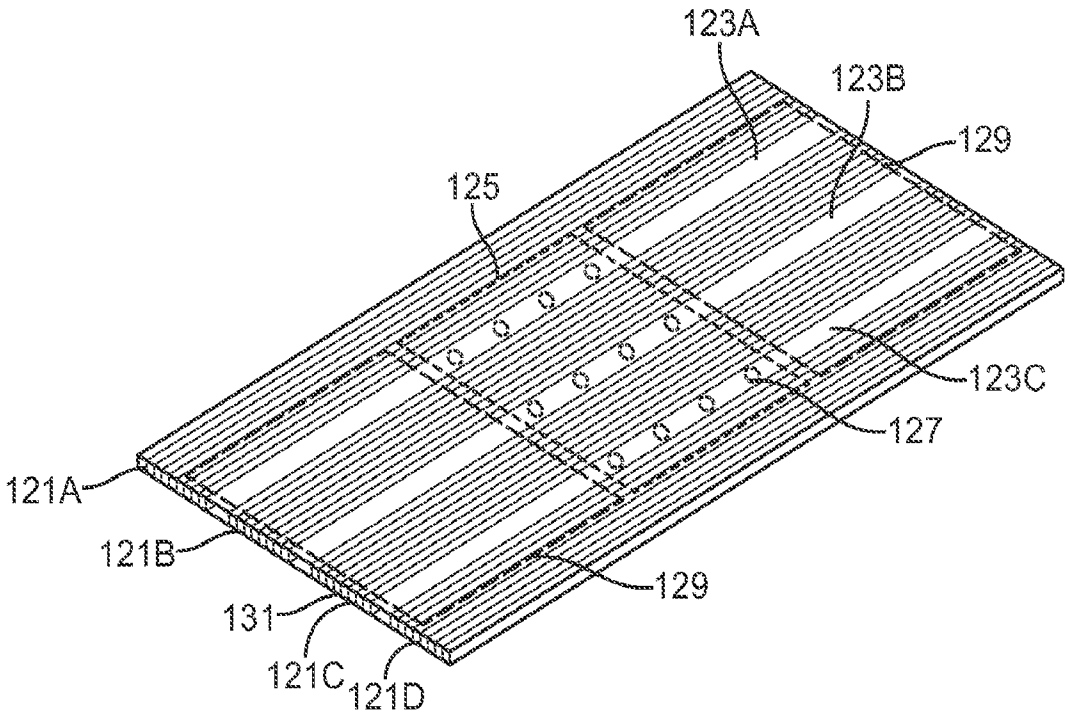

FIG. 8

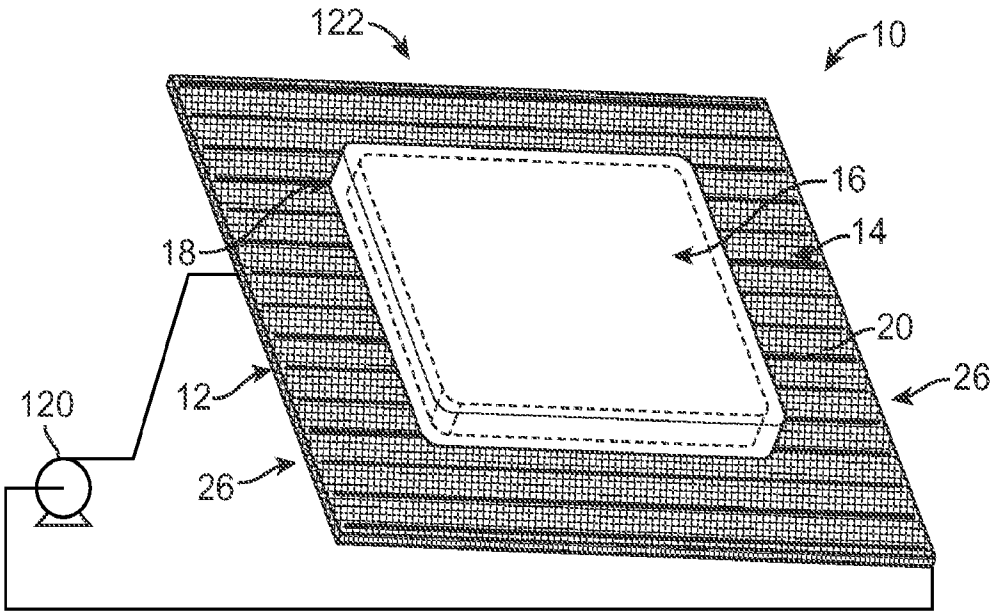

FIG. 9

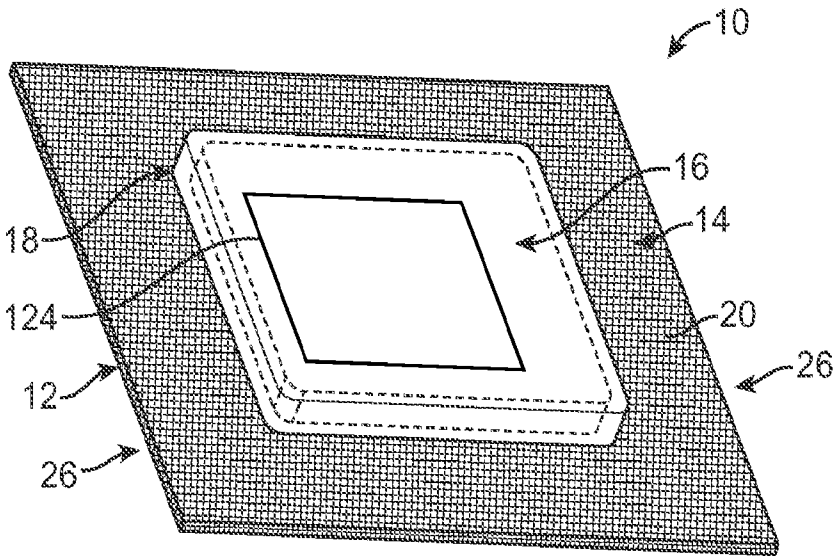

FIG. 10

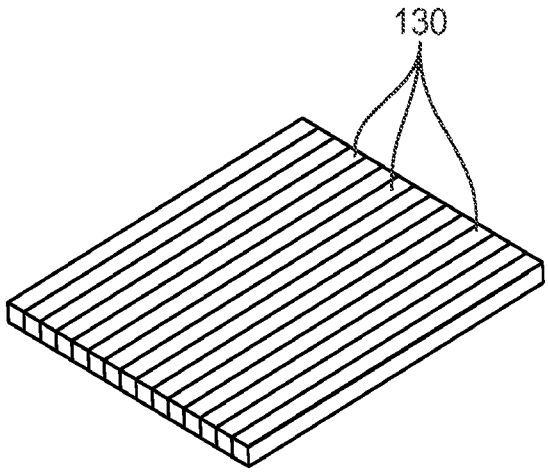

FIG. 11A

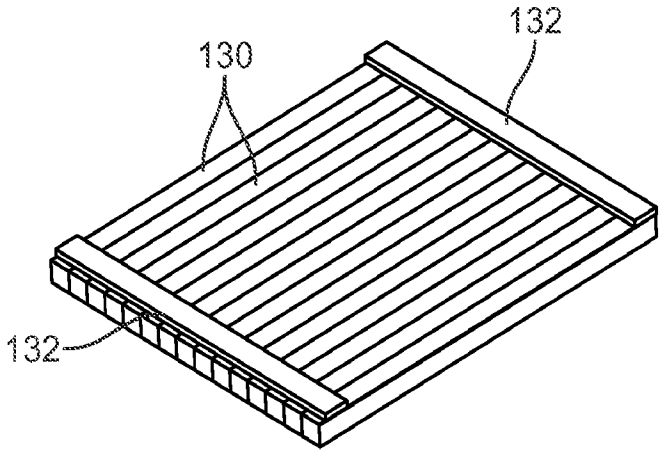

FIG. 11B

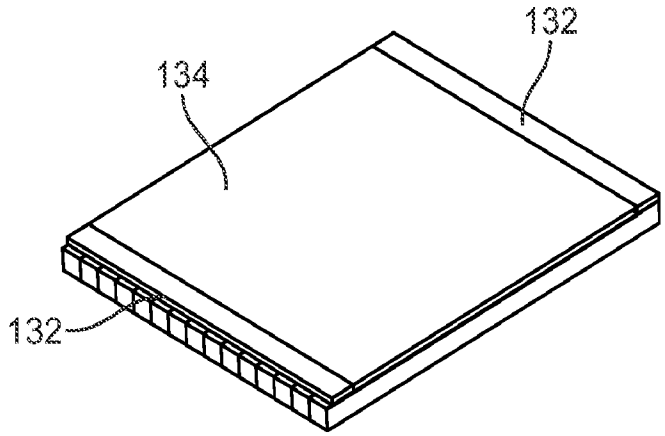

FIG. 11C

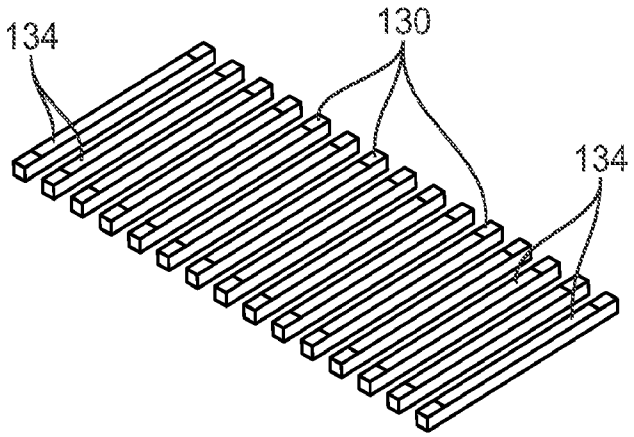

FIG. 11D

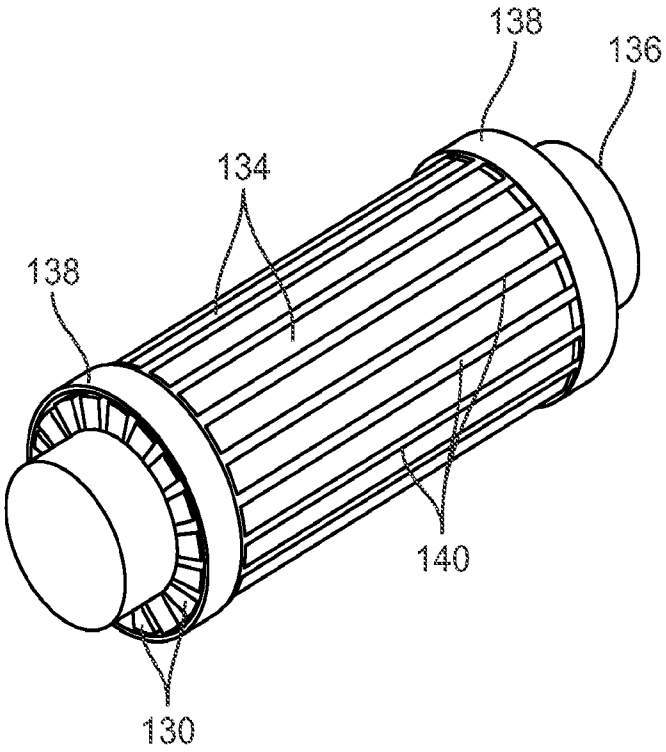

FIG. 11E

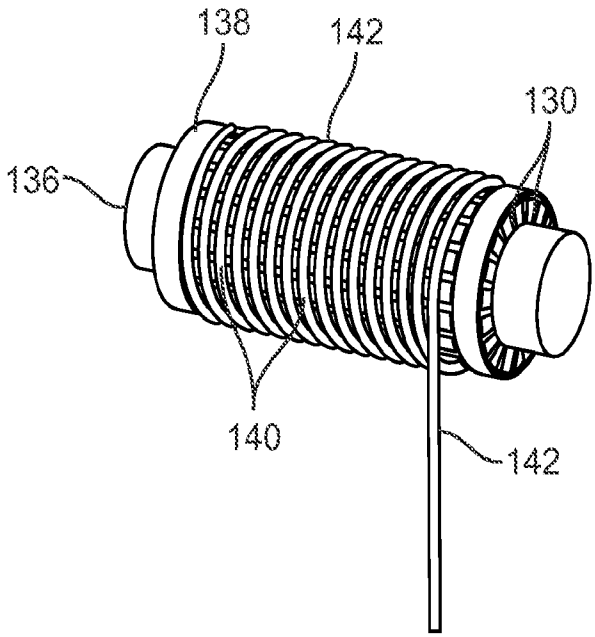

FIG. 11F

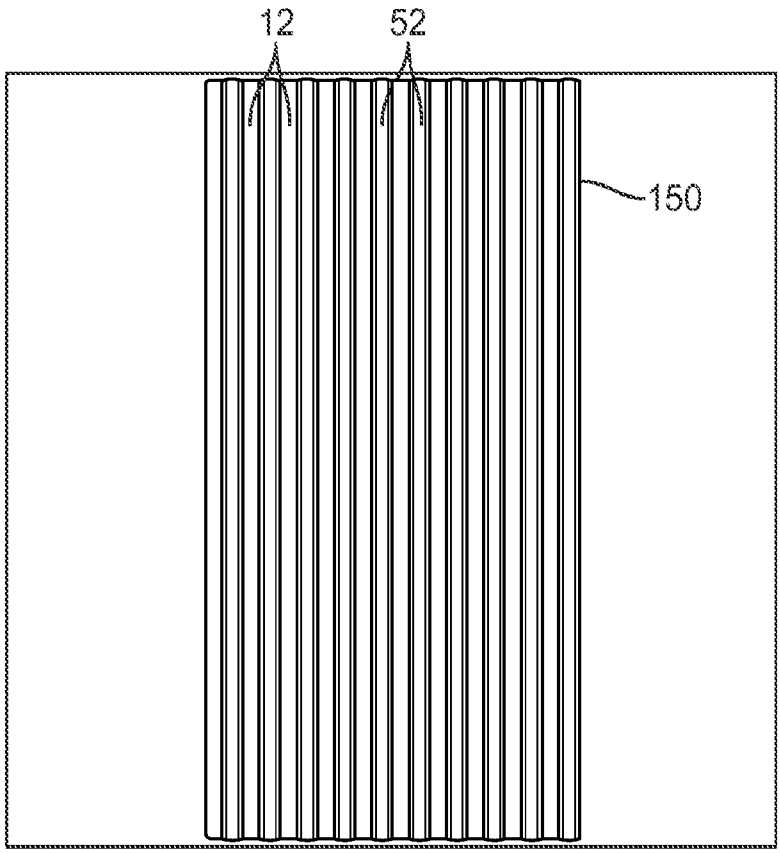

FIG. 12A

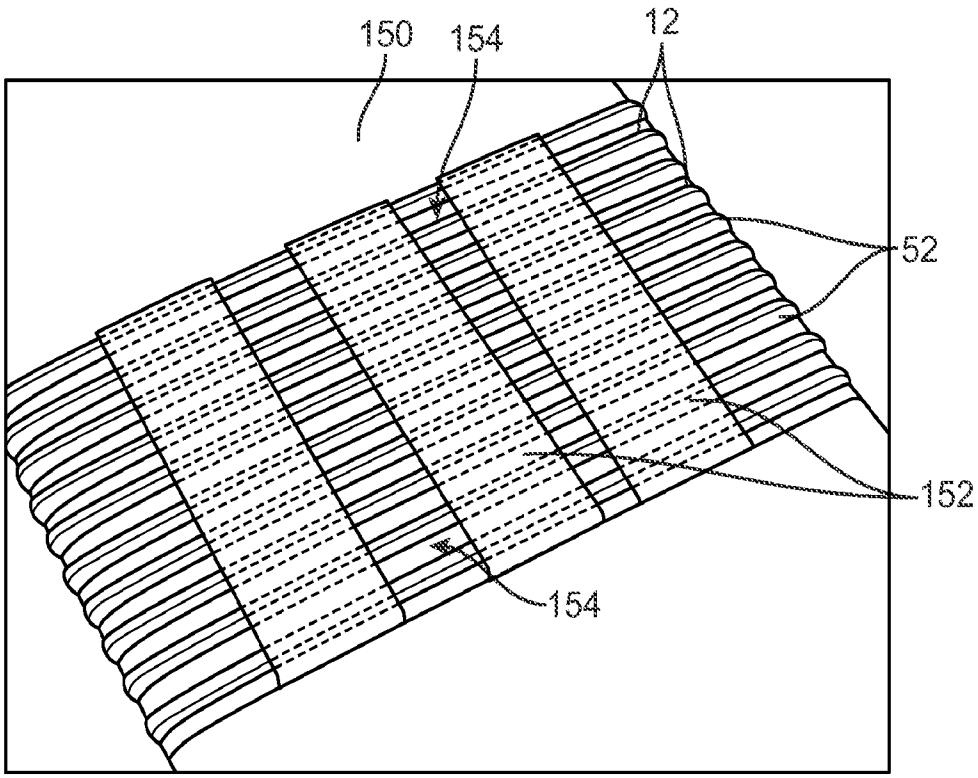

FIG. 12B

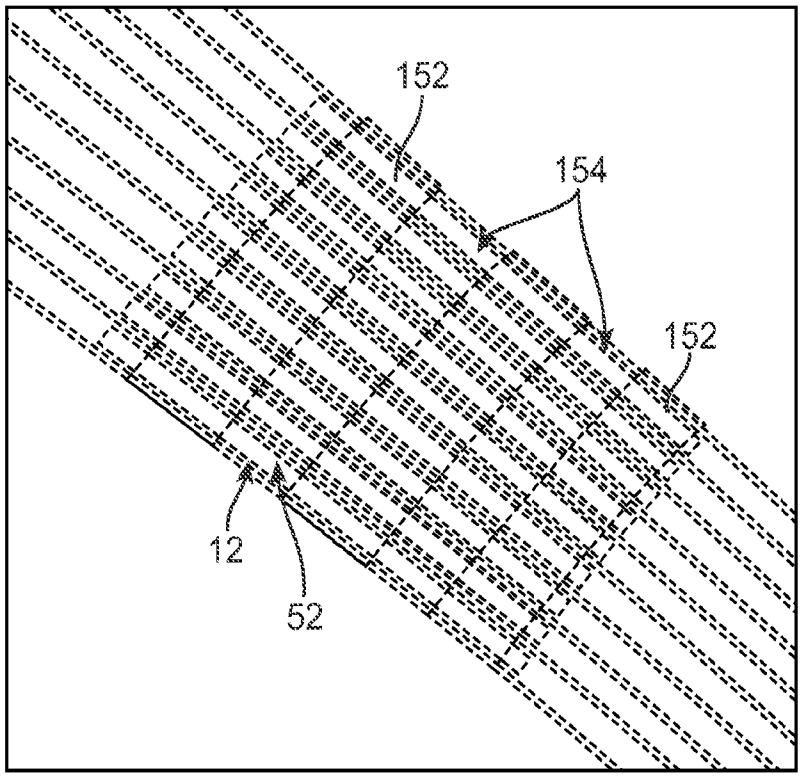

FIG. 12C

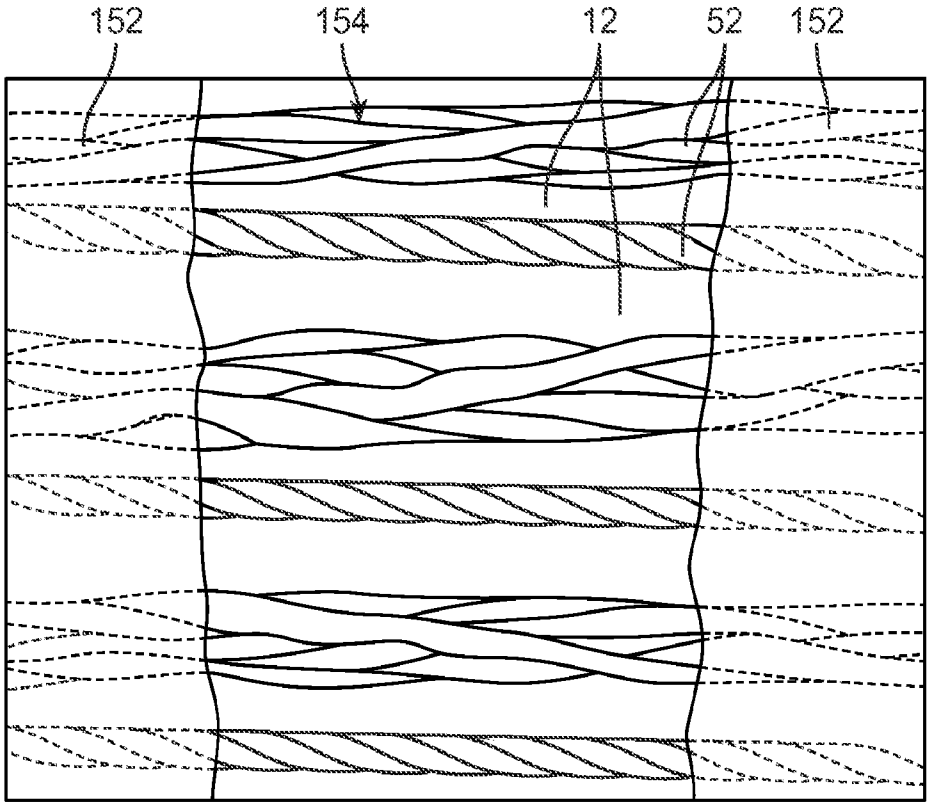

FIG. 12D

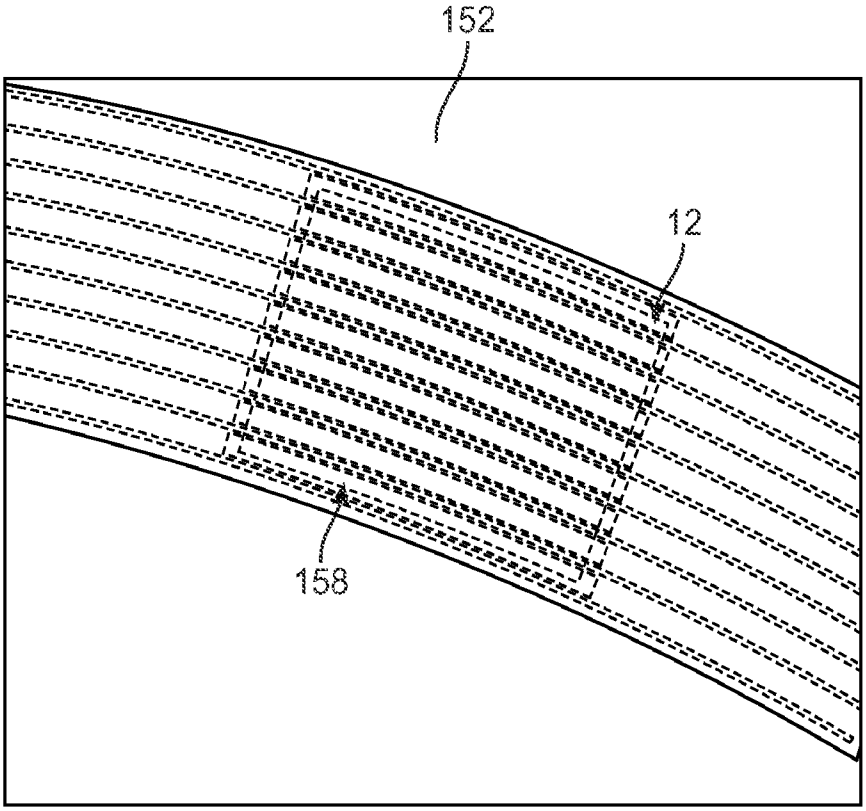

FIG. 12E

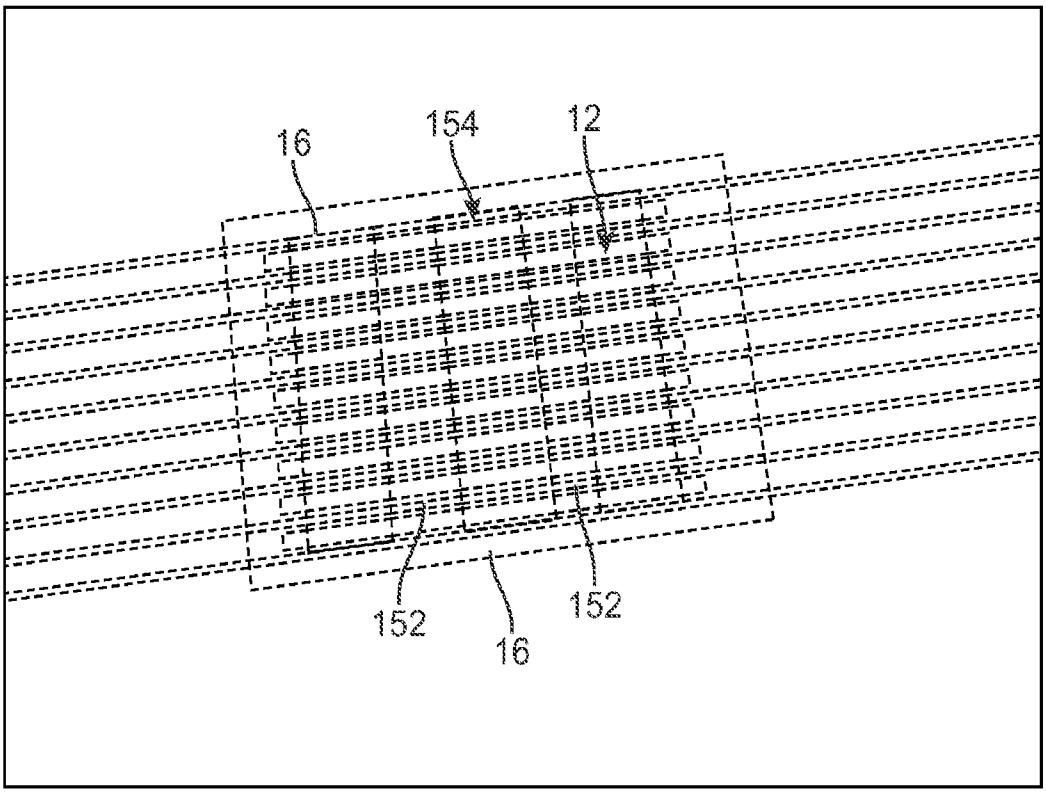

FIG. 12F

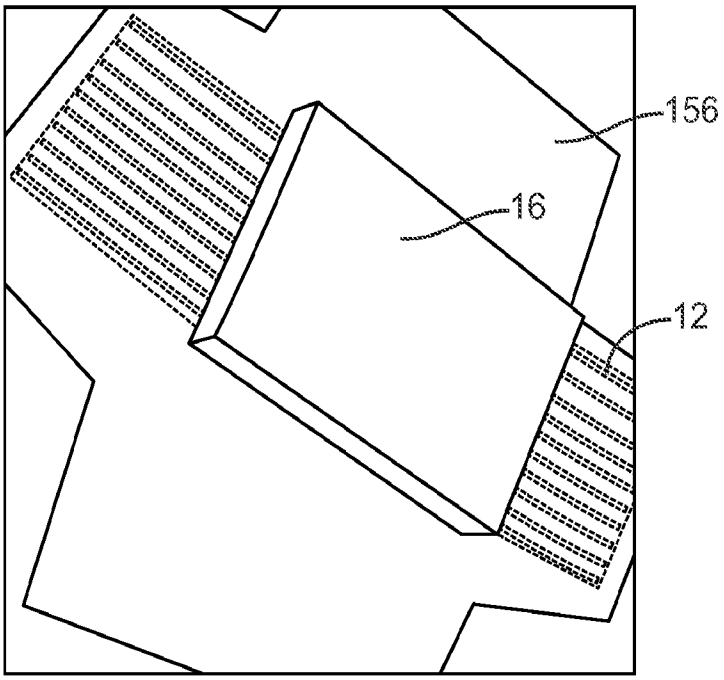

FIG. 12G

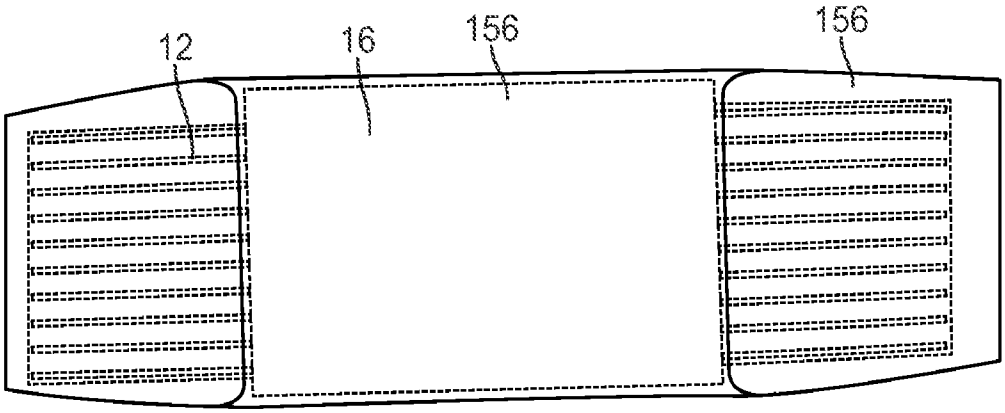

FIG. 12H

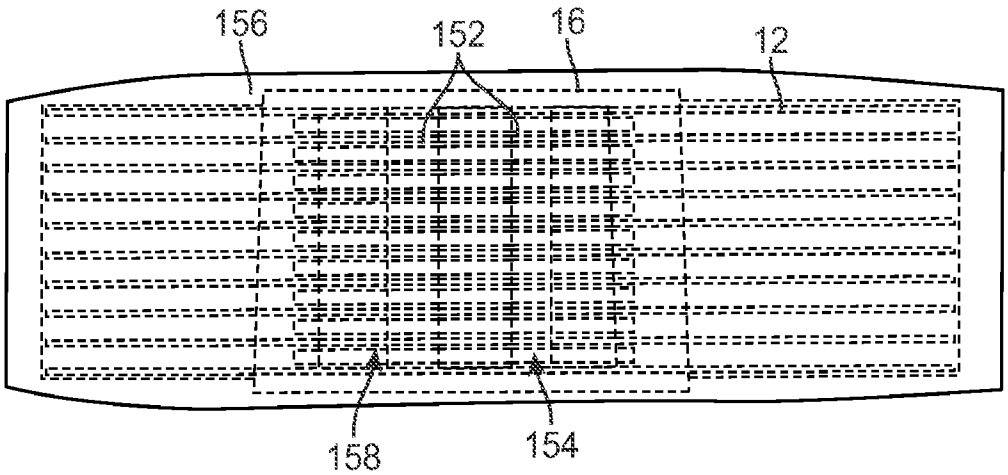

FIG. 12I

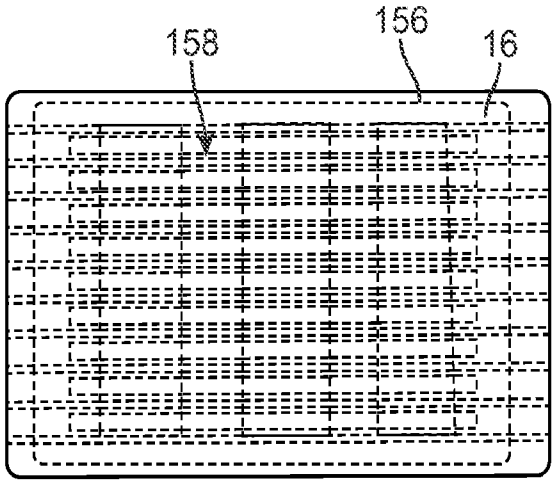

FIG. 12J

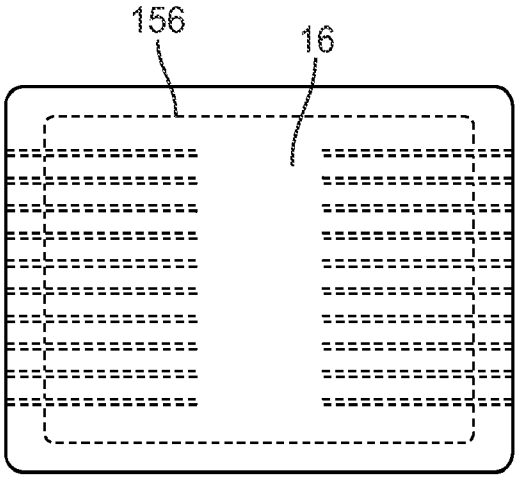

FIG. 12K

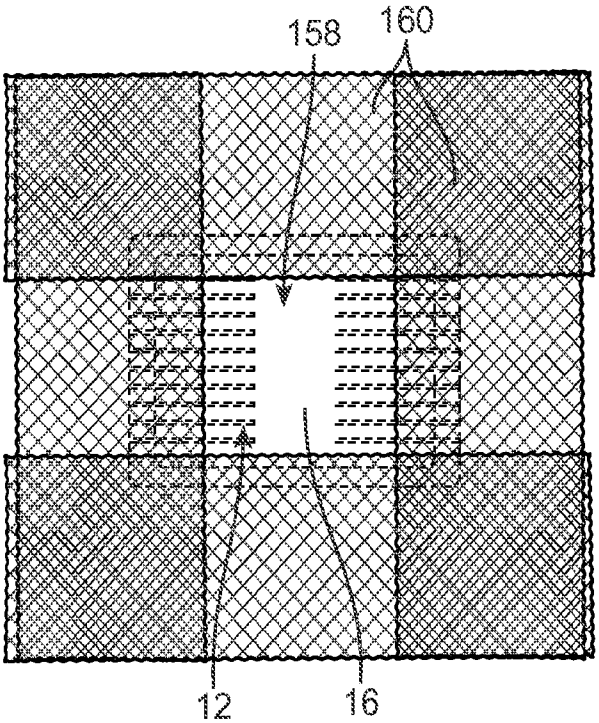

FIG. 12L

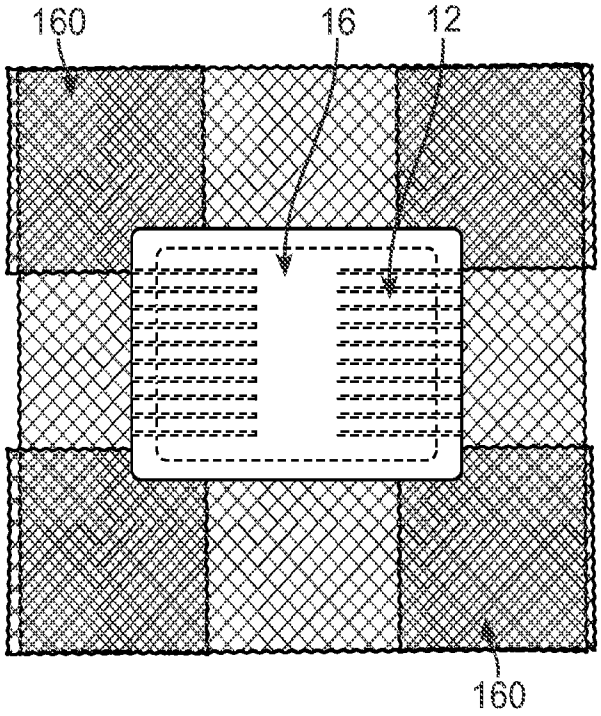

FIG. 12M

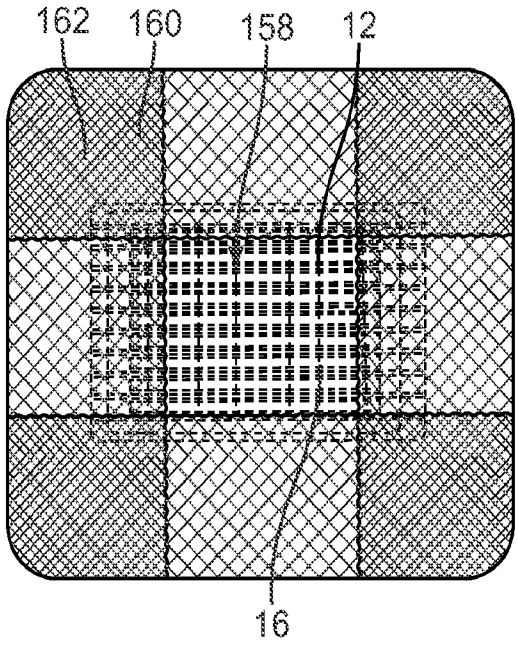

FIG. 12N

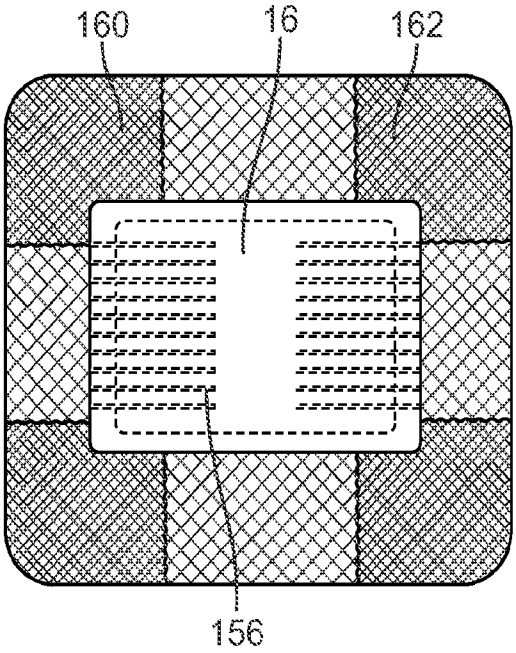

FIG. 12O

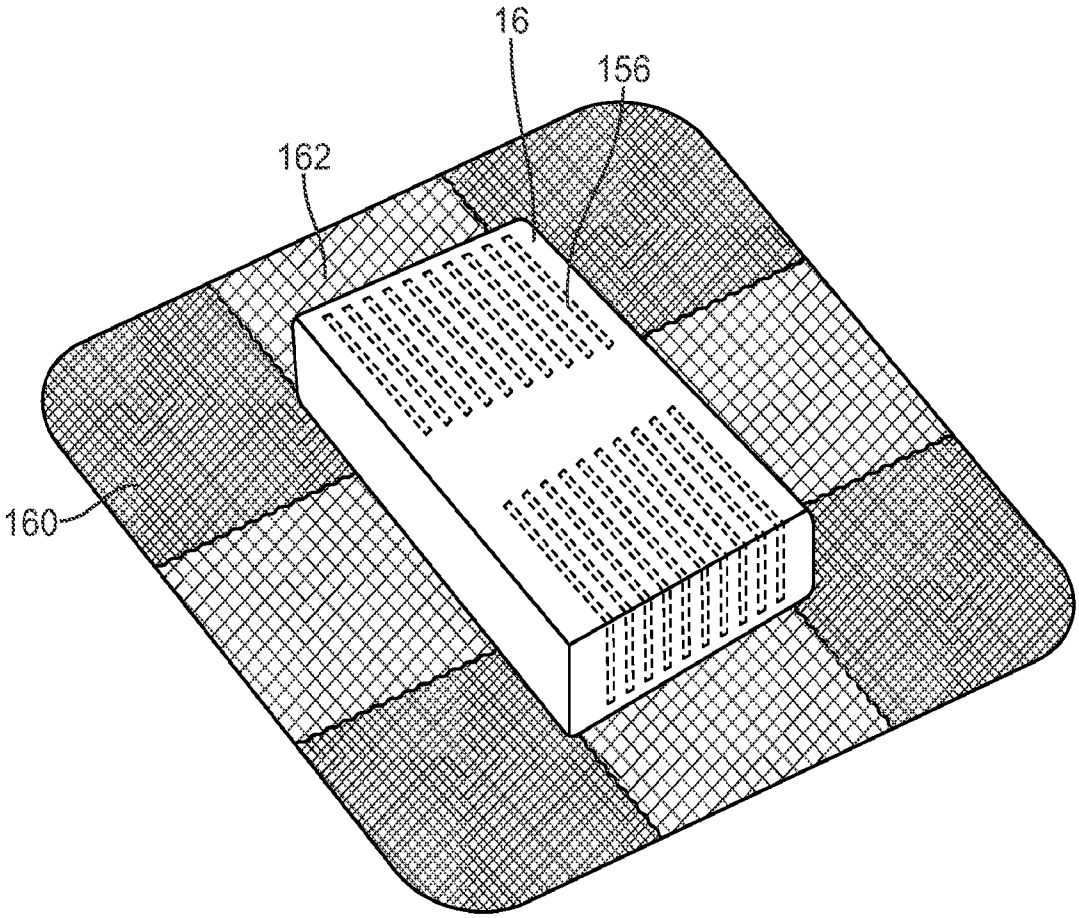

FIG. 12P

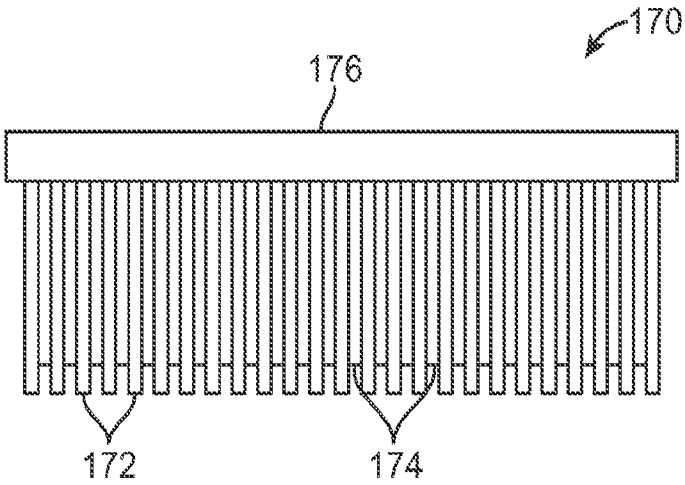

FIG. 13A

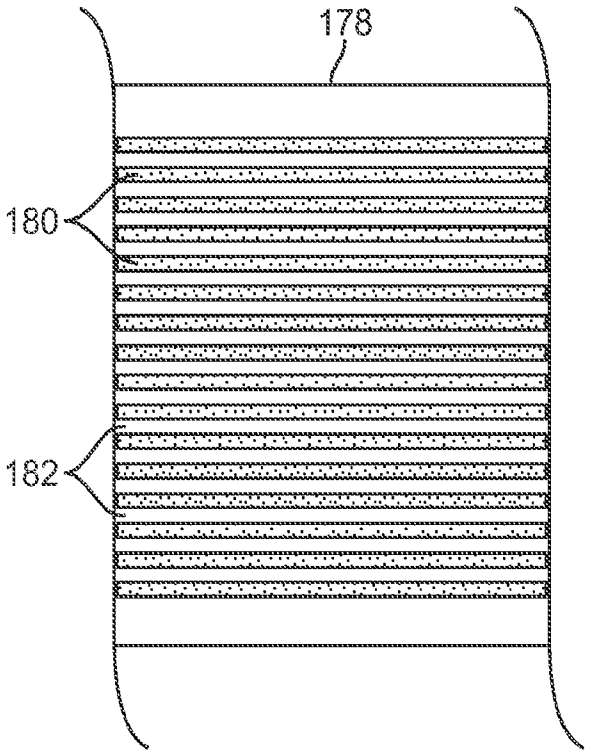

FIG. 13B

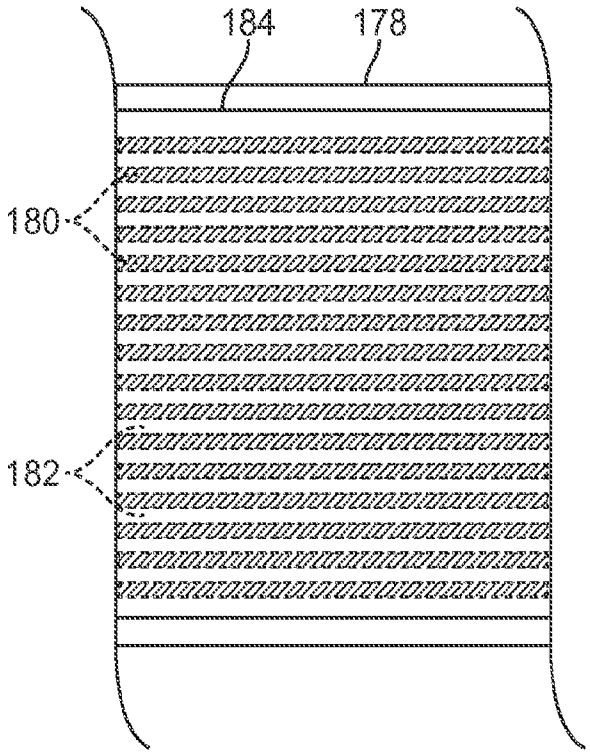

FIG. 13C

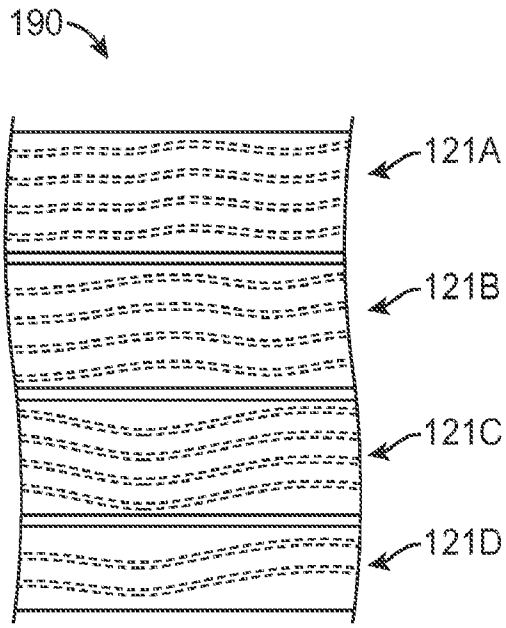

FIG. 14A

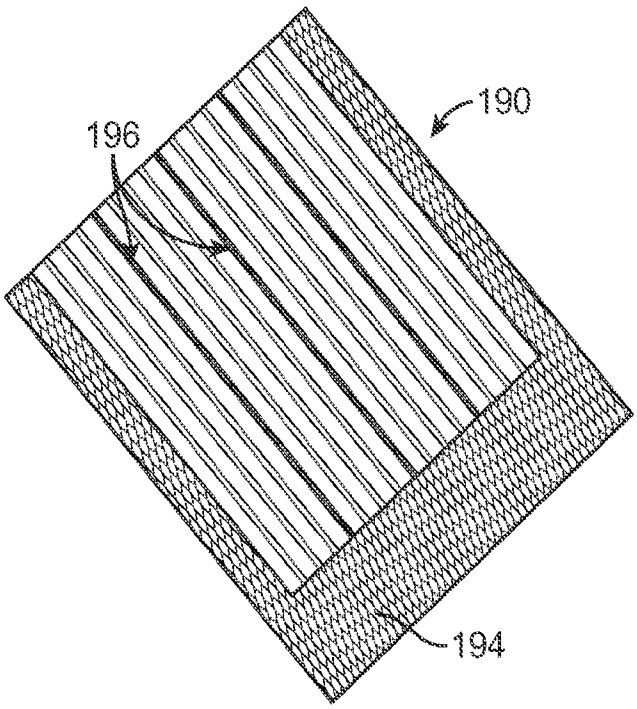

FIG. 14B

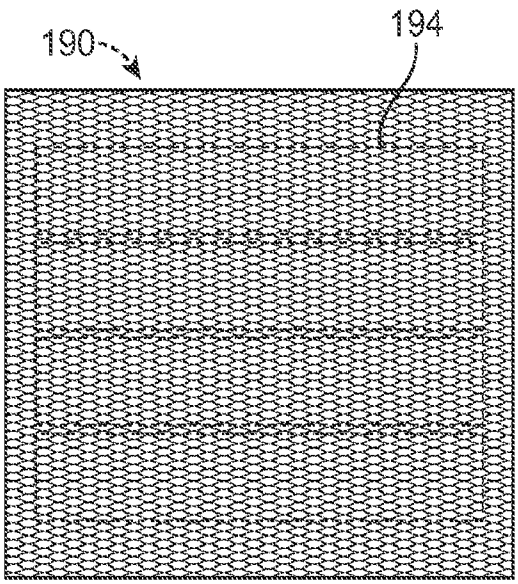

FIG. 14C

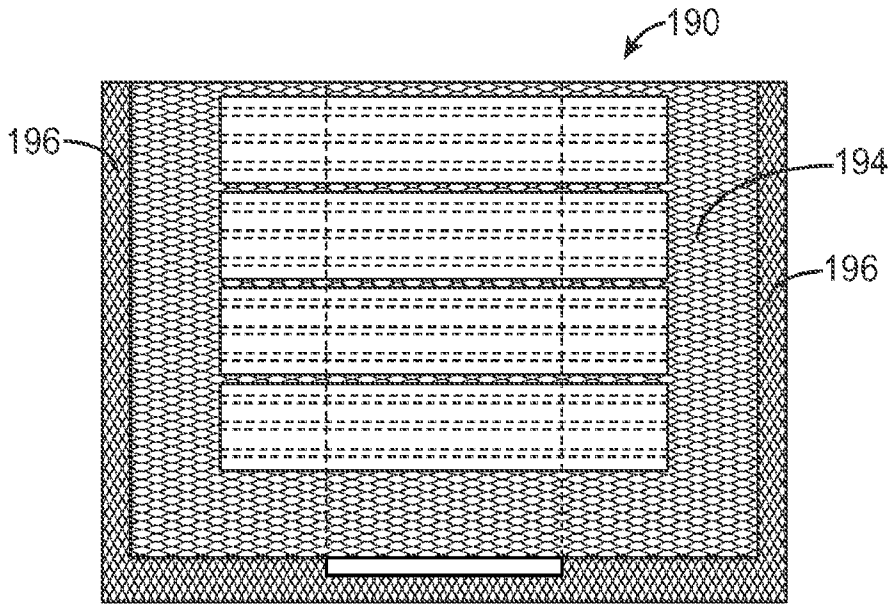

FIG. 14D

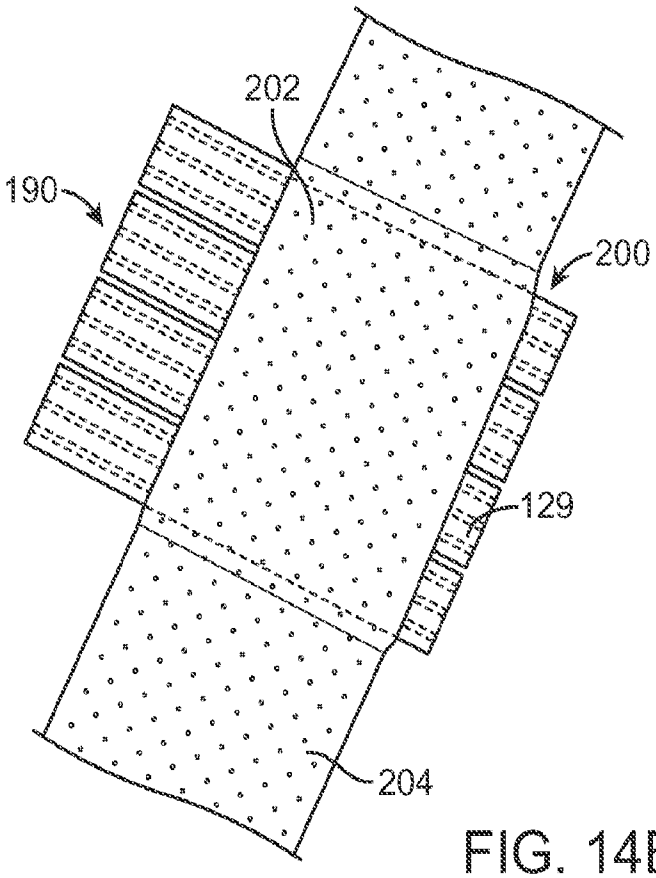

FIG. 14E

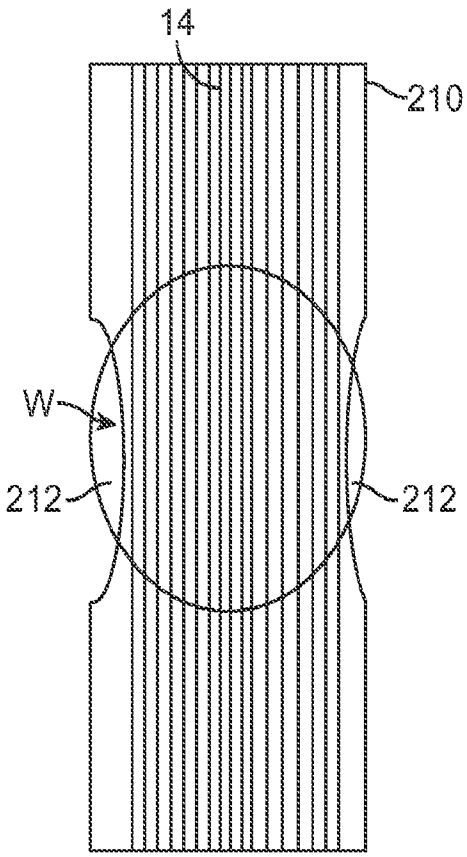

FIG. 15A

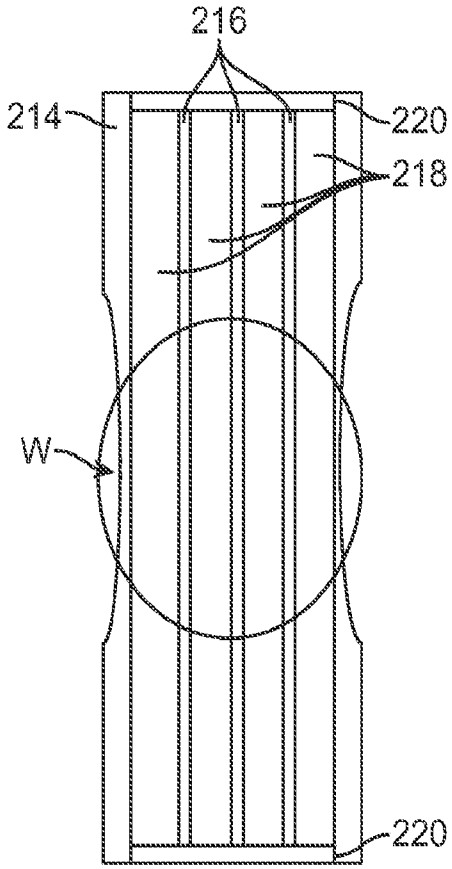

FIG. 15B

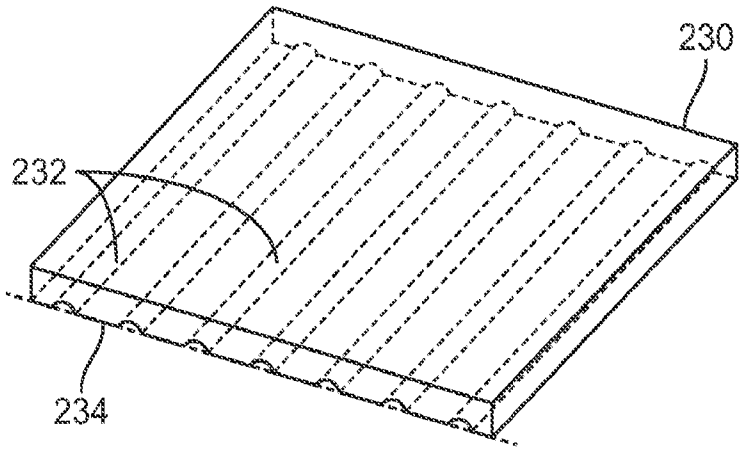

FIG. 16

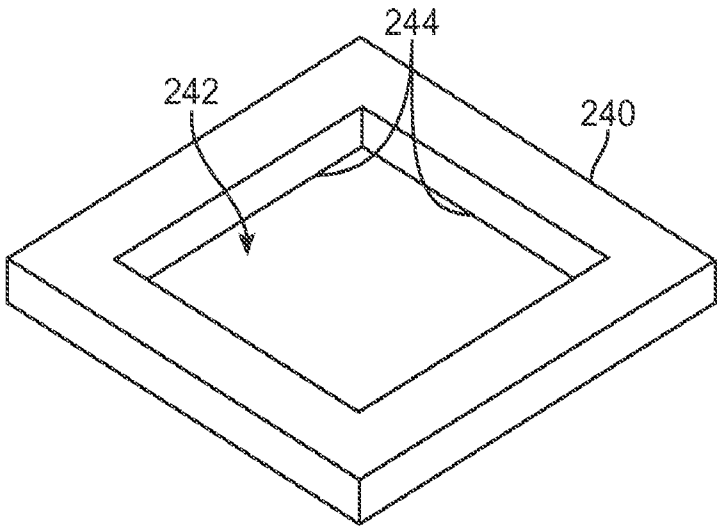

FIG. 17

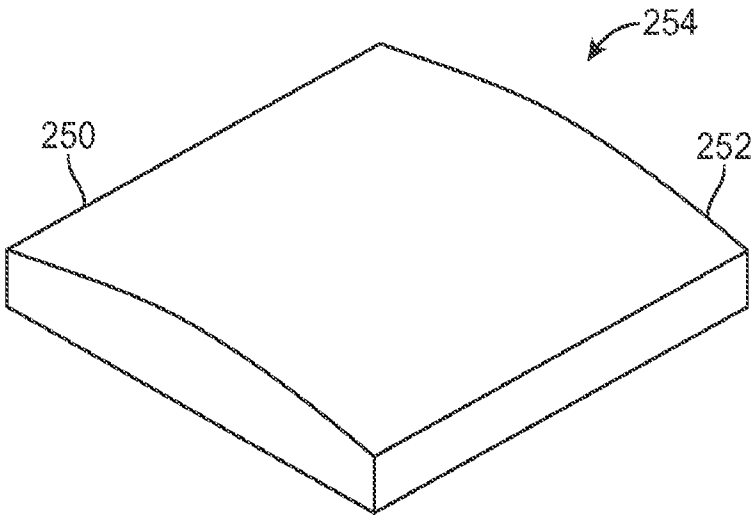

FIG. 18

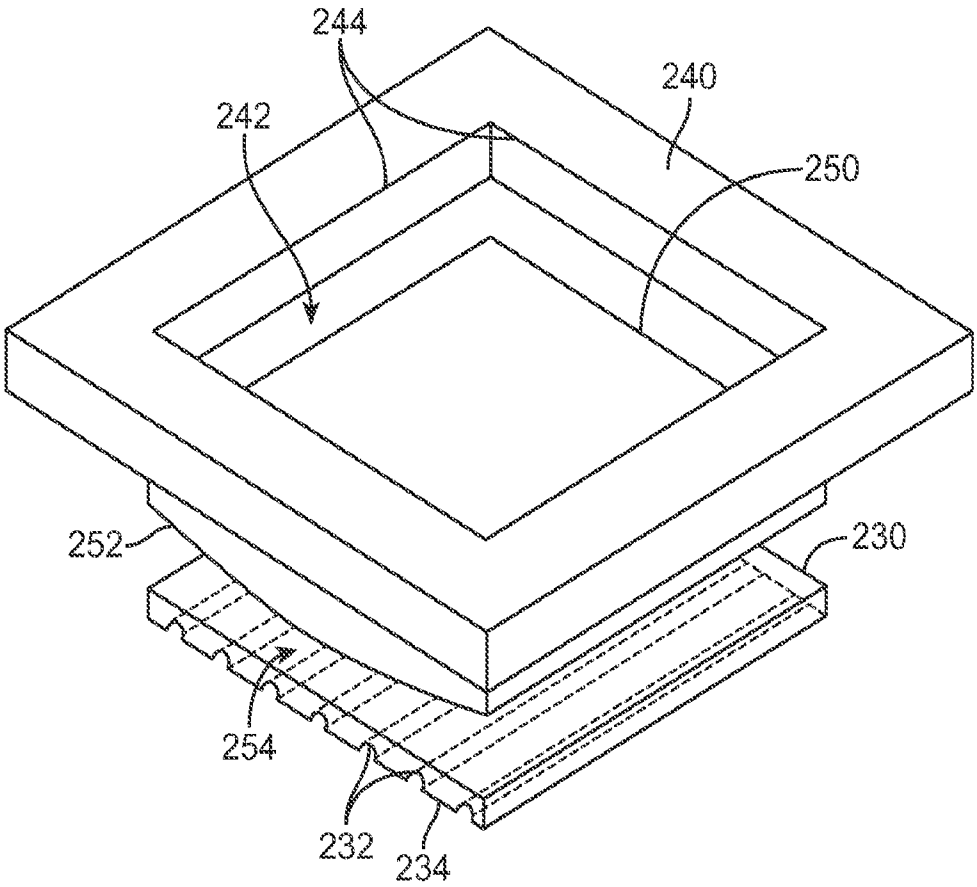

FIG. 19A

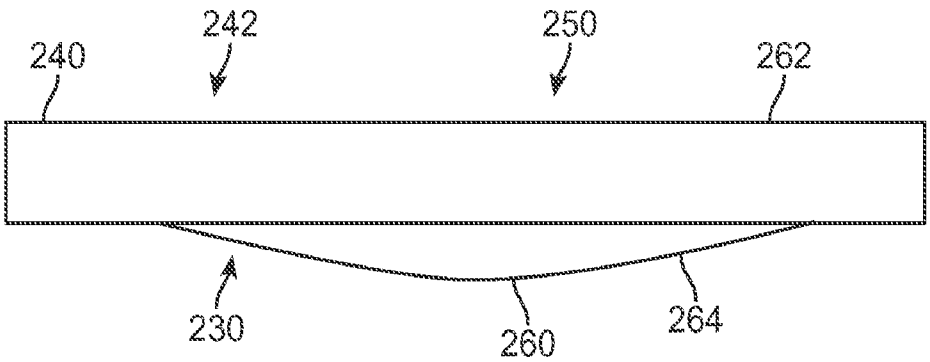

FIG. 19B

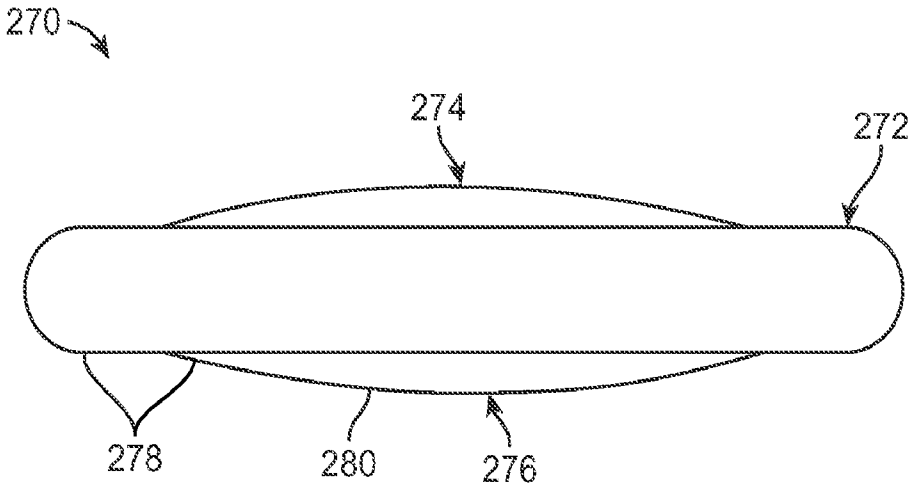

FIG. 20A

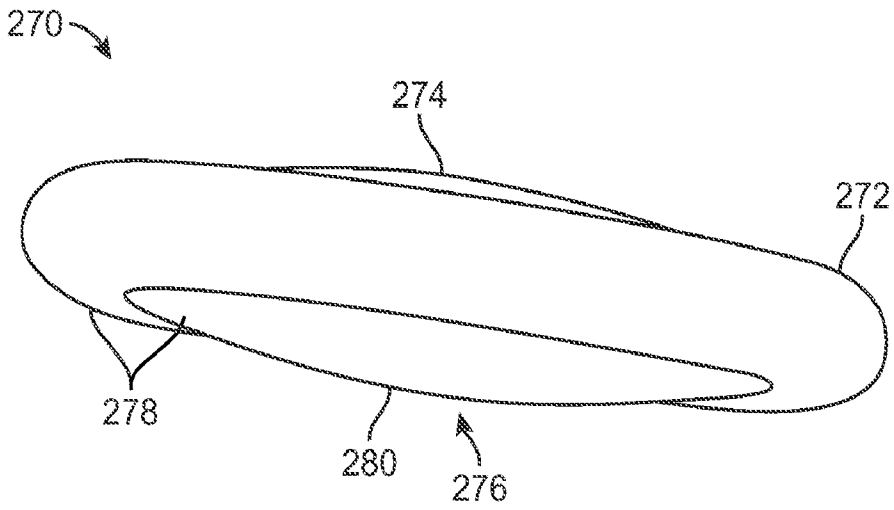

FIG. 20B

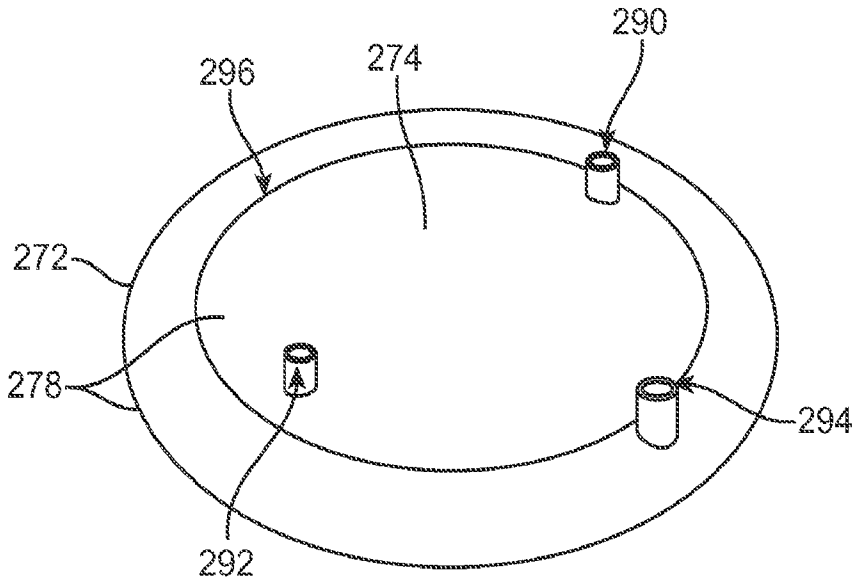

FIG. 21A

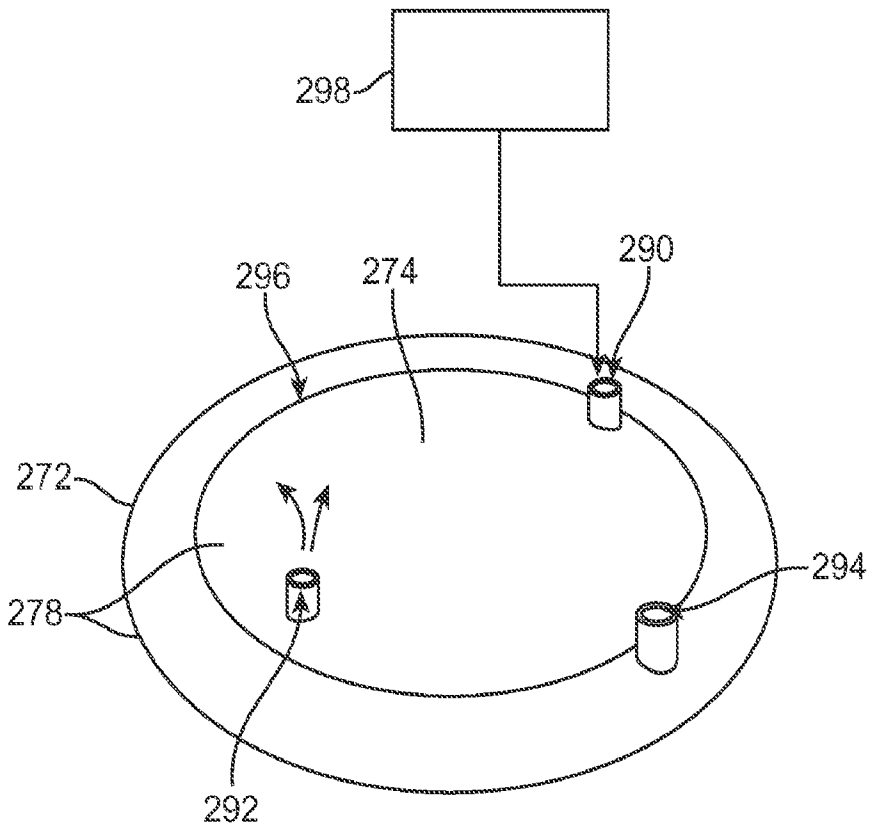

FIG. 21B

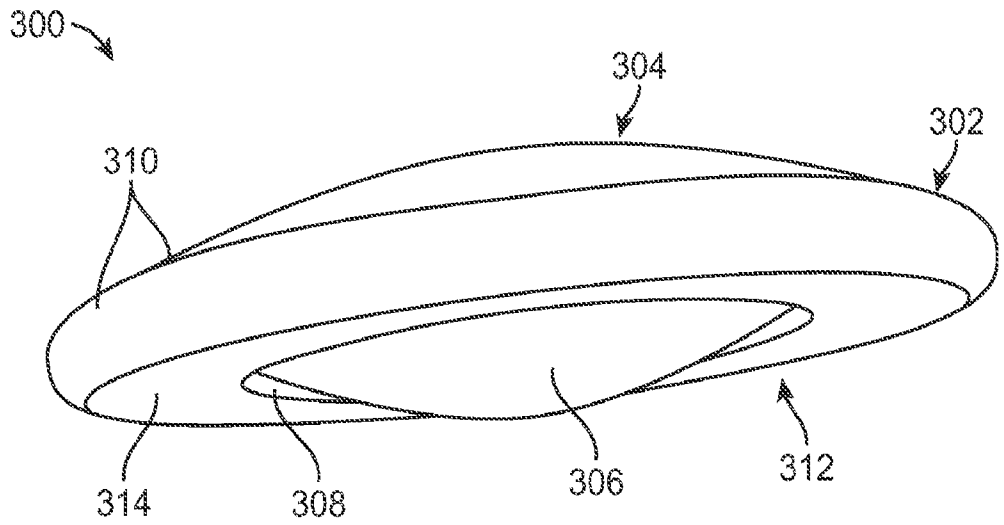

FIG. 22

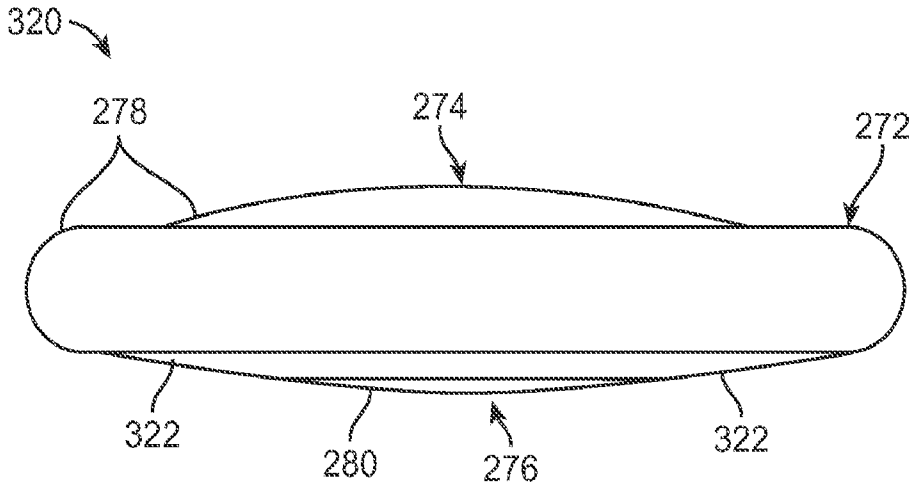

FIG. 23

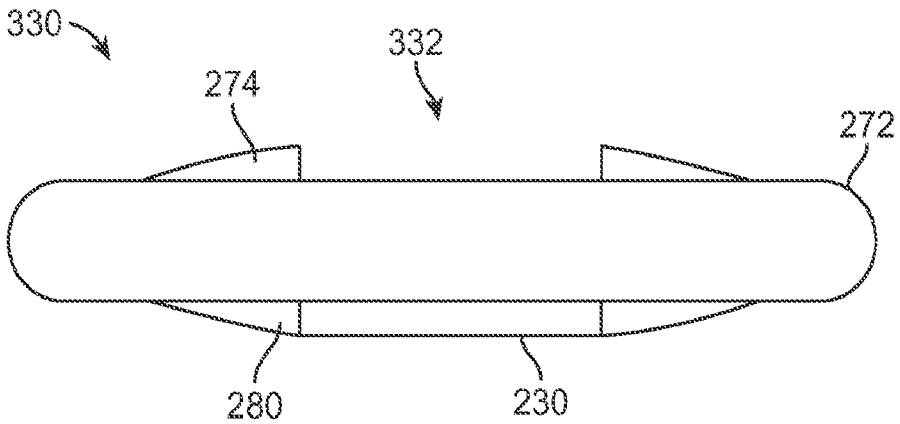

FIG. 24

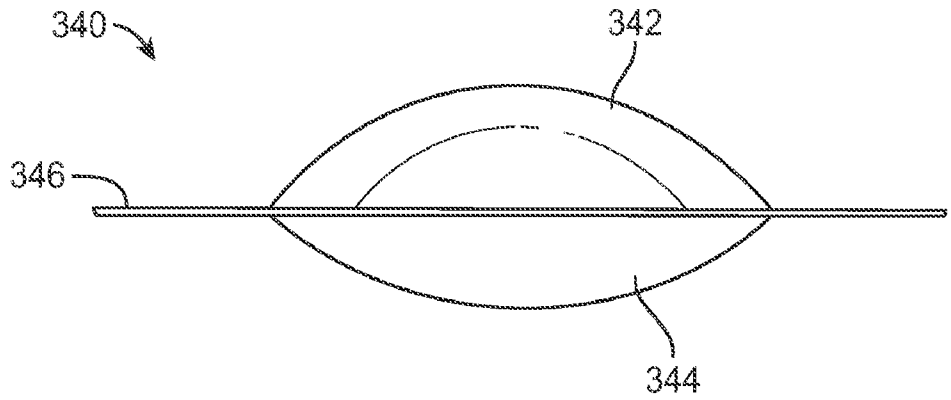

FIG. 25A

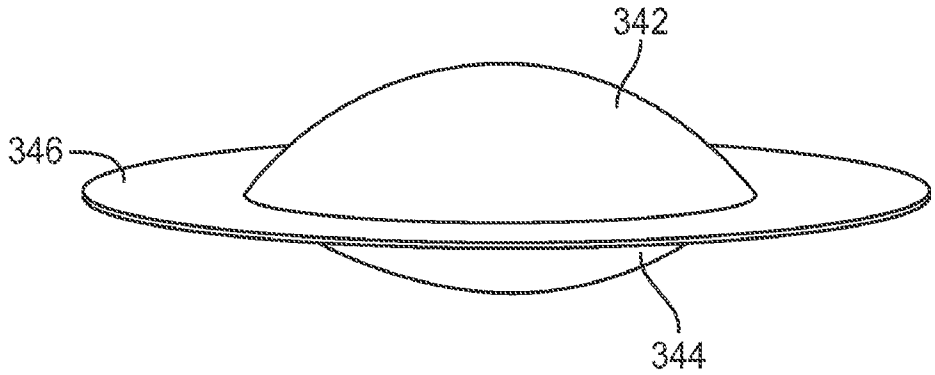

FIG. 25B

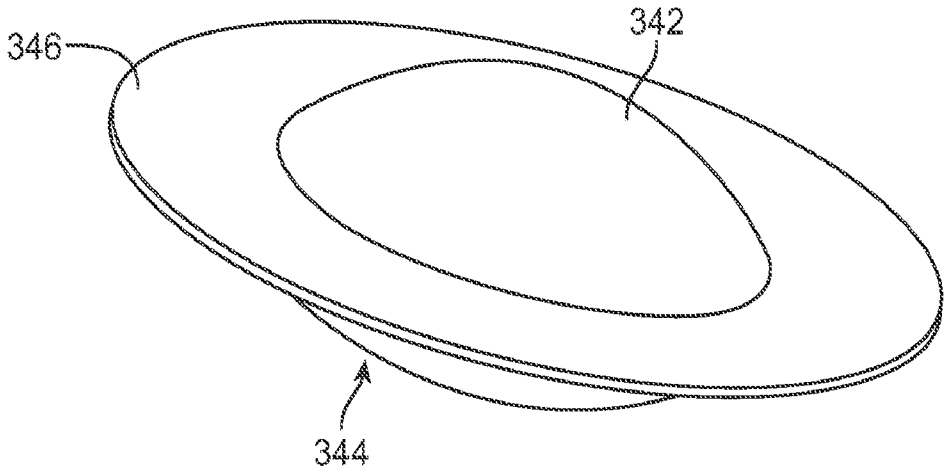

FIG. 25C

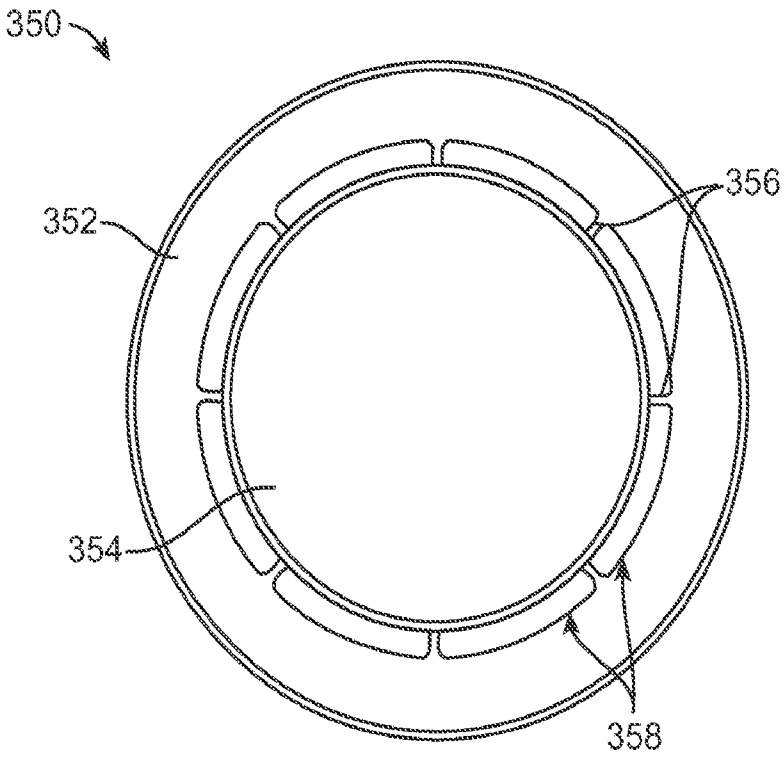

FIG. 26A

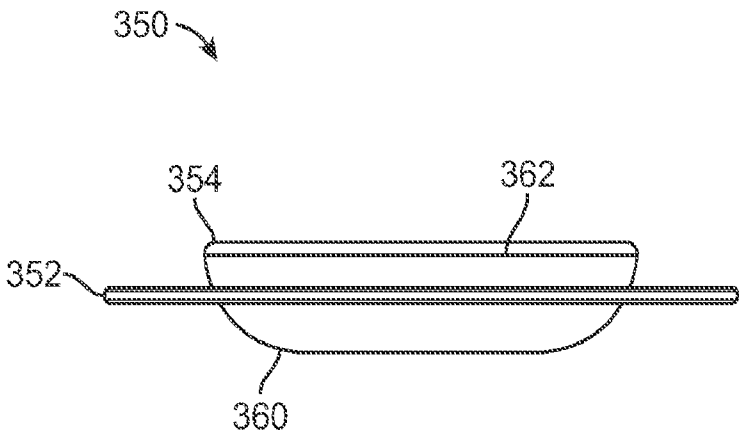

FIG. 26B

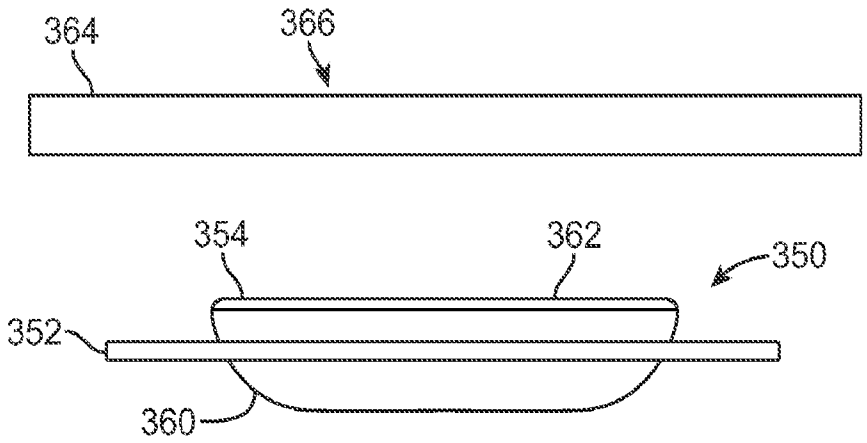

FIG. 27A

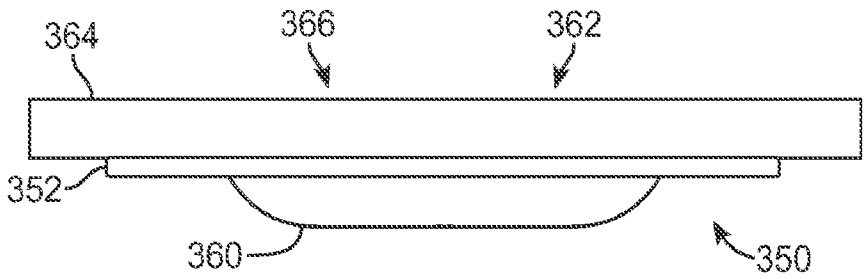

FIG. 27B

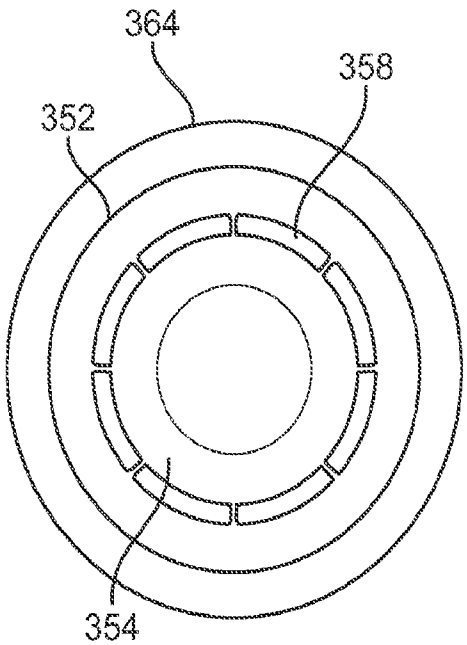

FIG. 27C

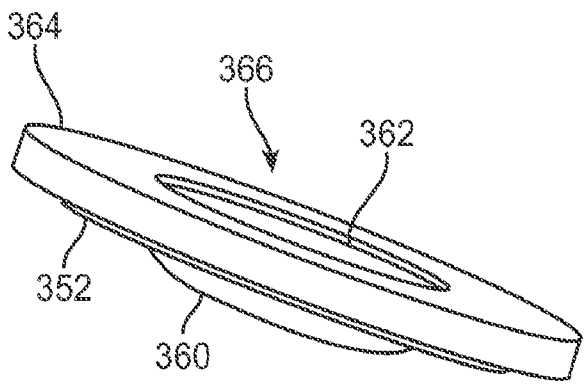

FIG. 27D

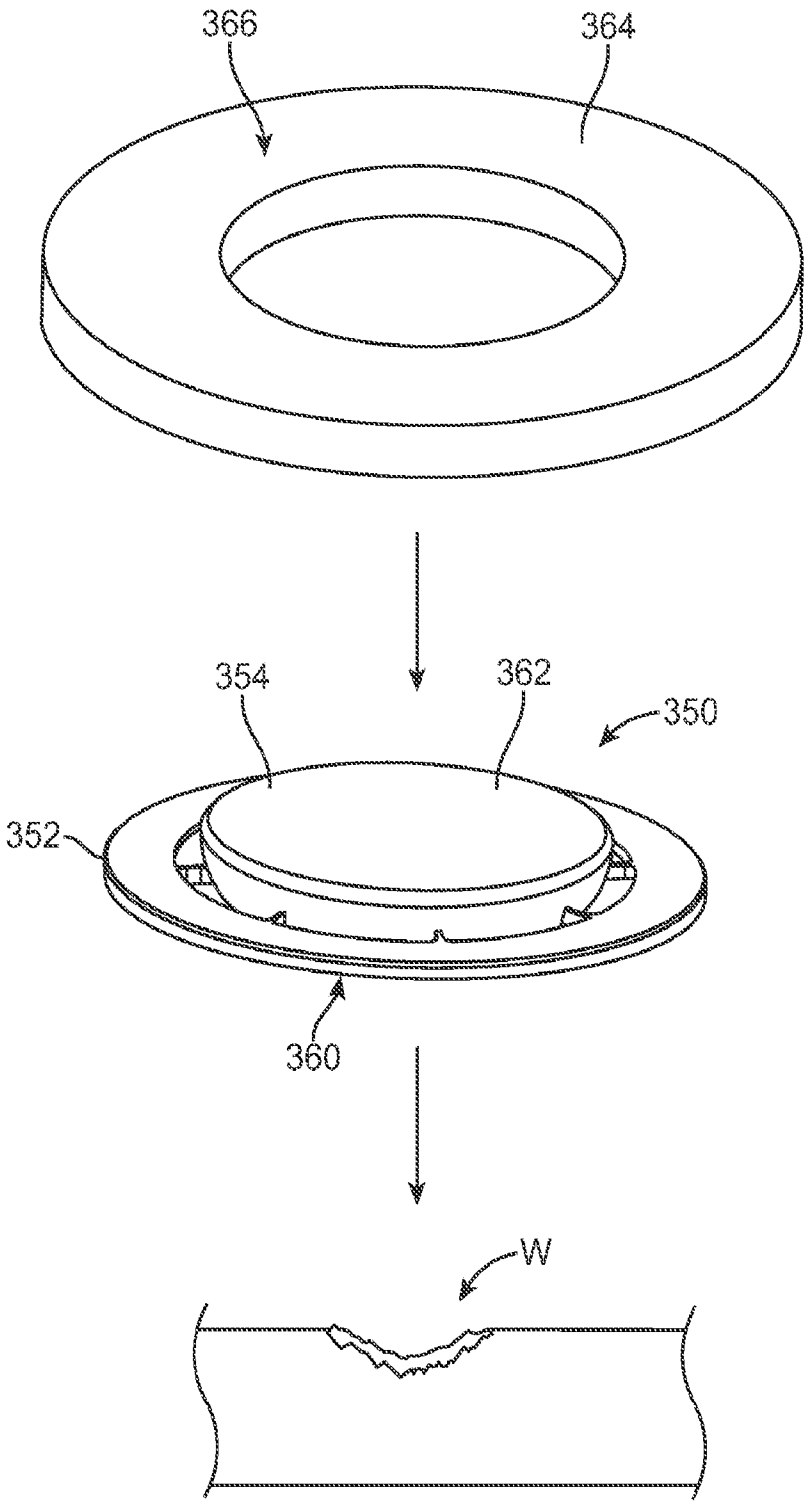

FIG. 28

International application No.
PCT/US13/54937

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

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

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

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

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:

Group I: Claims 1-36 are directed toward a wound dressing and a method of treating a wound with a hydrophilic absorbent material in fluid communication with at least one portion of a periphery of an oxygen diffusive substrate, wherein at least one portion of the substrate presses against a wound surface.

Group II: Claims 37-186 are directed toward a wound dressing, comprising at least one conduit having an oxygen diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length.

Group III: Claims 187-200 are directed towards a method of forming a wound dressing.

-***- Details on Extra Sheet -***-

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-36

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT PCT/US2013/054937 24.01.2014

International application No.
PCT/US13/54937

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 13/02, B65B 31/00 (2013.01)

USPC - 604/368; 424/445

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61F 13/02, B65B 31/00 (2013.01)
USPC: 604/368; 424/445

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

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

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); DialogPRO; Google Scholar; Medline/PubMed: absorb*, air, bandage, breath*, diaper, diffus*, dressing, hydrogel, hydrophilic, nappy, oxygen, permeabl*, porous, superabsorbent, wound

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4803078 A (SAKAI, M) February 7, 1989; figures 1-3; column 2, lines 24-28; column 3, lines 14-24, 52-57;	1, 5, 6, 9 --- 2-4, 7, 8, 10-36
Y	US 2004/0126413 A1 (SIGURJONSSON, GF, et al.) July 1, 2004; paragraphs [0054], [0083], [0084], [0087], [0118], [0124]	2, 18, 19, 25, 28, 31
Y	US 6221460 B1 (WEBER, MEG, et al.) April 24, 2001; figures 1, 2, 4; column 2, lines 20-24; column 3, lines 66-67; column 4, lines 36-56; column 9, lines 14-18	3, 4, 7, 8, 24-36
Y	US 6077526 A (SCULLY, DC, et al.) June 20, 2000; figure 1; column 5, lines 66-67; column 6, lines 1-6	10, 36
Y	US 2012/0078154 A1 (PIGG, W, et al.) March 29, 2012; paragraphs [0018], [0033]	11-14, 29, 30
Y	US 2007/0225663 A1 (WATT, PW, et al.) September 27, 2007; figures 1, 4; paragraph [0076], [0081]	15-17, 27, 34, 35
Y	US 5738642 A (HEINECKE, SB, et al.) April 14, 1998; column 7, lines 26-31; column 8, lines 17-21	20-23
Y	US 2012/0220973 A1 (CHAN, JW, et al.) August 30, 2012; paragraph [0027]	32-33

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
01 November 2013 (01.11.2013)	24 JAN 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

International application No.
PCT/US13/54937

-***-Continued from Box III - Observations where unity of invention is lacking -***-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-36 are directed toward a wound dressing and a method of treating a wound with a hydrophilic absorbent material in fluid communication with at least one portion of a periphery of an oxygen diffusive substrate, wherein at least one portion of the substrate presses against a wound surface.

Group II: Claims 37-186 are directed toward a wound dressing, comprising at least one conduit having an oxygen diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length.

Group III: Claims 187-200 are directed towards a method of forming a wound dressing.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include such that exudate from the wound is urged to flow laterally along the substrate and into the absorbent material; and diffusing oxygen through the oxygen diffusive substrate and into the wound, which are not present in Groups II-III; the special technical features of Group II include at least one conduit having an oxygen diffusive coating and a lumen which allows diffusion of oxygen or oxygenated fluid along its length, wherein the at least one area of the conduit is positioned to extend exposed along the open area in contact with the wound surface and adjacent to the fluid absorbent material such that the wound surface and hydrophilic absorbent material are in fluid communication, and wherein the at least one channel has at least one portion further exposed to ambient air, which are not present in Groups I and III; the special technical features of Group III include passing a length of multi-filament fiber through a coating solution such that the fiber is coated via the solution while maintaining continuous inter filament spaces through the fiber; arranging the length of coated fiber to align in parallel upon a supporting frame such that a coated fiber array is formed; securing the coated fiber array via one or more adhesive stripes placed transversely relative to a length of the coated fiber; removing the coated fiber array from the supporting frame; positioning the coated fiber array between an open area of a hydrophilic absorbent material envelope and a hydrophilic absorbent material such that the hydrophilic absorbent material is positioned at a distance from the open area; and securing the envelope such that the material is sealed therein while the coated fiber array remains exposed, which are not present in Groups I-II.

The common technical features of Groups I-III are a wound dressing, comprising: hydrophilic absorbent material.

These technical features are disclosed by US 4,803,078 A (SAKAI). Sakai discloses a wound dressing (wound dressing is provided; column 2, line 8), comprising: hydrophilic absorbent material (the chitin layer 2 may be formed on film 1 with a water-absorbing macromolecular material 4 which will absorb blood and other liquids interposed between layer 2 and film 1; figures 1, 3; column 3, lines 18-19).

Since the common technical features are previously disclosed by the Sakai reference, the common features are not special and so Groups I-III lack unity.

The common technical features of Groups I and II are a wound dressing, comprising: hydrophilic absorbent material in fluid communication with at least one portion of a periphery of an oxygen diffusive substrate, wherein at least one portion of the substrate presses against a wound surface.

These technical features are disclosed by the Sakai reference. Sakai discloses a wound dressing (wound dressing is provided; column 2, line 8), comprising: a hydrophilic absorbent material in fluid communication with at least one portion of a periphery of the oxygen diffusive substrate (the chitin layer 2 may be formed on the aforementioned film 1 with a water-absorbing macromolecular material 4 which will absorb blood and other liquids interposed between layer 2 and film 1 (hydrophilic absorbent material in fluid communication with oxygen diffusive substrate; figures show absorbent material in contact with a portion of the periphery of the oxygen diffusive substrate, front edge); figures 1, 3; column 3, lines 18-19), wherein at least one portion of the substrate is configured to press the contact surface against a wound surface (covering material (contact surface) fits effectively over the area of the wound; figures 1-3; column 3, lines 52-55).

Since the common technical features are previously disclosed by the Sakai reference, the common features are not special and so Groups I and II lack unity.

The common technical features of Groups II and III are a wound dressing, comprising: hydrophilic absorbent material envelope.

This technical feature is disclosed by shared by US 6,566,575 B1 to Stickels, et al. (hereinafter 'Stickels'). Stickels discloses a wound dressing (absorbent dressing; abstract), comprising: hydrophilic absorbent material envelope (a pouch or envelope that surrounds the hydrophilic gel absorbent layer, into which the exudate from the wound passes; column 9, lines 49-52).

Since the common technical features are previously disclosed by the Stickels reference, the common features are not special and so Groups II and III lack unity.