(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 December 2014 (24.12.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/203049 A1

(51) International Patent Classification:
A61F 13/00 (2006.01) *B32B 3/30* (2006.01)
A61L 15/44 (2006.01) *B32B 33/00* (2006.01)
B32B 3/24 (2006.01)

(21) International Application Number:
PCT/IB2014/000444

(22) International Filing Date:
28 March 2014 (28.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/956,970	21 June 2013 (21.06.2013)	US
61/958,758	6 August 2013 (06.08.2013)	US
13/970,940	20 August 2013 (20.08.2013)	US

(72) Inventor; and
(71) Applicant : **BARBERIO, Alessandro** [CA/CA]; 14845/6 Yonge Street, Aurora, Ontario L4G 6H8 (CA).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

WO 2014/203049 A1

(54) Title: MEDICAL PROTRUDED PADS OR DRESSINGS FOR WOUND CARE INCLUDING USE WITH ORTHOPEDIC AND PROSTHETIC DEVICES

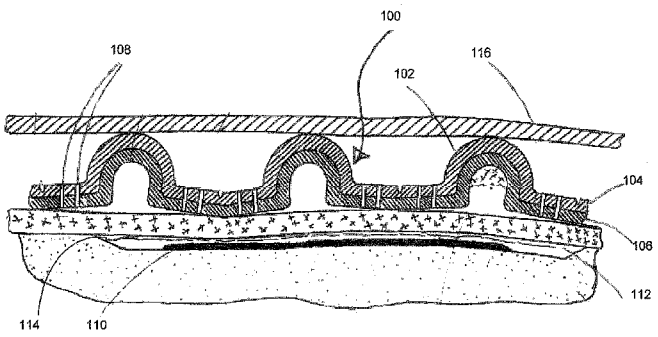


FIG. 1

(57) Abstract: Methods and devices for dressing a wound are disclosed. One such dressing includes a layer of spaced protrusions, each protrusion shaped to receive medication for treating a wound and a plurality of holes defined in the layer, the holes configured to allow evaporation of exudate from the wound. A second layer is disposed above the first layer and comprises a compression band. Another such dressing includes multiple layers, each layer sandwiched over the next and including spaced protrusions, with alternate layers comprising absorptive materials. The alternate layers of absorptive materials can communicate via holes in the non-absorptive layers to allow exudate to travel from between the absorptive layers and away from the wound.

MEDICAL PROTRUDED PADS OR DRESSINGS FOR WOUND CARE INCLUDING USE WITH ORTHOPEDIC AND PROSTHETIC DEVICES

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of U. S. Patent Application Serial No. 13/970,940, filed August 20, 2013, U.S. Provisional Patent Application Serial No. 61/956,970, filed June 21, 2013, and U.S. Provisional Patent Application Serial No. 61/958,758, filed August 6, 2013. The contents of these applications are incorporated herein by reference.

FIELD OF THE DISCLOSURE

[0002] The present invention relates generally to the field of wound treatment and medical uses of treatment devices for the same.

BACKGROUND OF THE INVENTION

[0003] Today, wounds are treated with great care, but dermatologists do not always agree on the procedures for wound treatment. Wounds need to breathe, having access to oxygen and a moist environment. But, with current procedures for wound treatment and existing wound care supplies, wounds do not receive enough oxygen or adequate moisture to heal. Frequent applications of new dressings and medication are needed and can be costly.

[0004] An example procedure from providing moisture to the wound is to cover the wound with a hydrogel pad. This pad is designed to keep the wound moist, but, because of its lack of absorption, a hydrogel pad may not be an appropriate choice for moderately weeping wounds as the hydrogel pad does not always provide sufficient moisture to heal open wounds.

[0005] The embodiments in this application improve and extend the second part of European Patent Application No. 08706194.1 describing a mini-perforated sheet made of the bumpy or protruded layer. The '194.1 application describes the layer as comprising ethylene-vinyl acetate (EVA) made from medical sterilized silicone in combination with different materials of different hardness.

SUMMARY OF THE INVENTION

[0006] One aspect of the disclosed embodiments is a wound dressing. The wound dressing includes a layer including spaced protrusions. Each protrusion is shaped to receive medication for treating a wound. The wound dressing also includes a plurality of holes defined in the layer. Each of the holes is configured to allow evaporation of exudate from the

wound. The layer may be a first layer where the wound dressing includes a second layer disposed above the first layer, the second layer comprising a compression band.

[0007] Another aspect of the disclosed embodiments is a multi-layered wound dressing. The multi-layered wound dressing includes a first layer comprising absorptive material for application proximate to a wound and a second layer comprising non-fluid permeable material disposed above the first layer. The multi-layered wound dressing also includes a third layer comprising absorptive material disposed above the second layer and a fourth layer comprising non-fluid permeable material disposed above the third layer. Each of the layers includes spaced protrusions. The multi-layered wound dressing also includes a plurality of spaced rings each extending from inner walls of the spaced protrusions of the second layer, the spaced rings configured to collect exudate. Additionally, the multi-layered wound dressing includes a plurality of holes defined in the spaced protrusions of the second layer, the holes configured to allow exudate to pass from the first layer to the third layer.

[0008] Other advantages, features and characteristics of the present invention, as well as methods of operation and functions of the related elements of the structure, and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following detailed description and the appended claims with reference to the accompanying photographs, the latter being briefly described hereinafter.

BRIEF SUMMARY OF THE DRAWINGS

[0009] The description herein makes reference to the accompanying drawings wherein like reference numerals refer to like parts throughout the several views and wherein:

[0010] FIG. 1 is an example embodiment of a pad or dressing for treating and dressing wounds;

[0011] FIG. 2 is an alternative embodiment of the pad or dressing for treating and dressing wounds as described in FIG. 1;

[0012] FIG. 3 is another example embodiment of a pad or dressing for treating and dressing wounds;

[0013] FIG. 4 is an alternative embodiment of the pad or dressing for treating and dressing wounds as described in FIG. 3;

[0014] FIG. 5 is an example embodiment of a protrusion configured for use with any of the pads or dressings of FIGS. 1-4;

[0015] FIG. 6 is an alternative embodiment of the protrusion of FIG. 5;

[0016] FIG. 7 shows the trajectory of vapors and liquids traveling within the protrusion of FIG. 5;

[0017] FIG. 8 is an example embodiment of a dressing for use in compressive therapy integrating a protrusion similar to the protrusion of FIG. 5;

[0018] FIG. 9 shows the collection of exudate along the spaced rings of a protrusion of the dressing of FIG. 8;

[0019] FIG. 10 is an example embodiment of a protrusion configured for use with a multi-layered pad or dressing;

[0020] FIG. 11 is an example embodiment of a multi-layered dressing integrating the protrusion of FIG. 10;

[0021] FIG. 12 is an example embodiment of a sheathed multi-layered dressing integrating the protrusion of FIG. 10;

[0022] FIGS. 13A and 13B show an example embodiment of a wrap-style dressing integrating segments of protrusions similar to the protrusions of FIGS. 5, 6, and 10;

[0023] FIGS. 14A-F show a sequence representing the application of a wrap-style dressing, a layer of which includes segments of protrusions similar to the protrusions of FIGS. 5, 6, and 10 to a limb;

[0024] FIGS. 15A-E show a sequence representing the construction of a multi-layered dressing such as the multi-layered dressing shown in FIG. 12;

[0025] FIGS. 16A-D show multi-layered dressings similar to those described in FIGS. 12 and 15A-E configured for use in a walking boot or brace; and

[0026] FIG. 17 shows a sock-style dressing configured for use with the wrap-style dressings of FIGS. 13A-B and14A-F.

DETAILED DESCRIPTION

[0027] Existing wound dressings and treatments that covers the foot or leg can become very hot and uncomfortable and can cause the patient to perspire unnecessarily. This disclosure describes various embodiments of an improved multi-perforated pad or dressing, for example, partially made of medical silicone. The pad or dressing is designed to allow air to pass through it and the reach the area of a wound. The pad or dressing is also designed to be flexible and capable of covering irregular shapes associated with the body of a human or animal.

[0028] The pads or dressings described in the below embodiments can deliver medication, provide ventilated support, and rapidly absorb and lock away exudate, all while keeping bacteria away from a wound and decreasing the risk of maceration of a patient's skin. Additionally, the improved pads and dressings have an overall lower cost based on the decreased number of dressing changes necessary to provide treatment to a patient's wound.

[0029] FIG. 1 is an example embodiment of a pad or dressing 100 for treating and dressing wounds. Many types of wounds can be treated with pad or dressing 100 described both in this example and the pads or dressings described in the additional example embodiments below. For example, blisters, burns, lesions, bed sores, venous ulcers, arterial ulcers, post-operative wounds, edema inside casted limbs, and exuding wounds of superficial, deep, chronic, or acute nature can be treated. Pad or dressing 100 can be used for aeration and medication inside the walls of walking braces, to replace treatment foams, as part of a wrist brace, or as the internal wall of a prosthetic device.

[0030] Pad or dressing 100 can be designed with protrusions or bumps 102. Pad or dressing 100 can consist of a layer 104 made of EVA or medical silicone and a layer 106 made of medical sterilized silicone. Layers 104, 106 can alternatively be formed of one or more nanofibers, for example, polyvinylalcohol, chitosan, carboxymethylcellulose gelatin, collagen, hyaluronic acid, or polyurethane. Layers 104, 106 can be manufactured as a single piece, or separately, and are also known as backings for pad or dressing 100. Protrusions or bumps 102 can be equally spaced by a distance of approximately one centimeter. A series of holes 108 are disposed proximate to protrusions or bumps 102. The diameters of these holes 108 can, for example, range from 0.5 to 1 mm.

[0031] As shown in Fig. 1, a wound 110 can be covered by an antibiotic or equivalent sterilizer 112 such as Aquafor™. On top of sterilizer 112, a hydrogel sheet 114 for assisting the maintenance of a moist environment can be applied. Hydrogel sheets 114 are cross-linked polymer gels. Some hydrogel sheets 114 are available with an adhesive border. In this instance, hydrogel sheets 114 can be applied as narrow strips separated equidistantly by 1 cm. The use of narrow strips of hydrogel sheets 114 allows the section of wound 110 that is not covered by hydrogel sheet 114 to receive more oxygen penetration from the outside through series of holes 108.

[0032] Because of the empty space beneath protrusions or bumps 102, there remains room for oxygen and moisture. One of the many advantages of this embodiment is that protrusions or bumps 102 and holes 108 both contribute to wound 110 having more moisture and more oxygen, allowing pad or dressing 100 to fight anaerobic bacteria, including odorous bacteria. By the addition of oxygen to the wound via series of holes 108, such wounds 110 as diabetic ulcers can avoid the disadvantageous application of hyperbaric oxygen therapy. The flow of air that travels through series of holes 108 can be regulated by applying an external cover or sheet 116 of a hydrophobic nature. Sheet 116 can be made of medical foam or silicone.

[0033] The dimensions of pad or dressing 100 can be scaled depending on its use, for example, made larger or smaller overall. Pad or dressing 100 is suitable for use in dressing and treating wounds in both humans and animals. Pad or dressing 100 can also be used as an immobilizing cast for aerobic ventilation or for decompression of limbs to prevent edema. Pad or dressing 100 can also be used in many prosthetic devices or inside the walls of walking shoes. Most importantly, it will be used inside the walls of any walking brace, thus replacing the foam that surrounds the foot or leg of the patient. Pad or dressing 100 can also be washable.

[0034] FIG. 2 is an alternative embodiment of pad or dressing 100 for treating and dressing wounds as described in FIG. 1. In this example, a deep wound 200 is shown. Given the depth of wound 200, holes 108 are not as important for wound breathing purposes. In fact, pad or dressing 100 as shown in this embodiment can be used with or without holes 108. Protrusions or bumps 102 can be filled with a hydrogel paste 202 that provides moisture as needed due to the size of the wound. No hydrogel paste 202 is necessary in the regions between protrusions or bumps 102. Avoiding application of hydrogel paste 202 in the areas between protrusions or bumps 102 ensures that series of holes 108 will be free to allow air to enter pad or dressing 100 and reach skin 204 or wound 200. Pad or dressing 100 thus allows wound 200 to receive hydrogel paste 202 that is stored inside each protrusion or bump 102 to speed healing and allow for pad or dressing 100 to be changed less often.

[0035] Pad or dressing 100 can be made of a medical sterilized silicone. Pad or dressing 100 can also be made of two layers of silicone, each of a different hardness. In some embodiments, the harder layer is toward the top. A second layer of an EVA material can also be added to pad or dressing 100. The EVA material can help pad or dressing 100 to withstand external pressure should the patient make contact with an external object. Additionally, adhered strips of cotton can be applied between protrusions or bumps 102. The application of these cotton strips can allow medication to adhere more easily to pad or dressing 100 while facilitating mess-free handling by medical professionals.

[0036] The medications used inside pad or dressing 100 can also vary. For example, a hydrocolloid paste can be used for shallow wounds or several layers of cotton can be used for deep wounds, such as wound 200. Different or additional dressings can be also be used in protrusions or bumps 102, depending on the severity of the wound. Pads or dressings 100 can also be constructed such that differing medications are present in each of protrusions or bumps 102, the medications being existing medications known to medical professionals and those yet to be developed.

[0037] Pad or dressing 100 shown in FIG. 2 also includes backing layers 104, 106 constructed of medical silicone and EVA, respectively. Alternatively, layers 104, 106 can be constructed of a breathable TPU film. The TPU film can allow wound 200 to receive air vapor and oxygen but will also protect wound 200 from germs and bacteria. In this alternative construction, holes 108 are important for transmission of air from outside of pad or dressing 100. Other materials possible for construction of backing layers 104, 106 include Pellethane™ or Saran™, for example, in use with small wounds. Additionally, external cover or sheet 116 in this embodiment can be gauze, a tubular stokinette, or a tubular net such as Surgilast™. Cover or sheet 116 can be excluded when flat or small areas are being treated.

[0038] FIG. 3 is another example embodiment of a pad or dressing 300 for treating and dressing wounds 302. In this example embodiment, pad or dressing 300 includes multiple, closely spaced protrusions 304, 306. The crest of protrusion 304, for example, is of equal size to the crest of protrusion 306 but is reversed in shape along the length of pad or dressing 300, creating an alternating pattern of crests. This embodiment of pad or dressing 300 is configured for dressing and treatment of deeper wounds, such as wound 302, and will adapt or sink more easily inside the cavity of wound 302. In a similar manner as pad or dressing 100 described in FIG. 1, this pad or dressing 300 can also be made of more than one layer and medications can be pre-packed within protrusions 304, 306. The medications can be in the form of pastes, dressings, or meshes. Pad or dressing 300 can also include holes 308 at positions at the crest or around protrusions 304, 306 if there is no medication inside protrusions 304, 306.

[0039] FIG. 4 is an alternative embodiment of the pad or dressing 300 for treating and dressing wounds as described in FIG. 3. In this alternative embodiment, pad or dressing 300 is covering a shallow, flat wound 400. A shallow, flat wound 400 requires a lot of medication—therefore, each protrusion 304, 306 can be filled with the appropriate kind of medication. The height of the protrusions 304, 306 can vary, and more medicated paste is need in the larger, taller protrusions. Larger protrusions can allow the patient's skin 402 to receive a higher concentration of medication. Using pads or dressings 300 with this design can save money because pads or dressings 300 will need to be changed less frequently. This design also has the advantage of covering a large wound area with medication because distance Z along the internal cavity of a protrusion is much larger than the distance W where no medication is present.

[0040] FIG. 5 is an example embodiment of a protrusion 500 configured for use with any of the pads or dressings of FIGS. 1-4. Protrusion 500 is shown in cross-section. In this

example, protrusion 500 includes an internal cavity 502 and a pair of spaced rings 504, 506 circling the walls of internal cavity 502. Each of spaced rings 504, 506 is angled, for example, at 30 degrees to the walls of internal cavity 502, stretching toward the crest of protrusion 500. The function of spaced rings 504, 506 is further described below. Protrusion 500 may also include a series of holes 508, though holes 508 are not required. A lower layer 510 that forms part of the pad or dressing can be an absorptive material.

[0041] FIG. 6 is an alternative embodiment of protrusion 500 of FIG. 5. In this example, lower layer 510 that forms part of the pad or dressing extends along the walls of internal cavity 502 of protrusion 500, covering spaced rings 504, 506. Again, lower layer 510 can be formed of absorptive material.

[0042] FIG. 7 shows the trajectory of vapors and liquids traveling within protrusion 500 of FIG. 5. Vapors produced while a wound heals can include evaporated exudate and the liquids produced can include molecules of liquid coming from the wound that can saturate the absorptive material of lower layer 510. If the exudate or liquid molecules from the wound excessively accumulate on lower layer 510 of a pad or dressing, lower layer 510 can become saturated with unwanted organisms and liquid or vapor can wick around the edges of the pad or dressing, leading to unwanted odors and maceration of a patient's skin. In addition, once too much liquid accumulates on lower layer 510, it can seep back toward the wound. Protrusion 500 shown in this example is designed to avoid excess exudate returning to the wound.

[0043] Spaced rings 504, 506 of protrusion 500 can capture exudate and liquid from the cavity or surface of the wound. The trajectory of the exudate and liquid from the wound to spaced rings 504, 506 is represented with arrows numbered one through ten. The path starts at arrow one and continues through arrow ten, depositing excess materials within spaced rings 504, 506 based on the upward facing direction of spaced rings 504, 506, in this example, at an angle of approximately 30 degrees in respect to the wall of protrusion 500. Once the excess material is stored within spaced rings 504, 506, it is not returned to the wound. Protrusion 500 and spaced rings 504, 506 can be of singular construction of silicone, polyurethane, polyamide, polyester, EVA, gel, plastazote, plastic, cork, foam, or any other hypoallergenic material. Alternatively, protrusion 500 and spaced rings 504, 506 can be separate layers of different materials.

[0044] The use of protrusions 500 of the style shown in FIG. 7 is beneficial in pads, dressings, or coverings for wounds where external pressure is expected to be applied, as protrusions 500 shield the wound. Protrusions 500 can have a hard exterior and soft exterior,

keeping them from compressing during external pressure, acting, as such, as a bumper when a patient faces a situation where pressure is applied to protrusion 500. Further, the use of protrusions 500 with pads, dressings, or coverings for wounds can capture more exudate or liquid than would a flat-surface style dressing, as there is more surface area on the curved surfaced of protrusions 500. Given the additional exudate or liquid captured, fewer pads or dressings will be needed, saving money for the patient or caregiver.

[0045] FIG. 8 is an example embodiment of a dressing for use in compressive therapy integrating a protrusion 800 similar to protrusion 500 of FIG. 5. Compressive therapy is used to apply uniform pressure to dressings, for example, to control leg ulcers or apply pressure to the bottom of a patient's foot. Prior art dressings used in compressive wound therapy allow exudate to wick across the dressing, affecting healthy tissue outside of the wound and causing maceration and unwanted odors. The dressing of FIG. 8 can be used to apply pressure to a wound 802, such as an ulcer, by means of an elastic strap 804.

[0046] Protrusion 800 in FIG. 8 is similar to protrusion 500 of FIGS. 5-7 in that it includes spaced rings 806 that collect exudate and keep the exudate from flowing back into wound 802. In this example, spaced rings 806 extend at an angle of 15 degrees from the wall of protrusion 800. Protrusion 800 and spaced rings 806 are designed not to collapse under the influence of external pressure and provide a larger layer of absorptive material that would be possible with a flat dressing. The shape of multiple protrusions 800 along a compressive dressing will act as a bumper, protecting wound 802 from compression.

[0047] FIG. 9 shows the collection of exudate 900 along spaced rings 806 of protrusion 800 of the dressing of FIG. 8. Exudate 900 can accumulate at different rates, the rate depending on the nature of the components of exudate 900, the health of the patient using the dressing, the mechanism of exchanged gases passing through the dressing, etc. The inclusion of spaced rings 806 allows collection of larger amounts of exudate 900 that would be possible with other dressings, minimizing the risk of leaks. In addition, exudate 900 from wound 802 will force the absorptive layer to swell, which could cause the dressing to be a carrier of unwanted bacteria and odor, but, because the backing of the dressing is porous, it is antibacterial in nature and permeable to moisture and air, allowing exudate 900 from wound 802 to evaporate once collected.

[0048] The dressings described in FIGS. 8 and 9 can be used with or without medications, and the medications can have a continuous or non-continuous spread along the dressing on the side proximate the patient's wound. The material of at least some of the layers of the dressing can be Coban,™ supporting flexibility of the dressing while at the same time

keeping the dressing pressed to the patient's skin. The shape of the dressings can be tubular to allow coverage of limbs having mostly uniform diameter, or rectangular, square, oval, circular, concave, or any other shape configured to conform to the given wound. The dressings can also be framed with a backing carrying an adhesive allowing a medical professional to adhere the dressing to a wound. The adhesive can extend along all or most of the perimeter of the backing, with the exception of two small tab-style areas. The non-adhesive tab-style areas can be used to remove the dressing without damaging the skin, for example, as could occur caused by a medical provider's nails when the medical provider attempts to dig under a corner of the dressing for removal.

[0049] FIG. 10 is an example embodiment of a protrusion 1000 configured for use with a multi-layered pad or dressing. Protrusion 1000 is designed to handle high levels of exudate seeping from wound 1002. The pad or dressing including protrusion 1000 can include both a first outer layer 1004 and a second outer layer 1006, where exudate can be collected both below first outer layer 1004 and between first outer layer 1004 and second outer layer 1006. First outer layer 1004 and second outer layer 1006 are made of materials that are generally not permeable to exudate. Protrusion 1000 includes spaced rings 1008 extending at an angle to the inside wall of protrusion 1000 in a similar manner to the protrusions described in previous embodiments. However, at the junction of the wall formed by first outer layer 1004, openings are present, allowing exudate to flow both between first outer layer 1004 and second outer layer 1006 as well as into a recess within first outer layer 1004.

[0050] The exudate is first absorbed directly from wound 1002 on absorptive layer 1011 beneath first outer layer 1004. The exudate drawn into protrusion 1000 is then further drawn into the storage space between first outer layer 1004 and second outer layer 1006 as shown by absorption paths 1010. This exudate will not wick or leak back toward wound 1002 based both on the non-compressibility of protrusion 1000 and the presence of another absorptive layer 1012 between first outer layer 1004 and second outer layer 1006. The direction of absorption of exudate thus starts at absorptive layer 1011, flows up into protrusion 1000, along the edges of spaced rings 1008, through the holes at the base of spaced rings 1008, and onto absorptive layer 1012. Protrusion 1000 includes holes 1014 and second outer layer 1006 also includes holes 1016, allowing exudate collected in protrusion 1000 and absorptive layer 1012 to evaporate.

[0051] Though prior art dressings or pads can also use more than one layer of absorptive material to collect exudate, the danger of wicking or leaking during compression is

still present in these prior art dressings. The shape and non-compressible nature of protrusion 1000 alleviates this issue, and the openings along spaced rings 1008 provide an efficient collection means to move exudate onto mid-level absorptive layer 1012 without allowing the exudate to return to wound 1002 during compression of the pad or dressing.

[0052] FIG. 11 is an example embodiment of a multi-layered dressing integrating protrusion 1000 of FIG. 10. Absorptive layer 1011, first outer layer 1004, spaced rings 1008, absorptive layer 1012, and second outer layer 1006 all function as described in FIG. 10. FIG. 11 is included to describe the assembly and application of the dressing. A weld 1100 or other attachment adheres first outer layer 1004 to second outer layer 1006, keeping exudate locked within absorptive layer 1012. An adhesive layer 1102 is also attached to second outer layer 1006 for adhering the dressing to a patient's skin. As was the case with previously described dressing embodiments, the size of the multi-layered dressing can be scaled to the size of wound 1002, and adhesive layer 1102 can be scaled to the size of the dressing.

[0053] FIG. 12 is an example embodiment of a sheathed multi-layered dressing integrating protrusion 1000 of FIG. 10. In this example, sheath 1200 can be, for example, a tubinette or tubular gauze, stretchy in nature, such that the dressing is suitable for ulcer compression therapy. Different sections of protrusions within sheath 1200 can be separated using stitches 1202 to form separate compartments. Only one protrusion 1000 is shown in this example as stitched within its own section of tubinette or tubular gauze, but additional protrusions can be stitched within proximate sections of the tubinette or tubular gauze as well to construct the full dressing. Compression of sheath 1200 is achieved using a compressive layer 1204, for example a Coban ^{TM} compression layer. An optional second compressive layer 1205 can also be used for compression therapy. Compressive layers 1204, 1205 can be made of breathable material, for example, some types of elastics or cotton, and can be adhered together using adhesives, welding, sewing, thermoforming, or a combination of these or other techniques.

[0054] Absorptive layer 1011, first outer layer 1004, spaced rings 1008, absorptive layer 1012, second outer layer 1006, and holes 1014 can all function in a manner similar to that as described in FIGS. 10 and 11. However, the perimeter of the dressing differs from that as described in FIG. 11. Instead of adhesive layer 1102 described in FIG. 11, an extended spiral edge layer 1206 adheres first outer layer 1004 and second outer layer 1006. Absorptive layer 1011 extends along the entire length of spiral edge layer 1206, increasing the amount of exudate that can be collected at the edges of the sheathed dressing. Once the exudate becomes trapped within spiral edge layer 1206, it is no longer able to return to the area of the wound as

it would need to counteract gravitational forces to do so. Spiral edge layer 1206 also becomes heavier than protrusion 1000 portion of the sheathed multi-layered dressings once it absorbs exudate. Further, absorptive layer 1011 can be made of cotton mixed with a powdered superabsorbent polymer (SAP) which assists in keeping the exudate or liquid away from the wound and avoids significant lateral wicking. Absorptive layer 1011 can also be made of foam woven or non-woven with hypoallergenic substrates.

[0055] FIGS. 13A and 13B show an example embodiment of a wrap-style dressing integrating segments 1300 of protrusions similar to the protrusions of FIGS. 5, 6, and 10. In this example, multiple segments 1300 of protrusions can be spread along a first surface 1302 of a wrap-style dressing, for example, along a stretchy gauze material suitable for wrapping, for example, body parts such as arms, legs, wrists, or ankles. Segments 1300 of protrusions in this example are installed only along half of the width of first surface 1302 because wrap-style dressings are configured such that effective compression is achieved when approximately half of the width of the dressing is overlapped with each rotation around a body part. Second surface 1304 of the wrap-style dressing can be an alternative material, for example, breathable cotton to ensure proper evaporation.

[0056] FIG. 13A shows the wrap-style dressing in a straight configuration, before application to a patient. FIG. 13B shows the flexibility of the wrap-style dressing, curved in a manner that could be experienced when a medical provider begins to apply the wrap-style dressing to a patient. The spacing between segments 1300 of protrusions should be such that proper absorption of liquids or exudate and sufficient compression are possible given the type of wound being treated while at the same time allowing the flexibility needed for the wrap-style dressing to be applied to various shapes of body parts.

[0057] FIGS. 14A-F show a sequence representing the application of a wrap-style dressing, a layer of which includes segments of protrusions 1400 similar to the protrusions of FIGS. 5, 6, and 10 to a limb 1402. FIG. 14A shows a naked limb, in this example, a leg and foot of a patient. No wounds are shown, but it can be understood that the wound can be present. FIG. 14B shows an under-wrap 1404, for example, of cotton. FIG. 14C shows a tubular wrap 1406, for example, a stoikinette applied over under-wrap 1404. FIG. 14D shows the application of the wrap-style dressing including protrusions 1400 as described at length in previous embodiments of the disclosure. The wrap-style dressing is applied to the leg, but not the foot, as the compression caused by a patient walking on protrusions 1400 without additional support could cause protrusions 1400 to collapse. FIG. 14E shows the addition of a compression band 1408 above the wrap-style dressing of protrusions 1400. FIG. 14F shows

the addition of a secondary compression band 1410, for example, a COBAN™ layer. The proper application of the complete wrap-style dressing allows for successful compression therapy of a wound, for example, an ulcer.

[0058] FIGS. 15A-E show a sequence representing the construction of a multi-layered dressing such as the multi-layered dressing shown in FIG. 12. FIG. 15A shows a tubular tubinette 1500, for example, of cotton, that serves as the outer sheath of the multi-layered dressing. Tubinette 1500 is expandable. FIG. 15B shows a perforated layer of hypoallergenic material 1502. FIG. 15C shows a sectioned, or quilted, multi-layered wound dressing 1504 formed of multiple protrusions 1506 in the style of the protrusions shown in FIG. 12. FIG. 15D shows how the three components from FIGS. 15A-15C are constructed, in the style of a pocket sandwich, for example. Hypoallergenic material 1502 is disposed on top of multi-layered wound dressing 1504 and the combination of these components can be inserted into tubinette 1500. FIG. 15E shows the combined construction of multiple tubinettes 1500, each containing a certain length and width of hypoallergenic material 1502 and multi-layered wound dressing 1504. Each separate assembly can be combined, for example, using lines of stitches 1508. The multi-layered dressing shown in FIG. 15E can be used to cover the foot of a limb, for example the limb shown in FIGS. 14A-F, based on its increased flexibility.

[0059] FIGS. 16A-D show multi-layered dressings similar to those described in FIGS. 12 and 15A-E configured for use in a walking boot or brace. FIG. 16A shows a compound boot-shape dressing configured in two parts, one part for situation below the leg and foot and the other part for situation above the leg and foot of a patient. The boot-shape can be formed of connected sections of tubular, enclosed multi-layered dressings, the connections established by stitching, welding, adhesive, or any other method. FIG. 16B shows a top view of an internal base for the boot-shaped dressing, formed of connected tubinettes including separated sections of protrusions. FIG. 16C shows a front cross-section of the boot-shape dressing as applied to a patient's foot. The internal base of FIG. 16B is disposed below the foot and a compression-style dressing is disposed above the foot, both dressings including protrusions as described in previous embodiments. FIG. 16D shows a side cross-section of the boot-shape dressing as applied to the entire lower limb of a patient, the various layers wrapped on the lower limb in a manner consistent with providing compression therapy, for example, to an ulcerous wound.

[0060] FIG. 17 shows a sock-style dressing configured for use with the wrap-style dressings of FIGS. 13A-B and14A-F. Once the wrap-style dressing is partially applied, the sock-style dressing can be pulled onto a patient's foot, for example, in the same manner as

putting on a sock. The wrap-style and sock-style dressings can thus be used in combination to provide compression therapy to a patient's lower limb while at the same time allowing the patient to apply pressure to the foot, for example, using a walking cast.

[0061] The sock-style dressing can include a stretchy layer 1700, for example, of Surgilast™ material. The flexibility of stretchy layer 1700 allows the dressing to be applied to an area of the body that can experience constant motion, such as the foot. Spaced protrusions 1702, for example, similar in style to protrusions described in previous embodiments, can be disposed below stretchy layer 1700, proximate to the patient's foot for use in wound treatment and compression therapy. In addition, supportive spacers 1704 can be coupled to stretchy layer 1700 between spaced protrusions 1702. Spacers 1704 can be spherical in shape, with one half of each spacer connected to the other half through stretchy layer 1700. Spacers 1704 can be formed of durable materials, such as metal alloy or cork, of sufficient strength to support the patient walking on the sock-style dressing while additionally keeping protrusions 1702 from being crushed by the force of the patient's gait.

[0062] The sock-style dressing can be used in combination with a wrap-style dressing on a patient's leg as described above, used underneath a walking cast when the patient has a wound on the foot, used with a prosthetic device to treat a wound experiencing force when in use with the prosthetic, or used under an elastic-wrap, for example, Coban™ for compressive therapy. As with previous embodiments, a layer of cotton or stokinette can be applied to the wound before pulling on the stock-style dressing.

[0063] While the invention has been described in connection with certain embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments but, on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims, which scope is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures as is permitted under the law.

What is claimed is:

1. A wound dressing, comprising:

a first layer including spaced protrusions, each protrusion shaped to receive medication for treating a wound;

a plurality of holes defined in the first layer, the holes configured to allow evaporation of exudate from the wound; and

a second layer disposed above the first layer, the second layer comprising a compression band.

2. The dressing of claim 1, wherein outer surfaces of the spaced protrusions are hardened to withstand compression.

3. The dressing of claim 1, further comprising:

a ring extending from an inner wall of each spaced protrusion, the ring configured to collect exudate from the wound.

4. The dressing of claim 1, wherein the plurality of holes are located between the spaced protrusions.

5. The dressing of claim 1, wherein the plurality of holes are located on the spaced protrusions.

6. The dressing of claim 1, further comprising:

a third layer disposed beneath the first layer proximate to the wound, the third layer comprising absorptive material for collecting exudate from the wound.

7. The dressing of claim 6, further comprising:

a fourth layer disposed above the first layer, the fourth layer comprising a cover or sheet of hydrophobic nature.

8. The dressing of claim 1, wherein the first layer comprises medical silicone.

9. A multi-layered wound dressing, comprising:

a first layer comprising absorptive material for application proximate to a wound;

a second layer comprising non-fluid permeable material disposed above the first layer;

a third layer comprising absorptive material disposed above the second layer;

a fourth layer comprising non-fluid permeable material disposed above the third layer;

each of the layers including spaced protrusions;

a plurality of spaced rings each extending from inner walls of the spaced protrusions of the second layer, the spaced rings configured to collect exudate; and

a plurality of holes defined in the spaced protrusions of the second layer, the holes configured to allow exudate to pass from the first layer to the third layer.

10. The dressing of claim 9, wherein at least some of the holes are disposed at the base of the spaced rings.

11. The dressing of claim 9, further comprising:

a fifth layer disposed above the fourth layer, the fifth layer comprising a compression band.

12. The dressing of claim 9, further comprising:

a plurality of holes defined in the spaced protrusions of the fourth layer, the holes configured to allow evaporation of exudate from the dressing.

13. The dressing of claim 9, wherein outer surfaces of the spaced protrusions of the fourth layer are hardened to withstand compression.

14. The dressing of claim 9, wherein the second layer and fourth layer comprise medical silicone.

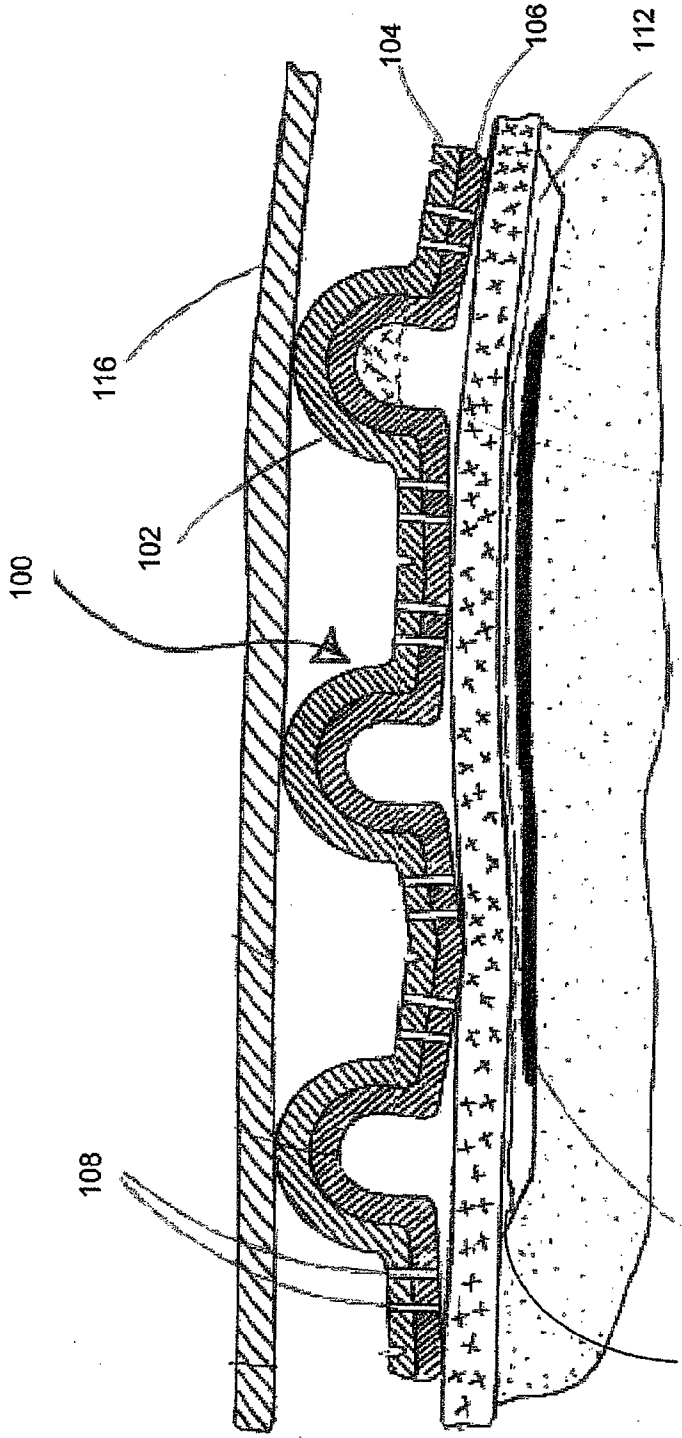


FIG. 1

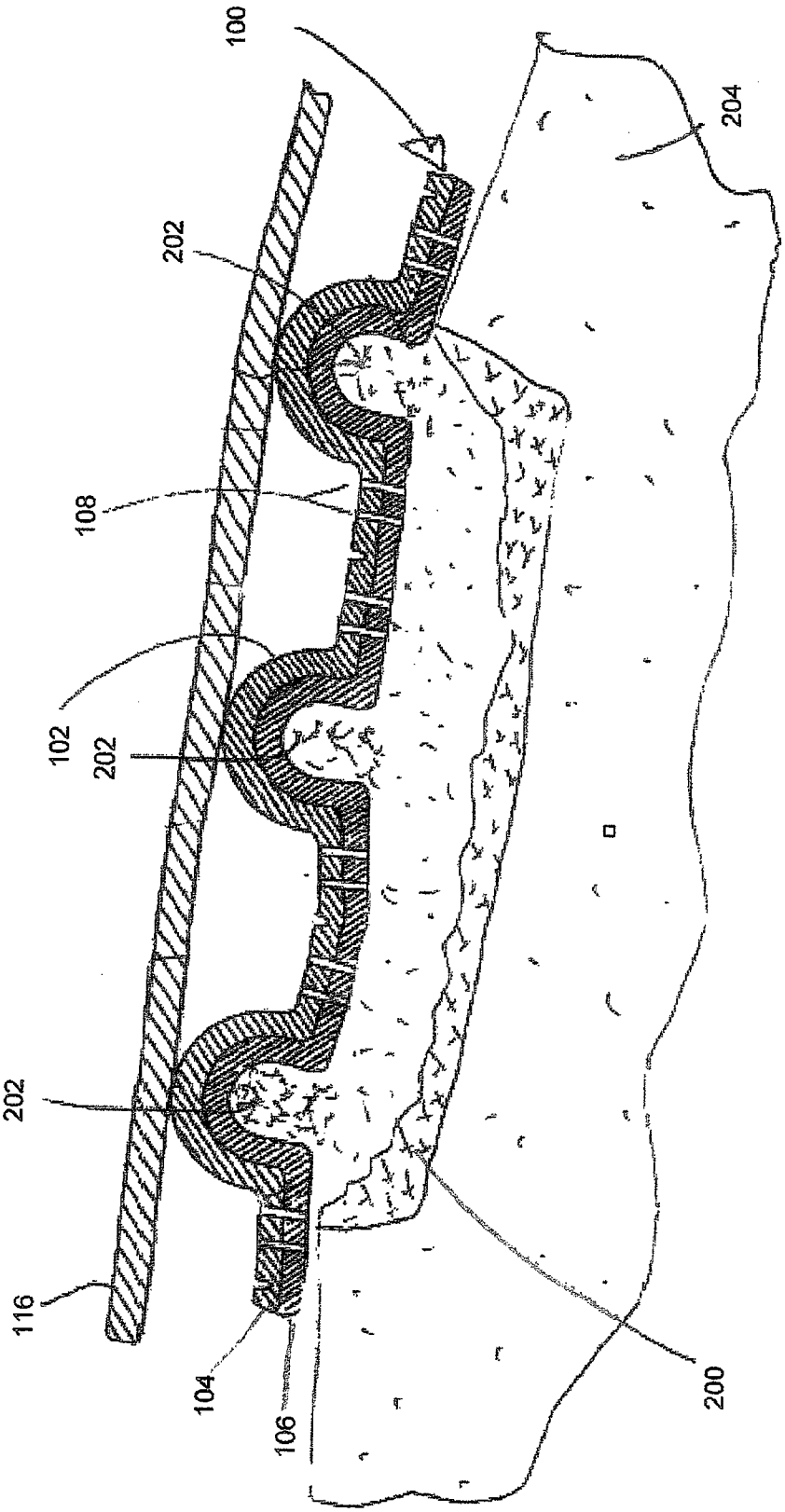


FIG. 2

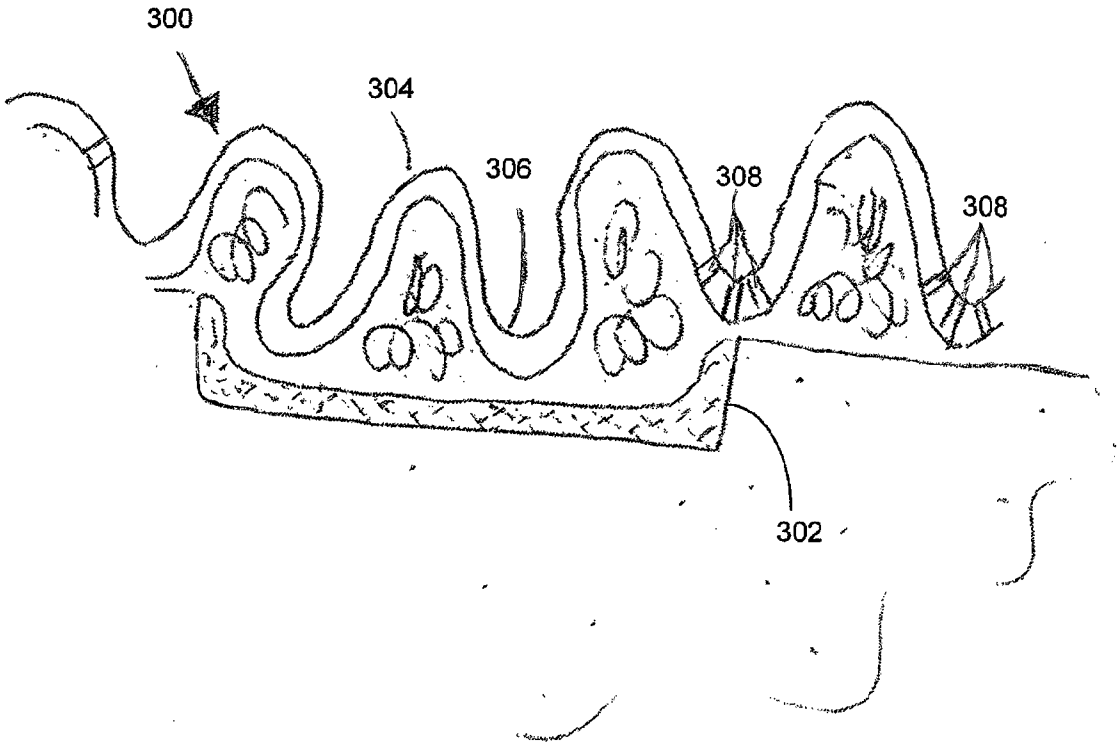


FIG. 3

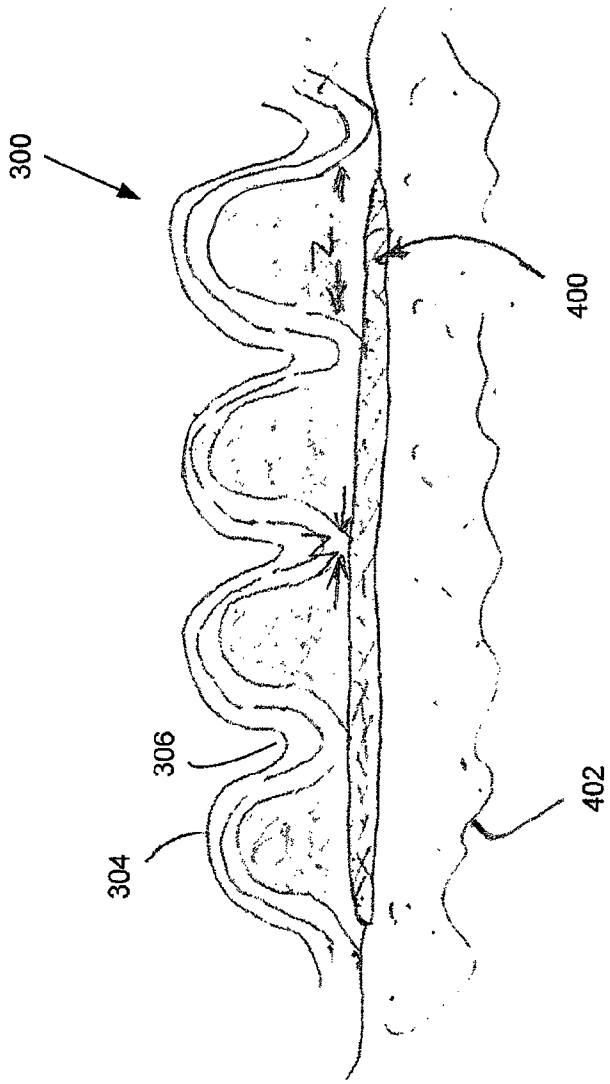


FIG. 4

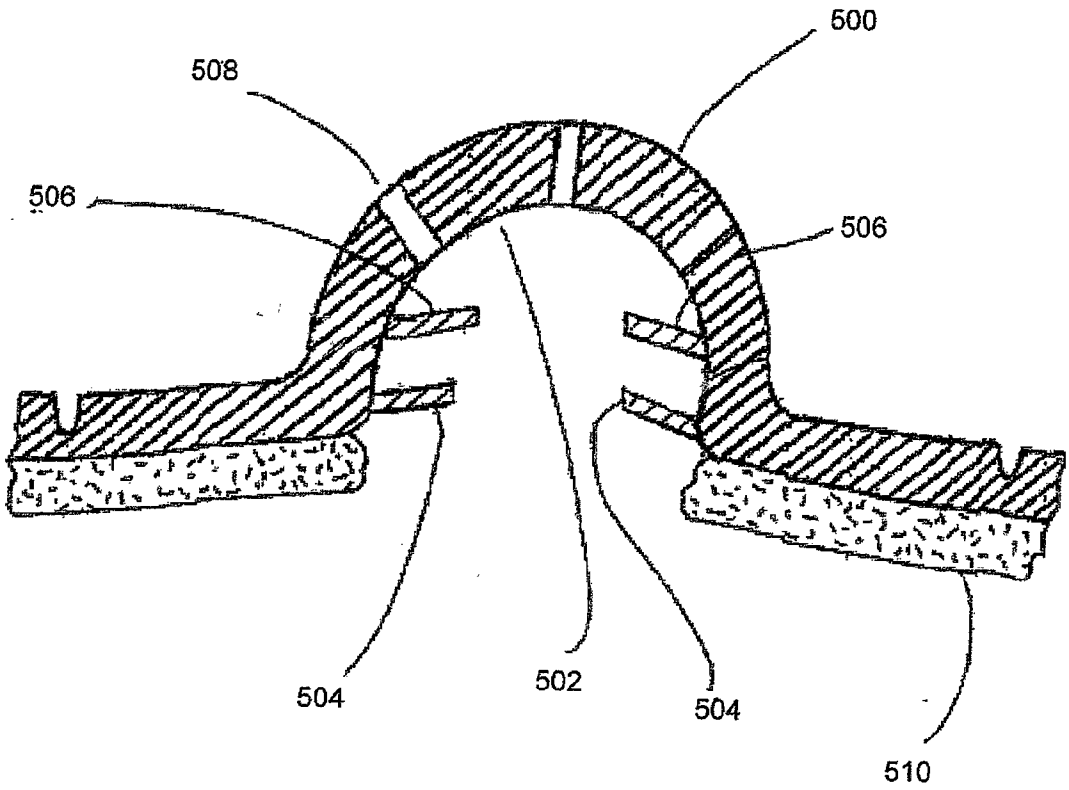


FIG. 5

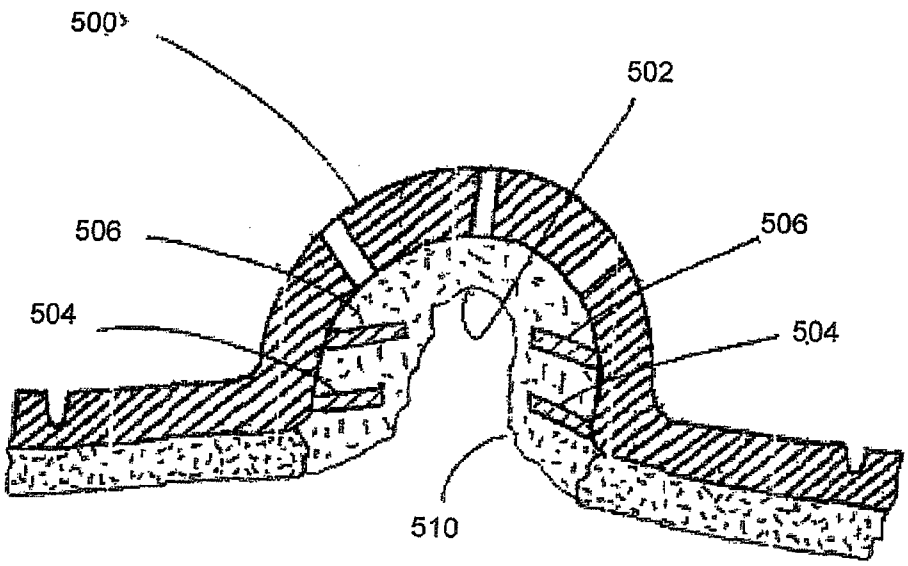


FIG. 6

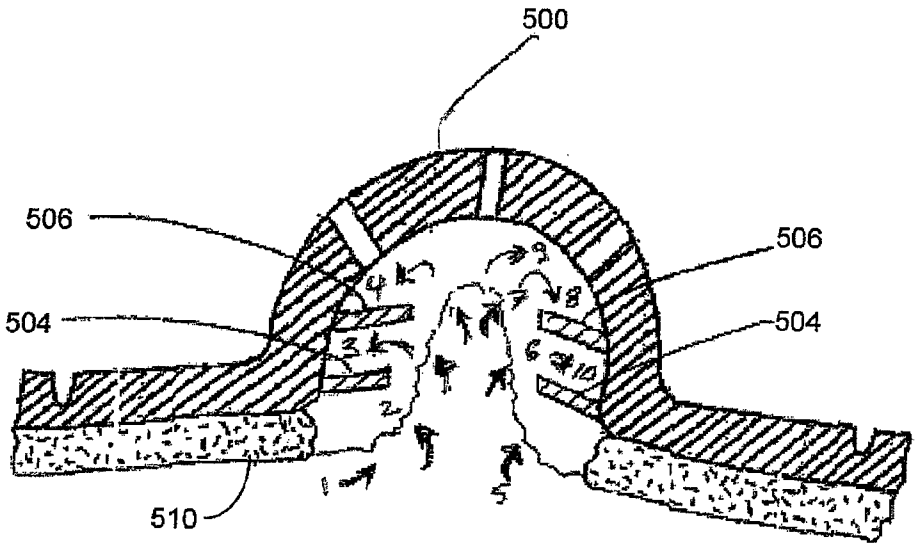


FIG. 7

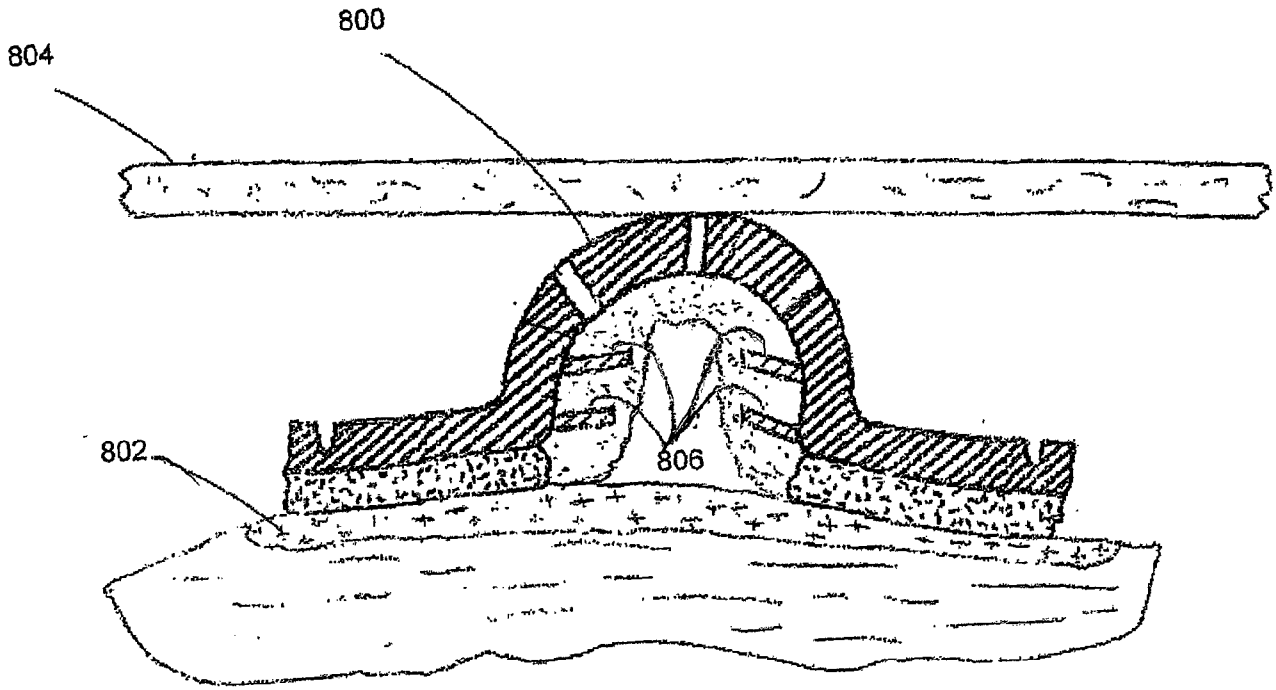


FIG. 8

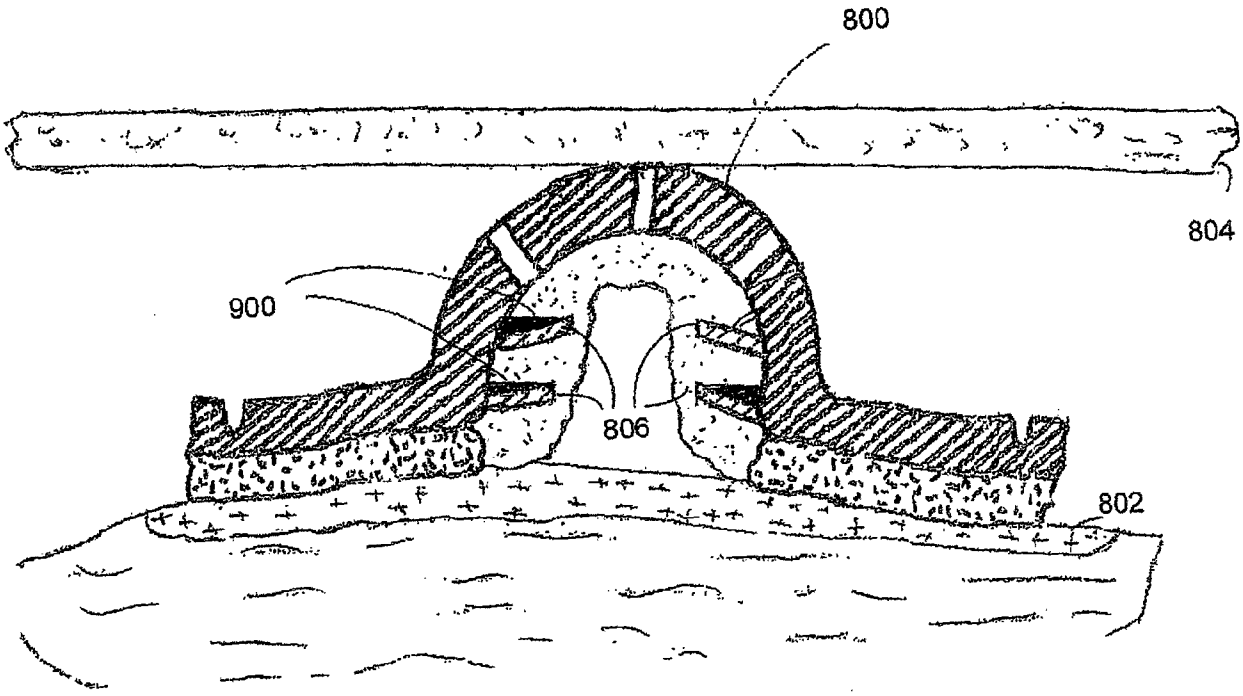


FIG. 9

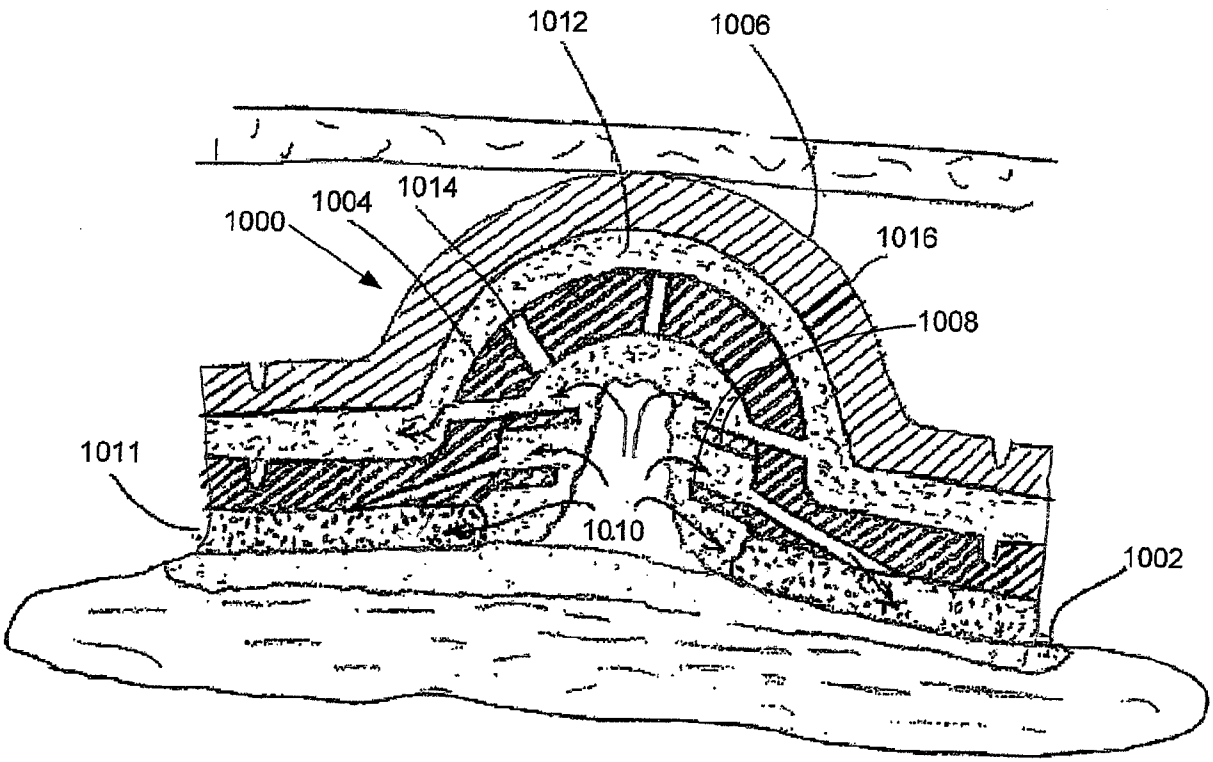


FIG. 10

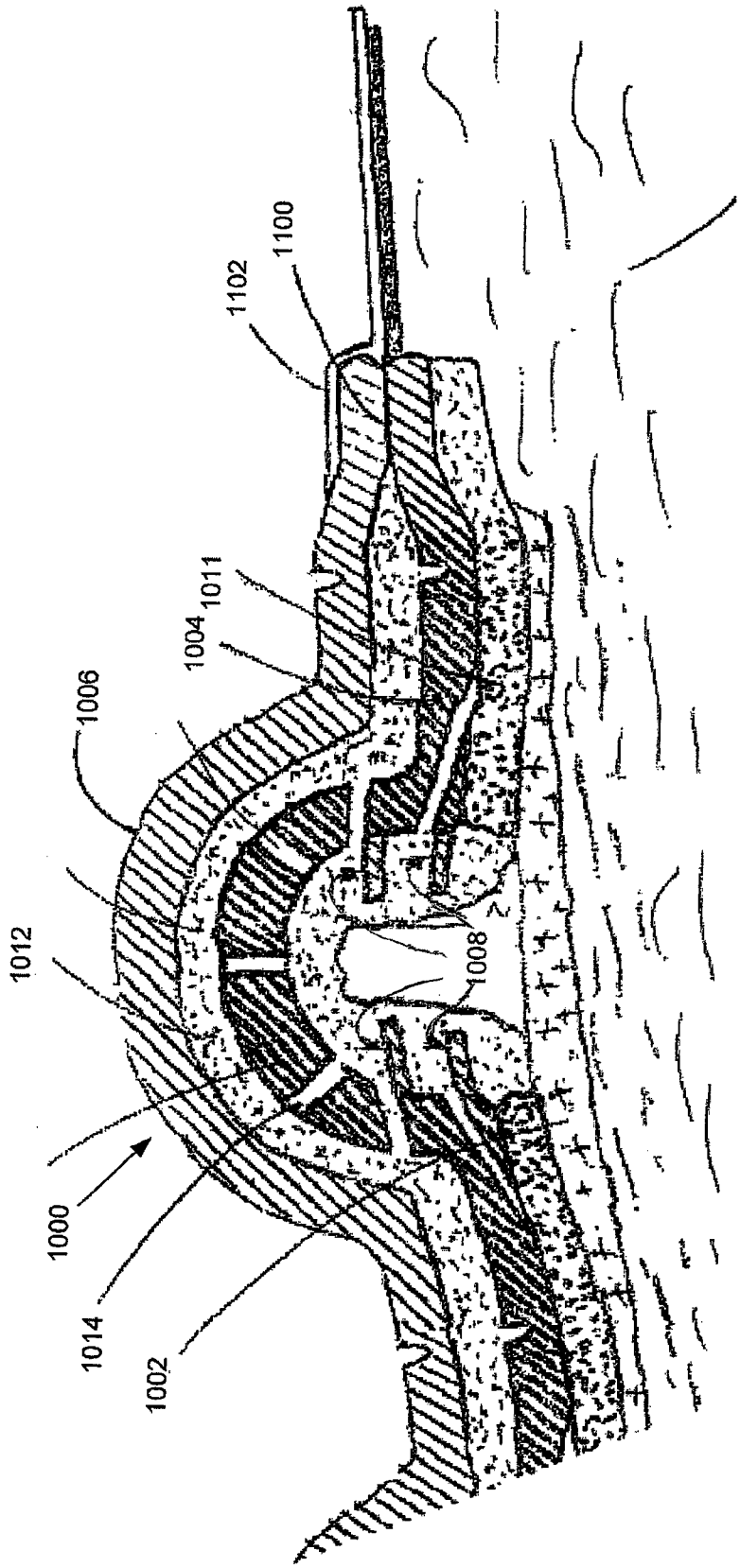


FIG. 11

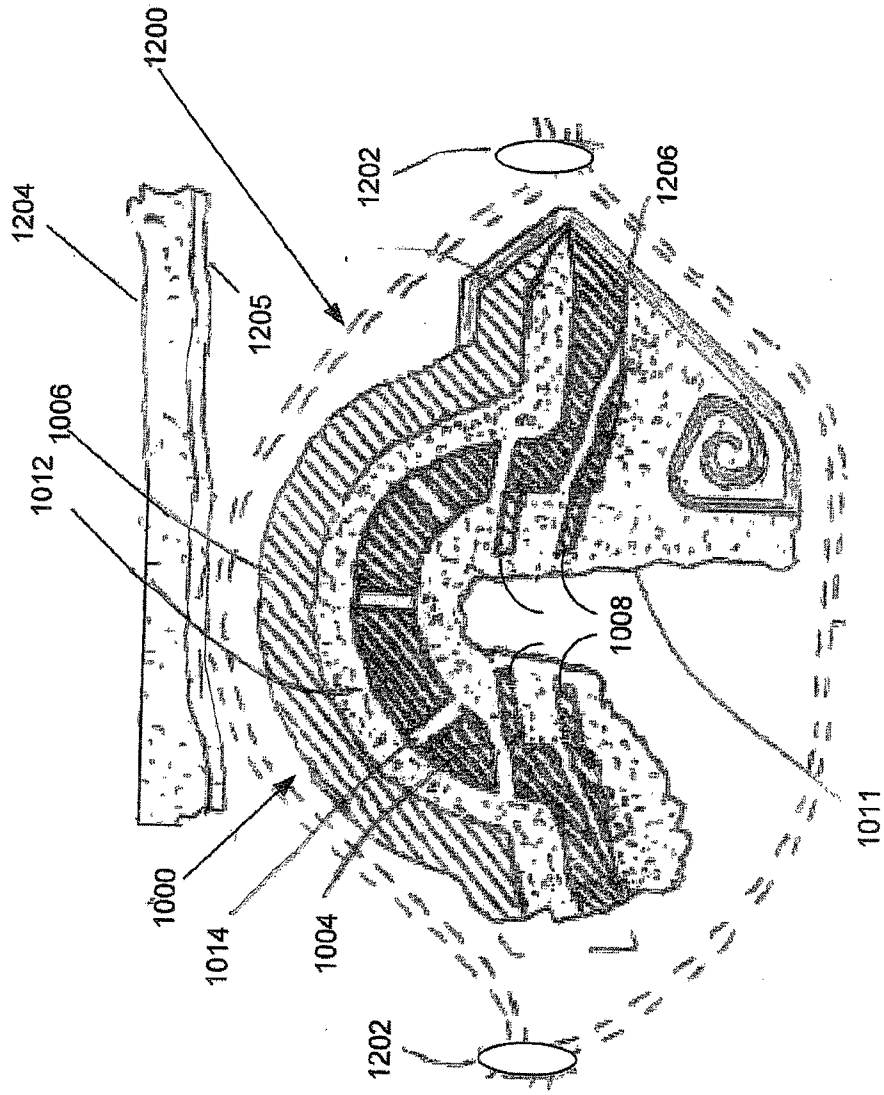

1200
1202
1206
1204
1205
1006
1012
1008
1011
1000
1014
1004
1202

FIG. 12

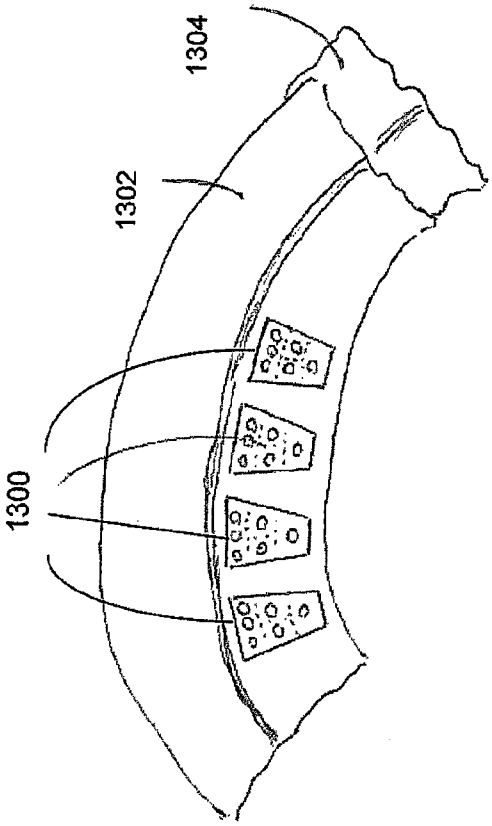


FIG. 13B

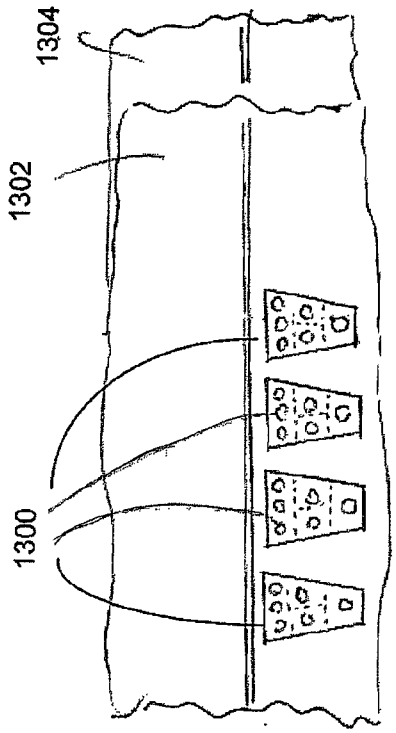


FIG. 13A

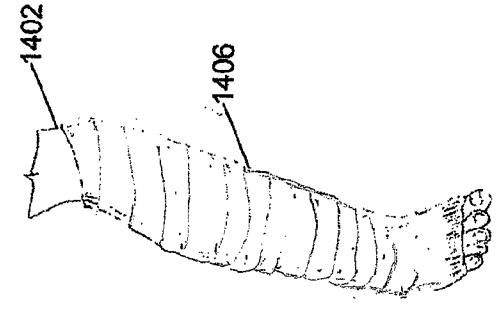


FIG. 14C

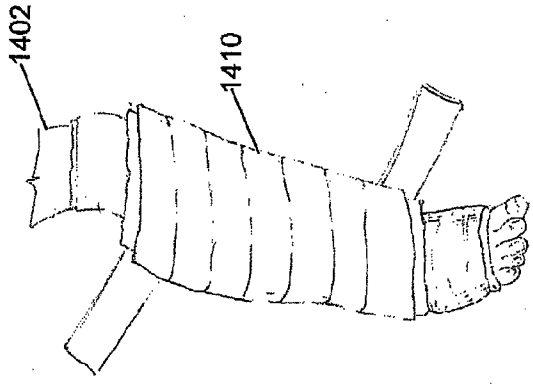


FIG. 14F

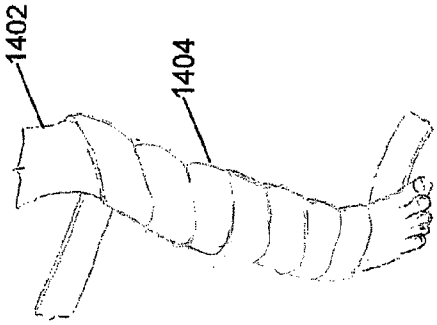


FIG. 14B

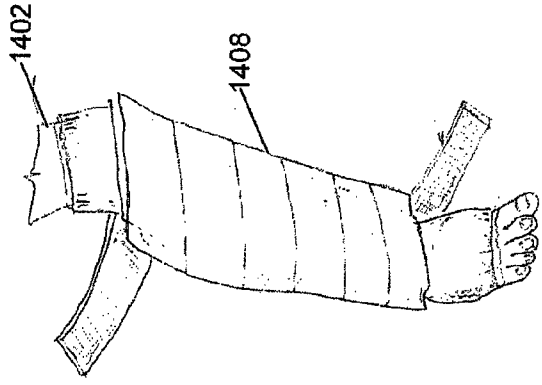


FIG. 14E



FIG. 14A

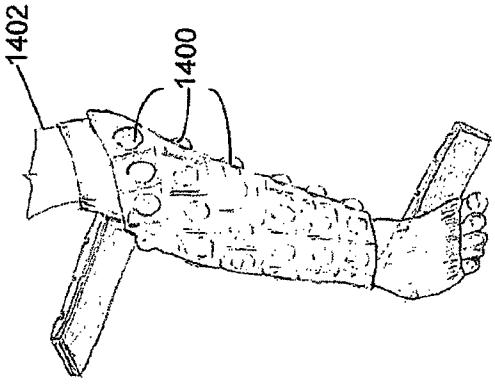


FIG. 14D

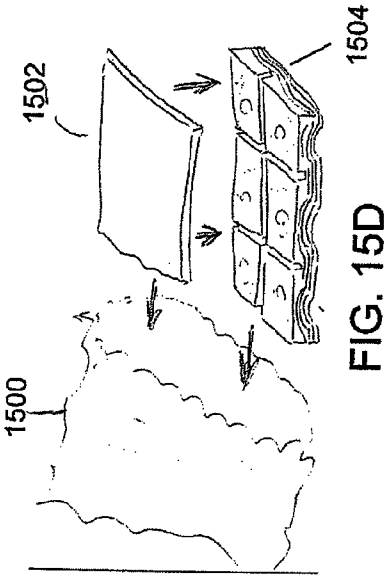


FIG. 15D

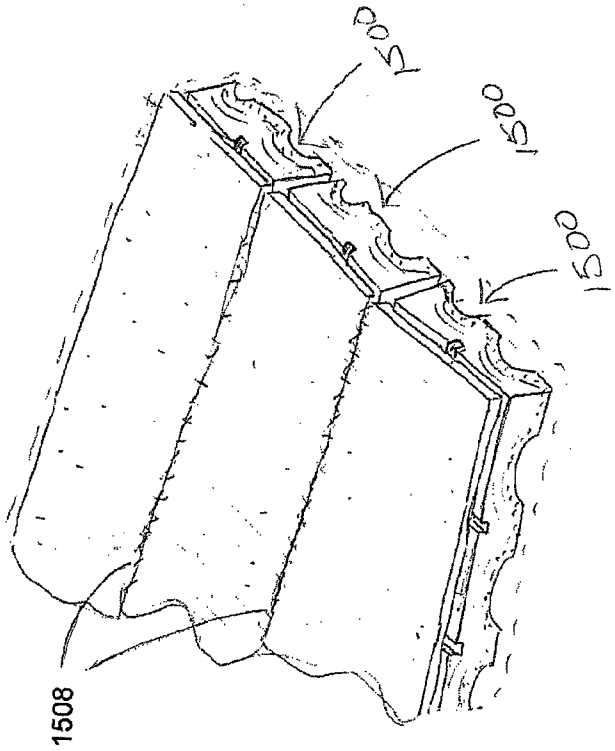


FIG. 15E

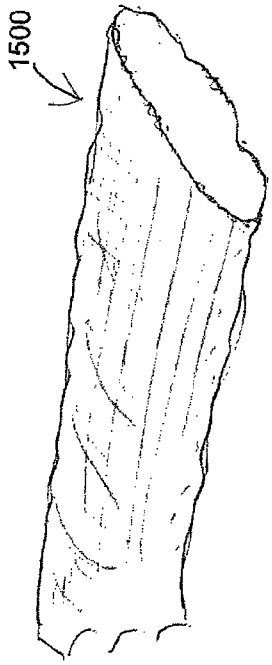


FIG. 15A

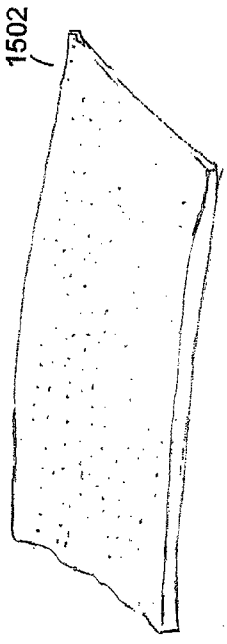


FIG. 15B

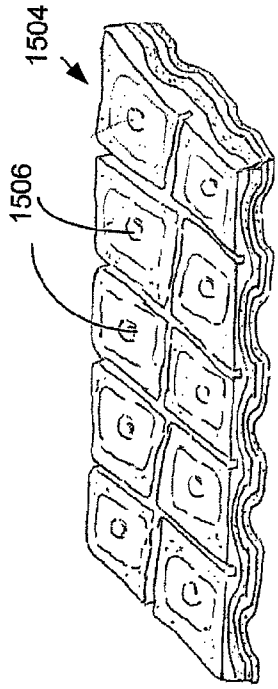


FIG. 15C

FIG. 16B

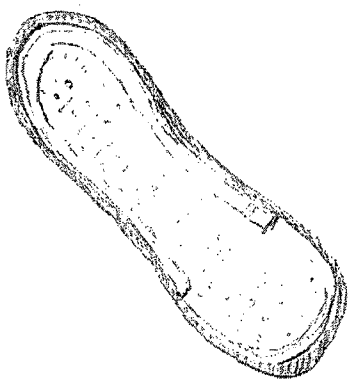
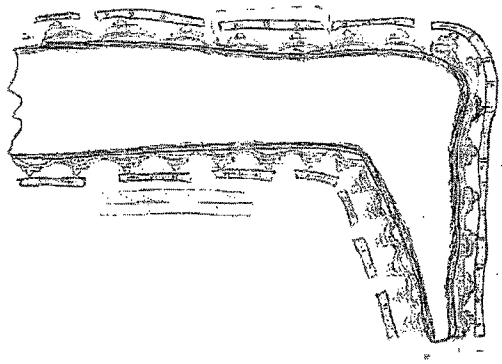


FIG. 16D



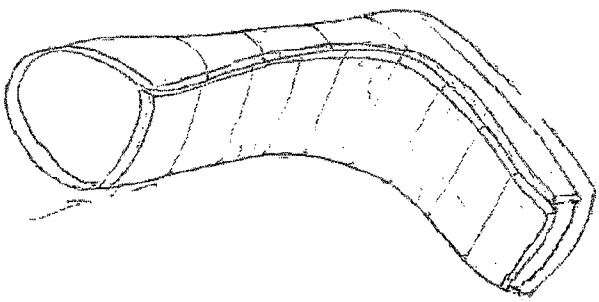


FIG. 16A

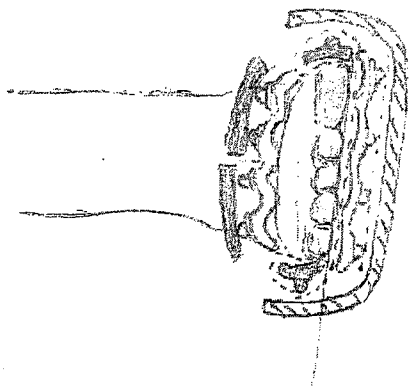


FIG. 16C

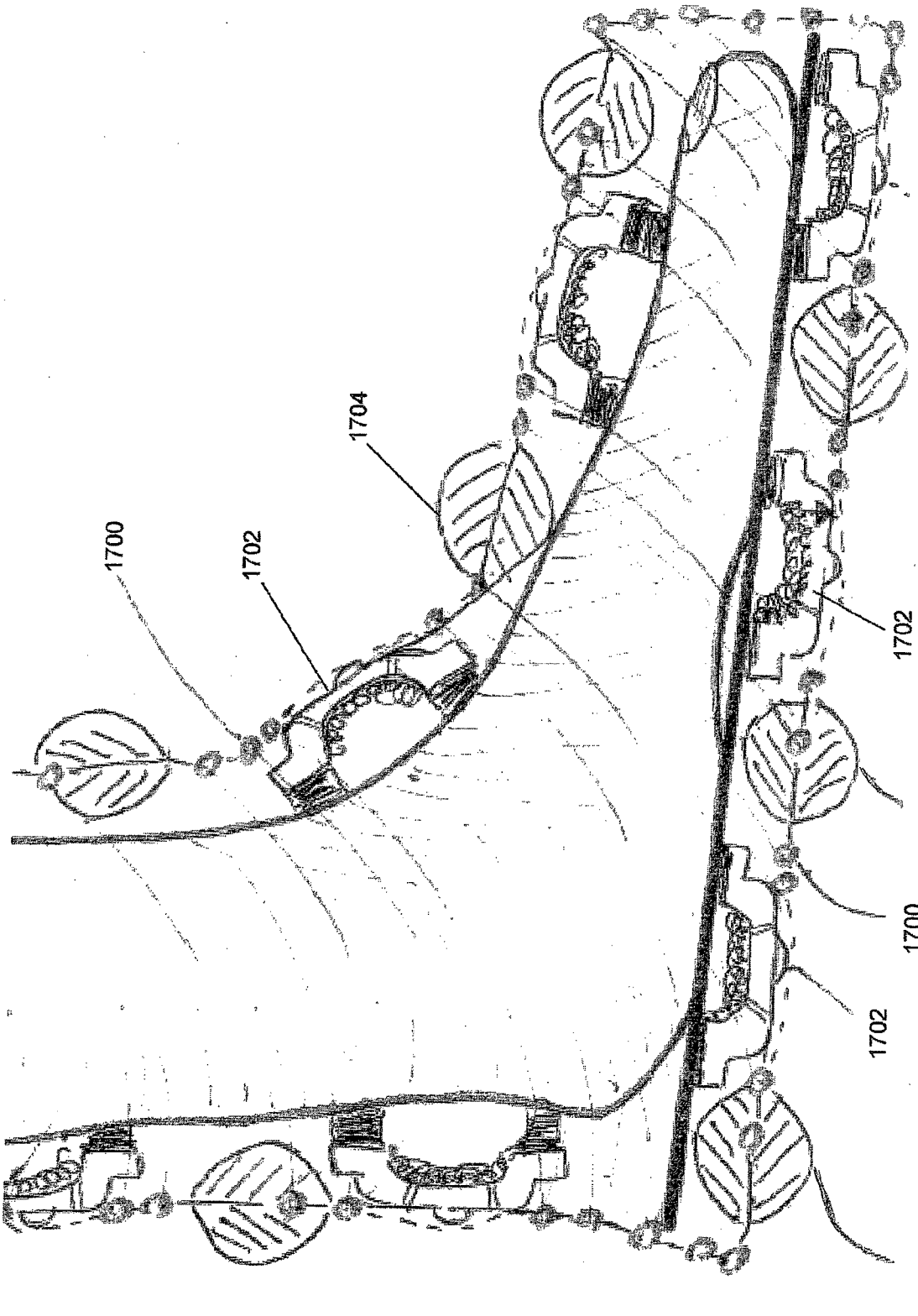


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/000444

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61F 13/00*** (2006.01), ***A61L 15/44*** (2006.01), ***B32B 3/24*** (2006.01), ***B32B 3/30*** (2006.01), ***B32B 33/00*** (2006.01)

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: ***A61F 13*** (2006.01), ***A61L 15/44*** (2006.01), ***B32B 3/24*** (2006.01), ***B32B 3/30*** (2006.01), ***B32B 33/00*** (2006.01)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Questel Orbit, Canadian Patents Database
Keywords: protrusion, projection, bump, layer, hole, perforat+, bandage, dressing, ring, ledge, edge

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP2107899A1, BARBERIO, A., 14 October 2009 (14-10-2009) *Cited in Application* * Figs. 1, 2a, 2b, 6; Paragraphs 0001, 0009, 0017-0020, 0026, 0037, 0038, 0040*	1, 2, 4, 5, 6 7, 8
X Y	US2009093779A1, RIESINGER, B., 09 April 2009 (09-04-2009) *Fig 1a, 2; Paragraphs 0001-0004, 0007, 0011, 0012, 0016, 0019, 0023, 0028, 0029, 0032, 0050; Claims 1, 14-16*	1, 3, 5 7, 8
X Y	US2002115972A1, DABI, S. et al, 22 August 2002 (22-08-2002) *Figs. 3-6; Paragraphs 0001, 0012, 0013, 0015, 0032-0041, 0045*	1, 5 7,8
Y	US2010268144A1, LU, Y.-P. et al, 21 October 2010 (21-10-2010) *Paragraphs 0016, 0019*	7, 8

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

☑ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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
08 July 2014 (08-07-2014)	17 July 2014 (17-07-2014)

Name and mailing address of the ISA/CA	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Allison Bramwell (819) 934-8566

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO2009047564A2, COTTON, S., 16 April 2009 (16-04-2009) *Page 6, lines 26-31*	8
A	US2011183109A1, SEYLER, R. J. et al, 28 July 2011 (28-07-2011) *Entire Document*	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2014/000444

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
EP2107899A1	14 October 2009 (14-10-2009)	EP2107899A1	14 October 2009 (14-10-2009)
		EP2107899A4	28 December 2011 (28-12-2011)
		EP2107899B1	11 June 2014 (11-06-2014)
		AU2008204680A1	17 July 2008 (17-07-2008)
		AU2008204680B2	04 April 2013 (04-04-2013)
		CA2689160A1	17 July 2008 (17-07-2008)
		US2011152735A1	23 June 2011 (23-06-2011)
		WO2008083477A1	17 July 2008 (17-07-2008)
US2009093779A1	09 April 2009 (09-04-2009)	US2009093779A1	09 April 2009 (09-04-2009)
		US8603053B2	10 December 2013 (10-12-2013)
		AT512651T	15 July 2011 (15-07-2011)
		CA2651455A1	25 October 2007 (25-10-2007)
		CA2651455C	17 June 2014 (17-06-2014)
		DE102006017194A1	25 October 2007 (25-10-2007)
		DE102006017194B4	04 November 2010 (04-11-2010)
		DK2004116T3	19 September 2011 (19-09-2011)
		EP2004116A1	24 December 2008 (24-12-2008)
		EP2004116B1	15 June 2011 (15-06-2011)
		ES2368090T3	14 November 2011 (14-11-2011)
		WO2007118652A1	25 October 2007 (25-10-2007)
US2002115972A1	22 August 2002 (22-08-2002)	None	
US2010268144A1	21 October 2010 (21-10-2010)	US2010268144A1	21 October 2010 (21-10-2010)
		CA2695796A1	21 October 2010 (21-10-2010)
		EP2258406A2	08 December 2010 (08-12-2010)
		EP2258406A3	30 May 2012 (30-05-2012)
		JP2010253269A	11 November 2010 (11-11-2010)
		TW201038258A	01 November 2010 (01-11-2010)
		TWI409053B	21 September 2013 (21-09-2013)
WO2009047564A2	16 April 2009 (16-04-2009)	WO2009047564A2	16 April 2009 (16-04-2009)
		WO2009047564A3	08 April 2010 (08-04-2010)
		GB0719683D0	21 November 2007 (21-11-2007)
US2011183109A1	28 July 2011 (28-07-2011)	US2011183109A1	28 July 2011 (28-07-2011)
		US8383227B2	26 February 2013 (26-02-2013)
		BRPI1100788A2	24 July 2012 (24-07-2012)
		CN102138842A	03 August 2011 (03-08-2011)
		CN102138842B	04 June 2014 (04-06-2014)
		EP2353562A1	10 August 2011 (10-08-2011)
		JP2011156351A	18 August 2011 (18-08-2011)
		KR20110088447A	03 August 2011 (03-08-2011)
		TW201125546A	01 August 2011 (01-08-2011)
		US2013158496A1	20 June 2013 (20-06-2013)
		US8765250B2	01 July 2014 (01-07-2014)