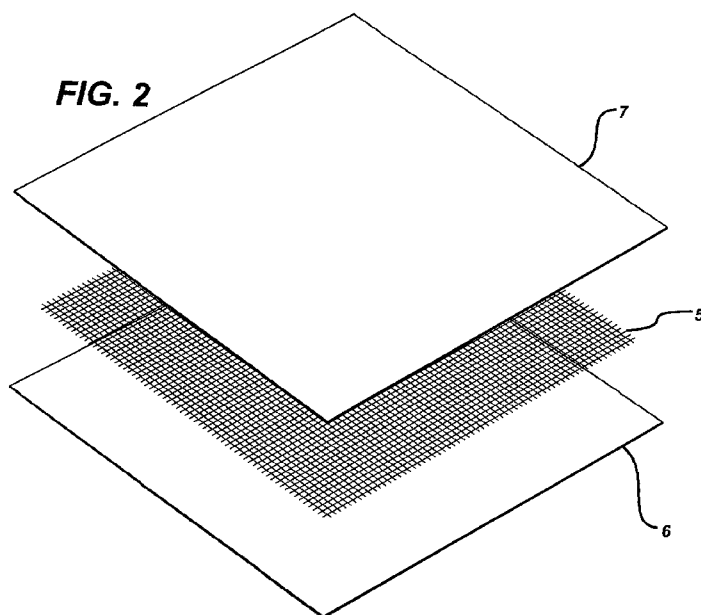




- (51) International Patent Classification:
A61F 13/02 (2006.01)
- (21) International Application Number:
PCT/GB2012/000099
- (22) International Filing Date:
31 January 2012 (31.01.2012)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1101662.3 31 January 2011 (31.01.2011) GB
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- (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, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, 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, MD, 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, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report (Art. 21(3))

(54) Title: SILICONE WOUND DRESSING LAMINATE AND METHOD FOR MAKING THE SAME



(57) Abstract: A method of making a wound dressing comprising the steps of: providing an apertured substrate layer; coating the substrate layer with a fluid silicone prepolymer composition; thermally partially curing said silicone prepolymer composition to form a partially cured silicone coating on the substrate; laminating the coated substrate layer to a base layer to form a laminate having said partially cured silicone coating in contact with a surface of the base layer; followed by exposing the laminate to ionizing radiation, to further cure the partially cured silicone coating and to bond the silicone coating to said surface of the base layer. The radiation cure results in strong bonding between the siliconized substrate and incompatible base layers such as polyurethane foams. Also provided are wound dressings obtainable by the process of the invention.

SILICONE WOUND DRESSING LAMINATE AND METHOD FOR MAKING THE SAME

The present invention relates to wound dressings comprising a laminate of a base layer and a silicone-coated layer, wherein the silicone-coated layer is bonded to the base layer.

5 The invention also relates to methods of making such laminates.

Dressing materials for application to the surface of wounds should desirably be non-adherent to the moist wound surface. For this purpose a soft non-adherent or tacky (i.e. weakly adhesive) hydrophobic material is suitable for the wound contacting surface of
10 the material. The wound contacting material should desirably be liquid-permeable to allow passage of wound fluid, especially for heavily exuding wounds such as burns. The material should also be non-irritating, inexpensive, and stable to common sterilization methods such as ionizing radiation.

15 Traditional "tulle gras" dressings generally consist of a layer of gauze coated with paraffin wax. Such dressings have a number of desirable properties, and for this reason have been used extensively for many years. Among these advantages are their high degree of conformability and deformability, and the fact that their tackiness makes them very easy to apply. That is to say, a tulle gras dressing applied to a wound will usually
20 remain in place simply by adhesion of the paraffin wax to the patient's skin (or to itself in the case of a dressing wrapped around a finger, for example) while a securing bandage is applied. Tulle gras dressings are also quite inexpensive. However, tulle gras dressings do have a number of disadvantages. Principal amongst these is that, although initially non-adherent, they often become "dry" (in the sense of losing their paraffin coating) and
25 consequently adhere to the wound to which they are applied. This effect is due to the paraffin coating becoming mobile at body temperatures and migrating into the wound or being absorbed into the backing of the dressing or bandage. In some cases, removal of a tulle gras dressing which has become dry in this way can cause considerable trauma. Indeed, it is quite common to have to soak tulle gras dressings in order to remove them.
30 If tulle gras dressings are changed more frequently, in an attempt to avoid them becoming attached to the wound, this may delay wound healing and adds to nursing costs.

A further disadvantage of traditional tulle gras dressings is that fibres from the gauze may become incorporated in the wound, as may the paraffin coating of the dressing. Some authorities see the migration of paraffin into a wound as an undesirable effect and any paraffin found in a wound can be difficult to remove with normal aqueous wound
5 cleansing agents. Moreover, the pores of the gauze may become occluded if the paraffin coating is too heavy or as a result of the mobility of the paraffin during use of the dressing. While occlusive dressings are appropriate in some circumstances, it is undesirable that the nursing staff should have no control over whether the dressing used is in fact occlusive.

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Still further disadvantages of conventional tulle gras dressings are that they are effectively opaque and of somewhat unsightly appearance, and the paraffin can run during storage, making them particularly messy to apply.

15 EP-A-0251810 describes wound dressing s that overcome the above disadvantages by replacing the paraffin wax coating of conventional tulle gras by a tacky or non-tacky, hydrophobic silicone coating on a gauze or mesh substrate. In certain embodiments, the gauze may be provided with a tacky silicone coating on one side and a non-tacky silicone coating having a different composition on the other side. Similar materials are
20 described in WO-A-8705206.

EP-A-0342950 describes similar wound dressings having a non-adherent silicone coating. The adherence of the silicone is reduced by addition of an amine-extended polyurethane.

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WO-A-9319710 describes similar dressings further comprising a region of absorbent material laminated to the silicone-coated apertured substrate, and a fluid barrier layer behind the absorbent layer.

30 The above silicone-coated gauze dressings have achieved widespread use. However, a difficulty with the silicone-coated gauzes is that it can be difficult to laminate them securely to further dressing layers, such as a microorganism-impermeable semipermeable backing sheet or an absorbent layer. This is because the hydrophobic

silicone is by its nature completely or substantially non-adherent. It would be desirable to make wound dressings having a laminated structure in which the apertured, silicone-coated wound contacting layer is securely bonded to one or more further layers, such as absorbent layers or continuous backing film layers.

5

WO-A-20100056544 describes gentle-to-skin silicone gel adhesives prepared by crosslinking a silicone prepolymer with electron beam or gamma radiation. The adhesives may be applied to suitable substrates before crosslinking.

- 10 The present inventors have found that normally non-adherent silicone-coated substrates can be strongly bonded to further wound dressing layers, such as absorbent layers or backing sheets, without the use of adhesives or silicone primer layers. This bonding is achieved by applying a silicone-coated layer wherein the silicone is incompletely cured to the further layer, followed by final curing of the silicone with ionizing radiation. The resulting laminates are useful as or in
- 15 wound dressings.

In a first aspect, the present invention provides a wound dressing comprising: a base layer and an apertured layer laminated to the base layer, said apertured layer comprising an apertured substrate and a silicone coating layer on said substrate, wherein the apertured layer has been

20 bonded to the base layer by ionizing radiation-induced bonding of the silicone coating to said base layer.

In a second aspect, the present invention provides a wound dressing comprising: a base layer and an apertured layer laminated to the base layer, said apertured layer comprising an

25 apertured substrate and a silicone coating layer on said substrate, wherein the silicone coating is directly covalently bonded to the base layer.

In a third aspect, the present invention provides a wound dressing comprising: a base layer and an apertured layer laminated to the base layer, said apertured layer comprising

30 an apertured substrate and a silicone coating layer on said substrate, wherein the apertured layer is directly bonded to the base layer and the peel strength required to separate the apertured layer from the base layer is greater than about 200mN/cm, preferably greater than about 300mN/cm, for example from about 400 mN/cm to about 1000 mN/cm.

In a further aspect, the invention provides a method of making a wound dressing comprising the steps of: providing an apertured substrate layer; coating the substrate layer with a fluid silicone prepolymer composition; thermally partially curing said silicone prepolymer composition to form a partially cured silicone coating on the substrate; laminating the coated substrate layer to a base layer to form a laminate having said partially cured silicone coating in contact with a surface of the base layer; followed by exposing the laminate to ionizing radiation, to further cure the partially cured silicone coating and to bond the silicone coating to said surface of the base layer.

It appears that the final cure with ionizing radiation results in chemical (e.g. covalent) bonding between the silicone and the base layer, thereby overcoming the normally non-adherent or weakly adherent nature of the silicone and resulting in a strong bond between the silicone and the base layer. It has been found that the use of certain silicone prepolymer formulations as described below is particularly advantageous for achieving an incomplete thermal cure that results in strong bonding of the silicone and the base layer in the final ionizing radiation treatment.

The term “wound dressing” herein refers primarily to products for topical application to wounds. However, it may encompass products for application to internal wounds. The products of the present invention may also be useful for application to intact skin, for example for transdermal administration of medicaments.

The base layer suitably provides a protective covering, cushioning, mechanical support and/or liquid absorbency to the wound dressing. Suitably, the base layer is formed from a material that is hydrophilic, suitably a material that does not swell or dissolve significantly in water or wound fluid. Suitably, the base layer is in the form of a sheet, for example a sheet having an uncompressed thickness of from about 0.2mm to about 15mm, for example from about 0.5 mm to about 5mm.

The base layer may be any of the layers conventionally used to form layers over a wound contacting layer in a laminated wound dressing, for example absorbent layers or backing layers. In certain embodiments, the base layer is a backing layer in the form of a sheet of continuous semipermeable or impermeable polymer. In other embodiments the base layer may be an absorbent layer for example a hydrophilic foam, a sponge, a film, or a textile

layer. The textile may be nonwoven, knitted or woven. In yet other embodiments the base layer may be a layer of pressure-sensitive adhesive, for example a layer of adhesive coated on a backing sheet. In these embodiments, the bonding between the silicone coating and the adhesive layer is stronger than would be expected simply from the effect
5 of the adhesive, as will be explained further below.

The present invention achieves strong bonding between the silicone coating and base layer surfaces that are normally incompatible with and non-adherent to silicone, including hydrophilic surfaces such as polyurethane or hydrocolloid surfaces. This
10 bonding is achieved without the use of a silicone primer to improve adhesion, i.e. it is direct bonding between the silicone and the material of the base layer.

In particular embodiments, the base layer is (a) a semipermeable or impermeable polymer film, or (b) a hydrophilic foam sheet, or (c) a nonwoven web.

15 Suitable semipermeable or impermeable polymer films for the base layer include any of the semipermeable films conventionally used to form a backing sheet of wound dressings. The films are suitably continuous, i.e. they do not comprise macroscopic apertures that would allow passage of wound fluid. Suitably, the base layer in these embodiments is also microorganism-impermeable. Suitable continuous conformable
20 base layers of this type will suitably have a moisture vapor transmission rate (MVTR) of the base layer alone of 300 to 5000 g/m²/24hrs, suitably 500 to 2000 g/m²/24hrs at 37.5 °C at 100% to 10% relative humidity difference. It has been found that such moisture vapor transmission rates allow the wound under the dressing to heal under moist conditions without causing the skin surrounding the wound to macerate. The base layer
25 thickness in these embodiments is suitably in the range of 10 to 1000 micrometers, more suitably 100 to 500 micrometers.

Suitable polymers for forming the base layer in these embodiments include polyurethanes and polyalkoxyalkyl acrylates and methacrylates. Suitably, the base layer
30 in these embodiments comprises a continuous layer of a high density blocked polyurethane foam that is predominantly closed-cell. A suitable backing sheet material is the polyurethane film available under the Registered Trade Mark ESTANE 5714F.

Also suitable are elastomeric polymeric esters such as Du Pont HYTREL (Registered Trade Mark).

Suitable hydrophilic foam sheets for use as the base layer include polyurethane foams, carboxylated butadiene-styrene rubber, polyacrylate, polyvinyl or cellulosic foams. The hydrophilic foam may be open-cell or closed-cell. Suitably, the foam comprises a polyurethane, and more suitably it comprises at least 50% by weight of one or more polyurethanes, for example at least 75% by weight thereof.

- 10 The hydrophilic polyurethane foam materials are formed by reacting particular diisocyanates or isocyanate-capped prepolymers with suitable chain extending compounds having amine and/or alcohol multiple functionality. Chain terminating compounds such as mono-amines or monohydric alcohols may be included in the reaction mixture. Water may be included in the reaction mixture, since it reacts with
- 15 isocyanate to liberate carbon dioxide for foaming the mixture.

The hydrophilic foams used in the base layers of the invention may also have the property of swelling and expanding when water is absorbed. The degree of swelling of the hydrophilic foams on complete saturation with an aqueous medium is typically at

20 least 100% (expressed in terms of increase in volume), and suitably at least 200%. Preferred foams swell by 400 to 800%. Despite this high degree of swelling, however, the foams of the invention retain their integrity even after absorption of large quantities of water. Typically, the cells of the hydrophilic foams have an average diameter in the range 0.1 to 0.6 mm. Suitably hydrophilic foams are as described in EP-A-0541391.

25 These foam layers are available from Systagenix Wound Management under the Registered Trade Marks TIELLE and HYPOL.

Suitably, the basis weight of the hydrophilic foam when used as a base layer in the materials of the present invention is from 0.2 to 1.5 kg/m², more suitably 0.5 to 1.0

30 kg/m².

Suitable textiles for use as the base layer include any of those conventionally used for absorbent products, including cellulose woven or nonwoven webs, or cellulose

derivatives such as viscose, rayon or oxidized regenerated cellulose. In certain embodiments, the fabric comprises at least about 10wt.% of hydrogel-forming absorbent fibers based on the dry weight of the fabric, for example, the fabric comprises at least about 20wt.% of the hydrogel-forming fibers, for example from about 30wt.% to about 50wt.% of such fibers.

The term "hydrogel-forming fibers" refers to fibers that can absorb at least about twice their own weight of water, suitably at least about four times their own weight of water, to form a hydrogel. The fibers are normally insoluble in water. Suitable materials for the hydrogel-forming fibers include alginates, carboxymethylcelluloses, hydroxyethyl-celluloses, polyacrylates, and hyaluronates. Suitable materials are calcium alginate and sodium carboxymethylcellulose and mixtures thereof.

Suitably, the fabric comprises at least about 10wt.% based on the dry weight of the fabric of substantially non-water-absorbent textile fibers, and suitably it comprises at least about 20wt.% of such fibers, for example from about 30wt.% to about 60wt.% of such fibers. Suitable non-absorbent textile fibers include polyamide fibers such as nylon fibers, polyolefin fibers, and viscose fibers.

Suitably, the absorbent layer is similar to those described in WO03/053584. That is to say, the absorbent layer comprises or consists essentially of a nonwoven fabric made up of a mixture of from about 10wt.% to about 90wt.% of hydrogel-forming absorbent fibers and from about 90wt.% to about 10wt.% of non-absorbent textile fibers. In certain embodiments, at least some of the non-absorbent textile fibers are coated with metallic silver (Ag^0) as an antimicrobial agent. Suitably, the amount of silver in the fabric is from about 0.1% to about 10wt.%, based on the dry weight of the fabric. Textiles of this kind are available from Systagenix Wound Management under the Registered Trade Mark SILVERCEL.

The basis weight of the textile base layer may be in the range of 50-500 g/m^2 , such as 100-400 g/m^2 . The uncompressed thickness of the textile layer may be in the range of from 0.5 mm to 10 mm, such as 1 mm to 4 mm. The free (uncompressed) liquid absorbency measured for physiological saline may be in the range of 5 to 30 g/g at 25°C.

In embodiments, the base layer may be a layer of adhesive, in particular a pressure-sensitive adhesive. The base layer adhesive may be moisture vapor transmitting and/or patterned to allow passage of water vapor therethrough. The adhesive layer is suitably a continuous moisture vapor transmitting, pressure-sensitive adhesive layer of the type conventionally used for island-type wound dressings, for example, a pressure sensitive adhesive based on acrylate ester copolymers, polyvinyl ethyl ether and polyurethane as described for example in GB-A-1280631. The basis weight of the adhesive layer is suitably 20 to 250 g/m², and more suitably 50 to 150 g/m². Polyurethane-based pressure sensitive adhesives are preferred.

In further embodiments, the base layer may comprise or consist of an odor absorbent textile, such as a charcoal cloth. GB-A-1301101 EP-A-0053936 and GB-A-2127389 describe activated carbon cloth for use as an odor absorbent wound dressing, for example in the treatment of heavily infected wounds, varicose ulcers and fungating carcinomas. The cloth is produced by carbonising a cellulosic cloth, such as a suitably treated woven viscose rayon cloth. The activated carbon cloth is relatively friable, and tends to shed particles of carbon in use. For this reason it is preferably enclosed or covered by a suitable protective, permeable cover, such as a spunbonded nylon nonwoven or a gauze to prevent particles of carbon from escaping into the wound in use. Products of this type are commercially available under the Registered Trade Mark ACTISORB from Systagenix Wound Management. In these embodiments, the silicone coated substrate may be bonded directly to the charcoal cloth, or it may be bonded to a scrim enclosing the charcoal cloth.

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In further embodiments, the base layer may comprise or consist of a second layer of the silicone coated apertured layer, which may be the same or different from the first layer of silicone coated apertured material. It has surprisingly been found that the methods of the present invention can achieve strong bonding between layers of apertured, silicone-coated materials. These embodiments allow the formation of envelopes of the silicone-coated substrate material having edges bonded together in face-to-face relation. The envelopes can contain any of the wound dressing materials described above, in sheet or particulate form.

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The silicone coated substrate is apertured, whereby the substrate is permeable to wound fluid. For example, the substrate may be a mesh or web or fabric suitably formed from a woven, nonwoven or knitted textile, or it may be a molded mesh.

- 5 In certain embodiments the substrate is a fabric such as a gauze, or a mesh, having an array of apertures. The size and shape of the apertures in the substrate are not critical, but the apertures should suitably be such as to ensure that the material can be adequately coated with silicone gel without them becoming occluded. The apertures generally have an aspect ratio of from 1:1 to 5:1, and preferably from 1:1 to 2:1. For example, the apertures
10 may be approximately circular or approximately square. The apertures suitably have an average diameter of from 0.3 to 4 mm, and more suitably from 0.5 to 2 mm.

The substrate is suitably formed from any medically acceptable material, such as cellulose, polyolefins, polyesters, or polyamides. An especially suitable material is
15 cellulose acetate gauze. Substrates having a weight of from 15 to 200 g/m² are generally found to be suitable for use in the products of the invention, and fabrics weighing from 50 to 150 g/m² are most suitable. For example, certain embodiments employ a fabric of from 80 to 120 g/m².

- 20 Suitably, the silicone-coated substrate product retains open apertures to allow passage of wound fluid through the coated substrate. For example, an array of apertures may extend through said silicone coatings and the substrate layer. The open area of the coated substrate in the final product may for example be from about 1% to about 70%, for example from about 10% to about 50%.

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Suitably, the substrate is coated on both sides with the silicone coating, so that the face of the substrate opposite the base layer presents a silicone surface to the wound. The wound facing silicone surface may be non-adherent, or it may be tacky.

- 30 For example, the tackiness of the wound facing surface as measured by a loop tack test (described below) is suitably from about 0.4N to about 2N, more suitably from about 0.5N to about 1.5N.

The total coating weight of the silicone on the substrate is suitably from about 50 g/m² to about 500 g/m², for example from about 80 g/m² to about 200 g/m², typically from about 100 g/m² to about 150 g/m². The silicone is suitably a soft skin adhesive silicone composition. Suitable chemistry is described below. The silicone is suitably hydrophobic.

The effectiveness of encapsulation by silicone means that the substrate may be printed or dyed with decorative or informative matter with little danger of the ink or dye being released into the wound to which the dressing is applied. Visible indicia, such a colour or writing, may be provided on the substrate.

The coated substrate is laminated to the base layer, and optionally to further layers, to form the wound dressings according to the invention. Some of the laminate structures falling within the scope of the invention are as follows:

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Embodiment 1: An absorbent base layer in the form of a sheet of absorbent material (or adsorbent material, such as charcoal cloth) having upper and lower surfaces, and having the silicone-coated substrate bonded to at least one of the surfaces to provide a non-adherent wound-contacting surface. In certain embodiments, silicone-coated substrates are bonded to both surfaces to provide a dressing material that can be applied to the wound in either orientation.

Embodiment 2: a laminate according to Embodiment 1, further laminated to an adhesive-coated backing sheet to provide an absorbent dressing with a liquid-impermeable backing sheet. In these embodiments, the laminate is formed so that at least the wound facing surface of the absorbent layer opposite to the backing sheet is bonded to the silicone-coated substrate to provide a non-adherent wound contacting surface. Further layers, such as further absorbent layers, may be provided between the absorbent layer and the backing sheet.

Embodiment 3: Similar to Embodiment 2, but in the form of an island dressing such that the adhesive-coated backing sheet is larger than the absorbent layer whereby a margin of the backing sheet extends around the edges of the absorbent layer. In these embodiments, the silicone-coated substrate may be coterminous with the absorbent

island, or it may extend beyond the edges of the island whereby a margin of the silicone-coated substrate is bonded to the backing sheet or to the adhesive coating on the backing sheet around the absorbent island.

Embodiment 4: This embodiment has the silicone-coated substrate directly bonded to a liquid-impermeable backing sheet, or to a layer of adhesive on the backing sheet, i.e. there is no absorbent layer. These embodiments are suitable for more lightly exuding wounds for which water vapour permeability through the semipermeable backing sheet is sufficient.

Embodiment 5: This embodiment has the silicone-coated substrate directly bonded to a liquid-impermeable backing sheet, or to a layer of adhesive on the backing sheet, and further comprising an absorbent layer or absorbent island over the silicone-coated substrate, i.e. the substrate is sandwiched between the absorbent layer and the base layer. In the case of island dressings, the substrate may extend to the edges of the backing sheet to provide a more skin-friendly surface to the margin of the dressing. A further layer of the silicone-coated substrate may be bonded to the wound facing surface of the absorbent layer or island.

Embodiment 6: Two pieces (or one folded piece) of silicone coated substrate encasing an absorbent or adsorbent layer such as charcoal cloth. The silicone coated substrate is larger than the absorbent /adsorbent layer whereby the substrate overlaps around the edges of the absorbent/adsorbent layer to form margins which are bonded together in face-to-face fashion to form an envelope of the silicone-coated substrate around the absorbent /adsorbent layer.

Suitably, the wound dressing according to the present invention comprises less than 10% water prior to use as an absorbent, more suitably less than 5% water and more suitably it contains less than 2% of water before use.

Suitably, the wound dressing according to the present invention has a maximum total uncompressed thickness of from about 0.2mm to about 15mm, for example from about 0.5 mm to about 5mm. Suitably, the wound dressing according to the present invention is in the form of a piece having a total area of from about 1cm² to about 1000cm², for example from about 5cm² to about 400cm².

The dressing may comprise one or more releasable cover sheets over the wound facing surface of the substrate opposite to the base layer to protect the substrate surface before use. The cover sheets may comprise a film of polyethylene, polypropylene or
5 fluorocarbons and papers coated with these materials. Suitably, the cover sheet is a release-coated paper sheet, such as a silicone release-coated paper sheet. Examples of silicone-coated release papers are POLYSLIK (Registered Trade Mark) supplied by H.P. Smith & Co., offered in various formulations to control the degree of adhesion of the paper to the silicone coated substrate surface.

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In certain embodiments, the cover sheets may comprise two or more parts, such as a first removable part having a first edge and a second removable part that meets the first part along the first edge. Suitably, along each of said edges where the parts meet, one of the parts is folded back to provide a folded-back margin, and the other part overlaps the said
15 folded-back margin. This provides an easy-to-grasp margin on each part in the region of overlap to assist removal of the cover sheet by the care giver. In other embodiments, the cover sheets may comprise three parts, for example as described in detail in EP-A-0117632.

20 Suitably, the wound dressings of the invention are sterile and packaged in a microorganism-impermeable container.

In a further aspect, the invention provides a method of making a wound dressing comprising the steps of: providing an apertured substrate layer; coating the substrate
25 layer with a fluid silicone prepolymer composition; thermally partially curing said silicone prepolymer composition to form a partially cured silicone coating on the substrate; laminating the coated substrate layer to a base layer to form a laminate having said partially cured silicone coating in contact with a surface of the base layer; followed by exposing the laminate to ionizing radiation, to further cure the partially cured silicone
30 coating and to bond the silicone coating to said surface of the base layer.

The substrate layer is suitably as previously described for the products of the invention. Suitably, the substrate layer is permeable to the fluid silicone prepolymer composition.

The step of coating may be performed in any conventional way, for example immersion, spraying, or doctor blade. The step of coating suitably comprises passing the coated substrate through nip rollers to ensure smooth coating and penetration of the coating composition. Suitably, the step of coating is followed by a step of blowing gas (such as
5 air) through the substrate to ensure that the apertures in the material are open after coating.

The fluid silicone coating composition is suitably substantially or completely solvent-free. The methods of the present invention allow substrates having silicone coating on
10 the upper and lower surfaces to be made with a single silicone coating composition on both surfaces.

Suitably, the silicone composition is a so-called soft skin adhesive silicone elastomer. Such silicones can be made by an addition reaction (hydrosilylation) between (a) a vinyl
15 functional polydimethyl siloxane, such as bis-dimethyl vinyl PDMS, and (b) a hydrogen functional siloxane, such as dimethyl, methylhydrogen siloxane copolymers, hydrogen dimethylsiloxy terminated PDMS. The cure reaction is catalyzed by a hydrosilylation catalyst, such as a noble metal catalyst, suitably a platinum catalyst. Suitably the silicone prepolymer composition further comprises a polymerization inhibitor that is
20 evaporated from said composition during said step of thermally partially curing, for example 2-methyl-3-butyn-2-ol. The polymerization inhibitor is suitably present in an amount of from about 0.001wt.% to about 1wt.%, for example from about 0.01wt.% to about 0.1wt.% before curing.

25 Silicone skin adhesive compositions are suitably supplied as two-part systems: Part A contains at least the vinyl prepolymer and the catalyst, while Part B contains the vinyl prepolymer and the SiH siloxane cross linker. The components are mixed immediately before use, optionally with addition of the polymerization inhibitor.

30 In embodiments, the silicone coating composition comprises or consists essentially of the following components:

(A) a diorganopolysiloxane having at least 2 alkenyl groups in each molecule;

- (B) an organohydrogenpolysiloxane having at least 2 silicon-bonded hydrogen atoms in each molecule, in a quantity sufficient for the ratio between the number of moles of silicon-bonded hydrogen atoms in this component and the number of moles of alkenyl groups in component (A) to have a value of from about 0.6:1 to about 20:1,
- 5 (C) optionally a platinum group metal catalyst suitably in a quantity providing 0.1 to 500 weight parts as platinum group metal per 1,000,000 weight parts component (A); and
- (D) a volatile polymerization inhibitor, suitably selected from: alkyne alcohols such as 2-methyl-3-butyn-2-ol, 3,5-dimethyl-1-hexyn-3-ol, and phenylbutynol; ene-yne
- 10 compounds such as 3-methyl-3-penten-1-yne and 3,5-dimethyl-3-hexen-1-yne; tetramethyltetrahexenyl-cyclotetrasiloxane; and benzotriazole.

The diorganopolysiloxane, component (A), used in the instant invention is the base component of the total composition. This diorganopolysiloxane must contain at least 2

15 alkenyl groups in each molecule in order for this composition to cure into a rubbery elastic silicone rubber coating composition.

The diorganopolysiloxane (A) comprises essentially straight-chain organopolysiloxane with the average unit formula $R_nSiO_{(4-n)/2}$, wherein R is selected from substituted and

20 unsubstituted monovalent hydrocarbon groups and n has a value of 1.9 to 2.1. R may be exemplified by alkyl groups such as methyl, ethyl, propyl, and others; alkenyl groups such as vinyl, allyl, and others; aryl groups such as phenyl, and others; and haloalkyl groups such as 3,3,3-trifluoropropyl and others. The diorganopolysiloxane (A) should have a viscosity at 25° C of at least 100 centipoise (1 d Pa.s). When such factors as the

25 strength of the silicone rubber coating membrane, and blendability are taken into account, the viscosity of diorganopolysiloxane (A) at 25° C is preferably from 1,000 centipoise (1 Pa.s) to 100,000 centipoise (100 Pa.s). The diorganopolysiloxane (A) may be exemplified by dimethylvinylsiloxyl-endblocked dimethylpolysiloxanes, dimethylvinylsiloxyl-endblocked dimethylsiloxane-methylvinylsiloxane copolymers, and

30 dimethylvinyl-siloxyl-endblocked dimethylsiloxane-methylphenylsiloxane copolymers.

Component (B), an organopolysiloxane that contains at least 2 silicon-bonded hydrogen atoms in each molecule, is a crosslinker for the composition of the instant invention. The

organopolysiloxane (B) may be exemplified by trimethylsiloxy-endblocked methylhydrogenpolysiloxanes, trimethylsiloxy-endblocked dimethylsiloxanemethylhydrogensiloxane copolymers, dimethylphenylsiloxy-endblocked methylphenylsiloxanemethylhydrogensiloxane copolymers, cyclic methylhydrogenpolysiloxanes, and copolymers
5 that contain the dimethylhydrogensiloxy unit and $\text{SiO}_{4/2}$ unit. The organohydrogenpolysiloxane (B) should be added in a quantity that the ratio between the number of moles of silicon-bonded hydrogen atoms in this organohydrogenpolysiloxane and the number of moles of alkenyl groups in component (A) has a value of 0.6:1 to 20:1.

10

The platinum group metal catalyst, component (C), used in the compositions is a curing catalyst. The platinum group metal catalyst (C) may be exemplified by platinum micropowder, platinum black, chloroplatinic acid, platinum tetrachloride, olefin complexes of chloroplatinic acid, alcohol solutions of chloroplatinic acid, complexes
15 between chloroplatinic acid and alkenylsiloxanes, rhodium compounds, and palladium compounds. The platinum group metal catalyst (C) should be added generally at 0.1 to 500 weight parts as platinum group metal per 1,000,000 weight parts component (A), and is preferably used at 1 to 50 weight parts as platinum group metal per 1,000,000 weight parts component (A). The reaction will not develop adequately at less than 0.1
20 weight parts, while additions in excess of 500 weight parts are uneconomical.

The coated substrate is then subjected to thermal curing to partially cure the silicone. The thermal coating is suitably performed continuously by passing the coated substrate through an oven. Suitable thermal curing conditions include exposure to a temperature
25 of from about 80°C to about 200°C, for example about 120°C to about 180°C for a time of from about 1 minute to about 10 minutes, for example about 1.5 minutes to about 5 minutes. The elevated temperature results in evaporation of the polymerization inhibitor from the silicone composition and therefore in polymerization of the silicone. The resulting material is chemically polymerized, but capable of further curing by ionizing
30 radiation as explained further below. The partially thermally cured material is dimensionally stable, for example an elastomer or a gel, so that it can readily be laminated onto the base layer without substantial deformation.

The siliconized substrate is suitably laminated to the base layer after the step of thermal polymerizing since the silicone is no longer fluid at this stage so that handling is easier and the porosity of the substrate is preserved in the laminating step. The siliconized substrate is only weakly adhered to the base layer at this stage.

5

Suitably, the releasable cover sheet is applied over the surface of the substrate opposite the base layer also at this stage. In other embodiments, the releasable cover sheet is applied after the step of curing with ionizing radiation described below.

- 10 The partially cured material is then subjected to a final cure with ionizing radiation. The ionizing radiation is suitably selected from e-beam radiation and gamma radiation. A variety of procedures for E-beam and gamma ray curing are well-known. The cure depends on the specific equipment used, and those skilled in the art can define a dose calibration model for the specific equipment, geometry, and line speed, as well as other
- 15 well understood process parameters.

Commercially available electron beam generating equipment is readily available. For example, a Model CB-300 electron beam generating apparatus (available from Energy Sciences, Inc. (Wilmington, MA). Generally, a support film (e.g., polyester terephthalate

20 support film) runs through a chamber. Generally, the chamber is flushed with an inert gas, e.g., nitrogen while the samples are e-beam cured. Multiple passes through the e-beam sterilizer may be needed.

Commercially available gamma irradiation equipment includes equipment often used for

25 gamma irradiation sterilization of products for medical applications. Cobalt 60 sources are appropriate. Total absorbed doses are suitably from 20 to 60 kGy, more suitably from about 35 to 50kGy and dose rates are suitably about 7 to 8 kGy/hour.

The step of further curing with ionizing radiation is effective to bond the silicone surface

30 of the substrate strongly to the surface of the base layer. This is thought to be due to the ionizing radiation forming covalent bonds between the silicone and the base layer material. The effect is seen also when the base layer is coated with a conventional pressure sensitive medical adhesive, such as a polyurethane-based pressure sensitive

adhesive. In these cases, a bond is formed with the adhesive that has much higher peel strength than the bond formed with the adhesive before irradiation.

Suitably, the method comprises the step of packaging the material in a microorganism-
5 impermeable container prior to the step of further curing with ionizing radiation, whereby the step of further curing also sterilizes the material.

The methods of the invention may be used to make any products according to the invention. Conversely, any of the products of the invention may be obtainable by a
10 method according to the invention. Any feature disclosed herein in relation to any one or more aspects of the invention is suitable for use in any of the other aspects defined herein.

Specific embodiments of the invention will now be described further, by way of
15 example, with reference to the accompanying drawings, in which:

Fig. 1 shows a perspective view of a product according to the invention packaged in a microorganism-impermeable pouch;

Fig. 2 shows a perspective exploded view of a first product according to the invention;

20 Fig. 3 shows a partially cut away view of part of the product of Fig. 2;

Fig. 4 shows a perspective exploded view of a second product according to the invention;

Fig. 5 shows a partially cut away view of part of the product of Fig. 4;

Fig. 6 shows a perspective exploded view of a third product according to the invention;

25 Fig. 7 shows a perspective exploded view of a fourth product according to the invention;

Fig. 8 shows a partially cut away view of part of the product of Fig. 7;

Fig. 9 shows a perspective exploded view of a fifth product according to the invention;

Fig. 10 shows a partially cut away view of part of the product of Fig. 9;

Fig. 11 shows a perspective view of a sixth product according to the invention;

30 Fig. 12 shows a perspective exploded view of a seventh product according to the invention;

Fig. 13 shows a perspective view of the product of Fig. 12;

Fig. 14 shows a perspective partially exploded view of an eighth product according to the invention;

Fig. 15 shows a perspective exploded view of a ninth product according to the invention;

5 Fig. 16 shows a perspective view of the product of Fig. 15;

Fig. 17 shows a schematic drawing of the loop tack test configuration used in Procedure 1 below; and

Fig. 18 shows a schematic drawing of the peel strength test configuration used in Procedure 2 below.

10

Referring to Fig. 1, a packaged wound dressing 1 according to the invention is shown. The dressing 2 is sterile and packaged in a microorganism-impermeable envelope 3 of polypropylene or the like having a transparent window 4.

15 Referring to Figs. 2 and 3, the siliconized substrate 5 in this and all of the other embodiments shown in the drawings comprises a substrate of cellulose acetate gauze of density 107 grams per square meter nominal, coated with a hydrophobic, tacky, crosslinked silicone gel, prepared as described below. The silicone composition penetrates the gauze to form a single, chemically homogeneous silicone phase coating
20 the strands of the gauze. The coated substrate 5 has an array of apertures extending through the substrate and the silicone to allow passage of wound fluid through the material. The nominal total coating weight of the silicone is 120-130 grams per square meter.

25 The upper siliconized surface is bonded to a base layer 6, which in this embodiment is a semipermeable microporous polyurethane backing layer, which may or may not be coated with a polyurethane pressure-sensitive adhesive layer. The opposite surface of the siliconized substrate is covered by a release sheet 7 of siliconized paper that can be peeled off to expose the siliconized surface for application to a wound or to skin.

30

Referring to Figs. 4 and 5, the product 10 according to this embodiment comprises a siliconized substrate gauze 5 and releasable cover sheet 7 as before, but in this embodiment the base layer 11 is a sheet of water-absorbent hydrophilic polyurethane

foam prepared as described in EP-A-0541391. The foam can absorb wound fluid and swell in use, while remaining strongly bonded to the siliconized gauze wound contacting layer 5.

- 5 Referring to Fig. 6, the product according to this embodiment comprises a siliconized substrate gauze 5 as before, but in this embodiment the base layer 12 is a sheet of water-absorbent nonwoven textile, such as a nonwoven viscose web or a nonwoven alginate/nylon web. The absorbent textile 12 can absorb wound fluid and swell in use, while remaining strongly bonded to the siliconized gauze wound contacting layer 5. A
10 backing sheet 14 of semipermeable film coated with adhesive 15 is applied over the opposite surface of the textile layer to prevent leakage of liquid from the back of the dressing.

Referring to Figs. 7 and 8, the product according to this embodiment comprises a
15 siliconized substrate gauze 5 laminated to a hydrophilic foam layer and cover sheet as for the embodiment of Fig. 4. The embodiment of Figs 7 and 8 further comprises a backing sheet 14 of adhesive-coated semipermeable film as described for Fig. 6 that is applied over the opposite surface of the foam layer from the siliconized substrate to prevent leakage of liquid through the dressing.

20

Referring to Figs. 9 and 10, the product 16 according to this embodiment is an island dressing. It comprises a siliconized substrate gauze 5 laminated to a hydrophilic liquid-absorbent layer of textile material 17 and a polyurethane semipemeable backing sheet 14 as for the embodiment of Fig. 6. A silicone-coated paper release sheet 7 is provided over
25 the wound-facing surface of the gauze 5. However, the area of the textile material 17 is less than that of the gauze 5 or the backing sheet 14, whereby a margin 18 of the backing sheet extends around all edges of the textile material. The siliconized gauze is therefore directly bonded to the backing sheet over the margin, as well as to the wound-facing surface of the textile layer 17. This bonding of the siliconized gauze to the margin 18 of
30 the backing sheet 14 helps to keep the absorbent island in place on the backing sheet, and also provides the margin 18 with a skin-friendly, weakly adherent (tacky) siliconized surface for contact with the skin around a wound. The island dressings are less prone to

leakage of wound fluids from the edges of the dressing than the simple laminates described above.

Referring to Fig. 11, the product 20 is an envelope-type dressing formed from upper and lower sheets 5,19 of siliconized gauze, which may be separate sheets or a single sheet folded over. An island 17 of hydrophilic liquid-absorbent textile material is located centrally between the sheets 5,19. The sheets 5,19 are bonded to the island 17 and to each other in the marginal area around the island 17. The resulting envelope can be applied to a wound in either orientation.

10

Referring to Figs. 12 and 13, the product 21 according to this embodiment is an island dressing similar to that of Figs. 9 and 10. It comprises a siliconized substrate gauze 5 laminated to a hydrophilic liquid-absorbent layer of textile material 17 and a polyurethane semipemeable backing sheet 14 as for the embodiment of Fig. 6. A layer of polyurethane pressure-sensitive adhesive 15 is provided over the wound-facing surface of the backing sheet 14. In certain alternative embodiments, the gauze 5 is coterminous with the island 17 so that the margin 18 is solely adhesive-coated to provide adhesion to skin around a wound.

Referring to Fig. 14, an alternative island dressing structure is shown wherein the siliconized gauze layer 5 is laminated directly to a semipermeable polyurethane backing sheet 14, and an absorbent island 17 is laminated over and bonded to the gauze layer 5. In these embodiments, the gauze layer 5 acts as a tie layer to bond the absorbent island 17 to the backing sheet. A further siliconized gauze layer (not shown) may be bonded over the top of the absorbent layer, either coterminous with the absorbent layer 17 or coterminous with the backing sheet 14, in similar fashion as for the embodiments of Figs. 9-10 or 12-13.

Referring to Figs. 15 and 16, this embodiment is a sandwich structure having upper and lower sheets of siliconized gauze 5,19 sandwiching and bonded to a layer of nonwoven textile absorbent material 12. Suitably, the layers 5,12 and 19 are coterminous, or a small margin 24 of layers 5,19 directly bonded to each other may extend around the edges of the dressing.

30

The products according to the invention may be made by a process according to the invention. This process starts from a continuous web of cellulose acetate gauze that is passed through a fluid silicone coating composition and nip rollers to coat and
5 impregnate the gauze with the silicone composition. The silicone coating composition is prepared by mixing Components A and B of a soft silicone skin adhesive silicone elastomer kit supplied by Dow Corning under product reference Q7-9177. The components are mixed in weight ratio 50:50. Component A comprises a bis-dimethylvinyl terminated polydimethylsiloxane and a platinum catalyst. Component B
10 comprises a bis-hydride terminated polydimethylsiloxane. To the mixture is added 2-methyl-3-butyn-2-ol inhibitor at a concentration of 0.02wt.%.

The coated substrate then passes over a blower 17 to open the apertures of the coated substrate that may have been occluded by the silicone.

15

The coated gauze is then passed through an oven 18 held at 150°C. Typical conditions are 5 passes at 4.2m/min, total residence time 1.5 minutes. This results in thermal partial cure of the silicone coating. The coated material is then allowed to cool, and the base layer and a release coated paper cover sheet are then continuously applied to the upper
20 and lower surfaces.

The material is then cut and packaged as shown in Fig. 1, followed by gamma irradiation with 35-50kGy of Cobalt 60 radiation at 7-9kGy/hr to sterilize the products and complete the cure. The irradiation curing results in a further increase in both hardness
25 and tackiness of the silicone coating, and further bonds the silicone coating strongly to the base layer.

Procedure 1: Measurement of surface tackiness by the loop tack test

The tackiness of the silicone coatings produced by the methods of the invention was
30 measured in a tensile tester, such as an Instron tester, using the set-up shown in Fig. 17.

Samples of the coated fully cured gauze laminates were cut to dimensions 5 x 9.5cm. Margins of 1cm were marked out along the long edges by drawing straight lines 1cm

from the long edges. The cover sheets were removed, and the sheet of coated gauze 30 was looped around and the 1cm margins 30,32 on opposed edges of one surface (opposite the surface being measured) were applied firmly to opposite sides of a 2mm thick metal spacer bar 34. Strips of polypropylene film 1cm wide 36,37 were then
5 applied to the opposite surfaces of the coated gauze opposite the spacer bar 34 to prevent the coated gauze from adhering to the jaws of the measurement device.

The assembly of polypropylene strips, coated gauze and spacer bar was then gripped in the jaws 38 of the Instron tester. The loop of coated gauze 40 having the surface under
10 test outermost was then lowered onto a clean polycarbonate surface 42 of dimensions 15.5cm x 3.8cm so that the loop adheres to the surface, and raised to detach the loop from the surface. Lowering and raising are performed at 300mm/min, and the minimum distance between the jaws 38 and the polycarbonate surface 42 is 15mm. The measured tack (in Newtons) is the maximum force measured while detaching the loop from the
15 surface. Average of three measurements was used.

Procedure 2: Measurement of Peel Strength

The peel strength of the laminates produced by the methods of the invention was measured in a tensile tester, such as an Instron tester, using the set-up shown
20 schematically in Fig. 18. The test strip 50 is positioned horizontally with the substrate layer and base layer in respective jaws 52,54 of the tester to give 180 degree peel. The test was performed on strips of laminate of dimensions 25.4mm x 254mm. The pull rate was 400mm/minute. The reported peel strength was the average over the length of the strip in grams force (gf), whereby $1\text{gf} = 3.86\text{mN/cm}$ (cm refers to the width of the strip
25 in cm).

Example 1

Samples were prepared by the method of the present invention. The first sample comprises a silicone-coated gauze (ADAPTIC TOUCH available from Systagenix
30 Wound Management Manufacturing Ltd., Gargrave, UK) laminated to a polyurethane hydrophilic foam sheet (TIELLE, available from Systagenix Wound Management Manufacturing Ltd., Gargrave, UK).

Peel strength tests on the laminate before and after the final gamma sterilization and crosslinking step are shown in Table 1 below.

5

Table 1

TIELLE + TOUCH (separate sterilisation)	Average Load (gf)
1	5.71
2	4.87
3	4.58
Average	5.05
TIELLE + TOUCH (sterilised together)	
1	126.36
2	141.45
3	142.90
Average	136.90

It can be seen that the siliconized substrate adheres only weakly to the foam before irradiation, but exhibits strong bonding after irradiation.

10

Example 2

The method of Example 1 was repeated to prepare a laminate of a silicone-coated gauze (ADAPTIC TOUCH available from Systagenix Wound Management Manufacturing Ltd., Gargrave, UK) laminated to a semipermeable wound dressing backing sheet
 15 formed of 0.4mm high-density polyurethane foam of a blocked toluene di-isocyanate nature coated with an aliphatic polyurethane adhesive.

Peel strength tests on the laminate before and after the final gamma sterilization and crosslinking step are shown in Table 2 below. It can be seen that the siliconized
 20 substrate adheres only weakly to the foam before irradiation, but exhibits strong bonding after irradiation.

Table 2

Backing + Substrate (after separate sterilisation)	Average Load (gf)
1	3.44
2	3.94
3	too low to register
Average	3.69
Backing + Substrate (sterilised together)	
1	84.44
2	73.26
3	95.59
Average	84.43

5

It can be seen that gamma sterilization of the silicone coated substrate laminated to the base layer results in a very large increase in the bonding strength of the laminate. The siliconised apertured substrate can thus provide a non-adherent wound contacting surface to the polyurethane backing sheet.

10

Example 3

The method of Example 1 was repeated to prepare a laminate of a silicone-coated gauze (ADAPTIC TOUCH available from Systagenix Wound Management Manufacturing Ltd., Gargrave, UK) laminated to second sheet of the same silicone-coated gauze.

15

Peel strength tests on the laminate before and after the final gamma sterilization and crosslinking step are shown in Table 3 below.

Table 3

Substrate + Substrate (sterilised separately)	Average Load (gf)
1	13.14
2	15.90
3	21.71
Average	16.92

Substrate + Substrate (sterilised together)	Average Load (gf)
1	151.19
2	156.12
3	174.84

It can be seen that the siliconized substrate adheres only weakly to itself before irradiation, but exhibits strong bonding after irradiation.

5 Example 4

The method of Example 1 was repeated to prepare a laminate of a silicone-coated gauze (ADAPTIC TOUCH[®] available from Systagenix Wound Management Manufacturing Ltd., Gargrave, UK) laminated to sheet of nonwoven textile (SILVERCEL[®] available from Systagenix Wound Management Manufacturing Ltd., Gargrave, UK). The textile is a calcium alginate needled felt dressing incorporating metallic-silver-coated nylon fibers. The composition is as follows, by weight: calcium alginate and carboxymethyl cellulose (CMC) fibers 60% and silver coated nylon 40%. The basis weight of the fabric layer is about 150 g/m², and the uncompressed thickness of the fabric layer is about 2 mm. The total silver content of the fabric is about 8 wt.%.

15

Peel strength tests on the laminate before and after the final gamma sterilization and crosslinking step are shown in Table 3 below.

Table 4

Silvercel + substrate (sterilised separately)	Average Load (gf)
1	2.87
2	3.05
Average	2.96
Silvercel + Substrate (sterilised together)	
1	299.18
2	336.4
Average	317.79

It can be seen that the siliconized substrate adheres only weakly to itself before irradiation, but exhibits strong bonding after irradiation. In fact, under the peel test conditions the siliconized substrate does not peel from the surface of the textile, but instead the textile itself peels apart.

5

The above examples have been described by way of illustration only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

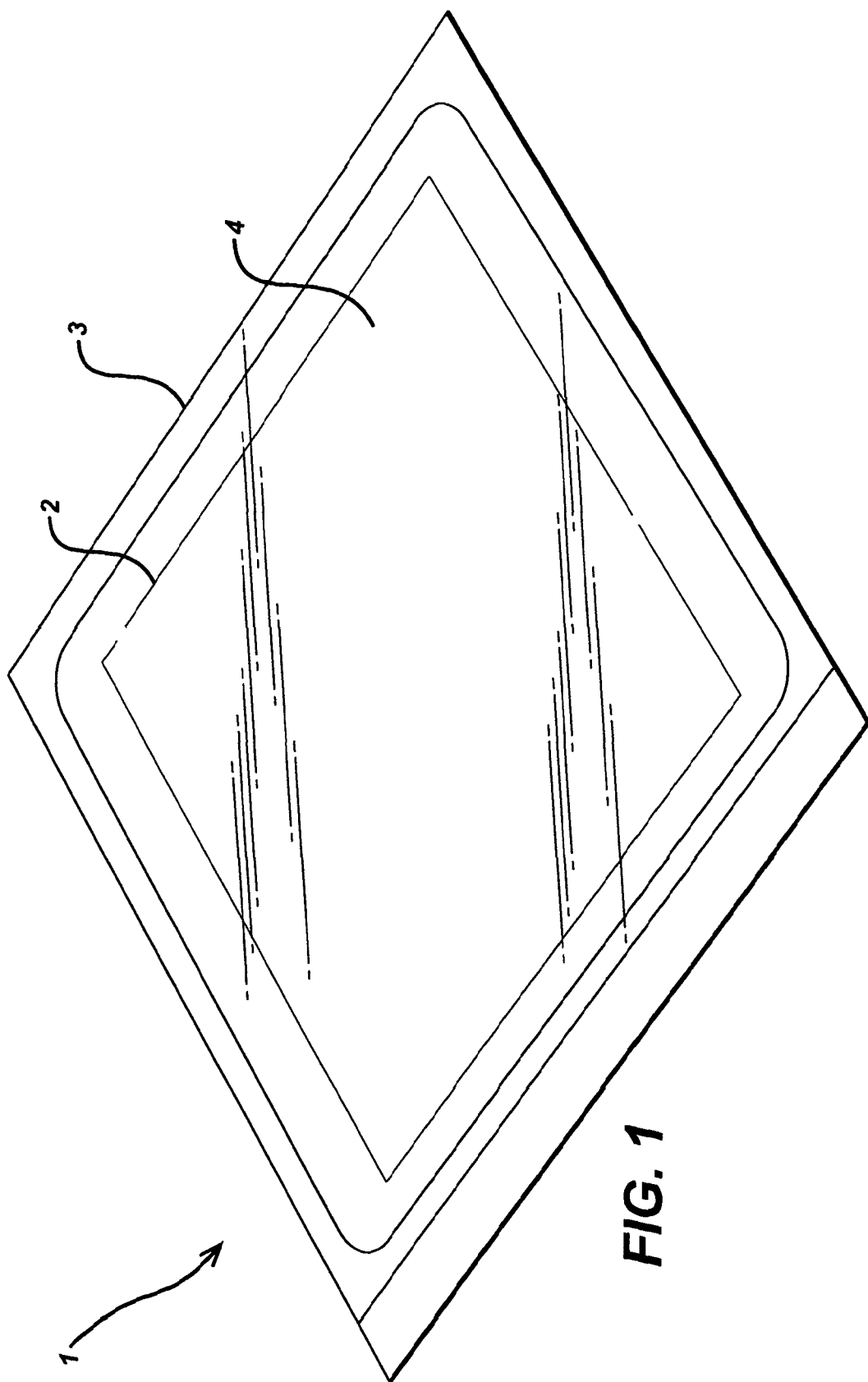
CLAIMS

1. A wound dressing comprising: a base layer and an apertured layer laminated to the base layer, said apertured layer comprising an apertured substrate and a silicone coating layer on said substrate, wherein the apertured layer is directly bonded to the base layer and the peel strength required to separate the apertured layer from the base layer is greater than about 200mN/cm.
2. A wound dressing according to claim 1, wherein the peel strength required to separate the apertured layer from the base layer is greater than about 300mN/cm.
3. A wound dressing according to claim 1 or 2, wherein the apertured layer has been bonded to the base layer by ionizing radiation-induced bonding of said silicone coating to said base layer.
4. A wound dressing according to any preceding claim, wherein the base layer is in the form of a sheet of a polymeric film, foam, sponge, film, a nonwoven, knitted or woven textile, or a second layer comprising an apertured substrate and a silicone coating layer on said substrate.
5. A wound dressing according to any preceding claim, wherein at least a surface of the base layer to which the silicone coating is bonded is hydrophilic.
6. A wound dressing according to any preceding claim, wherein at least a surface of the base layer to which the silicone coating is bonded comprises, consists essentially of, or consists of a polyurethane or a hydrocolloid.
7. A wound dressing according to claim 6, wherein the base layer is a semipermeable polyurethane film or a hydrophilic polyurethane foam sheet.
8. A wound dressing according to claim 6, wherein the base layer is a nonwoven web comprising hydrogel-forming fibres.

9. A wound dressing according to any preceding claim, wherein said substrate is coated on both sides with said silicone coating, and the surface of said silicone coating opposite said base layer is non-adherent or tacky.
- 5 10. A wound dressing according to any of claims 1 to 9 comprising or consisting essentially of an absorbent base layer in the form of a sheet of absorbent or adsorbent material having upper and lower surfaces, and having the silicone-coated substrate bonded to both surfaces to provide a dressing material that can be applied to the wound in either orientation.
- 10 11. A wound dressing according to any of claims 1 to 10 comprising or consisting essentially of an absorbent base layer in the form of a sheet of absorbent or adsorbent material having upper and lower surfaces, and having the silicone-coated substrate bonded to at least one of said surfaces, wherein said absorbent layer is further laminated to an adhesive-coated backing sheet to provide an absorbent dressing with a liquid-
15 impermeable backing sheet.
12. A wound dressing according to claim 11, in the form of an island dressing wherein the adhesive-coated backing sheet is larger than the absorbent layer whereby a margin of the backing sheet extends around the edges of the absorbent layer.
13. A wound dressing according to any of claims 1 to 9 comprising or consisting
20 essentially of the silicone-coated substrate directly bonded to a liquid-impermeable backing sheet, or to a layer of adhesive on the said backing sheet.
14. A wound dressing according to claim 13, further comprising an absorbent layer or absorbent island laminated over the silicone-coated substrate, whereby at least part of the substrate is sandwiched between the absorbent layer and the base layer.
- 25 15. A wound dressing according to any of claims 1 to 9 comprising or consisting essentially of two pieces or one folded piece of silicone coated substrate encasing an absorbent or adsorbent layer, wherein the silicone coated substrate is larger than the absorbent or adsorbent layer whereby the substrate overlaps around the edges of the absorbent or adsorbent layer to form margins which are bonded together in face-to-face
30 fashion to form an envelope of the silicone-coated substrate around the absorbent or adsorbent layer.

16. A wound dressing according to any preceding claim, further comprising a release sheet applied over a wound contacting surface of the wound dressing.
- 5 17. A wound dressing according to any preceding claim, wherein the wound dressing is sterile and is packaged in a microorganism-impermeable container.
18. A method of making a wound dressing comprising the steps of:
providing an apertured substrate layer;
10 coating the substrate layer with a fluid silicone prepolymer composition;
thermally partially curing said silicone prepolymer composition to form a partially cured silicone coating on the substrate;
laminating the coated substrate layer to a base layer to form a laminate having said partially cured silicone coating in contact with a surface of the base layer; followed
15 by
exposing the laminate to ionizing radiation, to further cure the partially cured silicone coating and to bond the silicone coating to said surface of the base layer.
19. A method according to claim 18, wherein the silicone prepolymer composition comprises a polymerization inhibitor that is evaporated from said composition during
20 said step of thermally partially curing,
20. A method according to claim 18 or 19, further comprising the step of packaging the laminate having said partially cured silicone coating in a microorganism-impermeable container prior to said step of exposing, and wherein said step of exposing
25 also sterilizes said laminate.
21. A method according to any of claims 18 to 20 for the preparation of a wound dressing according to any of claims 1 to 17.
- 30 22. A wound dressing obtainable by a method according to any of claims 18 to 21.

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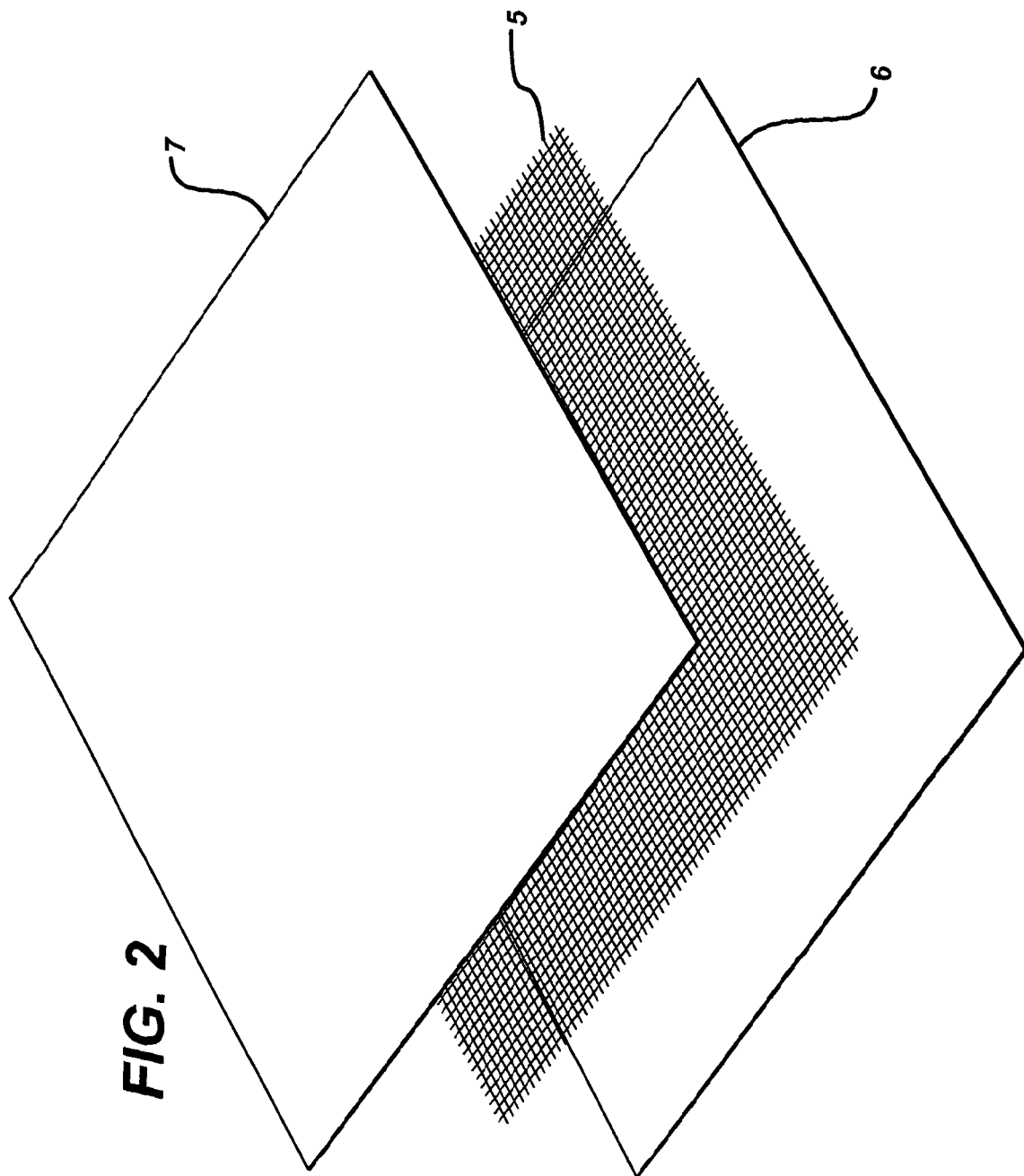


FIG. 5

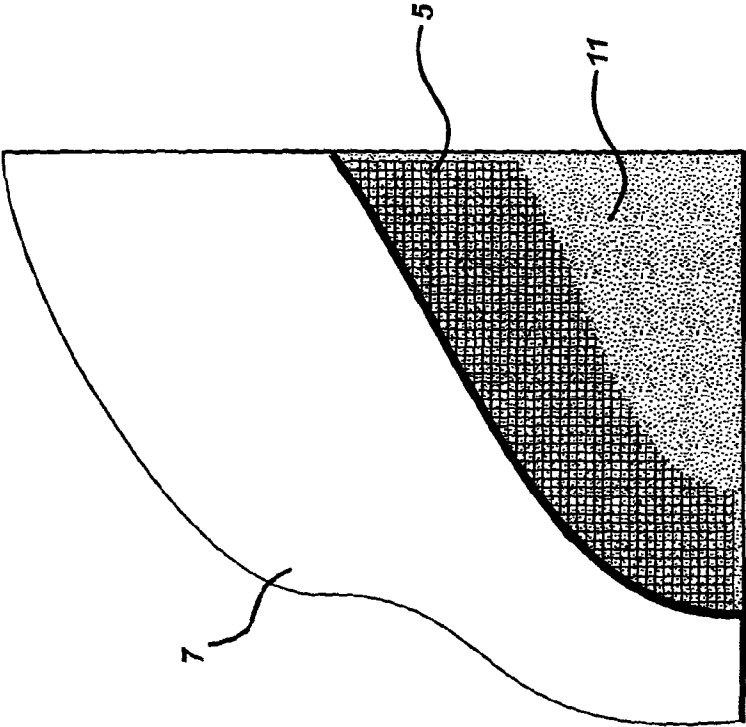
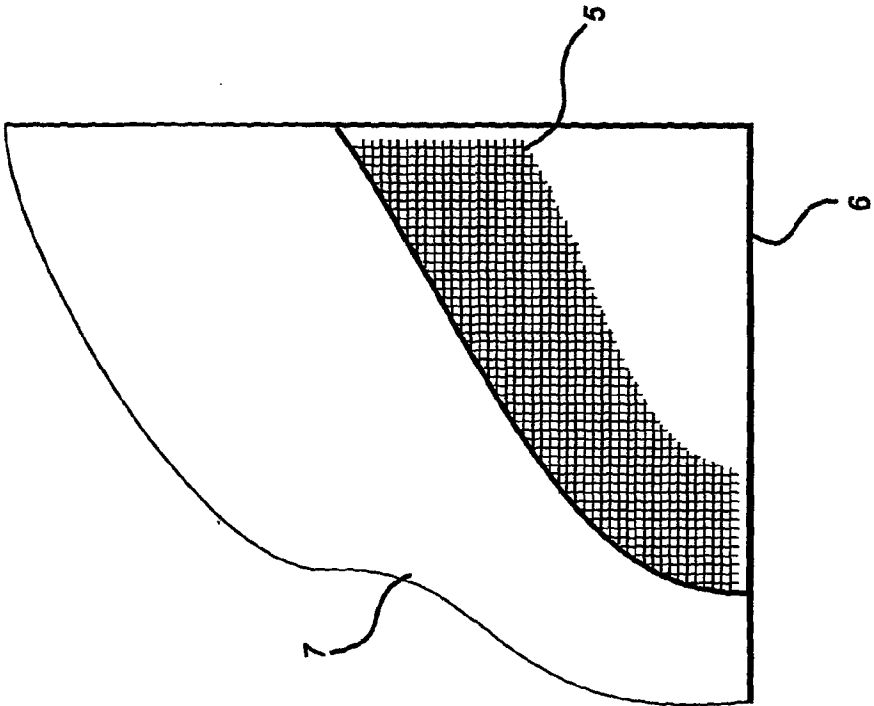
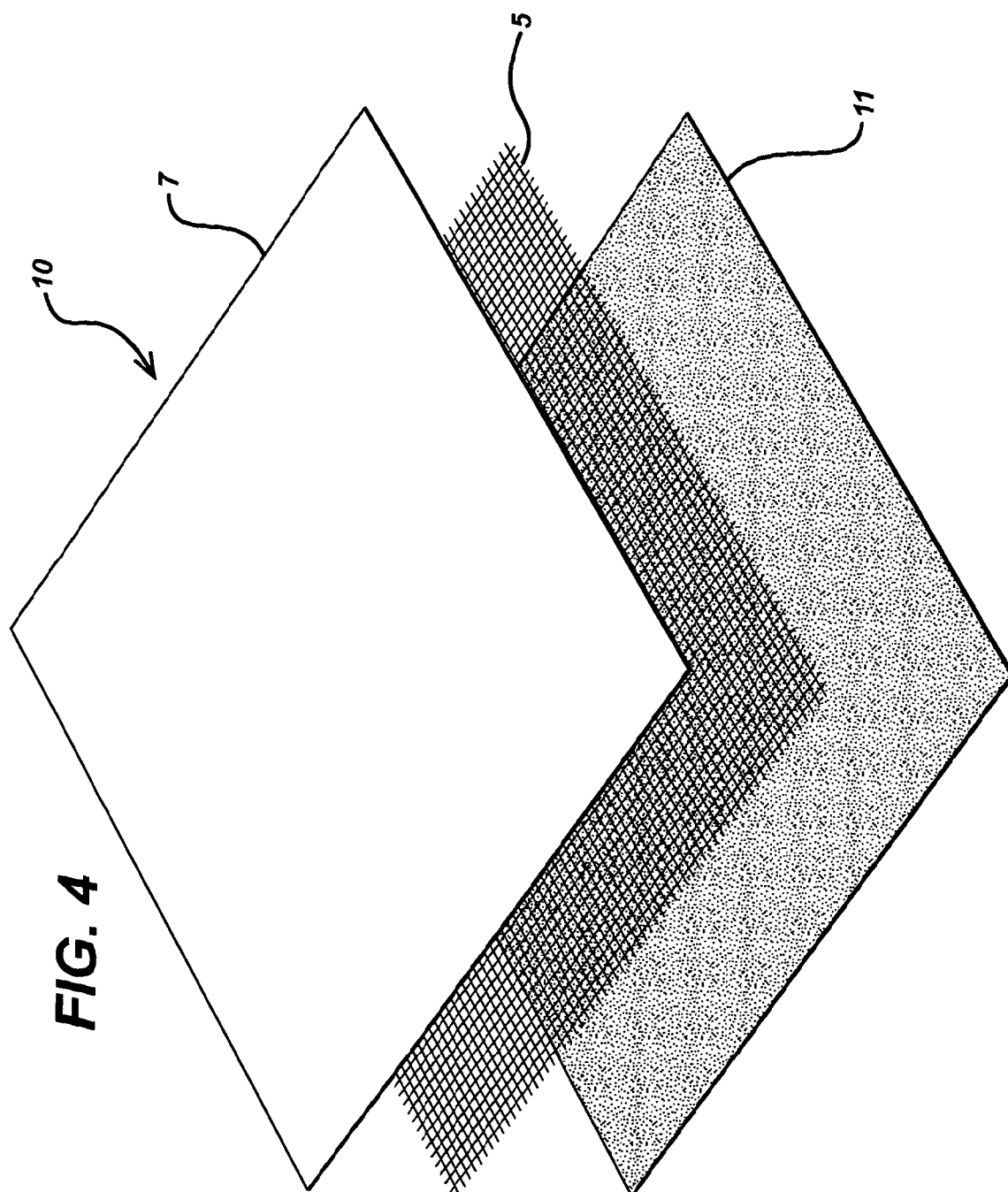


FIG. 3



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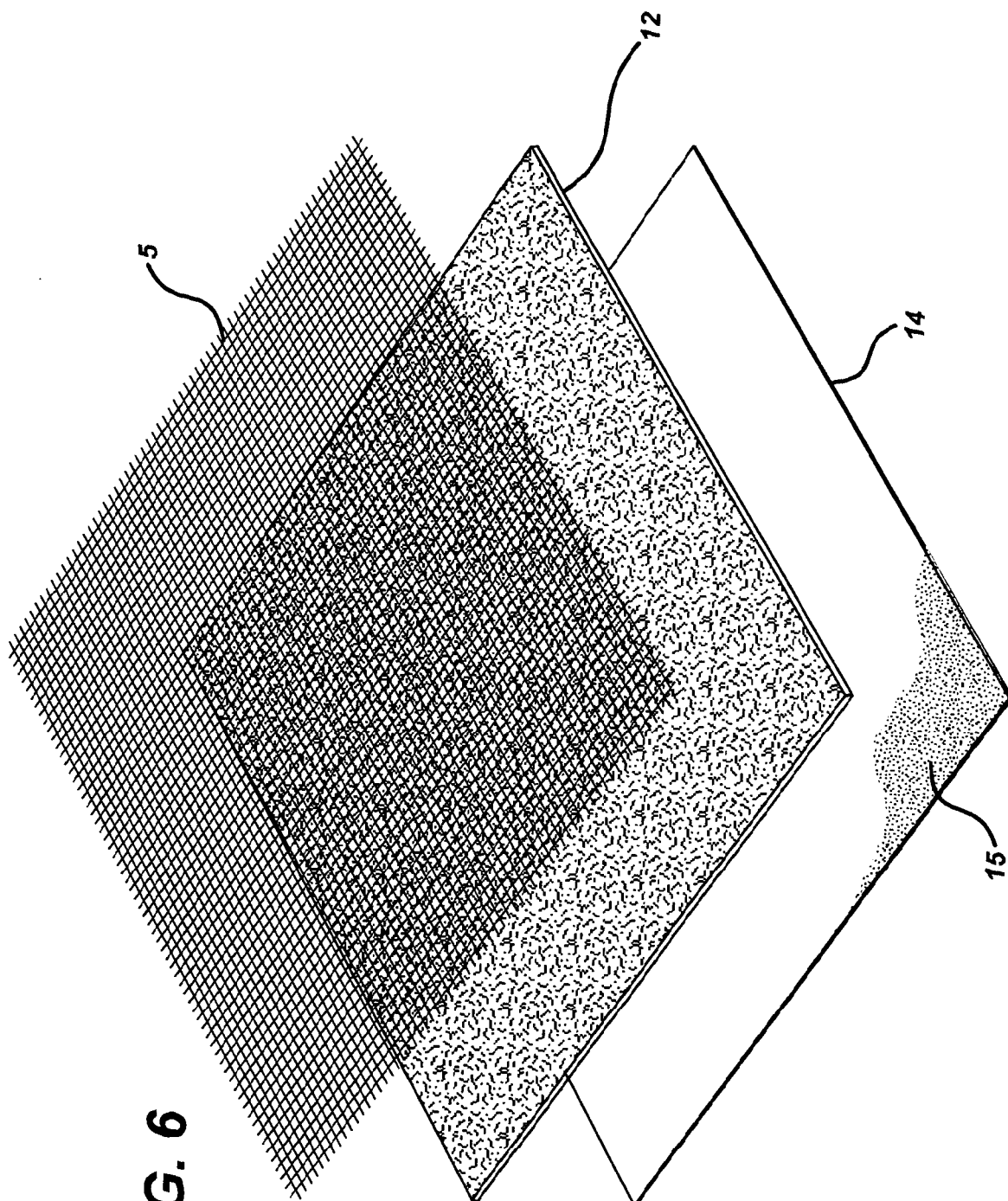


FIG. 6

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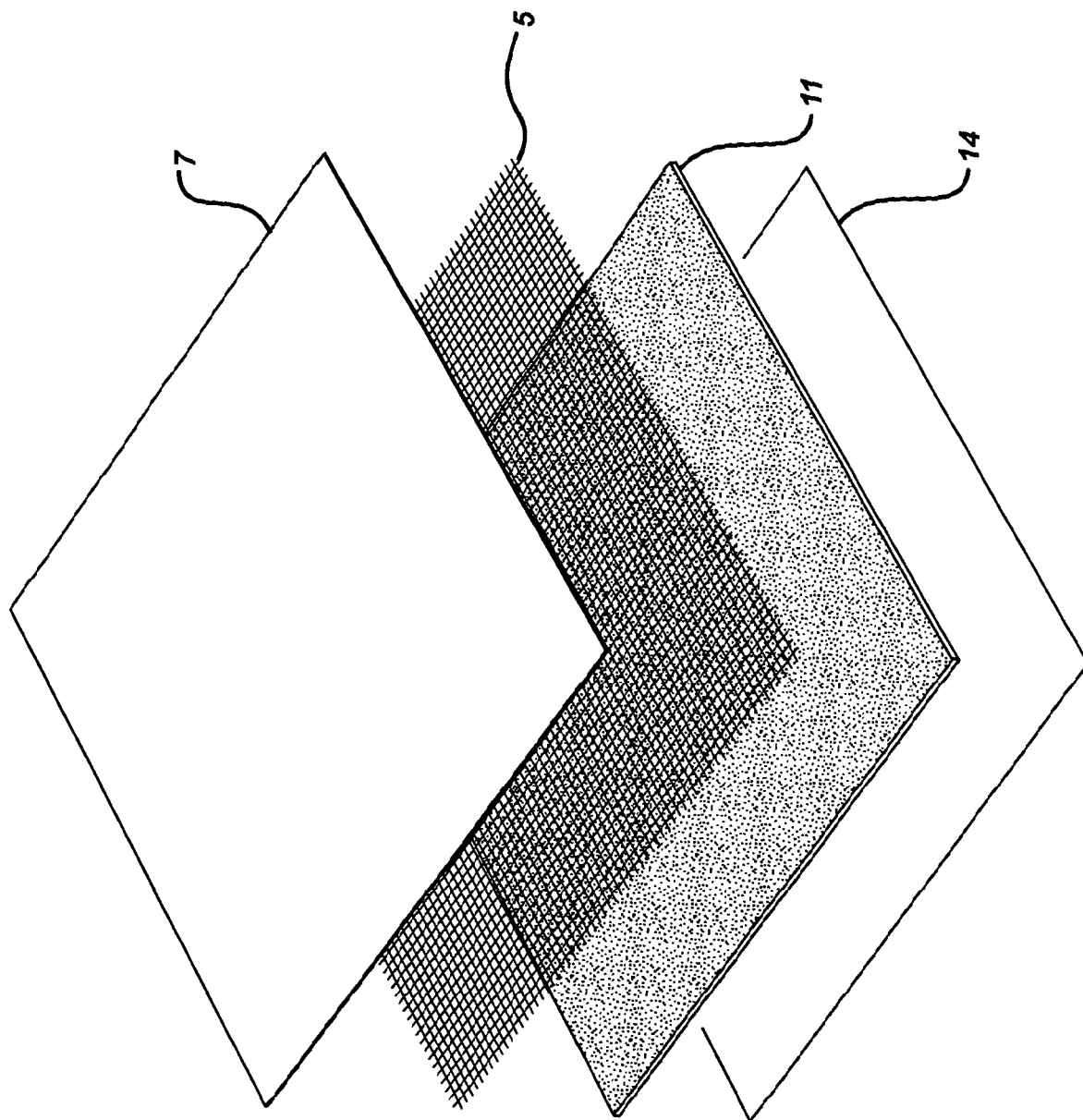


FIG. 7

FIG. 10

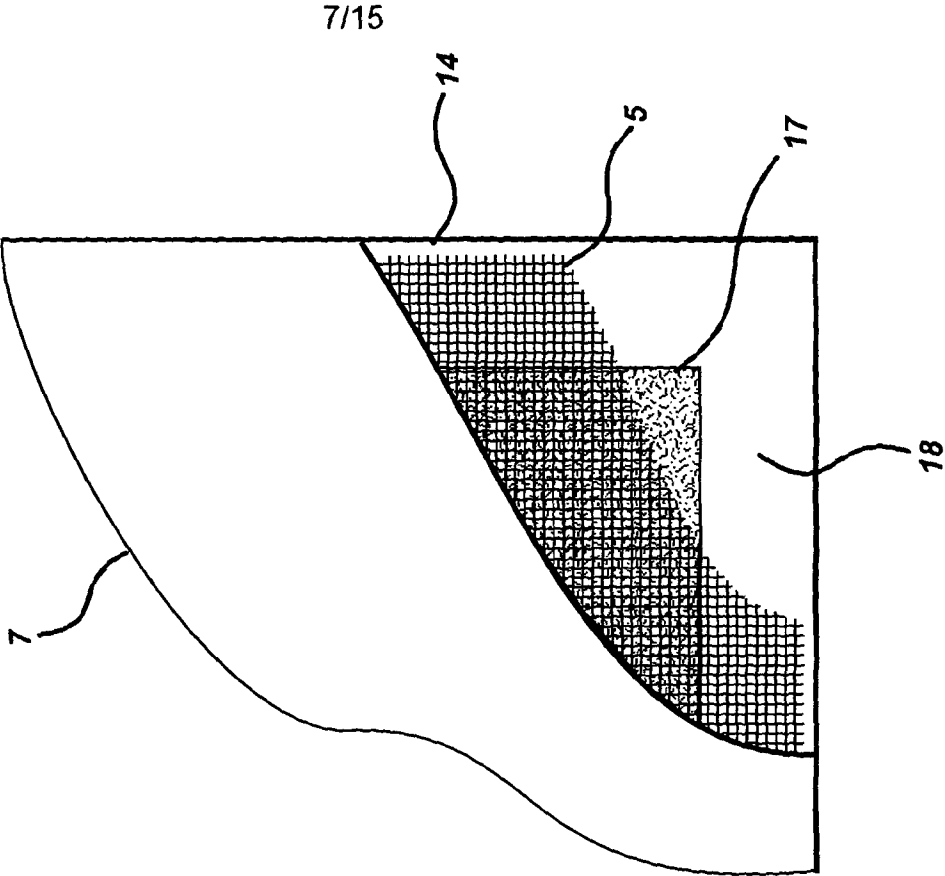
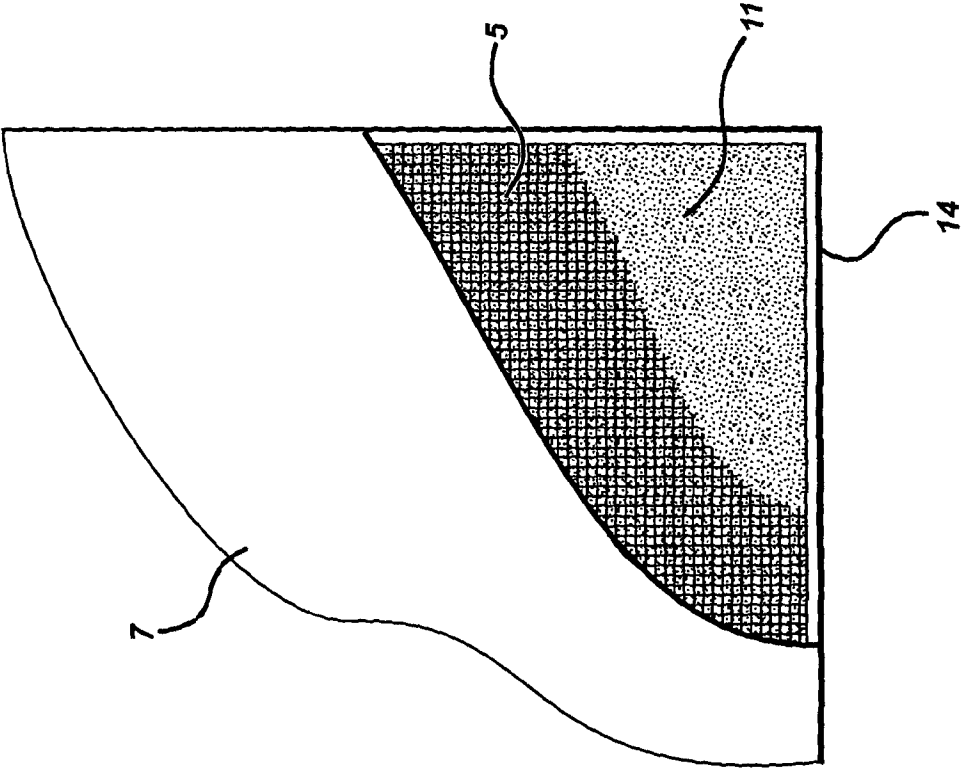
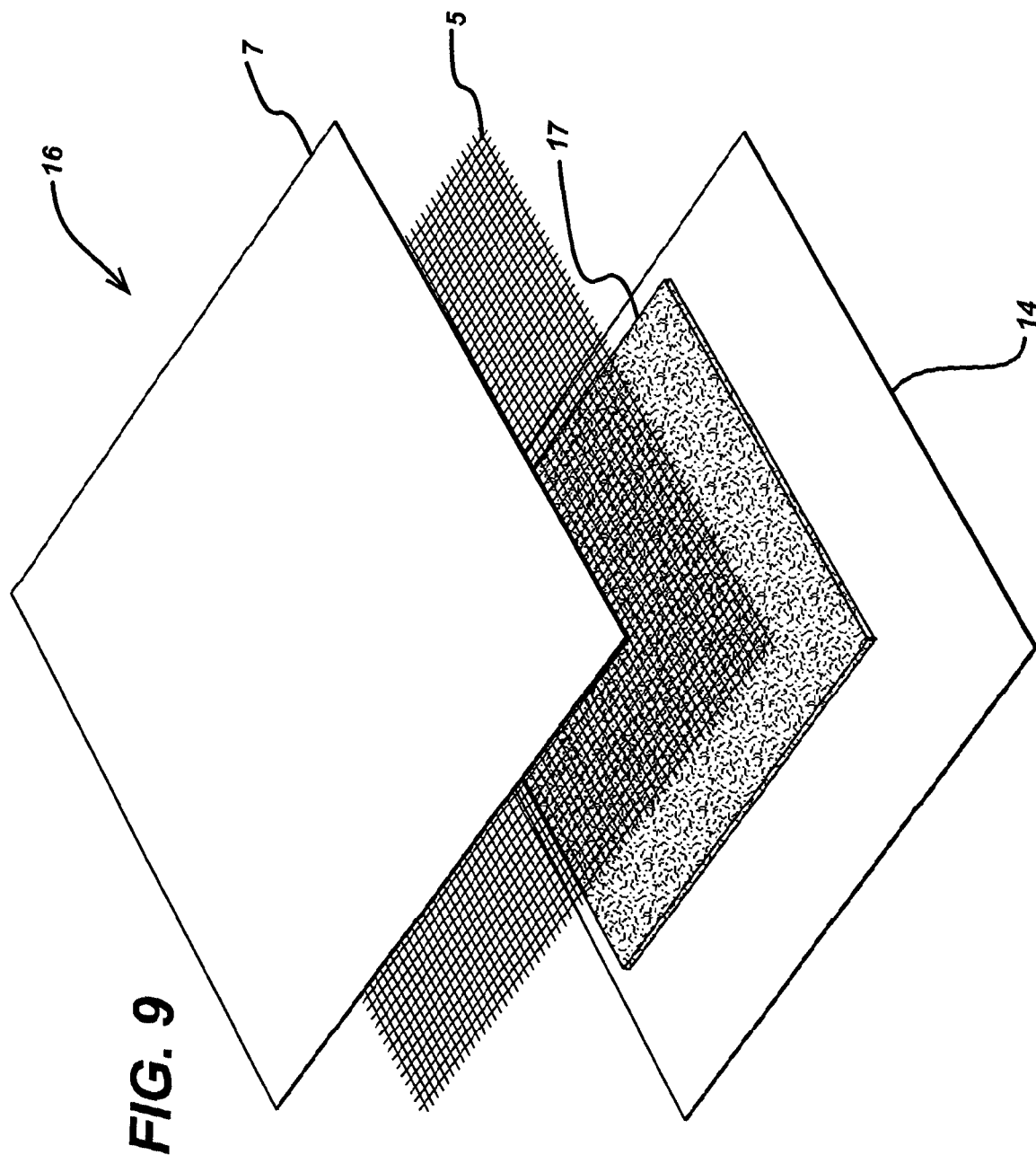


FIG. 8



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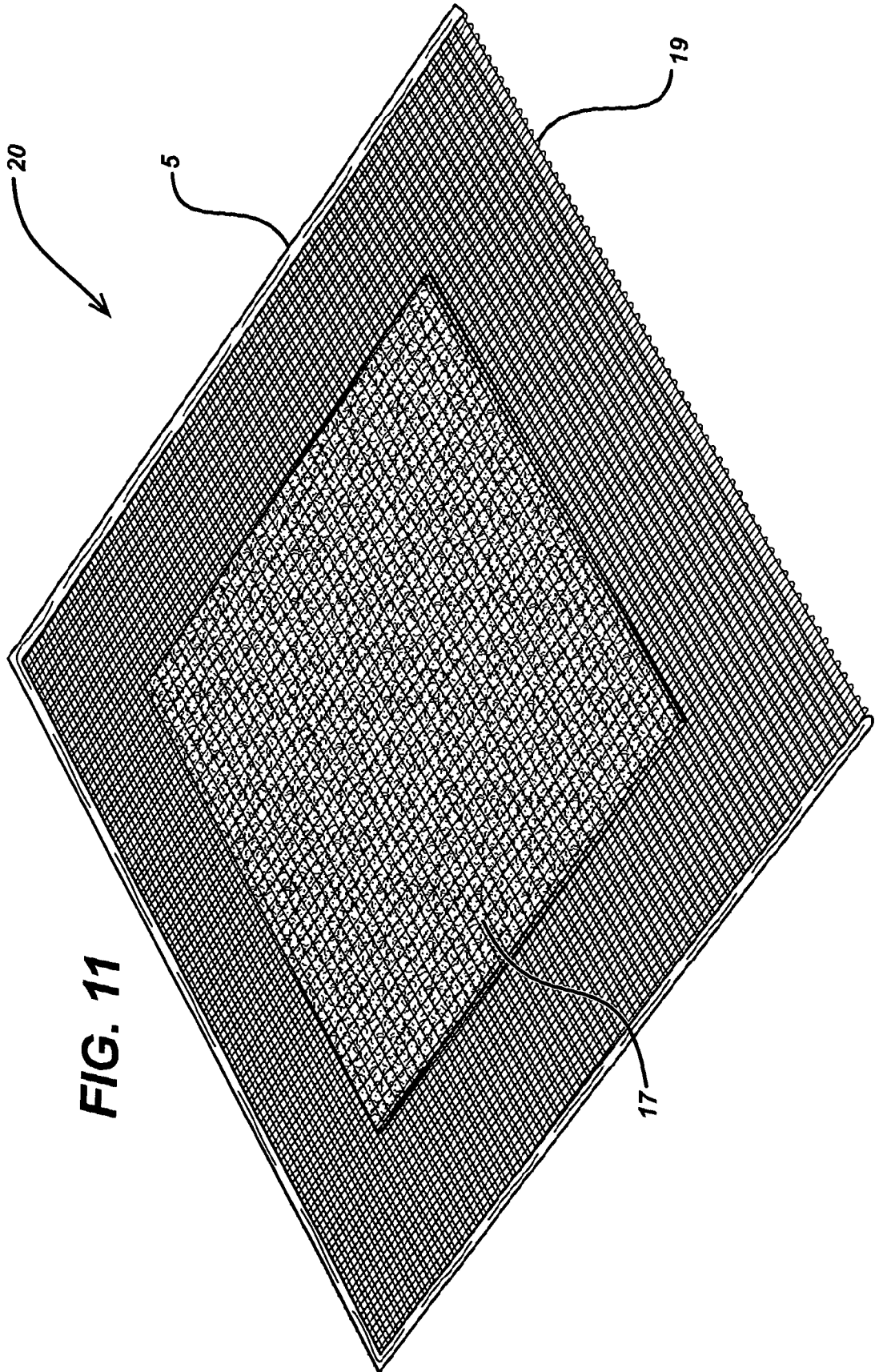


FIG. 11

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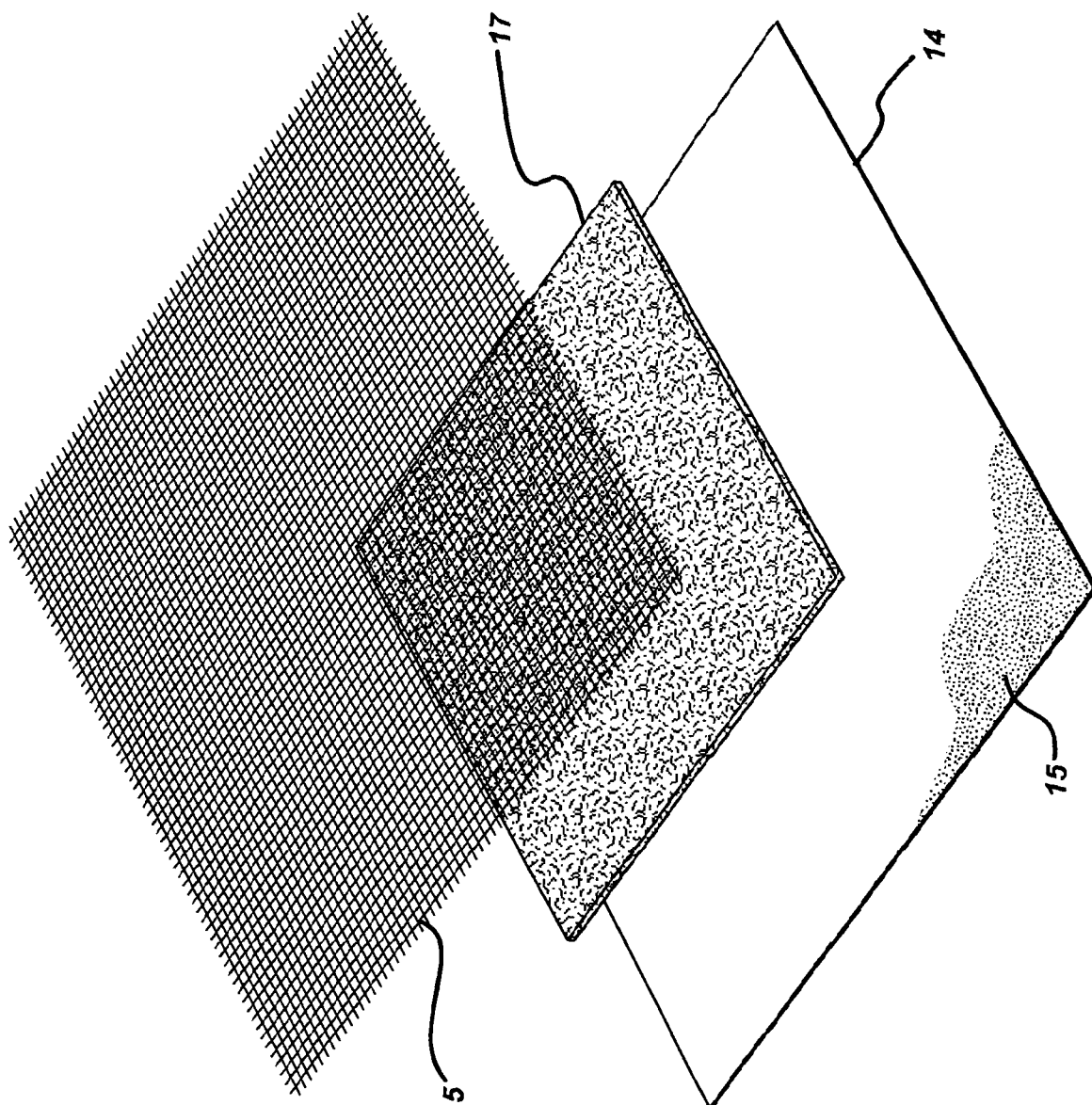
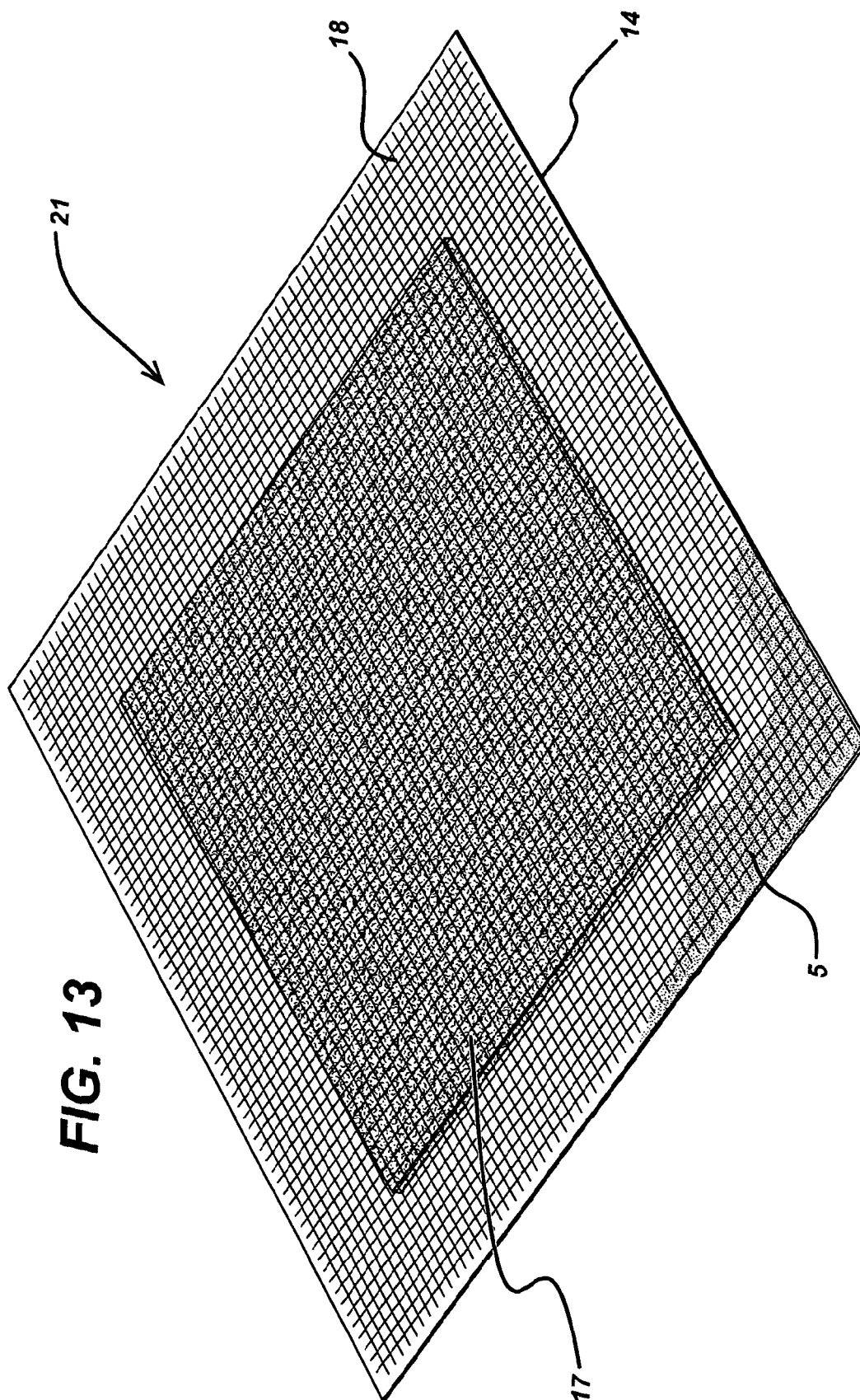
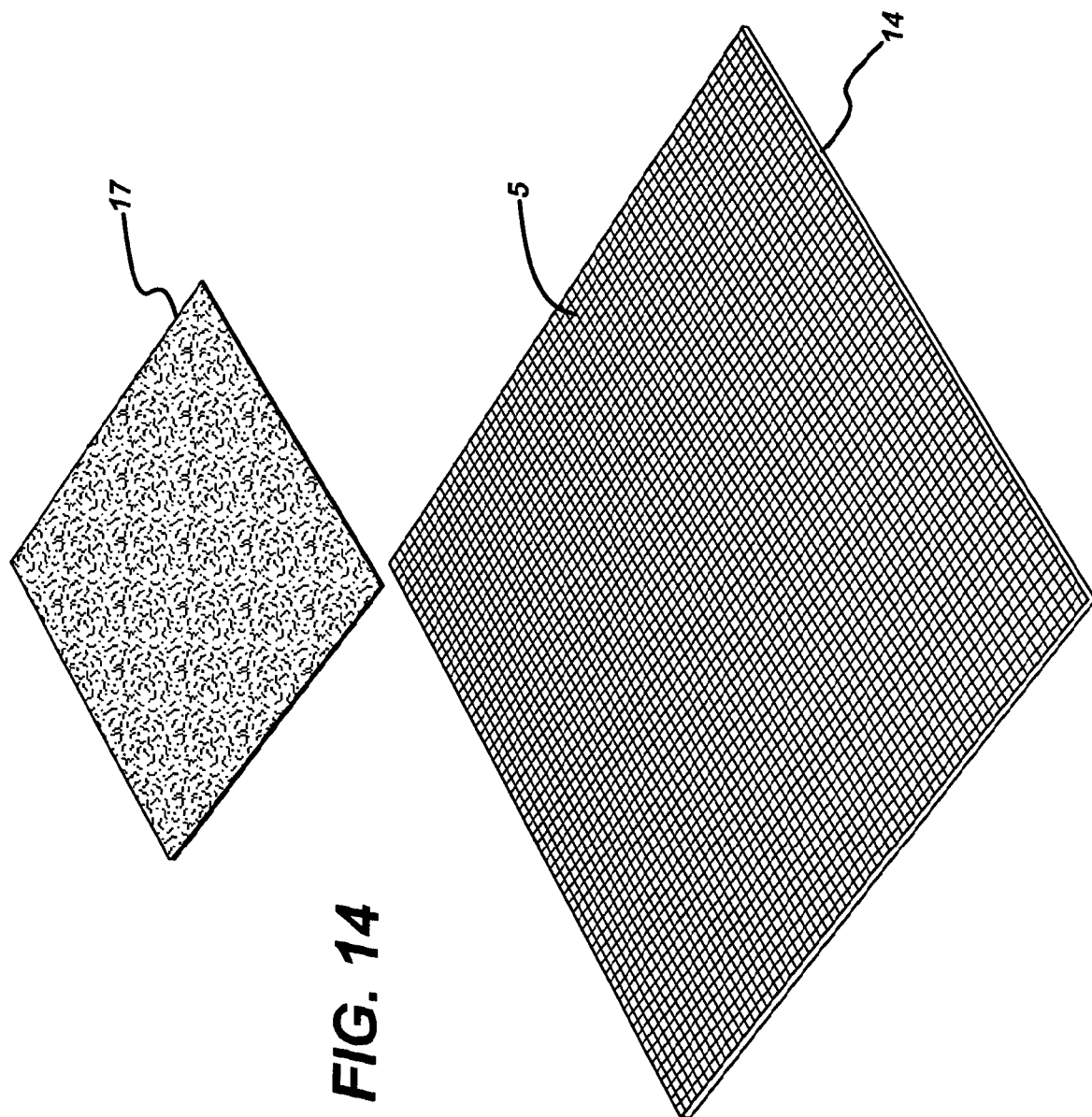


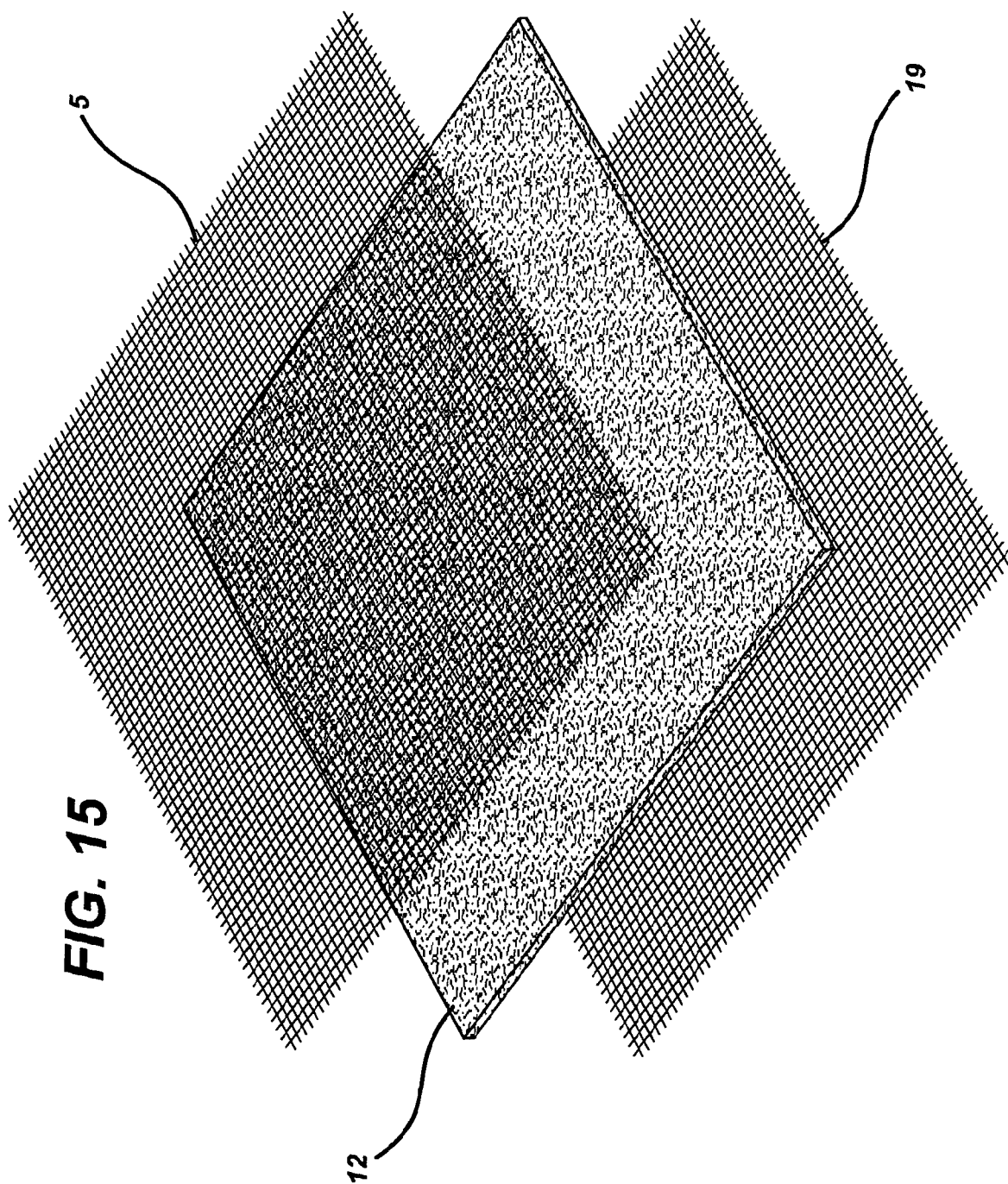
FIG. 12

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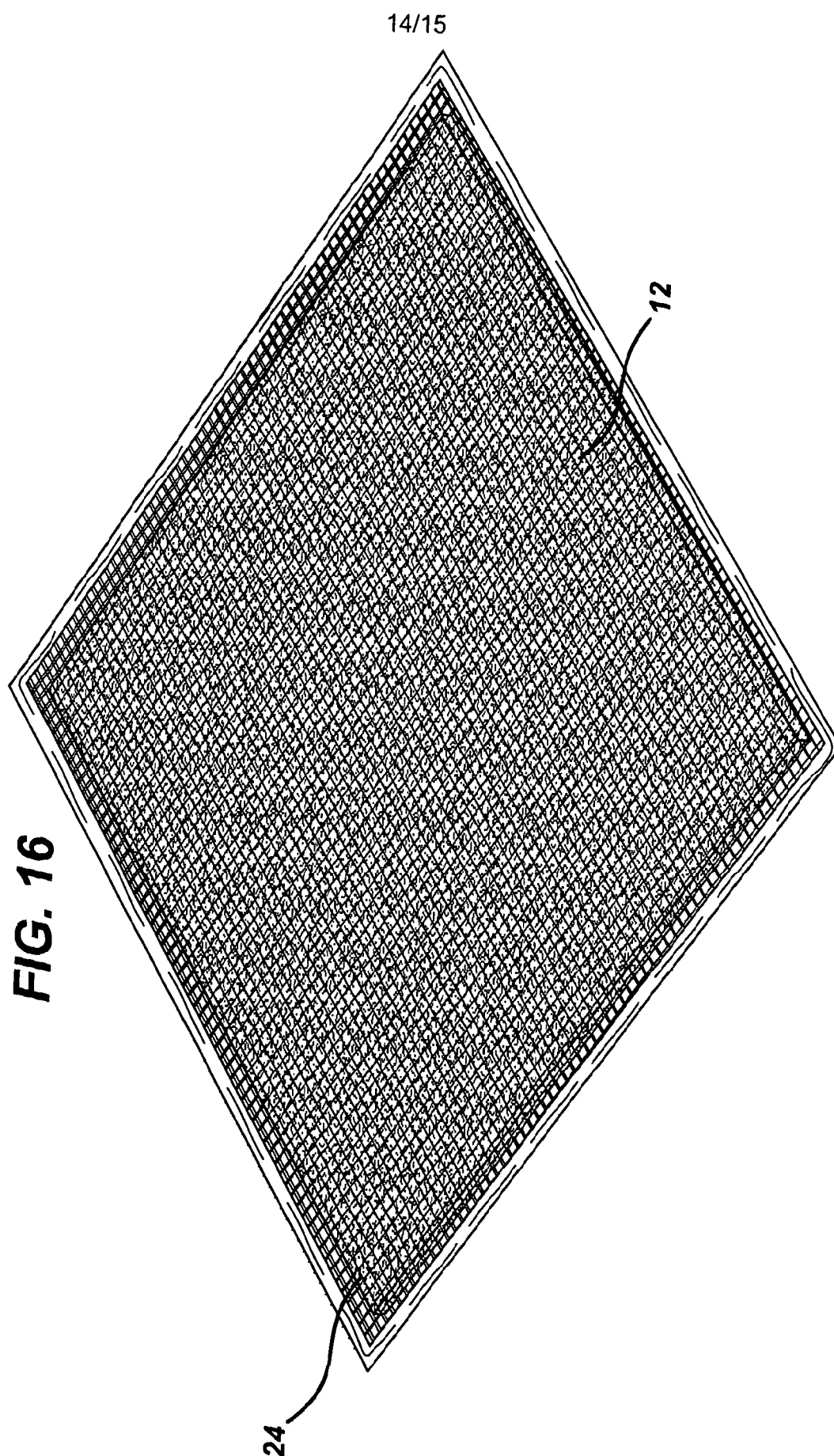


FIG. 17

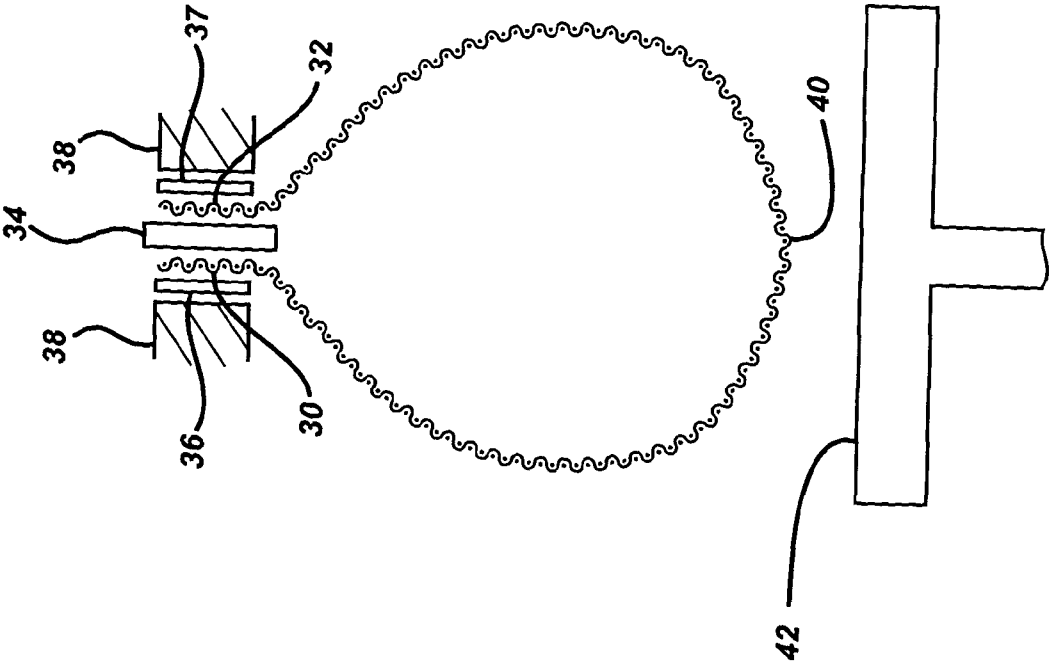
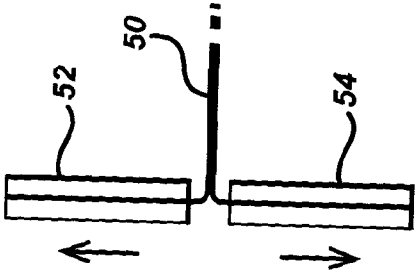


FIG. 18



INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2012/000099

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F13/02

ADD.

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)

A61F A61L

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

2 May 2012

Date of mailing of the international search report

14/05/2012

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