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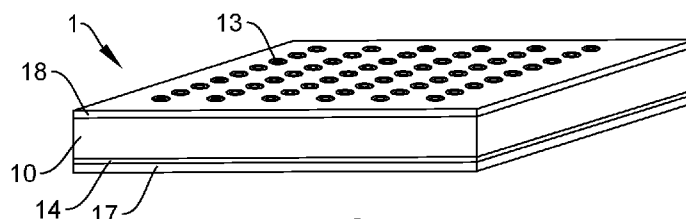


FIG. 10

(57) Abstract: An anisotropically electrically conductive material to electrically interface an electrode with a portion of a biological surface, the conductive material comprising: a substrate having a first surface parallel to a second surface; a first removable layer, the first removable layer being located over the first surface; a plurality of discrete perforations, each perforation extending through the substrate and the first removable layer; and a plurality of discrete electrically conductive elements, each of the conductive elements comprising a tubular core from a first end to a second end of the conductive element; each conductive element formed in a respective one of the perforations such as to extend through the substrate and through the first removable layer.



**Anisotropically conductive material with tubular conductive elements for use with a
biological surface**

TECHNICAL FIELD

[0001] The present invention relates to the interfacing of an electrode with a biological surface of a subject for therapeutic, diagnostic and/or general body characterisation purposes. More particularly, the present invention relates to the use of micro-tubular conductive elements embedded within surface electrodes.

BACKGROUND

[0002] The application of electrical signals to and detection of electrical signals from biological surfaces is widely utilized in a variety of therapeutic, diagnostic and general body characterisation techniques.

[0003] Transcutaneous electrical nerve stimulation (TENS) is a form of pain management that uses low-voltage electrical stimulation for therapeutic purposes. Electrical signals are applied to subject from a subject transcutaneously, using electrodes placed on or in close proximity to a biological surface or the skin surface of the subject. It generally works by sending electrical impulses through electrodes placed on the skin and over the area for treatment. The electrical stimulation can help reduce pain signals sent to the brain and stimulate the production of endorphins. It is appreciated that suitable electrode choice is important in therapeutic directed electrostimulation applications such as TENS because electrode area defines the key parameter of applied current density and the level of contact impedance affects power consumption and hence battery lifetime when batteries are used.

[0004] It is also appreciated that the quality and reproducibility of measurement between the electrode-skin interface is important. In electrodiagnostic applications, such as electrocardiography (ECG), electroencephalography (EEG), electromyography (EMG), electrical bioimpedance (EBI), it is desirable to measure as accurately as possible a biological electrical signal while minimising non-biological variations, which can occur

due to changes in the effective electrode area and noise from the electrode to skin interface. While it is not always necessary that the effective electrode area is the same as the physical electrode area, it can be highly desirable for the size of the effective electrode area to be easily reproducible to ensure measurement consistency.

[0005] For improving contact at the electrode-skin interface, an electrically conductive gel is typically used as a compliant interfacing layer, primarily to minimise contact impedance and achieve a reproducible effective electrode area. Generally, conductive gel is typically applied to the skin surface and/or electrode. Where a conductive solution such as sodium chloride is used, it can be soaked in an absorbent medium such as a gauze that is placed on the skin prior to placement of an electrode thereon. The electrode is typically held in place relative to the skin surface by medical tape or elastic bands. Often, however, the area of contact of the gel which is an important determinant of contact impedance will be undefined and inconsistent, and therefore tend to degrade any measurement or stimulation reproducibility. Thus, the use of conductive gel or solution when applying electrodes to skin includes a number of shortcomings, most notably through the high dependence on the skill of the user that must precisely apply the electrodes to the subject, and the lack of measurement or stimulation reproducibility. The use of conductive gel or solution can also be messy and awkward, requiring extensive cleaning of the subject's skin or electrode after completion, potentially decreasing use or compliance.

[0006] In an attempt to address these shortcomings, a newer generation of electrode contains a self-adhesive conductive layer, typically in the form of a semi-rigid conductive gel/polymer layer that is situated on the electrode surface. The layer has adhesive properties to ensure that the electrode, once placed on the skin, can stay in contact with the skin surface.

[0007] Semi-rigid conductive gel-based electrodes however are prone to drying out over time, adversely affecting signal quality and are therefore not suitable for long-term monitoring and electrostimulation applications. Moreover, also because of this limitation, packaging and storage requirements are more demanding compared to the case of non-gel

based electrode types. Other downsides relating to the use of gel electrodes include potential for allergenic skin reactions and presence of residual gel on the skin upon removal of the electrodes.

[0008] Anisotropically conductive electrode interface materials have been disclosed such as WIPO Publication No. WO2019/119045 and US Patent Application No.

2013/0092426 which disclose use of an aspect ratio greater than 1 of the z-oriented conductive micro-pylons. A disadvantage of using aspect ratio greater than 1, is that when a lower protective removable layer is removed, the z-oriented conductive micro-pylons can be sheared off, thereby reducing the effective skin contact area of the conductive micro-pylons which in turn results in greater than expected skin electrode contact impedance. A solution to this limitation is to develop tubular micro-pylons with an aspect ratio less than 1 so that prior to application of the electrode to the skin the tubular micro-pylons can take up water or aqueous electrolyte solution by capillary action within the tubular micro pylons. This can lower skin-electrode contact impedance even though the tubular micro-pylons will still undergo the shearing off effect. Secondary advantages of having tubular micro-pylons is that in the absence of application of externally applied water or aqueous electrolyte solution, the hollow micro-tubules can impart a degree of breathability to the electrode and also provide a means again by capillary action of reducing sweat accumulation at electrode-skin interface.

[0009] Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

SUMMARY

[0010] PROBLEMS TO BE SOLVED

[0011] It may be advantage to provide anisotropically conductive materials with tubular conductive elements such that aspect ratio is less than 1 so that the tubular micro-pylons can take up water or aqueous electrolyte solution within the tubular micro pylons that can

lower skin-electrode contact impedance, which is desirable for the acquisition of high-quality signals.

[0012] It may be an advantage to apply water or a suitable solution to the underside of the first removeable layer so that the solution can be taken up by the tubular conductive elements by capillary action prior to the first removable layer being removed. This is so to realize skin contact impedance of such non-gel electrodes similar to or lower than commercially-available adhesive gel electrodes but without the well-known limitations of the latter electrodes, particularly relating to shelf life and long-term monitoring and electrostimulation applications.

[0013] It may be an advantage to provide a macroscopic electrode layer on the upper surface or the second surface of the substrate so that it will provide a kind of “anchor” in reducing the tendency for micro-pylons or tubular conductive elements to be lost by a “plucking out” effect during the peeling away of the release layer of the first removable layer.

[0014] It may be advantage to provide tubular conductive elements as it allows for additional applications that a solid conductive element cannot do. For example, a unloaded tubular micro-pylon electrode array can take up sweat during long-term testing. The tubular conductive elements can allow for in situ or post-testing sweat analysis applications. An example of another application may be to use a loaded tubular conductive element for electrophoretic delivery of particular therapeutic agents.

[0015] It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

[0016] MEANS FOR SOLVING THE PROBLEM

[0017] A first aspect of the present invention may relate to an anisotropically electrically conductive material to electrically interface an electrode with a portion of a biological surface, the conductive material comprising a substrate which may have a first surface

parallel to a second surface. A first removable layer, wherein the first removable layer is located over the first surface. A plurality of discrete perforations, wherein each perforation may extend through the substrate and the first removable layer. A plurality of discrete tubular conductive elements, wherein each tubular conductive element may be formed in a respective one of the perforations so as to extend through the substrate and the first removable layer.

[0018] Preferably, the tubular conductive element is adapted to receive therein a solution, with the first removable layer located over the first surface.

[0019] Preferably, the solution is one selected from the group of: water, distilled water, aqueous electrolyte, an alcohol, an alcoholic solution, and a gel.

[0020] Preferably, each tubular conductive element is a pillar of conductive material.

[0021] Preferably, the pillar has a height to width ratio of less than 1.

[0022] Preferably, the anisotropically electrically conductive material comprises a first adhesive layer located over the first surface of the substrate between the first surface of the substrate and the first removable layer.

[0023] Preferably, the first end of each of the tubular conductive elements between the first surface and the first removable layer is adapted to be sheared off from the respective tubular conductive elements when the first removable layer is removed.

[0024] Preferably, the material further comprising one or more conductive members, wherein each conductive member is located over the second surface of the substrate such that each conductive member connects to a second end of a different subset of the plurality of tubular conductive elements.

[0025] Preferably, the material comprising at least two of the conductive members.

[0026] Preferably, each subset of the plurality of tubular conductive elements is provided by a respective cluster of the tubular conductive elements.

[0027] Preferably, at least two clusters of tubular conductive elements are each connected to the respective tubular conductive members and wherein no conductive elements are provided between the clusters of tubular conductive elements.

[0028] Preferably, one or more insulating layers are located over the second surface of the substrate and around the conductive members.

[0029] Preferably, conductive tracks extend from the one or more conductive members to an end of the electrode device.

[0030] Preferably, the conductive tracks are formed from printing using conductive ink.

[0031] Preferably, a further insulating layer is located over the conductive tracks.

[0032] Preferably, at least one opening partially surrounding the tubular conductive elements for observation of the biological surface and/or treatment of the biological surface.

[0033] Preferably, the device further comprising a retention dressing having an insulating layer within a semi-rigid disposable frame, wherein the insulating layer is located over the anisotropically electrically conductive material.

[0034] Preferably, the insulating layer is transparent.

[0035] Preferably, a disposable release film is adherable over the adhesive layer of the anisotropically electrically conductive material.

[0036] In another aspect, the present disclosure provides an anisotropically electrically conductive material to electrically interface an electrode with a portion of a biological

surface, the conductive material comprising: a substrate having first and second surfaces on opposite sides, respectively, of the substrate; a first removable layer, the first removable layer being located over the first surface; a plurality of discrete perforations, each perforation extending through the substrate and the first removable layer; and a plurality of discrete electrically conductive elements or tubular conductive elements, each conductive element or each tubular conductive element formed in a respective one of the perforations such as to extend through the substrate and at least partially through the first removable layer. The conductive material may further comprise a second removable layer, the second removable layer being located over the second surface. Each of the perforations may extend through the second removable layer in addition to extending through the substrate and the first removable layer.

[0037] In another aspect, there is provided a method of forming an anisotropically electrically conductive material to electrically interface an electrode with a portion of a biological surface, the method comprising: providing a substrate having first and second surfaces on opposite sides, respectively, of the substrate, a first removable layer being located over the first surface, a plurality of perforations extending through the substrate and the first removable layer; applying a conductive substance to the plurality of perforations to form a plurality of discrete electrically conductive elements or a plurality of discrete electrically tubular conductive elements, wherein the applying is such that, for each perforation, the conductive element or a tubular conductive element extends through the substrate and at least partially through the first removable layer. Preferably, a second removable layer may be located over the second surface and each of the perforations may additionally extend through the second removable layer. The applying of the conductive substance may be such that each conductive element or each tubular conductive element additionally extends at least partially through the second removable layer.

[0038] Preferably, each of the perforations may define openings in the substrate, the first removable layer and the second removable layer if present. When conductive substance is applied to the plurality of perforations, the conductive substance can substantially fill, for

each perforation, the opening in the substrate, the opening in the first removable layer and the opening in the second removable layer, if present.

[0039] Related to this, in accordance with one aspect, the present disclosure provides a method of forming an anisotropically electrically conductive material to electrically interface an electrode with a portion of a biological surface, the method may comprise: providing a substrate having first and second surfaces on opposite sides, respectively, of the substrate, a first removable layer being located on the first surface, a plurality of perforations extending through the substrate and the first removable layer such that each perforation defines an opening in the substrate and an opening in the first layer; applying a conductive substance to the plurality of perforations to form a plurality of discrete electrically conductive elements or a plurality of discrete electrically tubular conductive elements, wherein the applying is such that, for each perforation, the conductive substance substantially fills the opening in the substrate and the opening in the first layer. In this aspect, again a second removable layer may be located over the second surface and each of the perforations may additionally extend through the second removable layer and may define an opening in the second removable layer. The applying of the conductive substance may be such that, for each perforation, the conductive substance substantially fills the opening in the second removable layer in addition to the opening in the substrate and the opening in the first removable layer.

[0040] In any of the aspects described herein, the substantial filling of the openings in the substrate and the first and second layers may comprise filling at least 50%, at least 60%, at least 70%, at least 80% or at least 90% of the volume of each opening. The substantial filling may be such that there is a continuous connection between the conductive substance between each opening of the perforation. In any aspects described herein, the conductive material may comprise one or more adhesive portions such as an adhesive layer or element. For example, a first adhesive portion such as a first adhesive layer may be provided between the first surface of the substrate and the first removable layer. Additionally, or alternatively, a second adhesive portion such as a second adhesive layer may be provided between the second surface of the substrate and the second removable

layer. Each perforation may extend through the adhesive layer(s) in addition to extending through the substrate and the removable layer(s). Each perforation may define an opening in the adhesive layer(s) in addition to the substrate and the removable layer(s). The adhesive layers may be used to releasably adhere the first and/or second removable layers to the substrate. Adhesion between the first and/or second removable layers to the substrate may be achieved by other means such as via van der Waals forces. Additionally, or alternatively, the adhesive layers may be used to releasably adhere the conductive material to the biological surface and/or to the electrode. For example, after removal of one or both of the first and second removable layers. In any of the aspects described herein, more than one first removable layer may be located over the first surface of the substrate and/or more than one second removable layer may be located over the second surface of the substrate. In any of the aspects described herein, the perforations may provide moulds for forming of the conductive elements or the tubular conductive elements. The conductive substance may be a fluid, paste or gel when applied to the plurality of perforations and may solidify after being applied to the perforations, for example after filling the openings in the substrate, in the first layer and in the second layer, if present. A first end of each of the conductive elements or a first end of each of the tubular conductive elements may align with an outer surface of the first removable layer and a second opposite end of each of the conductive elements or tubular conductive elements may align with the second surface of the substrate or, if the second removable layer is present, with the outer surface of the second removable layer. Alternatively, the first end of each of the conductive elements or the first end of each of the tubular conductive elements may locate between the first surface of the substrate and the outer surface of the first removable layer and the second end of each of the conductive elements or the tubular conductive elements may locate between the second surface of the substrate and the outer surface of the second removable layer.

[0041] Once the conductive elements or the tubular conductive elements are formed in the conductive material, one or both of the first and second removable layers may be removed. The first and second removable layers may have a variety of different functions. One function of the first and second removable layers may be to assist with the

formation of conductive elements or the tubular conductive elements that have first and second ends that protrude from the first and second surfaces, respectively, of the substrate. As indicated, openings in the removable layer(s) may act, in concert with an opening in the substrate (and openings in adhesive portion(s) if present), as moulds for forming the conductive elements or the tubular conductive elements. The removable layer(s) can be retained over the substrate while forming the conductive elements or the tubular conductive elements. However, the removable layer(s) can be removed subsequently, exposing the first and/or second ends of the substrate as they protrude from the substrate or from other layers such as adhesive layers located over the substrate if present. By being exposed at and protruding from the substrate or other layers over the substrate, the first and second ends can achieve better electrical contact with a biological or electrode surface, for example, in comparison to an arrangement where the first and second ends are aligned with or even stop short of the first and second surfaces of the substrate or other layers located over the substrate. Nevertheless, after assisting with formation of the conductive elements or the tubular conductive elements, one or both of the first and second removable layers may be kept in position over the respective first and second surfaces to perform additional functions. For example, one or both of the first and second removable layers can act as protective layers or masks that expose only ends of the conductive elements or the tubular conductive elements while covering the surfaces of the substrates and any adhesive portions or other layers located thereon. As such, the first and second removable layers can prevent these underlying portions of the material from being contaminated with conductive substances that could potentially degrade material anisotropy following the formation of the conductive elements or the tubular conductive elements. Such contamination could occur during stacking, rolling or processing of the conductive material, for example. The conductive material can otherwise be vulnerable to contamination, not least when portions underlying the removable layers have adhesive character. When the removable layers are removed, any potentially contaminating substances can be removed with the layers, leaving behind a clean, anisotropic underlying structure ready for contact with a biological surface and electrode, for example.

[0042] In another preferred embodiment of the present invention, it may be desirable to contact one or both ends of the conductive elements or the tubular conductive elements with a further substance which promotes interfacial conductance, such as water, a conductive liquid or gel or conductive adhesive, for example, which substance may coat one or both of the ends of the conductive elements and/or be absorbed into the conductive elements, dependent on their material properties. One or both of the first and second removable layers can advantageously prevent underlying portions of the material from being contacted by that further conductive substance, which could potentially degrade material anisotropy. In another preferred embodiment, where the underlying portions have adhesive character, the removable layers may prevent contact of a further conductive substance that could adversely affect the adhesive character. When the removable layers are removed, any of the further conductive substance that is not coating or absorbed into the conductive elements or the tubular conductive elements, and which might otherwise cause electrical connection between adjacent conductive elements or adjacent tubular conductive elements, can be removed with the layers, leaving behind an anisotropic underlying structure ready for contact with a biological surface and electrode, for example. Wherein in use, the first surface of the substrate, or any adhesive portion located over the first surface of the substrate, may be located in close proximity to a biological surface such that the protruding first ends of the discrete conductive elements or the protruding first ends of the discrete tubular conductive elements electrically contact the biological surface. The biological surface may be a tissue surface such as a skin surface, including the epidermis, dermis or hypodermis, for example, although the conductive material may be used in conjunction with any biological surface of a subject, including surfaces of other tissues and/or organs such as bone, heart, liver, kidneys, lungs, stomach, eyes, brain, bladder, prostate, pancreas, or thyroid. Moreover, the biological surface may be a surface of tissue and/or of an organ that has been excised from a body, e.g., for transplant, research purposes or otherwise. The first surface of the substrate may contact, or at least face, the biological surface. The second surface of the substrate, or any adhesive portion located over the second surface of the substrate, may be located in close proximity to an electrode such that the second ends of a subset of the plurality of discrete conductive elements or the second ends of a subset of the plurality of

discrete tubular conductive elements, which may also protrude, electrically contact simultaneously a contact surface of the electrode. An electrode may be positioned anywhere on or over the second surface of the substrate such that its contact surface electrically contacts the second ends of conductive elements of different subsets of the plurality of discrete conductive elements or tubular conductive elements. For example, the electrode may contact a first subset of the plurality of discrete conductive elements or a first subset of the plurality of discrete tubular conductive elements and then may be moved to contact a second subset of the plurality of discrete conductive elements or a second subset of the plurality of discrete tubular conductive elements. Each subset of the discrete conductive elements may be defined, generally, by the area across which the contact surface of the electrode extends and will generally include multiple discrete conductive elements. For example, each subset may comprise and not limited to 2 or more conductive elements, 3 or more conductive elements, 5 or more conductive elements, 10 or more conductive elements, 20 or more conductive elements, 50 or more conductive elements, 100 or more conductive elements. By contacting the second ends of any subset of conductive elements or tubular conductive elements, the electrode electrically interfaces with the portion of the biological surface that is in electrical contact with the first ends of that subset of conductive elements or tubular conductive elements. Due to the anisotropy of the conductive material, there may be substantially no electrical interfacing between the electrode and the rest of the biological surface.

[0043] The perforations may be distributed across the substrate in an array. For example, in a substantially uniform array. The perforations may be provided in a regular array. The array may include equidistant rows and columns across the substrate, offset rows and columns. In another preferred embodiment, alternative distributions of perforations are possible such as and not limited to rectilinear arrays, curvilinear arrays, hexagonal arrays. In other preferred embodiments, the perforations may be in a line, or arranged in different shapes and patterns. For example, in clusters of perforations such as circular clusters of perforations. Preferably, the perforations may have a shape, in a plane perpendicular to their direction of extension through the conductive material, that is, a shape not limited to circular, square, triangular, irregular. Preferably, the shape of the perforations may be

substantially the same through the entire depth of the conductive material. Preferably, the perforations may extend in a direction that is perpendicular to the first and/or second surfaces of the substrate or that is at an angle to the first and/or second surfaces of the substrate. Preferably, the perforations may extend in a straight line. Preferably, the perforations may have an aspect ratio, i.e. a total perforation depth through the different layers of the conductive material to perforation diameter in the range of less than 1.0 to 4.0. Most preferably, the aspect ratio is less than 1.0. Preferably, the spacing between perforations (inter-perforation spacing) may be selected dependent on factors such as the desired density, conductance and/or lateral resistance of the conductive elements and the mechanical strength of conductive material. Too high a density may lead to the conductive material substrate tearing during or after application to the biological surface. Preferably, the perforations may be formed by any one or more of laser perforation, ultrasonic perforation, cold or hot needle perforation, electrostatic discharge perforation, water jet perforation, drilling. Preferably, the conductive substance applied to the perforations and the resultant conductive elements or the resultant tubular conductive elements may comprise conductive matter such as carbon, graphite, graphene, silver, gold, copper, carbon nanotubes, conducting polymers, polymer electrolytes, salts, conductive adhesive and/or combinations thereof. The conductive matter may in some embodiments be combined with carrier matter such as and not limited to polymers, solvents such as and not limited to water, organic solvents. The carrier matter may optimise physical properties of the conductive substance when applied to the perforations and/or optimise the physical properties of the tubular conductive elements formed in the perforations. The carrier matter may serve as and not limited to a binder, water absorber, adhesion promoter, flexibility enhancer. The carrier matter may ensure that the conductive substance can be applied more easily to the perforations, e.g., so that it can enter and fill the openings provided by the perforations, for example. The carrier matter may ensure that the conductive substance will adhere to the substrate, for example. The conductive substance may be homogeneous or heterogeneous. The conductive substance may be biocompatible. Preferably, the conductive substance as applied to the plurality of perforations may be an ink. The ink may comprise carrier matter comprising a solvent and may comprise conductive matter such as carbon, graphite, graphene, silver, gold,

copper, carbon nanotubes, conducting polymers, polymer electrolytes, salts, conductive adhesive and/or combinations thereof as indicated above. In other preferred embodiments, however, solvent-free inks may be used, which may comprise UV or electron-beam curable carrier matter, for example. The conductive substance may be applied as a solid, liquid, gel or paste. For example, depending on the presence and type of any carrier matter combined with the conductive matter. In other preferred embodiments, ink formulations may be either a single formulation or a two-part formulation that reacts upon mixing.

[0044] In another preferred embodiment of the present invention, the properties of the conductive substance, for example, the ink formulation, and/or the properties of the substrate, first removable layer and/or second removable layer, may be selected to ensure an adhesion strength of the conductive elements to the substrate that is greater than an adhesion strength of the conductive elements or the tubular conductive elements to the first and/or second removable layers. After application to the perforations, the conductive substance may be subjected to a drying process (e.g. thermal, vacuum or air flow drying treatment) or a curing process for example and not limited to thermal, UV, electron beam curing). If thermal treatment is used, temperatures may be selected to avoid damaging parts of the conductive material, including any adhesive portions that may be provided. As applied to the perforations, the conductive substance may completely fill the perforations. When the conductive substance is subject to subsequent processing to form the final conductive elements or tubular conductive elements, however, the size of the conductive elements may change. For example, if the conductive substance comprises a solvent, the solvent may evaporate following thermal treatment, causing the conductive elements or the tubular conductive elements to reduce in size. For example, so that they do not completely fill the perforations. Nevertheless, the conductive elements or the tubular conductive elements can still have a sufficient length to extend through the substrate and at least partially through the first layer and through the second layer, if present. The conductive substance may be applied to the perforations by any one or more of: screen printing, doctor blading, inkjet printing, pad printing, flexographic printing, gravure printing spraying, dip coating or otherwise. Preferably, it may be

preferable to apply the conductive substance to the side from which perforations are formed, for example, the side from which a laser or other tool is used to bore into the material to form the perforations. Preferably, the plurality of conductive elements may be distributed across the substrate in an array, for example, in a substantially uniform array. The conductive elements or the tubular conductive elements may be provided in a regular array. The array may include and not limited to equidistant rows and columns across the substrate, offset rows and columns. Alternative distributions of perforations are possible such as and not limited to rectilinear arrays, curvilinear arrays, hexagonal arrays. In some preferred embodiments, the conductive elements or the tubular conductive elements may be in a line, or arranged in different shapes and patterns, for example, circular clusters of conductive elements or tubular conductive elements.

[0045] Preferably, the conductive elements or the tubular conductive elements may have a shape, in a plane perpendicular to their direction of extension through the conductive material, that is a shape not limited to circular, square, triangular, irregular. Preferably, the conductive elements or the tubular conductive elements may extend in a direction that is perpendicular to the first and/or second surfaces of the substrate or that is at an angle to the first and/or second surfaces of the substrate. Preferably, the conductive elements or the tubular conductive elements may take the form of pillars or pylons, for example micro-pillars or micro-pylons, which may be tubular. The conductive elements of the tubular conductive elements may be monolithic. Preferably, the conductive elements or the tubular conductive elements may have an aspect ratio, i.e. a total conductive element depth through the different layers of the conductive material to conductive element diameter in the range of less than 1.0 to 4.0.

[0046] In another preferred embodiment, most preferably, the conductive elements, which may be tubular may have an aspect ratio, that is a total conductive element depth through the different layers of the conductive material to conductive element diameter less than 1. Preferably, the spacing between conductive elements may be selected dependent on factors such as the desired density, conductance and/or lateral resistance of the conductive elements or the tubular conductive elements and the mechanical strength

of conductive material. At the surface of the substrate, the distance between adjacent conductive elements or the distance between adjacent tubular conductive elements (for example, between adjacent first or adjacent second ends of tubular conductive elements) may be greater or less than a maximum dimension of the conductive elements or the tubular conductive elements across the surface of the substrate. At least where the distance between adjacent tubular conductive elements is less than the maximum dimension of the tubular conductive elements, a higher density array of conductive elements may be provided. By employing a substantially uniform array of substantially identical conductive elements or tubular conductive elements, conductance of the conductive material may be substantially constant over any area comprising a plurality of the conductive elements or the tubular conductive elements. Nevertheless, substantially constant conductance may still be achieved, particularly over larger areas, even where an irregular array and/or non-identical conductive elements are used. Moreover, in some embodiments, it may be desirable to vary the conductive properties of the conductive material over different areas of the conductive material, depending on its desired use. It may be desirable to reduce the occurrence of electrical cross-talk or short-circuiting between neighbouring conductive elements or neighbouring tubular conductive elements, particularly when pressure is applied to protruding ends of the conductive elements or the tubular conductive elements that could cause deformation of the ends of the conductive elements or tubular conductive elements. A reduction may be achieved by ensuring that the height of the protruding ends of the conductive elements or the height of the protruding ends of the tubular conductive elements, relative to the adjacent surfaces of the substrate, is less than half of the spacing between neighbouring conductive elements. So that multiple discrete conductive elements are available for contact with an electrode contact surface having a variety of different sizes, a relatively large number of conductive elements may be provided, the conductive elements or the tubular conductive elements may be relatively small in comparison to the electrode contact surface and the conductive elements or the tubular conductive elements may have a relatively high-density distribution across the conductive material. For example, the total number of conductive elements distributed across the conductive material may be greater than 10, greater than 20, greater than 50, greater than 100, greater than 500, or greater than 1000. For example,

the density of conductive elements across the conductive material may be at least 1 per cm^2 , at least 2 per cm^2 , at least 5 per cm^2 , at least 10 per cm^2 , at least 50 per cm^2 , at least 100 per cm^2 , at least 200 per cm^2 , at least 300 per cm^2 , at least 400 per cm^2 , at least 500 per cm^2 , at least 750 per cm^2 , or at least 1000 per cm^2 . For example, the area of each conductive element or the area of each tubular conductive element at its first or second end, in a plane substantially parallel to the first and/or second surfaces of the substrate, may be less than 0.5 cm^2 , less than 0.25 cm^2 , less than 0.1 cm^2 or less than 0.05 cm^2 , less than 0.01 cm^2 , less than 0.001 cm^2 , or less than 0.0001 cm^2 . For example, the maximum distances between neighbouring tubular conductive elements may be less than 1.0 cm, less than 0.75 cm, less than 0.5 cm, less than 0.25 cm, less than 0.1 cm, less than 0.05 cm, less than 0.01 cm, or less than 0.001 cm. In other preferred embodiments, the conductive elements or the tubular conductive elements may be distributed in a macroscopic or a microscopic scale. For example, when distributed in a microscopic scale, the surface area or the area of the annulus of each conductive element or each tubular conductive element at its first or second end, in a plane substantially parallel to the first and second surfaces of the substrate, may be less than 0.01 cm^2 . The maximum distances between the ends of neighbouring conductive elements or the ends of neighbouring tubular conductive elements may be less than 0.1 cm or 0.2 cm or any other distances.

[0047] The substrate, and the conductive material comprising the substrate, may be flexible. The conductive material may therefore be bendable to follow the curvature of a biological surface or other surface to which it is to make contact. The conductive material may be configured so that, upon bending during normal use, electrical independence of the discrete conductive elements or the discrete tubular conductive elements may still be maintained (that is, the discrete conductive elements or the discrete tubular elements may not come into electrical contact with each other). The substrate may comprise a single layer of material or multiple layers of material, for example multiple layers of material stacked on top of each other. The substrate may comprise a non-conductive material or an insulating material such as nylon, polyurethane, polyester, silicones, polyvinyl alcohol, polyimide, natural polymer such as chitosan, foam such as polyurethane foam, natural polysaccharide alginate foam, hydrocolloids such as those formed from carboxymethyl-

cellulose, alginate and elastomer, pre-swollen hydrogel of collagen or elastin, hyaluronic acid, or synthetic hydrogels of cross-linked poly(vinyl alcohol), polyvinylpyrrolidone or methacrylate. The substrate may be hydrophobic or hydrophilic. The substrate may be biodegradable. The substrate may be formed of medical grade material. The substrate may be at least partially transparent or translucent, for example, so that target sites on the biological surface for electrical interfacing can be identified through the substrate, or opaque. The substrate may be coloured or clear. The substrate may be substantially flat or it can be having a three-dimensional shape, for example a curved or otherwise structured shape. The three-dimensional shape may be pre-formed in the substrate. The substrate may have a thickness of between 5µm and 2mm or any other thickness. The first and/or second removable layer may comprise a film of material, for example, a waterproof or water resistant film.

[0048] The substrate may be substantially rigid and the conductive material may be flexible or rigid when it is necessary to ensure that the conductive elements do not undergo stretching-related shape distortion upon application of the anisotropic conductive film to a biological surface. An alternative means of imparting rigidity on an anisotropic conductive film with tracks is deposition of a rigid insulating film over the tracks.

[0049] The first and/or second removably layers may comprise polyethylene, polypropylene, polyester, polystyrene, silicone, fluoropolymer, polyethylene -coated kraft paper, glassine, clay-coated kraft paper. The first and/or second removable layer may have a thickness of between 3 µm and 1 mm, for example. The thickness may be selected depending on the desired degree of protrusion of the conductive elements. Where protrusion of a conductive element is not desired, a removable layer may be omitted, for example. Preferably, the adhesive portions, such as the adhesive layers, may comprise medically approved adhesive suitable for either short-term or long-term contact with a biological surface. The strength of the adhesive may be selected based on the particular intended application, the target biological surface site, or the intended length of use, for example. Advanced medically-approved adhesive layers which become adhesive (or non-adhesive) upon application of a selected “trigger” such as moisture or biological surface

temperature may also be used. The adhesive portions or layers may comprise and not limited to acrylic, hydrocolloid, rubber, hydrogel, polyurethane, and/or silicone (for example, soft silicone). Each adhesive layer may have a thickness in the range of 1 μm to 200 μm , for example. In aspects disclosed herein, the conductive material may provide an anisotropic conductive medium having good electrical conductance through the thickness of the material, that is in a direction substantially perpendicular to the first and second surfaces, but little or no electrical conductance laterally, that is in a direction parallel to the first and second surfaces. Different subsets of the conductive elements or different subsets of the tubular conductive elements may be selected as desired by varying the position of the electrode at the second surface and/or by varying the shape or size of the electrode contact surface. Different subsets of the tubular conductive elements may be selected in order to electrically ‘probe’ different parts of the biological surface, for example to enable surface potential monitoring such as ECG monitoring and/or bioimpedance monitoring and/or to apply electrostimulation across different regions of tissue. Moreover, the conductive material may be used with multiple electrodes simultaneously, each electrode being connected to a different, discrete subset of the tubular conductive elements. For a single electrode it may be desirable that, wherever the electrode is located with respect to the second surface of the substrate, its contact surface will electrically contact a subset of the plurality of conductive elements or a subset of the plurality of tubular conductive elements that contains substantially the same number of conductive elements. This may be desirable particularly where the conductive elements or the tubular conductive elements have substantially uniform sizes and shapes and therefore substantially the same electrical properties. Whether or not all of the conductive elements have substantially uniform sizes and shapes, the conductivity of the conductive material may be substantially constant over any area comprising multiple conductive elements. In addition to or as an alternative to varying the position of the electrode at the second surface and varying the shape or size of the electrode contact surface, different subsets of conductive elements or tubular conductive elements may also be selected by provision of a non-conductive, insulating layer, providing a mask element between the electrode and the conductive material. The mask element may locate between a portion of the electrode contact surface and the second surface of the conductive material,

preventing electrical contact between the electrode and some of the conductive elements or the tubular conductive elements over which the electrode is located. The mask element may comprise a sheet of non-conductive material that includes, for example, a hole or recess that defines the desired area of electrical contact between the electrode contact surface and the second surface of the conductive material. The mask element may comprise adhesive to attach the mask element to the second surface of the conductive material or to the electrode contact surface, or may be a mobile mask element that is designed to rest against rather than be attached to the electrode or conductive material. The conductive material may be used in addition to, or more preferably as replacement for, a conductive gel or conductive solution as an interface between an electrode and a biological surface. The conductive material may maintain low contact impedances and introduce high reproducibility in the quality of electrical contact and therefore measurement or stimulation values. The conductive material with an overlying insulating layer may provide a hygienic barrier between the biological surface and the electrode and associated electrical componentry. The conductive material with an overlying insulating layer, including the substrate thereof, may be substantially non-porous to prevent propagation of biological material such as body surface exudates and bacteria between the electrode and the biological surface. To achieve non porosity, the conductive elements or the tubular conductive elements may be sealingly engaged with the substrate as they extend through the substrate. The conductive material may provide a non-diffusive barrier. Moreover, the conductive material may be movable relative to the biological surface, reducing the possibility of irritation to the subject occurring in comparison to an approach where the conductive material is adhered directly to the biological surface, for example. In another preferred embodiment, the conductive material may be adapted to adhere to the biological surface as discussed above.

[0050] It may be appreciated that through use of multiple conductive elements or multiple tubular conductive elements to transfer electrical signals between the electrode and the biological surface, a signal-to-noise ratio may be improved. Each conductive element or each tubular conductive element may carry an individual signal component and an individual noise component. The overall signal transferred is a sum of the

individual signals' components, which are generally in phase with each other such that constructive interference between the individual signal components can occur. Similarly, the overall noise transferred is a sum of the individual noise components. However, since the individual noise components are random in nature, destructive interference between the individual noise components can occur. Therefore, the overall signal amplitude may be increased in comparison to the overall noise signal, improving the signal-to-noise ratio. The conductive material may provide, or may be comprised in, a medical interface such as a medical dressing. The medical dressing may be a pad, a patch, a compress, bandage or tape, which may also include kinesiology tape; wherein the medical dressing may be configured for application to tissue to promote healing of tissue, to protect the tissue from harm, to restrict or control movement of the tissue, and/or to generally allow monitoring of the tissue. The conductive material may be held in place by, or may be comprised in, a bandage, plaster, belt or band for example, a headband or wristband. Additionally, or alternatively, the conductive material may be held in place using adhesive tape, and/or through use of an adhesive layer that may form part of the dressing. The conductive material may provide and not limited to, an electrically conductive path to tissue for the purpose of monitoring the tissue, or electrostimulation of the tissue. The electrically conductive path may extend through a thickness of the conductive material. The conductive material may provide for, or enable contact with, an electrode. The tissue at which the conductive material, for example in the form of a medical dressing, may be applied may include a wound or other types of tissue damage and/or imperfections. For example, the conductive material may be applied at or in close proximity to tissue including and not limited to a cut, burn, surgical wound, chronic wound, abrasion, abscess, carbuncle, blister, wart, rash, scar, infection, bedsore, disease, muscle tear, ligament tear. The conductive material may be formed by processing of a pre-existing product such as a medical dressing, for example, a pad, a compress, bandage, plaster, patch or tape. The pre-existing product may include a substrate, a first layer and optionally a second layer as described above, for example. In this regard, medical dressings commonly include a substrate and a removable layer located over an adhesive layer on one surface of the substrate and in some instances a second removable layer located over a second surface of the substrate. Thus, processing of the pre-existing

product may include forming perforations in the product, including in the first and optionally second removable layers of the product, and applying a conductive substance to the perforations to form conductive elements or tubular conductive elements in accordance with the described embodiments. The pre-existing product may be processed in various forms, which may be and not limited to strips, sheets or rolls of material.

[0051] Conductive substance may be applied to the perforations via one or both sides of the multi-layer construct. Where first and second layers are provided that have a different configuration it may be preferable to apply the conductive material via one of the first and second layers and not the other. In some preferred embodiments, it may be preferable to apply the conductive substance to the side from which perforations are formed, for example the side from which a laser or other tool is used to bore into the material to form the perforations. An anisotropically conductive material is described relative to which an electrode can be moved in order to electrically interface with different portions of a biological surface over which the conductive material is placed. The conductive material may be adapted to be used in a fixed relationship relative to one or more electrodes. The conductive material may form part of an electrode device. For example, to form an electrode device, one or more conductive members, for example one or more conductive layers, may be introduced in a fixed relationship with the conductive material, and which electrically contact second ends of a plurality of the conductive elements or a plurality of the tubular conductive elements. A single conductive member may be provided. The single conductive member may be connected to second ends of some or all of the plurality of conductive elements, for example. Alternatively, multiple conductive members may be provided, each conductive member being connected to second ends of different subsets of the plurality of conductive elements or of the plurality of tubular conductive elements. Each conductive member may be in the form of a conductive layer that electrically contacts second ends of the conductive elements. Each conductive member may provide an electrode, which is fixed relative to the substrate, and which is wired to enable connection with external electrical componentry such as monitoring or electrostimulation apparatus and/or which includes a contact portion that can be releasably electrically connected to external electrical componentry as desired. The

contact portion may be in the form of a tab. The tab may extend beyond an edge of the substrate, for example, or may be located over the substrate, for example, at an end of the substrate or other layer located over the substrate. Other contact portions are possible such as a stud or a pre-wired contact. In other preferred embodiments, at least two conductive members, for example at least two electrodes, may be electrically connected to different subsets of the conductive elements or the tubular conductive elements. In other preferred embodiments, four conductive members, for example, four electrodes, may be electrically connected to different subsets of the conductive elements or the tubular conductive elements.

[0052] Alternatively, the conductive material may be formed with a uniform and/or wide distribution of conductive elements or tubular conductive elements, with only some of the conductive elements or tubular conductive elements being contacted by the conductive members. An insulating layer may be provided over the conductive members and/or a top layer of the conductive material from which the second ends of the conductive elements or the second ends of the tubular elements protrude, reducing the risk of any short-circuiting occurring between the conductive members and/or the conductive elements/tubular conductive elements, for example by preventing contact with an external conductor such as a finger or hand or an item such as scissors. The insulating layer may also provide protection against damage to these or other components of the electrode device. The insulating layer may also impart additional mechanical robustness/rigidity to the anisotropic conductive film. The conductive material used in the electrode device may be formed in accordance with conductive material described in preceding aspects. For example, the conductive material may include first and/or second removable layers located over first and second sides of the substrate, respectively. Additionally, or alternatively, the conductive material may include first and/or second adhesive elements or layers located over the first and second sides of the substrate, for example between the substrate and the first and/or second removable layers. The first and/or second removable layers may be removed prior to contact being made between the conductive members and the conductive elements or the tubular conductive elements. For example, the second removable layer may be removed to expose protruding second ends of the conductive

elements or tubular conductive elements which are subsequently contacted by the conductive members. Nevertheless, contact may be made between the second ends of the conductive elements or the second ends of the tubular conductive elements that are not arranged to protrude. When the electrode device includes adhesive elements or layers, the adhesive may be used to adhere the electrode device to the biological surface. In some preferred embodiments, anisotropically conductive material or an electrode device comprising the anisotropically conductive material as described herein, may be comprised in a garment. The garment may be any type of garment suitable to extend over a portion of a subject's body in a close fit manner. By extending in a close-fit manner, the conductive material may rest on a biological surface, particularly a skin surface, enabling good electrical contact to be achieved with the skin surface. Suitable garments may include, for example, gloves, socks which may include compression socks, hats, helmets, wrist bands, head bands, arm bands, ankle straps, shoulder straps, belts. The garment may be formed entirely of the conductive material or the conductive material may form one of multiple portions, for example layers, of the garment. For example, the conductive material may provide a liner of the garment, acting as a hygienic barrier between a main body of the garment and the skin surface. It may be appreciated that for the embodiments with tubular micropylons, the insulating overlayer is needed so as to maintain a hygienic barrier. In this example, the main body for example an outer layer of the garment may include one or more electrodes integrated therein, the electrodes being adapted to electrically interface with the skin surface through the liner comprising the conductive material. The conductive material or electrode device of the present disclosure may have a wide variety of applications where electrical signals are to be applied to and/or detected from a subject transcutaneously. For example, applications may include bioimpedance monitoring, electrostimulation, electrocardiography (ECG), electroencephalography (EEG), electromyography (EMG), targeted muscle reinnervation (TMR), electrocorticography, electrooculography, electroretinography, electroantennography, audiology and electrocochleography. The construction of the conductive material or electrode device may reduce a dependence on the skill of the person applying electrodes to a biological surface to achieve high quality electrode contact and measurement reproducibility. The construction may also reduce any mess or awkwardness associated

with the application of electrodes to a biological surface. The conductive material or electrode device may be suitable for use in a wide variety of conditions, including where an electrode is to be interfaced with a biological surface for extended periods of time, for example for longer than a few minutes, such as hours or even one or more days.

Moreover, the conductive material or electrode device may be sufficiently flexible to conform to both flat anatomical features and curved anatomical features, such as fingers, toes, joints, and various facial locations, for example. Further, the conductive material or electrode device may be used in contact or close proximity with compromised skin or other biological surfaces, since it may provide a relatively soft, supple, dry and inert contact surface. For example, the conductive material or electrode device may be used in contact with or in close proximity to wounds, ranging from acute cuts and bruises, to more chronic conditions, such as diabetic ulcers. The conductive material or electrode device may be easy to position on the biological surface. The quality of the electrical contact may be high, contact impedances may be low, and measurement and stimulation values may be consistent and reproducible. The conductive material or electrode device may have simple, reliable construction, providing for ease of manufacture at reduced costs. Reduced costs may allow the conductive material to be used as a disposable item. However, the conductive material or electrode device may also be suitable for washing, enabling reuse while maintaining sterility.

[0053] In the context of the present invention, the words “comprise”, “comprising” and the like are to be construed in their inclusive, as opposed to their exclusive, sense, that is in the sense of “including, but not limited to”.

[0054] The invention is to be interpreted with reference to the at least one of the technical problems described or affiliated with the background art. The present invention aims to solve or ameliorate at least one of the technical problems and this may result in one or more advantageous effects as defined by this specification and described in detail with reference to the preferred embodiments of the present invention.

BRIEF DESCRIPTION OF THE FIGURES

[0055] Figure 1 illustrates an oblique view of an anisotropically conductive material with tubular conductive elements protruding from a first surface and a second surface of the substrate according to an embodiment of the present disclosure.

[0056] Figure 2 illustrates a cross-sectional view of an anisotropically conductive material with tubular conductive elements of Figure 1.

[0057] Figure 3 illustrates a cross-sectional view of an anisotropically conductive material with tubular conductive elements with a first removable layer removed, in which the tubular conductive elements extended into the substrate and the first removable layer, while the second end of the tubular conductive element protrudes from the second surface of the substrate. A subset of the tubular conductive element is in good contact with metallic electrode at the second end, while the tubular conductive element is in good contact with skin at the first end.

[0058] Figure 4 illustrates a top view of a multilayer structure as it is processed to form an electrode device according to another embodiment of the present disclosure.

[0059] Figure 5 illustrates a cross sectional view of an anisotropically conductive material with solid conductive elements, showing an ideal peeling of the first removable layer, in which the electrode is in good contact with the second end of the conductive element at the second surface.

[0060] Figure 6 illustrates a cross sectional view of an anisotropically conductive material with solid conductive elements, showing a shearing of the solid conductive elements when peeling of the first removable layer, in which the electrode is in good contact with the second end of the conductive element at the second surface.

[0061] Figure 7 illustrates a cross sectional view of an anisotropically conductive material with tubular conductive elements, showing a shearing of the tubular conductive

elements when peeling of the first removable layer, in which the electrode is in good contact with the second end of the tubular conductive element at the second surface.

[0062] Figure 8 illustrates a perspective view of a transparent film with a semi-rigid frame applied over an electrode device with the anisotropically electrically conductive material with the tubular conductive elements.

[0063] Figure 9 illustrates a cross-sectional view of conductive material with tubular conductive elements according to an embodiment of the present disclosure.

[0064] Figure 10 illustrates an oblique view of the conductive material with tubular conductive elements of Figure 9 having removable layers located thereon according to an embodiment of the present disclosure.

[0065] Figure 11 illustrates a cross-sectional view of the conductive material with tubular conductive elements as shown in Figure 10.

[0066] Figure 12 illustrates an oblique view of the multilayer structure used in the formation of conductive material with tubular conductive elements according to an embodiment of the present disclosure.

[0067] Figure 13 illustrates a cross-sectional view of the multilayer structure of Figure 12.

[0068] Figure 14 illustrates an oblique view of the multilayer structure of Figure 12 with perforations formed therein.

[0069] Figure 15 illustrates a cross-sectional view of the multilayer structure of Figure 14.

[0070] Figure 16 illustrates an oblique view of the multilayer structure of Figure 1 with removeable layers partially removed showing how the layers are removed from the first surface and the second surface.

[0071] Figure 17 illustrates a cross-sectional view of the multilayer structure of Figure 16.

[0072] Figure 18 illustrates a cross-sectional view of the conductive material according to the present disclosure with a contaminant located thereon.

[0073] Figure 19 illustrates a cross-sectional view of the conductive material according to the present disclosure with a further conductive substance located thereon.

[0074] Figure 20 illustrates a cross-sectional view of the conductive material with tubular conductive elements adjacent a skin surface and having two electrodes located thereon.

[0075] Figure 21 illustrates an oblique view of a glove comprising conductive material with tubular conductive elements according to an embodiment of the present disclosure.

[0076] Figure 22 illustrates an oblique view of a medical dressing comprising conductive material with tubular conductive elements according to an embodiment of the present disclosure.

[0077] Figure 23 illustrates a cross-sectional view of an electrode device with tubular conductive elements according to an embodiment of the present disclosure.

[0078] Figures 24 to 27 illustrate top and cross-sectional views of a multilayer structure as it is processed to form an electrode device with tubular conductive elements according to another embodiment of the present disclosure.

[0079] Figures 28 to 31 illustrate top and cross-sectional views of a multilayer structure as it is processed to form an electrode device with tubular conductive elements according to another embodiment of the present disclosure.

[0080] Figures 32 to 35 illustrate top and cross-sectional views of a multilayer structure as it is processed to form an electrode device with tubular conductive elements according to another embodiment of the present disclosure.

[0081] Figures 36 to 39 illustrate top and cross-sectional views of the multilayer structure as it is processed to form an electrode device with tubular conductive elements according to another embodiment of the present disclosure.

[0082] Figures 40 and 41 illustrate top views of dressings according to embodiments of the present disclosure that include an exposed and covered opening respectively.

[0083] Figures 42 and 43 illustrate top views of electrode devices according to embodiments of the present disclosure that include an exposed and covered opening, respectively.

[0084] Figures 44 and 45 illustrate top views of a treatment patch and an electrode device according to an embodiment of the present disclosure retaining the treatment path, respectively.

[0085] Figures 46 to 48 show concept drawings of different samples of conductive material containing tubular conductive elements with different tubular conductive element spacings in an example of the present disclosure.

[0086] Figure 49 shows another concept drawing in an oblique view of conductive material containing tubular conductive elements with a tubular conductive element spacing in an example of the present disclosure.

[0087] Figure 50 shows a schematic view of an apparatus used to test samples in an example according to the present disclosure.

DESCRIPTION OF THE INVENTION

[0088] Preferred embodiments of the invention will now be described with reference to the accompanying drawings and non-limiting examples.

[0089] In an embodiment of the present invention, as illustrated in Figures 1 to 4, Figure 3 may relate to an electrode device 1000 for use on a portion of a biological surface 1002, the electrode device 1000 may comprise an anisotropically electrically conductive material 1004, as shown in Figures 3 and 4, which can electrically interface one or more conductive members 15 or electrodes 15. As shown in Figures 1 and 2, showing the conductive material with the first and second removal layers off, the conductive material 1 or 1004 may comprise a substrate 10 which may have a first surface 11 parallel to a second surface 12. A first removable layer 17, wherein the first removable layer 17 is located over the first surface 11. A plurality of discrete perforations 101, wherein each perforation 101 may extend through the substrate 10 and the first removable layer 17. A plurality of discrete conductive elements 13, wherein each conductive element 13 may be formed in a respective one of the perforations 101 so as to extend through the substrate 10 and the first removable layer 17.

[0090] In another preferred embodiment of the present invention, as shown in Figure 3, the electrode device 1000 may have discrete conductive elements 13 or discrete tubular conductive elements 13 that may extend through the substrate 10 and the first removable layer 17, and protruding out from the second surface 12. Each of the conductive element 13 or each of the tubular conductive element 13 may have a first end 131 and a second end 132. The first end 131 may extend out of the first removable layer 17, and the second end 132 may extend out of the second surface 12. The protrusions of the conductive elements 13 or tubular conductive elements 13, which may be conductive micro pylons 13 or tubular conductive micro pylons 13 respectively at the second end

132 advantageously promote good applying contact with conductive members 15 or electrodes 15. The conductive members 15 may be a reusable electrode 15 which can be removably mounted to the protruding second end 132 of the conductive elements 13 or tubular conductive elements 13. The adhesive layer 14, when included, may comprise acrylic, hydrocolloid, rubber, hydrogel, polyurethane, and/or silicone. It may be appreciated that the adhesive layer is non-conductive so as to not short circuit the electrically anisotropic tubular elements and not cause the effective contact area of the electrode to be ill defined. While generally non-conductive adhesives should be used, however, conductive adhesives could be used on the underside of patterned macroelectrodes of the type shown in Figure 4, for example to further reduce contact impedance. When conductive adhesives are used in the way, another protective disposable layer or another protective insulating layer has to be applied over the conductive adhesive layer. An energy source in communication with the mounted electrode 15 (representing a wire) provides for controlled electrical impulses to travel down the conductive elements 13 that is placed on the desired portion of a biological surface 1002 for treatment and/or monitoring.

[0091] In another preferred embodiment of the present invention as shown in Figure 1 an adhesive layer 14 may be positioned or located between the first removable layer 17 and the first surface 11 of the substrate 10. The first removable layer 17 may be constructed of a material or film that is gentle when removing the layer 17 and not shear away the first end 131 of the conductive elements 13 or the first end 131 of the tubular conductive elements 13. As such, in this embodiment, the length of the conductive element 13 or tubular conductive element 13 protruding through the first surface 11 may be of a length ideally determined by the thickness of the removable layer 17. An advantage of this particular embodiment is that the skin 1002 or biological surface 1002 that is in contact to the protruding first ends 131 of the conductive element 13 will have an expected predetermined contact impedance that is useful in tailoring treatment and/or monitoring of the desired portion of biological surface 1002.

[0092] In another preferred embodiment of the present invention as shown in Figures 1, 3, and 9, an adhesive layer 14 may be positioned or located between the first removable layer 17 and the first surface 11 of the substrate 10. The first removable layer 17 may be constructed of a material or film that may shear off or partially shear off the first ends 131 of the conductive elements 13 or the first ends 131 of the tubular conductive elements 13, in which the length of the conductive element 13 may have a relatively smaller protrusion compared to the ideal length of protrusion. Due to the smaller length of the conductive elements 13 or the smaller length of the tubular conductive elements 13 exposed when the first removable layer 17 is removed, a higher skin to electrode contact impedance is measured. In overcoming this higher skin to electrode contact impedance from shearing caused by removing the first removable layer 17, each of the conductive elements 13 or the tubular conductive elements 13 may be tubular. The conductive elements 13 or micro pylons 13 may be tubular and wherein each of the tubes define a hollow core 130 or an inside space 130 of a tubular structure wherein the inside space 130 is adapted to receive the option of a solution therein that thereby lowers contact impedance.

[0093] This preferred embodiment may have a through-hole aspect ratio (A. R.) in the base multilayer material 1004, that is, the ratio of film thickness (T) to hole diameter (D), in which the (A. R.) is less than 1. As first ends 131 of the tubular micro-pylons 13 can similarly be sheared off from the removal of the first removable layer 17, similar to solid micro-pylons, the tubular conductive elements 13 or tubular micro-pylons 13 can advantageously allow the person applying or using this electrical device 1000 additional options that expand the usability of this device 1000.

[0094] For example, prior to peeling away of the protective release or the first removable layer 17 later, the underside 17a of the first removable layer 17 can be wiped with water (or some suitable conductive solution, which may be aqueous electrolyte) which will cause the tubular micro-pylons 13 to be filled with water or the suitable solution by capillary action. Incorporation of water or the suitable solution in this way can advantageously give rise to an interface with considerably lower contact impedance. Essentially, the water or solution is intended to facilitate the electrical interfacing of the

micro-pylons with the skin on a microscopic scale. The water is replacing the air which from an electrical perspective is an improvement even though water is a poor conductor. Lower contact impedance can advantageously allow for improved electrical performance, reduced localised heat generation, and improved signal integrity. By applying water or the suitable solution in this way, that is, with the protective release layer 17 still located over the first surface, the water or the solution will be prevented from coming into contact with the adhesive layer where it could adversely affect the adhesive character of that adhesive layer 14 when an adhesive layer 14 is included on the skin contacting surface of the interface 14a.

[0095] Another application can be to use suitably solution loaded tubular micro-pylon based conductive elements 13 which may be an electrode array for electrophoretic delivery of particular agents, such as and not limited to through acupuncture points. Several advantages of electrophoretic delivery may include targeted delivery of agents or therapeutics to the desired portion of biological surfaces 1002, which can improve the effectiveness of the treatment while minimising the potential for side effects. This is particularly important in applications such as developing personalised medicine, and drug delivery, where targeted delivery is essential. Another advantage can include enhanced penetration of the therapeutic agents into tissues or cells by creating an electrical field that may allow the particles or therapeutics to penetrate deeper into the tissue of the area of interest which can improve the efficiency and effectiveness of the delivery. Another advantage of this can be that it is non-invasive as it does not require the use of needles or other invasive delivery methods. This can reduce the uncomfortableness of pain, or infections or other complications associated with invasive delivery methods. The application allows for high precision of delivery of agents to specific areas or tissues and that it minimises tissue damage by using low electrical currents to drive the agents into the tissue. This can reduce the potential for tissue damage or scarring.

[0096] Another application of these tubular micro-pylon electrode array is to take up or deal with sweat through capillary action during long-term testing or application of the electrode device 1000. Applications can be useful for allowing the array for in situ or

post-testing sweat analysis applications. Post-testing sweat analysis for example in monitoring athletic performance will assist in measuring changes in electrolyte balance, glucose levels, lactate levels and other metabolites through time-point analysis. The tubular micro-pylons 13 may pick up sweat that can allow for detecting drug use from a person where certain chemicals are secreted and can provide a longer detection window. Further, due to the non-invasive nature of this electrode device 1000 embodiment, it is a better form to use compared to known methods such as urine or blood testing.

[0097] From the perspective of manufacturing, the advantages of developing tubular conductive micro-pylons 13 with an aspect ratio (A. R.) less than one is so that it can provide greater stability while using less conductive material. This can reduce the overall weight and cost of the object while maintaining its strength. Further, it also increases flexibility and can be less prone to breaking under stress, and there is increased heat dissipation due to its larger surface area.

[0098] It may be preferred from a manufacturing perspective that the substrate 10 and the layers are microperforated by the cost-effective hot needle technique. In microperforation, the materials are perforated with a large number of small holes. The hole size and hole density can affect the properties of the perforated material. At least for the hot needle technique, lower density of wider diameter holes is preferred over higher density of smaller diameter holes. Advantages of this preference may include easier manufacturing as it can be more difficult to create a large number of small holes that are evenly spaced and or consistent size. Further advantage of the hot needle method is that at typical machine speeds, there was no build up of adhesive on the roller needles and so the roller needles can provide a consistent puncturing size to the substrate and layers.

[0099] It may be appreciated that the presence of the macroscopic electrode layer 15 or conductive member 15 mounted to the second end 132 of the conductive elements 13 (as shown in Figures 5 and 6) or tubular micro-pylons 13 (as shown in Figure 7) which may be either be protruding from or at the second surface 12 of the substrate 10 may advantageously provide an 'anchor' at the second end 132 of the conductive elements 13 or tubular conductive micro-pylons 13, in which when the first removable layer 1014 is

peeled in a direction away from the first end 1024, the tubular micro-pylons 1022 may also be pulled towards in the same direction. As such, by adhering to the electrode layer 15, it thereby prevents the conductive elements 13 to be pulled out of the substrate 10 which overcomes the shortcomings of fabrication of this electrode device 1000.

[00100] As shown in Figure 8, the electrode device 1000 may comprise user-friendly tabs 1040 (pointing to the expected underside location of the tab) and peelable frame 1042, which makes it easier and convenient for a person or a patient to put the electrode device 1000 on to the particular area themselves. As shown in Figure 8, the frame 1042 with a protective insulating layer 1044 or film 1044 can provide an extra layer of protection for the person or patient when applied over the desired area of skin. The protective insulating layer 1044 or film 1044 may preferably be transparent or translucent so as to advantageously provide easy control and precise placement of the material as it allows a user's fingers 1060 to hold and apply over the electrode device 1000 for an extra layer of protection for the person or patient. The transparency of the protective layer 1044 will allow for convenient identification of where the electrodes and materials are to be placed. While ideally the protective insulating layer may be transparent, it may not be transparent in which the protective insulating layer is primarily intended to protect the printed electrodes and tracks under the layer.

[00101] In another preferred embodiment of the present invention, as shown in Figures 9 to 11, a portion of conductive material 1 includes a flexible substrate 10 having first and second surfaces 11, 12, the first and second surfaces 11, 12 being located on substantially opposite sides of the substrate 10. The material 1 also includes a plurality of discrete conductive elements 13, similarly as shown in Figures 5 and 6, or a plurality of discrete tubular conductive elements 13 are distributed within respective perforations 101 in an array across the substrate 10. As shown in Figures 3 and 9, each conductive element 13 or each tubular conductive element 13 may extend through a respective perforation 101 in the substrate 10 such that a first end 131 of each conductive element 13 or tubular conductive element 13 is exposed at and protrudes from the first surface 11 of the substrate 10 and a second end 132 of each conductive element 13 or each conductive

element 13 is exposed at and protrudes from the second surface 12 of the substrate 10. The substrate 10 is formed substantially of non-conductive material such as a polymeric foam or film, and therefore the discrete conductive elements 13 or tubular conductive elements 13 are electrically isolated from each other through the substrate 10. In particular, the conductive material 1 provides an anisotropic conductive medium having good electrical conductance through the thickness of the material 1 (the thickness direction being indicated by arrow T in Figure 9) but little or no electrical conductance laterally through the material 1 (the lateral direction being indicated by arrow L in Figure 9). In this embodiment, an adhesive layer 14 is also located over the first surface of the substrate. In addition to being exposed at and protruding from the first surface 11 of the substrate 10, the first ends 131 of the conductive elements 131 or the tubular conductive elements are also exposed at and protrude from the adhesive layer 14. As shown in Figure 9, in use, the first surface 11 of the substrate 10 is located in close proximity to a biological surface such as a skin surface 16 of a subject such that the first surface 11 faces the skin surface 16 and the first ends 131 of the conductive elements 13 or the tubular conductive elements 13 each electrically contact the skin surface 16. The adhesive layer 14 over the first surface 11 may at least partly contact and adhere to the skin surface 16, maintaining the position of the conductive material on the skin surface 16. An electrode 15 can be located in close proximity to the second surface 12 of the substrate 10 such that a contact surface 151 of the electrode 15 faces the second surface 12 and the second ends 132 of a subset of the conductive elements 13 or the tubular conductive elements 13 each electrically contact the contact surface 151 of the electrode 15. The second surface 12 may at least partly contact the contact surface 151 of the electrode 15 or may be spaced slightly from the contact surface 151 by virtue of a protrusion of the second ends 132 of the conductive elements 13 or the tubular conductive elements 13.

[00102] In another preferred embodiment of the present invention, as shown in figures 10 and 11, the conductive material 1 can additionally comprise first and/or second removable layers 17, 18 disposed or located over the first and second surfaces 11, 12 of the substrate 10, respectively. The first removable layer 17 can be held in position over the first surface 11 by releasably adhering to the adhesive layer 14. The second

removable layer 18 can be held in position over the second surface 12 by other forces, such as a van der Waals forces, for example. In alternative embodiments, the first removable layer may be held in position over the first surface by other forces such as a van der Waals forces, for example, and/or the second removable layer may be held in position over the second by releasably adhering to an adhesive layer. When one or more adhesive layers are provided, each adhesive layer may be fixed to the substrate and releasable from the respective removable layer or fixed to the respective removable layer and releasable from the substrate. When the first and second removable layers 17, 18 are located over the substrate 10, the perforations 101 continuously extend through the substrate 10, the adhesive layer 14 and the first and second layers 17, 18.

[00103] A method of forming the conductive material 1 according to an embodiment of the present disclosure is now described with reference to Figures 10 to 16. As shown in Figures 10 and 11, a substrate 10 is provided having first and second surfaces 11, 12 on opposite sides, respectively, of the substrate 10. A first removable layer 17 is located over the first surface 11, and specifically over an adhesive layer 14 that is also located over the first surface 11, and a second removable layer 18 is located over the second surface 12. The substrate 10 may be flexible, meaning that it may bend to follow the curvature of a biological surface or other surface to which it is to make contact. In general, the substrate 10, and the conductive material 1 comprising the substrate, may be configured so that, upon bending during normal use, electrical independence of discrete conductive elements or discrete tubular conductive elements in the conductive material may be maintained. The substrate 10 can comprise a single layer of material as shown in Figures 10 and 11, or multiple layers of material, for example multiple layers of material stacked on top of each other. The substrate 10 can comprise a non-conductive or insulating material such as nylon, polyurethane, polyester, silicones, polyvinyl alcohol, polyimide, natural polymer such as chitosan, foam such as polyurethane foam, natural polysaccharide alginate foam, hydrocolloids such as those formed from carboxymethyl-cellulose, alginate and elastomer, pre-swollen hydrogel of collagen or elastin, hyaluronic acid, or synthetic hydrogels of cross-linked poly(vinyl alcohol), polyvinylpyrrolidone or methacrylate. The substrate 10 can be hydrophobic or

hydrophilic. The substrate 10 can be biodegradable. The substrate 10 can be formed of medical grade material. The substrate 10 can be at least partially transparent or translucent, for example, so that target sites on the biological surface for electrical interfacing can be identified through the substrate, or opaque. The substrate 10 can be coloured or clear. The substrate 10 can be substantially flat or it can have a three-dimensional shape, for example, a curved or otherwise structured shape. The three-dimensional shape may be pre-formed in the substrate 10. The substrate 10 can have a thickness of between 5 μ m and 2mm or any other thickness. The adhesive layer 14 can comprise a medically approved adhesive suitable for short-term or long-term contact with a biological surface. The strength of the adhesive of the layer 14 may be selected based on the particular intended application, the target biological surface site, or the intended length of use, for example. Advanced medically-approved adhesive layers which become adhesive or non-adhesive upon application of a selected “trigger” such as moisture or biological surface temperature may also be used. The adhesive layer 14 can comprise acrylic, hydrocolloid, rubber, hydrogel, polyurethane, and/or silicone (for example soft silicone), for example. The adhesive layer 14 can have a thickness in the range of 1 μ m to 200 μ m, for example. While a single adhesive layer 14 is provided over the first surface 11 of the substrate 10 in this embodiment, in alternative embodiments an adhesive layer may be provided over each of the first and second surfaces 11, 12 or over the second surface of the substrate only. Alternatively, an adhesive layer may not be provided over either over the first and second surfaces 11, 12. As shown in figures 14 and 15, a plurality of perforations 101 are formed through the substrate 10, the adhesive layer 14, the first removable layer 17 and the second removable layer 18. Thus, each perforation 101 defines an opening in each layer, including an opening 102 in the substrate, an opening 172 in the first removable layer 17 and an opening 182 in the second removable layer 18, along with an opening 142 in the adhesive layer 14. Opposite ends of each perforation 101 terminate at respective outer surfaces of the first and second removable layers 17, 18 where the perforations have respective first and second apertures 173, 183 through which access to the openings of the perforation 101 is possible. The perforations 101 can be formed by any one or more of laser perforation, ultrasonic perforation, cold or hot needle perforation, electrostatic discharge perforation, water jet perforation, drilling

or otherwise. In this embodiment, the perforations 101 are distributed across the substrate 10 in an array, for example a substantially uniform array, the array having equidistant rows and columns across the substrate 10. Nevertheless, alternative distributions of perforations 101 are possible such as rectilinear arrays, curvilinear arrays, hexagonal arrays or otherwise. In some embodiments, the perforations may be in a line, in a staggered arrangement, or arranged in different shapes and patterns, for example in clusters of perforations such as circular clusters of perforations. In this embodiment, the perforations 101 have a shape, in a plane perpendicular to their direction of extension through the conductive material, that is circular. In alternative embodiments, the shape may be square, triangular, irregular or any other shape, and may differ for different perforations. In this embodiment, the perforations 101 extend in a direction that is perpendicular to the first and second surfaces 11, 12 of the substrate 10. In alternative embodiments, the perforations may extend at an angle to the first and/or second surfaces of the substrate. In this embodiment, the conductive elements 13 or the tubular conductive elements 13 take the form of pillars 13 or pylons 13, for example micro-pillars 13 or micro-pylons 13 and the conductive elements 13 may be monolithic through forming in one-piece. In this embodiment, the perforations 101 have an aspect ratio (AR), that is, a total perforation depth through the different layers of the conductive material to perforation diameter in the range of less than 1.0 to 4.0. In this embodiment, the spacing between perforations 101 (inter-perforation spacing) is selected to provide a desired density, conductance and lateral resistance of the conductive elements and the mechanical strength of conductive material 1.

[00104] In another preferred embodiment, as shown in Figure 15, a conductive substance is applied to the plurality of perforations 101 to form the plurality of discrete electrically conductive elements 13. The conductive substance can be applied via the first aperture 173 and/or second aperture 183 of each perforation 101. In some embodiments, it may be preferable to apply the conductive substance to the side from which perforations are formed, for example the side from which a laser or other tool is used to bore into the material to form the perforations 101. The conductive substance can be applied to the perforations 101 by any one or more of: screen printing, doctor blading,

inkjet printing, pad printing, flexographic printing, gravure printing spraying, dip coating. In this embodiment, as shown in Figure 15, the applying of the conductive substance is such that, for each perforation 101, the conductive substance substantially fills the opening 102 in the substrate 10, the opening 172 in the first removable layer 17 and the opening 182 in the second removable layer, along with the opening 142 in the adhesive layer 14. A first end 131 of each resulting conductive element 13 substantially aligns with an outer surface of the first removable layer 17 and a second opposite end 132 of the conductive element 13 or the tubular conductive element 13 substantially aligns with the outer surface of the second removable layer 18 as shown in Figure 16. The conductive substance applied to the perforations 101 and the resultant conductive elements 13 can comprise conductive matter such as carbon, graphite, graphene, silver, gold, copper, carbon nanotubes, conducting polymers, polymer electrolytes, salts, conductive adhesive and/or combinations thereof. The conductive matter can in some embodiments be combined with carrier matter such polymers, solvents for example water, organic solvents, UV or electron-beam curable matter, or therapeutic agents such as drugs. The carrier matter can optimise physical properties of the conductive substance when applied to the perforations and/or optimise the physical properties of the conductive elements formed in the perforations. The carrier matter can serve as a binder, water absorber, adhesion promoter, flexibility enhancer or otherwise. The carrier matter can ensure that the conductive substance can be applied more easily to the perforations, for example so that it can enter and fill the openings 102, 142, 172, 182 provided by the perforations 101, for example. The carrier matter can ensure that the conductive substance will adhere to the substrate, for example. The conductive substance can be homogeneous or heterogeneous. The conductive substance can be biocompatible. The conductive substance as applied to the plurality of perforations 101 can be an ink. The ink can comprise carrier matter comprising a solvent and can comprise conductive matter such as carbon, graphite, graphene, silver, gold, copper, carbon nanotubes, conducting polymers, polymer electrolytes, salts, conductive adhesive and/or combinations thereof as indicated above. In some embodiments, however, solvent-free inks may be used, which may comprise UV or electron-beam curable carrier matter, for example. The conductive substance can be applied as a solid, liquid or paste, for example depending on the

presence and type of carrier matter combined with the conductive matter, for example. In some embodiments, ink formulations can be either a single formulation or a two-part formulation that reacts upon mixing. After application to the perforations, the conductive substance can be subjected to a drying process (for example thermal, vacuum or air flow drying treatment) or a curing process (for example thermal, UV, electron beam curing). If thermal treatment is used, temperatures can be selected to avoid damaging parts of the conductive material 1, including the adhesive layer 14.

[00105] As applied to the perforations 101, the conductive substance can completely fill the perforations. When the conductive substance 1 is subject to subsequent processing to form the final conductive elements 13 or tubular conductive elements 13, however, the size of the conductive elements or the tubular conductive elements can change in some embodiments. For example, if the conductive substance comprises a solvent, the solvent may evaporate following thermal treatment, causing the conductive elements to reduce in size, for example so that they do not completely fill the perforations. Nevertheless, the conductive elements or the tubular conductive elements may still have a sufficient length to extend through the substrate and at least partially through the first layer and through the second layer if present. Once the conductive elements 13 or the tubular conductive elements 13 are formed, an anisotropically electrically conductive material 1 is provided that can be used to electrically interface an electrode with a portion of a biological surface, as described above. Prior to use, as shown in figures 10, and 11, the first and second removable layers 17, 18 can be removed from the substrate 10, for example by peeling, as shown in Figures 16 and 17. The first and second removable layers 17, 18 have a variety of different functions. One function of the first and second removable layers 17, 18 is to assist with the formation of the conductive elements 13 or the tubular conductive elements that have first and second end 131, 132 that protrude from the first and second surfaces 11, 12, respectively, of the substrate 10. As is evident from the discussions above, the perforations 101, including the openings 102, 172, 182, 142 in the various layers 10, 17, 18, 14, act as moulds for forming the conductive elements 13 or for forming the tubular conductive elements 13 as shown in Figures 14 and 15. The removable layers 17, 18 are retained over the substrate

10 while forming the conductive elements 13 or forming the tubular conductive elements 13. Subsequent removal of the first and second removable layers 17, 18 as shown in the partially peeled right side of Figures 17 and 18, causes the first and second ends 131, 132 of conductive elements 13 or causes the first and second ends 131, 132 of tubular conductive elements 13 to be exposed as they protrude from the substrate 10 adhesive layer 14. By being exposed and protruding, the first and second ends 131, 132 can achieve better electrical contact with the biological surface 16 or the electrode surface 151, for example in comparison to an arrangement where the first and second ends are aligned with or even stop short of the first and second surfaces 11, 12 of the substrate 10 or of the adhesive layer 14 located thereon.

[00106] After assisting with formation of the conductive elements 13 or tubular conductive elements 13, one or both of the first and second removable layers 17, 18 may be kept in position over the respective first and second surfaces 11, 12 to perform additional functions. For example, one or both of the first and second removable layers 17, 18 can act as protective layers or masks that expose only ends of the conductive elements while covering the surfaces 11, 12 of the substrates 10 and adhesive layer 14 located thereon. The first and second removable layers 17, 18 can each prevent underlying portions of the material 1 from being subsequently contaminated with conductive contaminants that could potentially degrade material anisotropy prior to use. Such contamination may occur during stacking, rolling or processing of the conductive material 1, for example. When one or both of the removable layers 17, 18 are removed as shown in Figure 18 (in the process of removing both the removable layers from an end), any potentially contaminating substances 1100 can be removed with the layers 17, 18, leaving behind a clean, anisotropic underlying structure ready for contact with a biological surface 16 and electrode 15, for example. In some embodiments, as shown in Figure 19, it may be desirable to contact one or both ends 131, 132 of the conductive elements 13 or tubular conductive elements 13 with a further substance 1200, which promotes interfacial conductance, such as water or a conductive liquid or gel, which substance can coat one or both of the ends 131, 132 of the conductive elements 13 and/or be absorbed into the conductive elements 13, dependent on their material properties. It

may be appreciated that when the conductive elements 13 are tubular conductive elements 13, the water or a conductive liquid or gel may fill or partially fill the tubular conductive elements 13. As shown in Figure 19, one or both of the first and second removable layers 17, 18 can prevent or mask underlying portions of the material 1 from being contacted by that further conductive substance, which could potentially degrade material anisotropy or reduce the adhesive character of the layer 14. When the removable layers 17, 18 are removed, the further conductive substance, other than portions that coat or are absorbed into the conductive elements 13 or tubular conductive elements 13, can be removed with the layers 17, 18, leaving behind an anisotropic underlying structure ready for contact with a biological surface 16 and electrode 15, for example.

[00107] In another preferred embodiment or alternative embodiments, only one of the first and second removable layers may be provided, e.g. if it is only desired to form conductive elements or tubular conductive elements that protrude on one side of the substrate only, and not on the other side. When only one of the first and second removable layers is provided, a first end of each of the conductive elements or a first end of each of the tubular conductive elements may align with an outer surface of the first removable layer and a second opposite end of each of the conductive elements or a second opposite end of each of the tubular conductive elements may align with the second surface of the substrate, or a second end of each of the conductive elements may align with an outer surface of the second removable layer and a first opposite end of each of the conductive elements or tubular conductive elements may align with the first surface of the substrate. Different subsets of the conductive elements 13 or different subsets of the tubular conductive elements 13 can be contacted by the electrode 15. As shown in Figure 20, for example, a subset of conductive elements 13c or a subset of tubular conductive elements 13c is defined, generally, by the area across which the contact surface 151 of the electrode 15 extends. By contacting the second ends 132 of the conductive elements 13 or tubular conductive elements 13 of the subset 13c, the electrode 15 will electrically interface with a portion of the skin surface that is in contact with the first ends 131 of the conductive elements 13 or tubular conductive elements 13 of the subset 13c. Since the conductivity of the material 1 is anisotropic, there may be

substantially no electrical interfacing between the electrode and the rest of the skin surface. Different subsets of the conductive elements 13 or tubular conductive elements 13 can be selected as desired by varying the position of the electrode 15 on the second surface 12 of the substrate 10 and/or by varying the shape or size of the electrode 15. Different subsets of the conductive elements 13 or different subsets of the tubular conductive elements 13 can be selected in order to electrically ‘probe’ different parts of the skin surface of the subject, for example to enable bioimpedance monitoring and/or to apply electro-stimulation across different regions of tissue of the subject. As an example, after using the electrode 15 to electrically probe the area of the skin surface that is in contact with the first subset 13c of conductive elements or tubular conductive elements, the electrode 15 may be shifted to electrically probe an area of the skin surface that is in contact with a second subset 13d of conductive elements 13 or tubular conductive elements. Similarly, in another preferred embodiment, more than one electrode 15a, 15b may be used to electrically probe different areas of the skin surface at the same time by simultaneously contacting discrete, electrically isolated subsets 13c, 13d of the conductive elements 13 or tubular conductive elements 13. So that the electrodes 15 can contact multiple discrete conductive elements 13 or multiple discrete tubular conductive elements 13 that form each subset 13c, 13d of the conductive elements 13, the conductive elements or tubular conductive elements are relatively small in comparison to the electrode contact surface 151 and the conductive elements have a relatively high distribution density across the substrate 10. In general, it is not intended that the electrode 15 contacts only one conductive element. Rather, it is intended that the electrode contacts multiple conductive elements that form a subset of the plurality of conductive elements or a subset of the plurality of tubular conductive elements.

[00108] It may be appreciated that depending on the size of the substrate, the size of the conductive elements or tubular conductive elements, and the distribution density of the conductive elements, the total number of conductive elements or tubular conductive elements is essentially limitless. The total number of tubular conductive elements distributed across the substrate can be greater than 50, greater than 100, greater than 500, or greater than 1000, for example. The density of tubular conductive elements across the

substrate can be at least 1 per cm^2 , at least 2 per cm^2 , at least 5 per cm^2 , at least 10 per cm^2 , at least 50 per cm^2 , at least 100 per cm^2 , at least 200 per cm^2 , at least 300 per cm^2 , at least 400 per cm^2 , at least 500 per cm^2 , at least 750 per cm^2 , or at least 1000 per cm^2 , for example. The area of each tubular conductive element at its first or second end, in a plane substantially perpendicular to the first and second surfaces of the substrate, may be less than 0.5 cm^2 , less than 0.25 cm^2 , less than 0.1 cm^2 or less than 0.05 cm^2 , less than 0.01 cm^2 , less than 0.001 cm^2 , or less than 0.0001 cm^2 , for example. The maximum distances between the ends of neighbouring tubular conductive elements may be less than 1.0 cm, less than 0.75 cm, less than 0.5 cm, less than 0.25 cm, less than 0.1 cm, less than 0.05 cm, less than 0.01 cm, or less than 0.001 cm, for example. In some embodiments, the tubular conductive elements may therefore be distributed in a macroscopic or microscopic scale. For example, when distributed in a microscopic scale, the surface area of each conductive element or tubular conductive element at its first or second end, in a plane substantially perpendicular to the first and second surfaces of the substrate, may be less than 0.01 cm^2 , 0.001 cm^2 , or 0.0001 cm^2 . Moreover, the maximum distances between the ends of neighbouring conductive elements or neighbouring conductive elements may be less than 0.1 cm, or 0.2 cm or other distances.

[00109] Generally, to the extent that conductive elements or tubular conductive elements can remain electrically separated (i.e. that lateral resistance in the substrate can be maintained), the higher the density of conductive elements or tubular conductive elements, the closer the effective electrode area of the electrode 15 may be in size and shape to the physical electrode area of the electrode 15. The size and shape of the physical electrode area corresponds to the size and shape of the electrode contact surface 151. However, the size and shape of the effective electrode area is dependent on the number of conductive elements 13 or tubular conductive elements in the subset, and the shape and size of each conductive element 13 or tubular conductive element in the subset, particularly where they contact the skin surface 16. In general, the conductive material 1 can provide a biological interface for achieving electrical contact between an electrode and a biological surface such as a skin surface on which the conductive material 1 is located. The conductive material 1 may be provided in the form of a patch or cloth that is

freely locatable over any skin surface prior to electrode contact. As an alternative, the conductive material 1 may form all or part of a garment. In another preferred embodiment, as shown in Figure 21, the conductive material 1 forms part of a glove 2 or sock or elastic sleeve that is configured to fit over a hand or other body part in a tight-fit manner. The conductive material 1 provides a panel of the glove 2, for example, adapted to locate over the back of the hand, although it may be provided in other parts of the glove, e.g. the fingers or thumb of the glove, or the entire glove may be formed of the conductive material 1. Other garments into which the conductive material 1 can be integrated include, for example, socks (including compression socks), hats, wrist bands, head bands, arm bands, ankle straps, and shoulder straps, belts etc. In the embodiment, an electrode 15 can be electrically interfaced with a portion of the skin surface of the hand by electrically contacting any subset of the conductive elements 13 or tubular conductive elements 13 across which the contact surface of electrode 15 can reach. For example, a subset of electrodes that may be contacted by the electrode 15 is indicated in Figure 21 by circle 21. The conductive material 1 forms part of a main body of the garment. In an alternative embodiment, in which an insulating overlayer is provided, the conductive material 1 can provide a liner of a garment, acting as a hygienic barrier between a main body of the garment and the skin surface. The main body may include electrodes integrated therein, the electrodes being adapted to electrically interface with the skin surface through the conductive material of the liner. In another preferred embodiment, as shown in Figure 22, the conductive material 1 is provided in a medical interface and specifically in this embodiment a medical dressing such as a wound dressing 20. In this embodiment, the wound dressing 20 is comprised in a bandage 22 (located over a leg 23 in this example). An electrode can be brought into contact with the dressing 20 to electrically contact the wound and/or tissue surrounding the wound. The wound dressing 20 including the conductive material 1 can therefore provide protection and promote healing of a wound while also providing an electrically conductive path to the wound or tissue surrounding the wound, for the purpose of monitoring of the wound, electrostimulation or the wound, or otherwise. The tissue at which medical dressings according to the present disclosure may be applied may include a wound or other types of tissue damage and/or imperfections. For example, the dressing may be applied at or in

close proximity to tissue including but not limited to a cut, burn, sore, abscess, carbuncle, blister, wart, rash, scar, infection, disease, muscle tear, ligament tear. In some embodiments, the conductive material 1 may be formed by processing of a pre-existing product such as a medical dressing, for example, a pad, a patch, a compress, bandage, plaster or tape. The pre-existing product may include a substrate, a first and optionally a second layer (for example, a carrier layer), the first and second layers being removable. Medical dressings commonly include a substrate and a removable layer (for example, a release layer) located over an adhesive layer on one surface of the substrate and in some instances a second removable layer (for example, a carrier layer) located over a second surface of the substrate. Thus, processing of the pre-existing product may include forming perforations in the product and applying a conductive substance to the perforations to form conductive elements in accordance with discussions above. Alternatively, the pre-existing product may not include first and/or second removable layers and the pre-existing product may be modified to include one or both of these layers. An anisotropically conductive material is described relative to which an electrode can be moved in order to electrically interface with different portions of a biological surface over which the conductive material is placed. The conductive material may be adapted to be used in a fixed relationship relative to one or more electrodes. The conductive material may form part of an electrode device. For example, to form an electrode device, one or more conductive members, for example, one or more electrodes, may be introduced in a fixed relationship with the substrate, and which electrically contact second ends of a plurality of the conductive elements or which electrically contact second ends of a plurality of the tubular conductive elements. A single conductive member may be provided. The single conductive member may be connected to second ends of some or all of the plurality of conductive elements or tubular conductive elements, for example. Alternatively, multiple conductive members may be provided, each conductive member being connected to second ends of different subsets of the plurality of conductive elements or the plurality of tubular conductive elements.

[00110] The electrode device 3, as shown in Figure 23, can be integrated into a garment or used independently of any garment. The electrode device 3 includes

components that are also present in the conductive material 1, such as a substrate 10, and adhesive layer 14 and conductive elements 13, which can be formed in accordance with methods described above. In contrast to the embodiments described before, as shown in Figure 23, the second ends 132 of the conductive elements 13 or tubular conductive elements 13 are not configured to be selectively contacted by one or more electrodes. Rather, an electrically conductive member, in particular an electrically conductive electrode layer 31, is fixed to conductive material 1 so that it extends over the second surface 12 of the substrate 10 and contacts the second ends 132 of the conductive elements 13 or tubular conductive elements 13. The conductive layer 31 electrically contacts the second ends 132 of each one of the conductive elements 13 or each one of the tubular conductive elements 13. The conductive layer 31 includes a conductive tab 311 at one side, which tab 311 extends to or beyond an edge of the substrate 10. The tab 311 can be electrically connected, through hard wiring or a releasable wired connection, to external componentry. A releasable wired connection may utilise a conductive clip such as a spring or “crocodile” clip, which releasably attaches to the tab 311. Other contact portions are possible such as a stud or a pre-wired contact. In one embodiment, the electrode device 3, with or without the adhesive layer 311, may provide a medical interface, for example, a medical dressing such as a wound dressing, or any other type of biological interface. The dressing may function in a similar manner to the dressing 20 discussed previously. In this embodiment, rather than relying on an external electrode to electrically contact the conductive elements of the dressing and define an effective electrode contact area, the integrated conductive electrode layer 31 is in permanent contact with the conductive elements, such as to define an effective electrode contact area in a predetermined manner. In each case, the effective electrode contact area extends to the outer perimeter of the conductive elements that are electrically contacted. In one embodiment, the electrode device 3 may provide a general form of electrode. Variations of the electrode device 3 are possible, as evident, for example, from the following embodiments as shown in Figures 24 to 39. In these embodiments, rather than a single conductive member 31, multiple conductive members are fixed to conductive material to contact second ends conductive elements. For example, to form an electrode device 4 according to one embodiment as shown in Figure 24, a substrate 410 may have a first

removable layer 417 located over a first surface 411 of the substrate and an adhesive layer 414 also located over the first surface 411 of the substrate 410 between the first surface 411 and the first removable layer 417. Clusters 4012 of perforations 4101 are formed that extend through the substrate 410, the adhesive layer 414 and the first removable layer 417. The perforations can be formed according to methods as described above. Four clusters 4102 of perforations 4101 are formed in particular, the clusters each including a plurality of perforations that are distributed across respective substantially circular regions of the substrate 410. The clusters of perforations are spaced from each other, for example, along a longitudinal axis of the substrate 410. In this embodiment, there are no perforations provided between the clusters 4102. As shown in Figure 25, conductive substance is applied to the perforations 4101, for example, in accordance with methods described before, to form a plurality of discrete electrically conductive elements 413 that are in clusters 4131 according to the clustered arrangement of perforations. The electrically conductive elements 413 extend through the substrate 410, through the adhesive layer 414 and at least partially through the first removable layer 417. As shown in Figure 26, adjacent the second surface 412 of the substrate 410, a conductive member, and specifically an electrode 419, is formed, for example, by printing, over each one of the clusters of conductive elements 413 to contact second ends of the conductive elements 413. Conductive tracks are also formed, for example, by printing, over the second surface 412 of the substrate 410, the conductive tracks electrically connecting to each electrode 419 and extending across the second surface to a longitudinal end of the substrate 410. At the longitudinal end or sides, ends of the tracks may interface with external electrical componentry such as monitoring or electrostimulation apparatus for example. As shown in Figure 27, an insulating layer 420 is located over the electrodes 419 and the conductive tracks 4191, leaving only the ends of the conductive tracks 4192 that are adjacent the longitudinal end 4103 (or side or sides) of the substrate 410 exposed for contact. The resultant electrode device 4 can be used to electrically contact four discrete regions of a biological surface by bringing the first ends of the conductive elements 413 of each cluster 4131 into contact with the biological surface. Prior to contact, the first removable layer 417 may be removed, exposing the first ends of the conductive elements 413 such that they protrude from the electrode device 4 ensuring

more reliable contact with the biological surface. Removing of the layer 417 may also be conducted to remove contaminants or extraneous conductive gel, etc., as described above for preceding embodiments. A number of variations to the approach are possible, including the number and shape of the clusters and electrodes, which may be controlled to improve mechanical strength or ease of electrical connection, or in accordance with the purpose of electrical contact with the biological surface.

[00111] A variation of the technique for forming an electrode device is illustrated in Figures 28 to 31, where a second removable layer 518 is additionally provided in order to form the electrode device 5. To form the electrode device 5, a substrate 510 is provided as shown in Figure 28. A first removable layer 517 being located over a first surface 511 of the substrate 510, an adhesive layer 514 also located over the first surface 511 of the substrate 510 between the first surface 511 and the first removable layer 517. Moreover, a second removable layer 518 is located over a second surface 512 of the substrate 510. As also shown in Figure 28, clusters 5102 of perforations 5101 are formed that extend through the substrate 510, the adhesive layer 514, the first removable layer 517 and the second removable layer 518. The perforations 5101 can be formed according to methods as described above. Four clusters 5102 of perforations 5101 are formed in particular, the clusters 5102 each including a plurality of perforations 5101 that are distributed across respective substantially circular regions of the substrate 510. The clusters of perforations are spaced from each other, for example along a longitudinal axis of the substrate 510. In this embodiment, there are again no perforations provided between the clusters 5102. As shown in Figure 29, conductive substance is applied to the perforations 5101, for example in accordance with methods described above, to form a plurality of discrete electrically conductive elements 513 that are in clusters 5102 according to the clustered arrangement of perforations. The electrically conductive elements 513 extend through the substrate 510, through the adhesive layer 514, at least partially through the first removable layer 517 and at least partially through the second removable layer 518. As shown in Figure 30, the second removable layer 518 is removed to expose the second surface 512 of the substrate 510, where second ends of the conductive elements 513 are exposed at and protrude from the second surface 512 of the

substrate 510. Adjacent the second surface 512 of the substrate 510, a conductive member, and specifically an electrode 519, is formed, for example by printing, over each one of the clusters of conductive elements 513 to reach over and contact the second ends of the conductive elements 513. Conductive tracks 5191 are also formed, for example by printing, over the second surface 512 of the substrate 510, the conductive tracks 5191 electrically connecting to each electrode 519 and extending across the second surface 512 to a longitudinal end 5103 (and/or side or sides) of the substrate 510. At the longitudinal end (and/or side or sides), ends 5192 of the tracks 5191 may interface with external electrical componentry such as monitoring or electrostimulation apparatus for example. As shown in Figure 31, an insulating layer 520 is located over the electrodes 519 and the conductive tracks 5191, leaving only the ends 5192 of the conductive tracks 5191 that are adjacent the longitudinal end of the substrate 510 exposed for contact. The resultant electrode device 5 can again be used to electrically contact four discrete regions of a biological surface by bringing the first ends of the conductive elements 513 of each cluster into contact with the biological surface. Prior to contact, the first removable layer 517 may be removed, exposing the first ends of the conductive elements 513 or tubular conductive elements 513 such that they protrude from the electrode device 5 ensuring more reliable contact with the biological surface. Removing of the layer 517 may also be conducted to remove contaminants or extraneous conductive gel, etc., as described above for preceding embodiments.

[00112] In another preferred embodiment, as shown in Figures 32 to 35, an electrode device 6 is formed that, instead of having clusters of conductive elements or tubular conductive elements, has a uniform and/or more widespread distribution of conductive elements or tubular conductive elements, contact being made between electrodes and discrete subsets of the conductive elements or tubular conductive elements. To form the electrode device 6 according to an embodiment of the present disclosure, a substrate 610, as shown in Figure 32 may have a first removable layer 617 being located over a first surface 611 of the substrate 610, an adhesive layer 614 also located over the first surface 611 of the substrate 610 between the first surface 611 and the first removable layer 617. As shown in Figure 33, a uniform and/or relatively

widespread distribution of perforations 6101 is formed across the substrate 610, the perforations extending through the substrate 610, the adhesive layer 614, and the first removable layer 617. The perforations can be formed according to methods described previously. As shown in Figure 34, an insulating layer 620 is applied over the second surface 612 of the substrate such that it extends over the second ends of the conductive elements 613, except at four discrete circular regions (which may have non-circular shapes in other embodiments) that are spaced apart, e.g., along the longitudinal axis of the substrate 610. As shown in Figure 35, a conductive member, and specifically an electrode 619, is formed, for example, by printing, over each one of the circular regions 621 to contact second ends of the conductive elements 613. Conductive tracks 6191 are also formed, for example, by printing, over the insulating layer 620, the conductive tracks 620 electrically connecting to each electrode 619 and extending across the insulating layer to a longitudinal end of the substrate 610. At the longitudinal end 6103, ends 6192 of the tracks 6191 may interface with external electrical componentry such as monitoring or electrostimulation apparatus for example. Although not shown, a further insulating layer 520 may be located over the electrodes 619 and the conductive tracks 6191, leaving only the ends of the conductive tracks 6191 that are adjacent the longitudinal end 6103 of the substrate 610 exposed. Moreover, in alternative embodiments, a second removable layer may initially be provided over the second surface of the substrate so that the conductive elements are formed to protrude from the second surface, which may be shown in Figure 34. The resultant electrode device 6 can again be used to electrically contact four discrete regions of a biological surface by bringing the first ends of the conductive elements 613 into contact with the biological surface. Prior to contact, the first removable layer 617 may be removed, exposing the first ends of the conductive elements 613 such that they protrude from the electrode device 6 ensuring more reliable contact with the biological surface. Removing of the layer 617 may also be conducted to remove contaminants or extraneous conductive gel, etc., as described before for the preceding embodiments.

[00113] In another preferred embodiment of the present invention, as shown in Figures 36 to 39, where an electrode device 7 is formed that is similar to the electrode

device 6 but includes conductive elements formed in only some of the perforations, and specifically those positioned where contact with conductive members is to be made. To form the electrode device 7 according to an embodiment of the present disclosure, a substrate 710 is provided as shown in Figure 36, where a first removable layer 717 being located over a first surface 711 of the substrate 710, an adhesive layer 714 also located over the first surface 711 of the substrate 710 between the first surface 711 and the first removable layer 717. As also shown in Figure 36, a uniform and/or relatively widespread distribution of perforations is formed across the substrate 710, the perforations 7101 extending through the substrate 710, the adhesive layer 714, and the first removable layer 717. The perforations 7101 can be formed according to methods as described previously. As shown in Figure 37, an insulating layer 720 is applied over the second surface 712 of the substrate 710 such that it extends over the perforations 7101, except at four discrete circular regions 7201 (which may have non-circular shapes in other embodiments) that are spaced apart, e.g., along the longitudinal axis of the substrate 710. As shown in Figure 38, conductive substance is applied to the perforations 7101, but the insulating layer 720 ensures that only the perforations 7101 exposed via the circular regions 7201 receive the conductive substance to form a plurality of discrete electrically conductive elements 713 or a plurality of discrete electrically tubular conductive elements 713. The electrically conductive elements 713 or electrically tubular conductive elements 713 extend through the substrate 710, through the adhesive layer 714, and at least partially through the first removable layer 717. As shown in Figure 39, a conductive member, and specifically an electrode 719, is formed, for example, by printing, over each one of the circular regions 721 to contact second ends of the conductive elements 713 or to contact second ends of the tubular conductive elements 713. In other embodiments, the insulating layer 720 may be removed prior to forming of the conductive members. Conductive tracks are also formed, for example, by printing, over the insulating layer 720 or the second surface 712 of the substrate 710 if the insulating layer 720 has been removed. The conductive tracks 720 electrically connecting to each electrode 719 and extending across the insulating layer to a longitudinal end 7103 and/or sides 7103 of the substrate 710. At the longitudinal end 7103, ends 7192 of the tracks 7191 may interface with external electrical componentry such as monitoring or electrostimulation apparatus

for example. Although not shown, a further insulating layer may be located over the electrodes 719 and the conductive tracks, leaving only the ends of the conductive tracks that are adjacent the longitudinal end 7103 and/or sides 7103 of the substrate 710 exposed. Moreover, in alternative embodiments, a second removable layer may initially be provided over the second surface of the substrate so that the conductive elements are formed to protrude from the second surface. Moreover, in alternative embodiments, the electrodes and/or conductive tracks may be formed at the same time as the application of the conductive substance to the perforations. The resultant electrode device 7 can again be used to electrically contact four discrete regions of a biological surface by bringing the first ends of the conductive elements 713 or the first ends of the tubular conductive elements 713 into contact with the biological surface. Prior to contact, the first removable layer 717 may be removed, exposing the first ends of the conductive elements 713 or exposing the first ends of the tubular conductive elements 713 such that they protrude from the electrode device 7 ensuring more reliable contact with the biological surface. Removing of the layer 717 may also be conducted to remove contaminants or extraneous conductive gel, etc., as described above for preceding embodiments. In the embodiments described before with reference to Figures 24 to 39, electrode devices with four electrodes/four regions of electrical contact are provided. However, other numbers of electrodes/regions of electrical contact may be provided. Merely as one example, the electrode devices may be modified to include but not limited to two electrodes/two regions of electrical contact. It may be appreciated that electrode devices may be modified to be multi “macro-electrode” arrays consisting to greater than 4 electrodes, and it may be appreciated that the very small dots at shown in Figures 24 to 39 are all tubular conductive elements.

[00114] As shown in Figures 40 to 43, conductive material 1 according to the embodiments of the present disclosure may be provided, for example but not limited to as a part of a dressing 30, 30', or as part of an electrode device 40, 40', where the conductive material includes an opening 31, 31', 41, 41'. The opening 31, 31', 41, 41' may be partially or entirely surrounded by the conductive elements 13 or tubular conductive elements 13 of the conductive material 1, or located between conductive

members or electrodes 42 of the electrode device 40, 40', and may allow direct access to a biological surface underneath, for example, to allow observation of the biological surface and/or to allow application of treatment to the biological surface, such as light, heat, cold, topical drugs or ultrasound therapy. In some embodiments as shown in Figures 41 and 43, the opening may be covered by a transparent window 31', 41', again allowing observation and/or providing a means for application of phototherapy or other applications. As shown in Figures 44 to 45, a dressing, electrode device 4 or other construct such as tape, patch, bandage or otherwise, that comprises conductive material according to embodiments of the present disclosure, may be used as a means of retaining an item 8 in place at a biological surface. The retained item 8 may be a medical device or dressing, such as a primary dressing (for example, a treatment patch that is used to speed up wound healing or to provide muscle conditioning, prevention of muscle spasms, promotion of blood circulation, etc.). In addition to retaining the item, the construct 4 may enable electrical analysis of the biological surface that is subject to the treatment to be made. The approach may allow an assessment and tracking of the biological tissue beneath the primary dressing to be made. Primary dressings can be any of a vast type of dressings ranging from conventional (hydrogels, hydrocolloids, hydrofibre etc.) to active (silver based, microcell battery-based e.g. Procellera™, etc) that further promote wound healing, and/or provide antibacterial action, etc.

[00115] Figure 46 show an example of samples with 120 µm hole diameter silver-impregnated from the support side, and with tubular conductive element 13 spacings indicated by distance 'a' of 0.5 mm apart from the adjacent tubular conductive element 13. Figure 46 show an example of samples with 120 µm hole diameter silver-impregnated from the support side, and with tubular conductive element 13 spacings indicated by distance 'b' of 0.75 mm apart from the adjacent tubular conductive element 13. And Figure 46 show an example of samples with 120 µm hole diameter silver-impregnated from the support side, and with tubular conductive element 13 spacings indicated by distance 'c' of 1.0 mm apart from the adjacent tubular conductive element 13. It may be appreciated that the tubular conductive element 13 spacings may be of any predetermined distance apart from each other. While the dots are drawn small for

Figures 46 to 48, each of the tubes 13 define a hollow core 130 or an inside space 130 of a tubular structure. Figure 49 shows an oblique view of the electrode contacting surface of one of the samples silver-impregnated from the support side having hole diameter of 120 μm and hole spacing 0.5 mm. Protrusions of the silver tubular conductive elements 13 with the hollow core 130 showing or tubular micro-pylons 13, after removal of polyethylene liners are shown.

[00116] Resistance testing through each sample was tested in accordance with the experimental set-up as shown in Figure 50. After removing the removable layers, the sample 90 material including silver-based tubular conductive elements 901 was adhered to a conductive substrate 91, which may be aluminium foil. Two 10mm diameter metal contact pads 92 were placed a predetermined distance apart (centre to centre) on the top of the material. Resistance was measured using a multimeter 93 from one contact pad, through the material, along the conductive foil substrate, and up through the second contact pad. Additionally, each sample was also adhered to a non-conductive substrate of PET film and tested, to verify that there was no lateral conductance across the material.

[00117] It may be appreciated that conductive elements (micro pylons) mentioned in any of the previous embodiments can also be a tubular conductive element which is a conductive micro pylon that has a tubular core or an inside space of a tubular micro pylon structure.

[00118] Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms in keeping with the broad principles and the spirit of the invention described herein.

[00119] The present invention and the described preferred embodiments specifically include at least one feature that is industrial applicable.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An anisotropically electrically conductive material to electrically interface an electrode with a portion of a biological surface, the conductive material comprising:
 - a substrate having a first surface parallel to a second surface;
 - a first removable layer, the first removable layer being located over the first surface;
 - a plurality of discrete perforations, each perforation extending through the substrate and the first removable layer; and
 - a plurality of discrete electrically conductive elements, each of the conductive elements comprising a tubular core from a first end to a second end of the conductive element;
 - each conductive element formed in a respective one of the perforations such as to extend through the substrate and through the first removable layer.
2. The conductive material of claim 1, wherein the tubular core from the conductive element is adapted to receive therein a solution, with the first removable layer located over the first surface.
3. The conductive material of claim 2, wherein the solution is one selected from the group of: water, distilled water, aqueous electrolyte, an alcohol, an alcoholic solution, and a gel.

4. The conductive material of any one of claims 1 to 3, wherein each conductive element is a tube of conductive material.
5. The conductive material of claim 4, wherein the tubular conductive material has a height to width ratio of less than 1.
6. The conductive material of any one of claims 1 to 5, comprising a first adhesive layer located over the first surface of the substrate between the first surface of the substrate and the first removable layer.
7. The conductive material of any one of claims 1 to 6, wherein first end of each of the tubular conductive elements between the first surface and the first removable layer is adapted to be sheared off from the respective tubular conductive elements when the first removable layer is removed.
8. An electrode device comprising the conductive material of any one of claims 1 to 7, further comprising one or more conductive members, wherein each conductive member is located over the second surface of the substrate such that each conductive member connects to a second end of a different subset of the plurality of conductive elements.
9. The electrode device of claim 8, comprising at least two of the conductive members.

10. The electrode device of any one of claims 8 to 9, wherein each subset of the plurality of tubular conductive elements is provided by a respective cluster of the tubular conductive elements.
11. The electrode device of claim 10, wherein at least two clusters of tubular conductive elements is each connected to the respective tubular conductive members and wherein no conductive elements are provided between the clusters of tubular conductive elements.
12. The electrode device of any one of claims 8 to 11, wherein one or more insulating layers are located over the second surface of the substrate and around the conductive members.
13. The electrode device of any one of claims 8 to 12, wherein conductive tracks extend from the one or more conductive members to an end of the electrode device.
14. The electrode device of claim 13, wherein the conductive tracks are formed from printing using conductive ink.
15. The electrode device of any one of claims 13 to 14, wherein a further insulating layer is located over the conductive tracks.

16. The electrode device of any one of claims 8 to 15, comprising at least one opening partially surrounding the tubular conductive elements for observation of the biological surface and/or treatment of the biological surface.
17. The electrode device of any one of claims 9 to 14, further comprising a retention dressing having an insulating layer within a semi-rigid disposable frame, wherein the insulating layer is located over the anisotropically electrically conductive material.
18. The electrode device of claim 17, wherein the insulating layer is transparent.
19. The electrode device of any one of claims 17 to 18, wherein the transparent film is adherable over the anisotropically electrically conductive material.

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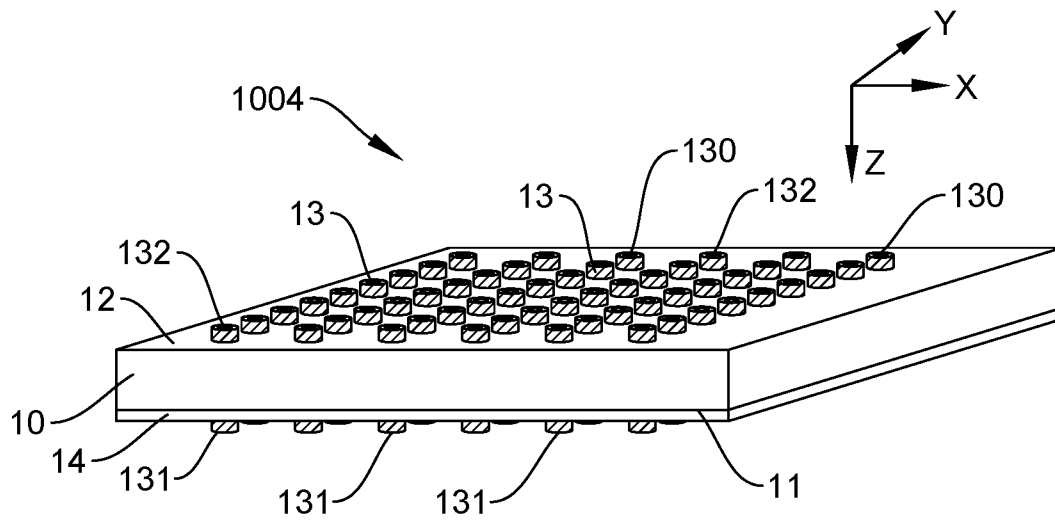


FIG. 1

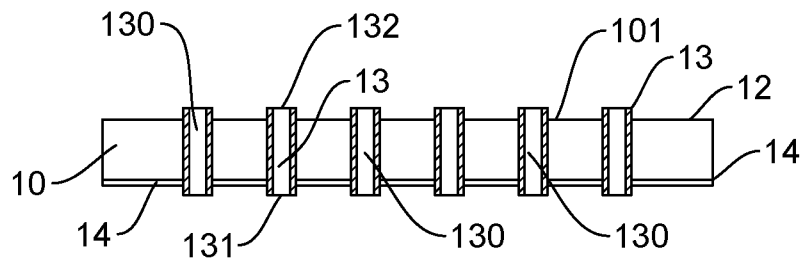


FIG. 2

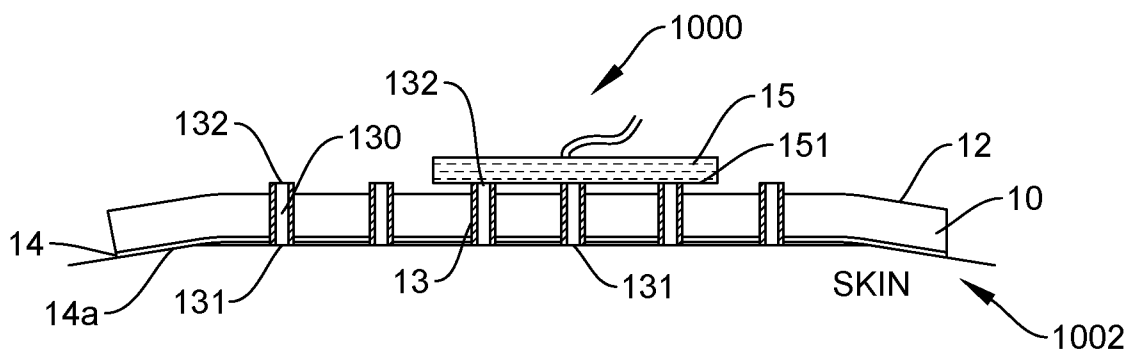


FIG. 3

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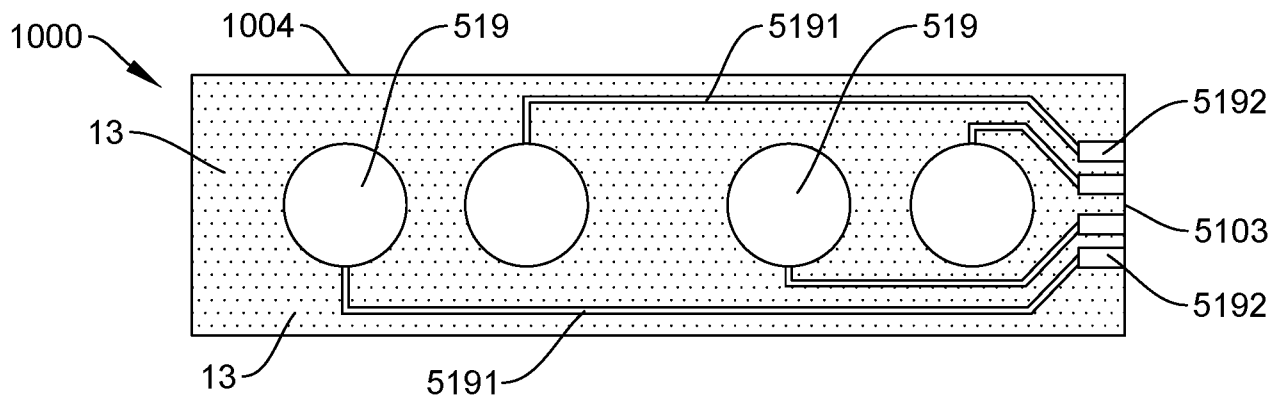


FIG. 4

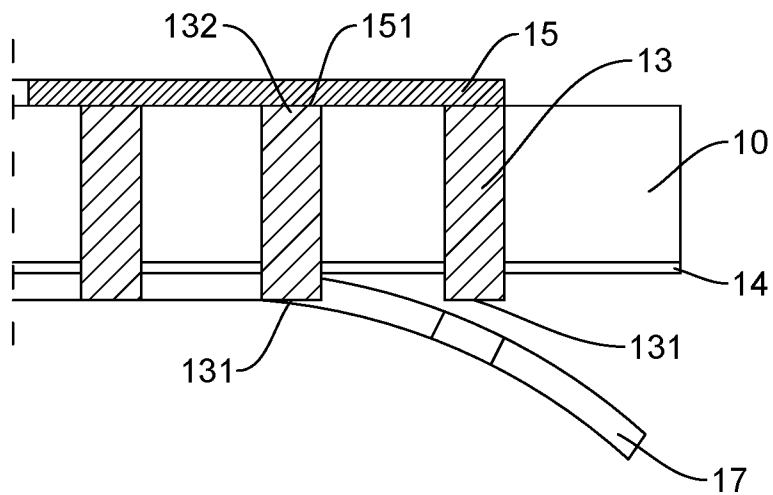


FIG. 5

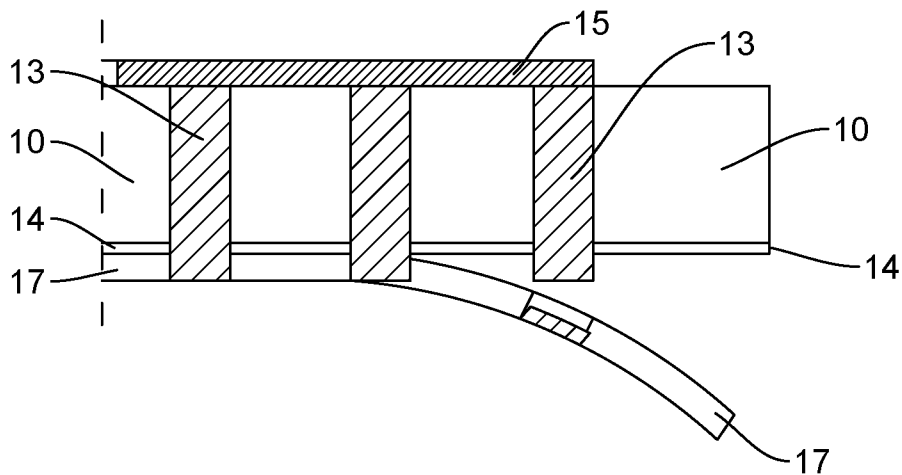


FIG. 6

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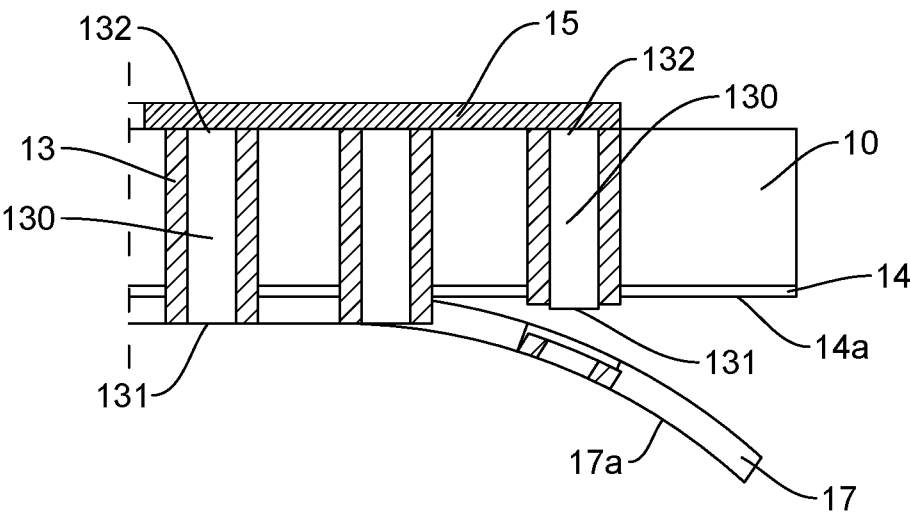


FIG. 7

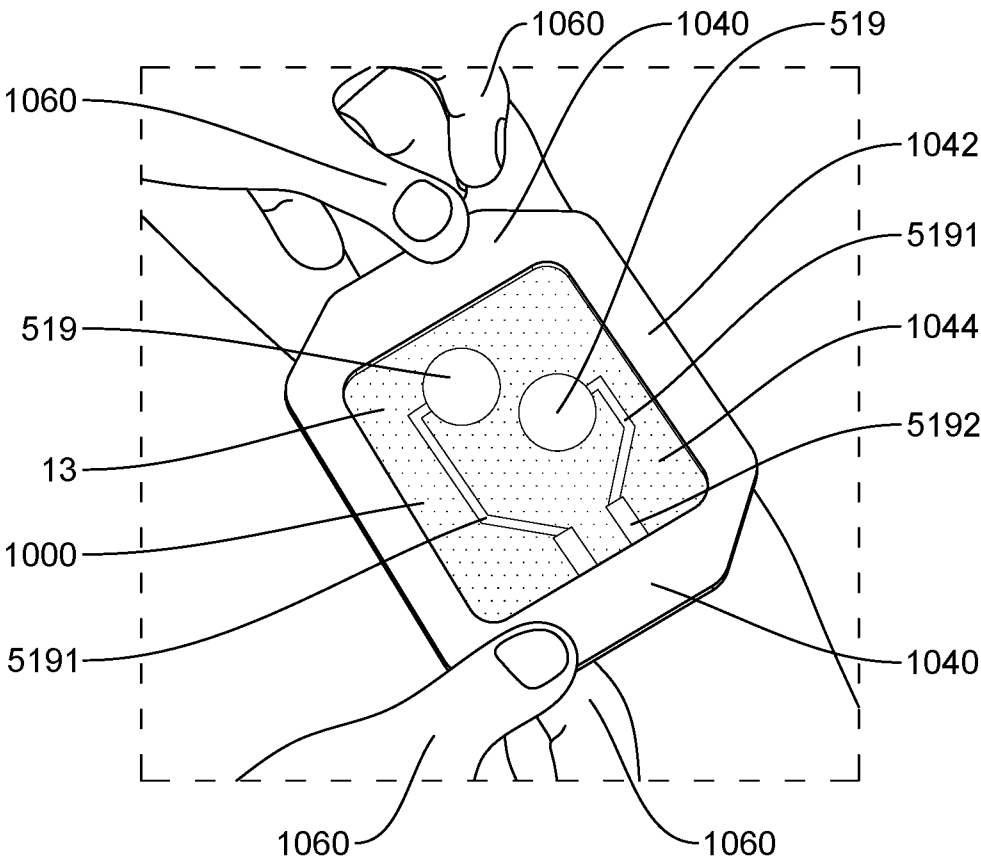


FIG. 8

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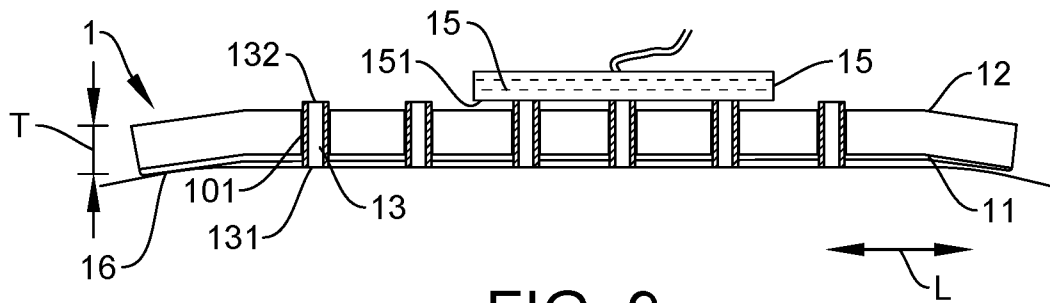


FIG. 9

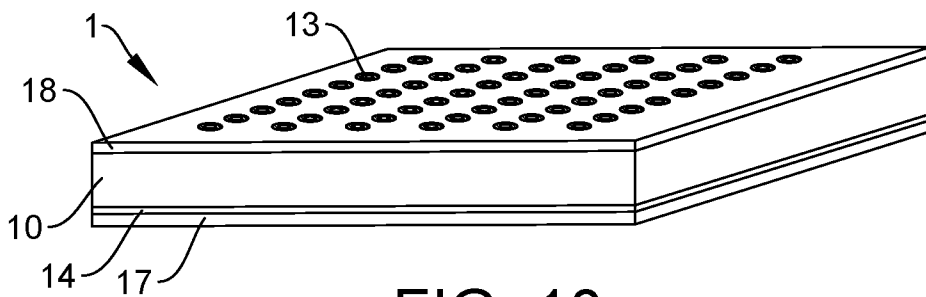


FIG. 10

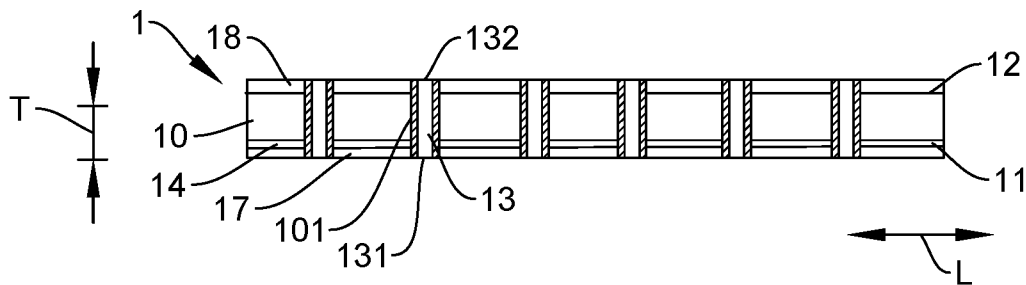


FIG. 11

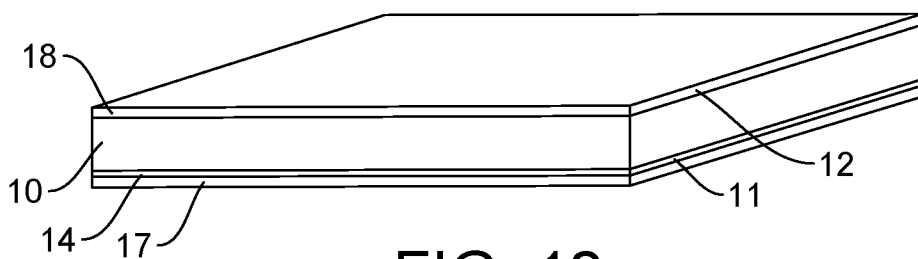


FIG. 12

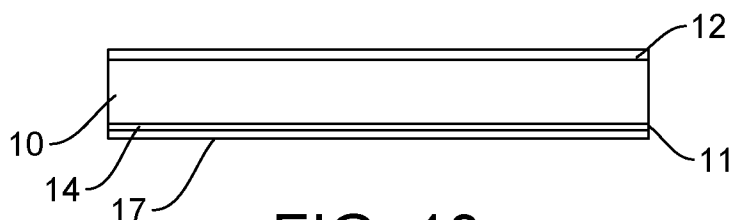


FIG. 13

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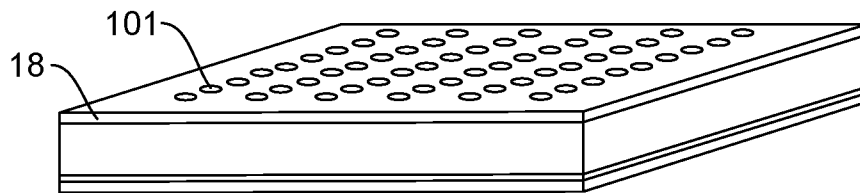


FIG. 14

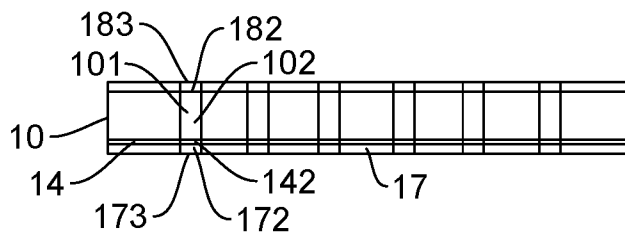


FIG. 15

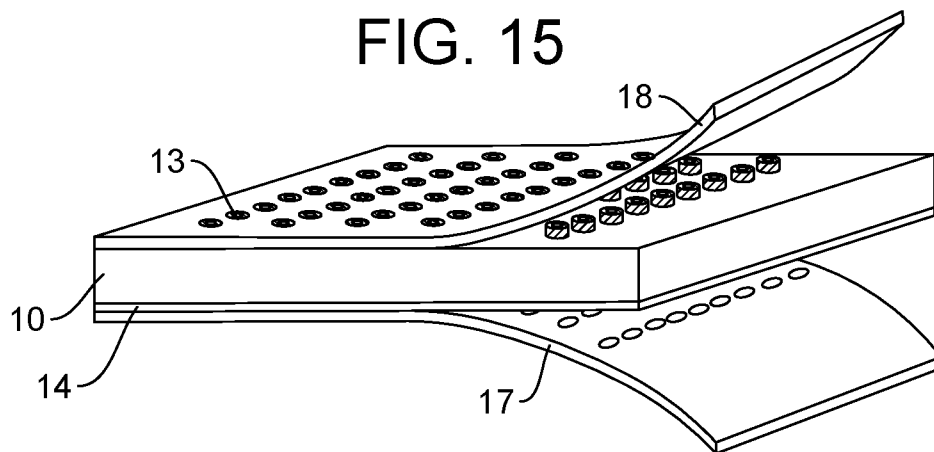


FIG. 16

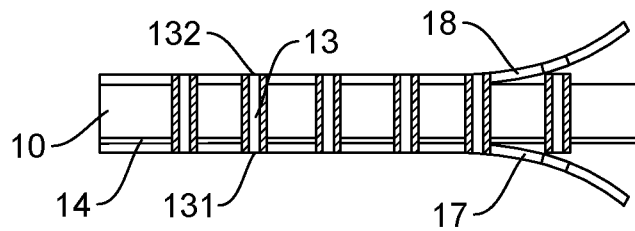


FIG. 17

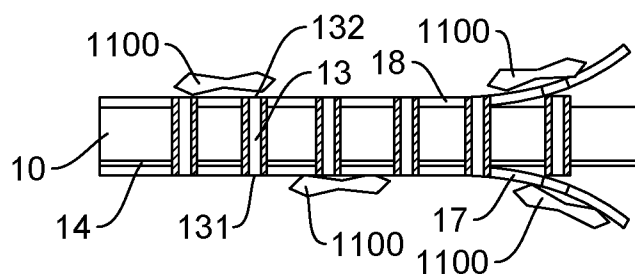


FIG. 18

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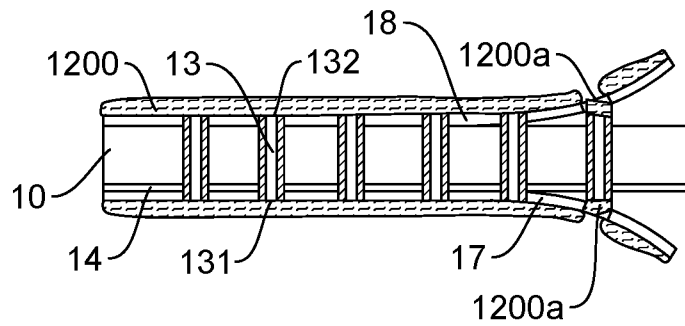


FIG. 19

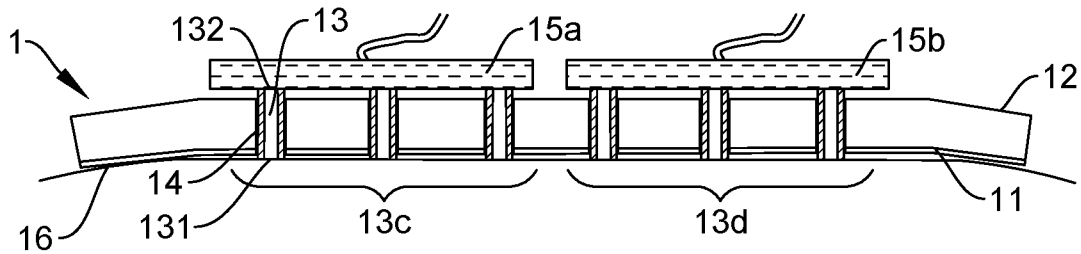


FIG. 20

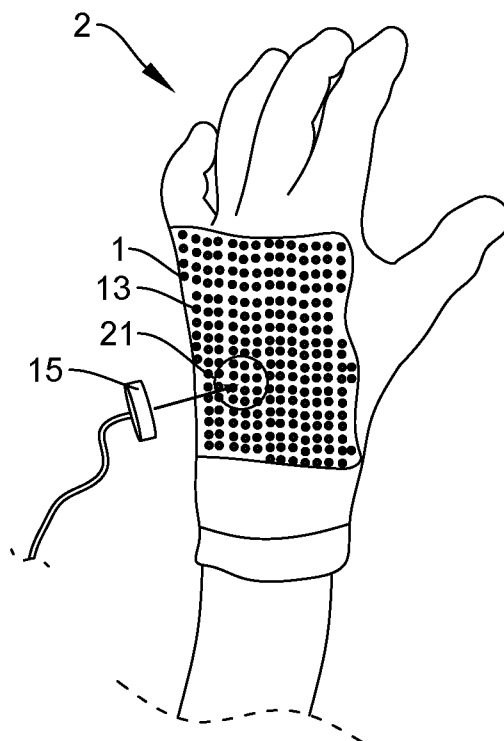


FIG. 21

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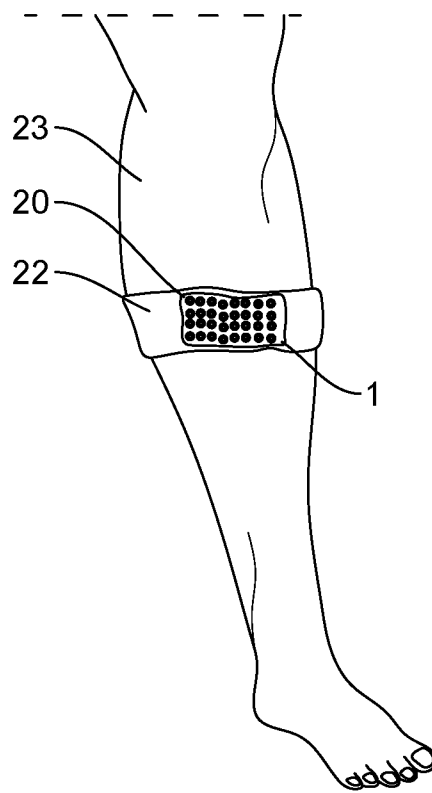


FIG. 22

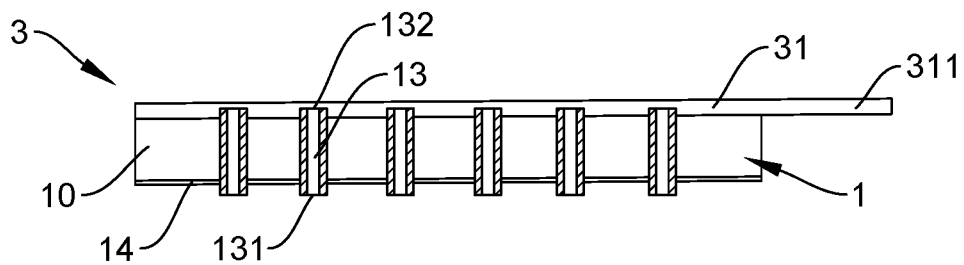


FIG. 23

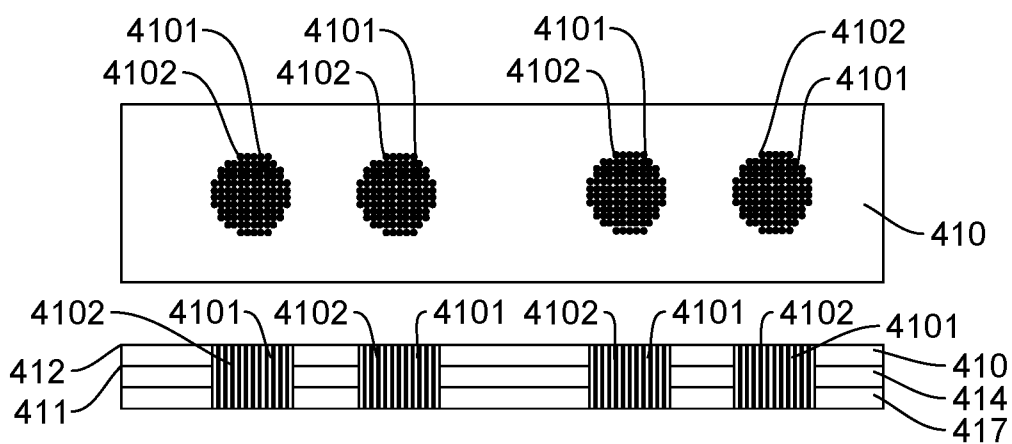


FIG. 24

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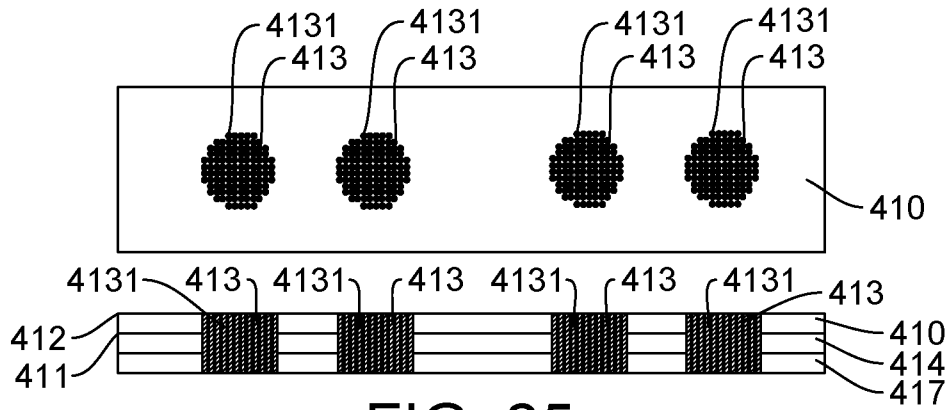


FIG. 25

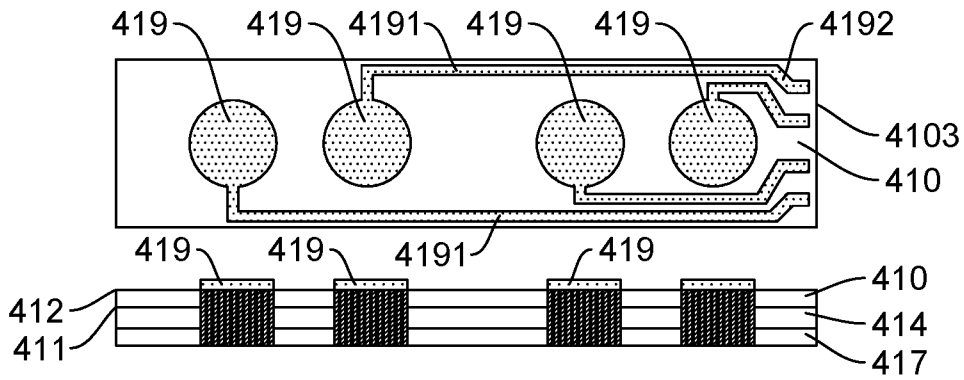


FIG. 26

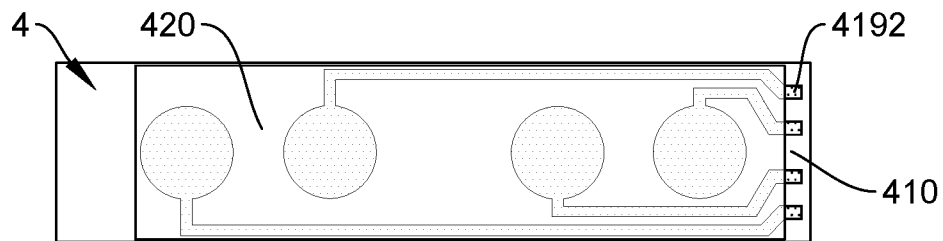


FIG. 27

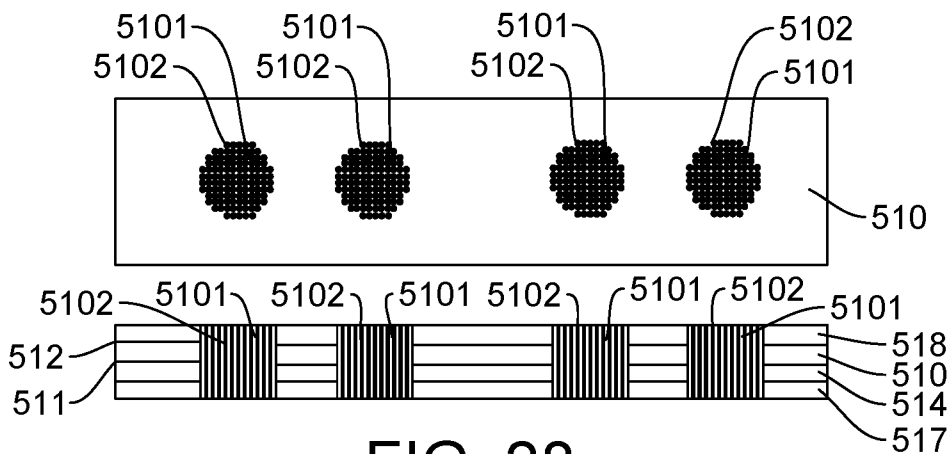


FIG. 28

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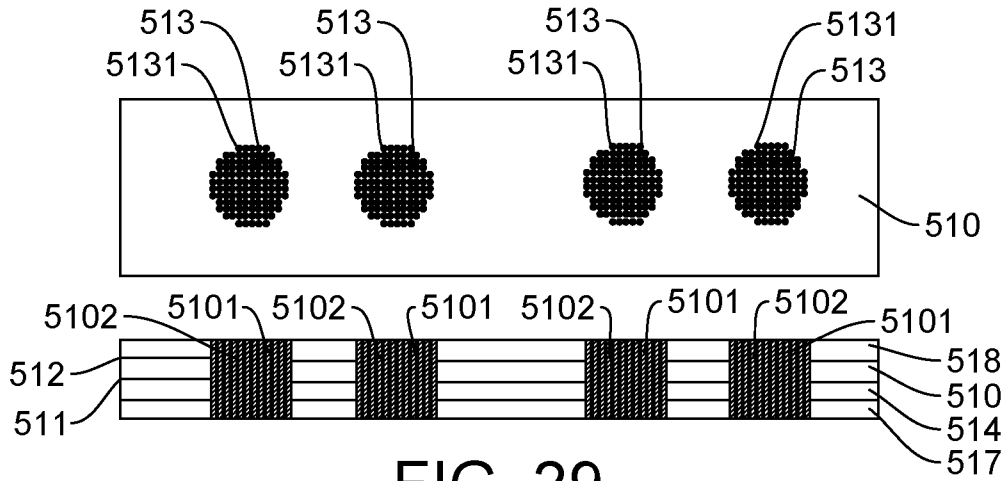


FIG. 29

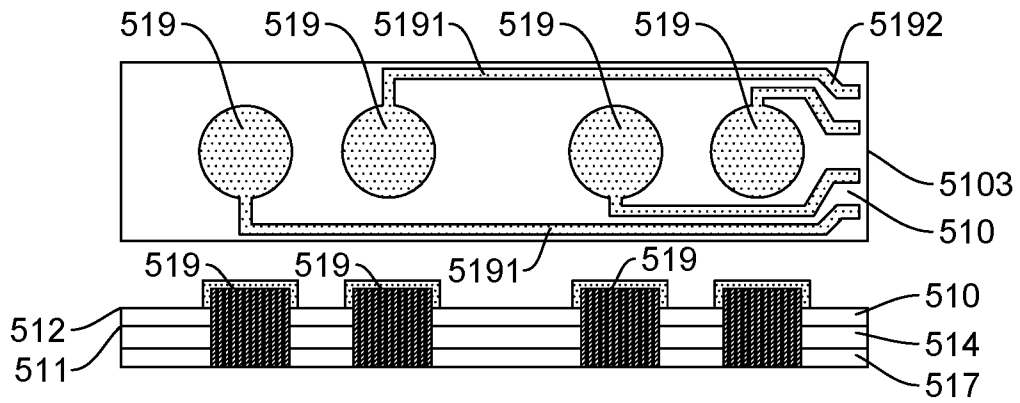


FIG. 30

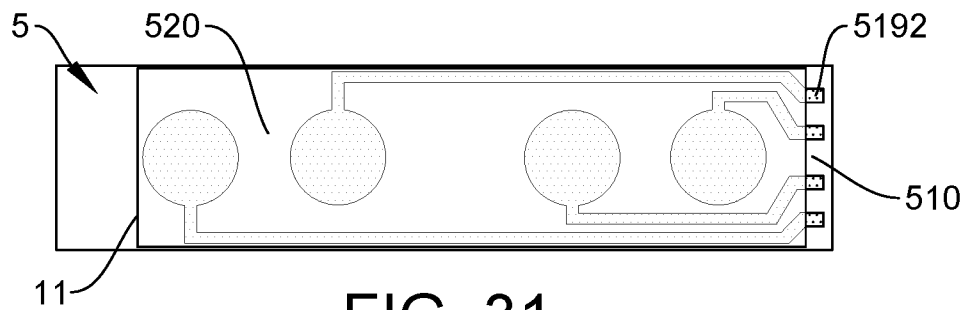


FIG. 31

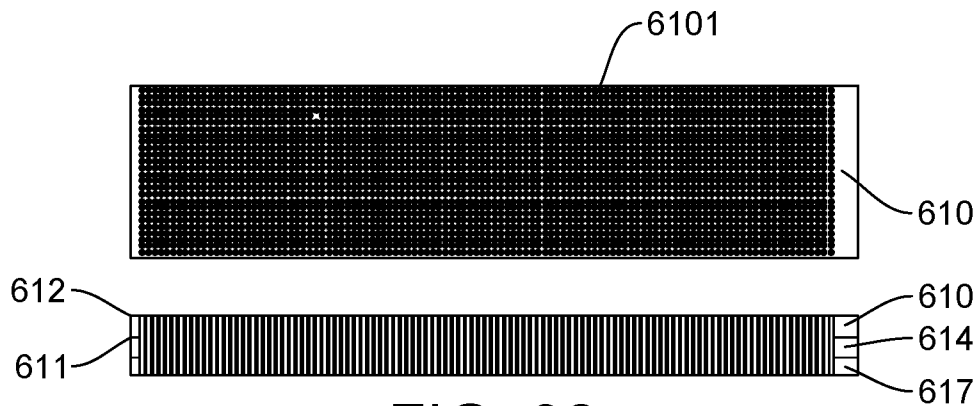


FIG. 32

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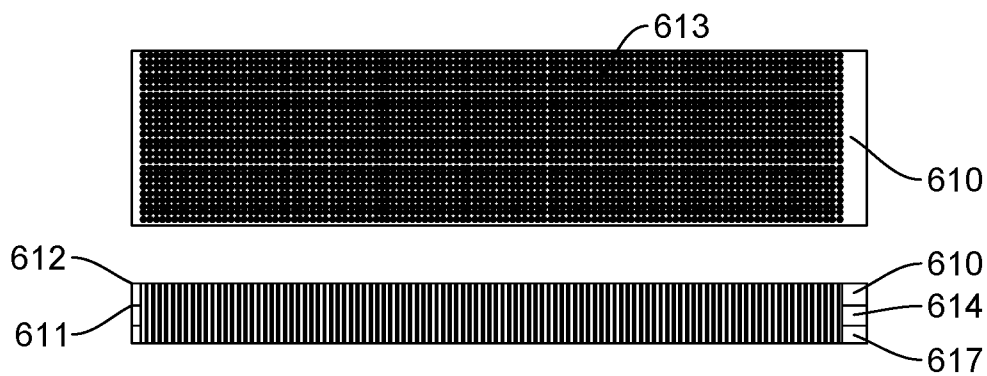


FIG. 33

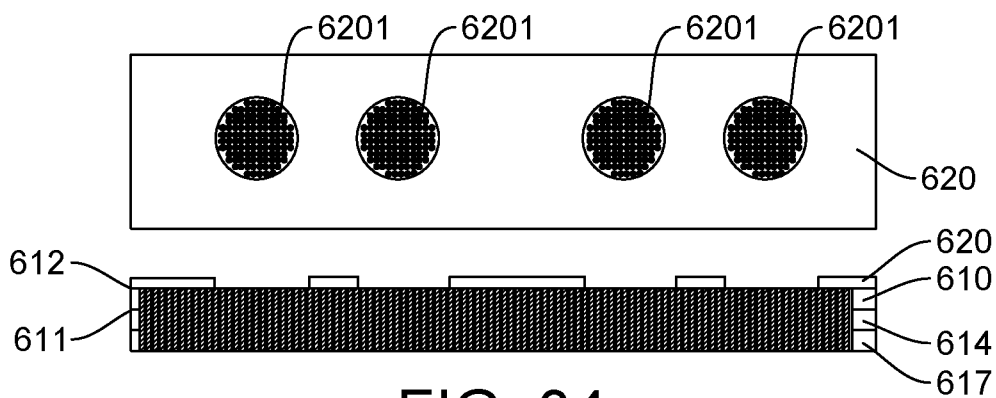


FIG. 34

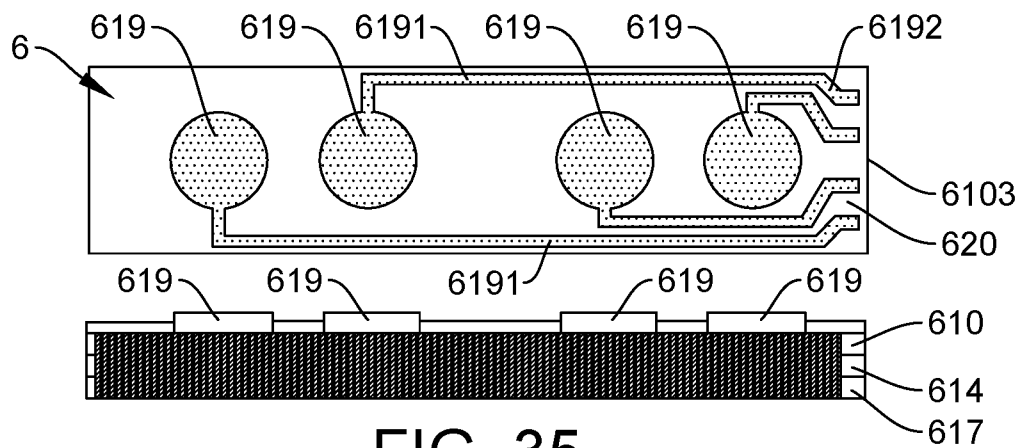


FIG. 35

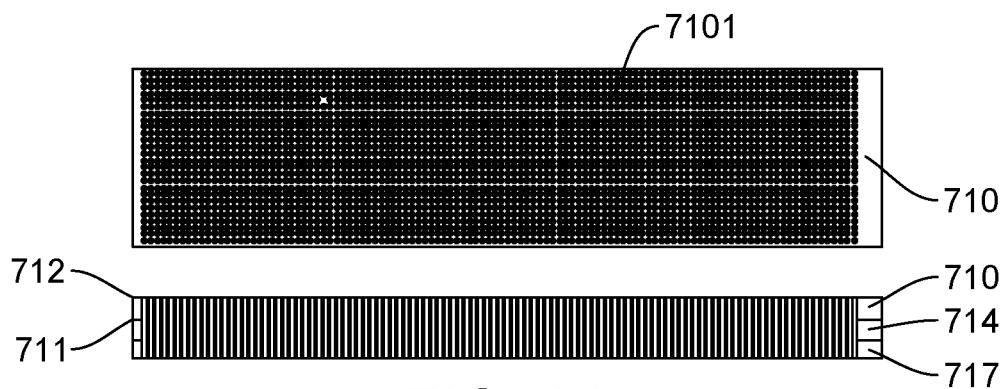


FIG. 36

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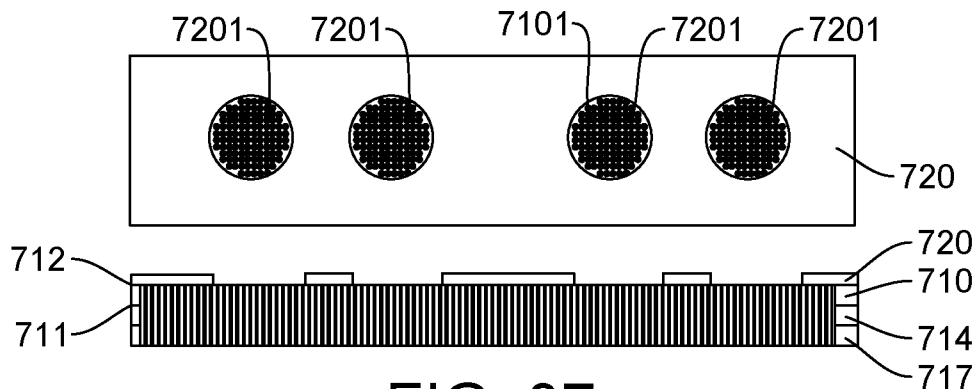


FIG. 37

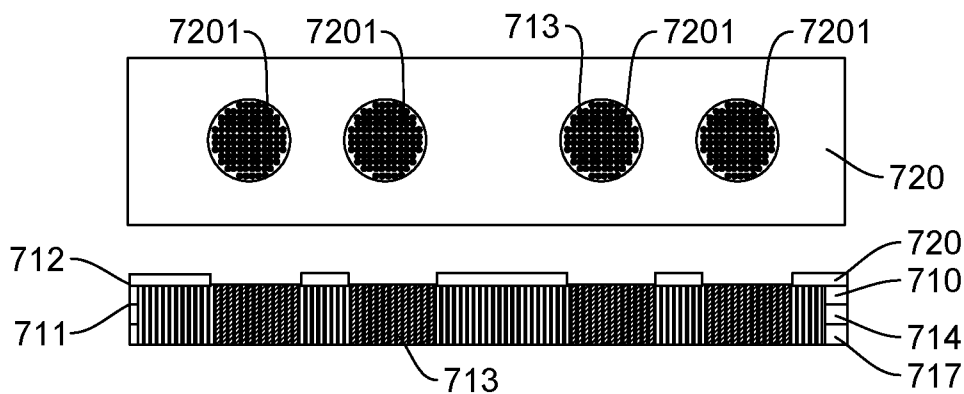


FIG. 38

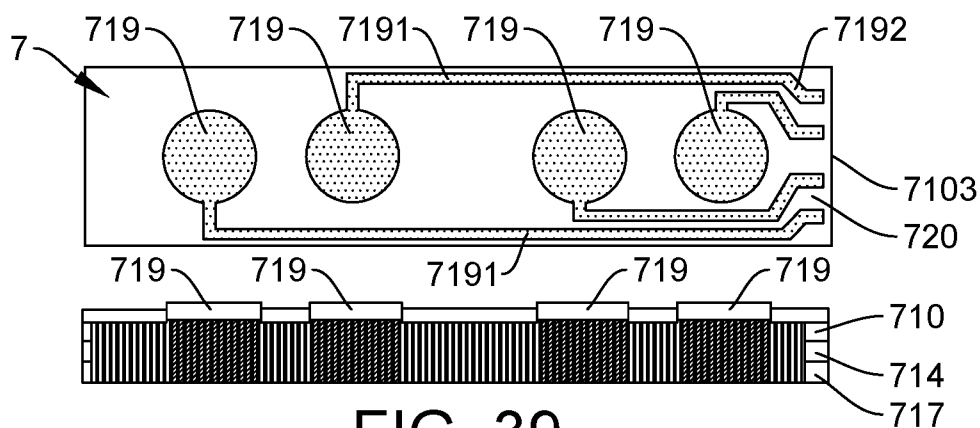


FIG. 39

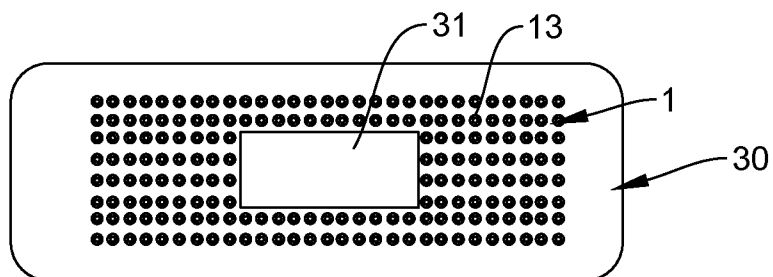


FIG. 40

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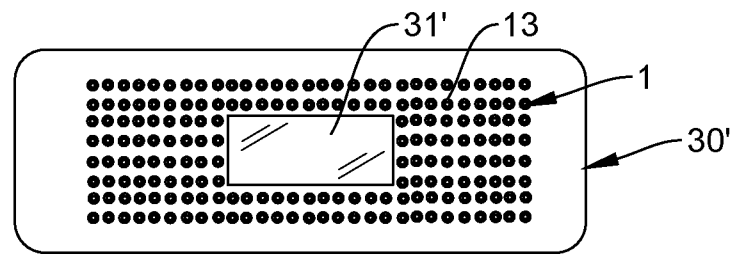


FIG. 41

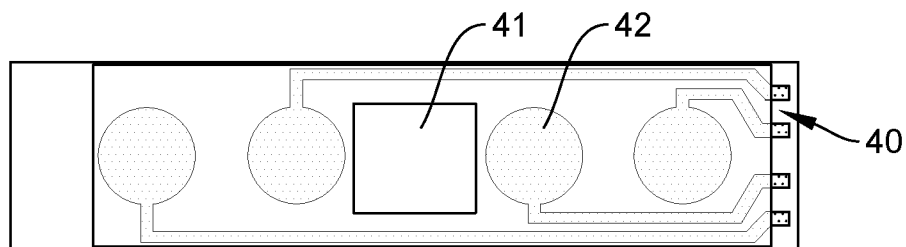


FIG. 42

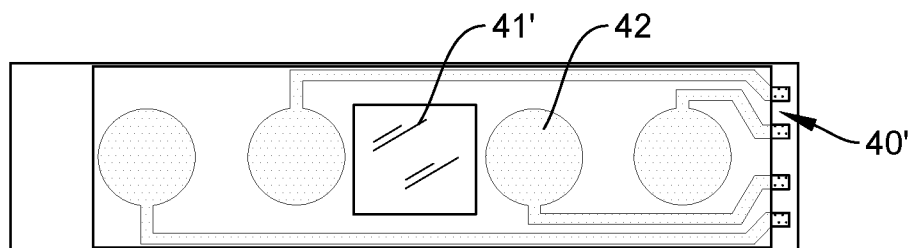


FIG. 43

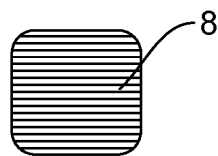


FIG. 44

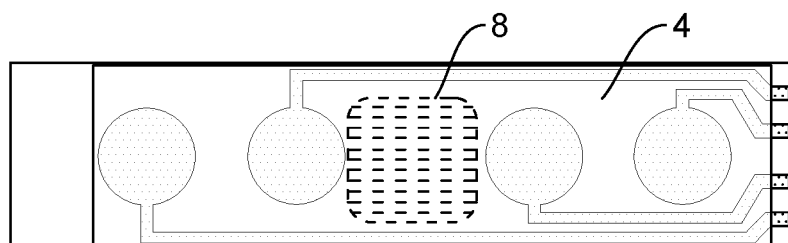


FIG. 45

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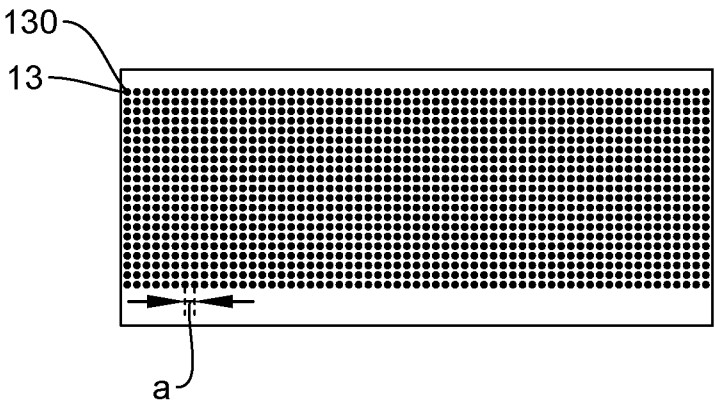


FIG. 46

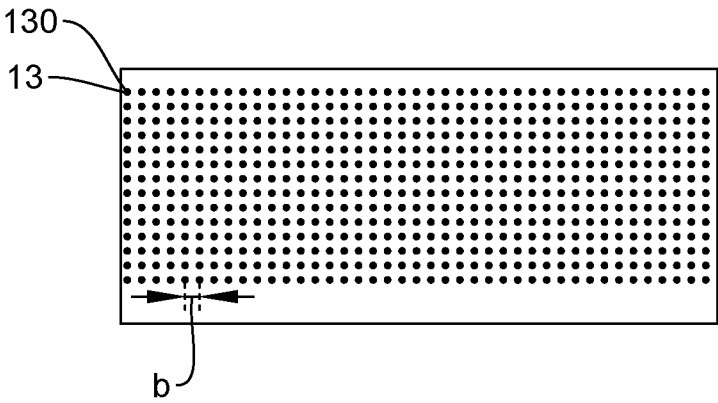


FIG. 47

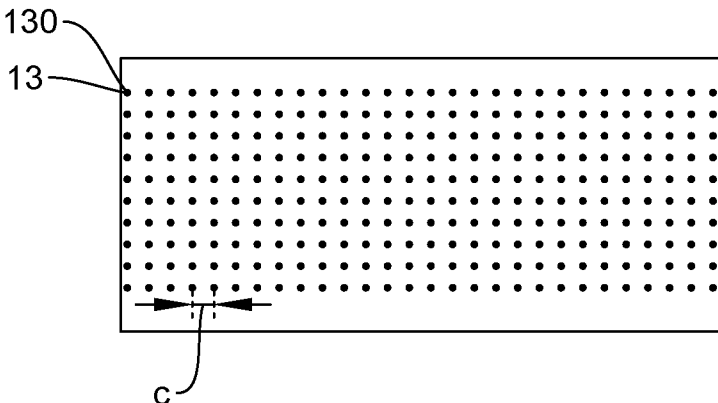


FIG. 48

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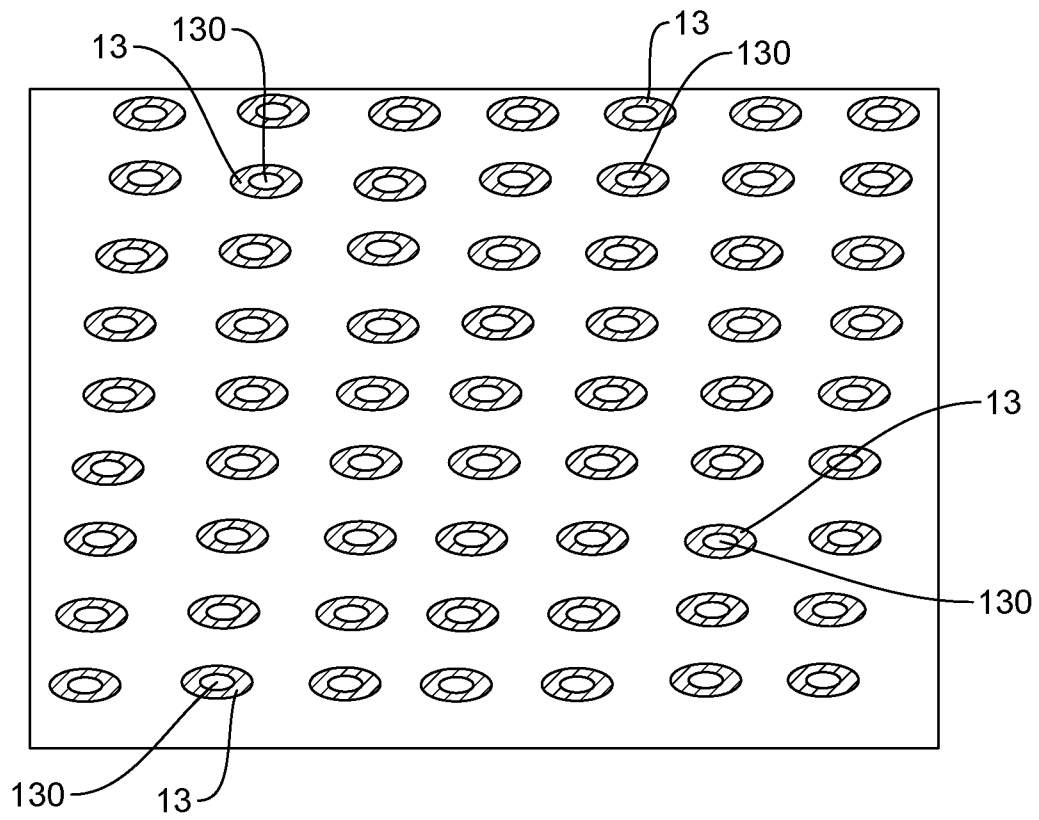


FIG. 49

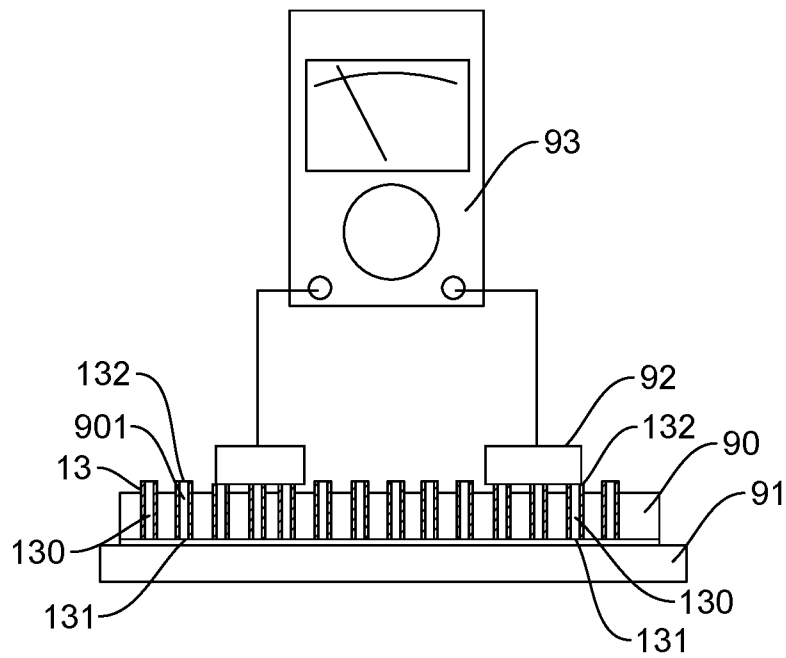


FIG. 50

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2024/050569

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/251 (2021.01) A61B 5/00 (2006.01) A61B 5/0531 (2021.01) A61B 5/257 (2021.01) A61B 5/282 (2021.01)
A61B 5/291 (2021.01) A61B 5/296 (2021.01) A61N 1/04 (2006.01) B32B 3/26 (2006.01) B32B 7/12 (2006.01)

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)

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)

PATENW: IPC/CPC: A61B5/6802, A61B5/251, A61B2562/14, A61B2562/164, A61B5/6801, A61B5/24, A61N1/0496, A61N1/0472, A61N1/04; Keywords: conduct, electrical, material, core, tube, tubular, perforated, duct, tunnel, slot, passage, bore, release, remove, peel, layer, liner, sheet, film, surface, cover, skin, biological, dermis, anisotropic.

ESPACENET, GOOGLE PATENTS: anisotropy, conduct, electrode, electric, sensor, material, patch, compound, release, peel, removable, layer, liner, sheet, film, tube, core, perforation, cylinder and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

☒ 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	"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
"D" document cited by the applicant in the international application	"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
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
26 July 2024

Date of mailing of the international search report
26 July 2024

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INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2024/050569
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2019119045 A1 (TI2 MEDICAL PTY LTD) 27 June 2019 Figures 2b, 9c, 12c-12d, 16a; Para 0006, 0027, 0043, 0062, 0110-0112, 0124, 0140, 0159-0160, 0187	1-19
X	WO 2016205881 A1 (TI2 MEDICAL PTY LTD) 29 December 2016 Figures 6, 7b, 8; Para 0006, 0012, 0028, 0052-0054, 0125-0127, 0129-0132	1-19
X	US 20130092426 A1 (Industrial Technology Research Institute) 18 April 2013 Figures 4, 8c; Para 0036, 0053-0055	1-19
X A	EP 3766413 A1 (Nitto Denko Corporation) 20 January 2021 Figures 4A-4D; Para 0120-0128 Whole Document	1-7 8-19
X	US 20130325096 A1 (ZOLL MEDICAL CORPORATION) 05 December 2013 Figure 6; Para 0057, 0059-0062	1-19

INTERNATIONAL SEARCH REPORT		International application No.	
Information on patent family members		PCT/AU2024/050569	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
Patent Document/s Cited in Search Report		Patent Family Member/s	
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		WO 2013181508 A1	05 Dec 2013
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			