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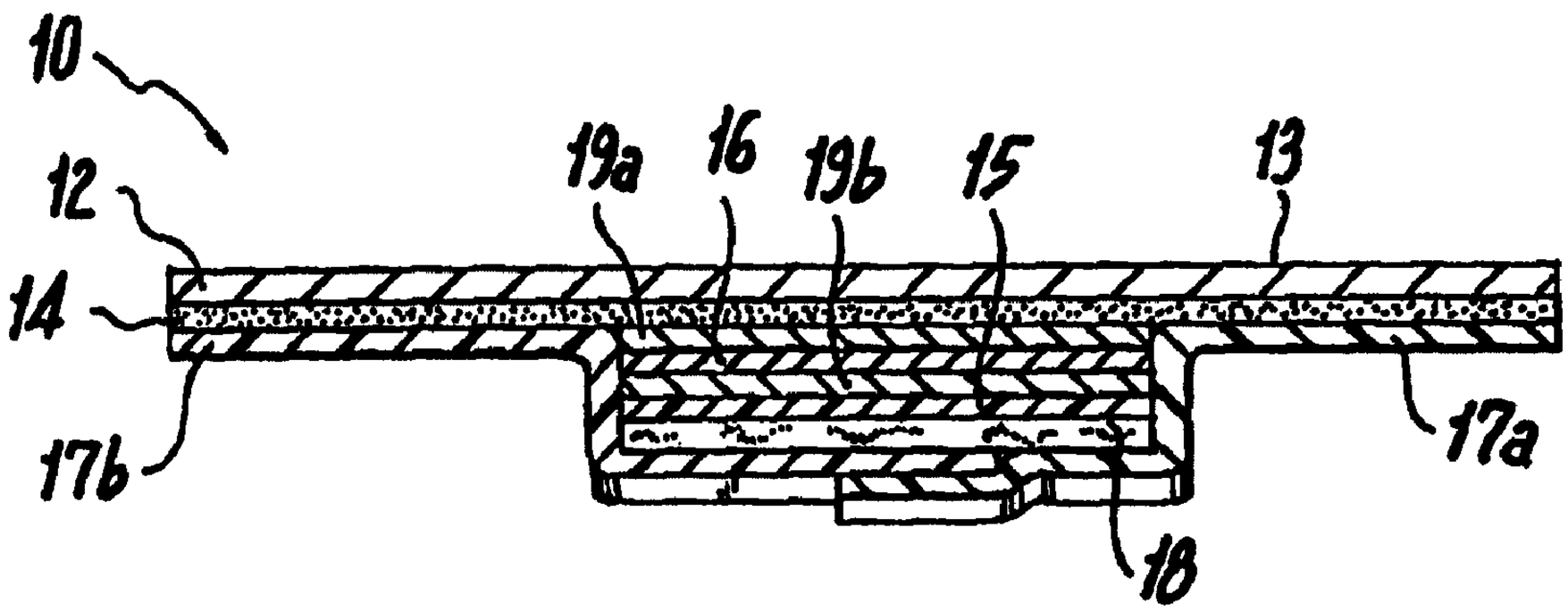
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(54) BANDAGES A ULTRASONS
(54) ULTRASOUND BANDAGES



(57) L'invention concerne des bandages (10) à ultrasons et des bandages à réseau de transducteurs à ultrasons permettant d'accélérer la cicatrisation des lésions par application de bandages (10) à ultrasons et de bandages à réseau de transducteurs à ultrasons à côté d'une lésion et par génération d'impulsions ultrasonores. Les bandages à ultrasons comprennent généralement (a) une couche de support (13), (b) une couche adhésive (14) appliquée sur la couche de support (13), et sensiblement coextensible avec celle-ci, et (c) un matériau transducteur (16) disposé sur au moins une partie de la couche adhésive (14). Les bandages à réseau de transducteurs à ultrasons comprennent généralement (a) une couche de support (13), (b) une couche adhésive (14) appliquée sur la couche de support (13), et sensiblement coextensible avec celle-ci, et (c) un réseau comprenant une pluralité de matériaux transducteurs (16) disposés de façon adjacente pour définir des espaces entre eux, ledit réseau étant disposé sur au moins une partie de la couche

(57) Ultrasound bandages (10) and ultrasound transducer array bandages are provided herein to accelerate the healing of wounds by positioning the ultrasound bandages (10) and ultrasound transducer array bandages adjacent to a wound and generating ultrasonic pulses. The ultrasound bandages (10) generally include (a) a backing layer (12), (b) an adhesive layer (14) applied to, and substantially coextensive with, the backing layer (12), and (c) a transducer material (16) disposed on at least a portion of the adhesive layer (14). The ultrasound transducer array bandages generally include (a) a backing layer (13), (b) an adhesive layer applied to, and substantially coextensive with, the backing layer, and (c) an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer. The resulting ultrasound bandages (10) and ultrasound transducer array bandages allows for medical therapeutic applications as promoting

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adhésive (14). Les bandages (10) à ultrasons et les bandages à réseau de transducteurs à ultrasons obtenus permettent des applications thérapeutiques médicales favorisant la cicatrisation des lésions telles que des abrasions, des lacérations, des incisions et des ulcères au niveau de n'importe quelle(s) partie(s) du corps humain, les bandages (10) à ultrasons et les bandages à réseau de transducteurs à ultrasons étant facilement jetables après chaque application et un nouveau bandage étant alors appliqué en vue de l'application suivante.

the healing of wounds such as abrasions, lacerations, incisions and ulcers at any section or multiple sections of the human anatomy with the ultrasound bandages (10) and ultrasound transducer array bandages being conveniently discarded after each application and a new bandage then being applied for the next application.

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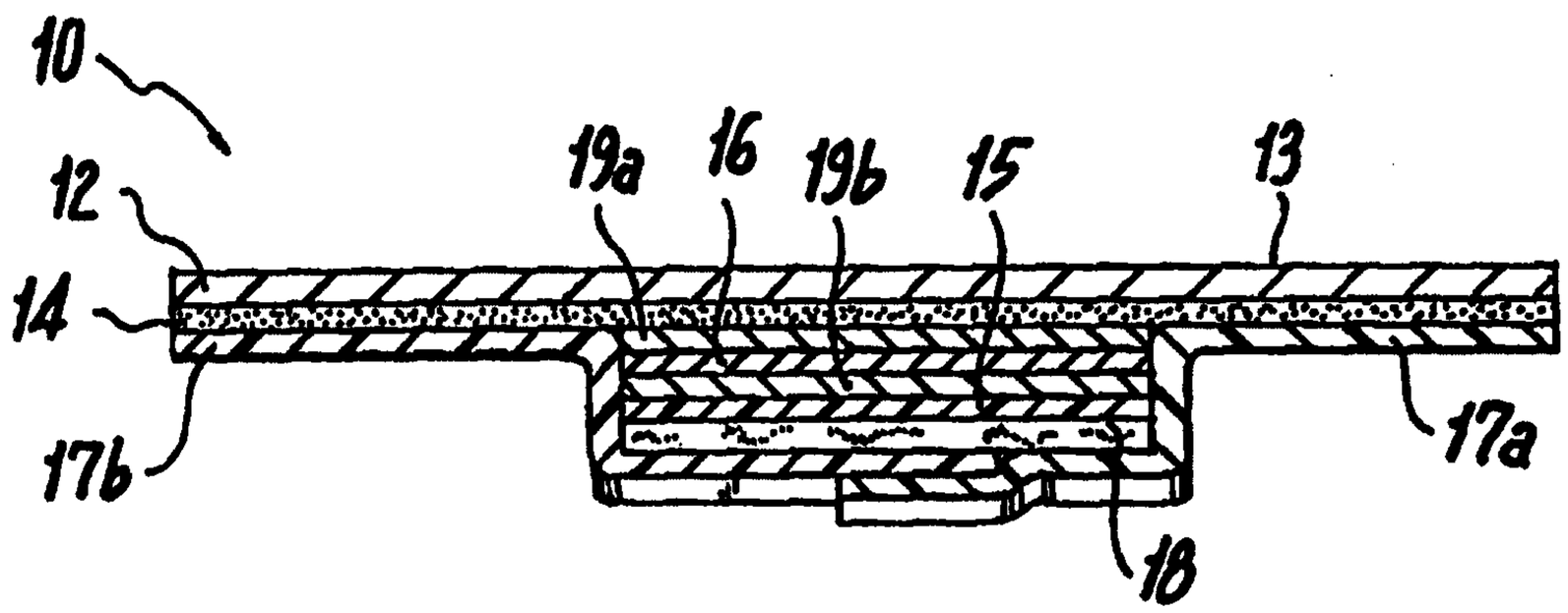
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(54) Title: ULTRASOUND BANDAGES



(57) Abstract

Ultrasound bandages (10) and ultrasound transducer array bandages are provided herein to accelerate the healing of wounds by positioning the ultrasound bandages (10) and ultrasound transducer array bandages adjacent to a wound and generating ultrasonic pulses. The ultrasound bandages generally include (a) a backing layer (13), (b) an adhesive layer (14) applied to, and substantially coextensive with, the backing layer (13), and (c) a transducer material (16) disposed on at least a portion of the adhesive layer (14). The ultrasound transducer array bandages generally include (a) a backing layer (13), (b) an adhesive layer (14) applied to, and substantially coextensive with, the backing layer (13), and (c) an array comprising a plurality of transducer materials (16) arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer (14). The resulting ultrasound bandages (10) and ultrasound transducer array bandages allows for medical therapeutic applications as promoting the healing of wounds such as abrasions, lacerations, incisions and ulcers at any section or multiple sections of the human anatomy with the ultrasound bandages (10) and ultrasound transducer array bandages being conveniently discarded after each application and a new bandage then being applied for the next application.

ULTRASOUND BANDAGES

BACKGROUND OF THE INVENTION

1. Field of the Invention

Novel ultrasound bandages and ultrasound transducer array bandages are described herein. Also described are methods for manufacturing the ultrasound bandages and ultrasound transducer array bandages. Additionally, use of the ultrasound bandages and ultrasound transducer array bandages in medical therapeutic ultrasound applications, e.g., for promoting the healing of wounds, i.e., wound healing, such as abrasions, lacerations, incisions and venous ulcers, are also described herein.

2. Description of the Related Art

The therapeutic value of ultrasonic waves is known. For example, U.S. Patent No. 4,530,360 to Duarte describes a basic non-invasive therapeutic technique and apparatus for applying ultrasonic pulses externally on the skin of the patient at a location adjacent to a bone fracture site. The applicator described in the '360 patent has a plastic tube which serves as a grip for the operator, an RF plug attached to the plastic tube for connection to an RF source, and internal cabling connected to a rigid ultrasonic transducer. To apply the ultrasonic pulses during treatment, an operator manually holds the applicator in place until the treatment is complete. The '360 patent also describes a range of RF signals for creating the ultrasound, ultrasound power density levels, a range of duration for each ultrasonic pulse, and a range of ultrasonic pulse frequencies.

As another example, U.S. Patent Nos. 5,003,965 and 5,186,162, both to Talish and Lifshey, describe an ultrasonic body treatment system in which the RF generator and transducer are both part of a modular applicator unit which is placed at the skin location. Both the '965 and '162 patents are concerned with healing, for example, bone fractures by placing the body treatment system within a cast and then surrounding the treatment site with the cast.

Yet another example is U.S. Patent No. 5,211,160 to Talish and Lifshey which describes a bandage assembly which is mounted on uncovered body parts, i.e., without a cast or other medical wrapping. The bandage assembly is typically wrapped around the region of the body, e.g., the leg, being subjected to ultrasonic therapy with a treatment head unit containing an ultrasonic transducer being removably assembled to the bandage assembly during treatment.

While these prior art systems provide accelerative healing of soft tissue wounds and bone fractures, none of the systems provide an ultrasound bandage having an adhesive layer with a transducer material disposed thereon for treatment of wounds.

Previous attempts have been made to provide a bandage having a transducer material. For example, U.S. Patent No. 4,787,888 discloses a bandage assembly for percutaneous administration of a medicament. The bandage assembly described in the '888 patent has a bandage member with a cavity containing a medicament and having two transducer materials, e.g., piezoelectric polymers, extending thereacross with a pair of electrical contacts disposed adjacent the opposite surfaces of the transducer material. The transducer materials, however, are employed to produce sonic vibrations

in the material from a sonic generator to stretch the pores of the skin thereby inducing the medicament into the pores for therapeutic treatment.

It would be desirable to provide an ultrasound bandage having an adhesive layer with a transducer material disposed on at least a portion thereof such that the bandage can be applied to the portion of the skin at or near a wound by way of the adhesive layer and the transducer material facilitating the transfer of acoustic energy during each therapeutic application to promote the healing of the wound with the ultrasound bandage being discarded upon completion of each application.

SUMMARY OF THE INVENTION

Novel ultrasound bandages and ultrasound transducer array bandages for use in therapeutic applications have been discovered. In one embodiment, the novel ultrasound bandages include at least a backing layer, an adhesive layer applied to, and substantially coextensive with, the backing layer, and a transducer material disposed on at least a portion of the adhesive layer. Electrode surfaces can be applied to opposite surfaces of the transducer material with a matching layer being applied to, and substantially coextensive with, the electrode surface not applied to the adhesive layer. A coupling pad can then be applied to, and substantially coextensive with, the matching layer.

In another embodiment, an ultrasound transducer array bandage is formed by disposing on at least a portion of an adhesive layer which is applied to, and substantially coextensive with, a backing layer, an array comprised of a plurality of

transducer materials arranged in adjacent relation to define spaces therebetween. Electrode surfaces ban be applied to opposite surfaces of each transducer material with a matching layer being applied to, and substantially coextensive with, the electrode surface not applied to the adhesive layer. A coupling pad can then be applied to, and substantially coextensive with, the array.

A method for making the ultrasound bandage has also been discovered. In the method, an adhesive layer is applied to, and substantially coextensive with, a backing layer, and a transducer material is disposed on at least a portion of the adhesive layer.

A method for making an ultrasound transducer array bandage has also been discovered. In the method, an adhesive layer is applied to, and substantially coextensive with, a backing layer, a plurality of transducer materials are arranged in adjacent relation to define spaces therebetween to form an array, the array being disposed on at least a portion of the adhesive layer, and, optionally, a coupling pad is applied to, and substantially coextensive with, the array.

A method for using the ultrasound bandage or ultrasound transducer array bandage in therapeutic applications has also been discovered. In the method, the ultrasound bandage or ultrasound transducer array bandage can be applied to a wound on the human anatomy or, alternatively, adjacent to the wound, in need of therapeutic stimulation and that section of the human anatomy is then exposed to a dosage amount of acoustic energy.

The term "wound" for the purposes of "wound healing" shall be understood herein to include ulcers such as venous ulcers, burns, ulcerated wounds due to, for

example, diabetes, incisions such as surgical incisions or other surgical cuttings including stitched surgical cuttings, skin grafts, hair transplants, revascularization, bed sores, tissue dehiscence, ligament and tendon repair and reconstruction, abrasions and lacerations.

The ultrasound bandages and ultrasound transducer array bandages described herein possess at least an adhesive layer having at least one transducer material disposed on at least a portion thereof to advantageously permit acoustic energy generated by the transducer(s) to be efficiently applied and coupled to the contours of the human anatomy for therapeutic applications. Additionally, after each application of therapeutic treatment, the ultrasound bandages and ultrasound transducer array bandages can be conveniently discarded with a new bandage being applied to the human anatomy for the next therapeutic application.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described below with reference to the drawings, which are described as follows:

FIG. 1 is a schematic cross-sectional view of an ultrasound bandage in accordance with the present invention;

FIG. 2A is a schematic cross-sectional view of the ultrasound bandage of FIG. 1 with a thicker coupling material;

FIG. 2B is a schematic transverse cross-sectional view of the ultrasound bandage of FIG 2A taken along axis 2B-2B illustrating the coupling material configured

as a wedge;

FIG. 3 is a schematic top view of the ultrasound bandage of FIG. 1 in an assembly;

FIG. 4 schematic side view of the ultrasound bandage assembly of FIG. 3 in accordance with the present invention;

FIG. 5 schematic cross-sectional view of a ultrasound transducer array bandage in accordance with the present invention;

FIG. 6A is a schematic cross-sectional view of the ultrasound transducer array bandage of FIG. 5 with a thicker coupling material;

FIG. 6B is a schematic transverse cross-sectional view of the ultrasound transducer array bandage of FIG 6A taken along axis 6B-6B illustrating the coupling material configured as a wedge;

FIG. 7 is a schematic top view of the ultrasound transducer array bandage of FIG. 5 in an assembly;

FIG. 8 is a schematic top view of ultrasound bandage possessing indicia thereon;

FIG. 9 is a perspective view of the ultrasound bandage assembly of FIG. 3 in use in accordance with the present invention; and,

FIG. 10 is a perspective view of the ultrasound transducer array bandage of FIG. 5 in use in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

One embodiment of an ultrasound bandage in accordance with the present invention is shown generally in FIG. 1 at 10. In general, the ultrasound bandage includes a backing layer 12 possessing upper and lower surfaces. Adhesive layer 14 is applied to, and substantially coextensive with, lower surface 13 of backing layer 12 for securing the ultrasound bandage 10 to the skin of the patient. Transducer material 16 can be disposed on at least a portion of adhesive layer 14 or, alternatively, transducer material 16 can be applied within at least a portion of adhesive layer 14. In this way, transducer material 16 can be removed, if desired, prior to disposal of ultrasound bandage 10 after use. Electrode surfaces 19a and 19b can be applied to, and substantially coextensive with, opposite surfaces of transducer material 16. Matching layer 15 can be applied to, and substantially coextensive with, electrode surface 19b. Coupling pad 18 can be applied to, and substantially coextensive with, matching layer 15, thereby providing an efficient coupling path between the transducer material 16 and the patient's skin and soft tissue for delivery of acoustic energy to the wound in need of therapeutic treatment. Alternatively, coupling pad 18 can include end portions (not shown) which extend beyond and fold over matching layer 15 to adhere to adhesive layer 14. Release liners 17a and 17b seal and protect adhesive layer 14, transducer material 16 and coupling pad 18 during the residency of ultrasound bandage 10 within its package with release liner 17a overlapping release liner 17b.

In general, backing layer 12 can be any material, woven or non-woven, synthetic or natural, porous or non-porous, perforated or non-perforated, elastic or non-

elastic, which will provide support and act as a protective covering for the bandage 10. Suitable materials include, for example, cellophane, cellulose acetate, ethyl cellulose, plasticized vinyl acetate-vinyl chloride copolymers, ethylene-vinyl acetate copolymer, polyethylene terephthalate, nylon, polyethylene, polypropylene, polyvinylidene, chloride, paper, cloth, aluminum foil and the like. Preferably, backing layer 12 is a moisture vapor permeable, liquid impermeable flexible thin film or sheet with the thin film being more preferred. A preferred thin film for use herein is a polyurethane film. If desired, the backing layer 12 can be fabricated from a composite of films. The composite can be a metallized, e.g., aluminized, film or a laminate of two or more films or a combination thereof. For example, a laminate of polyethylene terephthalate and polyethylene or a polyethylene/metallized polyethylene terephthalate/polyethylene laminate can be employed. Useful polymers include polyethylene, polypropylene, polyvinyl chloride, polyethylene terephthalate and the like. The width and thickness of backing layer 12 will vary according to the size of the bandage employed and are conventional in the art. Therefore, these widths and thicknesses need not be discussed in detail herein.

Adhesive layer 14 of bandage 10 is preferably a pressure sensitive adhesive layer and can be selected from any of the known and conventional medical grade adhesives, e.g., those based on polyacrylic, polyvinylether, or polyurethane resins. Useful pressure sensitive adhesives include those disclosed in U.S. Patent No. 4,573,996, the contents of which are incorporated by reference herein. It is an essential requirement that the amount of adhesive layer 14 applied to lower surface 13

of backing layer 12 be sufficient to achieve an acceptable level of adhesion of ultrasound bandage 10 to the skin and to apply and adhere transducers 16. Thus, the various shapes and sizes of adhesive layer 14 will depend, for example, on the area of a patient's body to which they are applied, the size and weight of transducer material 16, the size and shape of the external wound, etc. The amount of adhesive that will satisfy this criteria can be readily determined by simple and routine testing. Ordinarily, a medical grade adhesive applied to a thickness ranging from about 1.0 mils to about 3.5 mils and preferably from about 2.0 mils to about 2.5 mils (depending, of course, on the thickness of the backing layer) will meet this requirement reasonably well. Adhesive layer 14 may include holes or a permeable material to allow moisture to escape and provide oxygen to the skin.

Transducer material 16 can be formed from any transducer material known to one skilled in the art, e.g., an air backed quarter wave matched transducer material, polyvinyledene fluoride material (PVDF), etc. Preferably, transducer material 16 can be those disclosed in International PCT Application No. PCT/US99/06650, filed on March 26, 1999, the contents of which are incorporated by reference herein. For example, transducer material 16 can be formed from one or more fibers extruded from a composition containing a piezoelectric material. The extruded fibers can be knitted, woven or braided in 1, 2 or 3 dimensions to provide a structure that includes spaces which can be filled with a polymeric material to form a composite. Fibers made of piezoelectric material suitable for use herein can be prepared, for example, by using a viscous suspension spinning process and are available from Advanced Cerametrics

Incorporated (Lambertville, NJ). Suitable piezoelectric materials for use in the fibers include PZT powders commercially available from Morgan Matroc, Inc., ceramic, lead zirconate titanate $Pb(Zr,Ti)O_3$, lead metaniobate $Pb(Nb_2O_6)$, modified lead titanate $PbTi_3$ such as $(Pb,Ca)TiO_3$ and $(Pb,Sm)TiO_3$, barium titanate $BaTiO_3$, PMN-PT(1-x)$Pb(Mg_{1/3},Nb_{2/3})O_3$-x$PbTiO_3$, PZN-PT/BT $Pb(Zn_{1/3},Nb_{2/3})O_3$-x$PbTiO_3$-$BaTiO_3$, (1-x)$Pb(Zn_{1/3},Nb_{2/3})O_3$-x(y$PbTiO_3$-(1-y)$PbZrO_3$) and the like. In particularly useful embodiments, the extruded fibers are knitted, woven, braided or non-woven to form a fiber sheet. Preferably, a simple woven fabric is used as the fiber sheet. Optionally, the individual fibers in the fiber sheets can be coated with a film-forming polymer solution to improve the strength and wear resistance of the individual fibers prior to weaving, knitting and braiding. Suitable solutions of film-forming material are known to those in the textile art. By way of example, the solution can contain a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

Transducer material 16 can be of varying shapes and sizes depending, of course, on the size of the wound to be treated. This can be determined according to simple and routine experimental testing. Ordinarily, the thickness of transducer material 16 will range from about 0.1 mils to about 5 mils and preferably from about 1.5 mils to about 3.0 mils with the width of material 16 ranging from about 0.1 inch to about 1.5 inches and preferably from about 0.5 inch to about 1 inch.

Electrode surfaces 19a and 19b are applied to opposite surfaces of transducer material 16. Typically, electrode surface 19a will be applied onto one surface of the

transducer material by techniques known to one skilled in the art, e.g., utilizing photolithographic techniques. In general, electrode surface 19b will be applied to, and substantially coextensive with, the other surface of the transducer material. Electroding can be achieved employing techniques known to one skilled in the art, e.g., sputtering, painting. Materials useful in forming the electrode surfaces include copper, silver, nickel, gold, alloys, mixtures thereof and the like. Typically, electrode surface 19a will be positively charged and the other electrode surface 19b will serve as a ground.

Once electrode surfaces 19a and 19b have been applied, matching layer 15 can then be applied to, and substantially coextensive with, electrode surface 19b. Techniques for applying the matching layer are within the purview of one skilled in the art. Generally, the thickness of the matching layer can be chosen to correspond to one-quarter of the wavelength in the matching layer at the operating frequency of the transducer array. The acoustic impedance of the matching layer will preferably range from about 2.0 to about 7.0 MRayls.

Matching layer 15 will ordinarily be formed from a polymeric material, and optionally, a filler. The polymeric material should have good compatibility with the components of the composite, biocompatibility and flexibility. Useful polymeric materials include thermoplastics such as high density polyethylenes, polymethyl methacrylates, polypropylenes, polybutylene terephthalates, polycarbonates, polyurethanes such as CA 118 and CA 128 available from Morton Chemical and estane polyester, and the like; thermosets such as epoxies such as Spurr epoxy and Stycast 80, and the like; and rubbers such as silicone rubbers such as dispersion 236 available from

Dow Corning and RTV-141 available from Rhone-Poulenc, Inc. and the like. A preferred polymeric material for use herein is Stycast 1365-65. Because the acoustic impedance of many polymeric materials is less than the preferred range of 2.0 - 7.0 MRayls, it is necessary to increase the acoustic impedance of the polymer. Accordingly, one or more fillers can be incorporated therein. Suitable fillers include PZT, tungsten, alumina, silica glass, tungsten carbide, titanium, glass powder and the like with glass powder being preferred. The size of the filler particles should be in the range of about 0.1 to about 50 microns and preferably from about 0.5 to about 5 microns. The amount of filler employed will be that amount necessary to impart the desired acoustic impedance. Normally, from about 2 to about 50 percent filler by volume and preferably from about 5 to about 30 volume percent filler is employed.

Coupling pad 18 can be selected from any coupling material known to one skilled in the art. A preferred coupling material for use herein is a hydrogel pad. Coupling pad 18 can have a substantially planar surface as depicted in FIG. 1. Alternatively, coupling pad 18 can be configured, for example, as a wedge, i.e., possessing a non-planar surface, as depicted in FIG. 2A and FIG. 2B. Thus, when employing a coupling pad 18 configured as, for example, a wedge, the longitudinal waves are to be transmitted from the transducer off-axis, at an angle equal to or slightly greater than the critical angle, depending on Poisson's ratio for soft tissue, where the longitudinal waves are converted completely into shear waves (modal conversion) for therapeutic ultrasonic stimulation and treatment at the site of the wound.

Since the delivery of ultrasound to a target injury requires an efficient coupling

path between the transducer material and the patient's skin and soft tissue, a material for ultrasound coupling is typically employed to effect a proper interface for propagating acoustic energy into the patient's body. Commonly used materials include sonically conductive materials such as, for example, glycerol, water, oils, lotions, etc., which are applied onto the coupling pad prior to bandage 10 being placed on the patient's body.

Ultrasound bandage 10 is typically employed in an ultrasound bandage assembly as generally depicted in FIG. 3. Ultrasound bandage assembly 20 will include at least one or more ultrasound bandages 10 having connector assemblies 24 with leads 26 for coupling ultrasound transducers 16 to a portable main operating unit (MOU). Connector assemblies 24 include detachable connectors 22 for detachably connecting leads 26 to transducers 16 which is mounted on adhesive layer 14 (see FIG. 4). Connectors 22 are operatively coupled to transducers 16 and are preferably of the quick-connected type such that leads 26 may be detached and reused while ultrasound bandages 10 can be disposed of. The MOU supplies powers and provides signals for controlling transducers 16. In one embodiment, the MOU can be a commercially available device such as, for example, an SAFHS 2000 available commercially from Exogen, Inc. (Piscataway, NJ). A preferred MOU is described in further detail in U.S. Application Serial No. 09/040,157 which is incorporated by reference herein. The MOU preferably includes a processor which could be a microprocessor used in conjunction with transducers 16. The processor generates control signals which are amplified by an output driver to the desired power level and imparted to the transducers

The ultrasound transducer array bandages of the present invention can be obtained by forming an array of a plurality of the foregoing transducer materials. The transducer array bandage 30 can be formed, for example, by disposing an arrangement of transducer materials 32 in adjacent relation to one another to define spaces 34 therebetween as generally depicted in FIG. 5. It is to be understood that the transducer materials 32 can be of varying sizes when forming the array bandage described herein. In general, the transducer materials 32 can be placed close together or spaced further apart and the spacings need not be uniform or in perfect alignment.

The transducer materials 32 are disposed on or within at least a portion of adhesive layer 36 which is applied to, and substantially coextensive with, backing layer 38. Useful materials for forming backing layer 38 and adhesive layer 36 can be any of the aforementioned materials. Typically, the spaces between transducer materials 32 will range from about 0.5 mm to about 10 mm and preferably from about 1 mm to about 3 mm. The dimensions of the array will ordinarily range from about 0.5 inch to about 6 inches wide and from about 0.5 inch to about 12 inches long. The thickness of the array can effect the frequency of operation and will ordinarily range from about 0.05 mm to about 10 mm. It should, of course, be understood that the array can include transducer materials with different frequencies of operation. These differences in frequency of operation can be achieved by employing transducer materials of different thicknesses.

Electrode surfaces 39a and 39b can be applied to, and substantially coextensive

with, each transducer material 32 in the array. Once the electrode surfaces have been applied, matching layers 33 can then be applied to, and substantially coextensive with, electrode surfaces 39b. Useful materials for forming the electrode surfaces and the matching layer can be any of the aforementioned materials.

Coupling pad 35 can be, for example, a hydrogel pad, and is typically applied to, and substantially coextensive with, each matching layer 33, i.e., the array. Alternatively, coupling pad 35 can be applied to, and substantially coextensive with, each matching layer 33 (not shown). In use, coupling pad 35 can have a substantially planar surface as depicted in FIG. 5. Alternatively, coupling pad 35 can be configured, for example, as a wedge, i.e., possessing a non-planar surface, as depicted in FIG. 6A and FIG. 6B. Thus, when employing a coupling pad 35 configured as, for example, a wedge, the longitudinal waves are to be transmitted from the transducers off-axis, at an angle equal to or slightly greater than the critical angle, depending on Poisson's ratio for soft tissue, where the longitudinal waves are converted completely into shear waves (modal conversion) for therapeutic ultrasonic stimulation and treatment at the site of the wound. Release liners 37a and 37b seal and protect adhesive layer 36, transducer materials 32 and coupling pad 35 during the residency of ultrasound transducer array bandage 30 within its package with release liner 37a overlapping release liner 37b.

Once the ultrasound transducer array bandage 30 has been formed, connector assemblies 40 with leads 42 for coupling ultrasound transducers 32 to a portable main operating unit (MOU) are applied to the transducers 32 to form an ultrasound transducer array bandage assembly 44 as generally depicted in FIG.7. Connector

assemblies 40 include detachable connectors 48 for detachably connecting leads 42 to transducers 32 which is mounted on adhesive layer 36. Connectors 48 are operatively coupled to transducers 32 and are preferably of the quick-connected type such that leads 42 may be detached and reused while ultrasound transducer array bandages 44 can be disposed of.

The ultrasound bandages and ultrasound transducer array bandages of this invention can also possess a protective covering (not shown) instead of release liners 17a and 17b and 37a and 37b, respectively. Covers of this kind are known from U.S. Patent No. 4,627,429, the contents of which are incorporated by reference herein. In general, the protective covering can be made, for example, of a heat-sealable aluminum foil film laminate with the heat-sealable surface down. A formed cup, dome or square in the cover allows room for the transducer materials and coupling pad with the other portion of the cover being placed over the adhesive layer.

The ultrasound bandages and ultrasound transducer array bandages of this invention can be manufactured in a variety of sizes and shapes, e.g., rectangular, oval, etc., and can be planar or three-dimensional. Additionally, the ultrasound bandages and ultrasound transducer array bandages used herein can contain indicia thereon, e.g., text, color, etc., to indicate the direction of the transducer so that the ultrasonic waves can be directed toward the wound as depicted in FIG. 8.

The ultrasound bandages and ultrasound transducer array bandages of this invention are particularly useful in therapeutic applications. In general, the foregoing bandages will be applied adjacent to, or directly over, the wound to facilitate the

transfer of acoustic energy to promote the healing of wounds. As noted above, the term "wound" as used herein has a broad meaning as generally encompassing addressing damage to, and repair of, or restoration of soft tissue or wounds to the skin such as abrasions and lacerations. The present invention can be used, for example, to prevent surgical adhesions by stimulating the proper repair of surgical incisions. It can also prevent or arrest wound dehiscence by promoting vascularization at the surfaces adjacent surgical incisions. It can also be used in cosmetic surgery, for example, by enhancing the healing of hair transplants, or by directly stimulating regeneration of cells.

In general, once the acoustic energy enters the body, it passes into internal body tissue and/or fluids. The acoustic energy, in the form of ultrasonic pulses, is reflected off the surface of underlying bone or other ultrasound reflective material and the reflected ultrasound travels toward at least part of the internal surface or underside of the wound. Healing of the wound at the internal surface by the generation of epithelial cells is enhanced via the acoustic stimulation.

Preferably, a low frequency signal which is present as the modulation of the carrier frequency is transmitted as a longitudinal acoustic wave from the transducer material, through interposed soft tissue, and onto the surface of the bone. The longitudinal wave incident on the bone surface, or other designated reflection sites in the body, is reflected toward the internal surface of the wound as longitudinal and/or shear waves. These reflected waves flooding a region of the internal surface of the wound increase vascularization at the internal surface of the wound thus enhancing

growth of epithelial cells. The epithelial cell growth represents healing of the wound. The technique thus promotes healing of the wound from the internal surface of the wound.

The number, position and size of ultrasonic bandages used at the external skin location are chosen based on the size and position of the wound and the relative position and proximity of the bone from which the ultrasonic waves are reflected. Thus, more than one ultrasound bandage or ultrasound transducer array bandage can be employed at the site of the wound. For example, bandages 10 can be employed about a wound 50 on a body 52 and positioned and configured to provide enhanced healing treatment to wound 50 as generally depicted in FIG. 9 and FIG. 10. A portable MOU is shown for providing power and control to transducers 16 via connectors 26. Additionally, for example, ultrasound transducer array bandage 30 having a plurality of transducer materials 32 can be disposed over a wound 54 on a body 56 for treatment thereof with a portable MOU connected thereto.

Typically, the frequency of the acoustic energy applied during treatment will be in the range of from about 20 kHz to about 10 MHZ and preferably from about 0.5 to about 5 MHZ. Features characterizing the frequency of the acoustic energy are disclosed in U.S. Patent No. 5,520,612, the contents of which are incorporated by reference herein. It is to be understood that multiple sections of the human anatomy can be treated with multiple ultrasound bandages or ultrasound transducer array bandages at the same time. Thus, for example, in the case of an individual suffering from both an abrasion to the arm and an abrasion to the leg, an ultrasound bandage or

ultrasound transducer array bandage can be applied to the arm while a second ultrasound bandage or ultrasound transducer array bandage is being applied to the section of the leg suffering from the wound. The transmit frequency and acoustic energy applied to each section can vary according to the foregoing ranges.

When applying the foregoing bandages to the section of the human anatomy in need of therapeutic assistance, it is advantageous to apply a coupling gel to the transducer material prior to its employment on the part of the body. Additionally, when employing the foregoing ultrasound transducer array bandages, it may be desirable in certain cases to use selective energization of the transducer materials in the array such that certain elements will generate acoustic energy while other elements will not. This will permit the spatial, temporal, and frequency control of the distribution of acoustic energy in the body. Techniques for altering the acoustic energy of the transducer materials are disclosed in U.S. Patent No. 5,520,612.

Although the present invention has been described in preferred forms with a certain degree of particularity, many changes and variations are possible therein and will be apparent to those skilled in the art after reading the foregoing description. It is therefore to be understood that the present invention may be practiced otherwise than as specifically described herein without departing from the spirit and scope thereof.

WHAT IS CLAIMED IS:

1. An ultrasound bandage which comprises:

a) a backing layer possessing upper and lower surfaces;

b) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer; and,

c) a transducer material disposed on at least a portion of the adhesive layer.

2. The ultrasound bandage of Claim 1 wherein the backing layer is a polyurethane film.

3. The ultrasound bandage of Claim 1 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.

4. The ultrasound bandage of Claim 1 wherein the transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.

5. The ultrasound bandage of Claim 4 wherein the fiber sheet is a fabric woven from one or more fibers containing a piezoelectric material.

6. The ultrasound bandage of Claim 4 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $Pb(Zr,Ti)O_3$, lead metaniobate $Pb(Nb_2O_6)$, modified lead titanate $PbTi_3$, $(Pb,Ca)TiO_3$, $(Pb,Sm)TiO_3$, barium titanate $BaTiO_3$, PMN-PT$(1-x)Pb(Mg_{1/3},Nb_{2/3})O_3$-$xPbTiO_3$, PZN-PT/BT $Pb(Zn_{1/3},Nb_{2/3})O_3$-$xPbTiO_3$-$BaTiO_3$, $(1-x)Pb(Zn_{1/3},Nb_{2/3})O_3$-$x(yPbTiO_3$-$(1-y)PbZrO_3)$ and mixtures thereof.

7. The ultrasound bandage of Claim 4 wherein the fiber sheet is knitted, braided or woven from extruded fibers containing a piezoelectric material.

8. The ultrasound bandage of Claim 4 wherein the extruded fibers possess a coating formed thereon.

9. The ultrasound bandage of Claim 8 wherein the coating comprises a film-forming polymer solution.

10. The ultrasound bandage of Claim 9 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

11. The ultrasound bandage of Claim 1 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of the transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

12. The ultrasound bandage of Claim 11 wherein the matching layer comprises a polymeric material and optionally a filler.

13. The ultrasound bandage of Claim 12 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

14. The ultrasound bandage of Claim 12 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

15. The ultrasound bandage of Claim 12 wherein the matching layer includes glass powder as a filler.

16. The ultrasound bandage of Claim 11 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

17. The ultrasound bandage of Claim 11 further comprising a coupling pad applied to, and substantially coextensive with, the matching layer.

18. The ultrasound bandage of Claim 17 wherein the coupling pad is a hydrogel pad.

19. The ultrasound bandage of Claim 17 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from the transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

20. The ultrasound bandage of Claim 1 further comprising connector assemblies having connectors and leads, the connectors detachably connect leads to the transducer material and the leads are coupled to a portable main operating unit.

21. The ultrasound bandage of Claim 19 further comprising a cover covering the adhesive layer and the coupling pad and being applied to the adhesive layer.

22. A method for manufacturing an ultrasound bandage which comprises:

a) providing a backing layer possessing upper and lower surfaces;

b) applying an adhesive layer to, and substantially coextensive with, the lower surface of the backing layer; and,

c) disposing a transducer material on at least a portion of the adhesive layer.

23. The method of Claim 22 wherein the backing layer is a polyurethane film.

24. The method of Claim 22 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.

25. The method of Claim 22 wherein the transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.

26. The method of Claim 25 wherein the fiber sheet is a fabric woven from one or more fibers containing a piezoelectric material.

27. The method of Claim 25 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $Pb(Zr,Ti)O_3$, lead metaniobate $Pb(Nb_2O_6)$, modified lead titanate $PbTi_3$, $(Pb,Ca)TiO_3$, $(Pb,Sm)TiO_3$, barium titanate $BaTiO_3$, PMN-PT$(1-x)Pb(Mg_{1/3},Nb_{2/3})O_3-xPbTiO_3$, PZN-PT/BT $Pb(Zn_{1/3},Nb_{2/3})O_3-xPbTiO_3-BaTiO_3$, $(1-x)Pb(Zn_{1/3},Nb_{2/3})O_3-x(yPbTiO_3-(1-y)PbZrO_3)$ and mixtures thereof.

28. The method of Claim 25 wherein the extruded fibers possess a coating formed thereon.

29. The method of Claim 28 wherein the coating comprises a film-forming polymer solution.

30. The method of Claim 29 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

31. The method of Claim 22 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of the transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

32. The method of Claim 31 wherein the matching layer comprises a polymeric material and optionally a filler.

33. The method of Claim 32 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

34. The method of Claim 32 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

35. The method of Claim 32 wherein the matching layer includes glass powder as a filler.

36. The method of Claim 31 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

37. The method of Claim 31 further comprising applying a coupling pad to, and substantially coextensive with, the matching layer.

38. The method of Claim 37 wherein the coupling pad is a hydrogel pad.

39. The method of Claim 37 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from the transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

40. The method of Claim 22 further comprising connecting connector assemblies having connectors and leads to the transducer material of the ultrasonic bandage.

41. An ultrasound transducer array bandage which comprises:

a) a backing layer possessing upper and lower surfaces;

b) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer;

c) an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer; and,

d) a connector assembly applied to the array.

42. The ultrasound transducer array bandage of Claim 41 wherein the backing layer is a polyurethane film.

43. The ultrasound transducer array bandage of Claim 41 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.

44. The ultrasound transducer array bandage of Claim 41 wherein each transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.

45. The ultrasound transducer array bandage of Claim 44 wherein the fiber sheet is a fabric woven from one or more extruded fibers containing a piezoelectric

material.

46. The ultrasound transducer array bandage of Claim 44 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $Pb(Zr,Ti)O_3$, lead metaniobate $Pb(Nb_2O_6)$, modified lead titanate $PbTi_3$, $(Pb,Ca)TiO_3$, $(Pb,Sm)TiO_3$, barium titanate $BaTiO_3$, PMN-PT(1-x)$Pb(Mg_{1/3},Nb_{2/3})O_3$-x$PbTiO_3$, PZN-PT/BT $Pb(Zn_{1/3},Nb_{2/3})O_3$-x$PbTiO_3$-$BaTiO_3$, (1-x)$Pb(Zn_{1/3},Nb_{2/3})O_3$-x(y$PbTiO_3$-(1-y)$PbZrO_3$) and mixtures thereof.

47. The ultrasound transducer array bandage of Claim 44 wherein the fiber sheet is knitted, braided or woven from extruded fibers containing a piezoelectric material.

48. The ultrasound transducer array bandage of Claim 44 wherein the extruded fibers possess a coating formed thereon.

49. The ultrasound transducer array bandage of Claim 48 wherein the coating comprises a film-forming polymer solution.

50. The ultrasound transducer array bandage of Claim 49 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

51. The ultrasound transducer array bandage of Claim 41 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of each transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

52. The ultrasound transducer array bandage of Claim 51 wherein the matching layer comprises a polymeric material and optionally a filler.

53. The ultrasound transducer array bandage of Claim 52 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

54. The ultrasound transducer array bandage of Claim 52 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

55. The ultrasound transducer array bandage of Claim 52 wherein the matching layer includes glass powder as a filler.

56. The ultrasound bandage of Claim 51 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

57. The ultrasound transducer array bandage of Claim 51 further comprising a coupling pad applied to, and substantially coextensive with, the matching layer.

58. The ultrasound transducer array bandage of Claim 57 wherein the coupling pad is a hydrogel pad.

59. The ultrasound transducer array bandage of Claim 57 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from each transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

60. The ultrasound transducer array bandage of Claim 41 wherein the connector assemblies comprise connectors and leads, the connectors detachably connect leads to the array and the leads are coupled to a portable main operating unit.

61. The ultrasound transducer array bandage of Claim 41 further comprising a cover covering the adhesive layer and the coupling pad and being applied to the adhesive layer.

62. A method for manufacturing an ultrasound transducer array bandage which comprises:

a) providing a backing layer possessing upper and lower surfaces;

b) applying an adhesive layer to, and substantially coextensive with, the lower surface of the backing layer;

c) disposing an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween on at least a portion of the adhesive layer; and,

d) applying a connector assembly to the array.

63. The method of Claim 62 wherein the backing layer is a polyurethane film.

64. The method of Claim 62 wherein the adhesive layer is fabricated from a material selected from the group consisting of polyacrylic resin, polyvinylether resin and polyurethane resin.

65. The method of Claim 62 wherein each transducer material comprises a fiber sheet formed from a composition containing a piezoelectric material.

66. The method of Claim 65 wherein the piezoelectric material is selected from the group consisting of PZT powders, ceramic, PVDF, lead zirconate titanate $Pb(Zr,Ti)O_3$, lead metaniobate $Pb(Nb_2O_6)$, modified lead titanate $PbTi_3$, $(Pb,Ca)TiO_3$, $(Pb,Sm)TiO_3$, barium titanate $BaTiO_3$, PMN-PT$(1-x)Pb(Mg_{1/3},Nb_{2/3})O_3$-$xPbTiO_3$, PZN-PT/BT $Pb(Zn_{1/3},Nb_{2/3})O_3$-$xPbTiO_3$-$BaTiO_3$, $(1-x)Pb(Zn_{1/3},Nb_{2/3})O_3$-$x(yPbTiO_3$-$(1-y)PbZrO_3)$ and mixtures thereof.

67. The method of Claim 65 wherein the fiber sheet is a fabric woven from one or more fibers containing a piezoelectric material.

68. The method of Claim 65 further comprising the step of forming the fiber sheet by knitting, braiding or weaving the extruded fibers.

69. The method of Claim 68 further comprising applying a coating to the extruded fibers prior to forming the fiber sheet.

70. The method of Claim 69 wherein the coating comprises a film-forming polymer solution.

71. The method of Claim 70 wherein the film-forming polymer solution contains a mixture of a polyvinyl alcohol and polyvinyl acetate as a major component thereof and polyethylene glycol as a minor component thereof.

72. The method of Claim 62 further comprising an electrode surface applied to, and substantially coextensive with, opposite surfaces of each transducer material and a matching layer applied to, and substantially coextensive with, one of the electrode surfaces.

73. The method of Claim 72 wherein the matching layer comprises a polymeric material and optionally a filler.

74. The method of Claim 73 wherein the polymeric material is selected from the group consisting of thermoplastics, thermosets, rubbers, epoxy and mixtures thereof.

75. The method of Claim 73 wherein the matching layer includes a filler selected from the group consisting of PZT, tungsten, alumina, silica glass, tungsten carbide and titanium.

76. The method of Claim 73 wherein the matching layer includes glass powder as a filler.

77. The ultrasound bandage of Claim 72 wherein the matching layer has an acoustic impedance of from about 2.0 to about 7.0 MRayls.

78. The method of Claim 72 further comprising applying a coupling pad to, and substantially coextensive with, the matching layer

79. The method of Claim 78 wherein the coupling pad is a hydrogel pad.

80. The method of Claim 78 wherein the coupling pad is configured as a wedge to direct a longitudinal wave from each transducer material off-axis for to an internal designated reflection site and/or for modal conversion.

81. The method of Claim 62 wherein the connector assemblies comprise connectors and leads.

82. A method for accelerating the healing of wounds comprising:

a) positioning at least one ultrasound bandage adjacent to a body at the site of a wound;

b) the ultrasound bandage comprising:

I) a backing layer possessing upper and lower surfaces;

ii) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer; and,

iii) a transducer material disposed on at least a portion of the adhesive layer; and,

c) causing the transducer material to generate ultrasonic pulses.

83. The method of Claim 82 wherein at least one ultrasound bandage is positioned adjacent to a body at a plurality of sites of wounds.

84. The method of Claim 82 further comprising applying an electrode surface to, and substantially coextensive with, opposite surfaces of the transducer material, applying a matching layer to, and substantially coextensive with, one of the electrode surfaces and applying a coupling pad configured as a wedge to the matching layer.

85. A method for accelerating the healing of wounds comprising:

a) positioning at least one ultrasound transducer array bandage adjacent to a body at the site of a wound;

b) the ultrasound transducer array bandage comprising:

I) a backing layer possessing upper and lower surfaces;

ii) an adhesive layer applied to, and substantially coextensive with, the lower surface of the backing layer; and,

iii) an array comprising a plurality of transducer materials arranged in adjacent relation to define spaces therebetween, the array being disposed on at least a portion of the adhesive layer and,

c) causing the plurality transducer materials to generate ultrasonic pulses.

86. The method of Claim 85 wherein at least one ultrasound transducer array bandage is positioned adjacent to a body at a plurality of sites of wounds.

87. The method of Claim 85 further comprising applying an electrode surface to, and substantially coextensive with, opposite surfaces of each transducer material, applying a matching layer to, and substantially coextensive with, one of the electrode surfaces and applying a coupling pad configured as a wedge to the matching layer.

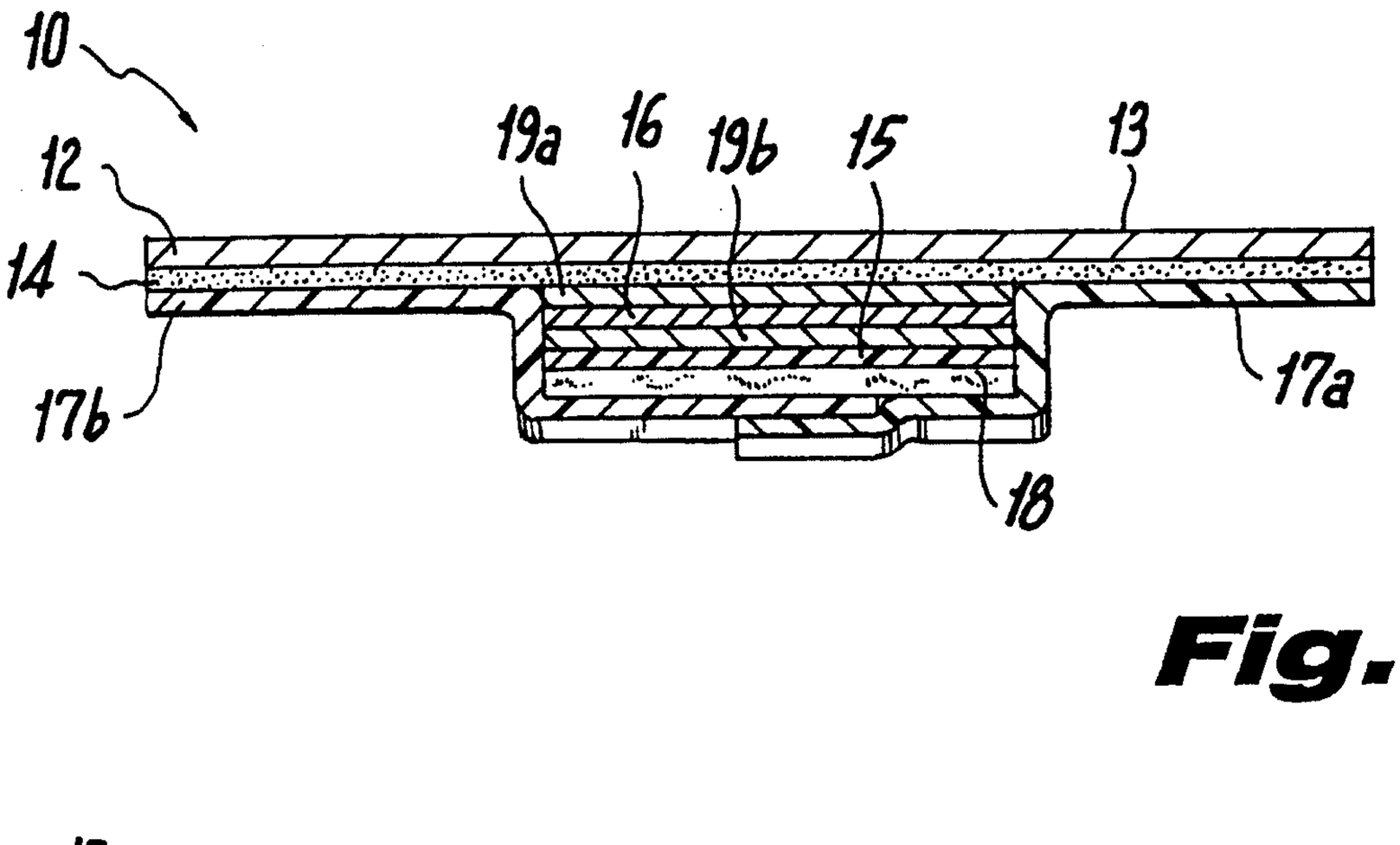


Fig. 1

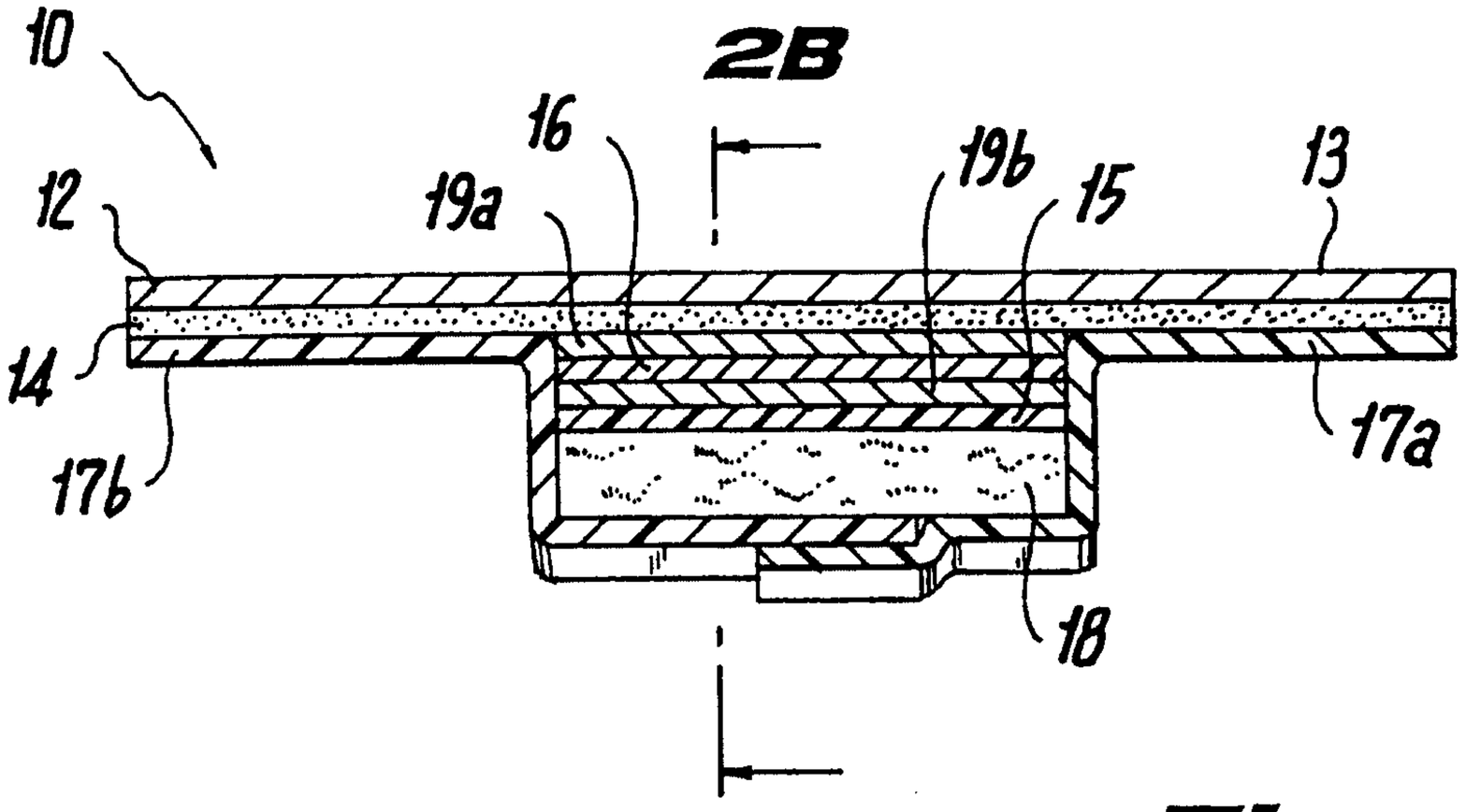


Fig. 2A

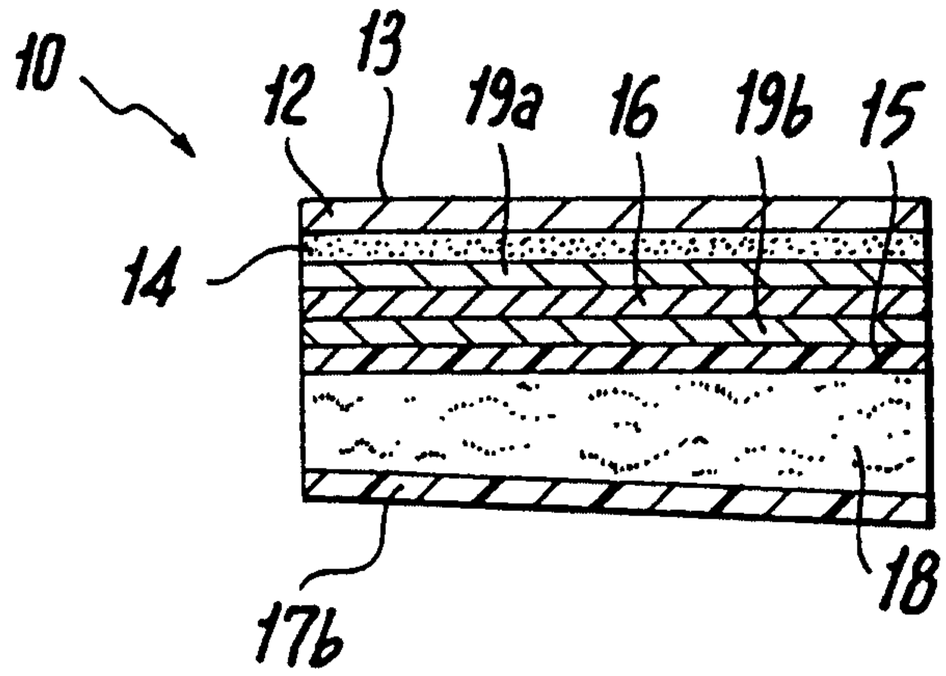


Fig. 2B

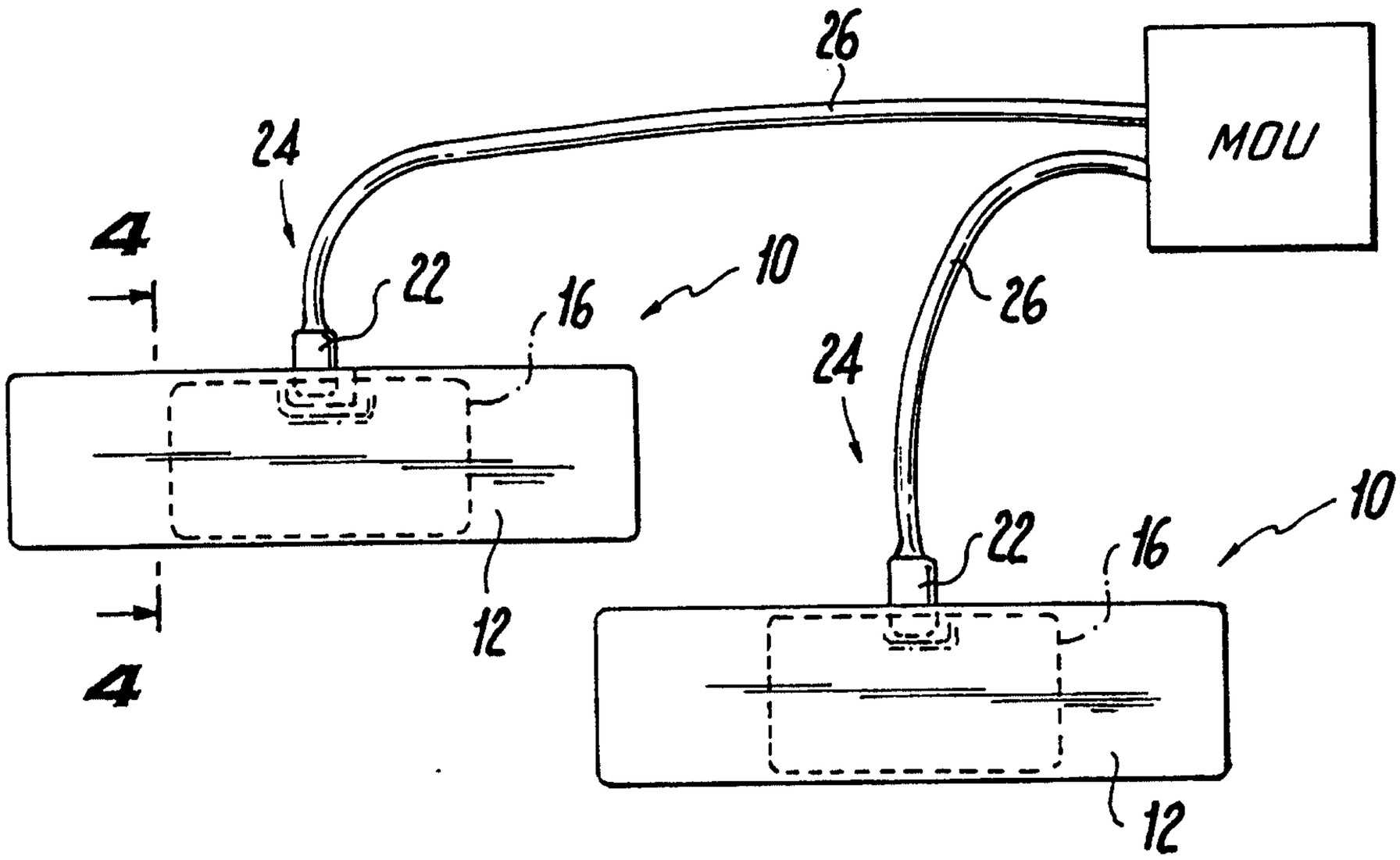


Fig. 3

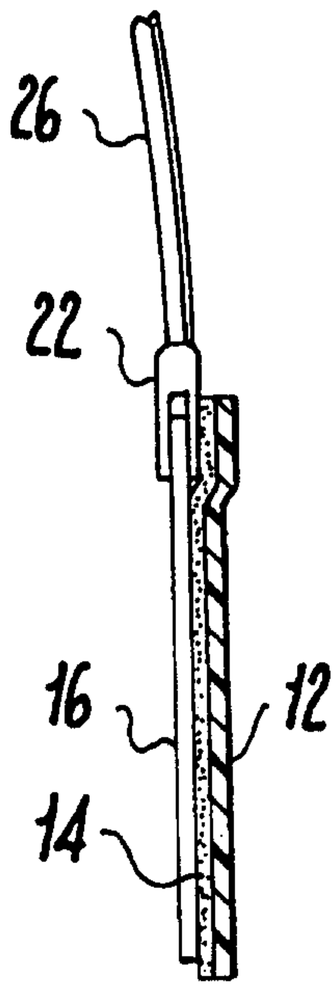


Fig. 4

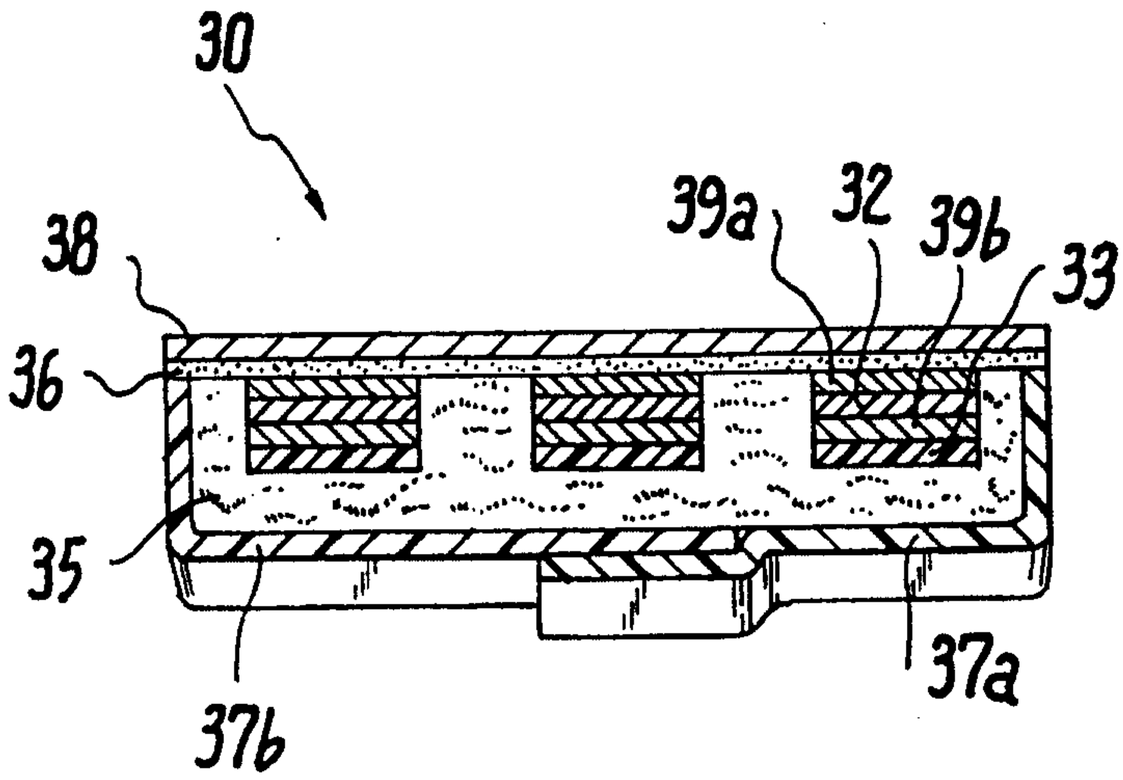


Fig. 5

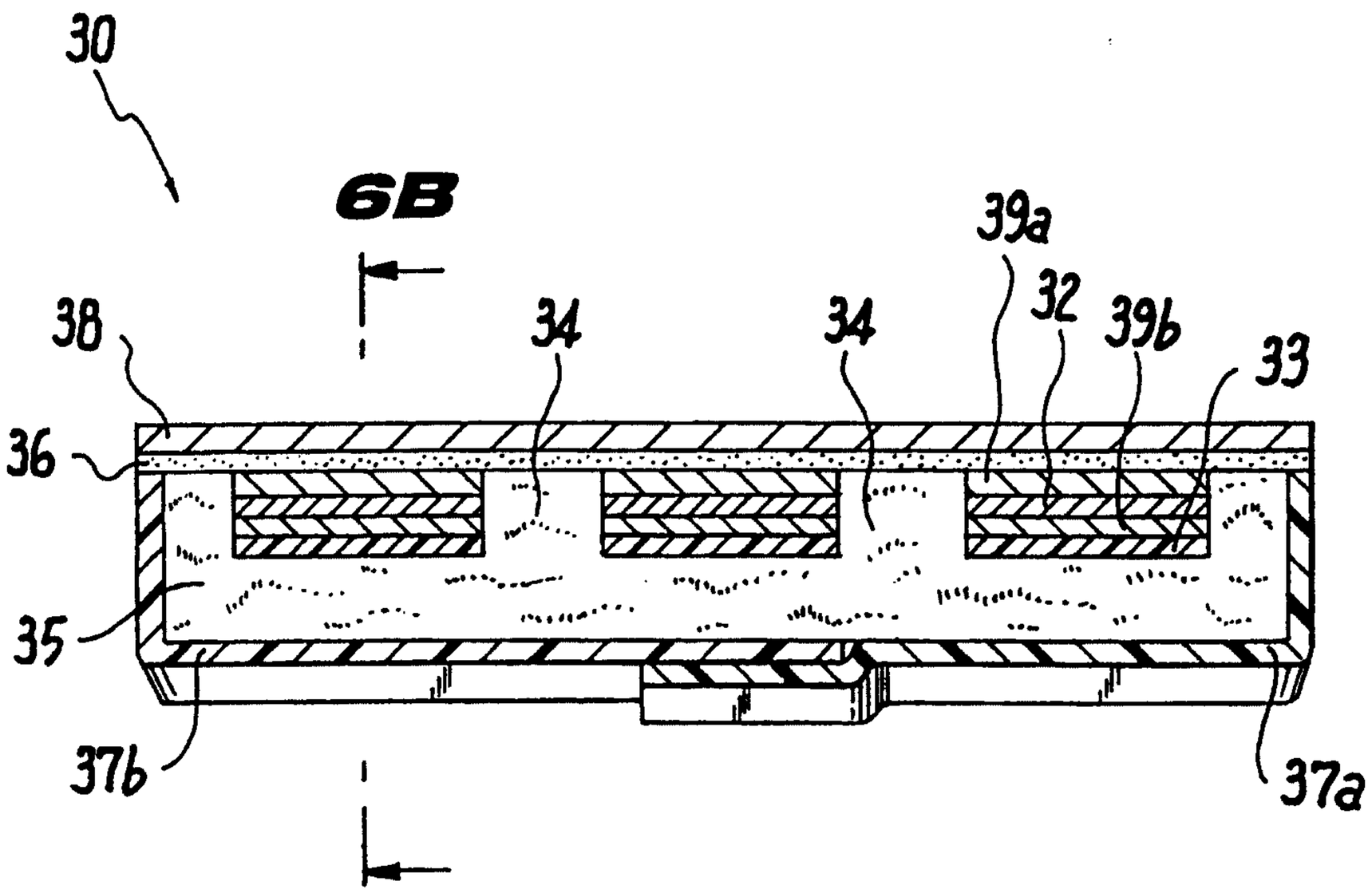

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6B
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32
39b
33
36
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37b
37a
39a
6B

Fig. 6A

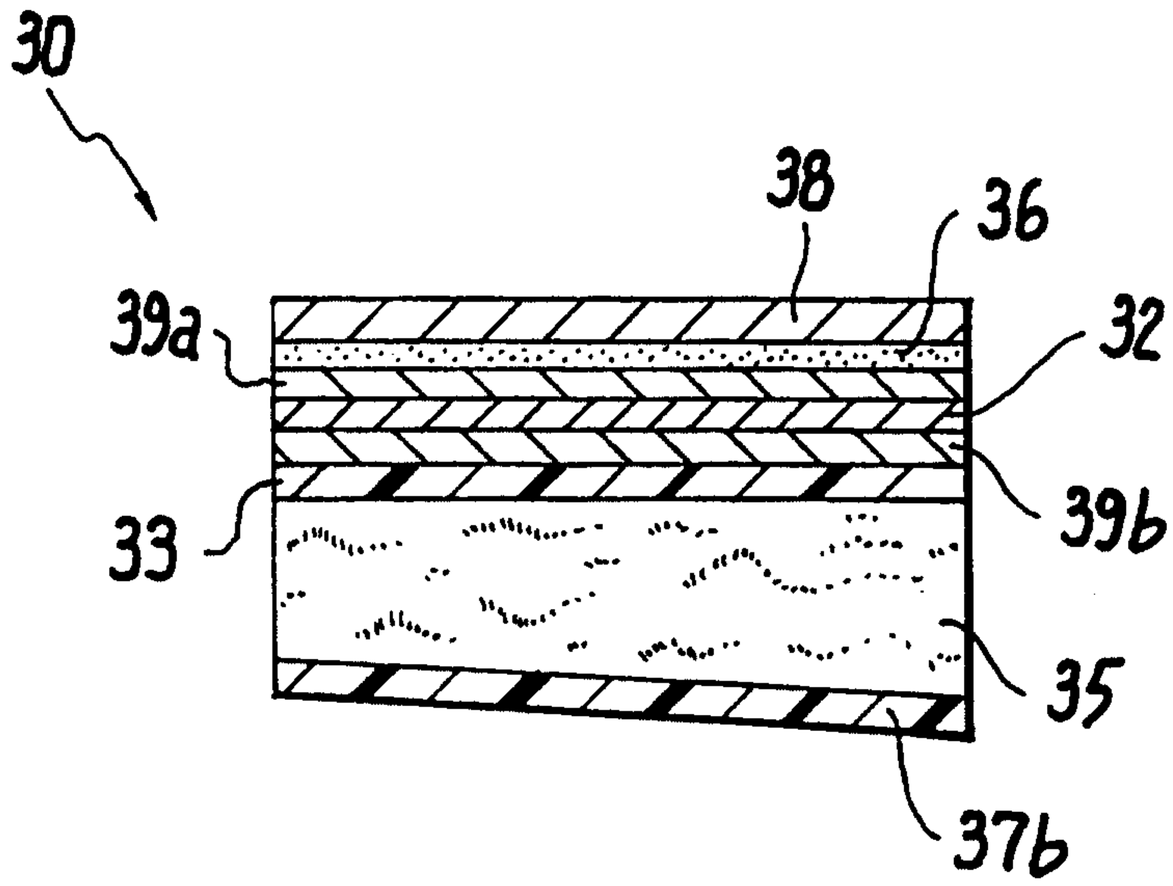

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38
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39a
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33
39b
35
37b

Fig. 6B

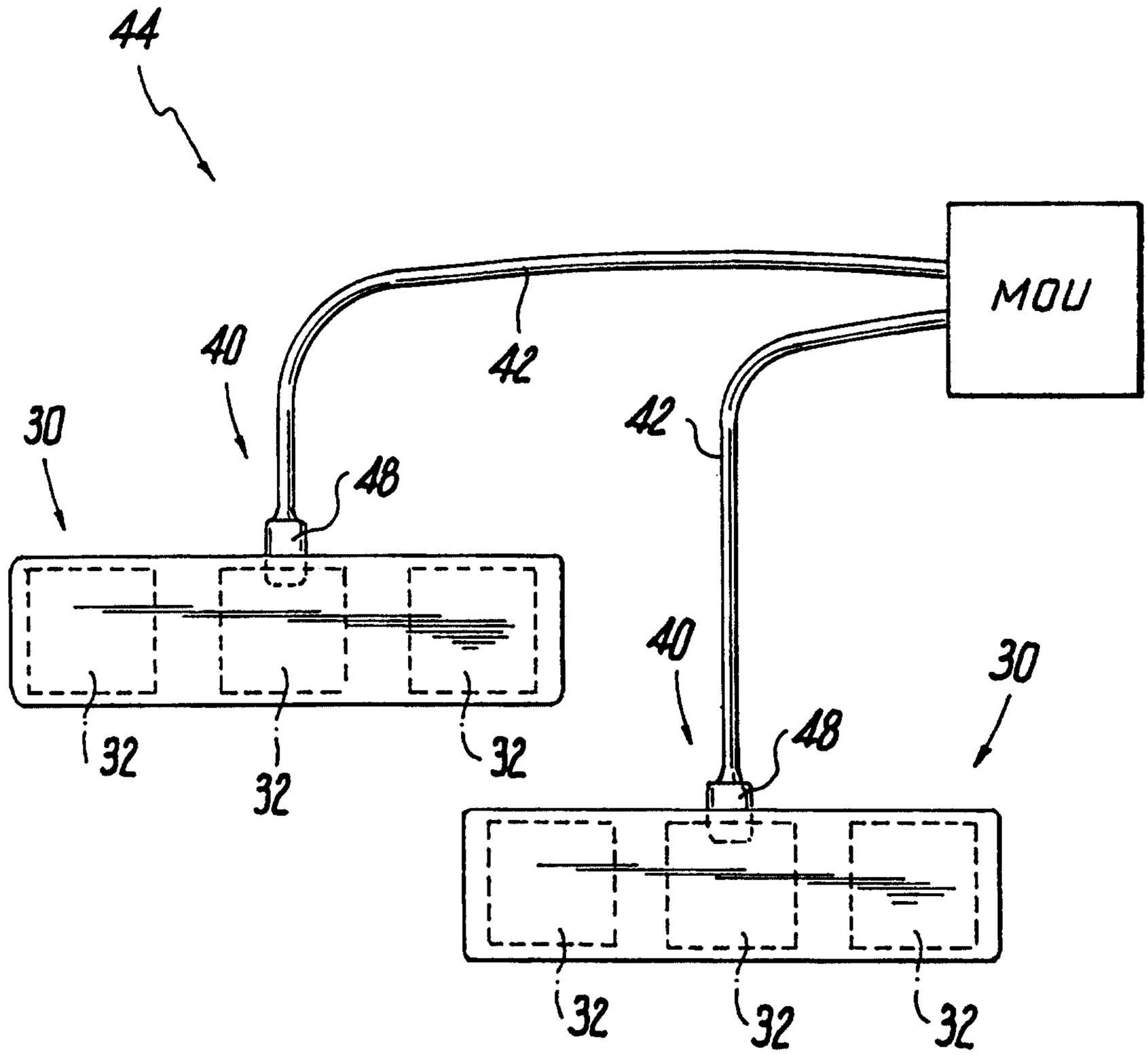


Fig. 7

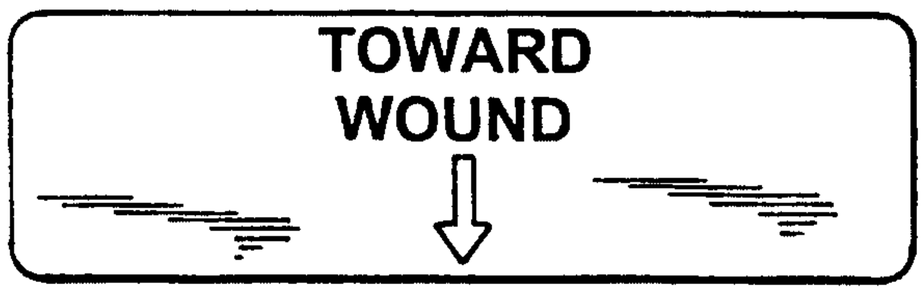


Fig. 8

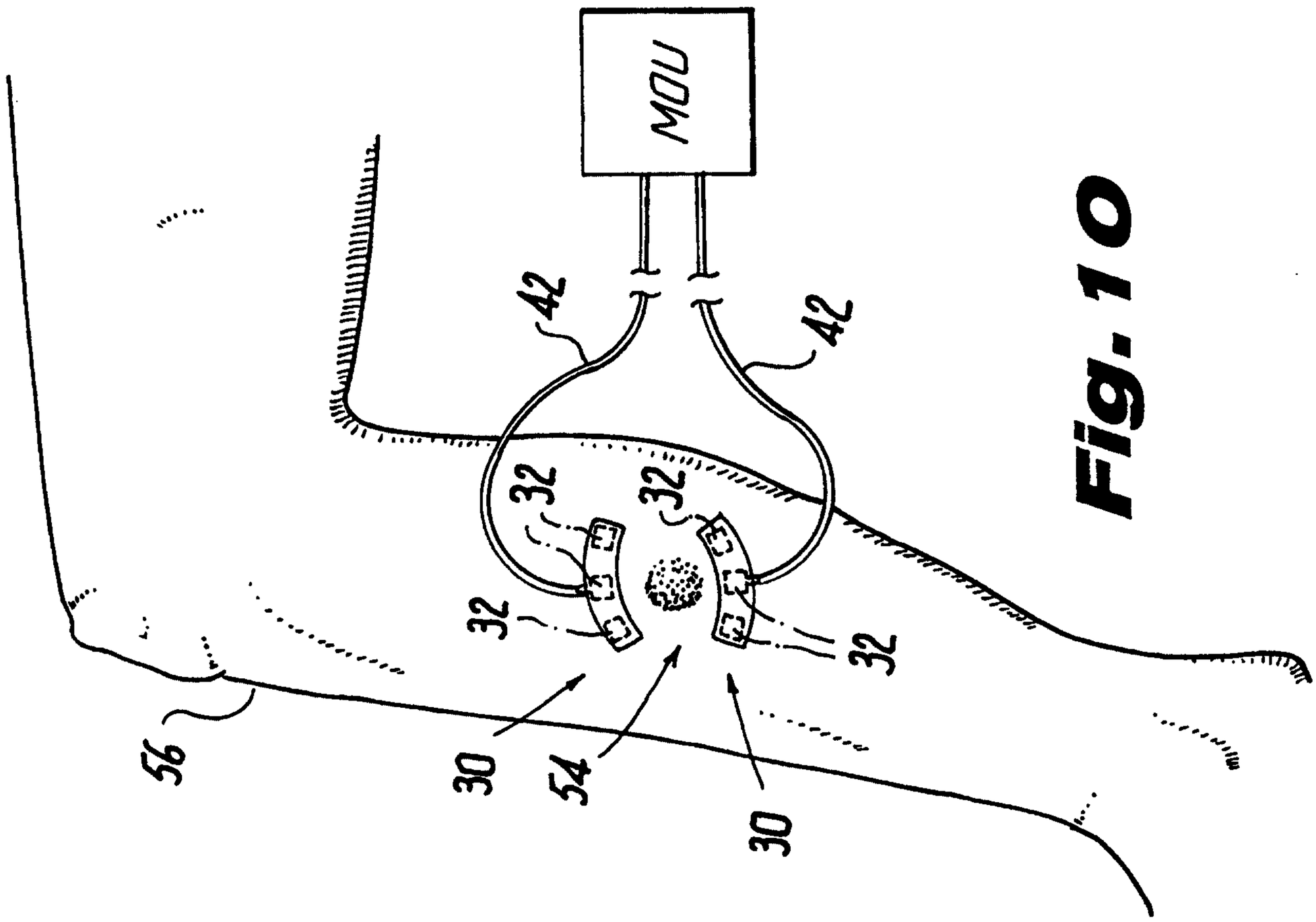


Fig. 10

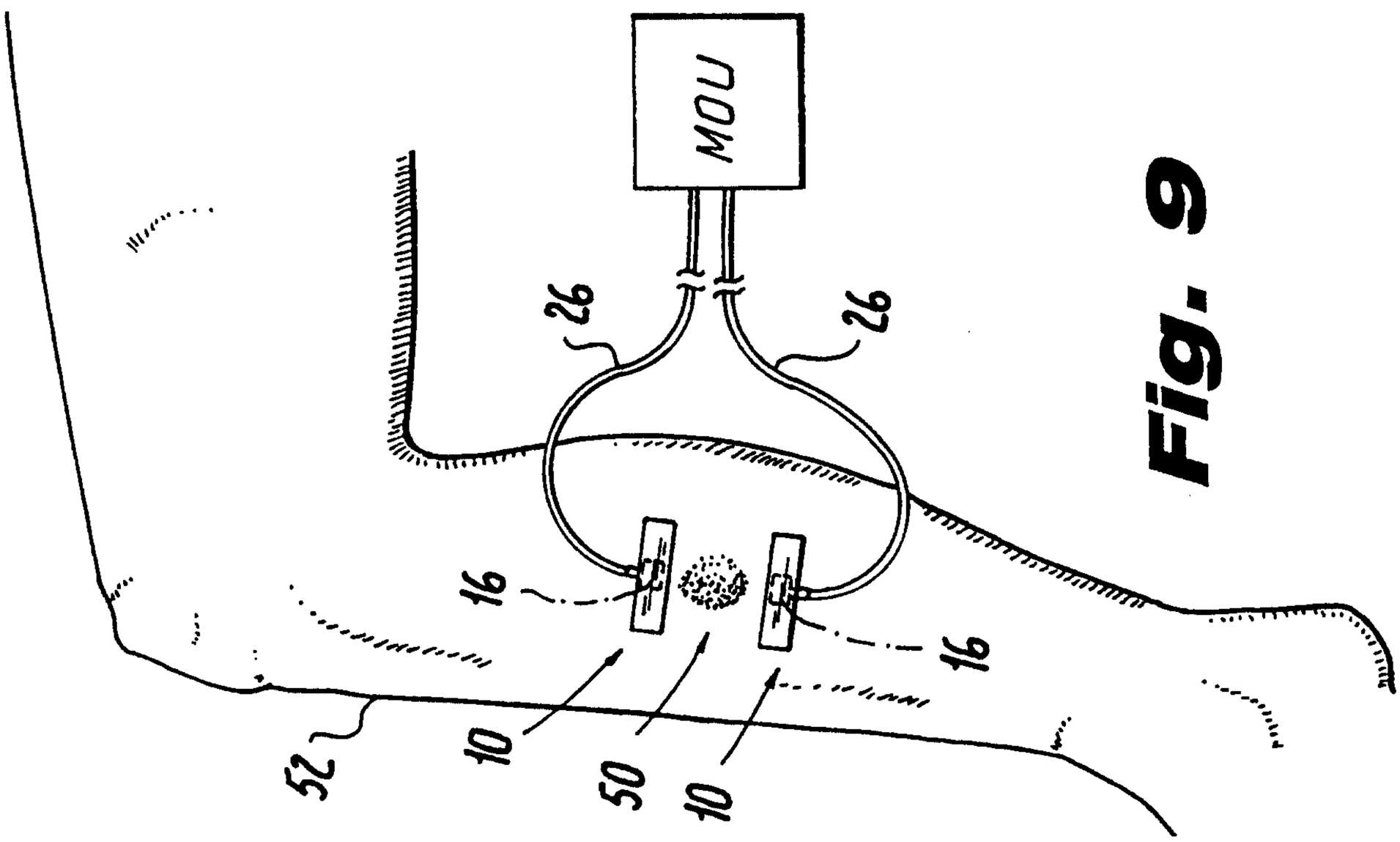
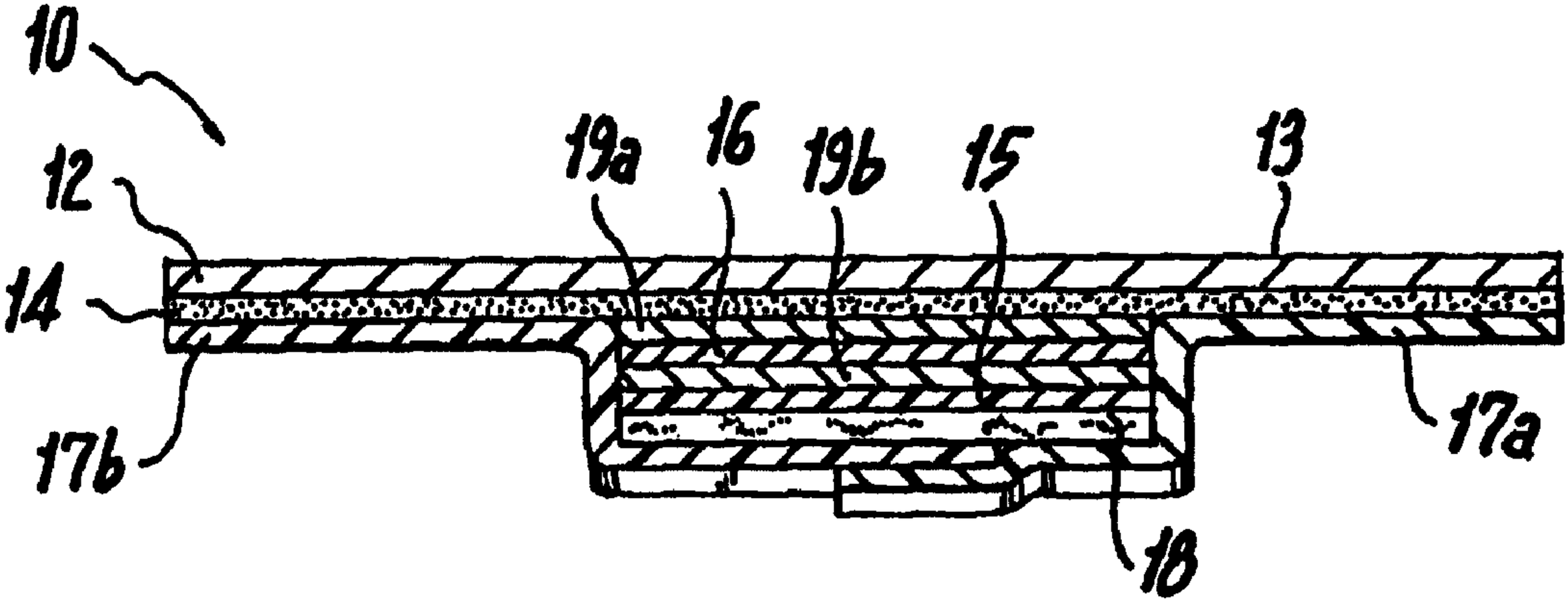


Fig. 9


10
12
14
19a
16
19b
15
13
17b
17a
18