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(71) Applicant *(for all designated States except US)*: **SMITH & NEPHEW, PLC** [GB/GB]; 15 Adam Street, London WC2N 6LA (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DAGGER, Anthony, C.** [GB/GB]; Smith & Nephew Research Centre, York Science Park, Heslington York YO10 5DF (GB). **FLOYD, Helen** [GB/GB]; Smith & Nephew Research Centre, York Science Park, Heslington York YO10 5DF (GB).

(74) Agent: **CONNORS, Martin**; Smith & Nephew Research Centre, York Science Park, Heslington York YO10 5DF (GB).

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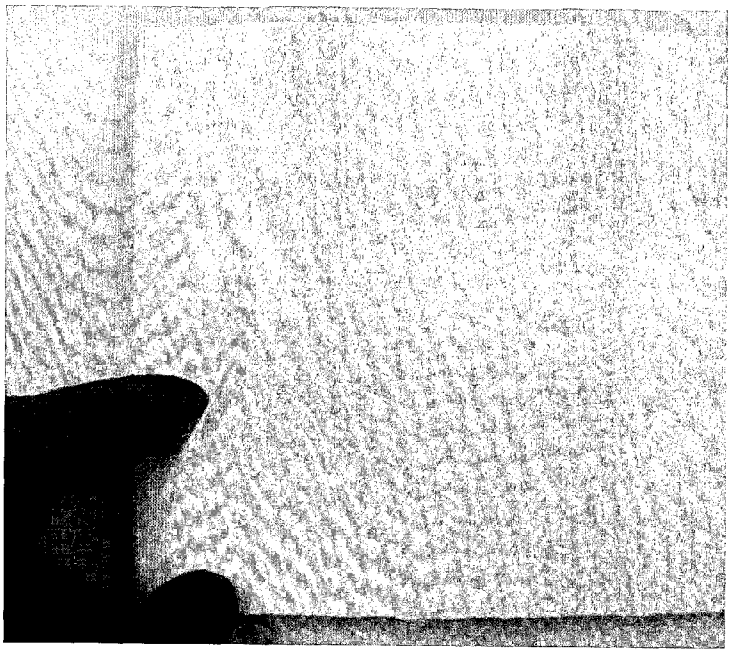
(54) **Title:** FIBROUS DRESSING



(57) **Abstract:** An apparatus for aspirating and/or cleansing wounds comprising a flow path comprising a wound dressing having a backing layer and at least one outlet pipe for connection to a fluid off take tube and which has a wound contact integer which in use is in contact with the wound bed and in which the wound contact integer comprises a biodegradable and/or bioabsorbable fibrous electrospun scaffold.

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FIBROUS DRESSING

The present invention relates to a medical wound dressing for aspirating, irrigating and/or cleansing wounds, and a method of treating wounds using such apparatus for aspirating, irrigating and/or cleansing wounds.

It relates in particular to such a wound dressing and method that can be easily applied to a wide variety of wounds, but in particular chronic, wounds, to cleanse them of materials that are deleterious to wound healing, whilst distributing within the wound or returning to the wound materials that are beneficial in some therapeutic aspect, in particular to wound healing.

It is known to apply negative pressure therapy to a range of dermal wounds, including acute, sub acute, chronic, traumatic and dehisced wounds. The therapy is used to remove wound exudate, reduce the bacterial burden and facilitate granulation tissue formation, and thus to facilitate the healing of the wound. In known forms of such wound therapy, only aspiration of the wound, the sequential aspiration and irrigation of the wound, or the irrigation and aspiration of the wound, in combination with cleansing and re-circulation of exudates back to the wound bed after the removal of detrimental factors, may be carried out.

Many such forms of negative pressure wound therapy tend to use a specific dressing, which has a fibrous, mesh or perforated integer, such as a reticulated sponge that is drawn onto the wound bed by the sub-atmospheric pressure, and is said to prevent overgrowth of the granulation tissue that is stimulated by the negative pressure. However, pain may be associated with negative pressure therapy. This pain can be due to the in-growth of granulation tissue into the sponge dressing or integer after a short period of time, and after such in-growth of the wound bed tissue, dressing removal can increase pain further.

It is also known, in a method of treating wounds with negative pressure therapy, to apply a scaffold to the wound bed (between the wound and the wound dressing contact layer) to create a favourable environment for tissue repair. Such scaffolds may be bio-scaffolds or synthetic scaffolds, may be biodegradable and/or bioabsorbable (and can remain within a wound), or non-biodegradable and/or non-bioabsorbable (and need to be removed.)

Such a scaffold is separate from the dressing which it underlies, so that such forms of negative pressure wound therapy require multiple application of different integers over the wound bed. For the same reason, the whole assembly tends to be less than optimally conformable. The scaffolds undergo infiltration by granulation tissue and cells, and nonbio-absorbable/-degradable scaffolds, used in known negative pressure therapy, suffer from the disadvantages of needing to be removed during or after wound healing, and on removal they cause damage to the wound bed and pain to the patient.

It would be desirable to provide a dressing which avoids these disadvantages of known negative pressure therapy scaffolds and can be easily applied to a wide variety of wounds, but in particular chronic, wounds, in an apparatus for aspirating, irrigating and/or cleansing wounds.

We have surprisingly found that this may be achieved by an electrospun scaffold that is an integral part of a negative pressure therapy dressing, e.g. of the underside of a wound contact layer in such a dressing.

Accordingly, in a first aspect of the present invention there is provided a conformable wound dressing that comprises
a backing layer with a wound-facing face which is capable of forming a relatively liquid-tight seal or closure over a wound, and has
at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face, the point at which the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound, and
a wound contact integer which in use lies in contact with the wound bed, characterised in that
the wound contact integer comprises a biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

According to the present invention there is provided an apparatus for aspirating, and/or cleansing wounds comprising

(a) a flow path comprising a wound dressing having a backing layer with a wound facing face and at least one outlet pipe for connection to a

fluid offtake tube, which passes through and/or under the wound-facing face;

(b) at least one device for moving fluid through the wound dressing and a wound contact integer which in use lies in contact with the wound bed;

(c) characterised in that the wound contact integer comprises a biodegradable and/or bioabsorbable fibrous electrospun scaffold.

In one embodiment of the first aspect of the invention, the fibrous electrospun scaffold which in use lies in contact with the wound bed comprises nanofibres that are electrospun directly onto and adhere to the wound contact integer as the electrospinning target.

In an additional embodiment of the first aspect of the invention, the fibrous electrospun scaffold which in use lies in contact with the wound bed comprises nanofibres that are electrospun directly onto the assembled dressing.

When used herein the term 'nanofibres' means the majority of fibre diameters in the scaffold are less than 1μm.

The dressing of the first aspect of the invention avoids the disadvantages of known negative pressure therapy scaffolds. It can be easily applied to a wide variety of wounds, but in particular chronic wounds, in an apparatus for aspirating, irrigating and/or cleansing wounds. It has the advantage of being a single application product. It is also more conformable as it is attached to the rest of the dressing.

In use, the scaffold is gradually released from the wound contact integer of the dressing by wound exudate, the action of which may be enhanced by irrigation of the dressing, so that none of the scaffold requires removal from the wound bed on dressing removal. This results in reduced pain and discomfort experienced by the patient and the reduction in the need to use topical anaesthetic.

The electrospun material of the scaffold tends to be in the form of nanofibres, leading to a higher surface area, higher porosity and increased fluid movement due to the high porosity, and hence faster degradation, compared to a standard bioscaffold.

In one embodiment of the first aspect of the invention, the dressing has no further pipe or pipes that pass through and/or under the wound-facing face and communicate with the wound space under the wound-facing face. Such an embodiment is typically used for the aspiration of the wound, or the sequential aspiration and irrigation of the wound with flow reversal, through the outlet pipe or pipes.

During aspiration of the wound, optionally in the sequential aspiration and irrigation of the wound, a source of sub-atmospheric pressure is applied to the outlet pipe via connection to a fluid offtake tube. This draws the wound contact integer onto the wound bed, and it lies in contact with the wound bed until atmospheric pressure is restored.

In some embodiments of the present invention the wound area may be subject to a sub atmospheric pressure or negative pressure. This negative pressure may be between about 1.01 and 100.3 kPa (0.01 and 0.99 atmospheres). Other suitable pressure ranges include (but not limited to) between 60 and 80 mmHg (0.079 and 0.105 atmospheres, 9.12 and 10.7 kPa).

For shallower wounds, the wound contact integer which in use lies in contact with the wound bed may typically be the backing layer with a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Alternatively, for shallower wounds, the wound contact integer which in use lies in contact with the wound bed may typically be a wound filler as a component of a wound dressing under the backing layer with a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold, which in use lies in contact with the wound bed.

Alternatively, for shallower wounds, the wound contact integer which in use lies in contact with the wound bed may typically be a wound filler as a component of a wound dressing under the backing layer which comprises or consist essentially of one or more conformable hollow bodies defining a manifold that

a) collects the fluid directly from the wound in aspiration or
b) also functions as an inlet pipe manifold that delivers fluid directly to the wound bed in irrigation.

It will have a wound-facing face bearing the biodegradable and/or more conformable hollow bodies defining bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

A more suitable wound contact integer for deeper wounds when the therapy is applied in this way may be one which comprises one or more conformable hollow bodies that at least partly surround(s) a solid integer. These may be defined by, for example, a polymer film, sheet or membrane. This may provide a system with better rigidity for convenient handling.

It will have a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Alternatively, in this form, the one or more conformable hollow bodies may define an outlet pipe manifold that

a) collects the fluid directly from the wound in aspiration or
b) also functions as an inlet pipe manifold that delivers fluid directly to the wound bed in irrigation.

It will have a wound-facing face bearing the biodegradable and/or more conformable hollow bodies defining bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

In another embodiment of the first aspect of the invention, the dressing has further pipe or pipes that pass through and/or under the wound-facing face and communicate with the wound space under the wound-facing face.

Such an embodiment is typically used for the simultaneous or sequential aspiration and irrigation of the wound without flow reversal, optionally in combination with cleansing and re-circulation of exudate back to the wound bed after the removal of detrimental factors.

The further pipe or pipes that pass through and/or under the wound-facing face and communicate with the wound space under the wound-facing face then function typically as at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, for the supply of irrigant to the wound bed.

Accordingly, in one embodiment of the first aspect of the present invention there is provided a conformable wound dressing that comprises
a backing layer with a wound-facing face which is capable of forming a relatively liquid-tight seal or closure over a wound, and has
at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the wound-facing face, and
at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face,
the point at which the or each inlet pipe and the or each outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure over the wound;
a wound contact integer which in use lies in contact with the wound bed,
characterised in that
the wound contact integer comprises a biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Again, for shallower wounds, the wound contact integer which in use lies in contact with the wound bed may typically be the backing layer with a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Alternatively, for shallower wounds, the wound contact integer which in use lies in contact with the wound bed may typically be a wound filler as a component of a wound dressing under the backing layer with a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Alternatively, for shallower wounds, the wound contact integer which in use lies in contact with the wound bed may typically be a wound filler as a component of a wound dressing under the backing layer which comprises or consist essentially of one or more conformable hollow bodies defining

a) an outlet pipe manifold that collects the fluid directly from the wound in aspiration or
b) more often an inlet pipe manifold that delivers fluid directly to the wound bed in irrigation.

It will have a wound-facing face bearing the biodegradable and/or more conformable hollow bodies defining bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

A more suitable wound contact integer for deeper wounds when the therapy is applied in this way may be one which comprises one or more conformable hollow bodies that at least partly surround(s) a solid integer. These may be defined by, for example, a polymer film, sheet or membrane,

This may provide a system with better rigidity for convenient handling. It will have a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Alternatively, in this form, the one or more conformable hollow bodies may define

a) an outlet pipe manifold that collects the fluid directly from the wound in aspiration or
b) more often an inlet pipe manifold that delivers fluid directly to the wound bed in irrigation.

It will have a wound-facing face bearing the biodegradable and/or more conformable hollow bodies defining bioabsorbable fibrous electrospun scaffold which in use lies in contact with the wound bed.

Examples of suitable biodegradable and/or bioabsorbable fibrous electrospun scaffolds include non-woven mats, pads, rolls and wadding of electrospun fibres, electrospun fibres into or onto woven materials or any form of support, or lyophilised, or in a gel, or sandwiched between any

other substance e.g. alginate.

In some embodiments of the present invention the wound contact integer may also comprise gauze, foam or other porous material onto which and/or in which the biodegradable and/or bioabsorbable fibrous electrospun scaffold/material is situated.

The apparatus of the present invention may also have in addition, in some embodiments, gauze or foam or other porous material as a filler material under the backing layer of the wound dressing.

Examples of suitable biodegradable and/or bioabsorbable electrospun fibres include electrospun fibres of diameters in the range of less than 100nm up to and above 100μm, in continuous or truncated fibres.

Suitable electrospun fibre diameters may be in the range of 150μm to 90nm, 50μm to 50nm, 75μm to 75nm, 90μm to 90nm, 80μm to 90nm, 110μm to 90nm or 120μm to 105nm.

Examples of suitable depths of the scaffold are in the range from below 50μm to above 3mm.

Suitable depths of the scaffold may also include 25μm to 3.1mm, 40μm to 3.1mm, 45μm to 3.25mm, 49μm to 3.1mm or 50μm to 2.5mm.

Examples of suitable biodegradable and/or bioabsorbable materials to be deposited onto and/or attached to the surface of the dressing wound contact integer include biodegradable and/or bioabsorbable materials such as
polylactic acid, polyglycolic acid, poly(D-)lactic acid, polyglycoliclactic acid, keratin, laminin, elastin, collagen and naturally occurring extracellular matrix proteins,
polydioxanones, polycaprolactone, and blends and co-polymers thereof.

The materials may be electrospun to be deposited onto and/or attached to the surface of the dressing wound contact integer by any means known to those skilled in the art.

Preferably, they are solvent spun using appropriate solvents, such as dimethylformamide, methylene chloride, chloroform, dichloromethane, acetonitrile, methanol, N-methylpyrolidone, hexafluoroisopropanol and dimethyl sulphoxide, with appropriate additives, such as sodium chloride, magnesium chloride, potassium dihydrogen phosphate, potassium iodate and potassium phosphate calcium carbonate, calcium phosphate and calcium lactate, in solution form or in nanoparticulate forms, and any other additives, solvents, polymers, bioactives, pharmaceutical agents, metals, metal oxides or cells or cellular components known to one skilled in the art, that can be integrated into an electrospun format.

According to the present invention there is provided a method of manufacturing a wound dressing comprising of the steps of: electrospinning, a biodegradable and/or bioabsorbable fibrous material onto a wound contact integer of a wound dressing which in use the wound contact integer lies in contact with the wound bed.

According to the present invention there is provided a method of treating wounds to promote wound healing using the apparatus according to claim 1 in which a negative pressure is applied to the wound.

The present invention is illustrated by the following figures and examples:

Figure 1 Shows an electrospun polycaprolactone fibre mat partially peeled from ALLEVYN ™ Non-Adhesive dressing.

Figure 2 Shows removal of ALLEVYN ™ Non-Adhesive dressing from an electrospun polycaprolactone fibre mat, which has adhered to the surface of pork after 6 hours 45 minutes under vacuum.

Figure 3 Shows removal of an electrospun polycaprolactone fibre mat from the surface of pork after 6 hours 45 minutes under vacuum.

Figure 4 Shows scanning electron micrograph of an electrospun polycaprolactone fibre mat deposited on ALLEVYN ™ Non-Adhesive dressing.

Figure 5 Shows electrospun polycaprolactone fibre mat partially peeled from wet ALLEVYN ™ Adhesive dressing.

Figure 6 Shows scanning electron micrograph of an electrospun polycaprolactone fibre mat deposited on ALLEVYN ™ Adhesive dressing.

Figure 7 Shows electrospun polycaprolactone fibre mat partially peeled from polyurethane foam.

Figure 8 Shows removal of polyurethane foam from an electrospun polycaprolactone fibre mat, which has adhered to the surface of pork after 6 hours 45 minutes under vacuum.

Figure 9 Shows removal of an electrospun polycaprolactone fibre mat from the surface of pork after 6 hours 45 minutes under vacuum.

Figure 10 Shows a scanning electron micrograph of an electrospun polycaprolactone fibre mat deposited on polyurethane foam.

Figure 11 Shows electrospun poly(lactic acid/glycolic acid) copolymer fibre mat partially peeled from polyurethane foam.

Figure 12 Shows a scanning electron micrograph of an electrospun poly(lactic acid/glycolic acid) copolymer fibre mat deposited on polyurethane foam.

Figure 13 Shows electrospun poly(lactic acid/glycolic acid) copolymer fibre mat partially peeled from poly(ethylene/vinyl acetate)/polystyrene film.

Figure 14 Shows an inflated foil/polymer laminate hollow body with a layer of electrospun polycaprolactone fibres.

Figure 15 Shows scanning electron micrograph of the electrospun polycaprolactone fibre mat deposited on a foil/laminate hollow body.

Figure 16 Shows an inflated foil/polymer laminate hollow body with a layer of electrospun poly(lactic acid/glycolic acid) copolymer fibres.

Figure 17 Shows a scanning electron micrograph of an electrospun poly(lactic acid/glycolic acid) copolymer fibre mat deposited on a foil/laminate hollow body.

Example 1

Fibre mat electrospun onto a polyurethane dressing wound contact layer

A 10% solution of polylacticglycolic acid (25% lactide, 75% glycolide) copolymer was prepared in dichloromethane. This was electrospun by passing through a needle at a flow rate of 0.03 ml/min and applying a DC electric potential of 20kV with a working distance of 15cm onto the wound contact layer of an ALLEVYN ™ non-adhesive dressing (Smith & Nephew) placed on a grounded stainless steel target. A thin mat of electrospun material was deposited onto the wound contact layer within about 10 minutes and this was allowed to air dry. The electrospun mat was found to be well attached to the surface of the wound contact layer and was quite conformable.

Example 2

Fibre mat electrospun onto a polyurethane dressing

A 20 % solution of polycaprolactone homopolymer was prepared in dichloromethane. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 6.5-25 kV with a working distance of 15 cm onto the wound contact layer of an ALLEVYN ™ Non-Adhesive polyurethane dressing (Smith & Nephew) placed onto a rotating grounded stainless steel mandrel. A 150-200 μm thick mat of electrospun material comprising fibres 6.5-8.7 μm in diameter was deposited onto the wound contact layer within 136 minutes. The electrospun fibre mat was found to be well attached to the surface of the

wound contact layer, but could be peeled off intact upon application of direct force.

After the ALLEVYN ™ dressing incorporating the layer of electrospun fibres had been applied to the surface of raw pork and dried in a vacuum oven for at least 3 hours at room temperature and a pressure of less than or equal to 10 mbar, the ALLEVYN ™ dressing could be easily peeled from the electrospun fibre layer, which remained intact on the surface of the pork. Control pieces of ALLEVYN ™ dressing without a layer of electrospun fibres adhered to the surface of the pork under identical conditions.

Example 3

Fibre mat electrospun onto a polyurethane dressing

A 20 % solution of polycaprolactone homopolymer was prepared in dichloromethane. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 7.0 kV with a working distance of 15 cm onto the wound contact layer of an ALLEVYN ™ Adhesive polyurethane dressing (Smith & Nephew) placed onto a rotating grounded stainless steel mandrel. A mat of electrospun material comprising fibres 6.7-9.1 µm in diameter was deposited onto the wound contact layer within 70 minutes. The electrospun fibre mat was found to be securely attached to the surface of the wound contact layer, but could be peeled off intact upon application of direct force after wetting the surface of the dressing. The peeled electrospun fibre mat was 70-90 µm thick.

Example 4

Fibre mat electrospun onto a polyurethane foam

A 20 % solution of polycaprolactone homopolymer was prepared in dichloromethane. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 7.0 kV with a working distance of 15 cm onto the 3 mm thick polyurethane foam component of an ALLEVYN ™ polyurethane dressing (Smith & Nephew) without the wound contact layer or backing layer, which was placed onto a rotating grounded stainless steel mandrel. A 70-100 µm thick mat of electrospun material comprising fibres 7.4-9.3 µm in diameter was deposited onto the foam surface within 60 minutes. The electrospun fibre mat was found to be well attached to the surface of the foam, but could be peeled off intact upon application of direct force.

After the polyurethane foam incorporating the layer of electrospun fibres had been applied to the surface of raw pork and dried in a vacuum oven for at least 3 hours at room temperature and a pressure of less than or equal to 10 mbar, the polyurethane foam could be easily peeled from the electrospun fibre layer, which remained intact on the surface of the pork. Control pieces of ALLEVYN ™ dressing without a layer of electrospun fibres adhered to the surface of the pork under identical conditions.

Example 5

Fibre mat electrospun onto a polyurethane foam

A 10 % solution of poly(lactic acid/glycolic acid) (10 % lactide, 90 % glycolide) copolymer was prepared in hexafluoroisopropanol. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 5.0 kV with a working distance of 15 cm onto the 4 mm thick polyurethane foam component of an ALLEVYN ™ polyurethane dressing (Smith & Nephew) without the wound contact layer or backing layer, which was placed onto a rotating grounded stainless steel mandrel. A 60-80 µm thick mat of electrospun material comprising fibres 1.7-2.7 µm in diameter was deposited onto the foam surface within 120 minutes. The electrospun fibre mat was found to be well attached to the surface of the foam, but could be peeled off intact upon application of direct force.

Example 6

Fibre mat electrospun onto a poly(ethylene/vinyl acetate)/polystyrene film

A 10 % solution of poly(lactic acid/glycolic acid) (10 % lactide, 90 % glycolide) copolymer was prepared in hexafluoroisopropanol. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 7.0 kV with a working distance of 15 cm onto a poly(ethylene/vinyl acetate)/polystyrene film placed onto a rotating grounded stainless steel mandrel. The film comprised a non-perforated poly(ethylene/vinyl acetate)/polystyrene film used in the manufacture of the wound contact layer of ALLEVYN ™ Cavity (Smith & Nephew). A 70-90 µm thick mat of electrospun material was deposited onto the polymer film within 120 minutes. The electrospun fibre mat was found to be well attached to the surface of the polymer film, but could be peeled off intact upon application of direct force.

Example 7

Fibre mat electrospun onto a hollow body formed from a foil/polymer laminate

A 20 % solution of polycaprolactone homopolymer was prepared in dichloromethane. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 7.0 kV with a working distance of 15 cm onto the polypropylene layer of a foil/polymer laminate hollow body placed onto a rotating grounded stainless steel mandrel. The hollow body was prepared by heat sealing together two sheets of four-layer laminate comprising oriented polypropylene, polyethylene, aluminium foil and polyethylene (FR 2175-B, Covalence Coated Products) so that the polypropylene layer formed the external layer. A 130-240 µm thick mat of electrospun material comprising fibres 7.0-9.7 µm in diameter was deposited onto the hollow body within 90 minutes. The electrospun fibre mat was found to be well attached to the surface of the hollow body, but could be peeled off intact upon application of direct force. The electrospun fibre mat did not detach from the hollow body after several cycles of inflation and deflation.

Example 8

Fibre mat electrospun onto a hollow body formed from a foil/polymer laminate

A 10 % solution of poly(lactic acid/glycolic acid) (10 % lactide, 90 % glycolide) copolymer was prepared in hexafluoroisopropanol. This was electrospun by passing through a needle at a flow rate of 0.03 $mLmin^{-1}$ and applying a DC electric potential of 5.0-7.0 kV with a working distance of 15 cm onto a foil/polymer laminate hollow body placed onto a rotating grounded stainless steel mandrel. The hollow body was prepared by heat sealing together two sheets of four-layer laminate comprising oriented polypropylene, polyethylene, aluminium foil and polyethylene (FR 2175-B, Covalence Coated Products) so that the polypropylene layer formed the external layer. A 30-90 µm thick mat of electrospun material comprising fibres 1.2-2.4 µm in diameter was deposited onto the hollow body within 90 minutes. The electrospun fibre mat was found to be well attached to the surface of the hollow body, but could be peeled off intact upon application of direct force. The electrospun fibre mat did not detach from the hollow body after several cycles of inflation and deflation.

CLAIMS

1. An apparatus for aspirating, and/or cleansing wounds comprising

(a) a flow path comprising a wound dressing having a backing layer with a wound facing face and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the wound-facing face;

(b) at least one device for moving fluid through the wound dressing and a wound contact integer which in use lies in contact with the wound bed;

(c) characterised in that the wound contact integer comprises a biodegradable and/or bioabsorbable fibrous electrospun scaffold.

2. An apparatus as claimed in claim 1 in which the backing layer is capable of forming a relatively fluid tight seal or closure over a wound.

3. An apparatus as claimed in claim 1 or 2 in which has an inlet pipe that passes through and/or under the backing layer for fluid irrigation.

4. An apparatus as claimed in any one of claims 1, 2 or 3 in which the point at which the/or each inlet/outlet pipe passes through and/or under the backing layer is capable of forming a relatively fluid-tight seal or closure over the wound.

5. An apparatus as claimed in any one of the preceding claims in which the fibrous electrospun fibres of the scaffold are electrospun directly onto and adhere to the wound contact integer as the electrospinning target.

6. An apparatus as claimed in any one of the preceding claims in which the fibrous electrospun fibres of the scaffold are electrospun directly onto the assembled wound dressing.

7. An apparatus as claimed in any one of the preceding claims in which the fibrous electrospun scaffold comprises nanofibres.

8. An apparatus as claimed in claim 3 in which there is sequential aspiration and irrigation of the wound.

9. An apparatus as claimed in any preceding claim in which a source of sub-atmospheric or negative pressure is applied to the wound.

10. An apparatus as claimed in claim 9 in which the area around the wound is subject to a negative pressure between 1.01 and 100.3 kPa (0.01 and 0.99 atmosphere).

11. An apparatus as claimed in any preceding claim in which the wound contact integer is the wound-facing face of the backing layer.

12. An apparatus as claimed in any one of claims 1 to 10 in which the wound contact integer is a wound filler; the wound filler is a component of the wound dressing situated under the backing layer.

13. An apparatus as claimed in claim 12 in which the wound filler comprises of one or more hollow bodies defining a manifold.

14. An apparatus as claimed in claim 13 in which the one or more hollow bodies defining a manifold has a wound-facing face bearing the biodegradable and/or bioabsorbable fibrous electrospun scaffold of the wound contact integer.

15. An apparatus as claimed in any preceding claim in which the biodegradable and/or bioabsorbable fibrous electrospun scaffold comprises a material that is chosen from the group: non-woven mat, pad: roll, wadding, woven, lyophilised, gel or laminated types or materials.

16. An apparatus as claimed in any one of the claims 1 to 14 in which the biodegradable and/or bioabsorbable fibrous electrospun scaffold has electrospun fibres into or onto woven material or any form of support.

17. An apparatus as claimed in any preceding claim in which the biodegradable and/or bioabsorbable electrospun fibres include electrospun fibres of diameters in the range of between 100nm and 100μm, in continuous or truncated fibres.

18. An apparatus as claimed in any preceding claims in which suitable depths of the scaffold are in the range between 50μm and 3mm.

19. A method of manufacturing a wound dressing comprising of the steps of: electrospinning, a biodegradable and/or bioabsorbable fibrous material onto a wound contact integer of a wound dressing which in use the wound contact integer lies in contact with the wound bed.

20. A method of treating wounds to promote wound healing using the apparatus according to any one of the claims 1 to 18.

21. A method of treating wounds to promote wound healing using the apparatus according to claim 1 in which a negative pressure is applied to the wound.

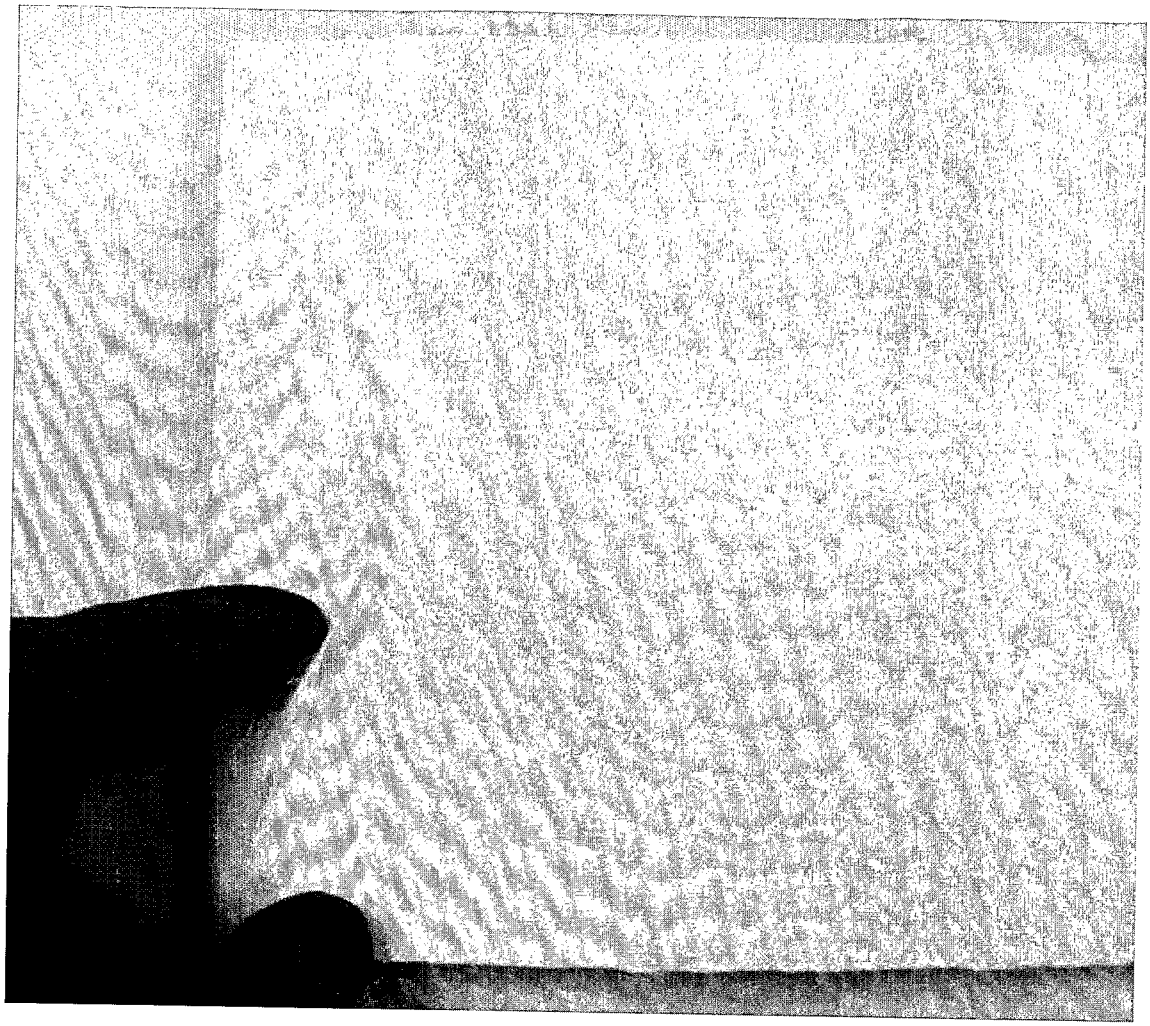

Figure 1

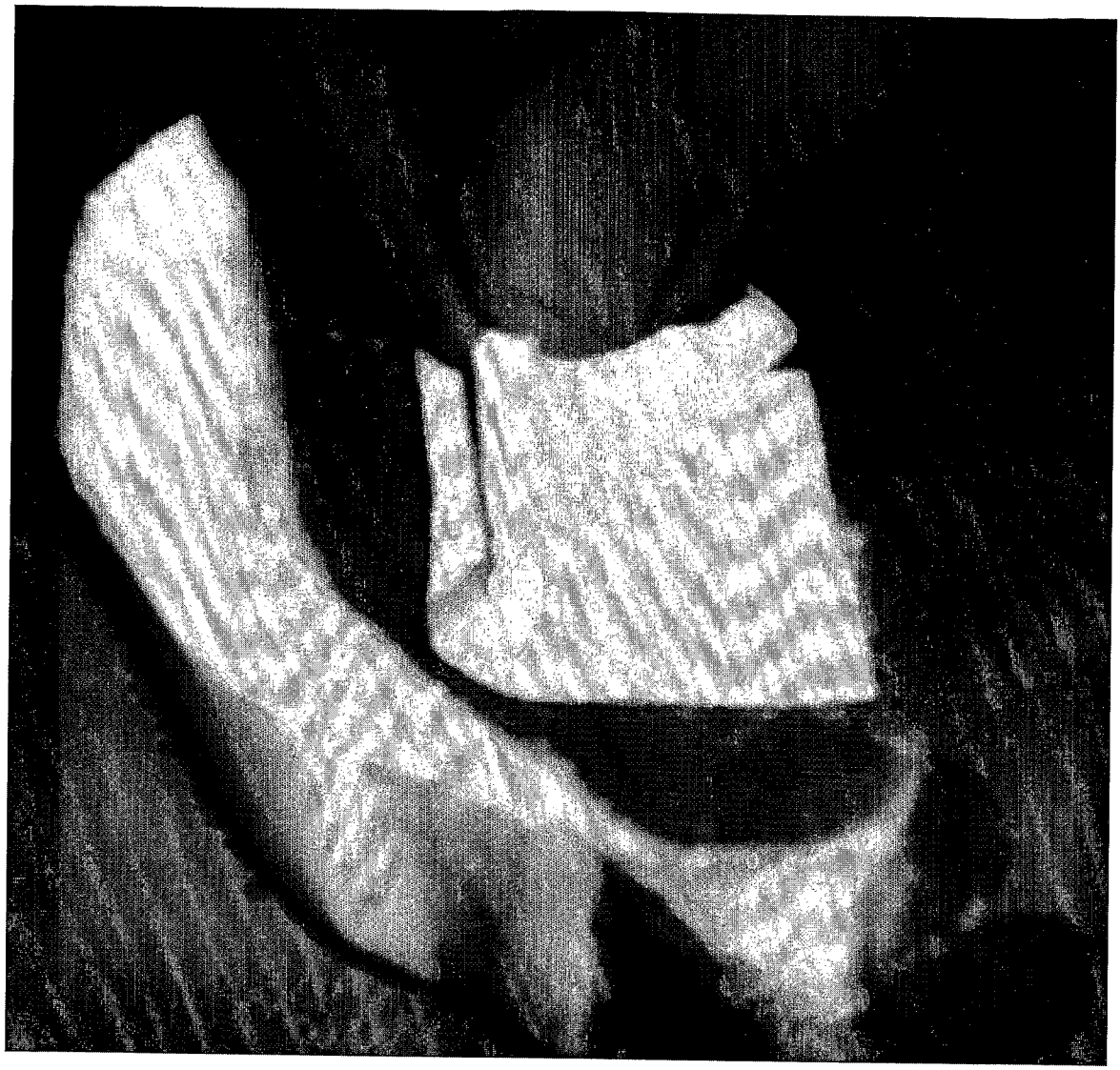

Figure 2

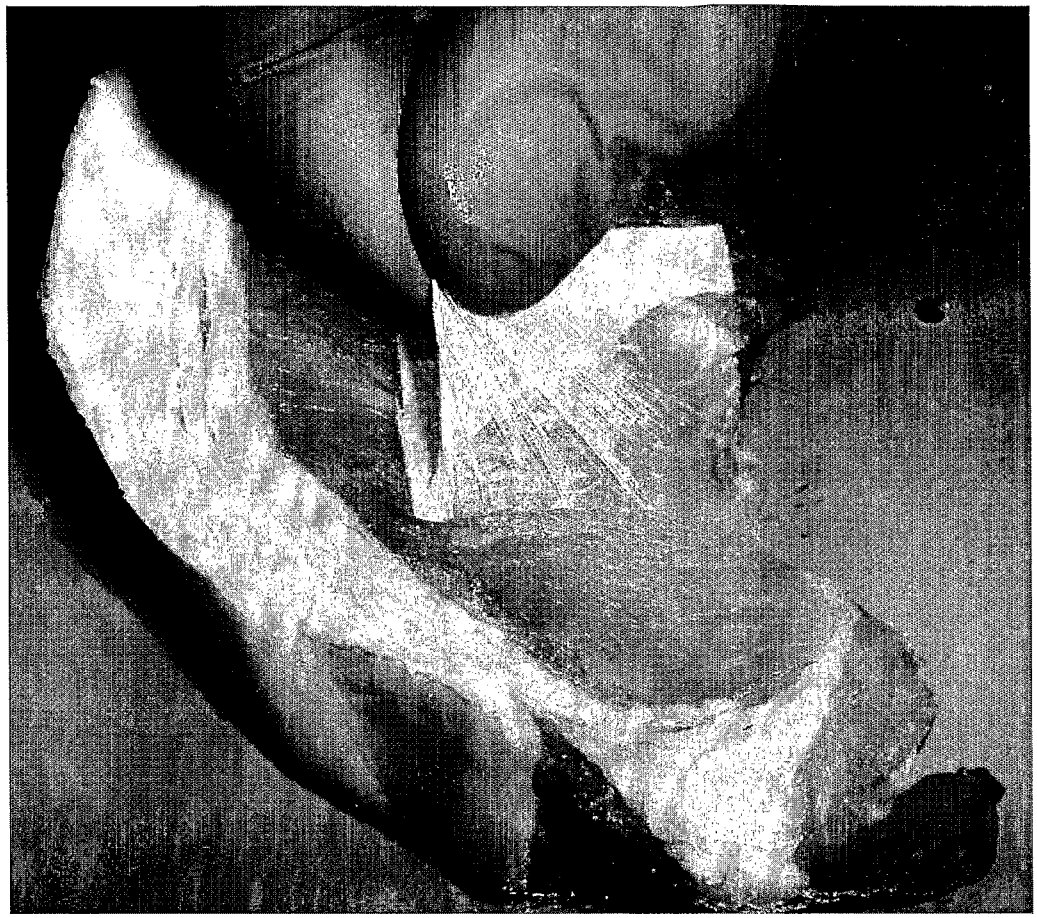

Figure 3

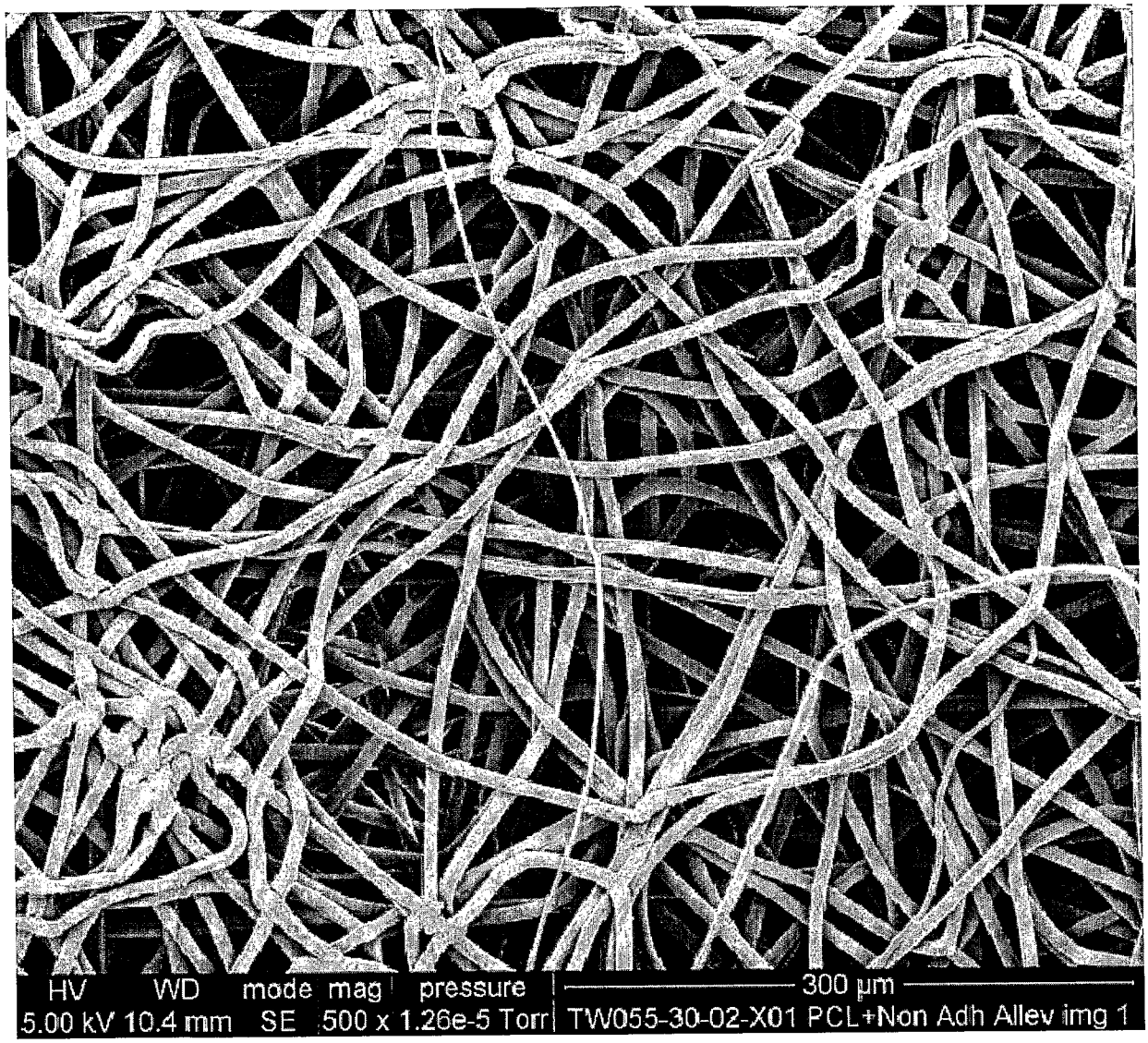
HV WD mode mag pressure
5.00 kV 10.4 mm SE 500 x 1.26e-5 Torr
300 µm
TW055-30-02-X01 PCL+Non Adh Allev img 1

Figure 4

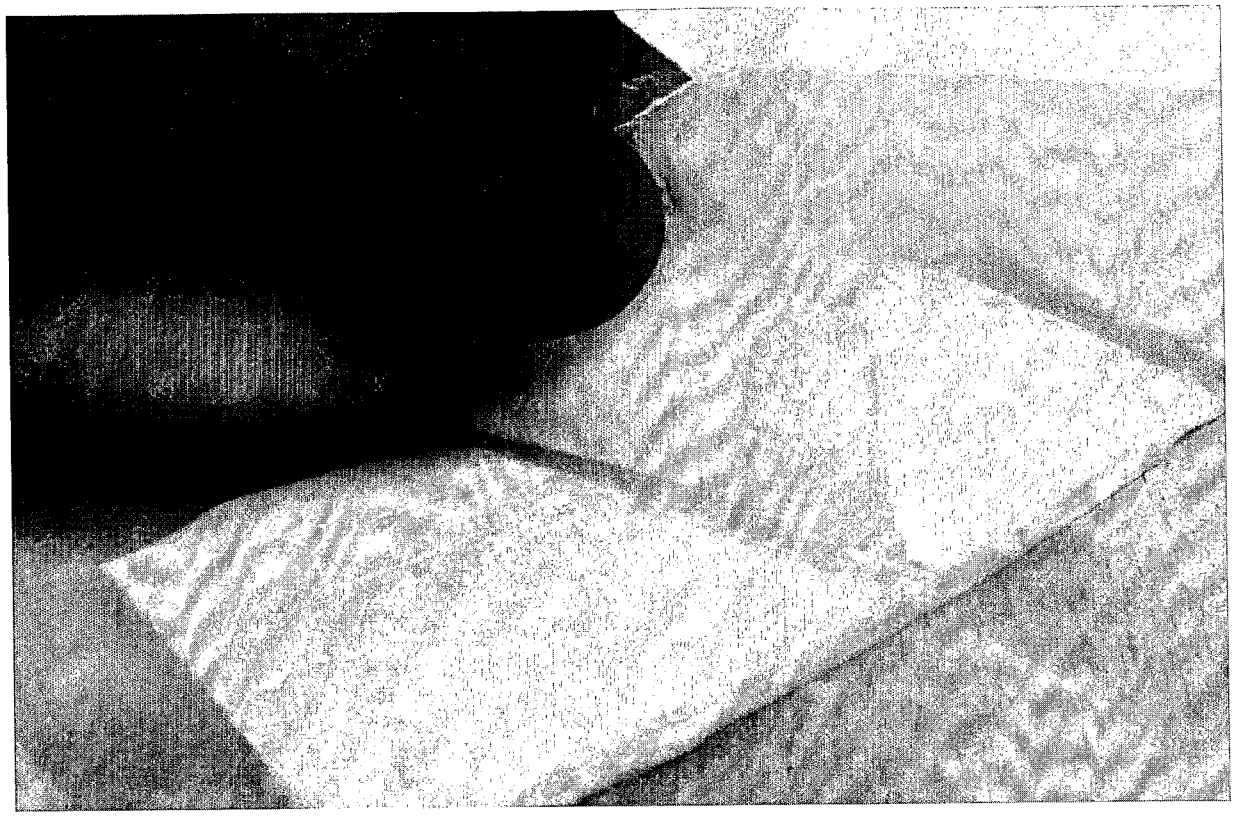

Figure 5

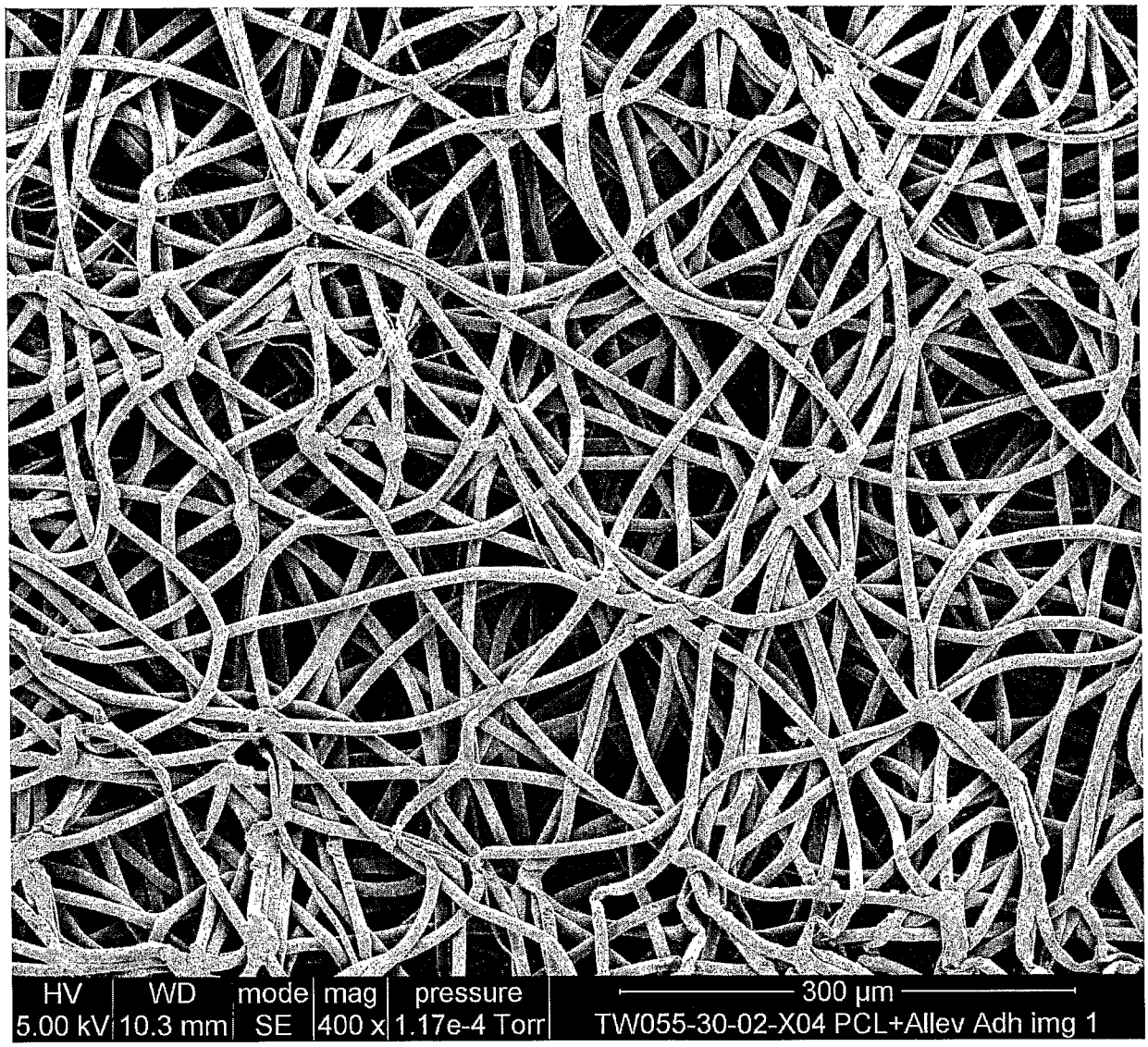
HV
5.00 kV
WD
10.3 mm
mode
SE
mag
400 x
pressure
1.17e-4 Torr
300 µm
TW055-30-02-X04 PCL+Allev Adh img 1

Figure 6

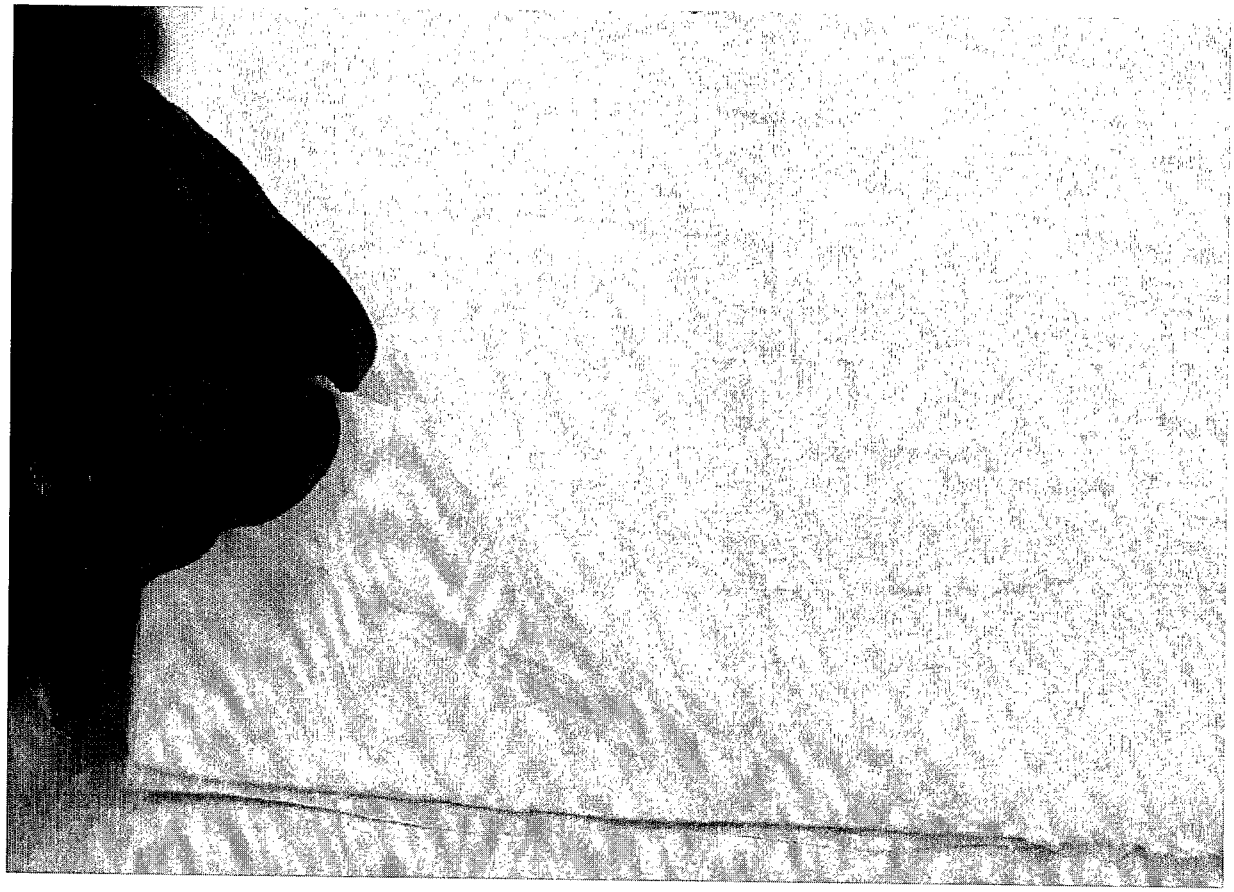

Figure 7

Figure 8

Figure 9

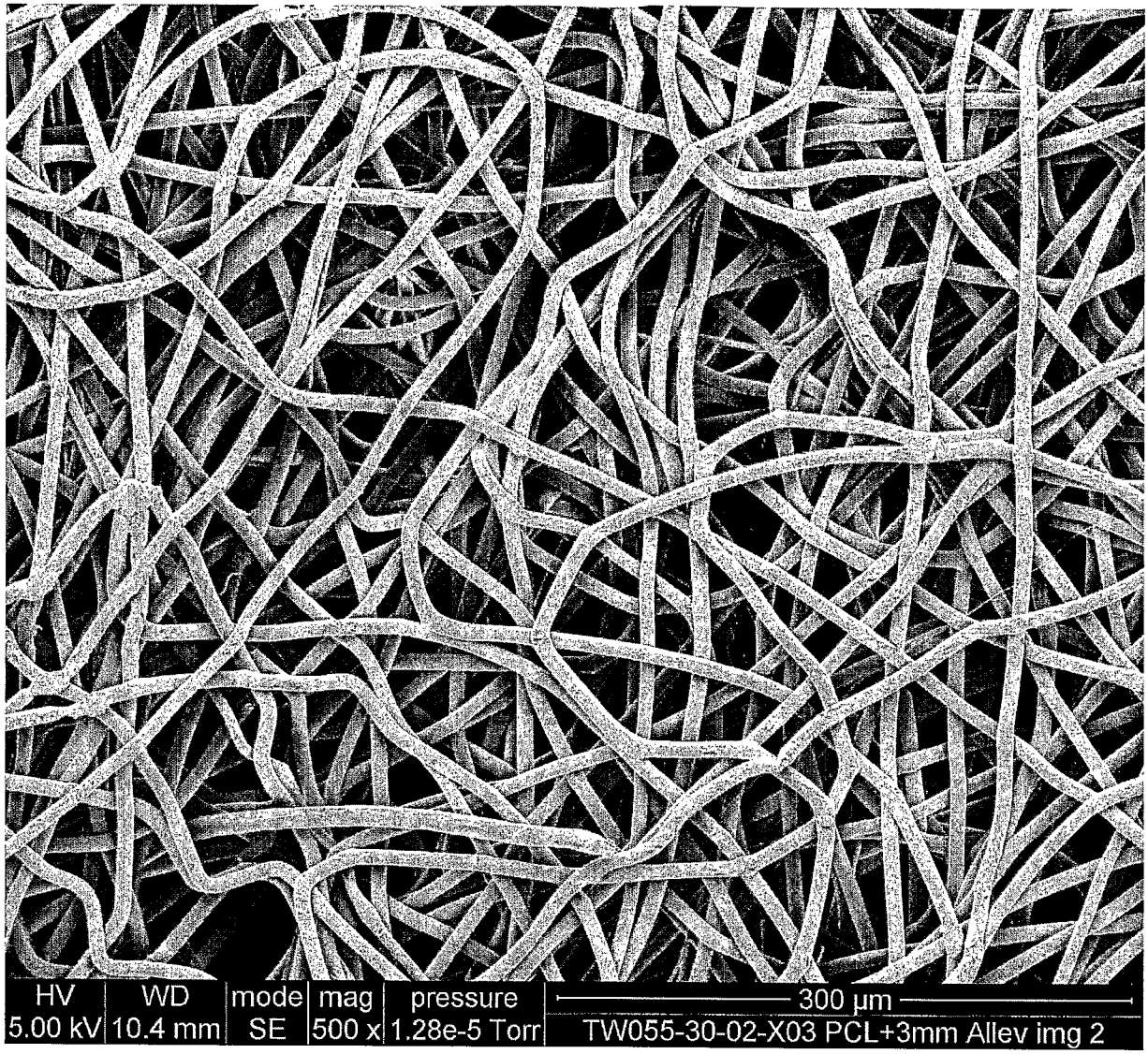
HV
5.00 kV
WD
10.4 mm
mode
SE
mag
500 x
pressure
1.28e-5 Torr
300 µm
TW055-30-02-X03 PCL+3mm Allev img 2

Figure 10

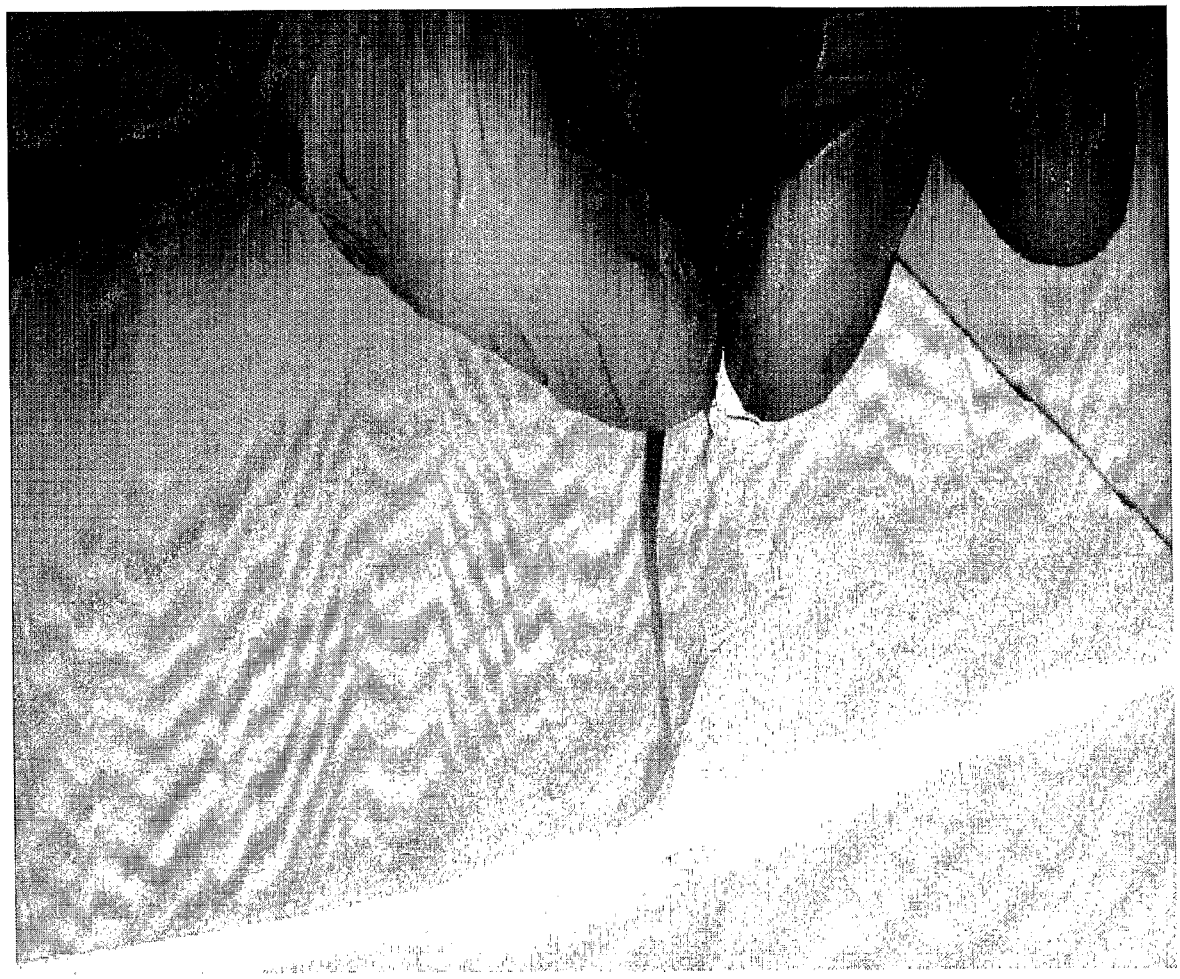

Figure 11

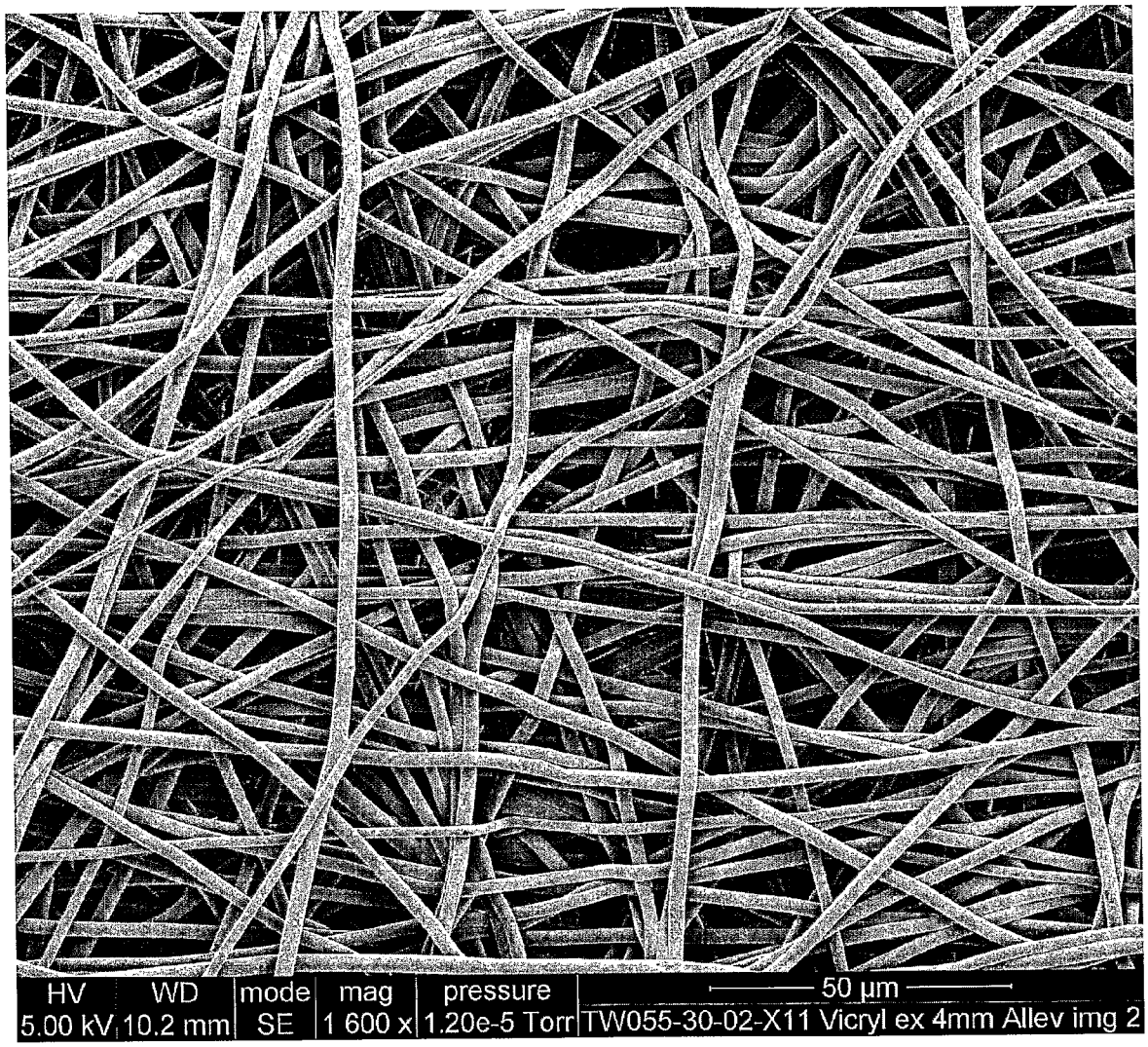
HV
5.00 kV
WD
10.2 mm
mode
SE
mag
1 600 x
pressure
1.20e-5 Torr
50 µm
TW055-30-02-X11 Vicryl ex 4mm Allev img 2

Figure 12

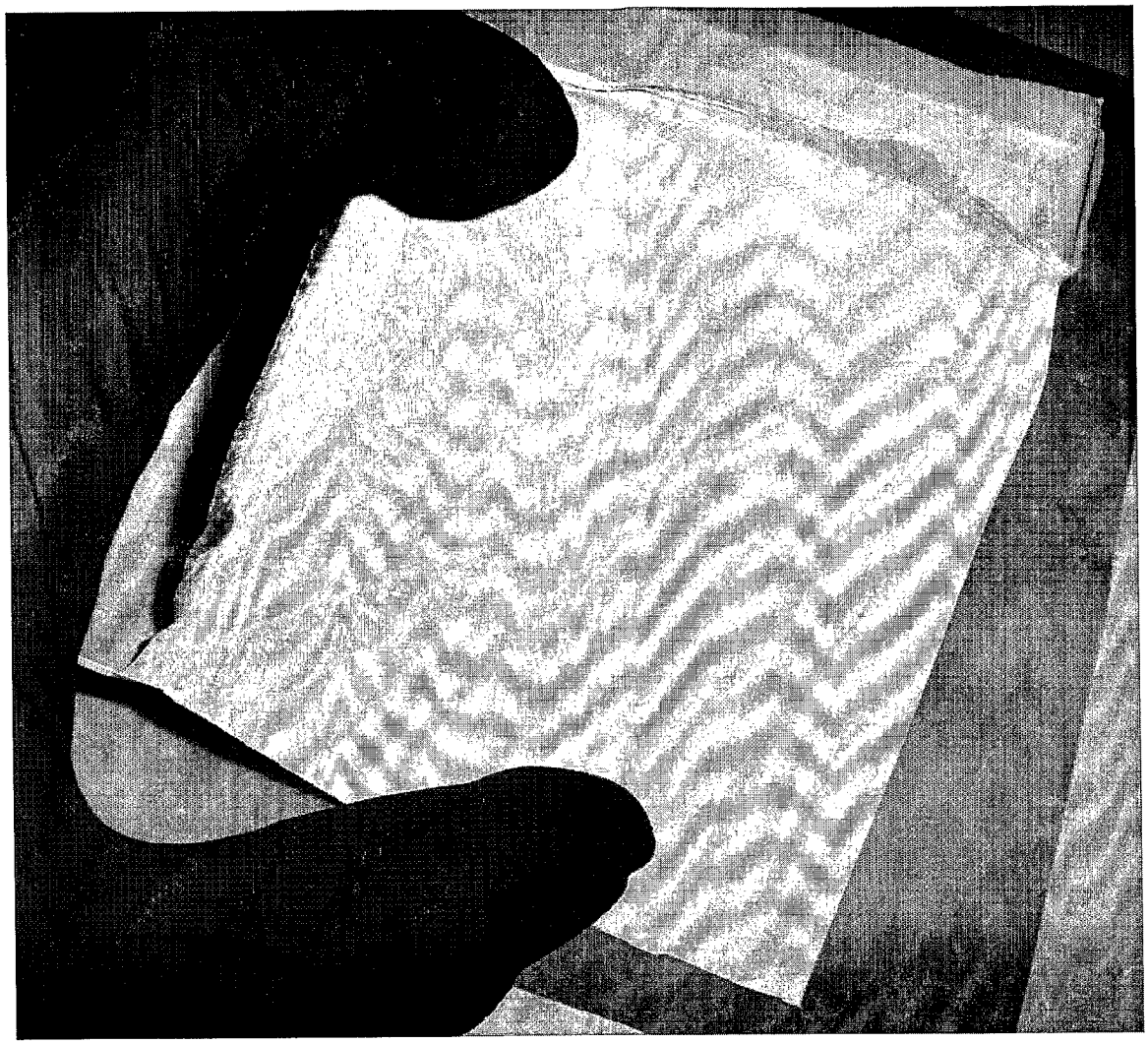

Figure 13

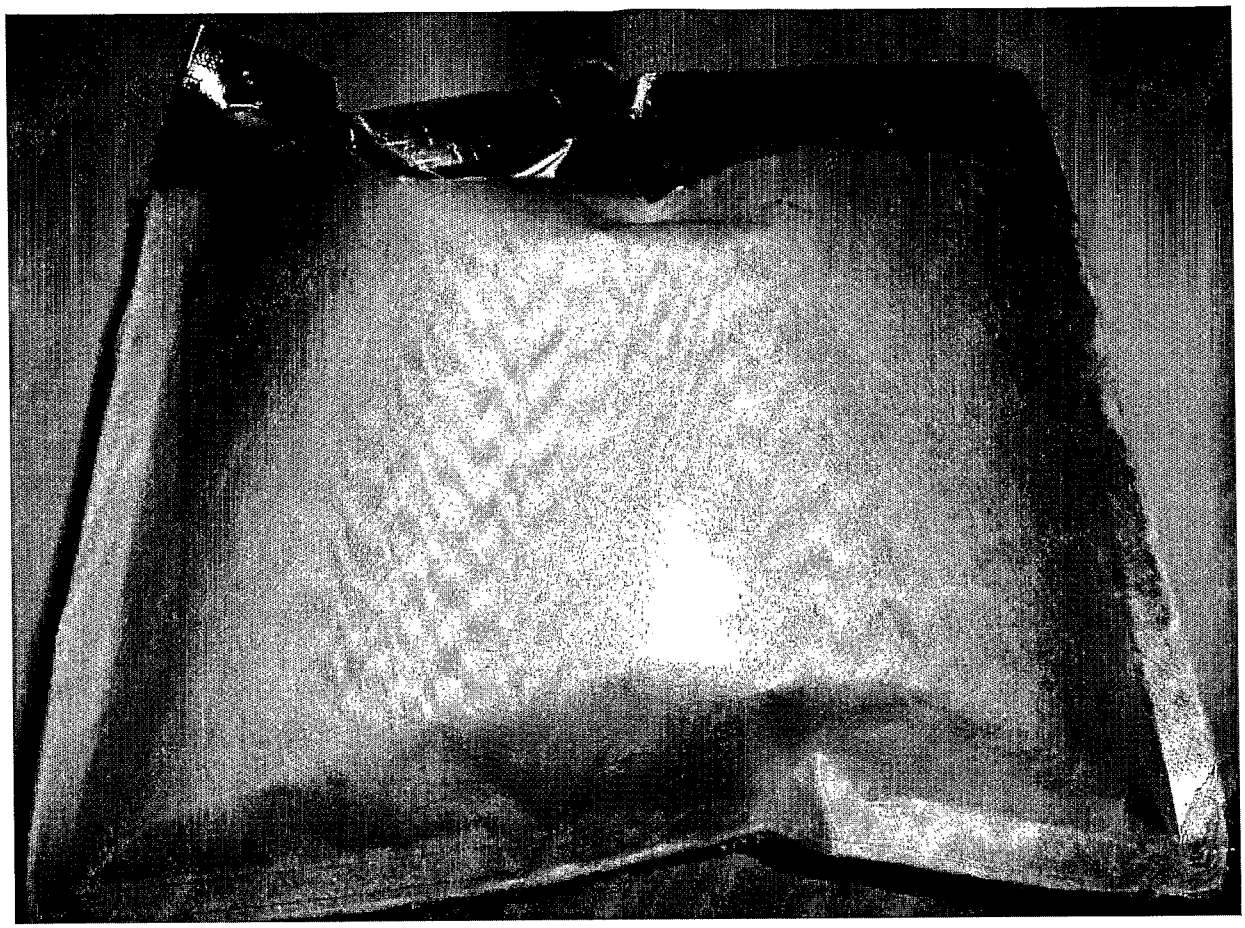

Figure 14

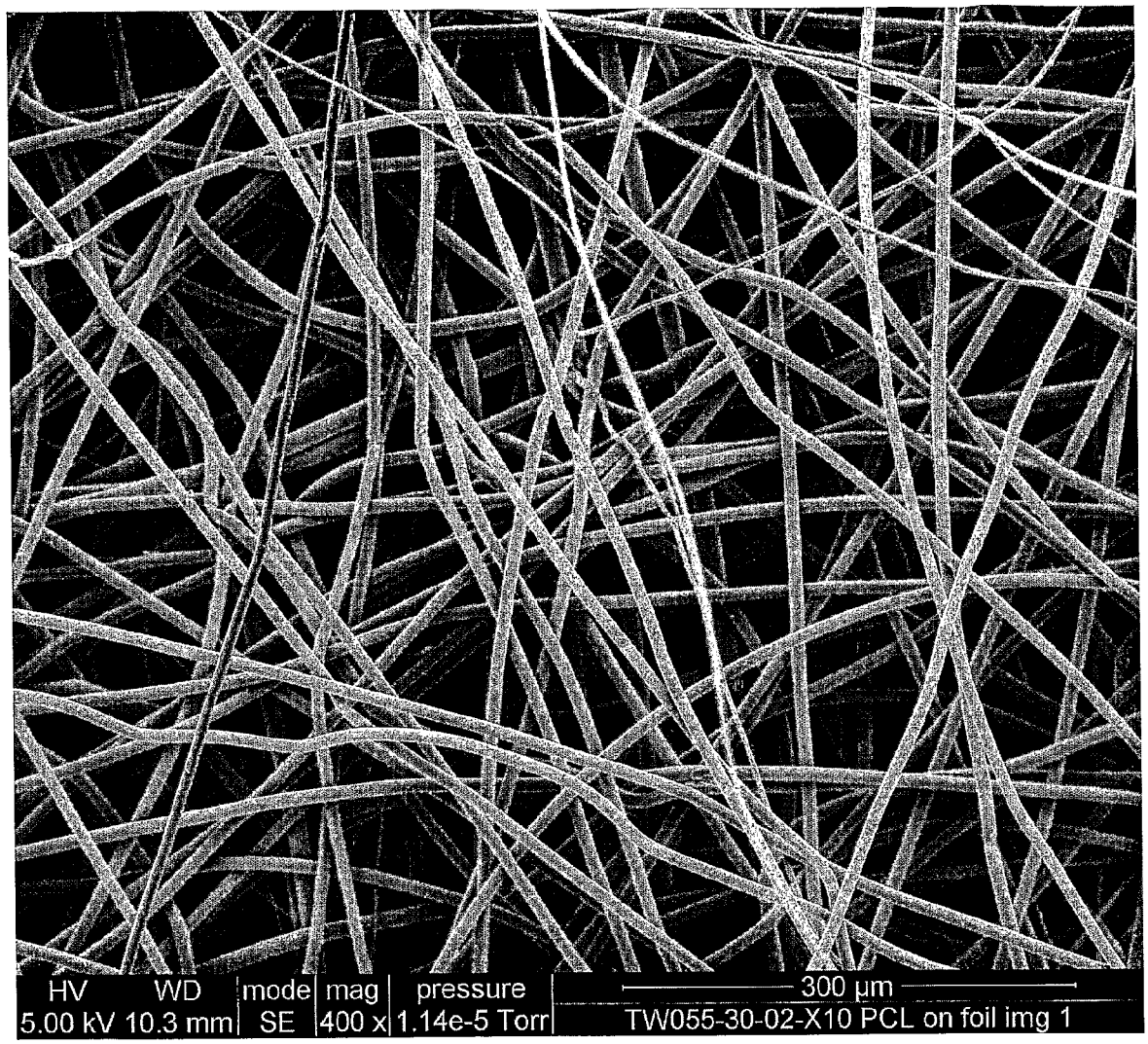
HV WD mode mag pressure
5.00 kV 10.3 mm SE 400 x 1.14e-5 Torr
300 µm
TW055-30-02-X10 PCL on foil img 1

Figure 15

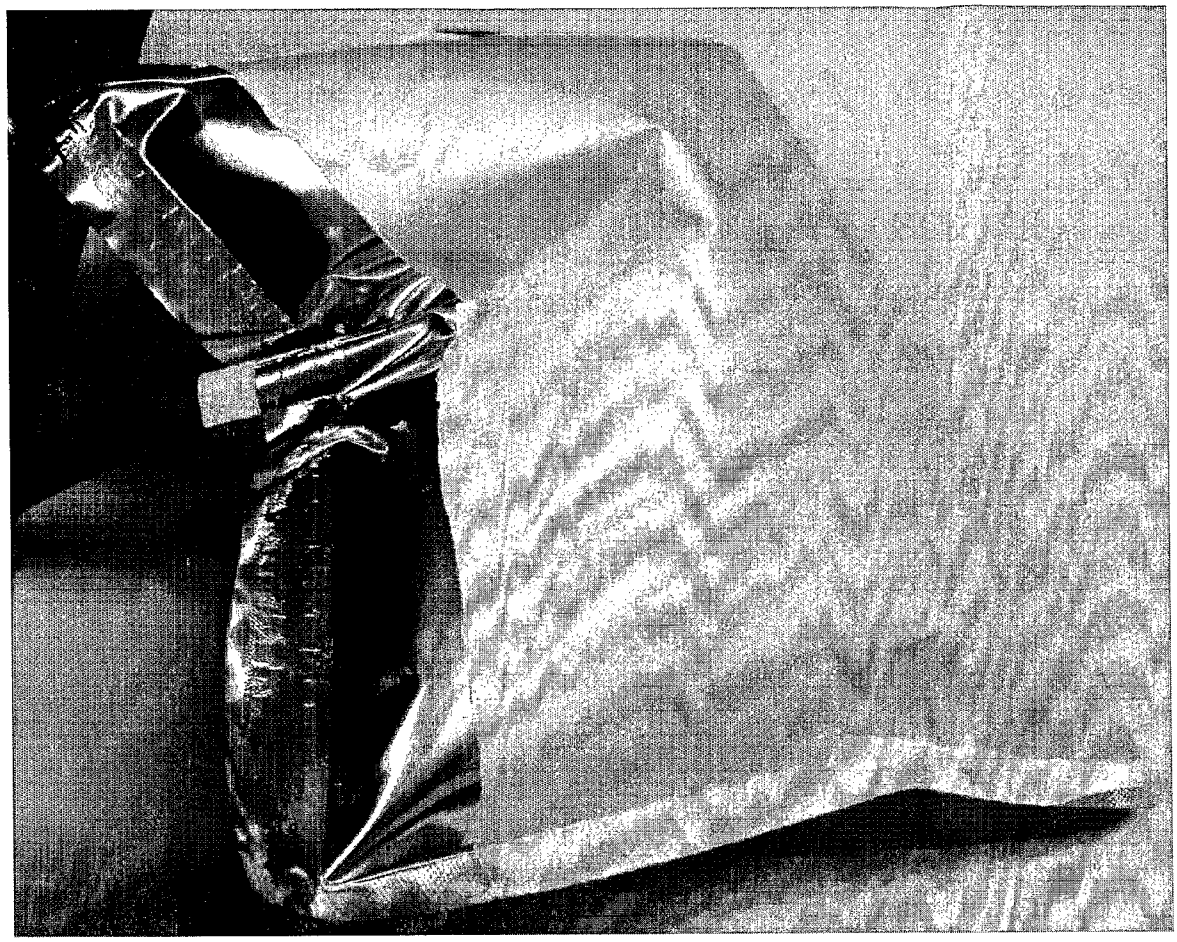

Figure 16

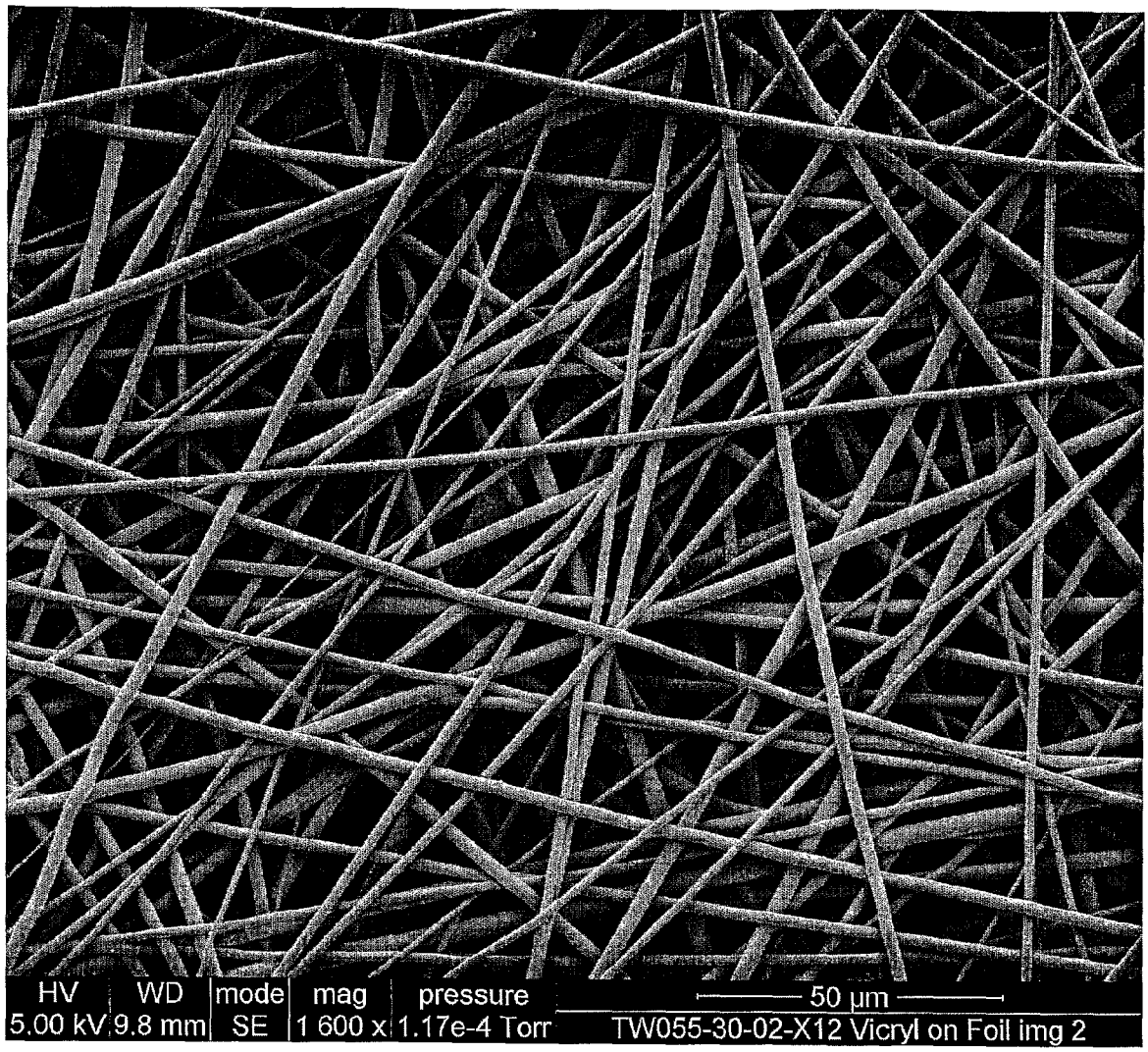
HV
5.00 kV
WD
9.8 mm
mode
SE
mag
1 600 x
pressure
1.17e-4 Torr
50 µm
TW055-30-02-X12 Vicryl on Foil img 2

Figure 17

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/004379

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00

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)
A61M D04H

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2005/046762 A (SMITH & NEPHEW [GB]; MARTIN ROBIN PAUL [GB]) 26 May 2005 (2005-05-26) page 56, line 34 - page 57, line 25; figure 1	1-18
X	WO 03/094811 A (POLYREMEDY LLC [US]; SYNYAGIN DMITRIY [US]) 20 November 2003 (2003-11-20)	19
Y	paragraphs [0040], [0043], [0072], [0075]	1-18
A	GB 1 224 009 A (BEIERSDORF AG [DE]) 3 March 1971 (1971-03-03) page 1, line 75 - line 77	1,19

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 March 2007	12/04/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, Angeliki

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/004379

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/115952 A1 (JOHNSON ROYCE [US] ET AL) 22 August 2002 (2002-08-22) abstract paragraph [0018]; figure 1	1
A	WO 02/092783 A (CHILDRENS MEDICAL CENTER [US]) 21 November 2002 (2002-11-21) page 8, line 24 - line 25	1,19
P,A	WO 2006/046060 A (SMITH & NEPHEW [GB]; MARTIN ROBIN [GB]) 4 May 2006 (2006-05-04) the whole document	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2006/004379

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20, 21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2006/004379

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005046762 A	26-05-2005	AU 2004289092 A1	26-05-2005
		CA 2543936 A1	26-05-2005
		CN 1874802 A	06-12-2006
		EP 1677855 A1	12-07-2006
		KR 20060113674 A	02-11-2006
		US 2007066945 A1	22-03-2007
WO 03094811 A	20-11-2003	AU 2003233510 A1	11-11-2003
		CA 2524934 A1	20-11-2003
		EP 1542631 A1	22-06-2005
GB 1224009 A	03-03-1971	NONE	
US 2002115952 A1	22-08-2002	NONE	
WO 02092783 A	21-11-2002	US 2003108587 A1	12-06-2003
WO 2006046060 A	04-05-2006	NONE	