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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 November 2011 (03.11.2011)

PCT

(10) International Publication Number
WO 2011/137230 A1

(51) International Patent Classification:
A61M 1/00 (2006.01)

(21) International Application Number:
PCT/US2011/034300

(22) International Filing Date:
28 April 2011 (28.04.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/329,764 30 April 2010 (30.04.2010) US
13/095,384 27 April 2011 (27.04.2011) US

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

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

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(54) Title: SYSTEM AND METHOD FOR SEALING AN INCISIONAL WOUND

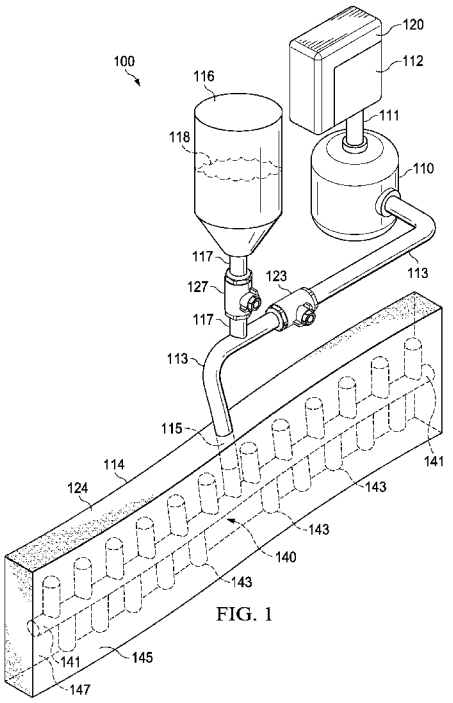

FIG. 1

(57) Abstract: An apparatus, system, and method for treating an incisional wound having incisional walls is disclosed. The apparatus includes a conduit having a first end for receiving reduced pressure and a second end. The apparatus further includes a scaffold. The scaffold has opposing surfaces for positioning adjacent the incisional walls and is fluidly coupled to the second end of the conduit for receiving the reduced pressure. The scaffold is generally elongated in shape and has a thickness between the opposing surfaces that is sufficiently thin for positioning within the incisional wound. The apparatus further includes an internal manifold that has a primary flow channel extending generally longitudinally within the scaffold and between the opposing surfaces of the scaffold. The internal manifold is fluidly coupled to the second end of the conduit. The application of the reduced pressure through the scaffold and the internal manifold induces tissue apposition between the incisional walls.

WO 2011/137230 A1

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

TITLE OF THE INVENTION

SYSTEM AND METHOD FOR SEALING AN INCISIONAL WOUND

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/329,764, filed April 30, 2010, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present disclosure relates generally to medical treatment systems and in particular to apparatuses and systems suitable for use as scaffolds in the treatment of wounds.

2. Description of Related Art

[0003] Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, including faster healing and increased formation of granulation tissue. Typically, reduced pressure has been applied to tissue through a porous pad or other manifolding device. The porous pad contains pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The porous pad often is incorporated into a dressing having other components that facilitate treatment. A scaffold can also be placed into a defect to support tissue growth into the defect. The scaffold is usually bioabsorbable, leaving new tissue in its place.

[0004] Synthetic and biologic scaffolds have been utilized to provide three-dimensional frameworks for augmenting endogenous cell attachment, migration, and colonization. To date, nearly all scaffolds have been designed with the idea that they can be made to work with the biology. Traditional scaffolding technologies, however, rely on the passive influx of endogenous proteins, cytokines, growth factors, and cells into the interstitium of the porous scaffold. As such, the colonization of endogenous cells into the scaffold is limited by the distance away from vascular elements, which provide nutrient support within a diffusion limit of the scaffold, regardless of tissue type. In addition, the scaffolds can also

elicit an immunogenic or foreign body response that leads to an elongated repair process. Taken together, these complications can all lead to less than desired functional tissue regeneration at the injury site.

[0005] It would therefore be advantageous to provide additional systems and apparatuses for the repair or regeneration of tissues resulting from specific injuries or incisions at various tissue sites. The present invention provides such systems and apparatuses.

SUMMARY

[0006] The systems, apparatuses, and methods of the illustrative embodiments described herein include an apparatus for treating an incisional wound having incisional walls. The apparatus includes a conduit having a first end for receiving reduced pressure and a second end. The apparatus further includes a scaffold. The scaffold has opposing surfaces for positioning adjacent the incisional walls and is fluidly coupled to the second end of the conduit for receiving the reduced pressure. The scaffold is generally elongated in shape and has a thickness between the opposing surfaces that is sufficiently thin for positioning within the incisional wound. The apparatus further includes an internal manifold that has a primary flow channel extending generally longitudinally within the scaffold and between the opposing surfaces of the scaffold. The internal manifold is fluidly coupled to the second end of the conduit. The application of the reduced pressure through the scaffold and the internal manifold induces tissue apposition between the incisional walls.

[0007] According to another illustrative embodiment, a system for treating an incisional wound having incisional walls includes a pressure source to supply reduced pressure, a conduit fluidly coupled to the pressure source that has a first end for receiving the reduced pressure and a second end, and a scaffold fluidly coupled to the second end of the conduit. The scaffold has opposing surfaces, is formed from a porous material, and is generally elongated in shape. The system further includes an internal manifold that has a primary flow channel extending generally longitudinally within the scaffold between the opposing surfaces. The internal manifold is fluidly coupled to the second end of the conduit. The application of the reduced pressure through the scaffold and the internal manifold induces tissue apposition between the incisional walls.

[0008] According to another illustrative embodiment, a system for treating an incisional wound having incisional walls includes a pressure source to supply reduced pressure, a conduit fluidly coupled to the pressure source that has a first end for receiving the reduced pressure and a second end, and a scaffold fluidly coupled to the second end of the

conduit. The scaffold has opposing surfaces, is formed from a porous material, and is generally elongated in shape. The system further includes an internal manifold that has a primary flow channel extending generally longitudinally within the scaffold between the opposing surfaces. The internal manifold is fluidly coupled to the second end of the conduit. The internal manifold further includes tributary flow channels fluidly coupled to the primary flow channel and extending generally transversely within the scaffold between the opposing surfaces. The tributary flow channels extend generally perpendicular from the primary flow channel. The application of the reduced pressure through the scaffold and the internal manifold induces tissue apposition between the incisional walls.

[0009] According to yet another illustrative embodiment, a method for treating an incisional wound having incisional walls includes fluidly coupling a conduit to a source of reduced pressure, wherein the conduit has a first end for receiving reduced pressure and a second end. The scaffold is fluidly coupled to the second end of the conduit for receiving the reduced pressure, wherein the scaffold is formed from sufficiently thin porous material having an internal manifold extending generally longitudinally between opposing surfaces of the scaffold. The opposing surfaces of the scaffold are positioned between the incisional walls of the incisional wound and the internal manifold is fluidly coupled to the second end of the conduit. The incisional wound is surgically closed and reduced pressure is provided through the conduit to the scaffold and the internal manifold onto the incisional wound, whereby the scaffold induces tissue apposition between the incisional walls.

[0010] Other objects, features, and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Figure 1 is a schematic, perspective view of a reduced pressure treatment system including a scaffold according to one illustrative embodiment;

[0012] Figure 2 is a schematic, cross-sectional, perspective view of an incisional wound and the scaffold shown in Figure 1 positioned within the incisional wound;

[0013] Figure 3 is a schematic, cross-sectional, perspective view of an incisional wound and the scaffold shown in Figure 1 positioned below the opening of the incisional wound; and

[0014] Figure 4 is a schematic, cross-sectional, perspective view of an incisional wound and the scaffold shown in Figure 2 including a drape covering the incisional wound.

DETAILED DESCRIPTION

[0015] In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part herein. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the illustrative embodiments are defined only by the appended claims.

[0016] Referring to Figs. 1 and 2, a reduced pressure treatment system 100 for applying a reduced pressure to a tissue site 102 of a patient according to an illustrative embodiment is shown. The reduced pressure treatment system 100 applies reduced pressure to an incisional wound 104 through an incisional opening 103 in epidermis 105 extending through dermis 106 into the fascial layers or subcutaneous tissues 107 at the tissue site 102. The term "incisional wound" refers to severed tissue at a tissue site such as, for example, a laceration, incision, or puncture that may have been caused by trauma, surgery, or degeneration. For example, an incisional wound may be an incision or puncture made by a surgeon in otherwise healthy tissue that extends up to 40 cm or more in length. In this sense, the incisional wound 104 is substantially a long and narrow shape, elongated shape, wherein

the length represents the longitudinal axis of the incisional wound 104. Incisional wounds may extend to different depths extending up to 15 cm or more, or be subcutaneous depending on the type of tissue and the cause of the incision. The depth represents the transverse axis of the incisional wound 104. The incisional wound 104 is surrounded by tissue adjacent the incisional opening 103 at the tissue site 102 and is formed by incisional walls 108 and 109. Although the incisional wound 104 is shown as an epidermal incision at the tissue site 102, the incisional wound 104 may also be, for example, an incision in an organ adjacent a fistula. Subcutaneous, absorbable sutures (not shown) may be placed in one or more fascial layers or the subcutaneous tissues 107.

[0017] The system 100 comprises a canister 110 having a filter (not shown) contained with the canister 110 and a reduced pressure source 112 coupled in fluid communication with the canister 110 via a first conduit 111. The system 100 further comprises a scaffold 114 positioned within the incisional wound 104 between the incisional walls 108, 109. The scaffold 114 includes an upper edge portion 124 positioned adjacent the incisional opening 103 of the incisional wound 104, a lower edge portion 125, and opposing, interfacial surfaces 145 and 147 positioned adjacent the faces of the incisional walls 109 and 108, respectively, of the incisional wound 104. The scaffold 114 is coupled in fluid communication with the reduced pressure source 112 through the canister 110 via a second conduit 113 which is fluidly coupled to the scaffold 114 by a conduit connector 115. The system 100 may also comprise a fluid supply 116 coupled in fluid communication to the scaffold 114 via a third conduit 117 either directly (not shown) or indirectly through the second conduit 113 for delivering a fluid 118 to the incisional wound 104 at the tissue site 102.

[0018] The reduced pressure source 112 is an electrically-driven vacuum pump. In another implementation, the reduced pressure source 112 instead may be a manually-actuated or manually-charged pump that does not require electrical power. The reduced pressure source 112 may be any other type of reduced pressure pump, or alternatively a wall suction port such as those available in hospitals and other medical facilities. The reduced pressure source 112 may be housed within or used in conjunction with a reduced pressure treatment unit 120 which may also contain a processing unit, sensors, alarm indicators, memory, databases, software, display units, and user interfaces that further facilitate the application of reduced pressure treatment to the tissue site 102. In one example, a sensor or switch (not shown) may be disposed at or near the reduced pressure source 112 to determine a source pressure generated by the reduced pressure source 112. The sensor may communicate with a processing unit (not shown) that monitors and controls the reduced pressure that is delivered

by the reduced pressure source 112. The canister 110 may be a fluid reservoir, or collection member, to filter or hold exudates and other fluids removed from the tissue site 102. In one embodiment, the canister 110 and the reduced pressure source 112 are integrated into a single housing structure.

[0019] The fluid supply 116 may be used to deliver growth and/or healing agents to the scaffold 114 for the incisional wound 104 including, without limitation, an antibacterial agent, an antiviral agent, a cell-growth promotion agent, an irrigation fluid, or other chemically active agents. The system 100 further comprises a first valve 127 positioned in the third conduit 117 to control the flow of fluid 118 to the scaffold 114, and a second valve 123 positioned in the second conduit 113 between the reduced pressure source 112 and the juncture between the second conduit 113 and the third conduit 117 to control the flow of reduced pressure. The processing unit of the reduced pressure treatment unit 120 is operatively connected to the first and second valves 127, 123 to control the delivery of reduced pressure and/or fluid from the fluid supply 116, respectively, to the scaffold 114 as required by the particular therapy being administered to the patient. The fluid supply 116 may deliver the fluids as indicated above, but may also deliver air to the scaffold 114 to promote healing and facilitate drainage of the incisional wound 104. The fluid 118 may be gas or liquid, and may contain growth factors, healing factors, or other substances to treat the incisional wound 104 at the tissue site 102. For example, the fluid 118 may be water, saline, or dye saline.

[0020] The term "scaffold" as used herein refers to a substance or structure applied to or positioned in a wound or defect that provides a structural matrix for the growth of cells and/or the formation of tissue. A scaffold is a three-dimensional, porous structure having dimensions roughly corresponding to the shape of the specific wound defect. The scaffold 114 may be infused with, coated with, or comprised of cells, growth factors, extracellular matrix components, nutrients, proteins, or other substances to promote cell growth. The scaffold 114 may possess characteristics of a manifold by directing the flow of fluids through its structural matrix. For example, the scaffold 114 may take on the characteristics of a manifold by directing reduced pressure or delivering fluids to a tissue site, or removing fluids from a tissue site. As used herein, the term "manifold" refers to a substance or structure that is provided to assist in directing reduced pressure or delivering fluids to a tissue site, or removing fluids from a tissue site. A manifold can include a plurality of flow channels or pathways that are interconnected to improve distribution of fluids provided to and removed from the area of tissue around the manifold. Examples of manifolds may include, without limitation, devices

that have structural elements arranged to form flow channels, cellular foams such as open-cell foam, porous tissue collections, and liquids, gels and foams that include or cure to include flow channels. The scaffold 114 possesses the characteristics of a manifold as described above.

[0021] The scaffold 114 may be a biologic or synthetic scaffold used to support protein adhesion and cellular in-growth for tissue repair and regeneration. The current state of the art in scaffold technology relies upon the inherent characteristics of the surrounding tissue space for the adsorption of proteins and migration of cells. The scaffold 114 for use according to the invention, and coupled with its function as a manifold, provides physical guidance to direct the pathway of fluid flow within the incisional wound 104, creating avenues for the movement and migration of adhesive proteins and cells, respectively, which are integral to the establishment of a provisional matrix in predetermined patterns of organization within the tissue space. The methods and apparatuses described for fluid flow-induced generation of tissues have direct implications into the design of the scaffold 114. In certain aspects, the scaffold 114 may be a reticulated structure, such as, for example, a reticulated foam, comprising a high void fraction for improved bioabsorption properties.

[0022] Non-limiting examples of suitable scaffold materials include extracellular matrix proteins such as fibrin, collagen or fibronectin, and synthetic or naturally occurring polymers, including bioabsorbable or non-bioabsorbable polymers, such as polylactic acid (PLA), polyglycolic acid (PGA), polylactide-co-glycolide (PLGA), polyvinylpyrrolidone, polycaprolactone, polycarbonates, polyfumarates, caprolactones, polyamides, polysaccharides (including alginates (*e.g.,* calcium alginate) and chitosan), hyaluronic acid, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyethylene glycols, poloxamers, polyphosphazenes, polyanhydrides, polyamino acids, polyortho esters, polyacetals, polycyanoacrylates, polyurethanes, polyacrylates, ethylene-vinyl acetate polymers and other acyl substituted cellulose acetates and derivatives thereof, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinylimidazole), chlorosulphonated polyolefins, polyethylene oxide, polyvinyl alcohol, Teflon®, and nylon. The scaffold 114 can also comprise ceramics such as hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate or other carbonates, bioglass, allografts, autografts, xenografts, decellularized tissues, or composites of any of the above. In particular embodiments, the scaffold 114 comprises collagen, polylactic acid (PLA), polyglycolic acid (PGA), polylactide-co-glycolide (PLGA), a polyurethane, a polysaccharide, an hydroxyapatite, or a polytherylene glycol. Additionally, the scaffold 114 may comprise combinations of any two, three or more materials, either in

separate areas of the scaffold 114, or combined noncovalently, or covalently (*e.g.*, copolymers such as a polyethylene oxide-polypropylene glycol block copolymers, or terpolymers), or combinations thereof.

[0023] In one embodiment, the scaffold 114 is formed from a scaffold material comprising PLGA fibers formed by a felting process that also functions as a manifold as described above. Such material known as Scaftex™ is available from Biomedical Structures, Inc. Any of the biodegradable or bioresorbable materials listed above that are reticulated and possess a high void fraction (low mass for degradation or resorption) may be used. The elastomeric materials, pliable materials, and gels are embodiments that are preferred for soft-tissue applications such as the incisional wound 104. The scaffold 114 is relatively thin between the opposing, interfacial surfaces 145, 147 which are positioned adjacent the incisional walls 109, 108, respectively, of the incisional wound 104. In one non-limiting example, the scaffold 114 may be approximately 0.25 mm to 3.0 mm thick between the opposing, interfacial surfaces 145, 147. Comparing the thickness of the scaffold 114 to the length and depth of the incisional wound 104, the scaffold 114 may be described as being relatively thin. In one embodiment, a ratio of the length to the thickness of the scaffold 114 is greater than about 10. Preferably, the scaffold 114 should be as thin as possible to fit within the incisional wound 104, minimizing the distance between the incisional walls 108, 109 to facilitate tissue apposition. Although the scaffold 114 is sufficiently thin, the material forming the scaffold 114 still comprises a matrix of pathways (not shown) to facilitate the flow of fluid between the incisional walls 108, 109. These pathways of the scaffold 114 extend through the scaffold 114 between the opposing, interfacial surfaces 145, 147 to induce tissue apposition by promoting the growth of tissue between the incisional walls 108, 109 as an interfacial scaffold matrix within the incisional wound 104.

[0024] The scaffold 114 may be of any size or shape depending on a variety of factors such as, for example, the type and size of the incisional wound 104 and the type of treatment being implemented to repair the wound. For example, the scaffold 114 may be substantially rectangular extending the full length of the incisional wound 104 along the longitudinal axis and the full depth of the incisional walls 108, 109 along the transverse axis. The scaffold 114 of such dimensions forms a full interfacial scaffold matrix between the two incisional walls 108, 109 to induce tissue apposition between the two. However, depending on the treatment, the scaffold 114 may only partially contact the incisional walls 108, 109. For example, the scaffold 114 may not extend to the bottom of the incisional wound 104 into the subcutaneous tissues 107. The upper edge portion 124 of the scaffold 114 may be positioned flush with the

incisional opening 103 of the incisional wound 104 adjacent the epidermis 105, and secured within the incisional wound 104 by a plurality of sutures 130 that close the incisional wound 104 when stitched.

[0025] The scaffold 114 may further comprise an internal manifold structure 140 to supplement the flow of fluid through the reticulated pathways that already exist within the scaffold 114. The internal manifold structure 140 may comprise one or a plurality of primary flow channels 141 fluidly coupled to the conduit connector 115 that extend generally longitudinally through the scaffold 114 between the incisional walls 108, 109. The internal manifold structure 140 may also comprise additional tributary channels 143 fluidly coupled to one or more of the primary flow channels 141. The tributary channels 143 extend generally transversely within the scaffold 114 between the opposing, interfacial surfaces 145, 147 to further facilitate fluid flow over a larger area of the interfacial scaffold matrix within the incisional wound 104. The tributary channels 143 may extend from the primary flow channel 141 in any direction relative to the primary flow channel 141 and may form any shape to enhance the area of the scaffold 114 covering the interfacial surfaces 145, 147. For example, as shown in a specific, non-limiting embodiment, the tributary channels 143 extend in a direction generally perpendicular from the primary flow channel 141 in a linear direction as opposed to having a curved shape. Thus, the internal manifold structure 140 provides a supplemental matrix for fluid flow coextensive with the reticulated pathways of the scaffold 114 by using the plurality of primary flow channels 141 or a single primary channel that may include the plurality of tributary channels 143 or a combination of both. This supplemental matrix of the internal manifold structure 140 may be formed with a pattern that further induces apposition of the incisional walls 108, 109.

[0026] Although the primary flow channel 141 is shown as a generally tubular shape in the figures, the primary flow channel 141 may be a variety of different shapes as long as such flow channel extends generally longitudinally through the scaffold 114 between the incisional walls 108, 109. The primary flow channel 141 does not need to be straight, but may undulate longitudinally within the scaffold 114 between the upper edge portion 124 and lower edge portion 125. The primary flow channel 141 may also be an anisotropic material property of the scaffold 114 itself extending generally longitudinally between the incisional walls 108, 109. For example, the anisotropic property may be a differential resistance to fluid flow through interconnected pores within the scaffold 114 extending along a generally longitudinal axis of the scaffold 114. The anisotropic property may also be the alignment of pores and their interconnectivity within the scaffold 114, or the variation of pore size within the scaffold

114 that permits or facilitates fluid flow along a longitudinal axis of the scaffold 114. In another embodiment, the primary flow channel 141 may be formed by a bioresorbable tubing.

[0027] The tributary channels 143 may be asymmetric in shape and formed from anisotropic properties of the scaffold 114. In another embodiment, the tributary channels 143 may be formed by a bioresorbable tubing. Although inlets of the tributary channels 143 are shown extending from the surface of the primary flow channel 141, the tributary channels 143 may also extend from loci within the primary flow channel 141 and diverge within the scaffold 114 as non-parallel, asymmetric passages. The inlets of such tributary channels 143 are in fluid communication with the primary flow channel 141 to facilitate the flow of fluids between the incisional walls 108, 109. The inlets of several tributary channels 143 may also originate and diverge from a single locus within the primary flow channel 141 in a star-pattern, for example, generally in parallel with and between the incisional walls 108, 109.

[0028] Referring to Fig. 3, the scaffold 114 may be positioned within the incisional wound 104 so that the upper edge portion 124 of the scaffold 114 is seated below the epidermis 105 such that sutures 230 may be used to close the entire scaffold 114 within the incisional wound 104. Seating the upper edge portion 124 of the scaffold 114 below the epidermis 105 of the incisional wound 104 may facilitate closure of the incisional opening 103 of the incisional wound 104 and help maintain the reduced-pressure within the incisional wound 104 for a longer period of time. Referring back to Fig. 2, in an alternative embodiment (not shown) the upper edge portion 124 of the scaffold 114 may protrude out of the incisional opening 103 above the epidermis 105 so that the sutures 130 may be stitched through the upper portion of the scaffold 114 to hold it firmly in place within the incisional wound 104. In this embodiment, the sutures 130 may be stitched sufficiently tight to substantially close the incisional opening 103 of the wound to further facilitate healing as described above.

[0029] In another embodiment shown in Fig. 4, the scaffold 114 may be exposed through the incisional opening 103 in the epidermis 105 as opposed to being closed within the incisional wound 104. In this embodiment, the system 100 may further comprise an external manifold 150 in fluid communication with the scaffold 114 and a drape 152 covering the external manifold 150 to maintain reduced pressure beneath the drape 152 within the incisional wound 104. The drape 152 includes an aperture 153 through which the conduit connector 115 extends to provide fluid communication between the second conduit 113 and the external manifold 150. The drape 152 may also include a periphery portion 154 that extends beyond the incisional opening 103 and includes an adhesive or bonding agent (not shown) to secure the drape 152 to the healthy tissue adjacent the incisional opening 103. The

adhesive provides a seal between the drape 152 and the epidermis 105 to better maintain reduced pressure within the incisional wound 104. In another embodiment, a seal layer (not shown) such as, for example, a hydrogel or other material, may be disposed between the drape 152 and the epidermis 105 to augment or substitute for the sealing properties of the adhesive. The drape 152 may also be used in conjunction with the embodiments shown in Fig. 2 and 3 described above.

[0030] The drape 152 may be any material that provides a pneumatic or fluid seal. The drape 152 may, for example, be an impermeable or semi-permeable, elastomeric material. As stated above, the drape 152 may include an adhesive layer on the periphery portion 154.

[0031] In view of the above, it will be seen that the advantages of the invention are achieved and other advantages attained. As various changes could be made in the above methods and compositions without departing from the scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

[0032] It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. It will further be understood that reference to "an" item refers to one or more of those items.

[0033] Where appropriate, aspects of any of the examples and embodiments described above may be combined with aspects of any of the other examples described to form further examples having comparable or different properties and addressing the same or different problems.

[0034] It will be understood that the above description of preferred embodiments is given by way of example only and that various modifications may be made by those skilled in the art. The above specification, examples and data provide a complete description of the structure and use of exemplary embodiments of the invention. Although various embodiments of the invention have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention.

CLAIMS

We claim:

Claim 1. An apparatus for treating an incisional wound having incisional walls, the apparatus comprising:

a conduit having a first end for receiving reduced pressure and a second end;

a scaffold having opposing surfaces for positioning adjacent the incisional walls and fluidly coupled to the second end of said conduit for receiving the reduced pressure, said scaffold being generally elongated in shape and having a thickness between the opposing surfaces sufficiently thin for positioning within the incisional wound; and

an internal manifold having a primary flow channel extending generally longitudinally within said scaffold between the opposing surfaces and fluidly coupled to the second end of said conduit;

whereby application of the reduced pressure through said scaffold and said internal manifold induces tissue apposition between the incisional walls.

Claim 2. The apparatus of claim 1, wherein the internal manifold further comprises tributary flow channels fluidly coupled to the primary flow channel and extending generally transversely within said scaffold between the opposing surfaces.

Claim 3. The apparatus of claim 2, wherein the tributary flow channels extend generally perpendicular from the primary flow channel.

Claim 4. The apparatus of claim 2, wherein one or more of the tributary flow channels originate from a single location within the primary flow channel.

Claim 5. The apparatus of claim 1, wherein the primary flow channel undulates between an upper and lower edge portion of said scaffold.

Claim 6. The apparatus of claim 1, wherein the primary flow channel is an anisotropic property of said scaffold.

Claim 7. The apparatus of claim 1, wherein the primary flow channel is formed by a bioresorbable tubing.

Claim 8. The apparatus of claim 1, wherein the primary flow channel is formed by an

alignment of interconnected pores of said scaffold.

Claim 9. The apparatus of claim 1, wherein the thickness of said scaffold is less than about 3.0 mm.

Claim 10. The apparatus of claim 1, wherein the thickness of said scaffold is greater than about 0.25 mm.

Claim 11. The apparatus of claim 1, wherein a ratio of a length to the thickness of said scaffold is greater than about 10.

Claim 12. The apparatus of claim 1, wherein said scaffold further comprises an edge portion not in contact with the incisional walls and an external manifold in fluid communication with the edge portion and fluidly coupled to the second end of said conduit.

Claim 13. The apparatus of claim 12, wherein said external manifold is positioned outside the incisional wound.

Claim 14. The apparatus of claim 1, wherein the scaffold is bioresorbable.

Claim 15. The apparatus of claim 1, wherein the scaffold is formed from polylactide-co-glycolide.

Claim 16. The apparatus of claim 1, wherein said scaffold is formed from resorbable polyurethane.

Claim 17. The apparatus of claim 1, wherein said scaffold is formed from decellularized biological material.

Claim 18. The apparatus of claim 1, wherein the scaffold is formed from collagen.

Claim 19. The apparatus of claim 1, wherein the scaffold is a reticulated structure.

Claim 20. The apparatus of claim 1, further comprising:

an external manifold in fluid communication with a portion of the scaffold; and

a drape formed of substantially impermeable material to cover said external manifold and said scaffold within the incisional wound.

Claim 21. A system for treating an incisional wound having incisional walls, the system comprising:

a pressure source to supply reduced pressure;

a conduit fluidly coupled to the pressure source having a first end for receiving the reduced pressure and a second end;

a scaffold fluidly coupled to the second end of said conduit for receiving the reduced pressure and having opposing surfaces for positioning within the incisional wound adjacent the incisional walls, said scaffold being formed from a porous material generally elongated in shape for positioning within the incisional wound; and

an internal manifold having a primary flow channel extending generally longitudinally within said scaffold between the opposing surfaces and fluidly coupled to the second end of said conduit;

whereby application of the reduced pressure through said scaffold and said internal manifold induces tissue apposition between the incisional walls.

Claim 22. The system of claim 21, wherein the internal manifold comprises tributary flow channels fluidly coupled to the primary flow channel and extending generally transversely within said scaffold between the opposing surfaces.

Claim 23. The system of claim 22, wherein the tributary flow channels extend generally perpendicular from the primary flow channel.

Claim 24. The system of claim 21, wherein one or more of the tributary flow channels originate from a single location within the primary flow channel.

Claim 25. The system of claim 21, wherein the primary flow channel undulates between an upper and lower edge portion of said scaffold.

Claim 26. The system of claim 21, wherein the primary flow channel is an anisotropic property of said scaffold.

Claim 27. The system of claim 21, wherein the primary flow channel is formed by bioresorbable tubing.

Claim 28. The system of claim 21, wherein the primary flow channel is formed by an alignment of interconnected pores of said scaffold.

Claim 29. The system of claim 21, wherein said scaffold further comprises an edge portion not in contact with the incisional walls and an external manifold structure in fluid communication with the edge portion and fluidly coupled to the second end of said conduit.

Claim 30. The system of claim 29, wherein the incisional wound has an opening between the incisional walls and the edge portion is exposed through the opening.

Claim 31. The system of claim 30, wherein said external manifold is positioned outside the incisional wound.

Claim 32. The system of claim 21, wherein the incisional wound has an opening between the incisional walls and further comprises means for substantially closing the opening.

Claim 33. The system of claim 21, further comprising:

an external manifold in fluid communication with a portion of the scaffold; and

a drape formed of substantially impermeable material to cover said external manifold and said scaffold within the incisional wound.

Claim 34. The system of claim 21, further comprising a fluid source fluidly connected to the scaffold.

Claim 35. A system for treating an incisional wound having incisional walls, the system comprising:

a pressure source to supply reduced pressure;

a conduit fluidly coupled to the pressure source having a first end for receiving the reduced pressure and a second end;

a scaffold fluidly coupled to the second end of said conduit for receiving the reduced pressure and having opposing surfaces for positioning within the incisional wound adjacent the incisional walls, said scaffold being formed from a porous material generally elongated in shape for positioning within the incisional wound, said scaffold having a thickness greater than about 0.25 mm and less than about 3.0 mm ; and

an internal manifold comprising:

a primary flow channel extending generally longitudinally within said scaffold between the opposing surfaces and fluidly coupled to the second end of said conduit;

tributary flow channels fluidly coupled to the primary flow channel and extending generally transversely within said scaffold between the opposing surfaces, the tributary flow channels extending generally perpendicular from the primary flow channel

whereby application of the reduced pressure through said scaffold and said internal manifold induces tissue apposition between the incisional walls.

Claim 36. The system of claim 35, further comprising:

an external manifold in fluid communication with a portion of the scaffold; and

a drape formed of substantially impermeable material to cover said external manifold and said scaffold within the incisional wound.

Claim 37. A method for treating an incisional wound having incisional walls, the method comprising:

fluidly coupling a conduit to a source of reduced pressure, the conduit having a first end for receiving reduced pressure and a second end;

fluidly coupling a scaffold to the second end of said conduit for receiving the reduced pressure, wherein the scaffold is formed from sufficiently thin porous material having an internal manifold extending generally longitudinally between opposing surfaces of the scaffold;

positioning the opposing surfaces of the scaffold between the incisional walls of the incisional wound;

fluidly coupling the internal manifold to the second end of the conduit for receiving the reduced pressure;

surgically closing the incisional wound to maintain the reduced pressure therein; and

providing the reduced pressure through the conduit to the scaffold and the internal manifold for the incisional wound, whereby the scaffold induces tissue apposition between the incisional walls.

Claim 38. The method of claim 37, wherein said scaffold includes an edge portion adjacent the opposing surfaces, the method further comprising:

adjusting said scaffold between the incisional walls so the edge portion is not in contact with the incisional walls;

positioning an external manifold in fluid communication with the edge portion; and

placing a drape formed of substantially impermeable material over said external manifold and said scaffold.

Claim 39. The method of claim 38 further comprising:

positioning the external manifold outside the incisional wound.

Claim 40. The method of claim 37, wherein the scaffold includes an edge portion adjacent the opposing surfaces and wherein the incisional wound has an opening between the incisional walls, the method further comprising:

positioning said edge portion below the opening and in contact with the incisional walls; and

covering the surgically closed incisional wound with a substantially impermeable material to substantially maintain the reduced pressure within the incisional wound.

Claim 41. An apparatus for treating an incisional wound having incisional walls, the apparatus comprising:

a scaffold having opposing surfaces for positioning adjacent the incisional walls, said scaffold being generally elongated in shape and having a thickness between the opposing surfaces sufficiently thin for positioning within the incisional wound; and

an internal manifold having a primary flow channel extending generally longitudinally within said scaffold between the opposing surfaces for fluidly coupling to a reduced pressure source.

Claim 42. The apparatus of claim 41, wherein the internal manifold further comprises tributary flow channels fluidly coupled to the primary flow channel and extending generally transversely within said scaffold between the opposing surfaces.

Claim 43. The apparatus of claim 42, wherein the tributary flow channels extend generally perpendicular from the primary flow channel.

Claim 44. The apparatus of claim 42, wherein one or more of the tributary flow channels originate from a single location within the primary flow channel.

Claim 45. The apparatus of any of claims 41 to 44, wherein the primary flow channel undulates between an upper and lower edge portion of said scaffold.

Claim 46. The apparatus of any of claims 41 to 45, wherein the primary flow channel is an anisotropic property of said scaffold.

Claim 47. The apparatus of any of claims 41 to 46, wherein the primary flow channel is formed by bioresorbable tubing.

Claim 48. The apparatus of any of claims 41 to 47, wherein the primary flow channel is formed by an alignment of interconnected pores of said scaffold.

Claim 49. The apparatus of any of claims 41 to 48, wherein the thickness of said scaffold is less than about 3.0 mm.

Claim 50. The apparatus of any of claims 41 to 49, wherein the thickness of said scaffold is greater than about 0.25 mm.

Claim 51. The apparatus of any of claims 41 to 50, wherein a ratio of a length to the thickness of said scaffold is greater than about 10.

Claim 52. The apparatus of any of claims 41 to 51, wherein said scaffold further comprises an edge portion not in contact with the incisional walls and an external manifold in fluid communication with the edge portion and fluidly coupled to the second end of said conduit.

Claim 53. The apparatus of claim 52, wherein said external manifold is positioned outside the incisional wound.

Claim 54. The apparatus of any of claims 41 to 53, wherein the scaffold is bioresorbable.

Claim 55. The apparatus of any of claims 41 to 54, wherein the scaffold is formed from polylactide-co-glycolide.

Claim 56. The apparatus of claim 55, wherein said scaffold is formed from resorbable polyurethane.

Claim 57. The apparatus of claim 56, wherein said scaffold is formed from decellularized biological material.

Claim 58. The apparatus of any of claims 41 to 57, wherein the scaffold is formed from collagen.

Claim 59. The apparatus of any of claims 41 to 58, wherein the scaffold is a reticulated structure.

Claim 60. The apparatus of any of claims 41 to 59, further comprising:

an external manifold in fluid communication with a portion of the scaffold; and

a drape formed of substantially impermeable material to cover said external manifold and said scaffold within the incisional wound.

Claim 61. The apparatus of any of claims 41 to 59, further comprising a conduit for fluidly coupling to the primary flow channel.

Claim 62. The apparatus of claim 61, further comprising a reduced pressure source fluidly coupled to the conduit.

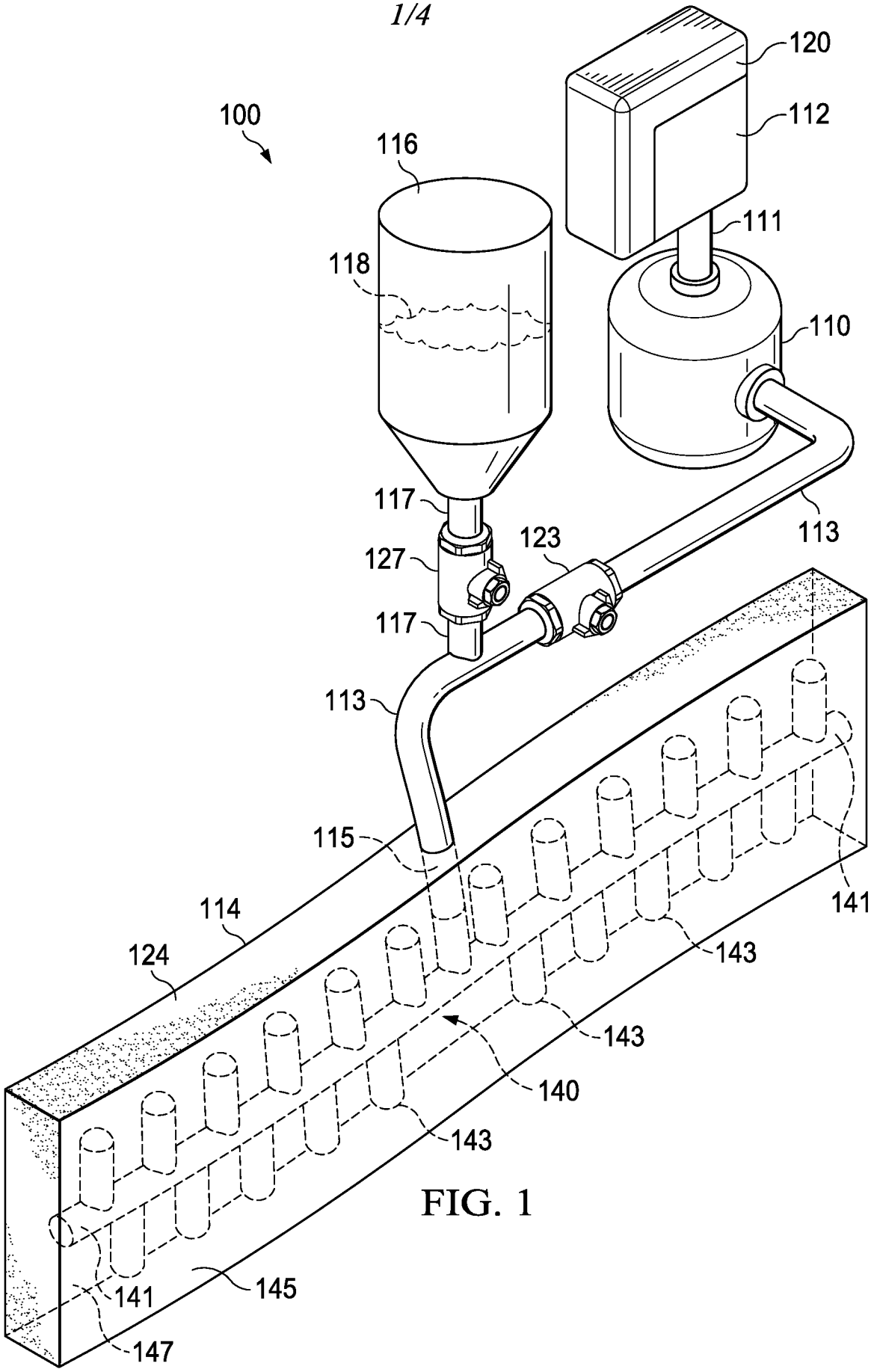
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FIG. 1

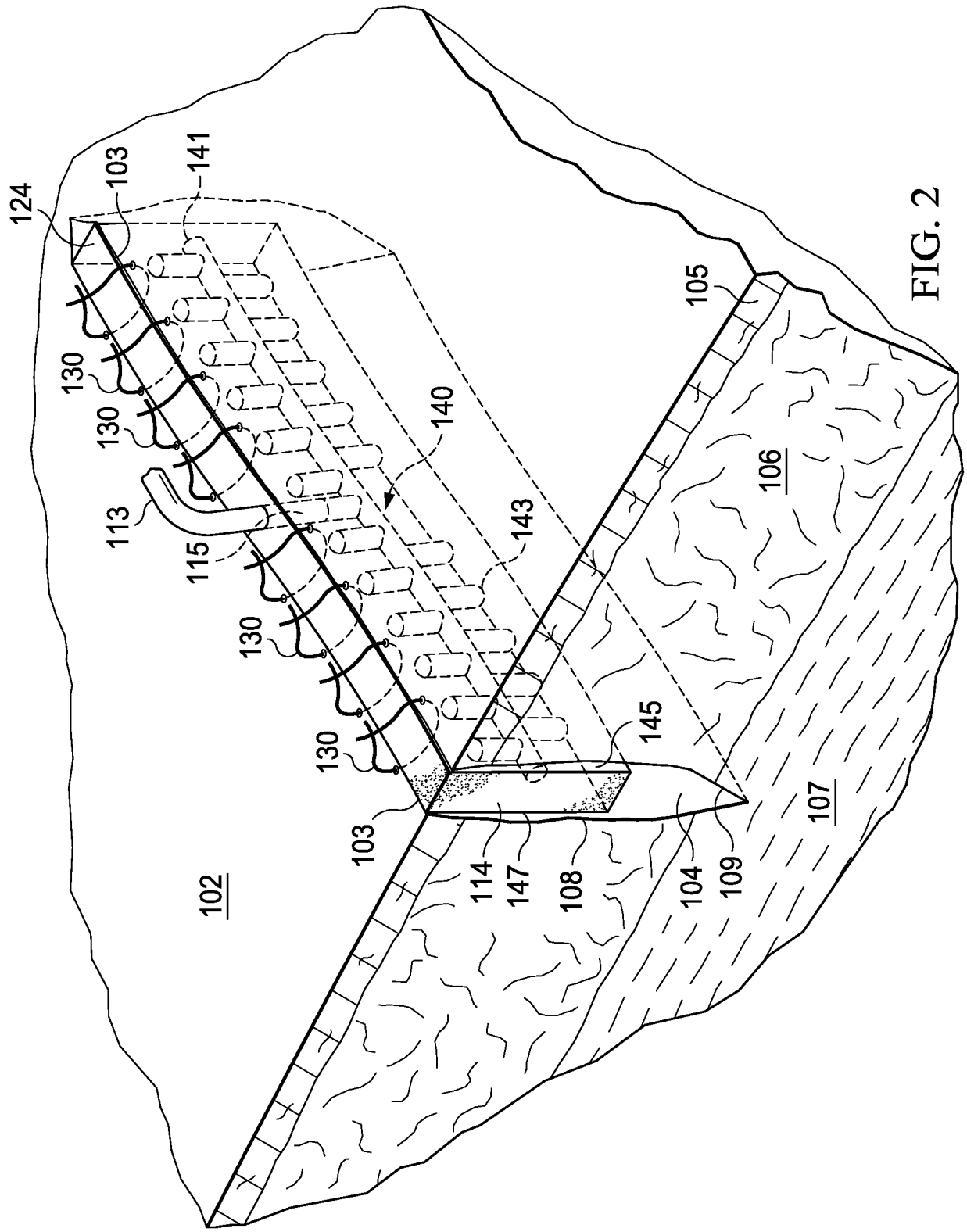
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FIG. 2

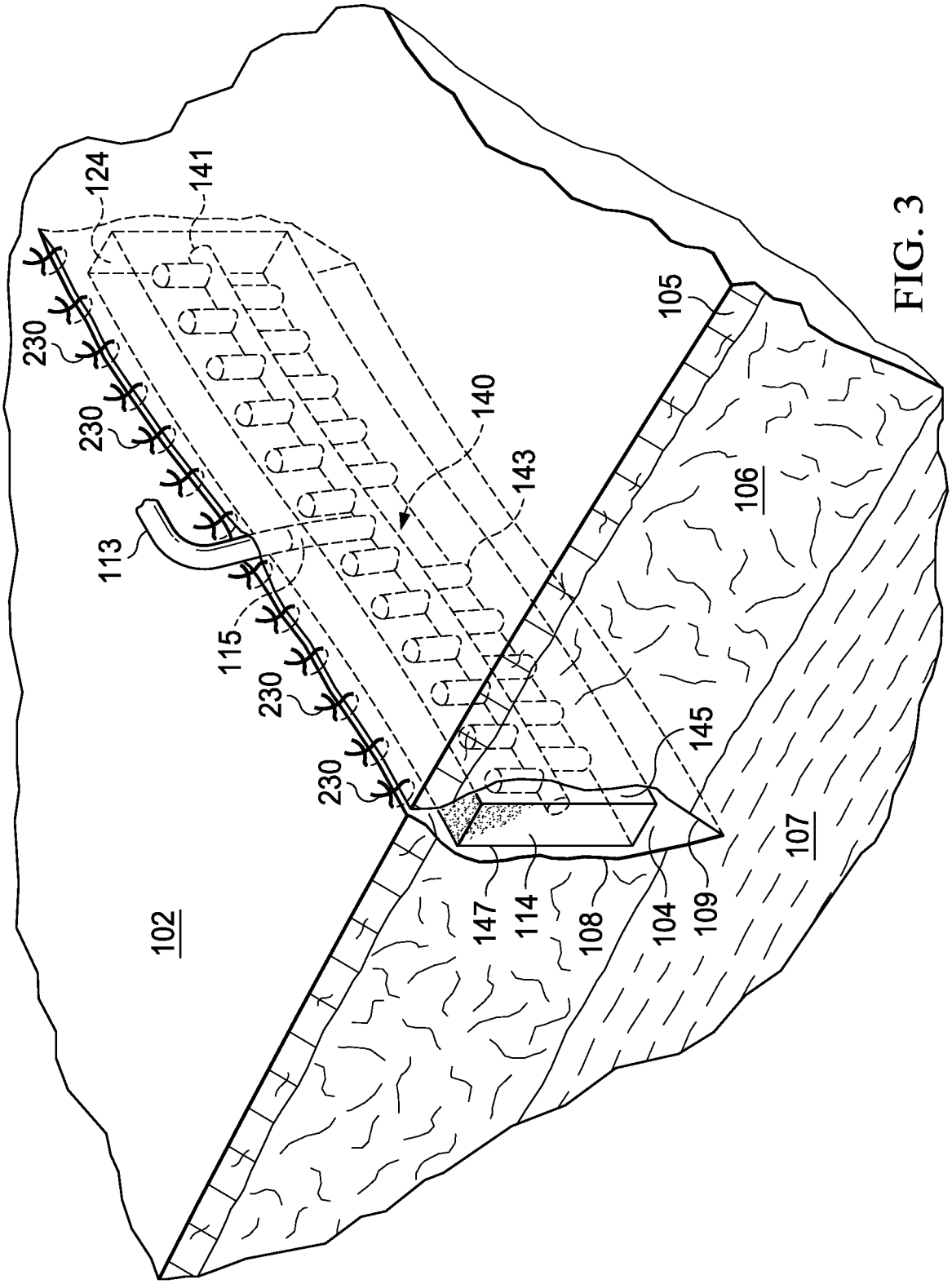
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FIG. 3

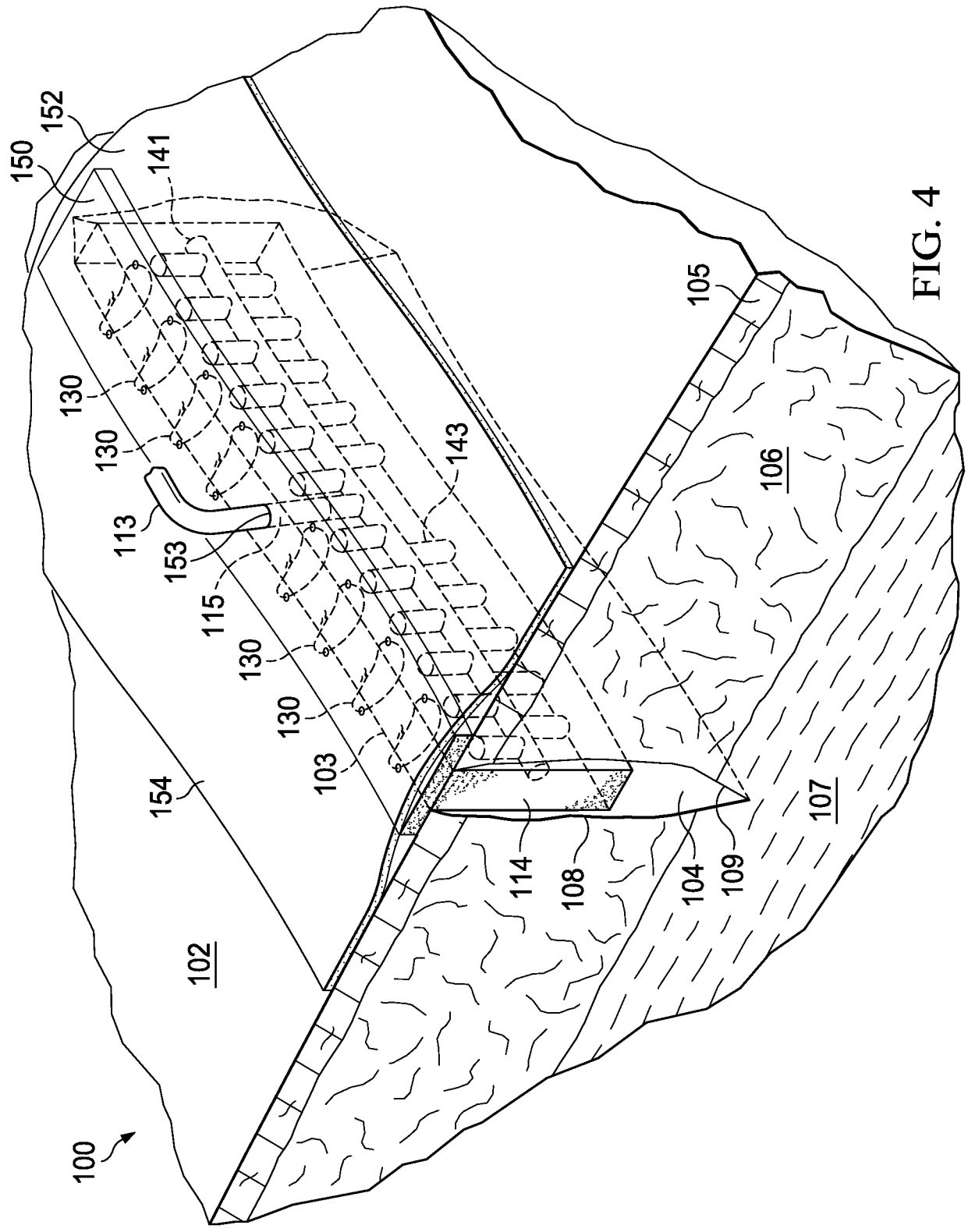
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FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/034300

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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.
X	US 2007/219497 A1 (JOHNSON ROYCE W [US] ET AL) 20 September 2007 (2007-09-20) paragraphs [0066], [0070], [0073], [0090], [0091], [0112], [0144]; figures 3,4a,5-6,9	1-36, 41-62
A	US 2004/039415 A1 (ZAMIEROWSKI DAVID S [US]) 26 February 2004 (2004-02-26) paragraph [0063]; figure 8	12,20, 29-33, 52,53,60

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

☒ See patent family annex.

* Special categories of cited documents :

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

"E" earlier 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
16 August 2011	30/08/2011

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, Fax: (+31-70) 340-3016	Persson, David

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/034300

Box No. 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.: 37-40
because they relate to subject matter not required to be searched by this Authority, namely:

Methods for treatment of the human or animal body by surgery
See separate sheet for details.

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 No. 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 fees, this Authority did not invite payment of additional fees.

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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/034300

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007219497 A1	20-09-2007	AU 2007225048 A1	20-09-2007
		AU 2007225049 A1	20-09-2007
		AU 2007225050 A1	20-09-2007
		AU 2007225051 A1	20-09-2007
		AU 2007225053 A1	20-09-2007
		AU 2010257431 A1	20-01-2011
		BR PI0709320 A2	12-07-2011
		CA 2644864 A1	20-09-2007
		CA 2644865 A1	20-09-2007
		CA 2644898 A1	20-09-2007
		CA 2644901 A1	20-09-2007
		CA 2646241 A1	20-09-2007
		CN 101437472 A	20-05-2009
		CN 101460205 A	17-06-2009
		CN 101563067 A	21-10-2009
		CN 101454044 A	10-06-2009
		CN 101563118 A	21-10-2009
		EP 1993651 A2	26-11-2008
		EP 1993652 A2	26-11-2008
		EP 1993653 A2	26-11-2008
		EP 1993491 A2	26-11-2008
		EP 1993512 A2	26-11-2008
		JP 2009529969 A	27-08-2009
		JP 2009529970 A	27-08-2009
		JP 2009529971 A	27-08-2009
		JP 2009529972 A	27-08-2009
		JP 2009532080 A	10-09-2009
		KR 20080111465 A	23-12-2008
		KR 20090013166 A	04-02-2009
		KR 20090007313 A	16-01-2009
		KR 20080104054 A	28-11-2008
		KR 20090007315 A	16-01-2009
		US 2007219489 A1	20-09-2007
		US 2007219471 A1	20-09-2007
		US 2007219585 A1	20-09-2007
		US 2007218101 A1	20-09-2007
		US 2008033324 A1	07-02-2008
		WO 2007106589 A2	20-09-2007
		WO 2007106590 A2	20-09-2007
		WO 2007106591 A2	20-09-2007
		WO 2007106592 A2	20-09-2007
		WO 2007106594 A2	20-09-2007
		ZA 200807377 A	28-10-2009
		ZA 200807412 A	26-08-2009
		ZA 200807707 A	30-09-2009
		ZA 200807708 A	29-07-2009
US 2004039415 A1	26-02-2004	US 2005177190 A1	11-08-2005
		US 2005182445 A1	18-08-2005
		US 2005240220 A1	27-10-2005
		US 2005234510 A1	20-10-2005
		US 2008228221 A1	18-09-2008
		US 2008228222 A1	18-09-2008
