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- (54) **Title:** SURGICAL CAVITY DRAINAGE AND CLOSURE SYSTEM

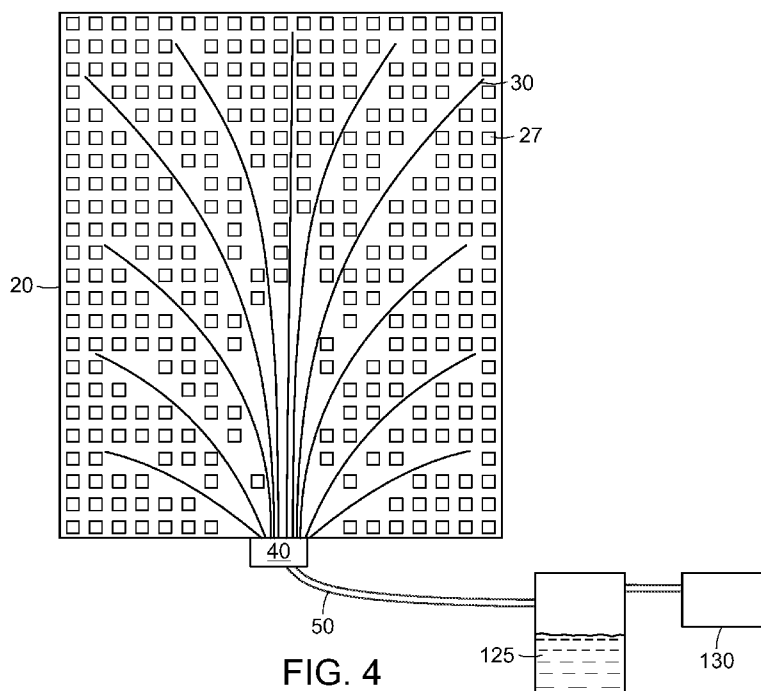


FIG. 4

(57) **Abstract:** A surgical drain device includes an adhesion matrix of biodegradable polymer material and a plurality of drain tubes attached to the matrix. The device is implanted within a surgical wound to treat the presence of seromas, for example, and is used to promote drainage, tissue adhesion, and wound closure. The drain tubes converge into a common collection tube that leads wound fluid outside the body under gravity feed or negative pressure applied to the collection tube. The matrix contains an array of apertures that allow tissue contact across the device. The device also can include a coating of surgical adhesive and a tissue anchoring system of hooks or barbs. The device and systems containing the device are particularly useful to promote the healing of surgical wounds from abdominal surgery.



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TITLE OF THE INVENTION
SURGICAL CAVITY DRAINAGE AND CLOSURE SYSTEM

CROSS REFERENCE TO RELATED APPLICATION

This application claims the priority to U.S. Application No. 61/475,945, filed April 15, 2011. The entire contents of the above application being incorporated herein by reference.

BACKGROUND OF THE INVENTION

A variety of systems have been proposed for draining surgical wounds. The efficacy of such systems has been limited, however, especially for larger surgical spaces or those in which certain characteristics, such as motion or shape, or certain physiological characteristics, such as lymphatic drainage or low protein exist. Seroma is a frequent complication following surgery, and can occur when a large number of capillaries have been severed, allowing plasma to leak from the blood and lymphatic circulation. Surgical wounds that can lead to seroma formation include wounds resulting from surgery involving an abdominal flap, such as abdominoplasty surgery, breast reconstruction surgery, panniculectomy, and ventral hernia repair.

Available surgical drain devices suffer from several deficiencies, particularly when applied following abdominal flap surgery. They fail to drain fluid adequately, are prone to clogging, and fail to promote tissue adhesion within the wound. Thus, there remains a need to develop improved treatments for surgical wounds. The need is particularly acute in abdominal surgery, such as for the prevention and treatment of seromas, but also for any surgical wound predisposed to conditions of excess fluid drainage or tissue motion, or benefitting from tissue adhesion needs, such as pressure ulcers or wounds resulting from a tissue harvesting procedure.

SUMMARY OF THE INVENTION

The invention provides a surgical drain device for the prevention and treatment of seromas as well as for general use in promoting drainage of surgical wounds and wound closure. The drain device includes a plurality of drain tubes disposed on a substrate termed an "adhesion matrix," which is designed to promote tissue adhesion within the seroma or wound space. The adhesion matrix has a conformable configuration and is made of a compliant material having planar surfaces that can curve to adapt to the shape of the wound space.

In a preferred embodiment, the adhesion matrix contains a plurality of apertures, or gaps in the matrix material, which allow tissue contact across the matrix, so as to promote adhesion and wound closure. Thus, a tissue surface on a first side of the matrix can directly contact a tissue surface on a second, or opposite, side of the matrix to promote rapid healing and stabilization of the wound. The number, size and distribution of the apertures extending through the matrix can be selected based on the geometry of the wound. For abdominal wounds, for example, the drain tubes can be positioned in a fan shaped array with a plurality of three or more tubes extending from a manifold. The matrix and/or the tubing can be cut or shaped by the user to conform to the shape of the wound. The matrix can also be used as a medication carrier to assist in the administration of a drug to a patient. The matrix can optionally include a layer of adhesive on at least a portion of any of its surfaces. The drain tubes can be removed from the device once drainage flow is sufficiently reduced, and the adhesion matrix can remain within the body, where it is degraded and absorbed over time, remaining in place to optimize tissue healing. The matrix can comprise a porous biodegradable polymer material. As the plurality of tubes extend from a single exit site into the wound with spaced apart distal ends, a user can readily remove all the tubes simultaneously from the wound.

The surgical drain device can include a tissue anchoring system, whereby the device is mechanically attached to surrounding tissues by an array of surface barbs or hooks. These surface structures can be located on any exposed surface of the adhesion matrix. When the device is implanted, the surrounding tissues can be pressed against the barbs or hooks to embed them within the tissue and anchor the device. The use of surface barbs or hooks can be used in combination with a surgical adhesive, providing a much stronger bond between tissue layers than the adhesive alone, and providing temporary adhesion while the adhesive sets. The structure of the hooks can have various forms depending on the tissue they are intended to bind. Longer hooks can be used for loosely bound tissues such as fat or connective tissue, while shorter hooks can be used for denser tissues such as muscle. Anchors with more rigid stems can be utilized to penetrate denser tissues.

Another aspect of the invention is a system for surgical wound drainage. The system includes the drain device described above together with a vacuum source, such as a pump, and a tube connecting the vacuum source to the drain tubes of the drain device. The system optionally also can include a fluid trap to collect drained fluid and a control unit to monitor and control the application of vacuum and the collection of fluid. Further components of the system can include a vacuum or pressure gauge, a flow meter, and a computer to monitor vacuum and flow and to regulate vacuum or flow.

Another aspect of the invention is a method for treating or preventing a seroma, or promoting the drainage or closure of a surgical wound. The method includes positioning the drain device described above into a seroma, or a surgical wound, such as a wound at risk of forming a seroma, and allowing the device to drain fluid from the wound for a period of time. The device can include surgical adhesive and/or barbs or hooks on its surface to create adhesion between tissue layers within the wound and to anchor the device in place. Drainage can be by gravity flow or

can be vacuum assisted by attaching a vacuum source to the drain tubes of the device, using a manifold to merge the flow paths of the drain tubes to a common drain tube for collection. Negative pressure applied to the drain tubes can be used to hold the tissue layers above and below the device together until a surgical adhesive has set, or until the wound healing process binds the tissues together. The application of negative pressure further facilitates contact between tissue on opposite sides of the matrix through the apertures in the matrix to promote tissue adhesion. This improves the rate of healing while at the same time providing for drainage. Optionally, the drain tubes of the device can be removed from the body after drainage flow is reduced, thereby reducing the burden for resorption by the body. Removal of the drain tubes can be facilitated by the inclusion of drain tube channels, or drain tube release tabs, within the adhesion matrix. Release of the drain tubes is then accomplished by sliding the tubes out of the channels or appropriately maneuvering the drain tube assembly to break release tabs. The adhesion matrix is allowed to remain in the seroma or surgical wound where it is resorbed over time.

The flow rate from the drain tubes can be regulated by flow control elements. The flow rate can also be measured or the pressure of fluids can be measured by ultrasound devices or by other methods. The system can also be used in conjunction with wound dressings that can also be attached to a negative pressure source to remove fluids from the wound.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a drawing of the abdomen of a patient who has an abdominal flap wound resulting from abdominal surgery.

Fig. 2 shows a drawing of a surgical drain device according to the invention which has been inserted through an abdominal flap wound.

Fig. 3 shows a cross-sectional view of a surgical drain device according to the invention installed in the abdomen of a human patient between subcutaneous tissue and a layer of abdominal muscle.

5 Fig. 4 is a schematic diagram of a surgical wound drainage system according to the invention.

Figs. 5A-5G are illustrations of embodiments of a surgical drain device according to the invention, depicting the disposition of drain tubes within the device and features of the drain tubes and polymer matrix. Figs. 5A - 5D show representative embodiments
10 having different mechanisms of attaching drain tubes to the polymer matrix. In Fig. 5A the drain tubes are encased within drain tube channels, and in Fig. 5B the drain tubes are attached via retaining structures. In Fig. 5C the drain tubes are glued
15 onto the matrix, and in Fig. 5D the drain tubes are spot welded onto the matrix. Figs. 5E and 5F show embodiments having different configurations of drain tubes within drain tube channels. Fig. 5G shows a drain tube embodiment having lateral apertures for collection of fluid.

20 Figs. 6A-C show illustrations of embodiments of an adhesion matrix having different types of tissue contact apertures. Fig. 6D is an illustration of an adhesion matrix embodiment possessing tissue anchors on its surface. Fig. 6E shows a cross-sectional view of the adhesion matrix of Fig. 6D.

25 Figs. 7A - 7C are cross-sectional illustrations of different embodiments of the drain device positioned within a wound or seroma. These embodiments include one or more layers of adhesive.

Fig. 8 illustrates a process sequence of performing wound closure treatment in accordance with preferred embodiments of the
30 invention.

Fig. 9 illustrates a wound drainage and wound dressing system in which the wound dressing does not overlies the drainage exit site.

Fig. 9B illustrates a wound drainage and dressing system in
35 which the wound dressing overlies the drainage exit site.

Figs. 10A and 10B illustrate cross-sectional view of drainage exit tube assemblies that can be used in preferred embodiments of the invention.

Fig. 11 is a side view of a tissue anchoring mesh in accordance with preferred embodiments of the invention.

Fig. 12 is a process flow diagram illustrating a method of using a wound dressing and drainage system in accordance with preferred embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a surgical drain device, system, and method that allow fluid to be drained from surgical wounds and promote the healing of the wound. Preferred embodiments are used to prevent or treat seromas, for example.

The drain device features a set of drain tubes that are attached to a substrate, herein referred to as an adhesion matrix, that is designed to promote adhesion of tissues within the wound or seroma and to encourage cellular infiltration into the device itself. The drain tubes are distributed across the adhesion matrix to promote even drainage across the device. To promote optimum drainage, the drain tubes can be uniformly distributed across the adhesion matrix. The drainage device can be left in place within the wound for a period of time, e.g., until fluid seepage diminishes, after which the drain tubes can be withdrawn from the device and removed from the patient without disturbing the adhesion matrix, which is left in place to biodegrade or become incorporated into the healing process. The device efficiently promotes the healing of even large area wounds such as those resulting from abdominal flap surgery.

A surgical drain device according to the invention is inserted through an incision in the skin of a patient and placed within a wound formed during surgery. A first purpose is to drain fluid during the surgical procedure. The system can be left in place and to provide drainage for days or even weeks following surgery. The device can be used for the treatment of a seroma,

e.g., to drain a seroma and thereby promote its healing, it can also be used to prevent seroma formation. For example, the drain device can be placed routinely into surgical incision areas immediately following surgery and used to drain the area and aid in the prevention of seroma formation. Alternatively, the device can be placed into a seroma that has already formed by opening the seroma and installing the device. The use of the drain device is understood to "prevent" seroma formation even if it merely reduces the likelihood of seroma formation. Similarly, the use of the drain device is understood to "treat" seroma formation even if it merely increases the likelihood that the seroma will heal. Fig. 1 shows an abdominoplasty or abdominal flap wound (10) in a patient resulting from abdominal surgery. Fig. 2 shows surgical drain device 20 inserted through abdominal flapwound 10 and into the space occupied by seroma 15.

The device according to the invention includes a number of removable drain tubes 30 attached at their proximal ends to manifold 40, which connects to a vacuum source through vacuum tubing 50. The drain device collects and removes fluid from the abdominal region or from the fluid space of a seroma through the drain tubes, which divert the fluid outside the patient through the aid of a vacuum source. The number of drain tubes can vary depending upon the needs of the device, including the amount of fluid to be drained and the size of the wound and shape of the device. Typically, the device will contain from 2 to about 20 drain tubes. In a preferred embodiment, the device contains preferably at least 3 tubes, and for larger areas such as the abdomen, for example, from about 5 to about 12 tubes.

The drain tubes can be fabricated from any biocompatible thermoplastic or thermoset material. Examples include surgical grade silicone rubber, polyurethane, polyamide, polyimide, PEEK (polyether ether ketone), polycarbonate, PMMA (polymethylmethacrylate), and polyvinylchloride. The drain tubes are intended to be removed after fluid build-up has reduced to a level that is stable without drainage. However, in an alternative

embodiment, the drain tubes can be made of a biodegradable material and can be left in place. The drain tubes can be flexible so as to conform to the tissues surrounding the device and to accommodate movement of the patient without causing discomfort. The drain tubes can be open ended or close ended. In a preferred embodiment, the drain tubes are close ended and possess apertures or holes along their length for the uptake of fluid.

Fig. 3 shows drain device 20 installed in the abdomen between subcutaneous tissue 70 and a layer of abdominal muscle 80 and associated fascia 90. While this position can be used following abdominal flap surgery, other anatomical locations of the device are also possible and are contemplated as suitable uses of the invention.

Fig. 4 schematically depicts a system for drainage of a seroma through an abdominal flap wound. System 21 includes drain device 20, having a plurality of drain tubes 30 attached to adhesion matrix 25 and configured so as to drain the full extent of the seroma. The drain tubes are connected at their proximal ends to manifold 40, which is in turn connected through vacuum tubing 50 to a vacuum pump 130 or other vacuum source. Fluid drained from the wound can be optionally accumulated in fluid trap 120. Vacuum pump or other vacuum source 130 can include one or more electronic devices, such as a microprocessor with memory and software, to monitor the vacuum level, pneumatic resistance, and/or fluid removal amount or rate. The electronic device(s) also can be used to control the operation of the system over time according to user-defined parameters, according to a preset program, or in response to data collected on vacuum, resistance, and/or fluid removal.

Figs. 5A-5G depict representative embodiments of a drain device according to the invention, showing several possible configurations of the drain tubes within the device. Fig. 5A shows an embodiment in which each drain tube 30 is disposed within a separate drain tube channel 35. The drain tube channels are

embedded within or attached to the surface of adhesion matrix 25 and determine the orientation and distribution of the drain tubes within the device. In a preferred embodiment, the drain tube channels, and consequently the drain tubes, are evenly distributed across the surface area of the drain device, as shown in Fig. 4. These can extend in a generally radial distribution from one edge or region on the matrix to enable use of a single exit tube from the wound. However, the drain tubes can be unevenly distributed if desired, e.g., to increase the drainage capacity or rate from specific areas of the device. The use of drain tube channels ensures that the drain tubes remain in position within the patient and ensures that the drain tubes can be removed easily at the appropriate time, without disrupting the wound healing process. Drain tube channels require a mechanism to accept fluid and pass it on to the drain tubes within. Suitable mechanisms include using apertures or holes of any desired shape and distribution along the length of the channels (see, e.g., apertures 33 on channels 35 in Fig. 6D), and using a porous material to form the drain tube channels (see drain tube channels 35 in Figs. 5E and 5F, constructed of a porous polymer matrix).

Several alternative embodiments are also contemplated which lack drain tube channels. Fig. 5B depicts the use of retaining structures 35a instead of channels in order to removably attach the drain tubes to the adhesion matrix, while allowing removal of the tubes by sliding or by breaking off the retaining structures. The retaining structures can have any form compatible with their function. Fig. 5C shows an embodiment in which drain tube 20 is held in place by layer of adhesive 31, and the tube is fitted within a depression on the surface of adhesion matrix 25. In the related embodiment shown in Fig. 5D, the drain tube is held in the matrix depression by spot welds or adhesion points 32, which can be broken through suitable manipulation to remove the tubes.

Figs. 5E and 5F present cross-sectional views of a portion of the adhesion matrix 25 of an embodiment of a drain device according to the invention. The adhesion matrix contains regions

for receiving drain tubes or can include one or more drain tube channels 35 which surrounds drain tubes 30, having lumen 34, through which seroma or other wound fluid is removed. A round Blake drain is depicted as the drain tube in Fig. 5E, and a
5 flattened version in Fig. 5F. A variety of drain tube profile shapes are possible, including oval, elliptical, square, rectangular, triangular, flattened, compound (i.e., having 2 or more parallel lumens, interconnected or separated), or irregular. The drain tubes optionally can be coated with a lubricant on their
10 outer surfaces to facilitate their removal from the channels.

In a preferred embodiment the drain tubes possess openings or apertures 33 along their length to permit fluid to enter for drainage. Fig. 5G depicts one such embodiment. The relative surface area and distribution of such apertures can be chosen so
15 as to regulate flow through the drain tubes. For example, pressure drop (i.e., loss of vacuum) along the length of the drain tubes can be compensated by increasing the open surface area or the density of apertures towards the distal end of the drain tubes. Drain tubes are preferred which have an aperture
20 distribution that provides an essentially constant rate of fluid uptake along the length of the drain tubes (e.g., increasing aperture area towards the distal end), so that uniform drainage is obtained across the drain device.

Adhesion matrix 25 includes a plurality or matrix of
25 apertures 27 which allow tissue contact through the drain device. Such tissue contact promotes wound healing and the sealing of capillaries, which is important for treating seromas or preventing their formation. In the drain device according to the present invention, the promotion of tissue contact works in combination
30 with fluid drainage to promote wound healing. The adhesion matrix 25 and its drain tube channels 35 preferably are constructed of one or more biodegradable polymer materials and can be left within the wound, where they stabilize tissue infiltration and adhesion and thus promote the healing process. The size, shape, and
35 distribution of the tissue contact apertures 27 can be varied

according to individual needs. However, greater tissue contact across the device will promote better adhesion, drainage, and wound closure. Therefore, it is preferred that at least about 50%, 60%, or 70%, and preferably about 75-80% of the total surface area (one side) of the drain device remains open in the form of tissue contact apertures. The distribution and spacing of tissue contact apertures can be varied as desired, and the apertures can be the same, similar, or different in shape, size, and distribution across the device. For example, the apertures can be distributed with an average center-to-center spacing in the range of about 2 mm to about 20 mm or more, and the average individual aperture surface area can be in the range from about 1 mm² to about 5 cm². In a preferred embodiment, the apertures have about 1 cm² average surface area, and their number or their collective surface area become progressively larger from the proximal end of the drain device (i.e., near the exit point from the body) toward the distal end of the device (deep within the wound or seroma), so that tissue adhesion and wound closure progress from deep within the wound towards the surface of the body.

Figs. 6A-E show several embodiments of the adhesion matrix. A portion of the adhesion matrix 25 between two neighboring drain tubes 30 and drain channels 35 is shown. The embodiment shown in Fig. 6A has a regular arrangement of rectangular apertures 27 to allow tissue contact through the device. Circular apertures are shown in Fig. 6B. The embodiment of Fig. 6C includes apertures 27 that are formed into lateral channels. Fluid flows laterally through these channels toward openings 36 in the drain tube channels, drawn by the reduced pressure in the drain tubes. As shown in Figs. 6D and 6E, the surfaces of the adhesion matrix, including the drain channels, can be endowed with an array of hooks or barbs to promote anchoring of the device to adjacent tissues. In the embodiment shown in Fig. 6E, the hooks on the upper side 28 are longer than the hooks on the lower side 29. This arrangement can be used where the tissues on either side of the device are of different density. For example, longer hooks

such as about 1.5 to about 3 mm in length are preferred for less dense tissue, such as subcutaneous fat tissue, whereas shorter hooks such as about 0.5 to about 1.5 mm in length are preferred for denser tissues such as fascia and muscle.

5 The adhesion matrix, including any drain tube channels and hooks or barbs, can be fabricated from a biodegradable polymer material, as these structures are intended to remain in place in the patient's body after removal of the drain tubes, so as not to disrupt the healing process. Examples of suitable biodegradable
10 or resorbable materials include Vicryl (polyglycolic acid), Monocryl (glycolic acid- ϵ -caprolactone copolymer), PDS (polydioxanone, PDO), PLA (polylactic acid, polylactide), PLLA (poly-L-lactic acid), PDLA (poly-D-lactic acid), PGA (polyglycolic acid, polyglycolide), PLGA (poly(lactic-co-glycolic acid)), PHB
15 (polyhydroxybutyrate), and PCL (polycaprolactone). In a preferred embodiment, the adhesion matrix, including any drain tube channels, is formed of an open network of polymer chains that has sufficient porosity to allow infiltration by cells and fluid flow across the material. Cellular infiltration can promote tissue
20 adhesion and the biodegradation of the polymer after the wound has healed. In some embodiments, the adhesion matrix including any drain tube channels is permeable to seroma fluid but not permeable to cells. In other embodiments, the adhesion matrix, including any drain tube channels, is permeable to fluid and electrolytes
25 but is impermeable to proteins. The permeability properties of the matrix polymer material that makes up the basic substrate of the matrix can be the same or different compared to the material that makes up the drain tube channels. In a preferred embodiment, the polymer chains, or fibers composed of polymer chains, of the
30 adhesion matrix are aligned along an axis substantially perpendicular to the axes of the nearest drain tubes. This alignment pattern promotes the flow of fluid through or along the surface of the adhesion matrix towards the drain tubes.

 The adhesion matrix, and thus the overall drain device, can
35 have any form suitable for insertion into the wound or seroma

where it is to be inserted. Generally, the form is that of a thin sheet having an essentially rectangular shape. However, the shape can be rounded, circular, elliptical, oval, or irregular.

Preferably the corners are rounded so as to minimize mechanical irritation of surrounding tissues. The size of the device is also determined by the particular use and anatomy of the patient. For example, the adhesion matrix can have an overall width and length in the range from about 2 cm to 25 cm, such as about 10 cm x 12 cm or about 20 cm x 25 cm. The thickness of the adhesion matrix can be from about 0.5 mm to about 1 cm; where the sheet of material is preferably less than 5 mm in thickness and preferably the adhesion matrix is about 1-2 mm thick. The thickness of the entire drain device, including the sheet of the adhesion matrix, drain tubes, and any hooks or glue pads is about 5 mm or less, 10 mm or less, or about 5-10 mm.

The adhesion matrix can be coated with an adhesive material such as a surgical glue either in addition to or instead of using hook or barb structures that stabilize tissue layers on either side of the drain device. Any type of surgical adhesive suitable for use within the body can be used, including polyethylene glycol polymers, adhesive proteins, gelatin-thrombin mixtures, albumin-glutaraldehyde, and fibrin-based sealants. Cyanoacrylates are to be avoided, as they cause inflammation if used internally. An adhesive coating can be placed on one or both surfaces of the adhesion matrix. Adhesive coatings can be applied to the device prior to its placement in a patient, i.e., as part of the device fabrication process. An adhesive coating can cover all or a portion of a surface of the device. A surgical adhesive can be used in the form of a fibrous mat or pad that is soaked with an adhesive composition. The mat or pad is preferably fabricated from a biodegradable polymer, such as the type used to prepare the adhesion matrix. One or more layers of adhesive material can be placed between the device and surrounding tissue at the time of placement in the patient. Figs. 7A-7C illustrate the placement of supplemental adhesive layers with the drainage device. In Fig.

7A, adhesive layer or pad 140 has been placed into a wound or seroma adjacent to exposed tissue 150. In Fig. 7B, drainage device 20 has been placed onto the adhesive layer as shown in Fig. 7A, and the wound then closed and vacuum applied, so that the device-adhesive pad sandwich is surrounded by tissue 150. Fig. 7C depicts the structure obtained if a second adhesive pad or layer 140 is added adjacent to the drainage device on the opposite side of the first adhesive layer.

The invention also provides a method for treating or preventing a seroma as illustrated in Fig. 8. The method also can be used to promote wound closure after surgery 210, to prevent infection after surgery, and to improve the strength and/or cosmetic appearance of a surgical wound after it has fully healed. A drain device according to the invention is positioned into a surgical wound 220, such as a wound following abdominal flap surgery. The device has been sterilized prior to placement within the wound. Optionally, one or more layers of surgical adhesive is placed on one or both sides of the device, interfacing between the device and surrounding tissue 230. If the device includes hooks or barbs on one or both sides, pressure is applied to the surface of the device in order to set the hooks or barbs into the surrounding tissue. The wound is then partially surgically closed at the surface, leaving a single tube exiting the wound. The tube is then attached to a vacuum source 240, and vacuum is applied 250 so as to initiate drainage through the device. The rate of drainage is controlled by the level of vacuum applied. The amount of vacuum is sufficient to promote drainage without causing damage to the tissues surrounding the implanted device. For example, the vacuum can be in the range from about 75 to 250 mm Hg. After the rate of fluid drainage has decreased to acceptable levels, the vacuum is removed and the drain tubes are removed 260 by slowly pulling them out through the remaining wound opening, which is subsequently closed. The adhesion matrix remains in the patient and is biodegraded and absorbed over a period of weeks to months.

Illustrated in connection with Figs. 9A and 9B are uses of a wound dressing in combination with the adhesion matrix or mesh device and a negative pressure drainage system. After placement of the matrix 404, as described in detail herein, the drainage tubing 405 extends through an exit site 409 of the skin 401 of a patient. The wound can frequently require the use of a wound dressing 402 that is placed externally on the skin of a patient. The wound dressing can either overlies the exit site 456 as shown in Fig. 9B, or the wound dressing can be placed laterally (or non-overlying) from the exit site 409 as shown in Fig. 9A. The tubing 405 can either connect directly to the pump 420, or can utilize a connector or manifold 412 positioned on or above the skin 401, which can be connected to the pump 420. A valve 408 can be used to control the application of negative pressure. A flow meter can be included at the connector or manifold 412 or at the valve 408 to measure the fluid removal rate and total amount of fluid removed. A quantitative measure of the fluid removed can thereby be measured and recorded. Other diagnostic measurement devices, such as ultrasound, can also be used to measure the amount and location of fluid or seromas within the wound. This information can be used to adjust the amount and distribution of negative pressure applied within both the wound using drainage system 404, 454 and the wound dressing 402, 452.

Negative pressure can be applied to the wound dressing 402 through separate tube 415 that can be attached to the same pump 420 as the drainage system or a second pump. A valve 406 can be used to regulate pressure to the wound dressing. In the embodiment of Fig. 9B, tube or tubes 458 can exit the wound and attach at connector 462 to the underside of the dressing 452. A manifold 470 can control the distribution of negative pressure to both the dressing 452 and the drainage device 454 using passive or active flow control elements. The manifold can be attached using a single tube 460 to pump 480. The pump 420, 480 can be operated by hand or electronically. The pump can have internal electronic

control, memory and display features 485 to control system operation and record patient data.

Shown in Figs. 10A and 10B are preferred embodiments of drainage tube assemblies that can be used in conjunction with the invention. The drainage tubing 405, 458 preferably exits the wound as a single tube or as a cluster of tubes within an outer tube. The outer tube 504 can either be a flattened shape 500 of a plurality of three or more tubes 502 arranged in line as shown in Fig. 10A, or can be circular 520 with drainage tubes 522 extending within outer tubes 522 to the pump or connector. In certain applications, it may be advantageous to remove the tubes separately at different times from the drainage system as certain regions may drain more quickly. However, for many wounds it is useful to simultaneously remove all drainage tubes from the wound.

Shown in Fig. 11 is a side view of an adhesion matrix or mesh 540 used in preferred embodiments of the invention. It can frequently be useful to employ such a mesh to facilitate wound adhesion and healing using an absorbable material that can adhere on both sides to tissues within a wound. Frequently, these tissue are of different types on opposite sides of the mesh. Thus, the mesh can include a conformable layer 542 having tissue anchors 544, 546 on both sides. However, as one side may be used to attach to the fatty or adipose tissue on the underside of a flap of skin, the first plurality of tissue anchors 544 has a shape and rigidity suitable for attaching to adipose tissue. The second plurality of tissue anchors can be shaped and sized to attach to less compliant tissues such as fascia or muscle. More rigid hooks or barbs are needed to enable this attachment.

Shown in Fig. 12 is a sequence of steps in a method 600 of applying a drainage and wound dressing system in accordance with the invention. After performing a procedure 610 on a patient, a wound closure device is inserted 620 into the wound of a patient. This can be a combination of elements, such as meshes as shown in Fig. 11 in certain regions of the wound, and a drainage and mesh system as described generally herein in regions of the wound

requiring drainage of fluid. This can also include the user 630 of adhesives and/or tissue anchors to enable more direct contact of tissues through the mesh and thereby improve the rate of healing. A wound dressing can also be applied 640 to the wound as described herein. A pump can then be attached 650 to the drainage system and/or the wound dressing and a negative pressure can be applied 660 to one or both elements to drain fluid and promote contact between tissues through the implanted mesh or matrix. The flow rate of fluid through each tube can be measured and recorded 10 and the presence of fluid can be monitored 670 by ultrasound or other systems. The drainage tubing can be removed 680 when the drainage rate diminishes. The wound dressing can be replaced 690 as needed and can continue to be used to drain 690 the wound.

While this invention has been particularly shown and 15 described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and/or details therein and equivalents thereof may be made without departing from the spirit and scope of the invention as set forth by the appended claims.

CLAIMS

What is claimed is:

1. A surgical drain device comprising a plurality of drain tubes
5 positioned with an adhesion matrix, the adhesion matrix having a wound conforming shape and comprising a plurality of apertures for tissue contact through the matrix, the drain tubes being removable from the device and the adhesion matrix comprising a biodegradable polymer.
- 10 2. The device of claim 1 wherein the adhesion matrix further comprises an adhesive.
3. The device of claim 1 wherein the adhesion matrix further
15 comprises a tissue anchor.
4. The device of claim 1 wherein the plurality of drain tubes comprises at least three tubes connected to a manifold.
- 20 5. The device of claim 1 wherein the adhesion matrix comprises a sheet having a thickness of less than 2 mm.
6. A system for surgical wound drainage, the system comprising the drain device of claim 1, a vacuum source, and a tube
25 connecting the vacuum source to the drain tubes of said drain device.
7. The device of claim 1 wherein the adhesion matrix comprises a polymer mesh having a first plurality of tissue anchors on a
30 first side surface and a second plurality of tissue anchors on a second side surface.
8. The device of claim 1 wherein each drain tube extends from a wound entry site at a proximal portion to a distal end
35 positionable within a wound.

9. The system of claim 6 wherein the device further comprises a wound dressing.

10. The system of claim 9 wherein the wound dressing is coupled to a vacuum source.

11. The system of claim 9 wherein the wound dressing overlies a drain tube exit site.

12. The system of claim 6 further comprising a flow regulation system that regulates flow from the drain tubes.

13. The device of claim 1 wherein the apertures have varying sizes.

14. The device of claim 1 wherein the apertures have a total of at least 50 percent of a total surface area of the matrix.

15. The device of claim 7 wherein the first anchors are more rigid than the second anchors.

16. The device of claim 3 wherein the manifold is connectable to a negative pressure source.

17. The device of claim 1 wherein the drain tubes are positioned in a spaced array emanating along different radial directions from an edge of the matrix.

18. The device of claim 1 wherein the drain tubes are positioned in drain channels of the matrix.

19. The device of claim 1 wherein the apertures are positioned to promote flow to the drain tubes.

20. A method for treating or preventing a seroma, the method comprising the steps of:

positioning an adhesion matrix and a drain device into a surgical wound;

5 attaching a negative pressure source to a plurality of drain tubes of said device;

draining fluid from the wound for a period of time; and

removing the drain tubes such that the adhesion matrix remains in the wound.

10

21. The method of claim 20 further comprising attaching tissue to the adhesion matrix with a plurality of tissue anchors.

22. The method of claim 20 further comprising using an adhesive
15 to attach tissue.

23. The method of claim 20 further comprising applying sufficient pressure to provide tissue contact through apertures of the matrix.

20

24. The method of claim 20 further comprising applying a wound dressing to the wound.

25. The method of claim 24 further comprising applying a
25 negative pressure to the wound dressing.

26. The method of claim 20 further comprising attaching the adhesion matrix with a first plurality of tissue anchors to adipose tissue.

30

27. The method of claim 20 further comprising attaching the adhesion matrix with a second plurality of tissue anchors to fascia and/or muscle tissue.

28. The method of claim 20 further comprising measuring a fluid flow rate through the drain device.

29. The method of claim 20 further comprising measuring an amount of seroma within the wound with an ultrasound device.

30. The method of claim 20 wherein the adhesion matrix has fluid channels that receive the drain tube.

31. The method of claim 20 wherein the adhesion matrix comprises apertures that enable flow of fluid laterally into the drain tubes.

32. The method of claim 20 further comprising attaching a wound dressing to the wound and applying negative pressure to the wound dressing.

33. The method of claim 20 further comprising attaching the drain tubes to the adhesion matrix.

34. The method of claim 23 wherein the apertures comprise at least 50 percent of a total matrix surface area.

35. A method for draining a surgical wound, the method comprising the steps of:

positioning a drain device with a plurality of drain tubes into a surgical wound in a body of a subject, each drain tubes of the device extending from a single exit site on the body to a distal end, the tubes being connectable to a negative pressure source; and

draining fluid from the wound through the drain tubes.

36. The method of claim 35 further comprising positioning a polymer matrix adjacent the drain device.

37. The method of claim 36 wherein the matrix comprises a mesh with a first plurality of tissue anchors on a first side and a second plurality of tissue anchors on a second site, the second anchors having a more rigid stem than the first anchors.

5

38. The method of claim 35 further comprising using a matrix with drain channels to receive spaced apart drain tubes.

39. The method of claim 35 further comprising using a matrix with spaced apertures to enable flow to the drain tubes.

10

40. The method of claim 35 further comprising using a matrix with apertures of varying size.

41. The method of claim 35 further comprising applying a wound dressing to the wound and using a pump to apply negative pressure to the wound.

15

42. A surgical drain device comprising matrix having a wound conforming shape and comprising a plurality of apertures for tissue contact through the matrix, the matrix comprising a biodegradable polymer and having regions for receiving a plurality of drainage tubes.

20

43. The device of claim 42 wherein the adhesion matrix further comprises an adhesive.

25

44. The device of claim 42 wherein the adhesion matrix further comprises a tissue anchor.

30

45. The device of claim 42 further comprising a plurality of drain tubes comprises at least three tubes connected to a manifold.

46. The device of claim 42 wherein the adhesion matrix comprises a sheet having a thickness of less than 2 mm.

47. The device of claim 42 wherein each of the apertures have an area in a range of 1 mm² to 5 cm².

48. The device of claim 42 wherein a total area of the apertures is at least 50% of the surface area of the matrix.

49. The device of claim 42 further comprising a first plurality of tissue anchors on a first side and a second plurality of tissue anchors on the second side, the first plurality of tissue anchors adapted to attach to adipose tissue and the second plurality of tissue anchors adapted to attach to fascia and/or muscle tissue.

50. An anchoring matrix comprising a biodegradable mesh, the mesh comprising a first surface with a first plurality of first tissue anchors on the first surface, the mesh further comprising a second surface with a second plurality of tissue anchors on the second surface, the first tissue anchors adapted to attach to a compliant tissue and the second tissue anchors adapted to attach to a less compliant tissue.

51. The anchoring matrix of claim 50 wherein the first plurality of tissue anchors are less rigid than the second plurality of tissue anchors.

52. The anchoring matrix of claim 50 wherein the first plurality of anchors attach to adipose tissue.

53. The anchoring matrix of claim 50 wherein the second tissue anchors attach to fascia and/or muscle tissue.

54. The anchoring matrix of claim 50 wherein the second tissue anchors comprise barbs.

55. The anchoring matrix of claim 50 wherein the matrix comprises a resorbable polymer mesh.

5 56. The anchoring matrix of claim 50 wherein the matrix comprises a plurality of spaced apertures.

57. The anchoring matrix of claim 50 wherein the matrix is porous such that fluid can flow along a matrix surface.

10

58. The anchoring matrix of claim 50 further comprising an adhesive to attach a side of the matrix to tissue.

59. The anchoring matrix of claim 50 wherein tissue anchors
15 comprise hooks.

60. The anchoring matrix of claim 50 wherein the matrix comprises a conformable layer having a thickness less than 2 mm.

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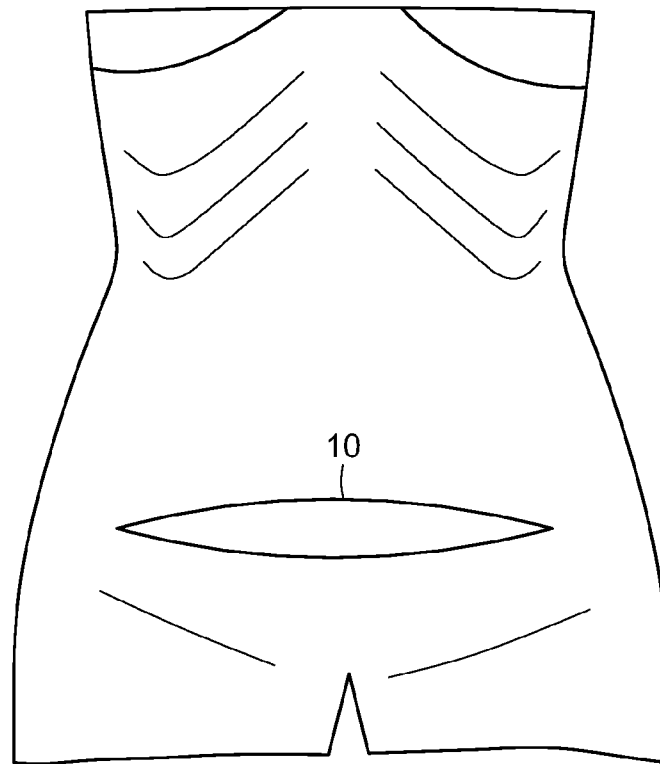


FIG. 1

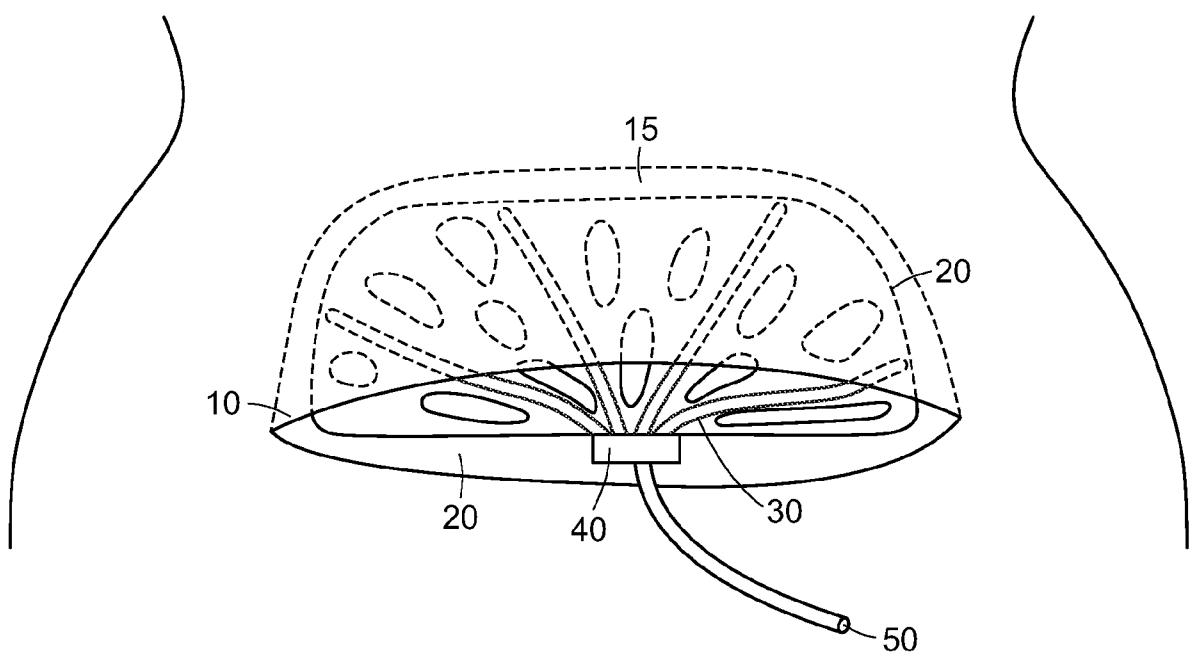


FIG. 2

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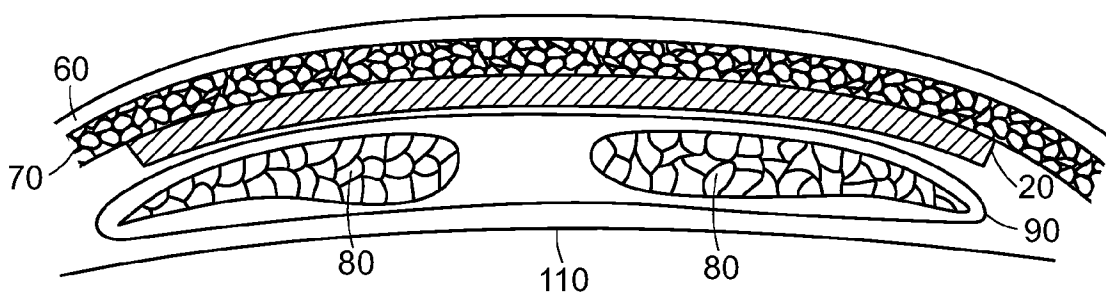


FIG. 3

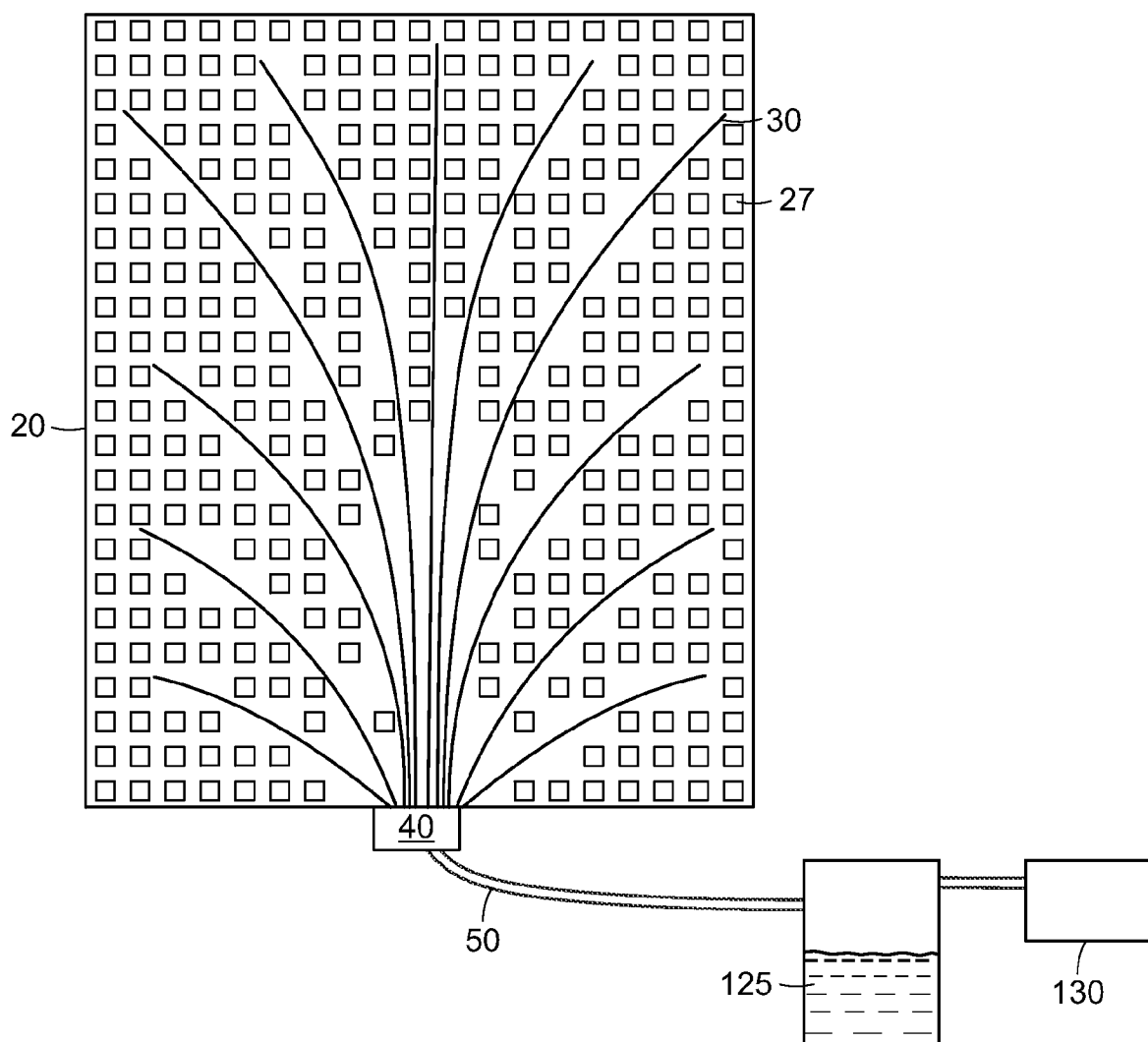


FIG. 4

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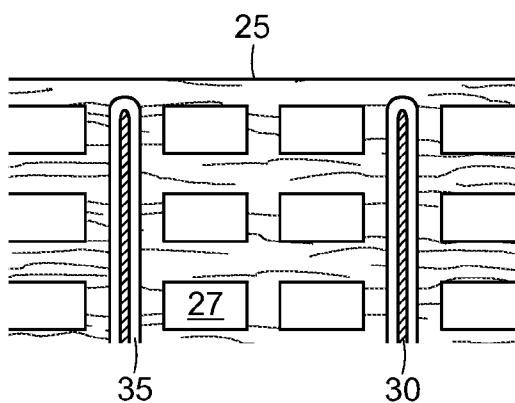


FIG. 5A

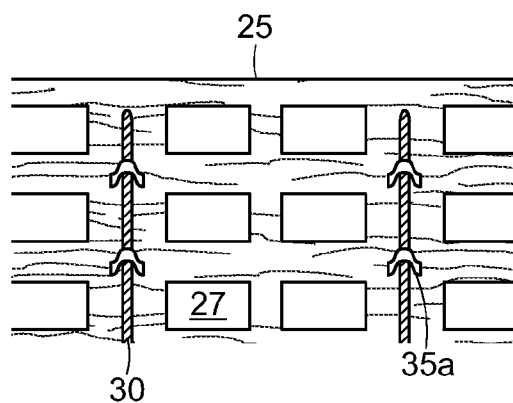


FIG. 5B

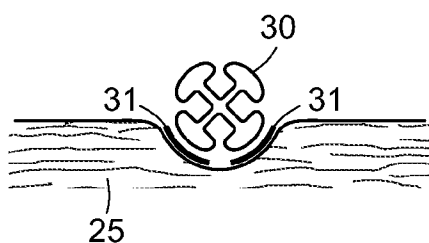


FIG. 5C

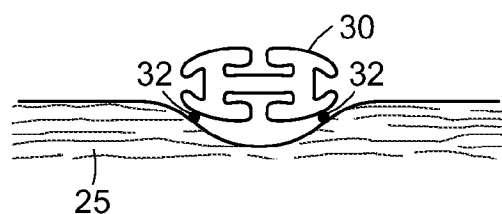


FIG. 5D

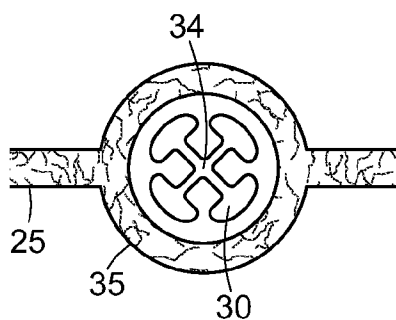


FIG. 5E

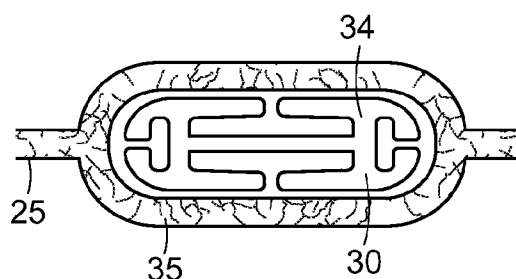


FIG. 5F

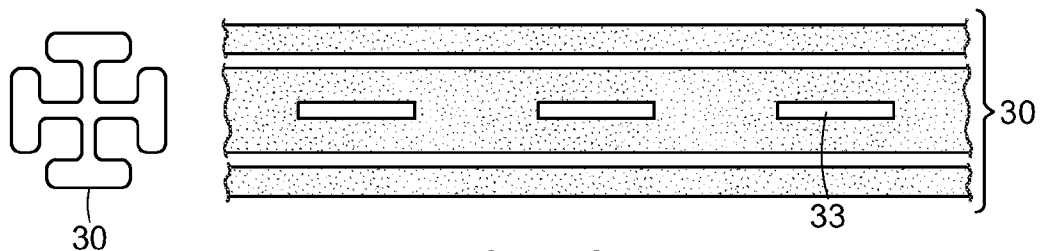
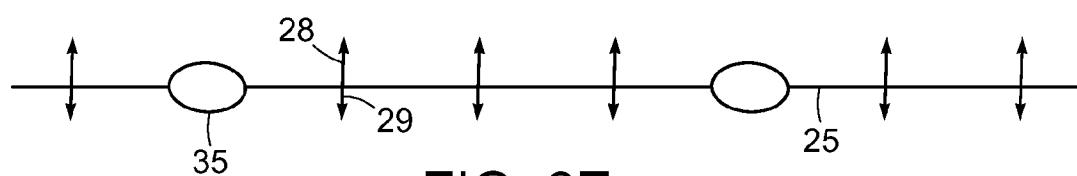
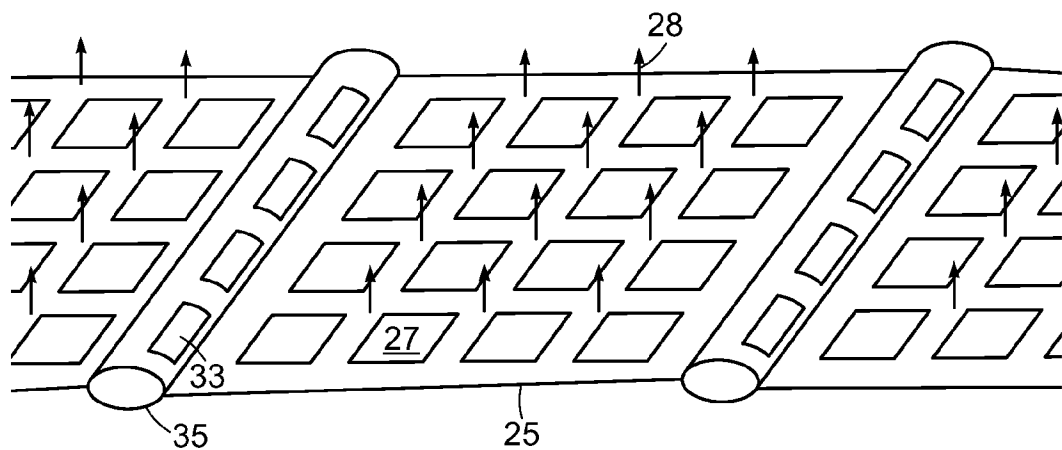
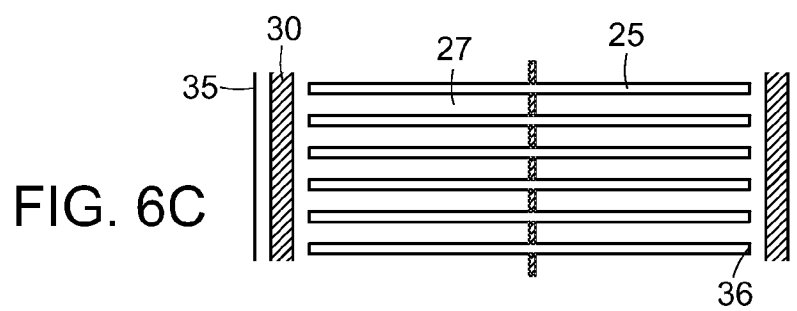
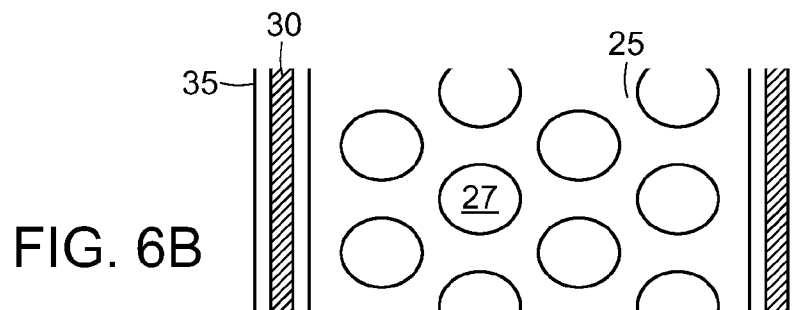
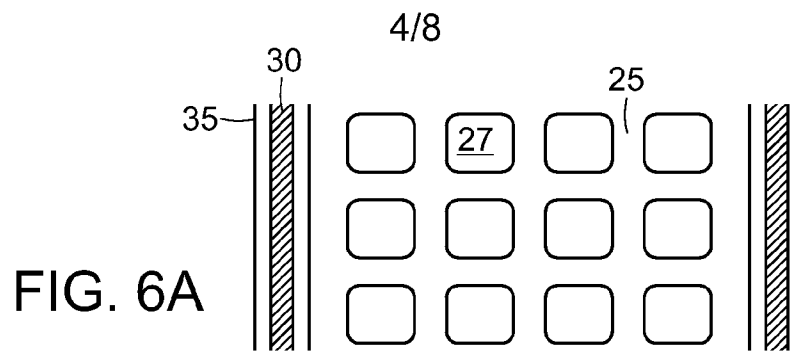


FIG. 5G



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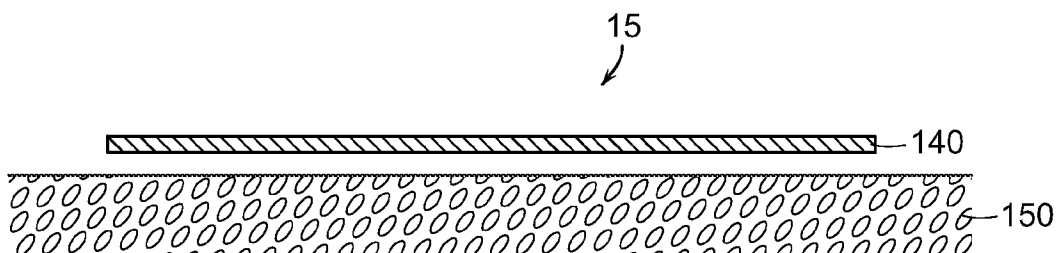


FIG. 7A

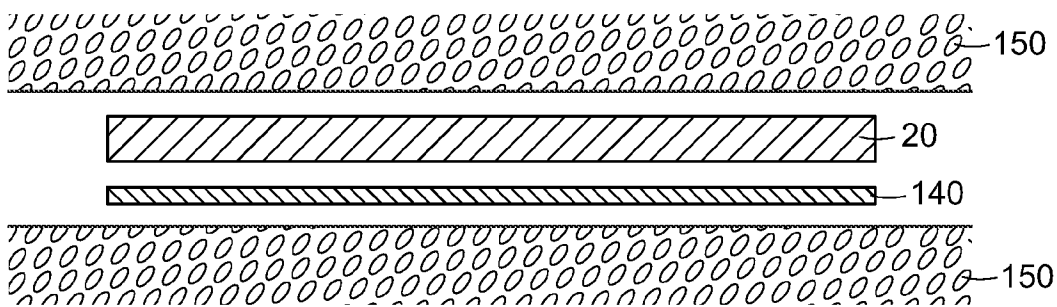


FIG. 7B

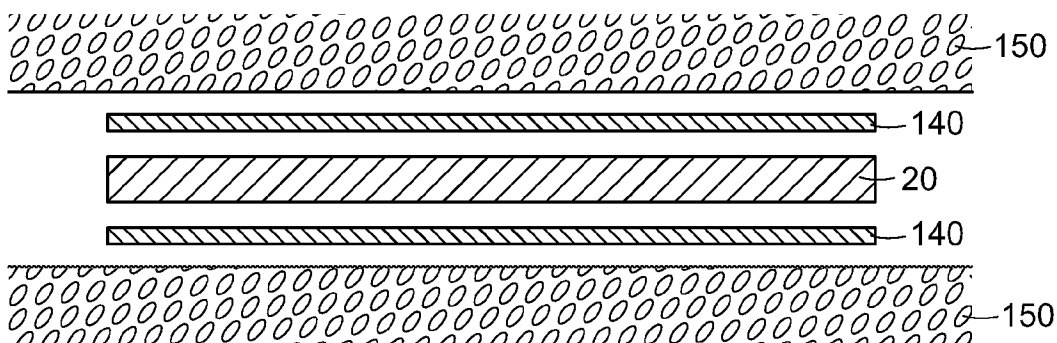


FIG. 7C

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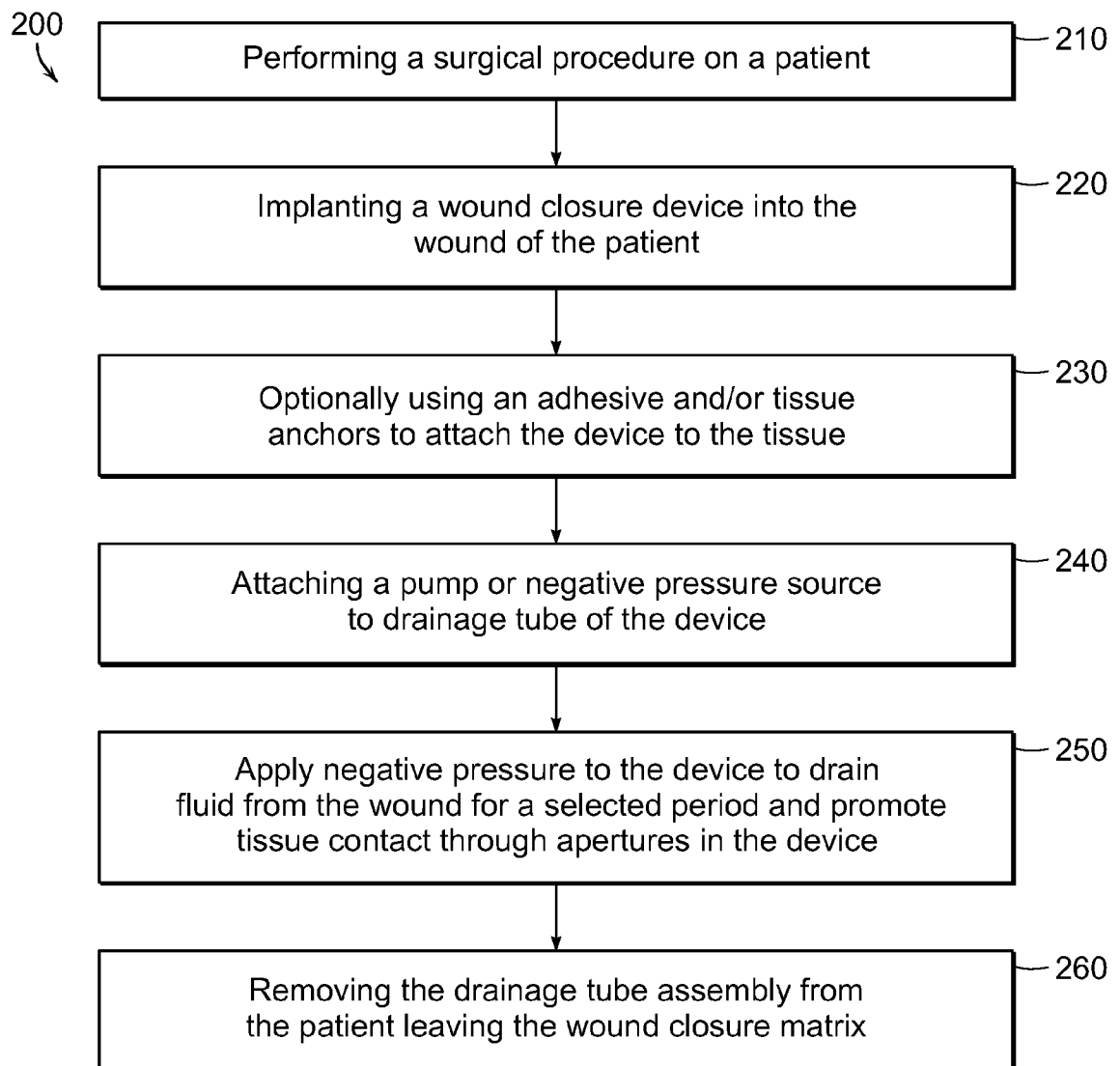


FIG. 8

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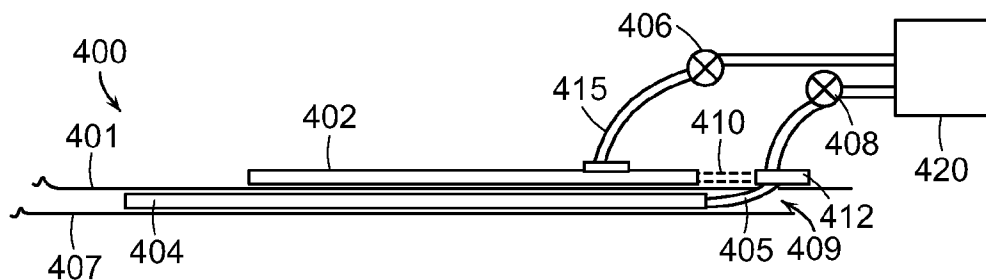


FIG. 9A

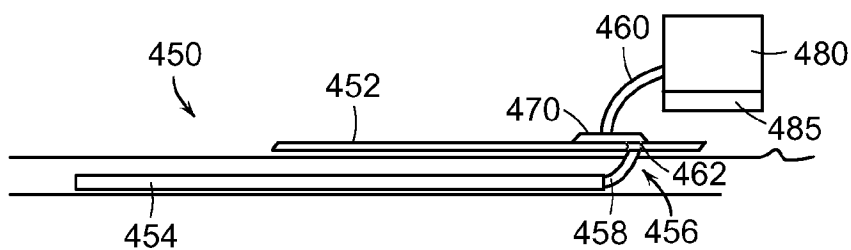


FIG. 9B

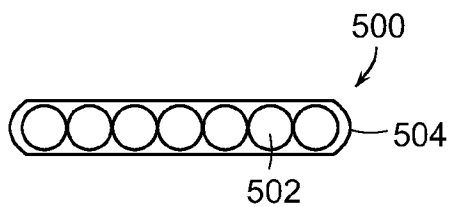


FIG. 10A

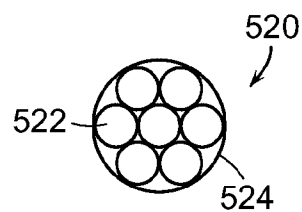


FIG. 10B

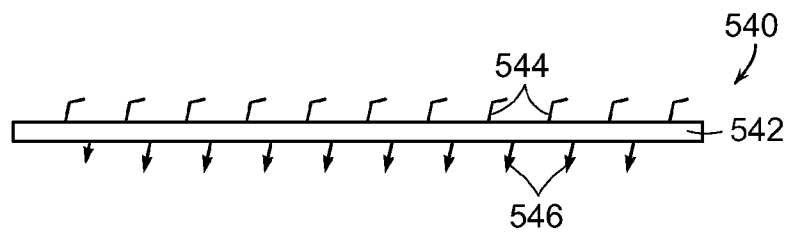


FIG. 11

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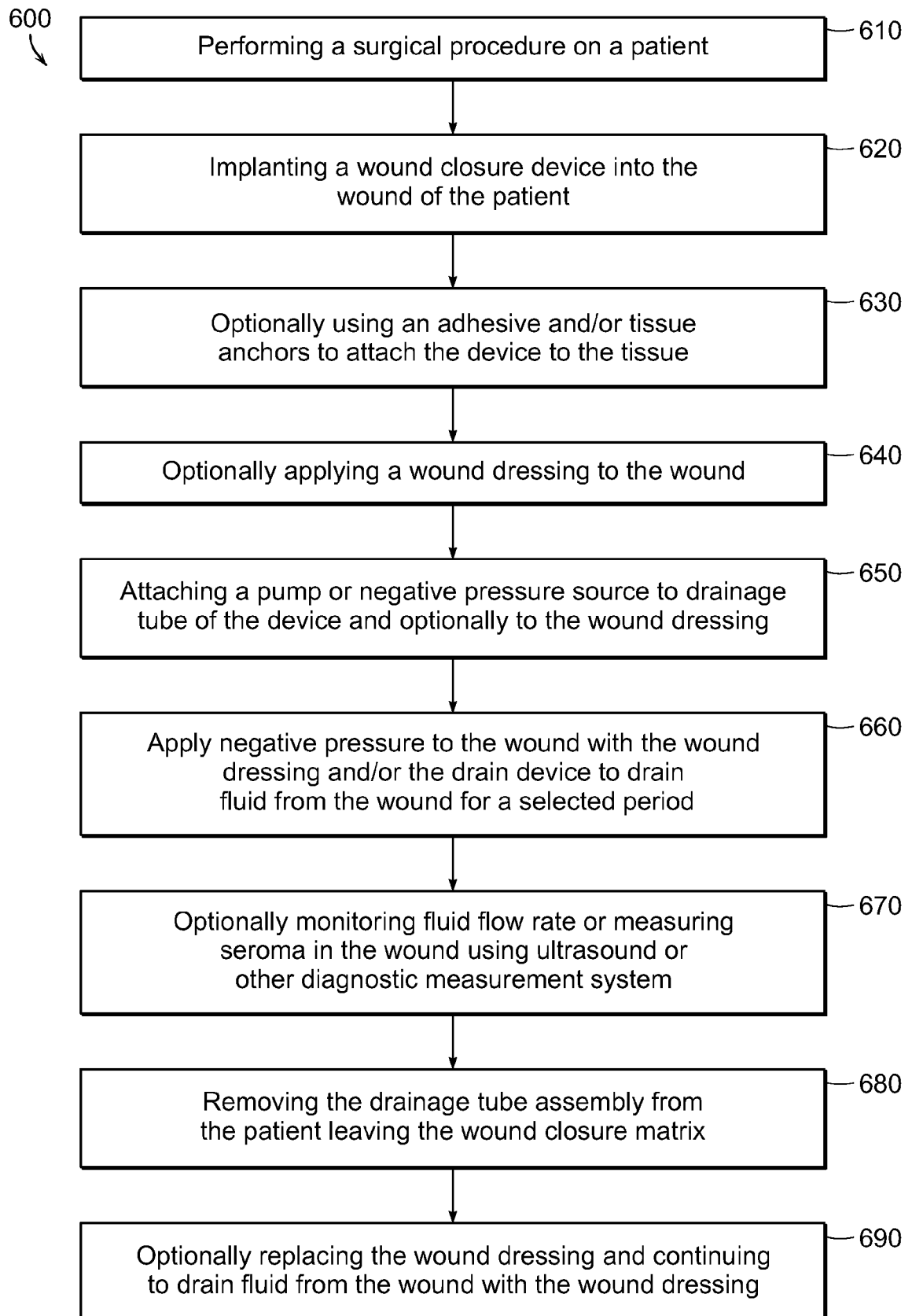


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/33608

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 1/00, 27/00 (2012.01)

USPC - 604/541

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)

ICP(8) - A61M 1/00, 27/00 (2012.01)

USPC - 604/541

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 604/35, 173, 176, 307, 327, 540

(Text Search)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Dialog Classic Files - 2,6,35,64,144,155,315,371,340,344,347,348,349,654,652,345,351; PubWEST (PGPB, USPT, USOC, EPAP, JPAB); Google Scholar; Google. Search terms - surgical;drain;seroma;hernia;mesh;matrix;polymer;plurality;tubes;adhesion; wound;flap; drain;closure;apertures;tissue;matrix;adhesion; biodegradable;polymer;adhesive;?tissue anchor?;

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2008/0033401 A1 (WATSON) 07 February 2008 (07.02.2008) fig 1; para[0006]-[0009], [0015], [0016], [0018]	35 and 40-41 1-34, 36-39 and 42-49
Y	US 2005/0107756 A1 (MCCRAW) 19 May 2005 (19.05.2005) fig 1-4; para [0018], [0039]-[0043]	1-34, 36-38 and 42-49
Y	US 2008/0114277 A1 (AMBROSIO et al.) 15 May 2008 (15.05.2008) para [0010], [0016], [0017], [0035], [0057], [0085]-[0087]	1-19, 23, 34 and 42-60
Y	US 2008/0200950 A1 (WOHLERT) 21 August 2008 (21.08.2008) claims 36-37; para [0017]-[0021], [0029], [0039], [0003], [0067], [0009], [0046], [0047], [0048]	3, 7, 15, 21, 26, 27, 37, 44 and 49-60
Y	US 2010/0160719 A1 (KASSAB et al.) 24 June 2010 (24.06.2010) para [0037], [0040]	19, 31 and 39
Y	US 2010/0234716 A1 (ENGEL) 16 September 2010 (16.09.2010) para [0008], [0009]	29
A	US 2009/0069904 A1 (PICHA) 12 March 2009 (12.03.2009) para [0039], [0042], [0055], [0056], [0020], [0021], [0022]	5, 14, 34, 40, 46, 48
A	US 2011/0004168 A1 (ERIKSSON et al.) 06 January 2011 (06.01.2011) para [0045]; FIG 14	17, 38 and 39

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



* 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 application or patent 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

26 June 2012 (26.06.2012)

Date of mailing of the international search report

05 JUL 2012

Name and mailing address of the ISA/US

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Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/33608

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 2010/0292717 A1 (PETTER-PUCHNER et al.) 18 November 2010 (18.11.2010) para [0018], [0019], [0022], [0015]	22, 43, 47, 55, 56, 58 and 60
A	US 2007/0299541 A1 (CHERNOMORSKY et al.) 27 December 2007 (27.12.2007) para [0058]	29
A	US 5,636,643 A (ARGENTA et al.) 10 June 1997 (10.06.1997) col 8, ln 27-65.	12 and 28