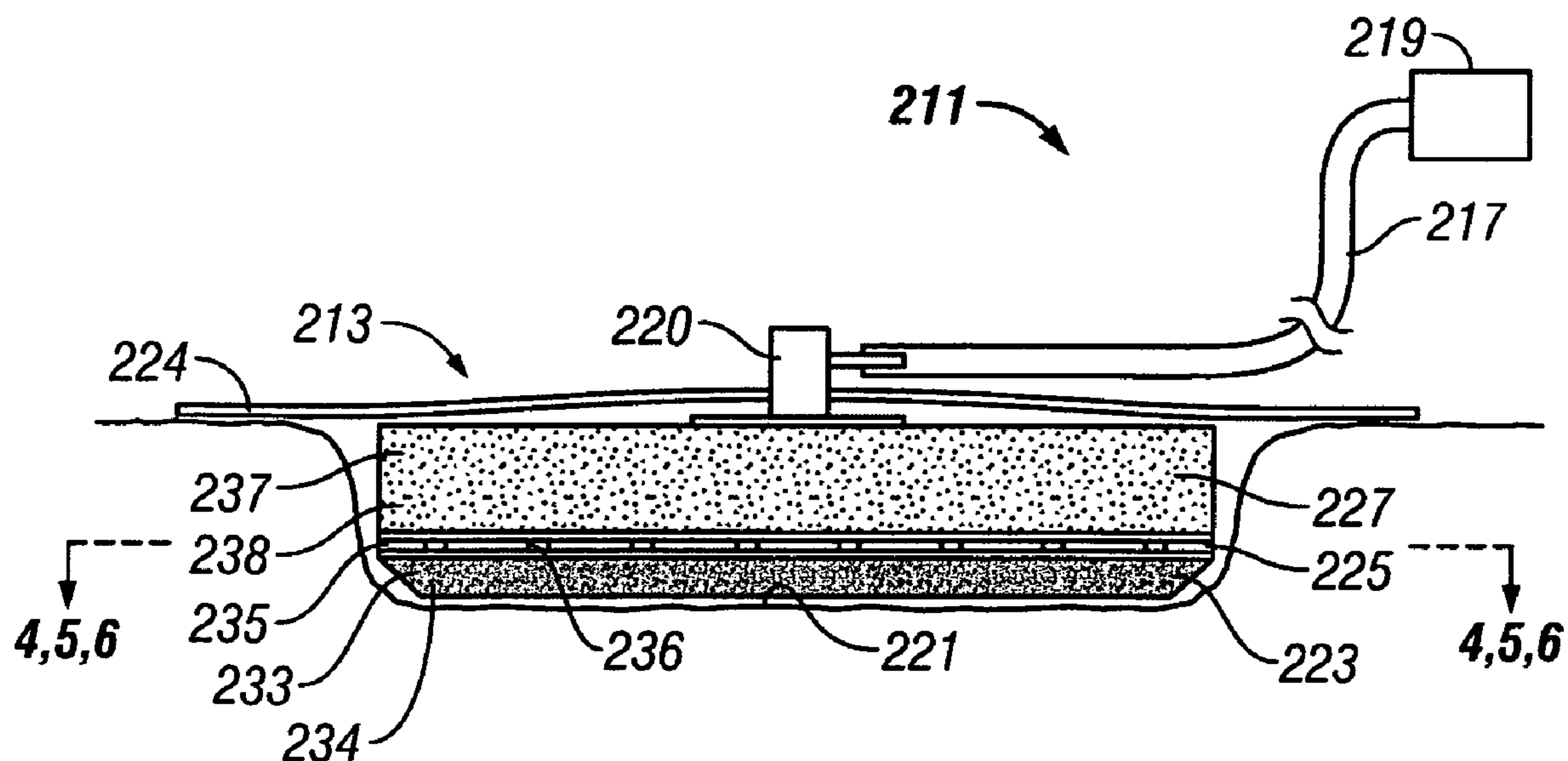




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(57) Abrégé/Abstract:

A multi-layer reduced pressure delivery apparatus is provided for applying reduced pressure tissue treatment to a tissue site. The multi-layer apparatus includes a tissue contact layer, a release layer, and a manifold layer. The tissue contact layer includes a scaffold adapted to contact the tissue site, the release layer includes a hydrogel-forming material and a plurality of flow channels, and the manifold layer includes a distribution manifold. The release layer is positioned between the tissue contact layer and the manifold layer to allow easy release of the manifold layer from the tissue contact layer following the administration of reduced pressure tissue treatment.



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(54) Title: **BIOCOMPATIBLE WOUND DRESSING**

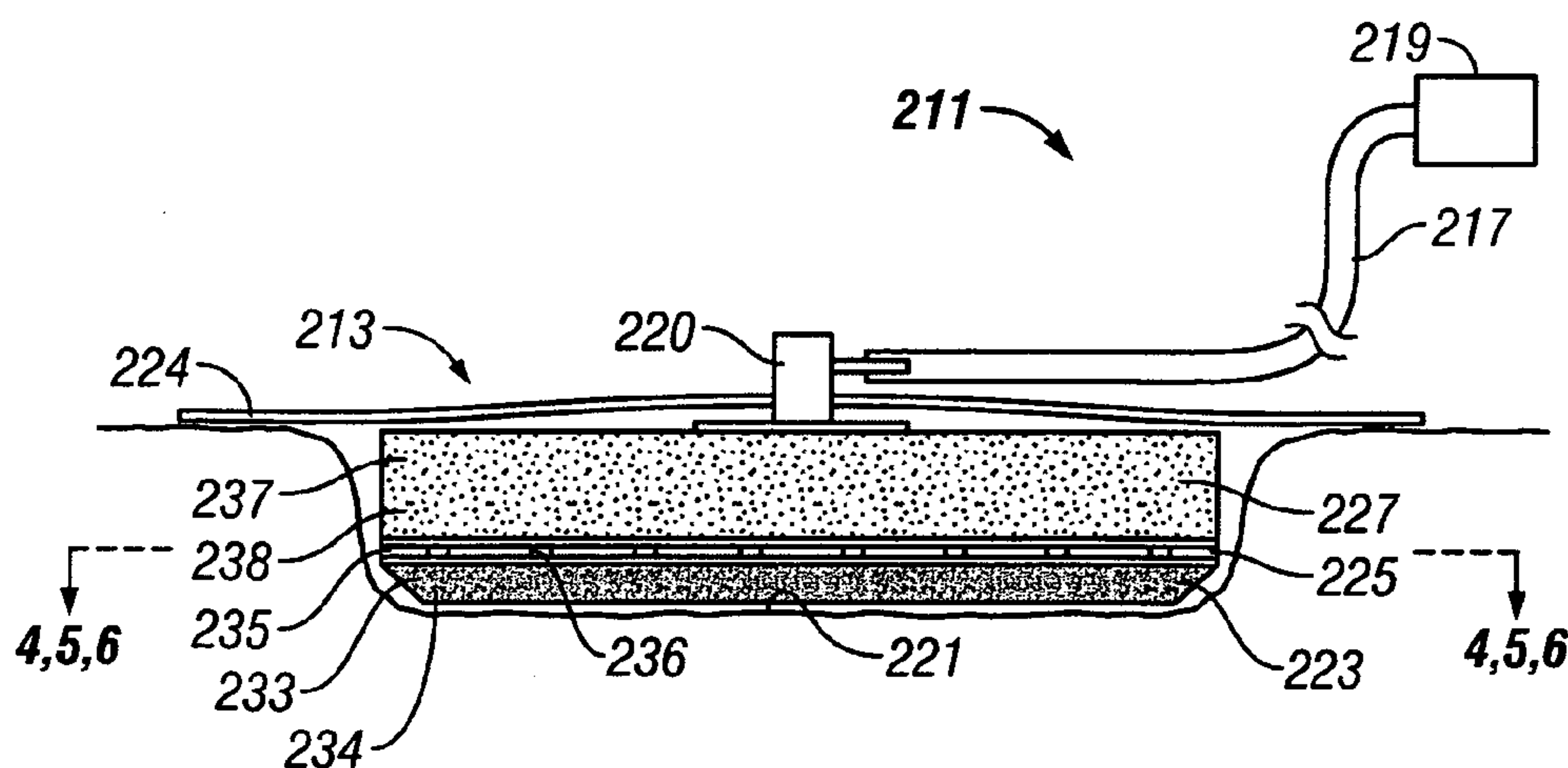


FIG. 2

(57) Abstract: A multi-layer reduced pressure delivery apparatus is provided for applying reduced pressure tissue treatment to a tissue site. The multi-layer apparatus includes a tissue contact layer, a release layer, and a manifold layer. The tissue contact layer includes a scaffold adapted to contact the tissue site, the release layer includes a hydrogel-forming material and a plurality of flow channels, and the manifold layer includes a distribution manifold. The release layer is positioned between the tissue contact layer and the manifold layer to allow easy release of the manifold layer from the tissue contact layer following the administration of reduced pressure tissue treatment.

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BIOCOMPATIBLE WOUND DRESSING

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates generally to a system or method of promoting tissue growth and more specifically to a multi-layer wound dressing having a tissue growth medium for enhancing the growth of tissue when exposed to reduced pressure.

2. Description of Related Art

10 Vacuum induced healing of open wounds has recently been popularized by Kinetic Concepts, Inc. of San Antonio, Tex., by its commercially available V.A.C.® product line. The vacuum induced healing process has been described in commonly assigned U.S. Pat. No. 4,969,880 issued on Nov. 13, 1990 to Zamierowski, as well as its continuations and continuations in part, U.S. Pat. No. 5,100,396, issued on Mar. 31, 1992, U.S. Pat. No. 5,261,893, issued Nov. 16, 1993, and U.S. Pat. No. 5,527,293, issued Jun. 18, 1996. Further improvements and modifications of the vacuum induced healing process are also described in U.S. Pat. No. 15 6,071,267, issued on Jun. 6, 2000 to Zamierowski and U.S. Pat. Nos. 5,636,643 and 5,645,081 issued to Argenta et al. on Jun. 10, 1997 and Jul. 8, 1997 respectively.

Substantial work has also been performed relating to the creation of bioabsorbable and includable, cell growth enhancing matrices, lattices, or scaffolds. Exemplary U.S. patents known to applicant include Kemp et al. U.S. Pat. No. 5,256,418 issued Oct. 26, 1993; 20 Chatelier et al. U.S. Pat. No. 5,449,383 issued Sep. 12, 1995; Bennett et al. 5,578,662 issued Nov. 26, 1996; and two patents issued to Yasukawa et al. U.S. Pat. No. 5,629,186 issued May 13, 1997 and U.S. Pat. No. 5,780,281 issued Jul. 14, 1998, both from a common parent application.

As is well known to those of ordinary skill in the art, closure of surface wounds 25 involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion; thereafter, cleanup and rebuilding operations may begin. Unfortunately, this process is 30 hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e.

an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but also are less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until the advent of vacuum induced therapy, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples may cause very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative gauge pressure, commercialized by Assignee or its parent under the designation "Vacuum Assisted Closure" (or "V.A.C.®") therapy, typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, V.A.C.® therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While V.A.C.® therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the very nature of V.A.C.® therapy dictates an atmospherically sealed wound site, the

therapy must often be performed to the exclusion of other beneficial, and therefore desirable, wound treatment modalities. One of these hitherto excluded modalities is the encouragement of cell growth by the provision of an in situ cell growth-enhancing matrix.

Additional difficulty remains in the frequent changing of the wound dressing. As the wound closes, binding of cellular tissue to the wound dressing may occur. Use of traditional V.A.C.® therapy necessitates regular changing of the dressing. Reckless dressing changes can result in some tissue damage at the wound site if cellular tissue has grown excessively into the dressing.

BRIEF SUMMARY OF THE INVENTION

The problems presented by existing tissue dressings are solved by the systems and methods of the present invention. In accordance with one embodiment of the present invention, a reduced pressure delivery system is provided for applying reduced pressure tissue treatment to a tissue site. The reduced pressure delivery system includes a multi-layer reduced pressure delivery apparatus having a tissue contact layer, a release layer, and a manifold layer. The tissue contact layer includes a scaffold adapted to contact the tissue site. The release layer includes a hydrogel-forming material and a plurality of flow channels, and the manifold layer includes a distribution manifold. The release layer is positioned between the tissue contact layer and the manifold layer, and the hydrogel-forming material of the release layer binds to at least one of the tissue contact layer and the manifold layer. A reduced-pressure delivery tube is fluidly connected to the manifold layer to deliver a reduced pressure to the tissue site.

In accordance with another embodiment of the present invention, a multi-layer reduced pressure delivery apparatus includes a first layer having a scaffold adapted to contact a tissue site and a second layer having a hydrogel-forming material and a plurality of flow channels. The hydrogel-forming material contacts the scaffold. The reduced pressure delivery apparatus further includes a third layer having a distribution manifold contacting the hydrogel-forming material.

In still another embodiment of the present invention, a multi-layer reduced pressure delivery apparatus includes a tissue contact, a manifold layer, and a release layer. The tissue contact layer includes a scaffold adapted to contact the tissue site to receive in-growth of new tissue from the tissue site. The tissue contact layer further includes a first plurality of flow channels. The manifold layer includes a cellular material and a third plurality of flow channels, the cellular material being capable of distributing a reduced pressure to the tissue site. The release layer is positioned between the tissue contact layer and the manifold layer

and includes a hydrogel-forming material connected to at least one of the tissue contact layer and the manifold layer. The hydrogel-forming material is adapted to form a hydrogel upon the absorption of a fluid to release the at least one of the tissue contact layer and the manifold layer. The release layer further includes a second plurality of flow channels in fluid
5 communication with the first and third plurality of flow channels.

In accordance with yet another embodiment of the present invention, a reduced pressure delivery apparatus is provided for applying reduced pressure tissue treatment to a tissue site. The reduced pressure delivery apparatus includes a scaffold adapted to contact a tissue site to receive in-growth of new tissue from the tissue site, a distribution manifold
10 adapted to distribute a reduced pressure to the tissue site through the scaffold, and a release material positioned between and in contact with the scaffold and the distribution manifold to substantially prevent contact between the scaffold and the distribution manifold in areas where the release material is disposed.

Also in accordance with the present invention, another embodiment of the reduced
15 pressure delivery system includes a reduced pressure delivery apparatus having a distribution manifold, a scaffold, and a hydrogel-forming material. The distribution manifold distributes a reduced pressure, and the scaffold encourages in-growth of new tissue from a tissue site. The distribution manifold and scaffold are bound together by the hydrogel-forming material, which is positioned between the distribution manifold and the scaffold. The system further includes
20 a reduced-pressure delivery tube having a distal end fluidly connected to the distribution manifold to deliver the reduced pressure through the distribution manifold and scaffold to the tissue site.

In accordance with another embodiment of the present invention, a tissue growth kit for promoting new tissue growth at a tissue site is provided. The tissue growth kit includes a
25 scaffold having a first and a second side, the first side adapted to contact the tissue site; a hydrogel-forming material adapted to contact the second side of the scaffold; and a distribution manifold adapted to contact the hydrogel-forming material to distribute a reduced pressure to the tissue site through the scaffold.

In yet another embodiment of the present invention, a method for promoting new tissue
30 growth at a tissue site includes positioning a scaffold in contact with the tissue site, positioning a hydrogel-forming material in contact with the scaffold, and positioning a manifold in contact with the hydrogel-forming material. A reduced pressure is applied to the tissue site through the manifold and scaffold.

In still another embodiment of the present invention, a method for promoting new tissue growth at a tissue site includes positioning a multi-layer reduced pressure delivery apparatus in contact with the tissue site. The multi-layer reduced pressure delivery apparatus includes a tissue contact layer having a scaffold adapted to contact the tissue site and a manifold layer having a distribution manifold. The reduced pressure delivery apparatus further includes a release layer having a hydrogel-forming material and a plurality of flow channels. The release layer is positioned between the tissue contact layer and the manifold layer, and the hydrogel-forming material of the release layer binds to at least one of the tissue contact layer and the manifold layer. The multi-layered reduced pressure delivery apparatus is oriented such that the tissue contact layer contacts the tissue site. A reduced pressure is applied to the tissue site through the distribution manifold, the flow channels, and the scaffold.

In another embodiment of the present invention, a method for promoting new tissue growth at a tissue site includes positioning a multi-layer reduced pressure delivery apparatus in contact with the tissue site. The multi-layer reduced pressure delivery apparatus includes a first layer having a scaffold adapted to contact the tissue site, and a second layer having a hydrogel-forming material and a plurality of flow channels. The hydrogel-forming material contacts the scaffold. A third layer having a distribution manifold contacts the hydrogel-forming material. The multi-layered reduced pressure delivery apparatus is oriented such that the tissue contact layer contacts the tissue site, and a reduced pressure is applied to the tissue site through the distribution manifold, the flow channels, and the scaffold.

In accordance with yet another embodiment of the present invention, a method for promoting new tissue growth at a tissue site includes positioning a scaffold in contact with the tissue site, a hydrogel-forming material in contact with the scaffold, and a distribution manifold in contact with the hydrogel-forming material. New tissue growth is stimulated at the tissue site by applying a reduced pressure to the tissue site through the distribution manifold and the scaffold.

Other objects, features, and advantages of the present invention will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a partially cut away perspective view of a wound dressing according to an embodiment of the present invention, the wound dressing being shown applied to a tissue site;

5 FIG. 2 depicts a cross-sectional side view of a reduced pressure delivery system according to an embodiment of the present invention, the system including a reduced pressure delivery apparatus having a tissue contact layer, a release layer, and a manifold layer;

10 FIG. 3 illustrates a cross-sectional side view of a reduced pressure delivery system according to an embodiment of the present invention, the system including a reduced pressure delivery apparatus having a tissue contact layer, a release layer, and a manifold layer;

FIG. 4 depicts a top view of one embodiment of the release layer of FIGS. 2 and 3 taken at 4-4;

FIG. 5 illustrates a top view of another embodiment of the release layer of FIGS. 2 and 3 taken at 5-5;

15 FIG. 6 depicts a top view of still another embodiment of the release layer of FIGS. 2 and 3 taken at 6-6;

FIG. 7 illustrates a method of promoting new tissue growth at a tissue site according to one embodiment of the present invention;

20 FIG. 8 depicts a method of promoting new tissue growth at a tissue site according to another embodiment of the present invention; and

FIG. 9 illustrates front view of a tissue growth kit according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific preferred embodiments in which the invention may be practiced. These
5 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 invention, the description may omit certain information known to those
10 skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

The term “manifold” as used herein generally refers to a substance or structure that is provided to assist in applying reduced pressure to, delivering fluids to, or removing fluids from a tissue site. A manifold typically includes a plurality of flow channels or pathways that
15 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 foam such as open-cell foam, porous tissue collections, and liquids, gels and foams that include or cure to include flow channels.

20 The term “reduced pressure” as used herein generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Although the terms “vacuum” and “negative pressure” may be used to describe the pressure applied to the tissue site, the actual pressure applied to the tissue site may be significantly less
25 than the pressure normally associated with a complete vacuum. Reduced pressure may initially generate fluid flow in the tube and the area of the tissue site. As the pressure around the tissue site approaches the desired reduced pressure, the flow may subside, and the reduced pressure is then maintained. Unless otherwise indicated, values of pressure stated herein are gage pressures.

30 The term “scaffold” as used herein refers to a substance or structure used to enhance or promote the growth of cells and/or the formation of tissue. A scaffold is typically a three dimensional porous structure that provides a template for cell growth. The scaffold may be infused with, coated with, or comprised of cells, growth factors, extracellular matrix

components, nutrients, integrins, or other substances to promote cell growth. A scaffold may be used as a manifold in accordance with the embodiments described herein to administer reduced pressure tissue treatment to a tissue site.

5 The term "tissue site" as used herein refers to a wound or defect located on or within any tissue, including but not limited to, bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments. The term "tissue site" may further refer to areas of any tissue that are not necessarily wounded or defective, but are instead areas in which it is desired to add or promote the growth of additional tissue. For example, reduced pressure tissue treatment may be used in certain tissue areas to grow
10 additional tissue that may be harvested and transplanted to another tissue location.

The present invention is a biocompatible wound dressing for use with negative pressure therapy. The term "wound" as used herein, may include burns, incisional wounds, excisional wounds, ulcers, traumatic wounds, and chronic open wounds. As used herein, the term "pad" refers to foam, screens, other porous-like materials. The term "conventional pad"
15 refers to polyurethane (PU) or polyvinylalcohol (PVA) foams commonly used with V.A.C.® therapy. The term "V.A.C.® therapy" as used herein, refers to negative pressure wound therapy as commercialized by the assignee or its parent, and further described in the aforementioned patents and patent applications.

Referring now to the figures, the present invention 10 is shown to generally comprise a
20 foam pad 11 for insertion substantially into the wound site 12 and a wound drape 13 for sealing enclosure of the foam pad 11 at the wound site 12. According to the invention, the foam pad 11 is modified to contain a cell growth-enhancing matrix, or lattice 14, whereby a desired highly porous cell growth enhancing substrate may be directed into and about the wound site 12. After insertion into the wound site 12 and sealing with the wound drape 13, the
25 foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage, as known to those of ordinary skill in the art. Foam pad 11 is modified from prior art pads in that the pad 11 comprises matrix 14 that is noninvasive to the known V.A.C.® therapy and therefore requires no modification thereof.

30 According to the preferred embodiment of the present invention, the foam pad 11, wound drape 13 and vacuum source are implemented as known in the prior art, with the exception of those modifications to the foam pad 11 detailed further herein. Each of these components is detailed in U.S. patent No. 7,611,500 filed Oct. 16, 1997.

As detailed in the '832 application, the foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction. As also detailed in the '832 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 15, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump. Finally, the '832 application also details the wound drape 13, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '832 application are generally employed as known in the art with the exception that the foam pad 11 is provided with a matrix 14. This matrix 14 is shown to comprise porous material 16 that has *been* formed into a plurality of sections 17. The material 16 is implanted in the foam pad 11 at the base 18 of the pad 11. Because it is necessary to trim the foam pad 11 in preparation for V.A.C.® therapy wound treatment, material 16 preferably is placed in the central portion of pad 11. Applicant does not intend to limit itself to a regular or symmetrical arrangement of material 16 or sections 17 by use of the term "matrix".

Alternatively, or in addition to the preferred embodiment, the foam pad may be comprised of bioabsorbable branched polymers alone (not shown), or in combination with the matrix 14.

Upon placement of the pad 11, having the matrix 14 embedded therein, and/or protruding therefrom, and/or comprised of bioabsorbable branched polymers, the wound drape 13 is applied over the pad to form an airtight seal over the wound site. In use, the V.A.C.® therapy is conducted as known and, if desired, cell growth enhancement therapy is added by simply providing the matrix 14 comprising material 16. In this manner, cell growth enhancement therapy may be conveniently combined with existing V.A.C.® therapies, without loss of V.A.C.® therapy performance and without inconvenience or overly increased cost.

EXAMPLE I

The above described open celled foam is formed into a pad. The general principles set forth in U.S. Pat. No. 5,795,584 issued to Totakura et al on Aug. 18, 1998 at Col. 5 lines 5 42, are followed to create a structure superimposed on the bottom of the pad. Holes are placed in those portions of the non-bioabsorbable substrate relatively remote from the bioabsorbable cell growth enhancing matrix substrate. The matrix covers a portion of the pad located within the boundaries of the wound being treated. The pad is then completely covered by an airtight drape, and subjected to sub atmospheric pressure, as is the standard practice for utilizing V.A.C.® therapy. The matrix is absorbed within the expected useful life of the pad, so, that when the pad is removed, the matrix had been absorbed, and the growing cells are not disturbed. The pad is replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

EXAMPLE II

A conventional pad is selected. A collagen cell growth matrix is applied to a portion of the bottom thereof. The general principles of V.A.C.® therapy are followed, with the matrix containing pad substituted for a conventional pad. During the expected duty cycle of the pad, the collagen matrix is absorbed by the growing cells, so that when the pad is removed, the matrix had been absorbed, and the growing cells are not disturbed. The pad is replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

EXAMPLE III

The procedure set forth in EXAMPLE II is followed. However, an ultra-low density fused-fibrous ceramic, sometimes referred to under the trademark P.R.I.M.M., is substituted for the collagen matrix thereof. The general principles of V.A.C.® therapy are followed. During the expected duty cycle of the pad, the ultra-low density fused-fibrous ceramic is absorbed by the growing cells, so that when the pad is removed, the ultra-low density fused-fibrous ceramic had been absorbed, and the growing cells were not disturbed. The pad is replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

EXAMPLE IV

Many suitable bioabsorbable materials have been used for sutures, surgical implements, and the like. A small sample of these materials are set forth in the following U.S. patents, to wit: U.S. Pat. No. 5,997,568, issued to Lin on Dec. 7, 1999 and the following

patents issued in 1999 to Roby et al.: U.S. Pat. Nos. 5,914,387; 5,902,874 and 5,902,875. A selected one or more of these, or similar materials, are placed upon a conventional pad. The general principles of V.A.C.® therapy are followed. During the expected duty cycle of the pad, the bioabsorbable material is absorbed by the growing cells, so, that when the pad is removed, the bioabsorbable material had been absorbed, and the growing cells were not disturbed. The pad is replaced, if necessary, either by a conventional pad or by a matrix containing pad, as deemed therapeutically necessary.

EXAMPLE V

A bioabsorbable branched polymer, similar to that described in U.S. Pat. No. 5,578,662 issued to Bennet et al., forms the pad. The general principles of V.A.C.® therapy are followed with the bioabsorbable branched polymer pad substituted for the conventional pad. During the expected duty cycle of the pad, the pad is absorbed by the growing cells, so that there is no need to replace the pad and disturb the wound site. If further treatment is deemed necessary, a conventional pad, or an additional matrix containing pad, or an additional bioabsorbable branched polymer pad may be placed in the wound site, and V.A.C.® therapy continued.

Referring to FIGS. 2 and 3, a reduced pressure delivery system 211 according to an embodiment of the present invention includes a biocompatible wound or tissue dressing, or reduced pressure delivery apparatus, 213, a reduced pressure delivery tube 217, and a reduced pressure source 219. The reduced pressure delivery system 211 is provided to administer a reduced pressure tissue treatment to a tissue site 221 of a person. The tissue site may include a burn or other wound, or alternatively may be healthy tissue upon which it is desired to promote new tissue growth. The reduced pressure source 219 is fluidly connected to a distal end of the reduced pressure delivery tube 217, and the reduced pressure delivery apparatus 213 is fluidly connected to a proximal end of the reduced pressure delivery tube 217. In FIG. 2, the reduced pressure delivery tube 217 is fluidly connected to the reduced pressure delivery apparatus 213 by a tubing connector 220 similar to that illustrated in FIG. 1. In FIG. 3, the reduced pressure delivery tube 217 is placed directly inside or adjacent to the reduced pressure delivery apparatus 213 and may include a plurality of apertures 222 for communicating with the reduced pressure delivery apparatus 213. The reduced pressure source delivers a reduced pressure through the reduced pressure delivery tube 217 to the reduced pressure delivery apparatus 213, and the reduced pressure delivery apparatus 213 distributes the reduced pressure to the tissue site 221. A membrane 224 is positioned over the reduced pressure delivery apparatus 213 and sealingly connected to the tissue surrounding the tissue site 221.

The membrane 224 reduces contamination of the tissue site 221 and assists in maintaining the reduced pressure at the tissue site 221.

The reduced pressure delivery apparatus 213 is a multi-layer apparatus having a first layer, or tissue contact layer 223, a second layer, or release layer 225, and a third layer, or manifold layer 227. The first layer 223 includes a scaffold 233 and a first plurality of flow channels 234. The second layer 225 includes a release material 235 such as a hydrogel-forming material or a water-soluble polymer. The second layer 225 further includes a second plurality of flow channels 236. The third layer 227 includes a distribution manifold 237 and a third plurality of flow channels 238. The three layers are arranged such that the second layer 225 is positioned between the first layer 223 and the third layer 227, the first layer 223 being adjacent to the second layer 225, the second layer 225 being adjacent to the first and third layers 223, 227, and the third layer 227 being adjacent to the second layer 225.

In one embodiment, each of the layers 223, 225, 227 is connected to adjacent layers by any connection means appropriate for the type of material in each layer. For example, the third layer 227 may be bonded to the second layer 225, or the first layer 223 may be bonded to the second layer 225, or all three layers 223, 225, 227 may be bonded together. Bonding may be accomplished by heating one, both, or all of the layers at their interface and applying a force to press the layers into a bonded connection. Alternatively, adhesives or mechanical fasteners may be used to connect the layers to one another as long as the fastening or bonding means does not substantially and negatively affect the distribution of pressure through the layers. In another embodiment, the layers 223, 225, 227 may not be connected to one another, but rather, the layers 223, 225, 227 may simply be placed in contact with one another prior to and/or during application of the reduced pressure tissue treatment. Alternatively, two of the layers may be bonded to one another, and a third of the layers placed in contact with one of the two bonded layers. For example, the second layer 225 may be connected to the third layer 227 in a way described previously, and the first layer 223 may be placed in contact with, but not connected to, the second layer 225. Instead, the second layer 225 may be connected to the first layer 223, and the second layer 225 may be placed in contact with, but not connected to, the third layer 227.

The first, second, and third plurality of flow channels 234, 236, 238 are provided in the first, second, and third layers 223, 225, 227, respectively, to allow distribution of reduced pressure within the reduced pressure delivery apparatus 213 and to the tissue site 221. The flow channels provided in each layer may be an inherent characteristic of the material

provided in that layer (e.g. a naturally porous material), or the flow channels may be chemically, mechanically, or otherwise formed in the material prior to or after assembly of the three layers 223, 225, 227. The placement of the layers 223, 225, 227 adjacent to one another allows the flow channels in one layer to fluidly communicate with the flow channels in the adjacent layer. For example, the relative positioning or connection of the layers as described above allow the first plurality of flow channels 234 to fluidly communicate with the second plurality of flow channels 236, which are capable of fluidly communicating with the third plurality of flow channels 238.

The scaffold 233 of the first layer, or tissue contact layer, 223 promotes new tissue growth and accepts in-growth of new tissue from the tissue site 221. The scaffold 223 may be any porous, bioresorbable material that is capable of accepting and/or integrating new tissue growth into the scaffold. The pores of the scaffold 233 are preferably interconnected to define the first plurality of flow channels 234, but additional flow channels may be provided by mechanically, chemically, or otherwise forming the flow channels within the scaffold.

Suitable scaffold materials may include, without limitation, polylactic acid (PLA), polyglycolic acid (PGA), polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyorthoesters, polyphosphazenes, polyurethanes, collagen, hyaluronic acid, chitosan, and copolymers, terpolymers, or blends of these materials. Additional materials, which may be used with hard tissue applications include, but are not limited to, ceramics such as hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate or other carbonates, bioglass, allografts, autografts, and composites of these ceramics with the previously listed polymeric materials. The scaffold material may further include a polymeric blend of PLA, PGA, polycarbonates, polyfumarates, caprolactones, and/or any of the above-mentioned materials. The scaffold 233 may be manufactured by any of the following processes: salt leaching, freeze-drying, phase-separation, weaving fibers, bonding non-woven fibers, foaming, or any other suitable manufacturing method for the selected material.

The pore sizes associated with the scaffold 233 are typically between about 50 and 500 microns, and more preferably between about 100 and 400 microns. Pore sizes below 50 microns tend to inhibit or prevent tissue growth. In one embodiment, the preferred average pore size of pores within the scaffold is about 100 microns.

The scaffold may be provided as a sheet or pad of material. The thickness of the scaffold is measured in a direction normal to the tissue site when the reduced pressure delivery apparatus is placed adjacent the tissue site. The thickness of the material may vary, but in one

embodiment the scaffold is about 1 to 4 mm in thickness. The dimensions of the sheet or pad of scaffold material in a plane normal to the thickness dimension may vary depending on the size of the tissue site to be treated. The pad or sheet of material may be provided in a large size and then trimmed to fit the tissue site.

5 The release material 235 of the second layer, or release layer, 225 minimizes points of contact between the first layer 223 and the third layer 227. In one embodiment, the release material 235 will prevent any contact between the first and third layers 223, 227. By minimizing contact between the first and second layers 223, 227, the release material 235 serves as a barrier to tissue in-growth from the scaffold 233 into the distribution manifold 237
10 of the third layer 227.

 The release material 235 also serves as a binder and a release agent for the first and third layers 223, 227. Prior to and during reduced pressure tissue treatment, the release material 235 may be used to bind the first and third layers as previously described. The release material 235 is preferably either a hydrogel-forming material or a water-soluble
15 polymer.

 As a hydrogel-forming material, the release material 235 is capable of forming a liquid and/or gel following exposure to water or other fluids. During initial application of the reduced pressure delivery apparatus 213 to the tissue site and during the administration of reduced pressure tissue treatment, the hydrogel-forming material is preferably in a solid, “non-
20 hydrated” state. In other words, the hydrogel-forming material has not yet transformed into a liquid and/or gel-like state. As reduced pressure tissue treatment is administered, the hydrogel-forming material may be exposed to wound exudate and other fluids being drawn from or administered to the tissue site, but the compression of the first, second, and third layers under the influence of the reduced pressure preferably reduces or eliminates the
25 absorption of fluids by the hydrogel-forming material. This allows the hydrogel-forming material to remain in a solid state until reduced pressure delivery is ceased. Following cessation of reduced pressure therapy, the hydrogel-forming material may be hydrated by either applying water, saline solution, or other fluids to the hydrogel-forming material or by allowing wound exudate to hydrate the hydrogel-forming material. As the hydrogel-forming
30 material hydrates, the material transforms into a liquid and/or gel state which allows easy release of the third layer 227 from the first layer 223.

 The hydrogel-forming material may be any suitable material that is capable of accepting and/or forming a liquid or gel-like substance after exposure to water or other fluids

for a specified period of time. The hydrogel-forming material is typically a cross-linked polymer; however, it is not required that the material be cross-linked. Suitable hydrogel-forming materials may include, without limitation, cross-linked polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazene hydrogels, collagen, gelatin, hyaluronic acid, glucosaminoglycans, chitosan, and alginate. Uncrosslinked polymers with hydrophobic and hydrophilic portions may also be used, such as a copolymer of ethylene glycol and lactic acid or a polyurethane with a very long hydrophilic soft segment.

The release material 235 may also be a water-soluble polymer. As a water-soluble polymer, the release material 235 is capable of dissolving in the presence of water or other liquids. During initial application of the reduced pressure delivery apparatus 213 to the tissue site and during the administration of reduced pressure tissue treatment, the water-soluble polymer is preferably in a "non-hydrated" form. In other words, the polymer has not yet absorbed water or other liquids. As reduced pressure tissue treatment is administered, the water-soluble polymer may be exposed to wound exudate and other fluids being drawn from or administered to the tissue site, but the compression of the first, second, and third layers under the influence of the reduced pressure preferably reduces the solubility of the water-soluble polymer, which prevents the water-soluble polymer from prematurely dissolving. This allows the water-soluble polymer to remain in a solid state until reduced pressure delivery is ceased. Following cessation of reduced pressure therapy, the water-soluble polymer may be hydrated by either applying a fluid to the polymer or by allowing wound exudate to hydrate the polymer. As the water-soluble polymer hydrates, the polymer dissolves into the hydrating liquid which allows easy release of the third layer 227 from the first layer 223.

The water-soluble polymer may include, without limitation, uncrosslinked polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazenes, collagen, hyaluronic acid, glucosaminoglycans, chitosan, and deoxyribonucleic acid (DNA).

The presence of the second plurality flow channels 236 in the second layer 225 allows the distribution of reduced pressure from the distribution manifold 237 to the scaffold 233.

The second plurality of flow channels 236 further allow passage of any fluids being provided to or being removed from the tissue site 221. While the second plurality of flow channels 236 may be an inherent characteristic of the release material 235 (i.e. interconnected pores or other flow channels within the material itself), it is more likely that the second plurality of flow

channels 236 are mechanically, chemically, or otherwise formed in the release material 235. For example, referring to FIG. 4, the second plurality of flow channels 236 may be defined by voids between adjacent strands of release material 235 arranged in a grid-like pattern. Alternatively, referring to FIG. 5, the release material 235 may be applied as beads of material
5 between the first and third layers 223, 227. In this particular configuration, the second plurality of flow channels 236 is defined by voids between adjacent beads of the release material 235. In still another configuration, referring to FIG. 6, a sheet of the release material 235 may be provided with apertures formed in the sheet to define the second plurality of flow channels 236. The shape, size, and positioning of the apertures and voids described above
10 could vary, and in one embodiment, may be random.

Regardless of whether pores, voids, apertures, or some combination thereof are used to define the second plurality of flow channels 236, the porosity of the second layer 225 may be less than the porosity of the scaffold 233 to minimize in-growth of tissue into the second layer 225. The porosity of the second layer 225 may be controlled by limiting the size of the pores,
15 voids, or apertures, or by controlling the number (i.e. density) of pores, voids, or apertures disposed in the second layer 225. The porosity of the second layer 225, however, must remain high enough to allow distribution of reduced pressure and the flow of fluids through the second layer 225.

Like the scaffold 233, the release material 235 may be provided as a sheet or pad of
20 material (see FIG. 6). Alternatively, the release material 235 may be provided in grids of strands, dots, or other individual pieces of material (see FIGS. 4 and 5). The shape, size, and distribution of these individual pieces of material may vary and in some situations, the shape, size, and distribution may be random. The thickness of the release material 235 is measured in a direction normal to the tissue site when the reduced pressure delivery apparatus is placed
25 adjacent the tissue site. Although not required, the thickness of the release material 235 is typically less than the thickness of the scaffold to save money on material costs. In one embodiment, the thickness of the release material 235 is about 200 to 500 microns prior to absorption of fluid. Following the hydration of the release material, the thickness may swell to about 500 microns to 1 millimeter. The dimensions of the sheet or pad of release material in a
30 plane normal to the thickness dimension may vary depending on the size of the tissue site to be treated, but will typically be about the same size in length and width as that of the scaffold. The pad or sheet of material may be provided in a large size and then trimmed to fit the tissue site.

The distribution manifold 237 of the third layer, or manifold layer 227 assists in distributing reduced pressure received from the reduced pressure delivery tube 217. The manifold may further be used to distribute fluids that are introduced to the tissue site or to manifold wound exudate and other fluids collected from the tissue site. The manifold 237
5 may be any porous material that is capable of accomplishing these tasks, and in one embodiment, the manifold is formed from a cellular material such as an open-cell foam. The material preferably includes cells that are fluidly connected to adjacent cells. The third plurality of flow channels 238 is formed by and between the “open cells” of the cellular material. The flow channels allow fluid communication throughout that portion of the cellular
10 material having open cells. The cells and flow channels may be uniform in shape and size, or may include patterned or random variations in shape and size. Variations in shape and size of the cells of the cellular material result in variations in the third plurality of flow channels 238, and such characteristics can be used to alter the flow characteristics of fluid through the cellular material. The cellular material may further include portions that include “closed
15 cells.” These closed-cell portions of the cellular material contain a plurality of cells, the majority of which are not fluidly connected to adjacent cells. Closed-cell portions of cellular material may be selectively combined with open-cell portions to prevent transmission of fluids through selected portions of the manifold 237.

In one embodiment, the manifold 237 is made from an open-cell, reticulated
20 polyetherurethane foam with pore sizes ranging from about 400-600 microns. An example of this foam may include GranuFoam manufactured by Kinetic Concepts, Inc. of San Antonio, Texas. The manifold 237 may also be polyurethane foam, polyvinyl alcohol foam, polyethylene foam, expanded polytetrafluoroethylene, silicone foam, loofa sponge, sea sponge, gauze, felted mats, or any other biocompatible material that is capable of providing
25 fluid communication through a plurality of flow channels in three dimensions.

Like the scaffold 233 and the release material 235, the manifold 237 may be formed from a sheet or pad of material. The thickness of the manifold 237 may vary, but in one embodiment, the thickness will be at least as great as the thickness of the scaffold 233. The dimensions of the manifold in a plane normal to the thickness dimension may also vary
30 depending on the size of the tissue site being treated. The pad or sheet of manifold material may be provided in a large size and then trimmed to fit the tissue site.

In operation, the reduced pressure delivery apparatus 213 is trimmed if necessary to match the shape and size of the tissue site 221. In many cases, the tissue site 221 may be an

open wound, burn, or other-damaged tissue, but the tissue site 221 may similarly be a site that contains healthy tissue upon which it is desired to grow additional tissue. The reduced pressure delivery apparatus 213 is placed adjacent the tissue site 221 such that the first layer 223 is in contact with the tissue site 221. As previously described, the multiple layers of the reduced pressure delivery apparatus 213 may be laminated, bonded, or otherwise connected, but the layers may also be separate from one another. If certain of the layers are not connected to one another, the various layers may be placed individually such that the first layer 223 is in contact with the tissue site, the second layer 225 is in contact with the first layer 223, and the third layer 227 is in contact with the second layer 225.

After positioning the reduced pressure delivery apparatus 213, a reduced pressure is delivered from the reduced pressure source 219 through the reduced pressure delivery tube 217 to the manifold 237 of the first layer 227. The reduced pressure is distributed through the third plurality of flow channels 238 associated with the manifold 237 to the second plurality of flow channels 236 associated with the second layer 225. The reduced pressure is then distributed to the first plurality of flow channels 234 associated with the scaffold 233 of the first layer 223. As reduced pressure reaches the tissue site 221, fluids at the tissue site 221 such as wound exudate may be drawn through the first, second, and third plurality of flow channels 234, 236, 238 and removed from the reduced pressure delivery apparatus 213. A reservoir (not shown) and various filters may be provided between the reduced pressure delivery apparatus 213 and the reduced pressure source 219 to collect exudate and protect the reduced pressure source 219. In addition to allowing distribution of reduced pressure and the withdrawal of fluids from the tissue site 221, the first, second, and third plurality of flow channels 234, 236, 238 may be used to distribute fluids such as irrigation fluids, medication, antimicrobials, antibacterials, antivirals, and growth factors to the tissue site 221.

The application of reduced pressure to the tissue site 219 induces new tissue growth. Some of the mechanisms by which new tissue growth is promoted include micro-deformation of the tissue, epithelial migration, and improved blood flow. These factors contribute to increasing the development of granulation tissue at the tissue site, which results in new tissue growth. While the discussion of providing reduced pressure tissue treatment often refers to “delivering” reduced pressure to the tissue site, it should be apparent to a person of ordinary skill in the art that delivery of reduced pressure typically involves creating a pressure differential between the reduced pressure source 219 and the tissue site 221. The pressure differential (with a lower pressure at the reduced pressure source 219 than at the tissue site

221) creates an initial fluid flow from the tissue site 221 toward the reduced pressure source 219. Once the pressure at the tissue site 221 nears or equals that of the pressure at the reduced pressure source 219, the reduced pressure may be maintained at the tissue site due to the fluid connection with the reduced pressure source 219 and the sealing function of the membrane

5 224.

As new tissue forms under the influence of reduced pressure, the new tissue is permitted to grow into the scaffold 233. The material chosen for the scaffold 233 preferably supports and encourages new tissue growth. Since the scaffold will remain at the tissue site following the administration of reduced pressure tissue treatment, it is preferred that new tissue penetrates the scaffold as much as possible. It has been observed that under the influence of reduced pressure, new tissue may penetrate up to 1 mm (thickness) of scaffold in a period of two days. Since the thickness of the scaffold 233 in some embodiments may only be about 1 to 4 mm, it may be desired to remove the second and third layers 225, 227 of the reduced pressure delivery apparatus 213 and replace the layers with a new dressing containing first, second, and third layers 223, 225, 227. In other words, a new scaffold 233 may be placed on top of the old scaffold 233 following removal of the second and third layers 225, 227. By removing only a portion of the reduced pressure delivery apparatus 213 and leaving the scaffold 233, it is possible to incrementally add new tissue growth to the tissue site 221 as new scaffolds 233 are stacked upon previously inserted scaffolds 233 that are already permeated with new tissue growth.

The release of the second and third layers 225, 227 from the first layer 223 is simplified by the presence of the release material 235. During the application of reduced pressure and removal of fluids from the tissue site 221, the release material 235 preferably remains in a solid state, thereby allowing the second plurality of flow channels 236 to remain open. While the release material will typically transform into a liquid or gel or will dissolve following the absorption of water or other fluids, this change is significantly reduced during the application of reduced pressure to the reduced pressure delivery apparatus 213. Reduced pressure results in a compression of the reduced pressure delivery apparatus 213, which reduces the surface area of the release material that is exposed to fluids flowing through the first, second, and third plurality of flow channels 234, 236, 238. Absorption of fluids by the release material 235 is thereby minimized until reduced pressure delivery is ceased.

During the application of reduced pressure, the release material preferably minimizes or prevents contact between the first and third layers 223, 227. New tissue growing into the

scaffold 233 is hindered from growing in the manifold 237 by this separation between the scaffold 233 and manifold 237 and by the release material 235 itself. While tissue growth into the manifold 237 may still occur, the growth is minimized, which lessens pain to the patient upon removal of the manifold 237.

5 Following application of reduced pressure for a selected period of time, the release material may be hydrated by soaking the reduced pressure delivery apparatus 213 with water, saline solution, or other fluids. Alternatively, the reduced pressure delivery apparatus 213 may be allowed to sit until bodily fluids from the tissue site hydrate the release material 235. If the release material 235 is a hydrogel-forming material, the release material 235 transforms
10 into a gel-like state and typically expands as it hydrates. This allows for easier removal of the manifold 237 from the scaffold 233. Any hydrogel-forming material (or hydrogel) that remains following removal of the manifold 237 may be manually removed or dissolved by the introduction of additional fluids. Alternatively, if the release material 235 is a water-soluble polymer, it will be dissolved as it absorbs water or other fluids, thus releasing the third layer
15 227 from the first layer 223.

Referring to FIG. 7, a method 711 of promoting tissue growth at a tissue site according to an embodiment of the present invention is illustrated. The method 711 includes positioning a multi-layer reduced pressure delivery apparatus in contact with the tissue site at 715. The reduced pressure delivery apparatus includes a scaffold, a release material, and a manifold. At
20 719, the apparatus is oriented such that the scaffold contacts the tissue site. A reduced pressure is applied to the tissue site through the manifold and the scaffold at 723.

Referring to FIG. 8, a method 811 of promoting new tissue growth at a tissue site according to an embodiment of the present invention is illustrated. The method 811 includes at 815 positioning a scaffold in contact with the tissue site, a release material in contact with
25 the scaffold, and a manifold in contact with the release material. At 819, new tissue growth is stimulated at the tissue site by applying a reduced pressure to the tissue site through the manifold and the scaffold.

Referring to FIG. 9, a tissue growth kit 911 for promoting new tissue growth at a tissue site according to an embodiment of the present invention includes a scaffold 913, a release
30 material 915, and a distribution manifold 917. The scaffold 913 includes a first and second side, the first side of the scaffold 913 being adapted to contact the tissue site. The scaffold 913 is similar to the scaffold 233 described previously with reference to FIGS. 2 and 3. The release material 915 is adapted to contact the second side of the scaffold 913 and is similar to

the release material 235 described previously with reference to FIGS. 2 and 3. The distribution manifold 917 is adapted to contact the release material 915 to distribute a reduced pressure to the tissue site through the scaffold 913. The distribution manifold 917 is similar to the manifold 237 described previously with reference to FIGS. 2 and 3. The tissue growth kit
5 911 may further include a container 921 for housing the scaffold 913, release material 915, and distribution manifold 917 prior to use of the components. The container 921 may be a flexible bag, a box, or any other container suitable for storing the scaffold 913, release material 915, and distribution manifold 917.

While the multi-layer reduced pressure delivery apparatus disclosed herein is used in
10 conjunction with a reduced pressure delivery source to provide reduced pressure tissue treatment to a tissue site, the reduced pressure delivery apparatus could also serve as an advanced tissue dressing alone in the absence of reduced pressure application. The same materials, relative positioning, and connectivity between layers may be used in the advanced tissue dressing. Similar to the reduced pressure delivery apparatus described herein, the
15 advanced tissue dressing may include a first layer to promote and accept growth of new tissue, a third layer to assist in directing fluids away from the tissue site, and a second layer to facilitate removal of the third layer from the first layer at a selected time. The third layer of the advanced tissue dressing, instead of having a “manifold”, may be considered to include a fluid reservoir for collecting and holding fluids exuded by the wound. The materials described
20 herein as being suitable distribution manifold materials are similarly suitable materials for the reservoir of the third layer. The only requirement of the reservoir is that it be made from a material that is capable of storing fluids produced by or present at the tissue site.

While the systems and methods of the present invention have been described with reference to tissue growth and healing in human patients, it should be recognized that these
25 systems and methods for applying reduced pressure tissue treatment can be used in any living organism in which it is desired to promote tissue growth or healing. Similarly, the systems and methods of the present invention may be applied to any tissue, including without limitation bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments. While the healing of tissue may be one focus of
30 applying reduced pressure tissue treatment as described herein, the application of reduced pressure tissue treatment may also be used to generate tissue growth in tissues that are not diseased, defective, or damaged. For example, it may be desired to apply reduced pressure tissue treatment to grow additional tissue at a tissue site that can then be harvested. The

harvested tissue may be transplanted to another tissue site to replace diseased or damaged tissue, or alternatively the harvested tissue may be transplanted to another patient.

It should be apparent from the foregoing that an invention having significant advantages has been provided. While the invention is shown in only a few of its forms, it is not just limited but is susceptible to various changes and modifications without.

5

CLAIMS

We claim:

1. A reduced pressure delivery system for applying reduced pressure tissue treatment to a tissue site comprising:
 - a multi-layer reduced pressure delivery apparatus having a tissue contact layer, a release layer, and a manifold layer, the tissue contact layer including a scaffold adapted to contact the tissue site, the release layer including a hydrogel-forming material and a plurality of flow channels, the manifold layer including a distribution manifold, the release layer being positioned between the tissue contact layer and the manifold layer, the hydrogel-forming material of the release layer binding to at least one of the tissue contact layer and the manifold layer; and
 - a reduced-pressure delivery tube fluidly connected to the manifold layer to deliver a reduced pressure to the tissue site.
2. The reduced pressure delivery system according to claim 1, wherein the hydrogel-forming material is positioned between the scaffold and the distribution manifold to substantially prevent contact between the scaffold and the distribution manifold in areas where the hydrogel-forming material is disposed.
3. The reduced pressure delivery system according to claim 2, wherein the distribution manifold contacts the scaffold in areas in which the hydrogel-forming material is not disposed during application of the reduced pressure.
4. The reduced pressure delivery system according to claim 1, wherein the tissue contact layer is from about 1 mm to about 4 mm in thickness.
5. The reduced pressure delivery system according to claim 1, wherein the thickness of the release layer is less than the thickness of the tissue contact layer.
6. The reduced pressure delivery system according to claim 1, wherein the plurality of flow channels of the release layer are provided by pores disposed in a sheet of the hydrogel-forming material.

7. The reduced pressure delivery system according to claim 6, wherein the pore sizes of the pores in the release layer are less than the pore sizes of the pores in the scaffold.
8. The reduced pressure delivery system according to claim 1, wherein:
 - the hydrogel-forming material is arranged in a grid pattern such that strands of the hydrogel-forming material are aligned in rows and columns; and
 - the plurality of flow channels are formed by voids disposed between the rows and columns of the hydrogel-forming material.
9. The reduced pressure delivery system according to claim 1, wherein:
 - the hydrogel-forming material is provided as a plurality of individual beads, each bead being spaced apart from adjacent beads by a void; and
 - the plurality of flow channels are formed by the voids disposed between the beads of the hydrogel-forming material.
10. The reduced pressure delivery system according to claim 9, wherein the porosity provided by the voids is less than the porosity provided by the scaffold.
11. The reduced pressure delivery system according to claim 1, wherein the distribution manifold is an open-cell, reticulated polyetherurethane foam.
12. The reduced pressure delivery system according to claim 1, wherein the hydrogel-forming material is a barrier to tissue penetration.
13. The reduced pressure delivery system according to claim 1, wherein the scaffold is comprised of at least one material selected from the group of polylactic acid, polyglycolic acid, polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyorthoesters, polyphosphazenes, polyurethanes, collagen, hyaluronic acid, chitosan, hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate, bioglass, allografts, and autografts.

14. The reduced pressure delivery system according to claim 1, wherein the hydrogel-forming material is comprised of at least one material selected from the group of polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazene hydrogels, collagen, gelatin, hyaluronic acid, glucosaminoglycan, chitosan, alginate, and uncrosslinked copolymers of ethylene glycol and lactic acid.
15. The reduced pressure delivery system according to claim 1, wherein the distribution manifold is comprised of at least one material selected from the group of polyurethane foam, polyvinyl alcohol foam, polyethylene foam, expanded polytetrafluoroethylene, silicone foam, loofa sponge, sea sponge, gauze, and felted mats.
16. The reduced pressure delivery system according to claim 1 further comprising:
 - a reduced pressure source fluidly connected to a proximal end of the reduced-pressure delivery tube.
17. A multi-layer reduced pressure delivery apparatus for applying reduced pressure tissue treatment to a tissue site comprising:
 - a first layer having a scaffold adapted to contact a tissue site;
 - a second layer having a hydrogel-forming material and a plurality of flow channels, the hydrogel-forming material contacting the scaffold; and
 - a third layer having a distribution manifold contacting the hydrogel-forming material.
18. The reduced pressure delivery apparatus according to claim 17, wherein the hydrogel-forming material is positioned between the first layer and the third layer and is connected to at least one of the scaffold and the distribution manifold.
19. The reduced pressure delivery apparatus according to claim 17 further comprising:
 - a reduced-pressure delivery tube fluidly connected to the third layer to deliver a reduced pressure to the tissue site.

20. The reduced pressure delivery apparatus according to claim 17, wherein the hydrogel-forming material is positioned between the scaffold and the distribution manifold to substantially prevent contact between the scaffold and the distribution manifold in areas where the hydrogel-forming material is disposed.
21. The reduced pressure delivery apparatus according to claim 17, wherein the distribution manifold contacts the scaffold in areas in which the hydrogel-forming material is not disposed during application of a reduced pressure.
22. The reduced pressure delivery apparatus according to claim 17, wherein a reduced pressure is delivered to the tissue site through the distribution manifold, the plurality of flow channels, and the scaffold.
23. The reduced pressure delivery apparatus according to claim 17, wherein the flow channels are capable of transmitting a fluid from the scaffold to the distribution manifold during the application of a reduced pressure.
24. The reduced pressure delivery apparatus according to claim 23, wherein the fluid is a wound exudate from the tissue site.
25. The reduced pressure delivery apparatus according to claim 17, wherein the first layer is from about 1 mm to about 4 mm in thickness.
26. The reduced pressure delivery apparatus according to claim 17, wherein the thickness of the second layer in a dehydrated state is less than the thickness of the first layer.
27. The reduced pressure delivery apparatus according to claim 17, wherein the scaffold includes pores having pore sizes ranging from about 50 microns to about 500 microns in diameter.
28. The reduced pressure delivery apparatus according to claim 17, wherein the scaffold includes pores having pore sizes ranging from about 100 microns to about 400 microns in diameter.
29. The reduced pressure delivery apparatus according to claim 17, wherein the plurality of flow channels of the second layer are provided by pores disposed in a sheet of the hydrogel-forming material.

30. The reduced pressure delivery apparatus according to claim 29, wherein the pore sizes of the pores in the second layer are less than the pore sizes of the pores in the scaffold.
31. The reduced pressure delivery apparatus according to claim 17, wherein:
the hydrogel-forming material is arranged in a grid pattern such that strands of the hydrogel-forming material are aligned in rows and columns; and
the plurality of flow channels are formed by voids disposed between the rows and columns of the hydrogel-forming material.
32. The reduced pressure delivery apparatus according to claim 17, wherein:
the hydrogel-forming material is provided as a plurality of individual beads, each bead being spaced apart from adjacent beads by a void; and
the plurality of flow channels are formed by the voids disposed between the beads of the hydrogel-forming material.
33. The reduced pressure delivery apparatus according to claim 32, wherein the porosity provided by the voids is less than the porosity provided by the scaffold.
34. The reduced pressure delivery apparatus according to claim 17, wherein the distribution manifold is a cellular foam.

35. The reduced pressure delivery apparatus according to claim 17, wherein the distribution manifold is an open-cell, reticulated polyetherurethane foam.
36. The reduced pressure delivery apparatus according to claim 17, wherein the distribution manifold includes pore sizes ranging from about 400 to about 600 microns in diameter.
37. The reduced pressure delivery apparatus according to claim 17, wherein the third layer includes an antimicrobial agent.
38. The reduced pressure delivery apparatus according to claim 17, wherein the hydrogel-forming material is bioabsorbable.
39. The reduced pressure delivery apparatus according to claim 17, wherein the hydrogel-forming material is a barrier to tissue penetration.
40. The reduced pressure delivery apparatus according to claim 17, wherein the tissue site is comprised of tissue selected from the group of adipose tissue, bone tissue, cartilage, connective tissue, dermal tissue, ligaments, muscle tissue, tendons, and vascular tissue.
41. The reduced pressure delivery apparatus according to claim 17, wherein the scaffold is comprised of at least one material selected from the group of polylactic acid, polyglycolic acid, polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyorthoesters, polyphosphazenes, polyurethanes, collagen, hyaluronic acid, chitosan, hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate, bioglass, allografts, and autografts.
42. The reduced pressure delivery apparatus according to claim 17, wherein the hydrogel-forming material is comprised of at least one material selected from the group of polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazene hydrogels, collagen, gelatin, hyaluronic acid, glucosaminoglycan, chitosan, alginate, and uncrosslinked copolymers of ethylene glycol and lactic acid.

43. The reduced pressure delivery apparatus according to claim 17, wherein the cellular material is comprised of at least one material selected from the group of polyurethane foam, polyvinyl alcohol foam, polyethylene foam, expanded polytetrafluoroethylene, silicone foam, loofa sponge, sea sponge, gauze, and felted mats.
44. The reduced pressure delivery apparatus according to claim 17, wherein the cellular material is chosen from the group of a woven porous pad, a non-woven porous pad, a loofa sponge, and a sea sponge.
45. A multi-layer reduced pressure delivery apparatus for applying reduced pressure tissue treatment to a tissue site comprising:
- a tissue contact layer having a scaffold adapted to contact the tissue site to receive in-growth of new tissue from the tissue site, the tissue contact layer further having a first plurality of flow channels;
 - a manifold layer having a cellular material to distribute a reduced pressure to the tissue site, the manifold layer further having a third plurality of flow channels; and
 - a release layer positioned between the tissue contact layer and the manifold layer, the release layer including a hydrogel-forming material connected to at least one of the tissue contact layer and the manifold layer, the hydrogel-forming material adapted to form a hydrogel upon the absorption of a fluid to release the at least one of the tissue contact layer and the manifold layer, the release layer further having a second plurality of flow channels in fluid communication with the first and third plurality of flow channels.
46. The reduced pressure delivery apparatus according to claim 45 further comprising a reduced-pressure delivery tube fluidly connected to the manifold layer to deliver the reduced pressure to the tissue site through the third plurality of flow channels, the second plurality of flow channels, and the first plurality of flow channels.
47. The reduced pressure delivery apparatus according to claim 45, wherein:
- the hydrogel-forming substantially prevents contact between the scaffold and the cellular material in areas where the hydrogel-forming material is disposed; and

the cellular material contacts the scaffold in areas in which the hydrogel-forming material is not disposed during application of the reduced pressure

48. The reduced pressure delivery apparatus according to claim 45, wherein the tissue contact layer is from about 1 mm to about 4 mm in thickness.
49. The reduced pressure delivery apparatus according to claim 45, wherein the thickness of the release layer is less than the thickness of the tissue contact layer.
50. The reduced pressure delivery apparatus according to claim 45, wherein the scaffold includes pores having pore sizes ranging from about 50 microns to about 500 microns in diameter.
51. The reduced pressure delivery apparatus according to claim 45, wherein the second plurality of flow channels of the release layer are provided by pores disposed in a sheet of the hydrogel-forming material.
52. The reduced pressure delivery apparatus according to claim 51, wherein the pore sizes of the pores in the release layer are less than the pore sizes of the pores in the scaffold.
53. The reduced pressure delivery apparatus according to claim 45, wherein:

the hydrogel-forming material is arranged in a grid pattern such that strands of the hydrogel-forming material are aligned in rows and columns; and the second plurality of flow channels are formed by voids disposed between the rows and columns of the hydrogel-forming material.
54. The reduced pressure delivery apparatus according to claim 45, wherein:

the hydrogel-forming material is provided as a plurality of individual beads, each bead being spaced apart from adjacent beads by a void; and the second plurality of flow channels are formed by the voids disposed between the beads of the hydrogel-forming material.
55. The reduced pressure delivery apparatus according to claim 54, wherein the porosity provided by the voids is less than the porosity provided by the scaffold.

56. The reduced pressure delivery apparatus according to claim 45, wherein the cellular material is an open-cell, reticulated polyetherurethane foam.
57. The reduced pressure delivery apparatus according to claim 45, wherein the hydrogel-forming material is a barrier to tissue penetration.
58. The reduced pressure delivery apparatus according to claim 45, wherein the scaffold is comprised of at least one material selected from the group of polylactic acid, polyglycolic acid, polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyorthoesters, polyphosphazenes, polyurethanes, collagen, hyaluronic acid, chitosan, hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate, bioglass, allografts, and autografts.
59. The reduced pressure delivery apparatus according to claim 45, wherein the hydrogel-forming material is comprised of at least one material selected from the group of polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazene hydrogels, collagen, gelatin, hyaluronic acid, glucosaminoglycan, chitosan, alginate, and uncrosslinked copolymers of ethylene glycol and lactic acid.
60. The reduced pressure delivery apparatus according to claim 45, wherein the cellular material is comprised of at least one material selected from the group of polyurethane foam, polyvinyl alcohol foam, polyethylene foam, expanded polytetrafluoroethylene, silicone foam, loofa sponge, sea sponge, gauze, and felted mats.
61. A reduced pressure delivery apparatus for applying reduced pressure tissue treatment to a tissue site comprising:
 - a scaffold adapted to contact a tissue site to receive in-growth of new tissue from the tissue site;
 - a distribution manifold adapted to distribute a reduced pressure to the tissue site through the scaffold; and
 - a release material positioned between and in contact with the scaffold and the distribution manifold to substantially prevent contact between the scaffold and the distribution manifold in areas where the release material is disposed.

62. The reduced pressure delivery apparatus according to claim 61, wherein the release material is connected to at least one of the scaffold and the distribution manifold.
63. The reduced pressure delivery apparatus according to claim 61 further comprising:
a reduced-pressure delivery tube having a distal end fluidly connected to the distribution manifold to deliver the reduced pressure to the distribution manifold.
64. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold contacts the scaffold in areas in which the release material is not disposed during application of the reduced pressure.
65. The reduced pressure delivery apparatus according to claim 61 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold.
66. The reduced pressure delivery apparatus according to claim 61, wherein the scaffold is from about 1 mm to about 4 mm in thickness.
67. The reduced pressure delivery apparatus according to claim 61, wherein the thickness of the release material is less than the thickness of the scaffold.
68. The reduced pressure delivery apparatus according to claim 61, wherein the scaffold includes pores having pore sizes ranging from about 50 microns to about 500 microns in diameter.
69. The reduced pressure delivery apparatus according to claim 61, wherein the scaffold includes pores having pore sizes ranging from about 100 microns to about 400 microns in diameter.
70. The reduced pressure delivery apparatus according to claim 61 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold; and

wherein the plurality of flow channels are provided by pores disposed in a sheet of the release material.

71. The reduced pressure delivery apparatus according to claim 70, wherein the pore sizes of the pores in the sheet of the release material are less than the pore sizes of pores in the scaffold.

72. The reduced pressure delivery apparatus according to claim 61 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold;
wherein the release material is arranged in a grid pattern such that strands of the release material are aligned in rows and columns; and
wherein the plurality of flow channels are formed by voids disposed between the rows and columns of the release material.

73. The reduced pressure delivery apparatus according to claim 61 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold;
the release material is provided as a plurality of individual beads, each bead being spaced apart from adjacent beads by a void; and
the plurality of flow channels are formed by the voids disposed between the beads of the release material.

74. The reduced pressure delivery apparatus according to claim 73, wherein the porosity provided by the voids is less than the porosity provided by the scaffold.

75. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold is a cellular foam.

76. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold is an open-cell, reticulated polyetherurethane foam.

77. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold includes pore sizes ranging from about 400 to about 600 microns in diameter.
78. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold is infused with an antimicrobial agent.
79. The reduced pressure delivery apparatus according to claim 61, wherein the release material is bioabsorbable.
80. The reduced pressure delivery apparatus according to claim 61, wherein the release material is a barrier to tissue penetration.
81. The reduced pressure delivery apparatus according to claim 61, wherein the tissue site is comprised of tissue selected from the group of adipose tissue, bone tissue, cartilage, connective tissue, dermal tissue, ligaments, muscle tissue, tendons, and vascular tissue.
82. The reduced pressure delivery apparatus according to claim 61, wherein the scaffold is comprised of at least one material selected from the group of polylactic acid, polyglycolic acid, polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyorthoesters, polyphosphazenes, polyurethanes, collagen, hyaluronic acid, chitosan, hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate, bioglass, allografts, and autografts.
83. The reduced pressure delivery apparatus according to claim 61, wherein the release material is comprised of at least one material selected from the group of polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazene hydrogels, collagen, gelatin, hyaluronic acid, glucosaminoglycan, chitosan, alginate, deoxyribonucleic acid, and uncrosslinked copolymers of ethylene glycol and lactic acid.
84. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold is comprised of at least one material selected from the group of polyurethane foam, polyvinyl alcohol foam, polyethylene foam, expanded polytetrafluoroethylene, silicone foam, loofa sponge, sea sponge, gauze, and felted mats.

85. The reduced pressure delivery apparatus according to claim 61, wherein the distribution manifold is chosen from the group of a woven porous pad, a non-woven porous pad, a loofa sponge, and a sea sponge.
86. A reduced pressure delivery system for applying reduced pressure tissue treatment to a tissue site comprising:
- a reduced pressure delivery apparatus having a distribution manifold to distribute a reduced pressure and a scaffold to encourage in-growth of new tissue from the tissue site, the distribution manifold and scaffold being bound together by a hydrogel-forming material positioned between the distribution manifold and the scaffold;
 - a reduced-pressure delivery tube having a distal end fluidly connected to the distribution manifold to deliver the reduced pressure through the distribution manifold and scaffold to the tissue site.
87. The reduced pressure delivery system according to claim 86, wherein the hydrogel-forming material substantially prevents contact between the scaffold and the distribution manifold in areas where the hydrogel-forming material is disposed.
88. The reduced pressure delivery system according to claim 86, wherein the distribution manifold contacts the scaffold in areas in which the hydrogel-forming material is not disposed during application of the reduced pressure.
89. The reduced pressure delivery system according to claim 86 further comprising:
- a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold.
90. The reduced pressure delivery system according to claim 86, wherein the scaffold is from about 1 mm to about 4 mm in thickness.
91. The reduced pressure delivery system according to claim 86, wherein the thickness of the hydrogel-forming material is less than the thickness of the scaffold.

92. The reduced pressure delivery system according to claim 86 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold; and
wherein the plurality of flow channels are provided by pores disposed in a sheet of the hydrogel-forming material.
93. The reduced pressure delivery system according to claim 92, wherein the pore sizes of the pores in the sheet of the hydrogel-forming material are less than the pore sizes of pores in the scaffold.
94. The reduced pressure delivery system according to claim 86 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold;
wherein the hydrogel-forming material is arranged in a grid pattern such that strands of the hydrogel-forming material are aligned in rows and columns; and
wherein the plurality of flow channels are formed by voids disposed between the rows and columns of the hydrogel-forming material.
95. The reduced pressure delivery system according to claim 86 further comprising:
a plurality of flow channels disposed between the scaffold and distribution manifold to allow fluid communication between the scaffold and distribution manifold;
the hydrogel-forming material is provided as a plurality of individual beads, each bead being spaced apart from adjacent beads by a void; and
the plurality of flow channels are formed by the voids disposed between the beads of the hydrogel-forming material.
96. The reduced pressure delivery system according to claim 95, wherein the porosity provided by the voids is less than the porosity provided by the scaffold.
97. The reduced pressure delivery system according to claim 86, wherein the distribution manifold is an open-cell, reticulated polyetherurethane foam.

98. The reduced pressure delivery system according to claim 86, wherein the hydrogel-forming material is a barrier to tissue penetration.
99. The reduced pressure delivery system according to claim 86, wherein the scaffold is comprised of at least one material selected from the group of polylactic acid, polyglycolic acid, polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polydioxanone, polyorthoesters, polyphosphazenes, polyurethanes, collagen, hyaluronic acid, chitosan, hydroxyapatite, coralline apatite, calcium phosphate, calcium sulfate, calcium carbonate, bioglass, allografts, and autografts.
100. The reduced pressure delivery system according to claim 86, wherein the hydrogel-forming material is comprised of at least one material selected from the group of polyethylene glycol, hydrophilic polyethers, polyvinyl alcohol, polyvinyl acetate, polyacrylates, polysulfonates, polyphosphazene hydrogels, collagen, gelatin, hyaluronic acid, glucosaminoglycan, chitosan, alginate, and uncrosslinked copolymers of ethylene glycol and lactic acid.
101. The reduced pressure delivery system according to claim 86, wherein the distribution manifold is comprised of at least one material selected from the group of polyurethane foam, polyvinyl alcohol foam, polyethylene foam, expanded polytetrafluoroethylene, silicone foam, loofa sponge, sea sponge, gauze, and felted mats.
102. The reduced pressure delivery system according to claim 86 further comprising:
a reduced pressure source fluidly connected to a proximal end of the reduced-pressure delivery tube.

103. A tissue growth kit for promoting new tissue growth at a tissue site comprising:
a scaffold having a first and a second side, the first side adapted to contact the tissue site;
a hydrogel-forming material adapted to contact the second side of the scaffold;
and
a distribution manifold adapted to contact the hydrogel-forming material to distribute a reduced pressure to the tissue site through the scaffold.
104. Use of a scaffold, a hydrogel forming material, and a manifold for promoting new tissue growth at a tissue site,
the scaffold for being in contact with the tissue site;
the hydrogel-forming material for being in contact with the scaffold; and
the manifold for being in contact with the hydrogel-forming material and for applying a reduced pressure to the tissue site through the manifold and scaffold.
105. The use according to claim 104, further comprising:
withdrawing exudate through the scaffold and manifold.
106. The use according to claim 104, wherein:
when the reduced pressure applied to the manifold is removed,
the hydrogel-forming material is hydratable into a gel form; and
the manifold is removable from the hydrogel-forming material.
107. The method according to claim 106, wherein the hydrogel-forming material is removable from the scaffold.

108. The use according to claim 106, wherein when the hydrogel-forming material is hydrated, a fluid is deliverable to the hydrogel-forming material through the manifold.
109. The use according to claim 106 wherein:
 when the manifold is removed, a second scaffold is positionable in contact with the first scaffold;
 a second hydrogel-forming material is positionable in contact with the second scaffold; and
 a second manifold is positionable in contact with the second hydrogel-forming material and for applying reduced pressure to the second manifold.
110. The use according to claim 104, wherein the tissue site comprises adipose tissue, bone tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments.
111. Use of a multilayer pressure delivery apparatus for promoting new tissue growth at a tissue site comprising:
 the multi-layer reduced pressure delivery apparatus positionable in contact with the tissue site, the multi-layer reduced pressure delivery apparatus including:
 a tissue contact layer having a scaffold adaptable to contact the tissue site;
 a manifold layer having a distribution manifold; and
 a release layer having a hydrogel-forming material and a plurality of flow channels, the release layer positionable between the tissue contact layer and the manifold layer, the hydrogel-forming material of the release layer bindable to at least one of the tissue contact layer and the manifold layer;
 the multi-layered reduced pressure delivery apparatus orientable such that the tissue contact layer contacts the tissue site; and
 the distribution manifold, flow channels, and the scaffold for applying a reduced pressure to the tissue site.

112. The use according to claim 111, further comprising:
 withdrawing exudate through the scaffold, the flow channels, and the
 distribution manifold.
113. The use according to claim 111, wherein when the reduced pressure is removed,
 the hydrogel-forming material is hydratable into a gel form; and
 the distribution manifold is removable from the hydrogel-forming material.
114. The use according to claim 113, wherein when the distribution manifold is
 removed, a second multi-layer reduced pressure delivery apparatus is positionable in
 contact with the first scaffold for applying reduced pressure to the second multi-layer
 reduced pressure delivery apparatus.
115. Use of a multilayer reduced pressure delivery apparatus for promoting new tissue
 growth at a tissue site comprising:
 the multi-layer reduced pressure delivery apparatus positionable in contact with
 the tissue site, the multi-layer reduced pressure delivery apparatus
 including:
 a first layer having a scaffold adapted to contact the tissue site;
 a second layer having a hydrogel-forming material and a plurality of
 flow channels, the hydrogel-forming material contacting the
 scaffold; and
 a third layer having a distribution manifold contacting the hydrogel-
 forming material;
 the multi-layered reduced pressure delivery apparatus orientable such that the
 tissue contact layer contacts the tissue site; and
 the distribution manifold, the flow channels, and the scaffold for applying a
 reduced pressure to the tissue site.
116. Use of a scaffold, a hydrogel-forming material and a distribution manifold for
 promoting new tissue growth at a tissue site comprising:
 a scaffold positionable in contact with the tissue site, a hydrogel-forming
 material in contact with the scaffold, and a distribution manifold in
 contact with the hydrogel-forming material; and

the distribution manifold and the scaffold for applying a reduced pressure to the tissue site.

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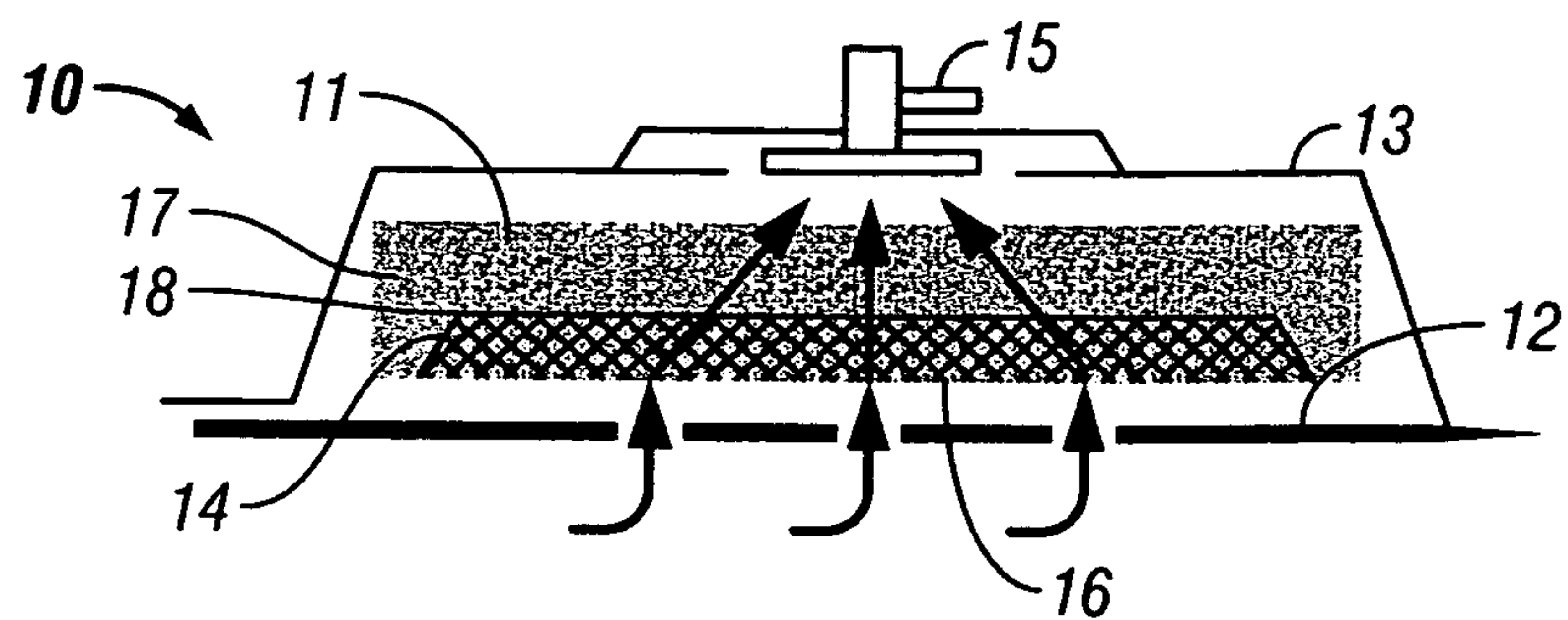


FIG. 1

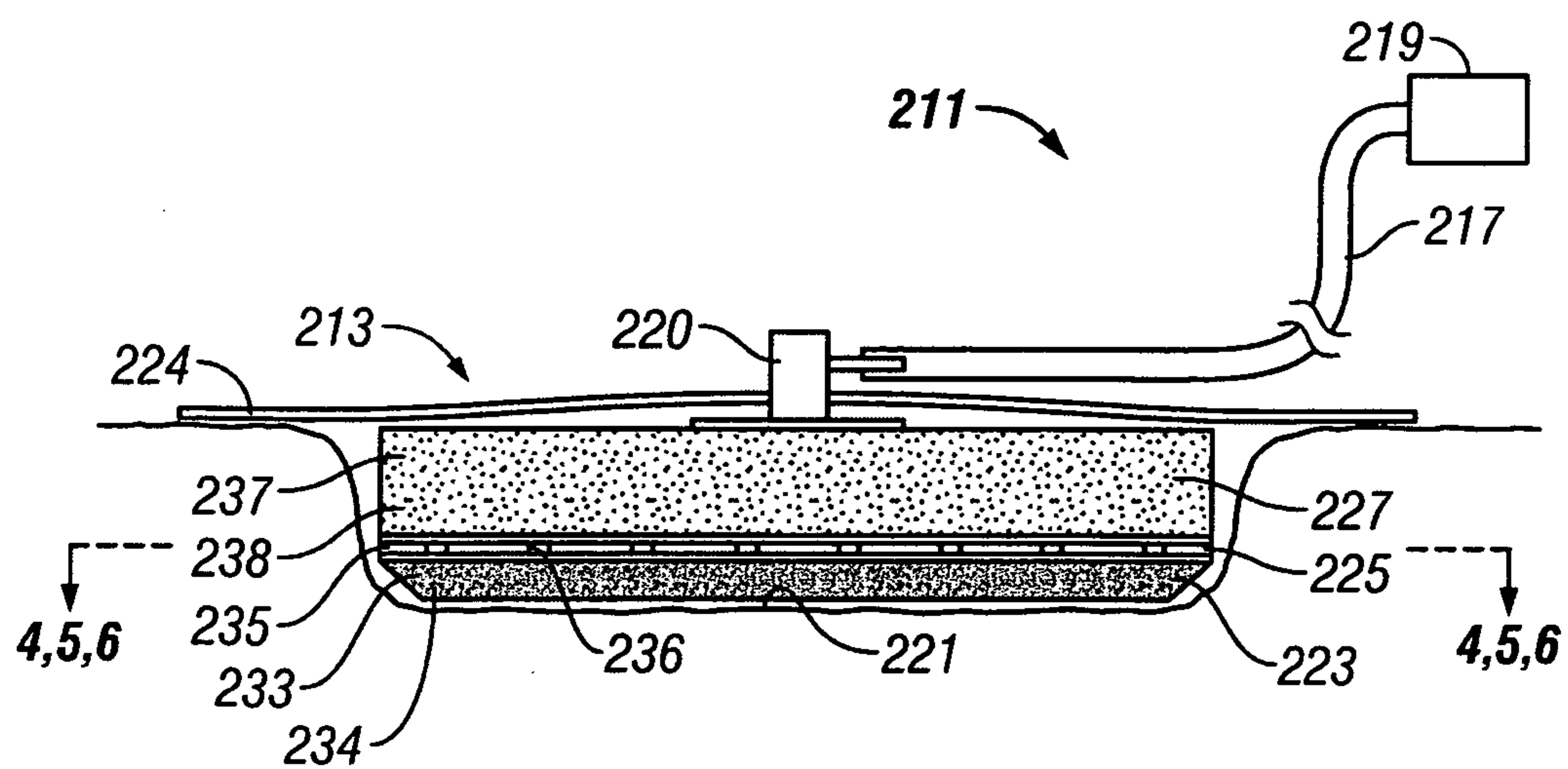


FIG. 2

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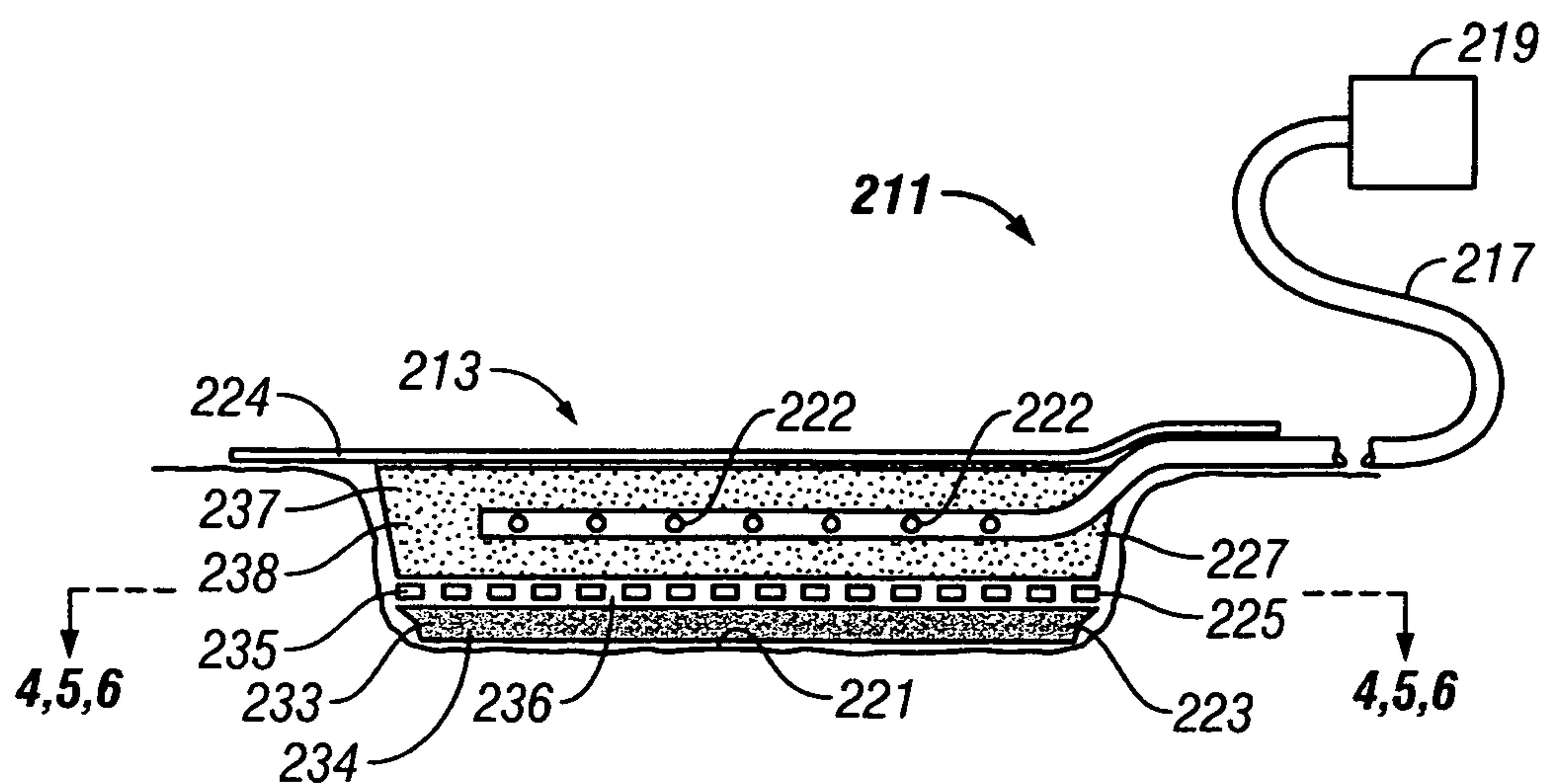


FIG. 3

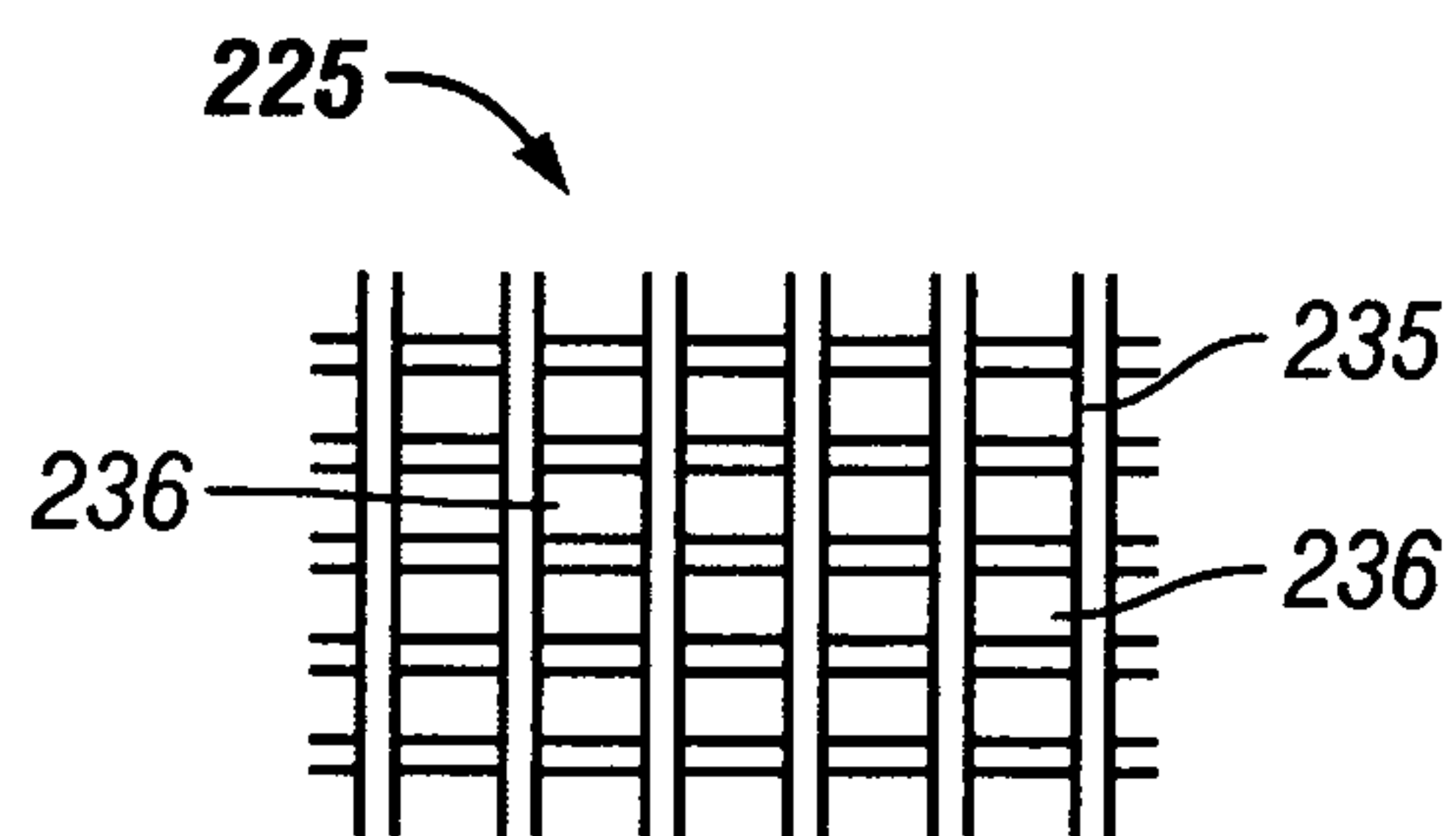


FIG. 4

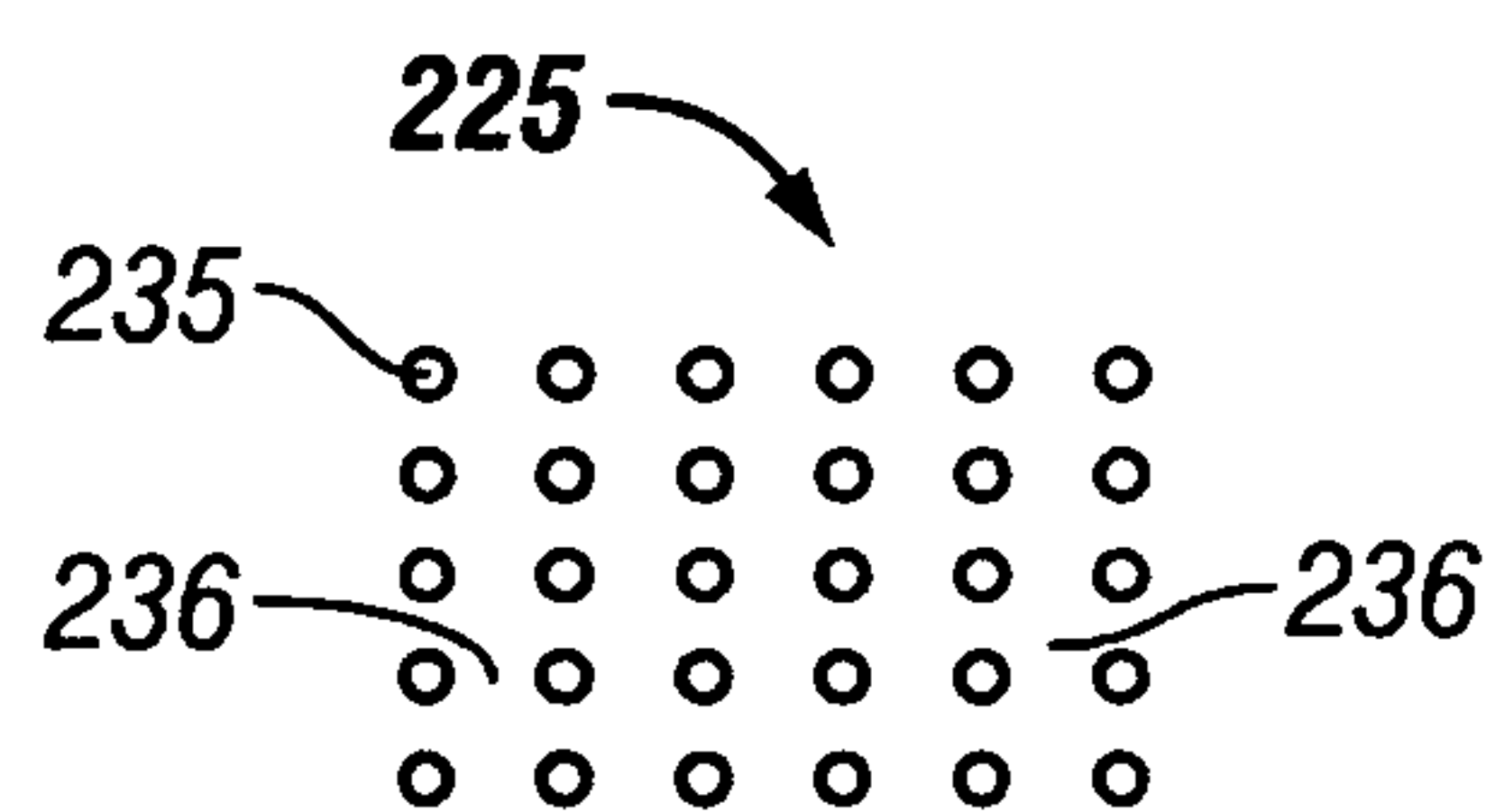


FIG. 5

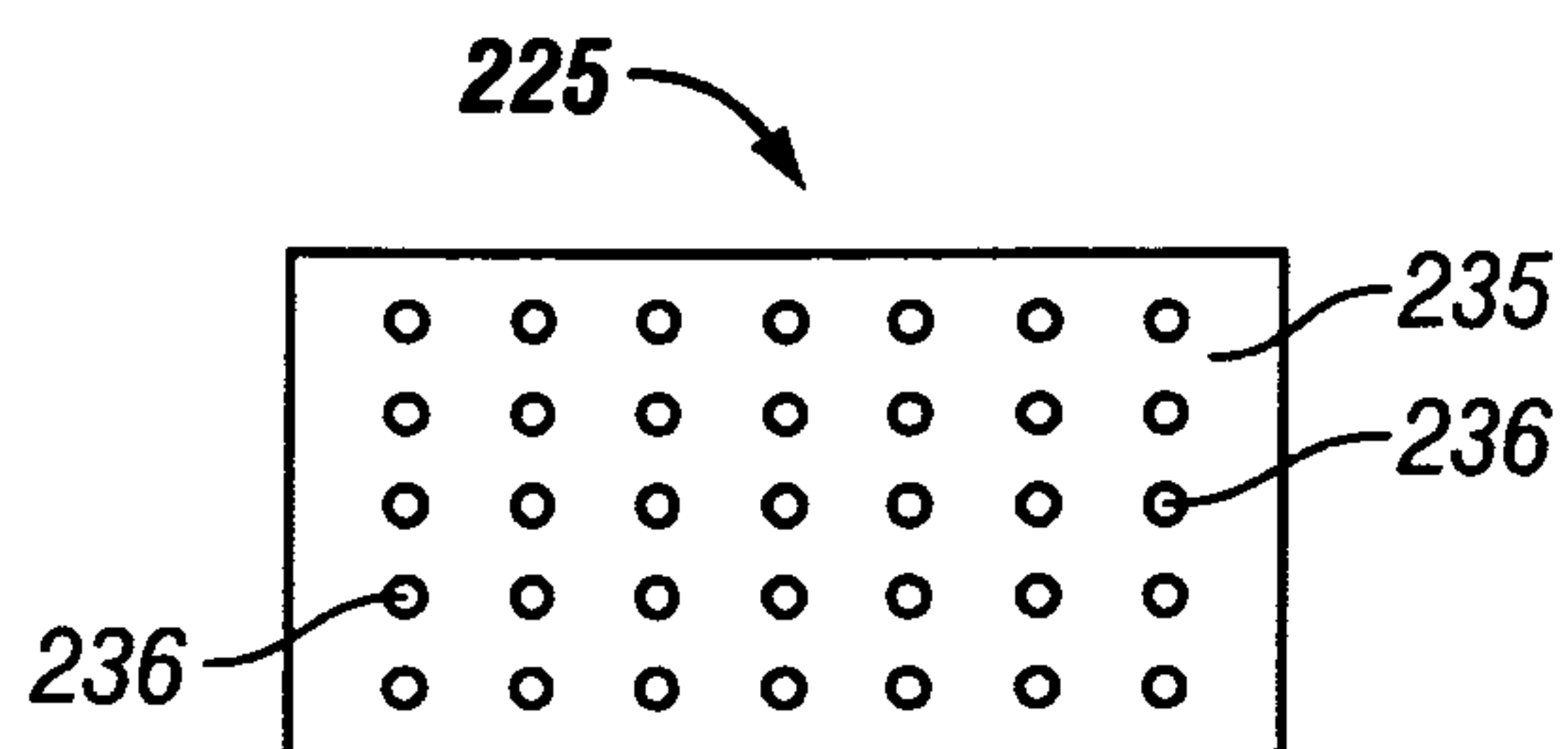
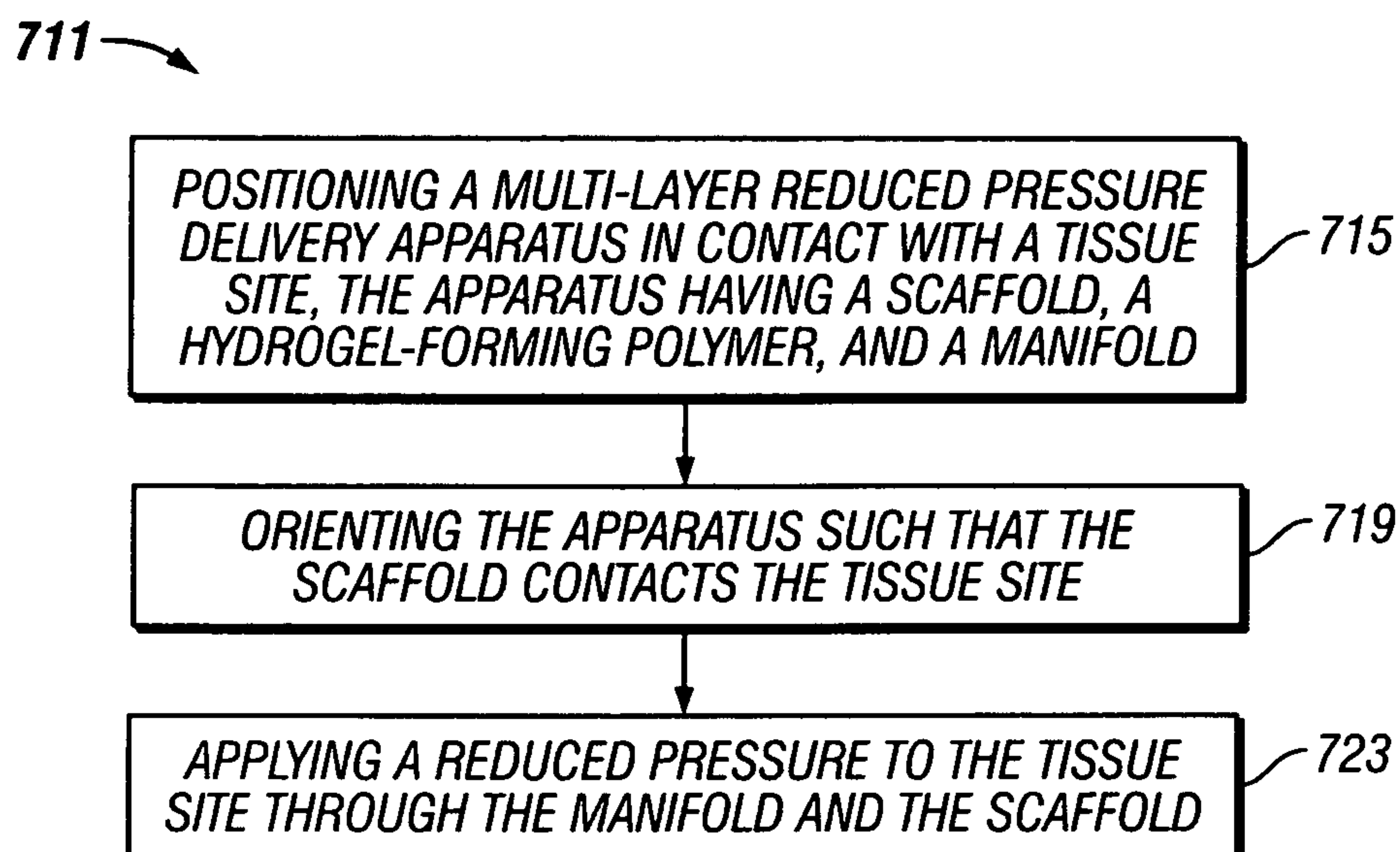
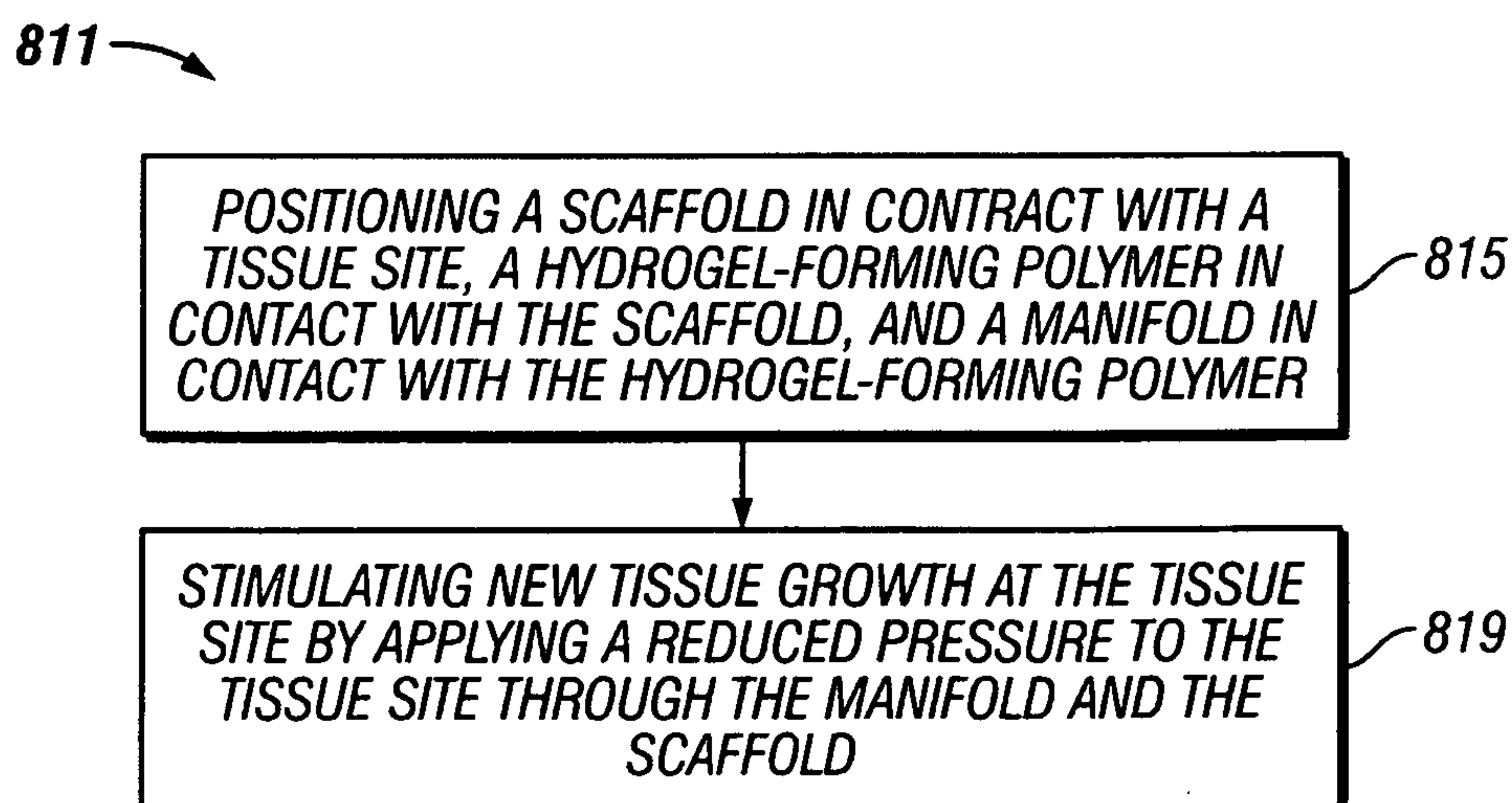
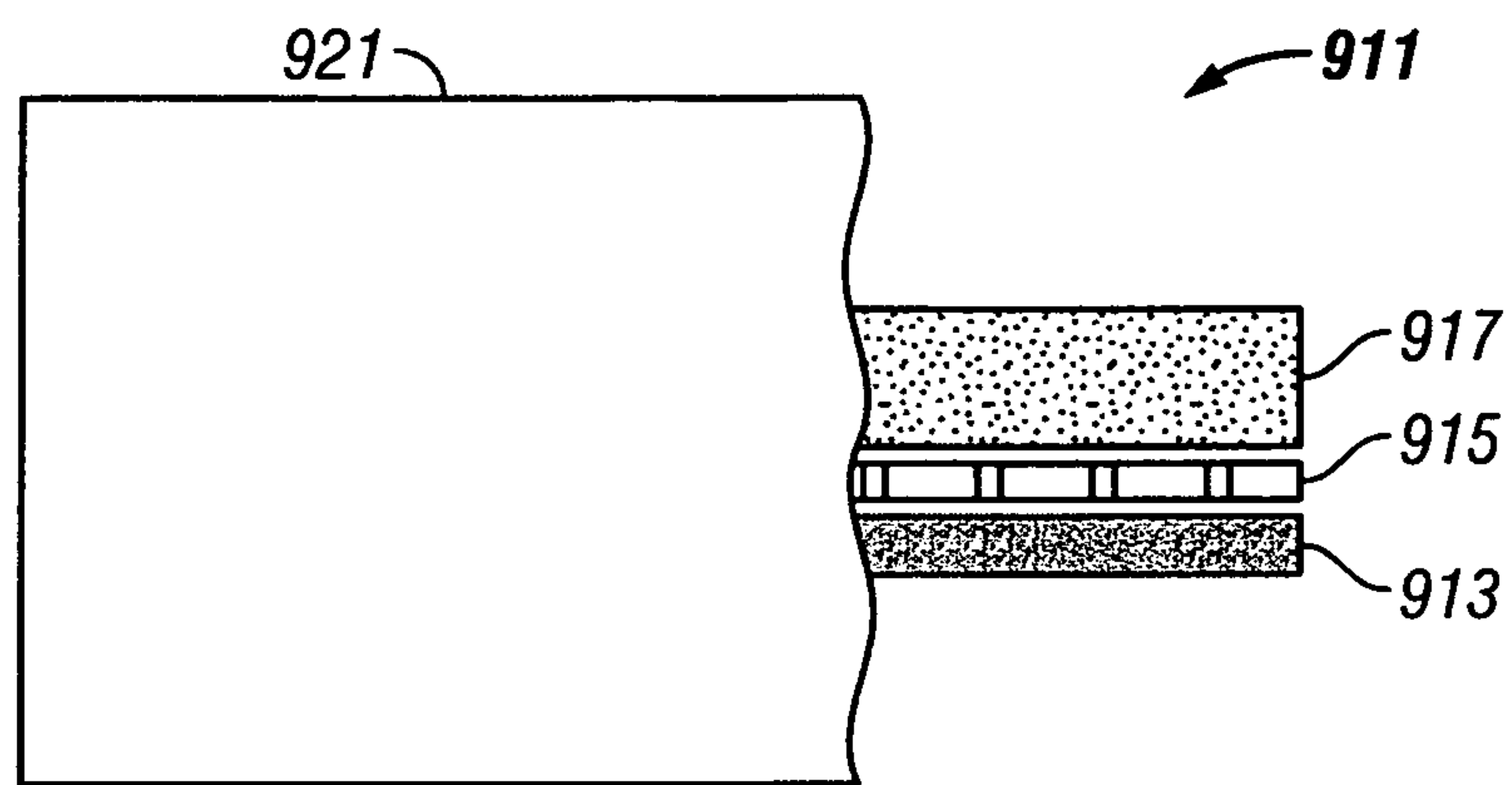


FIG. 6

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