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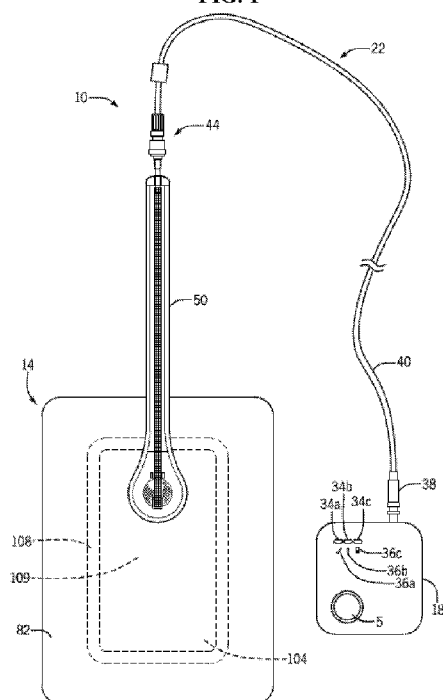
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(54) Title: **NEGATIVE PRESSURE WOUND DRESSING MANAGEMENT SYSTEM**

FIG. 1



(57) Abstract: A wound exudate management system includes a pump for generating negative pressure, a dressing for covering and protecting a wound of a user, a tube including an interior lumen, the tube disposed between the pump and the dressing such that the pump and the dressing are in fluid communication via the interior lumen. The dressing includes an adhesive layer for adhering the dressing adjacent the wound, a wound contact layer, a pressure dispersion layer, a plurality of layers of absorbent material disposed between the wound contact layer and the pressure dispersion layer, a backing layer having a first surface and a second surface, the first surface of the backing layer being adjacent, and in contact with, the pressure dispersion layer and the adhesive layer, and a flexible connector disposed on the second surface of the backing layer.

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NEGATIVE PRESSURE WOUND DRESSING MANAGEMENT SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.K. Patent Application No. 1608099.6, filed May 9, 2016, and U.S. Provisional Patent Application No. 62/370,667, filed August 3, 2016, both of which are expressly incorporated herein by reference and made a part hereof.

TECHNICAL FIELD

[0002] The present disclosure generally relates to wound dressing systems, and in particular, to a wound dressing system for use with a negative-pressure pump. Further, the present invention relates to dressings, systems and kits for treating a wound with a dressing that can be used with a source of negative pressure to deliver negative pressure therapy. The dressing is suitable for the treatment of a variety of wounds including chronic and acute types including infected wounds, venous ulcers, diabetic ulcers, burns, surgical wounds and the like.

BACKGROUND

[0003] Wound dressings are known and are generally suitable for treating a variety of wounds, including chronic and acute wound types, such as infected wounds, venous ulcers, diabetic ulcers, burns and surgical wounds.

[0004] Negative pressure has been used to treat a range of chronic and acute wounds. Negative pressure may facilitate wound healing through a number of mechanisms, including removal of excess exudate, reduction in periwound edema and increased perfusion. Combined with the physical forces exerted by the negative pressure which draw the wound edges together, this can result in improved wound outcomes. Conventional devices are generally large and require the use of sophisticated equipment which may include a suction pump to generate negative pressure, a pressure regulator, canisters for the collection of wound exudate and a wound dressing to deliver the therapy to the wound site. As a result, such devices may be bulky, costly and confine the patient to bed or at least render the patient immobile and unable to go about their usual activities.

[0005] More recently, portable systems have been developed which include a means to manage the exudate produced by the wound by collecting exudate within the wound dressing, typically in an absorbent material, and by evaporation through the dressing. Such systems mean that a separate collection canister may not be an essential part of the system. Such a system is described in EP 2021046. An advantage of not needing a canister is that the device is less bulky and more portable. A disadvantage with such devices is that if the dressing exceeds its fluid handling capacity, exudate may be drawn from the absorbent material(s) and enter the pump.

The presence of exudate in the pump will eventually cause it to fail and require its replacement. The therapy provided by the system may also be less than optimal due to the potential for excess exudate to collect at the wound interface. In order to prevent fouling of the pump with exudate, it is known to provide a barrier layer between the absorbent material and the pump. The liquid barrier layer does not however give the user of the device or care giver an indication that the dressing has exceeded its fluid handling capacity and needs to be changed.

[0006] In those devices where a canister is present, the user or care giver is given a visual indication of how much exudate is being produced by the wound by the presence of exudate in the canister. The presence of exudate in the canister will however only occur once the dressing has exceeded its fluid handling capacity. There is no early warning that the dressing needs to be changed.

[0007] There exists a need for an indication that the dressing has reached or exceeded its fluid handling capacity.

[0008] Additionally, existing portable negative-pressure wound dressing systems often include rigid dressing and connection components, adversely affecting system utility and user comfort. Additionally, existing portable negative-pressure wound dressing systems do not utilize absorbent materials and additional wound dressing components arranged to maximize the management of wound exudate within the dressing. Thus, there exists a need for a portable exudate management system that incorporates these, and other, features. The present disclosure seeks to overcome limitations and other drawbacks of the prior art, and to provide new features not heretofore available. A full discussion of the features and advantages of the present disclosure is deferred to the following detailed description, which proceeds with reference to the accompanying drawings.

SUMMARY

[0009] In one implementation, the present disclosure provides a negative pressure wound dressing for use in applying negative pressure to a wound comprising: an absorbent layer capable of absorbing exudate from the wound and allowing the passage of fluid through it; an outer cover layer covering the side of the absorbent layer furthest from the wound, the cover layer adapted to enable negative pressure to be applied at the wound and having a port; a conduit having a proximal end attached to the port and a distal end, the dressing provided with a pathway for fluid from the wound, through the absorbent layer, the port and to the distal end of the conduit; and an indicator means positioned in the pathway at a location between the absorbent layer and the distal end of the conduit, the indicator means capable of absorbing

exudate to indicate the presence of exudate at the side of the absorbent layer furthest from the wound.

[0010] In a further implementation, the present disclosure provides a negative pressure wound dressing for use in applying negative pressure to a wound comprising: an absorbent layer capable of absorbing exudate from the wound and allowing the passage of fluid through it; an outer cover layer covering the side of the absorbent layer furthest from the wound, the cover layer adapted to enable negative pressure to be applied at the wound and having a port; a conduit having a proximal end attached to the port and a distal end, the dressing provided with a pathway for fluid from the wound, through the absorbent layer, the port and to the distal end of the conduit; an indicator means positioned in the pathway at a location between the absorbent layer and the distal end of the conduit, the indicator means capable of absorbing exudate to indicate the presence of exudate at the side of the absorbent layer furthest from the wound; and a source of negative pressure connected to the distal end of the conduit.

[0011] Preferably the source of negative pressure is capable of generating a minimum of 75mmHg and a maximum of 125mmHg at the wound.

[0012] In some implementations of the disclosed subject technology, a wound exudate management system is provided. In one embodiment, the wound exudate management system comprises a pump for generating negative pressure, a dressing for covering and protecting a wound, the dressing comprising an adhesive layer for adhering the dressing adjacent the wound, a wound contact layer for contacting the wound, a pressure dispersion layer, a plurality of layers of absorbent material disposed between the wound contact layer and the pressure dispersion layer, and a backing layer having a first surface and a second surface, the first surface of the backing layer being adjacent, and in contact with, the pressure dispersion layer and the adhesive layer, a pressure tube having an interior lumen, the pressure tube disposed between the pump and the dressing such that the pump and the dressing are in fluid communication via the interior lumen, and, a flexible connector connected to the second surface of the backing layer.

[0013] The disclosed technology further relates to a dressing for covering and protecting a wound. The disclosed technology further relates to a wound exudate management system, comprising: a dressing for covering and protecting a wound, the dressing comprising: a wound contact layer, the wound contact layer having a first surface and a second surface, the wound contact layer further having a peripheral region and a central region, wherein the first surface of the wound contact layer contacts the wound when the dressing is adhered to skin adjacent the wound, a pressure dispersion layer having a peripheral region and a central region, a plurality of layers of absorbent material disposed between the second surface of the wound contact layer and

the pressure dispersion layer, and, an envelope formed by joining the peripheral region of the pressure dispersion layer with the peripheral region of the second surface of the wound contact layer, the plurality of layers of absorbent material being disposed substantially within an interior cavity of the envelope. Alternately, an envelope may be formed by joining the peripheral region of a thermoplastic spun lace layer connected to the pressure dispersion layer with the peripheral region of a nonwoven spun lace layer connected to the second surface of the wound contact layer, such that the plurality of layers of absorbent material are disposed substantially within an interior cavity of the envelope.

[0014] The disclosed technology further relates to a wound exudate management system further comprising a thermoplastic spun lace layer connected to the pressure dispersion layer, and a nonwoven spun lace layer connected to the wound contact layer, and wherein the envelope is formed by joining peripheral portions of the thermoplastic spun lace layer and the nonwoven spun lace layer, wherein the interior cavity of the envelope is formed by the nonwoven spun lace layer and the thermoplastic spun lace layer, and wherein the plurality of layers of absorbent material are disposed substantially within an interior cavity of the envelope.

[0015] The disclosed technology further relates to a wound exudate management system, comprising: a dressing for covering and protecting a wound, the dressing comprising a wound contact layer, a backing layer and at least one layer of absorbent material layer between the wound contact layer and the backing layer, a flexible connector having an interior lumen, the flexible connector secured to the backing layer of the dressing, an indicator between the backing layer and the flexible connector, a tube having an interior lumen, the tube connected to the flexible connector, wherein the interior lumen of the flexible connector and the interior lumen of the tube are in fluid communication, and, a pressure conveyance member disposed within the interior lumen of the tube.

[0016] The disclosed technology further relates to a wound exudate management system, comprising: a pump for generating negative pressure, a dressing for covering and protecting a wound, the dressing comprising a wound contact layer, a backing layer and at least one layer of absorbent material between the wound contact layer and the backing layer, a tube connecting the pump and the dressing, the tube having an interior lumen for placing the pump and the dressing in fluid communication via the interior lumen, and, a one-way valve in-line between the pump and the dressing to maintain a negative pressure within the dressing when the pump is disconnected from the tube.

[0017] The disclosed technology further relates to a wound exudate management system, comprising: a pump for generating negative pressure, a dressing for covering and protecting a

wound, a tube including an interior lumen, the tube disposed between the pump and the dressing such that the pump and the dressing are in fluid communication via the interior lumen of the tube, and, a plurality of layers of absorbent material disposed in the dressing, wherein the absorbent material has fibers that swell upon contact with wound exudate to manage a flow of wound exudate through a portion of the dressing.

[0018] In any of the wound exudate management systems, the system may be adapted to allow for fluid communication between the wound and a negative pressure source, such as a pump. Typically, a fluid communication pathway is provided from the wound, through the wound contact layer and through one or more layers of absorbent material disposed in the dressing, to the negative pressure source. The fluid communication pathway may extend through an opening in the backing layer to the interior lumen of a tube, optionally via the interior lumen or conduit of a flexible connector. Where an indicator such as an absorbent indicator member is present, the fluid communication pathway may also extend through the indicator.

[0019] Typically, the flexible connector is elongate with an interior lumen or conduit that runs parallel to the longitudinal axis of the flexible connector, wherein the flexible connector is attachable to the opening in the backing layer of the dressing in an orientation such that the longitudinal axis of the flexible connector is substantially parallel to the plane of the backing layer. The flexible member may comprise a head portion for securement to the backing layer via adhesive or other means. Typically, the fluid communication pathway extends from the interior lumen or conduit of the flexible connector through the opening in the backing layer in a direction substantially perpendicular to the longitudinal axis of the flexible connector. Once secured, a fluid-tight seal may be formed between the flexible connector and the backing layer.

[0020] In any of the above embodiments, the presence of an indicator means may have the advantage that the user or caregiver is given an indication of the need to change the dressing. The indicator means allows the user or caregiver to change the dressing and prevent fouling of the pump. The presence of exudate at the side of the absorbent layer furthest from the wound occurs when the absorbent layer has absorbed significant quantities of exudate. If the indicator means is located in the conduit of the dressing and is triggered by the absorption of exudate, exudate is present not only at the side of the absorbent layer furthest from the wound but has also been drawn out past the cover layer and into the conduit. It gives a forewarning to the user or caregiver that the fluid handling capacity of the dressing has been or shortly will be reached and that dressing change is advisable. The indicator means can give an indication that the dressing has reached its fluid handling capacity and that there is potential for exudate to be drawn from the dressing, into the conduit and eventually into the pump which is undesirable.

[0021] The indicator means may be visual or may result in an audible alarm or other signal. Preferably the indicator means is visual and is located so that it is visible to the user of the dressing. For example, the visual indicator means may be located in the port in the cover layer or it may be located in the conduit or in both the port and conduit. Similarly, in the wound exudate management systems, the visual indicator means may be located to traverse the opening in the backing layer and/or be located in the interior lumen or conduit of the flexible connector. Preferably the visual indicator means is a gelling absorbent which visually indicates that it has absorbed exudate by forming a gel. If the exudate is coloured then the gel will also be coloured and add to the visual indication. Alternatively the visual indicator means may indicate that it has absorbed exudate by changing colour for instance by activation of a dye in the indicator means.

[0022] Preferably the indicator means is provided by gel-forming fibres. By gel forming fibres is meant hygroscopic fibres which upon the uptake of wound exudate become moist slippery or gelatinous. The gel forming fibres can be of the type which retain their structural integrity on absorption of exudate or can be of the type which lose their fibrous form and become an amorphous or structureless gel. The gel forming fibres are preferably sodium carboxymethylcellulose fibres, chemically modified cellulosic fibres, alkyl sulphonate modified cellulosic fibres such as those described in WO2012/061225, pectin fibres, alginate fibres, chitosan fibres, hyaluronic acid fibres, or other polysaccharide fibres or fibres derived from gums. The cellulosic fibres preferably have a degree of substitution of at least 0.05 carboxymethyl groups per glucose unit. The gel forming fibres preferably have an absorbency of at least 2 grams 0.9% saline solution per gram of fibre (as measured by the free swell method).

[0023] The gel forming fibres are preferably chemically modified cellulosic fibres in the form of a fabric and in particular carboxymethylated cellulose fibres as described in PCT WO00/01425 to Azko Nobel UK Ltd. In this way, the indicator means can be provided by a layer of gel forming fibres preferably located in the port of the cover layer or as a layer of fibres in the conduit. When present in the conduit, the layer of fibres can also serve to keep the conduit open to the passage of fluid in the event that the conduit is kinked or otherwise restricted by being lain on or leaned on by the user. The carboxymethylated cellulosic fabrics preferably have a degree of substitution between 0.12 to 0.35 as measured by IR spectroscopy (as defined in WO00/01425) more preferably a degree of substitution of between 0.20 and 0.30 and are made by carboxymethylating a woven or non-woven cellulosic fabric such that the absorbency is increased. Particular preferred fabrics have an absorbency of between 10g/g of sodium/calcium chloride as defined above to 30g/g of sodium/calcium chloride as measured by the method described in BS EN 13726-1 (2002) "Test methods for primary wound dressings", section 3.2

“Free swell absorptive capacity”. Particularly preferred fabrics have an absorbency of 15g/g to 25g/g and most preferred of 15g/g to 20g/g of sodium/calcium chloride as measured by the method defined above.

[0024] The cellulosic fabric preferably consists solely of cellulosic fibre but may contain a proportion of non-cellulosic textile fibre or gel forming fibre. The cellulosic fibre is of known kind and may comprise continuous filament yarn and/or staple fibre. The carboxymethylation is generally performed by contacting the fabric with an alkali and a carboxymethylating agent such as chloroacetic acid in an aqueous system. The fabric is preferably of a non-woven type to reduce shedding in the wound on cutting the dressing. Preferably the fabric is hydroentangled and thus comprises a series of apertures on a microscopic scale.

[0025] The absorbent layer of the dressing is capable of absorbing exudate from the wound and allowing the passage of fluid through it. Although the absorbent layer can comprise any absorbent capable of absorbing exudate while allowing the passage of fluid through it, such as a foam, sponge or fibre-based material, preferably the absorbent layer is provided by gel forming fibres of the same type or of a different type as those used in the indicator means. The gel-forming fibres are hygroscopic fibres which upon the uptake of wound exudate become moist slippery or gelatinous and thus reduce the tendency for the surrounding fibres to adhere to the wound. The gel forming fibres are preferably spun sodium carboxymethylcellulose fibres, chemically modified cellulosic fibres, alkyl sulphonate modified cellulosic fibres such as those described in WO2012/061225, pectin fibres, alginate fibres, chitosan fibres, hyaluronic acid fibres, or other polysaccharide fibres or fibres derived from gums. The cellulosic fibres preferably have a degree of substitution of at least 0.05 carboxymethyl groups per glucose unit and more preferably are lightly substituted so that the absorbency of the fibres is limited. The gel forming fibres preferably have an absorbency of at least 2 grams 0.9% saline solution per gram of fibre (as measured by the method described above) but less than 30 grams 0.9% saline solution per gram of fibre. The gel forming fibres are preferably carboxymethylated cellulose fibres as described in PCT WO00/01425 to Azko Nobel UK Ltd which describes lightly carboxymethylated cellulose fabrics and more preferably are of the type used in the indicator means. The gel forming fibres are preferably lightly carboxymethylated in order to reduce the tendency of the absorbent layer to gel block and block the pathway for fluid from the wound, through the absorbent layer, the port and to the distal end of the conduit.

[0026] Preferably the absorbent layer is provided with fenestrations to aid the application of negative pressure to the wound and maintain the pathway for fluid from the wound, through the absorbent layer. Typically, however, fenestrations are only provided in internal absorbent

layers. External absorbent layers, including those in direct contact with the wound, generally do not have mechanically added fenestrations, however, they do have openings between the fibres.

[0027] Although the absorbent layer can be in direct contact with the wound, preferably the dressing comprises a wound contact layer, positioned between the wound and the absorbent layer. The wound contact layer is capable of absorbing exudate from the wound and transmitting it to the absorbent layer. Like the absorbent layer, the wound contact layer is capable of allowing the passage of fluid through it so that negative pressure may be applied to the wound and the pathway for fluid from the wound and to the distal end of the conduit may be maintained.

[0028] Preferably the wound contact layer comprises gel-forming fibres of the same or a similar type to those comprising the absorbent layer but the wound contact layer may be strengthened to increase its integrity and that of the dressing. For example the wound contact layer may be of the type described in EP 1904011 and comprise gel-forming fibres in the form of a mat with lines of longitudinal stitching made of cellulose or nylon or polyolefin yarn to increase the integrity of the layer. Preferably the wound contact layer is porous to maintain the pathway for fluid from the wound to the distal end of the conduit.

[0029] The outer cover layer of the dressing is a bacterial and viral barrier layer which preferably resists the ingress of liquid and air but allows moisture vapour transmission. In this way the outer cover layer enhances the overall fluid handling capacity of the dressing by allowing for the escape of moisture vapour through the cover while enabling the application of negative pressure to the wound. The outer cover layer is for instance a layer having a MVTR of at least 10,000 g m⁻² per 24 hours or in the range of from 10,000g m⁻² to 50,000g m⁻² per 24 hours measured by the method described in BS EN 13726-2 2002 "Test methods for primary wound dressings Part 2 Moisture vapour transmission rate of permeable film dressings". The cover layer may be in the form of a film of polyurethane, for example Epurex 912 T/129 manufactured by Covestro or Inspire 2350 manufactured by Coveris or Medifilm 426 manufactured by Mylan.

[0030] The cover layer is provided with a port for connection to the conduit. The port is preferably located in that part of the cover layer that overlies the absorbent layer but towards the periphery of the absorbent layer so that it is not directly in vertical alignment with the centre of the dressing (or the wound when in use). This assists in the spread of exudate across the full extent of the absorbent layer.

[0031] The conduit of the dressing is preferably a transparent passageway secured to the outside of the cover layer at the proximal end of the conduit so as to surround the port in the

cover layer from above. In this manner if the visual indicator is located in the port in the cover layer and/or in the conduit itself, the visual indicator may be seen by the user. Similarly, where the wound exudate management systems comprise a flexible connector, the flexible connector may be partially or entirely transparent so as to allow the visual indicator to be seen by the user. Typically the head of the flexible connector is transparent. The conduit of the dressing may comprise a connector, at its distal end, for connecting the dressing to a source of negative pressure, for example a pump. Preferably the connector is a luer lock to facilitate secure connection to the pump and to maintain the negative pressure on the wound while the pump is temporarily disconnected. The connector preferably comprises a one way lock to assist in the maintenance of negative pressure. The visual indicator may be located in the conduit and can be in the form of a knitted cylinder, or the like, of gel forming fibres. To resist collapse, the conduit may comprise an internal cylinder of nylon fibres to maintain openness of the conduit to fluid.

[0032] The dressing may further comprise a distribution layer, e.g., a pressure distribution layer, located between the absorbent layer and the outer cover layer which is gas and liquid permeable and particularly moisture vapour permeable and serves to aid access of exudate to a greater area of the absorbent layer by allowing it to spread under the distribution layer. The distribution layer also serves to even out the negative pressure applied to the wound over the whole dressing. The distribution layer preferably distributes exudate and negative pressure over the dressing. In this way, uptake of exudate by the absorbent layer is maximised before the exudate leaves the absorbent layer and activates the indicator means and the transfer of negative pressure to the wound is optimised. The distribution layer is preferably a foam layer such as a polyester foam of the type XD4200AS manufactured by Caligen or another suitable reticulated foam.

[0033] The dressing may also comprise additional optional layers such as an adhesive layer for adhering the dressing to the skin surrounding the wound to form a fluid tight seal. The adhesive layer may be applied to the side of dressing closest to the wound and may be provided with perforations to assist transport of exudate and fluid through the dressing. The adhesive layer may also be applied to any of the other layers to provide an island configuration such as to the cover layer.

[0034] It is understood that other embodiments and configurations of the subject technology will become readily apparent to those skilled in the art from the following detailed description, wherein various configurations of the subject technology are shown and described by way of illustration. As will be realized, the subject technology is capable of other and different

configurations and its several details are capable of modification in various other respects, all without departing from the scope of the subject technology. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] To understand the present disclosure, it will now be described by way of example, with reference to the accompanying drawings in which implementations of the disclosures are illustrated and, together with the descriptions below, serve to explain the principles of the disclosure.

[0036] FIG. 1 is a top view of a wound exudate management system according to exemplary implementations of the present disclosure, in particular showing a pump, a dressing and a tube, among other features.

[0037] FIG. 2 is a top view of a wound exudate management system according to exemplary implementations of the present disclosure, in particular showing a dressing and a portion of a flexible connector of the wound exudate management system.

[0038] FIG. 3A is a cross-sectional view about line 3-3 of FIG. 2 of a wound exudate management system according to exemplary implementations of the present disclosure, in particular showing a dressing, a portion of a flexible connector and various constituent elements of the dressing.

[0039] FIG. 3B is an alternate embodiment of a cross-sectional view about line 3-3 of FIG. 2 of a wound exudate management system showing a dressing, a portion of a flexible connector and various constituent elements of the dressing.

[0040] FIG. 4 is an enlarged cross-sectional view of the wound exudate management system of FIG. 3A, in particular illustrating the region indicated by arrow 4-4.

[0041] FIG. 5A is an exploded perspective view of a wound exudate management system according to exemplary implementations of the present disclosure.

[0042] FIG. 5B is an alternate embodiment of an exploded perspective view of a wound exudate management system of the present disclosure.

[0043] FIG. 6 is a bottom view of a wound exudate management system according to exemplary implementations of the present disclosure, in particular showing a removable cover and a portion of a flexible connector of the wound exudate management system.

[0044] FIG. 7 is a top view of a releasable connector of a wound exudate management system according to exemplary implementations of the present disclosure, in particular showing the releasable connector in a connected state.

[0045] FIG. 8 is a top view of the releasable connector of FIG. 7, in particular showing the releasable connector in a detached state.

DETAILED DESCRIPTION

[0046] While the wound exudate management system discussed herein may be implemented in many different forms, there is shown in the drawings, and will herein describe in detail, preferred implementations with the understanding that the present description is to be considered as an exemplification of the principles of the wound exudate management system and is not intended to limit the broad aspects of the disclosure to the implementations illustrated.

[0047] Referring now to the figures, and specifically to FIG. 1, one embodiment of a wound exudate management system 10 is shown. The wound exudate management system 10 of this embodiment has a wound dressing 14, a pump 18 and a tube 22 (also referred to as a pressure tube 22). Generally, the wound exudate management system 10 facilitates wound healing and wound protection. The dressing 14 is applied to the skin of a user, as will be described below, and the system 10 utilizes negative pressure generated by the pump 18 to aid wound healing. The dressing 14 and the pump 18 are fluidly connected via the tube 22. Negative pressure generated by the pump 18 is communicated to the dressing 14 by the tube 22, thereby enabling the dressing 14 to employ negative pressure for enhanced wound healing.

[0048] In various embodiments, the pump 18 operates to generate negative pressure in response to a variety of user inputs. In one embodiment, a user control 30 for the pump 18 is disposed on the pump 18 and/or remote to the pump 18. The user control 30 may be one or more of a button, switch, lever, sensor or any other control device. It is to be understood that any common user control 30 is within the scope of this disclosure. The pump 18 may also have one or more indicators 34a, 34b, 34c disposed on the pump 18 for apprising the pump user of a current operational status, condition, battery life, etc. of the pump 18. The indicators 34a-c may be lights including Light-Emitting Diodes (LEDs), however any other type of indicator may be used such as a speaker for generating an audible sound or a motor with a radially asymmetric flywheel for generating a vibration. Instructional indicia 36a, 36b, 36c may be associated with one or more of the indicators 34a-c for apprising a user of the significance of an operation of a particular indicator 34a-c. In some implementations, however, the pump 18 operates without a user input and generates negative pressure in response to a timer, remote signal, sensor reading or other stimulus.

[0049] In one embodiment, prior to operation of the pump 18, the indicators 34a-c for the pump 18 are preferably not illuminated. In such a state, the pump 18 is generally not generating negative pressure, which may correspond to the pump 18 being in an off condition. Further, in

one embodiment, when all of indicators 34a-c transition to an illuminated state, the pump 18 is preferably in a ready state and is ready for use. Further, in one embodiment, when one indicator 34a remains in an illuminated state and the remaining indicators 34b and 34c transition to a non-illuminated state, this is an indication that the pump 18 is in an operating state. Normal operation of the pump 18 may include the generation of negative pressure, alternating periods of negative pressure generation, and/or no generation of negative pressure. The pump 18 may transition between one or more of the off condition, ready state and operating state as a result of manipulation of the user control 30. Manipulation of the user control 30 to change the pump state may include and/or require manipulation of the user control 30 for a predetermined amount of time.

[0050] In the operational state, in a preferred embodiment the pump 18 generates a minimum pressure of 75mmHg at the wound and a maximum pressure of 125mmHg at the wound, however, alternate pressures may be generated by the pump 18. In one embodiment, the pump 18 generates negative pressure until a first pressure threshold is reached. The first pressure threshold may be, for example, a value between 75mmHg and 125mmHg, inclusive. The pump 18 may then refrain from generating negative pressure until a second threshold pressure is reached, at which point the pump 18 may generate negative pressure until the first pressure threshold is again reached. Alternate operations of the pump are allowable.

[0051] In one embodiment, as shown in FIG. 1, the pump 18 is connected to the pressure tube 22 with a pump connector 38. The pump connector 38 may allow for selective separation of the pump 18 and the tube 22.

[0052] In one embodiment, the tube 22 comprises a distal tube portion 40 and a proximal tubular portion 42. The proximal tubular portion 42 may be an extension of the flexible connector 50. A separable connector 44 may join the distal tube portion 40 and the proximal tubular portion 42, as shown in FIGS. 7 and 8. The pump connector 38 connects one end of the tube 22, and preferably the distal tube 40 portion of the tube 22, to the pump 18, as shown in FIG. 1. However, in an alternate embodiment, not shown, the pump connector 38 may connect the proximal tubular portion 42 to the pump 18. In one embodiment, the distal tube portion 40 forms a portion of the pressure tube 22 and may be flexible, transparent, partially-transparent, and/or formed from a polymer, metal, metal alloy or any other suitable material.

[0053] Turning to FIGS. 3A and 4, in one embodiment the flexible connector 50 is structurally connected to the dressing 14, and further includes a flexible connector lumen 54. The flexible connector lumen 54 is disposed within the flexible connector 50 along a portion, or all, of the flexible connector 50 and enables fluid communication between the pump 18 and the dressing

14. A flexible connector aperture 60 enables fluid communication between the flexible connector lumen 54 and the dressing 14. The flexible connector 50 may include a lower flexible connector portion 66 and an upper flexible connector portion 67. The lower flexible connector portion 66 and the upper flexible connector portion 67 may be joined by welding, adhesives or any other joining technique to form the flexible connector 50. The flexible connector 50 may preferably be formed from polyvinyl chloride, polyurethane or any other suitable material. In one embodiment the flexible connector 50 has a generally planar exterior surface.

[0054] In one embodiment, a pressure conveyance structure 62 is disposed within the flexible connector lumen 54. The pressure conveyance structure 62 enables the flexible connector 50 to convey fluid flow and/or pressure within the flexible connector lumen 54 without collapsing when the flexible connector 50 is made of a thin-walled flexible material, thereby enabling the dressing 14 to experience or exhibit negative pressure generated by the pump 18. The pressure conveyance structure 62 may include various materials including, but not limited to, nylon. Further, the pressure conveyance structure 62 may be comprised of a lattice structure 53. The shape, material and arrangement of the pressure conveyance structure 62 enables continued fluid flow along the flexible connector 50 that may otherwise be hindered by the shape, flexibility, material or arrangement of the flexible connector 50 in light of negative pressure generated by the pump 18 and in light of general wound exudate management system 10 use and positioning.

[0055] As best shown in FIGS. 3A, 4 and 5, the dressing 14 preferably includes an indicator 70, which in one embodiment is an upper absorbent indicator member 70 formed of an absorbent material. The indicator 70 may produce a signal, such as a visual, audible, vibrational, etc. signal. When the indicator 70 is made of an absorbent material the absorbent material may include gel-forming fibers, which may be hygroscopic fibers that become moist, slippery or gelatinous upon the intake of wound exudate or other fluids. The gel-forming fibers may retain their structural integrity upon absorption of exudate or they may lose their fibrous form and become an amorphous or structure-less gel. The gel-forming fibers are, in some implementations, sodium carboxymethylcellulose fibers, chemically modified cellulosic fibers, alkyl sulphonate modified cellulosic fibers such as those described in WO2012/061225, pectin fibers, alginate fibers, chitosan fibers, hyaluronic acid fibers, other polysaccharide fibers or fibers derived from gums.

[0056] The cellulosic fibers exemplarily have a degree of substitution of at least 0.05 carboxymethyl groups per glucose unit. The gel-forming fibers may have an absorbency of at least 2 grams 0.9% saline solution per gram of fiber (as measured by a free swell method) but less than 30 grams 0.9% saline solution per gram of fiber.

[0057] The gel-forming fibers are preferably chemically modified cellulosic fibers in the form of a fabric and in particular carboxymethylated cellulose fibers as described in PCT WO00/01425 to Azko Nobel UK Ltd. The carboxymethylated cellulosic fabrics exemplarily have a degree of substitution between 0.12 to 0.35 as measured by IR spectroscopy (as defined in WO00/01425) and further may have a degree of substitution of between 0.20 and 0.30. The carboxymethylated cellulosic fabrics may be formed by carboxymethylating a woven or non-woven cellulosic fabric such that absorbency is increased. The fabric may have an absorbency of between 10g/g of sodium/calcium chloride to 30g/g of sodium/calcium chloride as measured by the method described in BS EN 13726-1 (2002) "Test methods for primary wound dressings", section 3.2 "Free swell absorptive capacity." Some fabrics have an absorbency of 15g/g to 25g/g or 15g/g to 20g/g of sodium/calcium chloride. The gel-forming fibers may be lightly carboxymethylated to reduce a tendency of the absorbent material to gel block and block a fluid pathway from the wound and through the dressing 14.

[0058] The cellulosic fabric may consist solely of cellulosic fiber but may also contain non-cellulosic textile fibers or gel-forming fibers. The cellulosic fiber may be of known kind and may include continuous filament yarn and/or staple fiber. The carboxymethylation may be performed by contacting the fabric with an alkali and a carboxymethylating agent, such a chloracetic acid in an aqueous system. The fabric may be of a non-woven type, and may further be hydroentangled and thus comprise a series of apertures on a microscopic scale. The absorbent material may also comprise any absorbent material capable of absorbing exudate while allowing the passage of fluid therethrough, such as a foam, sponge or fiber-based material.

[0059] The upper absorbent indicator member 70 is preferably above the backing layer 82 and may be adjacent, joined to and/or in contact with the flexible connector 50 and may also be adjacent the flexible connector aperture 60. As best shown in FIG. 4, in one embodiment a first side of an upper adhesive 74 is adhered to both the upper absorbent indicator member 70 and the lower flexible connector portion 66 of the flexible connector 50. The lower flexible connector portion 66 is preferably adhered to a portion of the first side of the upper adhesive 74 radially outward from a portion of the upper adhesive 74 to which the upper absorbent indicator member 70 is adhered. The upper adhesive 74 also has an upper adhesive aperture 78 extending from the first side of the upper adhesive 74 to a second side of the upper adhesive 74 and arranged to be adjacent the upper absorbent indicator member 70 to limit interference with the vacuum effect of the negative pressure draw through the upper absorbent indicator member 70.

[0060] In one embodiment a backing layer 82 is disposed between both the indicator member 70 and the flexible connector 50 and the plurality of absorbent layers of the dressing 14. In one

embodiment the backing layer 82 is disposed below the upper adhesive 74. The backing layer 82 preferably has a backing layer aperture 86 disposed through the backing layer 82, and extending from a first surface 83 of the backing layer 82 to a second surface 84 of the backing layer. Accordingly, in one embodiment the upper adhesive 74 is provided adjacent the second surface 84 of the backing layer 82. In assembly, the aperture 86 of the backing layer 82 is provided adjacent the aperture 78 in the upper adhesive 74. In some implementations, the backing layer 82 is a bacterial and viral barrier layer which resists the ingress of liquid and air while allowing moisture vapor transmission. In this way, the backing layer 82 enhances an overall fluid handling capacity of the dressing 14 by allowing moisture vapor to escape through the backing layer 82 while enabling the application of negative pressure to the wound or dressing 14. The backing layer 82 may have a Moisture Vapor Transmission Rate (MVTR) of at least 10,000 g/m² per 24 hours or in the range of from 10,000g/m² to 50,000g/m² per 24 hours measured by the method described in BS EN 13726-2 2002 "Test methods for primary wound dressings Part 2 Moisture vapour transmission rate of permeable film dressings." The backing layer 82 may be partially or fully transparent. The backing layer 82 may be a layer, or film, of polyurethane, for example Epurex 912 T/129 manufactured by Covestro or Inspire 2350 manufactures by Coveris or Medifilm 426 manufactured by Mylan.

[0061] As shown in FIGS. 4 and 5A, in one embodiment a layer of adhesive 90, referred to as the backing layer adhesive 90, is disposed adjacent the second surface 82b of the backing layer 82. The backing layer adhesive 90 includes a backing layer adhesive aperture 94 preferably extending through the backing layer adhesive 90 from a first surface of the backing layer adhesive 90 to a second surface of the backing layer adhesive 90. The aperture 94 in the backing layer adhesive 90 is preferably positioned adjacent the aperture 78 in the upper adhesive member 74. It is to be understood that in a preferred embodiment, the flexible connector aperture 60, upper absorbent indicator member 70, upper adhesive aperture 78, backing layer aperture 86 and backing layer adhesive aperture 94 are all arranged substantially concentric such that fluid flow is enabled from the flexible connector aperture 60, across the upper absorbent indicator member 70, and through the upper adhesive aperture 78, backing layer aperture 86 and backing layer adhesive aperture 94. Further, it is also to be understood that in a preferred embodiment the upper flexible connector portion 67, lower flexible connector portion 66, upper absorbent indicator member 70, upper adhesive 74, backing layer 82, and backing layer adhesive 90 are arranged sequentially in the wound exudate management system 10.

[0062] Referring to FIG. 3A, the dressing 14, in some implementations, includes an inner envelope structure 100. The inner envelope structure 100 preferably houses a plurality of layers

of absorbent material to aid in exudate management. As best shown in FIGS. 3A, 4 and 5, in one embodiment the inner envelope structure 100 is defined by an upper envelope layer and a lower envelope layer. The upper envelope layer may have a peripheral section 108 and a central section 109. The peripheral section 108 of the upper envelope layer may also be referred to as the upper peripheral section 108, and the central section 109 of the upper envelope layer may also be referred to the upper central section 109. Similarly, the lower envelope layer may have a peripheral section 116 and a central section 117. The peripheral section 116 of the lower envelope layer may be referred to as the lower peripheral section 116, and the central section 117 of the lower envelope layer may be referred to as the lower central section 117.

[0063] An alternate embodiment of the dressing 14 of the wound management system 10 is shown in FIGS. 3B and 5B. In this alternate embodiment, a nonwoven spun lace layer 119 is preferably stitchbonded to the second surface 113 of the wound contact layer 112. In one embodiment a regenerated cellulose yarn is used for the stitchbonding. Further, in one embodiment the nonwoven spun lace material 119 may be comprised of an 80 gsm nonwoven layer comprising viscose fibers and polyester fibers in substantially equal portion, and preferably less than 5% acrylic co-polymer binder. Additionally, a thermoplastic spun lace layer 121, such as a polyamide layer, may be provided between the pressure dispensing layer 104 and the plurality of absorbent material layers 130. The thermoplastic spun lace layer 121 has a first surface 123 that may be heat bonded at its perimeter to the pressure dispersing layer 104, and a second surface 125 that may be similarly heat bonded at its perimeter around the plurality of absorbent material layers 130 to the nonwoven spun lace layer 119. Accordingly, the thermoplastic spun lace layer 121 and the nonwoven spun lace layer 119 form an inner enclosure or envelope around the absorbent material layers 130. The inner envelope or enclosure of this embodiment is defined by an upper envelope layer and a lower envelope layer. The upper envelope layer of this embodiment comprising the thermoplastic spun lace layer 121, and the lower envelope layer of this embodiment comprising the nonwoven spun lace material 119.

[0064] Accordingly, in one embodiment, as shown in FIG. 3A, the upper envelope layer is a pressure dispersing layer 104, and the lower envelope layer is a wound contact layer 112. In an alternate embodiment, as shown in FIG. 3B, the upper envelope layer is a thermoplastic spun lace layer 121 and the lower envelope layer is a non-woven spun lace layer 119.

[0065] In some implementations, the pressure dispersing layer 104, also referred to as the pressure distribution layer, serves to distribute pressure, or negative pressure, laterally across the pressure dispersing layer 104. The pressure dispersing layer 104 may be gas, liquid and moisture-vapor permeable and serves to aid exudate access to a greater portion of the dressing

14 by distributing negative pressure laterally over the dressing 14. In this way, uptake of exudate by the dressing 14 is maximized and a more uniform transfer of negative pressure to the wound, or dressing 14, is optimized. The pressure dispensing layer 104 may be formed from a foam such as a polyester foam of the type XD4200AS manufactured by Caligen, another suitable reticulated foam or a polyurethane foam.

[0066] In some implementations the wound contact layer 112 may be formed of an absorbent material. Further, the wound contact layer 112 may be comprised of a structurally reinforced material or structure to enhance the strength and physical properties of the lower envelope layer 112. For example, the wound contact layer 112 may be formed from carboxymethylated cellulose fibers. The structural reinforced material of the wound contact layer 112 may include stitching 118. In some implementations, the wound contact layer 112 is formed of an absorbent material that has reinforcing stitching 118, including reinforcing stitching 118 made of nylon. It is also understood that the pressure dispersing layer 104 and the wound contact layer 112 may be formed from any one of the absorbent materials described above.

[0067] The wound contact layer 112 has a first surface 114 and a second surface 113. In one embodiment, the first surface 114 of the wound contact layer 112 is an outer layer for contacting a wound of user when the dressing 14 is adhered to the skin of a user adjacent the wound. Further, in one embodiment, the second surface 113 of the wound contact layer 112 opposes the first surface 114, and the second surface 113 is an inner layer that is adjacent the plurality of absorbent material layers within the dressing 14, as described below.

[0068] The peripheral section 108 of the upper envelope layer 104 (i.e., in one embodiment the pressure dispersing layer 104) and peripheral section 116 of the lower envelope layer 112 (i.e., in one embodiment the wound contact layer 112) may be joined, as best shown in FIG. 3A. The upper peripheral section 108 and the lower peripheral section 116 may be joined by adhesives, welding, stitching or any other common joining method. The joining of the upper peripheral section 108 and the lower peripheral section 116 substantially forms the inner envelope 100 and further defines an envelope cavity 120 disposed within the envelope 100.

[0069] In a preferred embodiment, a plurality of absorbent material layers 130a, 130b, 130c, 130d, 130e, 130f, 130g, 130h, etc. are, in some implementations, disposed adjacent one another and substantially within the envelope cavity 120. In one embodiment there are eight layers of the absorbent material within the envelope cavity 120. In some implementations, the absorbent material layers 130a-h includes gel-forming fibers, such as those described above, and the gel-forming fibers may be sodium carboxymethylcellulose fibers. Further, the absorbent material layers 130a-h may include any of the absorbent materials, water-swellaable fibers or gel-forming

fibers as described above. For example, the absorbent material layers 130a-h may be formed from carboxymethylated cellulose fibers.

[0070] In some implementations, one or more of the absorbent material layers 130a-h includes one or more fenestrations 129, as shown in FIG. 5A. The fenestrations 129 may be slits or openings 129 in one or more directions on the absorbent material layers 130a-h, preferably in a direction planar to a longitudinal axis and transverse to a longitudinal axis of the absorbent materials, which aid in managing a flow of exudate through the various layers 130a-h of the dressing 14. In particular, the fenestrations 129 encourage or enable wound exudate to travel, or be absorbed, in a preferred direction. In some implementations, the fenestrations 129 encourage or enable wound exudate to travel laterally about each layer of the absorbent material layers, as opposed to axially from one layer to another. The fenestrations 129 may be formed mechanically, such as via cutting. The fenestrations 129 are preferably slits about 10 mm in length that may alternate vertically and horizontally in rows and columns across preferably each of the absorbent material layers. The fenestrations all for full use of the absorbent capacity of the absorbent material layers and can also assist in negative pressure transmission through these layers.

[0071] In various embodiments, the dressing 14 includes an adhesive layer 150. The adhesive layer 150 may assist in securing the dressing 14 to the skin of a patient. In one embodiment, the adhesive layer 150 may also assist in creating an exterior housing or envelope with the backing layer 82, within which the inner envelope 100 resides. As shown in FIG. 3A, in one embodiment the adhesive layer 150 is connected to both the backing layer 82 and the wound contact layer 112. In particular, in such an embodiment, the backing layer 82 is adhered to an exterior portion of the adhesive layer 150 radially outwardly from an interior portion of the adhesive layer 150 to which the wound contact layer 112 is adhered. As best shown in FIG. 5A, in one embodiment the adhesive layer 150 has a perimetral shape with a central aperture 154. The aperture 154 in the adhesive layer 150 enables the skin of a user to contact, or be in fluid communication with, the wound contact layer 112 when the dressing 14 is applied to the skin of a user.

[0072] As best shown in FIG. 4, in one embodiment the backing layer first surface 83 is preferably adjacent, and in contact with, the pressure dispersing layer 104 and the adhesive layer 150, while the flexible connector 50 is disposed on the backing layer second surface 84.

[0073] A removable cover 156 may be adhered to an outer surface of the adhesive layer 150. As shown in FIGS. 3A and 5, in one embodiment the removable cover 156 may be adhered to the outer surface of the adhesive layer 150, which is located on an opposite side of the adhesive

layer 150 to which the wound contact layer 112 and backing layer 82 are adhered. The removable cover 156, which may include multiple sections 156a, 156b with folded grip sections 158a, 158b, is removable from the adhesive layer 150. Thus, in a preferred embodiment the removable cover 156 protects the adhesive layer 150 when the removable cover 156 is adhered to the adhesive layer 150, but when the removable cover 156 is removed from the adhesive layer 150 for use of the dressing 14 the outer surface of the adhesive layer 150 is exposed and able to releasably secure the dressing 14 to the skin of a user.

[0074] Turning to FIGS. 7 and 8, the separable connector 44 is shown in detail along with the distal tube 40 and flexible connector 50 of the pressure tube 22. In one embodiment, the distal tube 40 includes, and preferably terminates at one end with, a distal connection portion 170. The distal connection portion 170 may include one or more distal splines 172 arranged radially around the distal connection portion 170. The distal splines 172 engage with corresponding internal splines 174 of a torque member 176 disposed around a portion of the distal tube 40. The torque member 176 assists in rotating the distal connection portion 170 to secure the distal connection portion 170 to the proximate connection portion 188.

[0075] The distal connection portion 170 also preferably includes a first mating member 180, such as threads 180, which may be helical threads. A corresponding second mating member 184, such as threads 184, may be disposed in a proximate connection portion 188, such that the distal connection portion 170 can releasably attach to the proximate connection portion 188 via the engagement of the first mating member 180 with the second mating member 184.

[0076] The combination of the internal splines 174 of the torque member 176 that are able to engage with the corresponding distal splines 172 of the distal connection portion 170 enables a user to more easily manipulate and rotate the distal connection portion 170 relative to the proximate connection portion 188 to selectively attach and detach the distal connection portion 170 to the proximate connection portion 188. FIG. 7 shows the distal connection portion 170 and the proximate connection portion 188 in an attached state, whereas FIG. 8 shows the distal connection portion 170 and the proximate connection portion 188 in a detached state.

[0077] As shown in FIGS. 7 and 8, in one embodiment the proximate connection portion 188 is connected to, and in fluid communication with, an interface tube 194 disposed substantially between the proximate connection portion 188 and the flexible connector 50. It is to be understood that the distal tube 40, distal connection portion 170, proximate connection portion 188, interface tube 194 and flexible connector 50 are all in fluid communication with each other along the tube 22, thus enabling fluid communication between the pump 18 and the dressing 14.

[0078] In a preferred embodiment, the proximate connection portion 188 includes a one-way valve 198. The one-way valve 198 allows fluid to travel through the one-way valve 198 in a first direction while substantially or completely preventing fluid from traveling through the one-way valve 198 in a second direction. As an example, the one-way valve 198 allows fluid to flow through the proximate connection portion 188 towards the pump 18 and away from the dressing 14 while preventing fluid flow away from the pump 18 and towards the dressing 14. Such an arrangement enables a dressing 14 to continue experiencing or exhibiting negative pressure when the distal connection portion 170 and the proximate connection portion 188 are releasably detached, as shown in FIG. 8, increasing user comfort, flexibility and utility of the dressing 14 even when detached from the pump 18.

[0079] The wound exudate management system 10 preferably also includes an indicator system 200 that indicates that a fluid handling capacity of the dressing 14 has been, or shortly will be, reached and that the dressing 14 should be changed to avoid exudate leaking from the dressing 14 or entering the pump 18. The indicator system 200 may produce a signal, such as a visual, audible, vibrational, etc. signal. As an example, the indicator system 200 includes one or more of a gelling absorbent disposed within one or more of the upper absorbent indicator member 70, the backing layer 82, the pressure dispersing layer 104, the wound contact layer 112, the absorbent material layers 130a-h or the flexible connector 50. The gelling absorbent may include the absorbent material described above. The indicator system 200 may visually indicate that exudate has been absorbed by forming a gel. The indicator system 200 may also visually indicate that exudate has been absorbed by changing color as a result of the wound exudate entering the indicator, as a result of the wound exudate contacting some component or material within the dressing, as a result of a color-changing dye activated by exudate or another fluid, or by some other means.

[0080] In some implementations, the wound exudate management system 10, and particularly the dressing 14, can be disposed in a plurality of states. For example, the dressing 14 can be in a first state where the dressing 14 is substantially free of exudate and fluids. The first state may correspond to fibers in the absorbent material of the dressing 14 having a first volume or size. Additionally, in the first state passages between the fibers have a first volume. The dressing 14 can also be in a second state where the fibers in the absorbent material of the dressing 14 have absorbed, and are partially or wholly saturated with, exudate. The first state may correspond to fibers in the absorbent material of the dressing 14 having a second volume or size. The first volume or size is relatively smaller than the second volume or size. Accordingly, the passages or openings between the fibers are relatively large. Similarly, in the second state, wherein after

the fibers swell upon contact with the wound exudate, the volume or size of the passages between the fibers decreases, and the passages or openings between the fibers are relatively small or the fibers close the passages or openings. Upon continued application of negative pressure the exudate is drawn through the saturated fibers of the absorbent material to the indicator system 200.

[0081] Put another way, FIG. 1 shows a wound dressing comprising an outer cover layer, which completely overlies the other layers of the dressing, and a conduit or tube. Beneath the cover layer is an absorbent pad forming a central raised island beneath the cover layer. In one embodiment the absorbent pad comprises the plurality of absorbent material layers.

[0082] The absorbent layer is capable of absorbing exudate from the wound. The outer cover layer covers the side of the absorbent layer furthest from the wound as shown in FIGS. 3A, 4 and 5, the cover layer, also referred to as the backing layer, adapted to enable negative pressure to be applied at the wound and having a port in fluid communication with the absorbent layer. The conduit, or tubing, allows fluid communication between the port and a source of negative pressure, the conduit being connected to the outer layer by an adhesive ring. An indicator means, or upper absorbent indicator member, is provided in the port. In one embodiment the indicator means comprises a layer of gel forming fibres. Alternatively, the indicator means may also be provided still in the port, but above the cover layer. The dressing further comprises a wound contact layer adhered to the absorbent layer by a layer of heat sealable lace consisting of a polyamide lace layer. The dressing further comprises an exudate and pressure distribution layer, also referred to as a pressure dispersing layer, preferably of polyester foam which serves to spread exudate across the absorbent layer and smooth the application of negative pressure across the dressing. A further heat sealable lace layer may be provided between the distribution layer and the cover layer. The heat sealable layers assist in adhering the layers together. The absorbent layer, the wound contact layer and the indicator means comprise gel forming fibres in the form of a layer or layers carboxymethylated cellulose fabric.

[0083] In one embodiment, the absorbent layer is smaller in area than the cover layer, as shown in FIG. 5A, so that it forms an island within a frame of the cover layer. A silicone adhesive may be applied to the frame on the side of the cover layer facing the wound so as to seal the dressing to the skin surrounding the wound. Alternatively, the dressing can be secured to the wound by a perforated adhesive covering the wound facing surface of the dressing with or without a window over the adhesive pad and/or by dressing strips applied to the outer surface of the cover layer and the skin surrounding the dressing.

[0084] In use, the dressing may be secured to the skin surrounding the wound and the conduit, connected to a source of negative pressure by the connector located at the distal end of the conduit. Negative pressure is applied to the wound by the application of negative pressure through the pathway for fluid leading from the wound, through the absorbent layer, the port and to the distal end of the conduit. Exudate is absorbed by the wound contact layer and transmitted to the absorbent layer by close contact. Fenestrations which may be present in the absorbent layer, assist with the absorbance of exudate and that application of negative pressure. As exudate is absorbed by the absorbent layer it spreads beneath the distribution layer so that a greater area of the absorbent layer is accessed by the exudate and a greater capacity of the absorbent layer is used. Once the absorbent capacity of the absorbent layer has been reached, the exudate spreads towards the port and is absorbed by the indicator means which gels. The formation of the gel and possible colour change of the indicator means is visible to the user of the dressing and indicates that the dressing needs to be changed. The indicator means may also or alternatively be present in the conduit or in its lock where it can also be seen by the user and may provide additional time for dressing change before the exudate is drawn into the pump or other source of negative pressure.

[0085] While some implementations have been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the disclosure, and the scope of protection is only limited by the scope of the accompanying claims. Further, the present disclosure provides a sign base and a sign assembly having increased structural strength, improved aesthetic design, a footprint facilitating flexible sign base placement and a wheel arrangement allowing easy sign assembly transportation.

[0086] The disclosed systems and methods are well adapted to attain the ends and advantages mentioned as well as those that are inherent therein. The particular implementations disclosed above are illustrative only, as the teachings of the present disclosure may be modified and practiced in different but equivalent manners apparent to those skilled in the art having the benefit of the teachings herein. Furthermore, no limitations are intended to the details of construction or design herein shown, other than as described in the claims below. It is therefore evident that the particular illustrative implementations disclosed above may be altered, combined, or modified and all such variations are considered within the scope of the present disclosure. The systems and methods illustratively disclosed herein may suitably be practiced in the absence of any element that is not specifically disclosed herein and/or any optional element disclosed herein. While compositions and methods are described in terms of “comprising,” “containing,” or “including” various components or steps, the compositions and methods can

also “consist essentially of” or “consist of” the various components and steps. All numbers and ranges disclosed above may vary by some amount. Whenever a numerical range with a lower limit and an upper limit is disclosed, any number and any included range falling within the range are specifically disclosed. In particular, every range of values (of the form, “from about a to about b,” or, equivalently, “from approximately a to b,” or, equivalently, “from approximately a-b”) disclosed herein is to be understood to set forth every number and range encompassed within the broader range of values. Also, the terms in the claims have their plain, ordinary meaning unless otherwise explicitly and clearly defined by the patentee. Moreover, the indefinite articles “a” or “an,” as used in the claims, are defined herein to mean one or more than one of the element that it introduces. If there is any conflict in the usages of a word or term in this specification and one or more patent or other documents that may be incorporated herein by reference, the definitions that are consistent with this specification should be adopted.

[0087] As used herein, the phrase “at least one of” preceding a series of items, with the terms “and” or “or” to separate any of the items, modifies the list as a whole, rather than each article of the list (i.e., each item). The phrase “at least one of” allows a meaning that includes at least one of any one of the items, and/or at least one of any combination of the items, and/or at least one of each of the items. By way of example, the phrases “at least one of A, B, and C” or “at least one of A, B, or C” each refer to only A, only B, or only C; any combination of A, B, and C; and/or at least one of each of A, B, and C.

CLAIMS

What is claimed is:

1. A wound exudate management system, comprising:
 - a pump for generating negative pressure;
 - a dressing for covering and protecting a wound, the dressing comprising:
 - an adhesive layer for adhering the dressing adjacent the wound;
 - a wound contact layer for contacting the wound;
 - a pressure dispersion layer;
 - a plurality of layers of absorbent material disposed between the wound contact layer and the pressure dispersion layer; and,
 - a backing layer having a first surface and a second surface, the first surface of the backing layer being adjacent, and in contact with, the pressure dispersion layer and the adhesive layer;
 - a pressure tube having an interior lumen, the pressure tube disposed between the pump and the dressing such that the pump and the dressing are in fluid communication via the interior lumen; and,
 - a flexible connector connected to the second surface of the backing layer.
2. The wound exudate management system of claim 1, wherein the dressing includes an envelope structure formed by joined peripheral portions of the pressure dispersion layer and the wound contact layer, the envelope structure defining a cavity.
3. The wound exudate management system of claim 1, further comprising a thermoplastic spun lace layer connected to the pressure dispersion layer, and a nonwoven spun lace layer connected to the wound contact layer, and wherein an envelope structure is formed by joining peripheral portions of the thermoplastic spun lace layer and the nonwoven spun lace layer such that the plurality of layers of absorbent material are disposed substantially within an interior cavity of the envelope structure.
4. The wound exudate management system of any of the preceding claims, wherein the absorbent material is disposed within the cavity of the envelope structure.
5. The wound exudate management system of any of the preceding claims, wherein the absorbent material comprises carboxymethylated cellulose fibers.
6. The wound exudate management system of any of the preceding claims, wherein the wound contact layer comprises carboxymethylated cellulose fibers.
7. The wound exudate management system of any of the preceding claims, wherein the wound contact layer has reinforcing nylon stitching.

8. The wound exudate management system of any of the preceding claims, wherein the pressure dispersion layer comprises a reticulated foam.
9. The wound exudate management system of any of the preceding claims, further comprising fenestrations in the one or more of the plurality of layers of absorbent material.
10. The wound exudate management system of any of the preceding claims, further comprising a pressure conveyance member disposed within the flexible connector.
11. The wound exudate management system of any of the preceding claims, further comprising an upper absorbent indicator member and an upper adhesive member, and wherein the upper adhesive member adheres the flexible connector and the upper absorbent indicator member to the backing layer.
12. A wound exudate management system, comprising:
 - a dressing for covering and protecting a wound, the dressing comprising:
 - a wound contact layer, the wound contact layer having a first surface and a second surface, the wound contact layer further having a peripheral region and a central region, wherein the first surface of the wound contact layer contacts the wound when the dressing is adhered to skin adjacent the wound;
 - a pressure dispersion layer having a peripheral region and a central region;
 - a plurality of layers of absorbent material disposed between the second surface of the wound contact layer and the pressure dispersion layer; and
 - an envelope formed by joining the peripheral region of the pressure dispersion layer with the peripheral region of the second surface of the wound contact layer, the plurality of layers of absorbent material being disposed substantially within an interior cavity of the envelope.
13. The wound exudate management system of claim 12, further comprising a thermoplastic spun lace layer connected to the pressure dispersion layer, and a nonwoven spun lace layer connected to the wound contact layer, and wherein the envelope is formed by joining peripheral portions of the thermoplastic spun lace layer and the nonwoven spun lace layer, wherein the interior cavity of the envelope is formed by the nonwoven spun lace layer and the thermoplastic spun lace layer, and wherein the plurality of layers of absorbent material are disposed substantially within an interior cavity of the envelope.
14. The wound exudate management system of claim 12 or claim 13, wherein the absorbent material includes carboxymethylated cellulose fibers.
15. The wound exudate management system of claim 12 or claim 13, wherein the wound contact layer includes carboxymethylated cellulose fibers.

16. A wound exudate management system, comprising:
- a dressing for covering and protecting a wound, the dressing comprising a wound contact layer, a backing layer and at least one layer of absorbent material layer between the wound contact layer and the backing layer;
 - a flexible connector having an interior lumen, the flexible connector secured to the backing layer of the dressing;
 - an indicator between the backing layer and the flexible connector;
 - a tube having an interior lumen, the tube connected to the flexible connector, wherein the interior lumen of the flexible connector and the interior lumen of the tube are in fluid communication; and,
 - a pressure conveyance member disposed within the interior lumen of the tube.
17. The wound exudate management system of claim 16, wherein the pressure conveyance member comprises a flexible lattice structure.
18. The wound exudate management system of claim 16 or claim 17, wherein the pressure conveyance member is disposed within the flexible connector.
19. The wound exudate management system of claim 16, wherein the flexible connector has a substantially planar exterior surface.
20. A wound exudate management system, comprising:
- a pump for generating negative pressure;
 - a dressing for covering and protecting a wound, the dressing comprising a wound contact layer, a backing layer and at least one layer of absorbent material between the wound contact layer and the backing layer;
 - a tube connecting the pump and the dressing, the tube having an interior lumen for placing the pump and the dressing in fluid communication via the interior lumen; and,
 - a one-way valve in-line between the pump and the dressing to maintain a negative pressure within the dressing when the pump is disconnected from the tube.
21. The wound exudate management system of claim 20, wherein the one-way valve is connected to one of the pump and the tube.
22. A wound exudate management system, comprising:
- a pump for generating negative pressure;
 - a dressing for covering and protecting a wound;
 - a pressure tube including an interior lumen, the pressure tube disposed between the pump and the dressing such that the pump and the dressing are in fluid communication via the interior lumen of the pressure tube; and,

a plurality of layers of absorbent material disposed in the dressing, wherein the absorbent material has fibers that swell upon contact with wound exudate to manage a flow of wound exudate through a portion of the dressing.

23. The wound exudate management system of claim 22, wherein the fibers in the absorbent material comprise carboxymethylated cellulose fibers.

24. The wound exudate management system of claim 22 or claim 23, wherein the fibers in the absorbent material have a first volume prior to wound exudate being introduced to the absorbent material, wherein the fibers in the absorbent material have a second volume after wound exudate is introduced to the absorbent material, and wherein the second volume is greater than the first volume.

25. The wound exudate management system of claim 22 or claim 23, wherein after the fibers swell upon contact with the wound exudate, a volume of passages between the fibers decreases.

26. A negative pressure wound dressing for use in applying negative pressure to a wound comprising:

an absorbent layer capable of absorbing exudate from the wound and allowing the passage of fluid through it;

an outer cover layer covering the side of the absorbent layer furthest from the wound, the cover layer adapted to enable negative pressure to be applied at the wound and having a port;

a conduit having a proximal end attached to the port and a distal end, the dressing provided with a pathway for fluid from the wound, through the absorbent layer, the port and to the distal end of the conduit; and,

an indicator positioned in the pathway at a location between the absorbent layer and the distal end of the conduit, the indicator means capable of absorbing exudate to indicate the presence of exudate at the side of the absorbent layer furthest from the wound.

27. A negative pressure wound dressing as claimed in claim 26 wherein the indicator means gives a visual indication of the presence of exudate at the side of the absorbent layer furthest from the wound.

28. A negative pressure wound dressing as claimed in claim 26 or claim 27 wherein the indicator means is located so that it is visible to the user of the dressing.

29. A negative pressure wound dressing as claimed in any of claims 26 to 28 wherein the indicator means is located in the port in the cover layer.

30. A negative pressure wound dressing as claimed in any of claims 26 to 29 wherein the indicator means is located in the conduit.

31. A negative pressure wound dressing as claimed any of claims 26 to 30 wherein the indicator means is a gelling absorbent which visually indicates that it has absorbed exudate by forming a gel.
32. A negative pressure wound dressing as claimed in any of claims 26 to 31 wherein the indicator means visually indicates that it has absorbed exudate by changing colour.
33. A negative pressure wound dressing as claimed in any of claims 26 to 32 wherein the indicator means is a layer of gel-forming fibres.
34. A negative pressure wound dressing as claimed in any of claims 26 to 33 wherein the outer cover layer is a barrier layer which resists the ingress of liquid and air but allows moisture vapour transmission from the wound.
35. A negative pressure wound dressing as claimed in any of claims 26 to 42 wherein the dressing is adhered to the skin surrounding the wound by an adhesive which provides a fluid tight seal between the dressing and the wound.
36. A negative pressure wound dressing as claimed in any of claims 25 to 35, wherein a distribution layer is positioned between the absorbent layer and the cover layer and serves to aid the spread of exudate across the absorbent layer.
37. A negative pressure wound dressing as claimed in claim 36 wherein the distribution layer is a foam layer.
38. A negative pressure wound dressing as claimed in any of claims 26 to 37 wherein the distal end of the conduit is connected to source of negative pressure.
39. A negative pressure wound dressing as claimed in claim 38 wherein the source of negative pressure is a battery operated pump.
40. A negative pressure system comprising a wound dressing as claimed in claim 26 and a source of negative pressure connected to the distal end of the conduit.
41. A negative pressure system as claimed in claim 40 further comprising a fluid collection chamber connected between the dressing and the source of negative pressure and in fluid communication therewith.
42. A negative pressure wound dressing as claimed in any of claims 26 to 41 wherein the absorbent layer is smaller than the cover layer and is positioned as an island within an outer perimeter of the cover layer so that the absorbent layer is framed by the cover layer.
43. A negative pressure wound dressing as claimed in claim 42 wherein the cover layer is provided with adhesive on its underside which adheres the dressing to the skin surrounding the wound with a fluid tight seal.

44. A negative pressure wound dressing as claimed in any of claims 26 to 43 wherein the absorbent layer is in direct contact with the wound.
45. A negative pressure wound dressing as claimed in any of claims 26 to 44 wherein the dressing further comprises a wound contact layer positioned between the wound and the absorbent layer.
46. A negative pressure wound dressing as claimed in any of claims 26 to 45 wherein the conduit further comprises a one way valve at its distal end.
47. A negative pressure wound dressing as claimed in any of claims 26 to 46 wherein the conduit further comprise a luer lock at its distal end.
48. A negative pressure wound dressing as claimed in claim 26 wherein the indicator means activates a remote alarm, for example an audible alarm on absorption of exudate.

FIG. 1

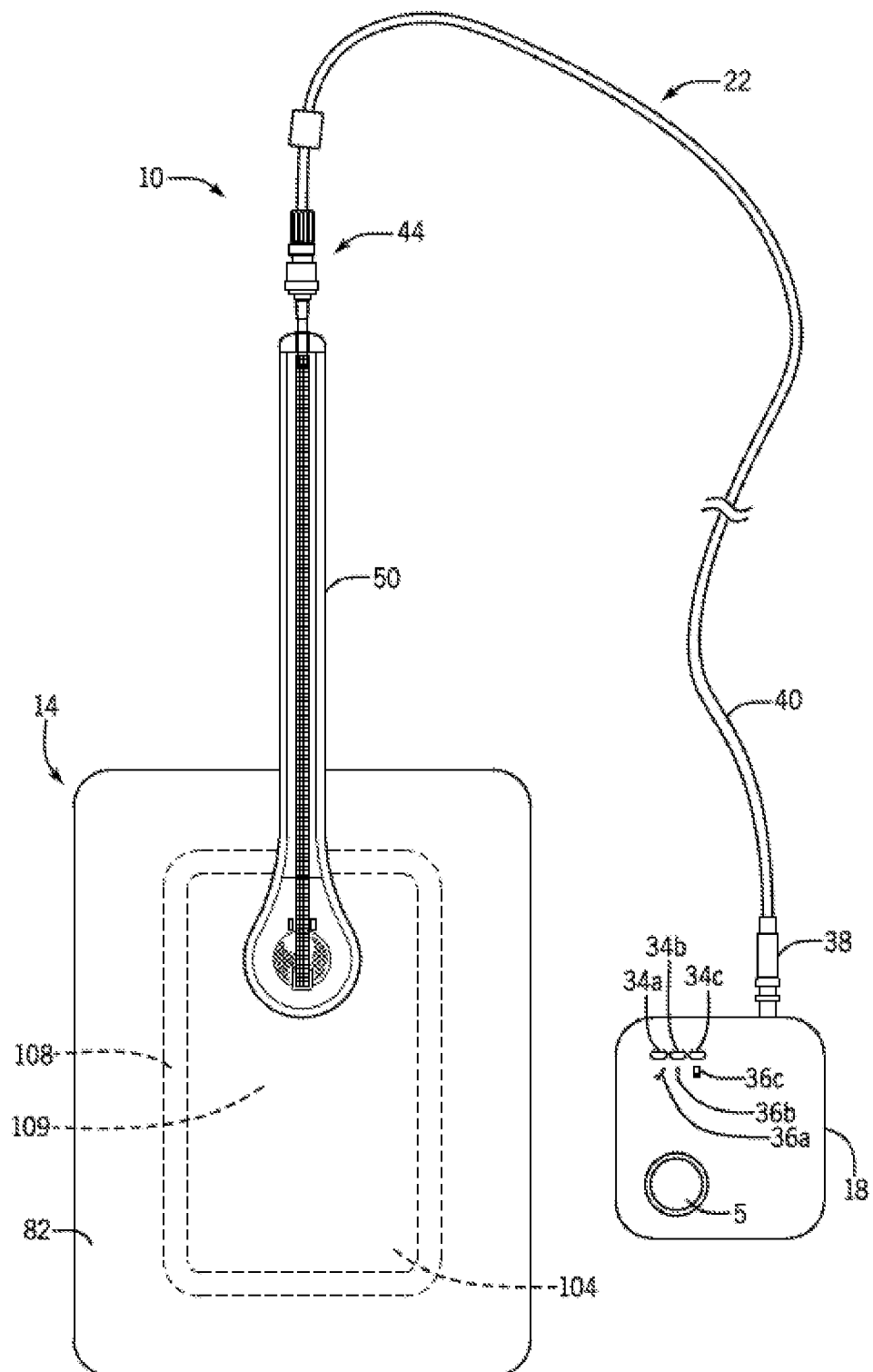
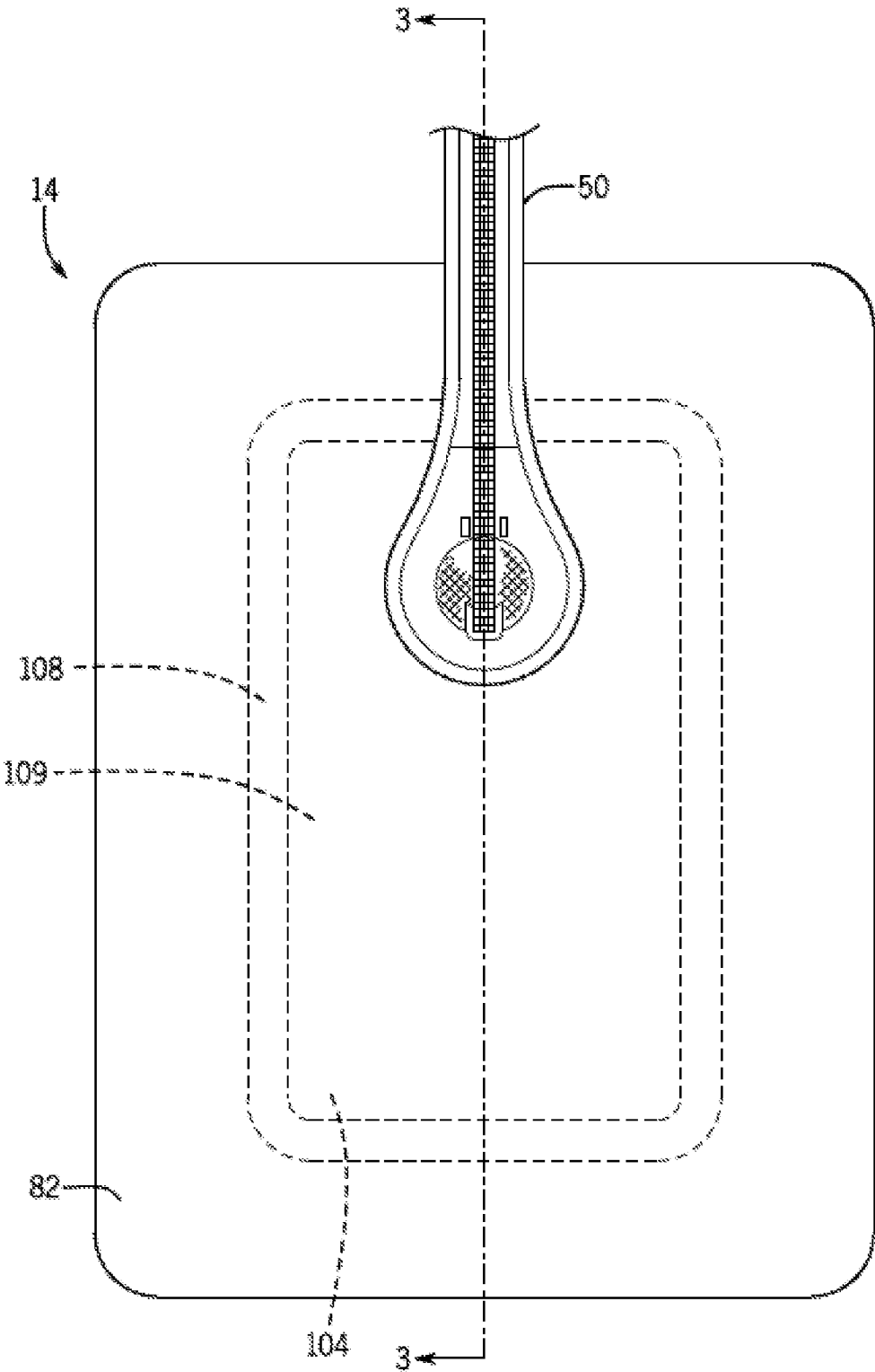


FIG. 2



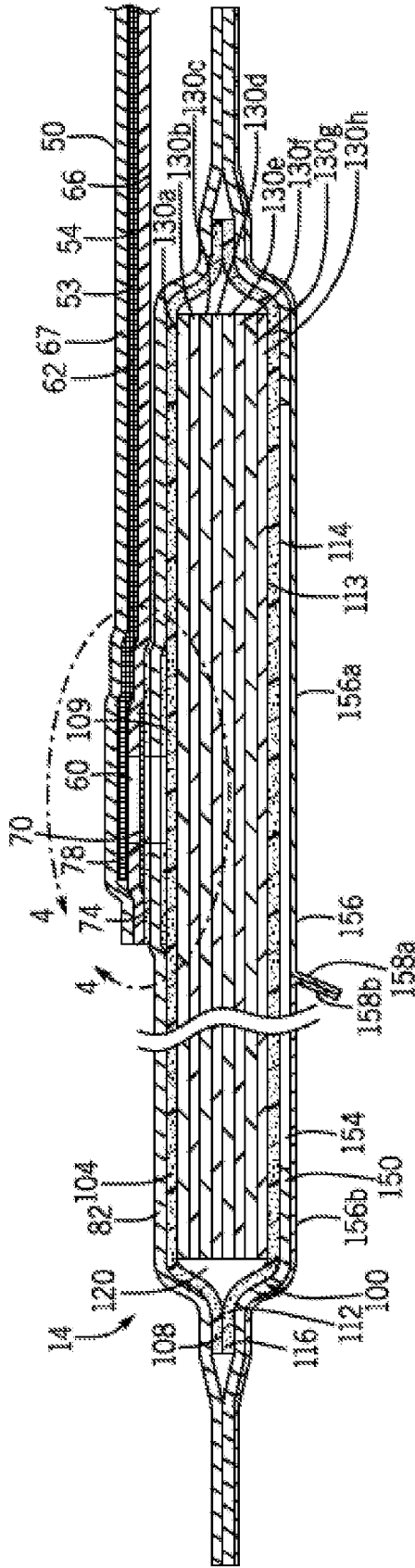


FIG. 3A

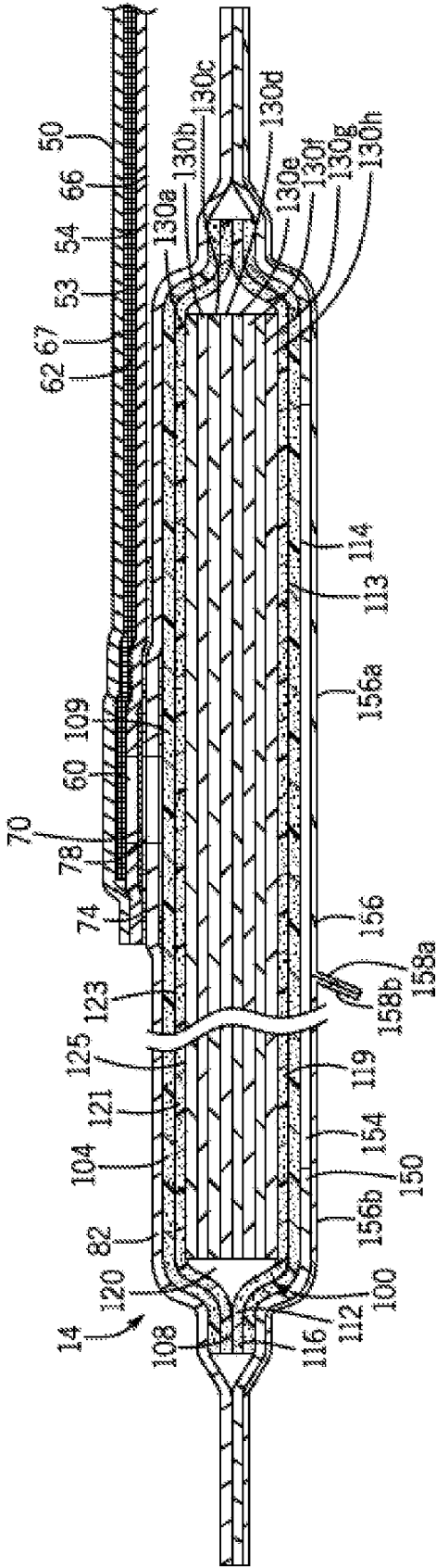


FIG. 3B

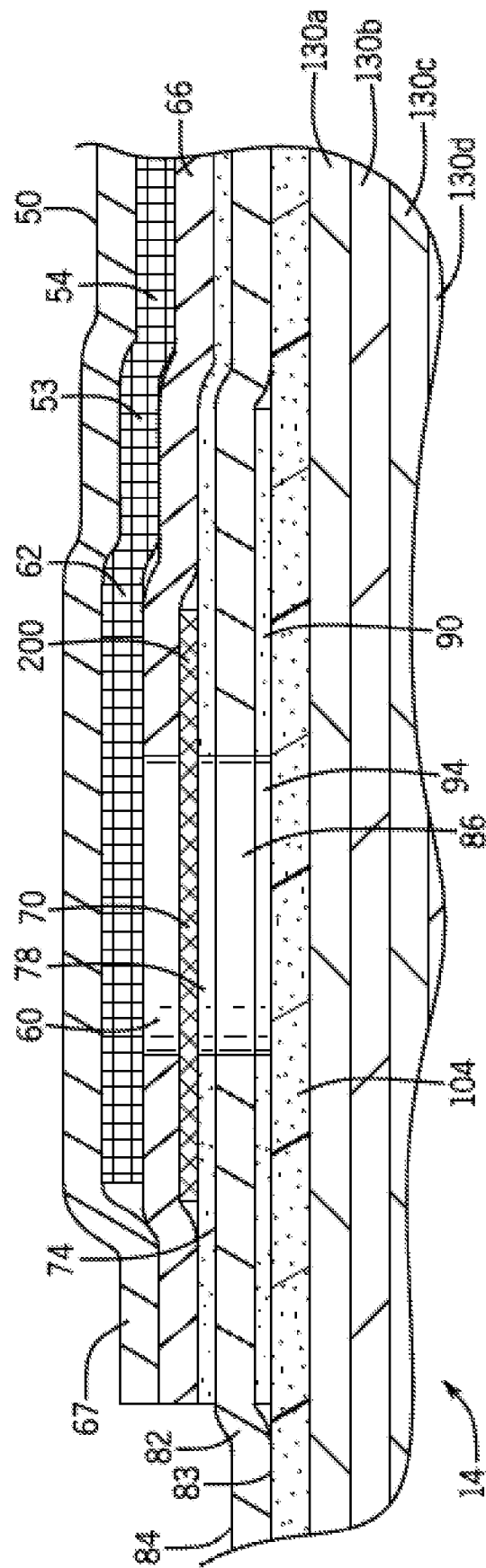


FIG. 4

FIG. 5A

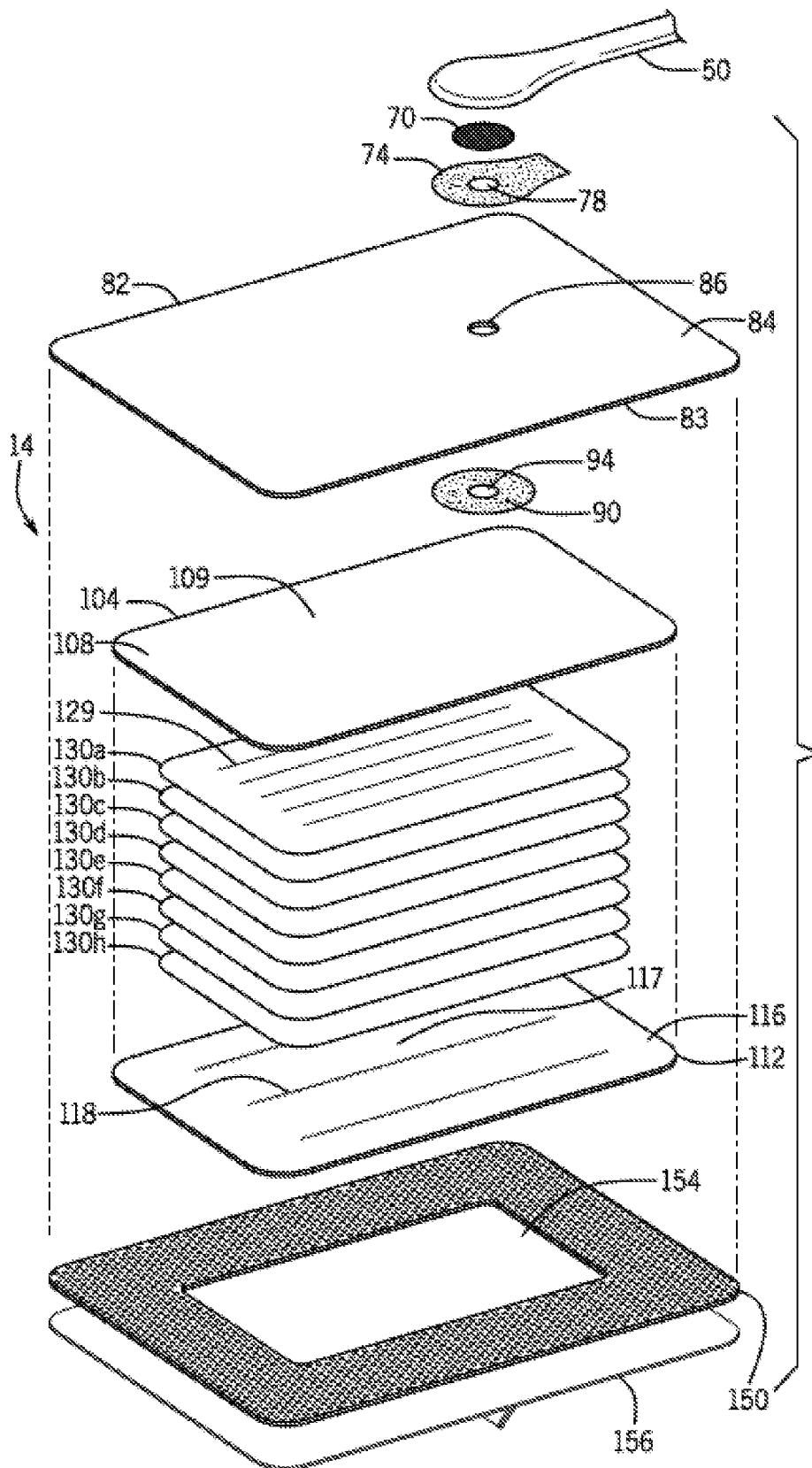


FIG. 5B

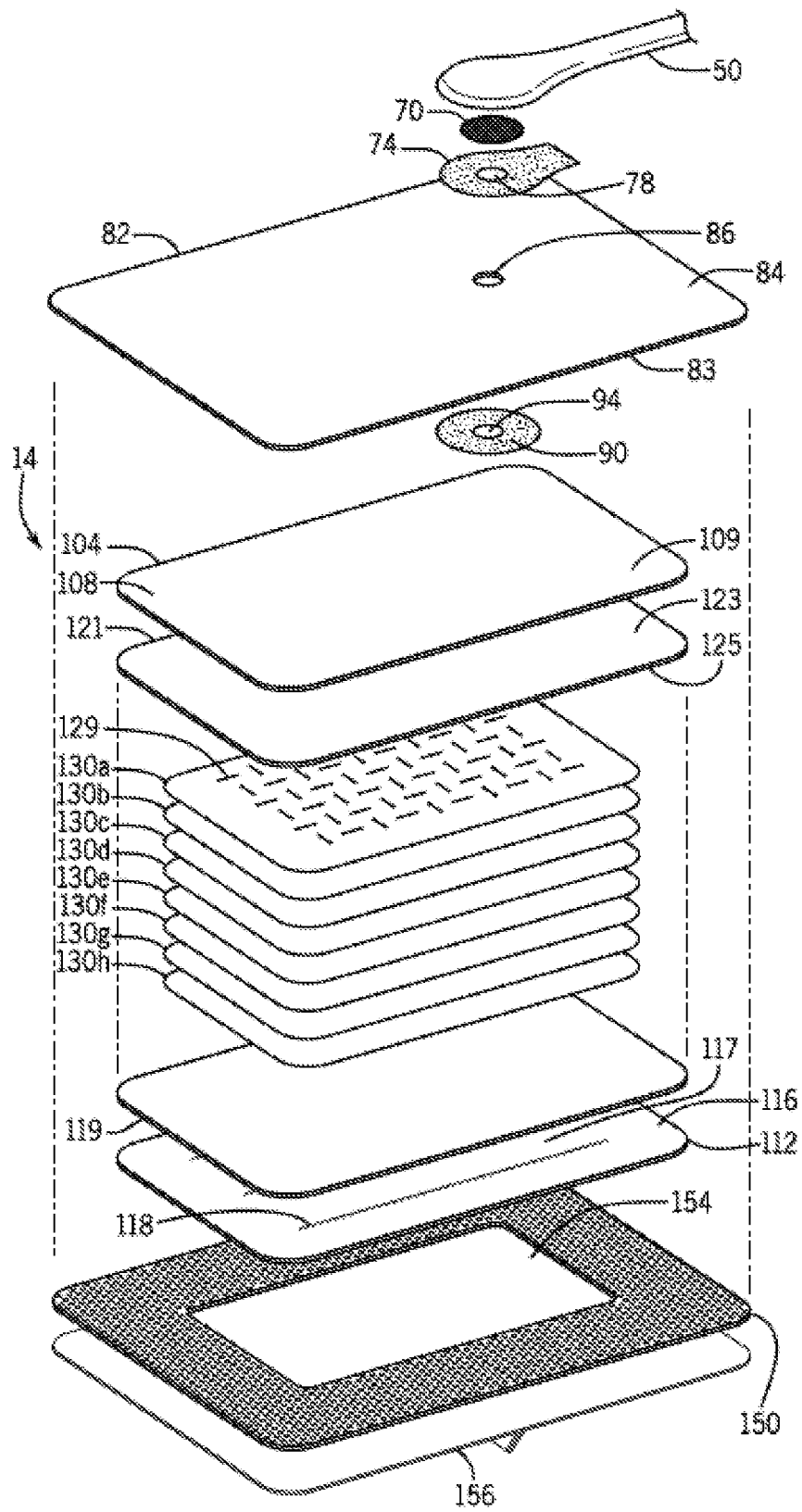


FIG. 6

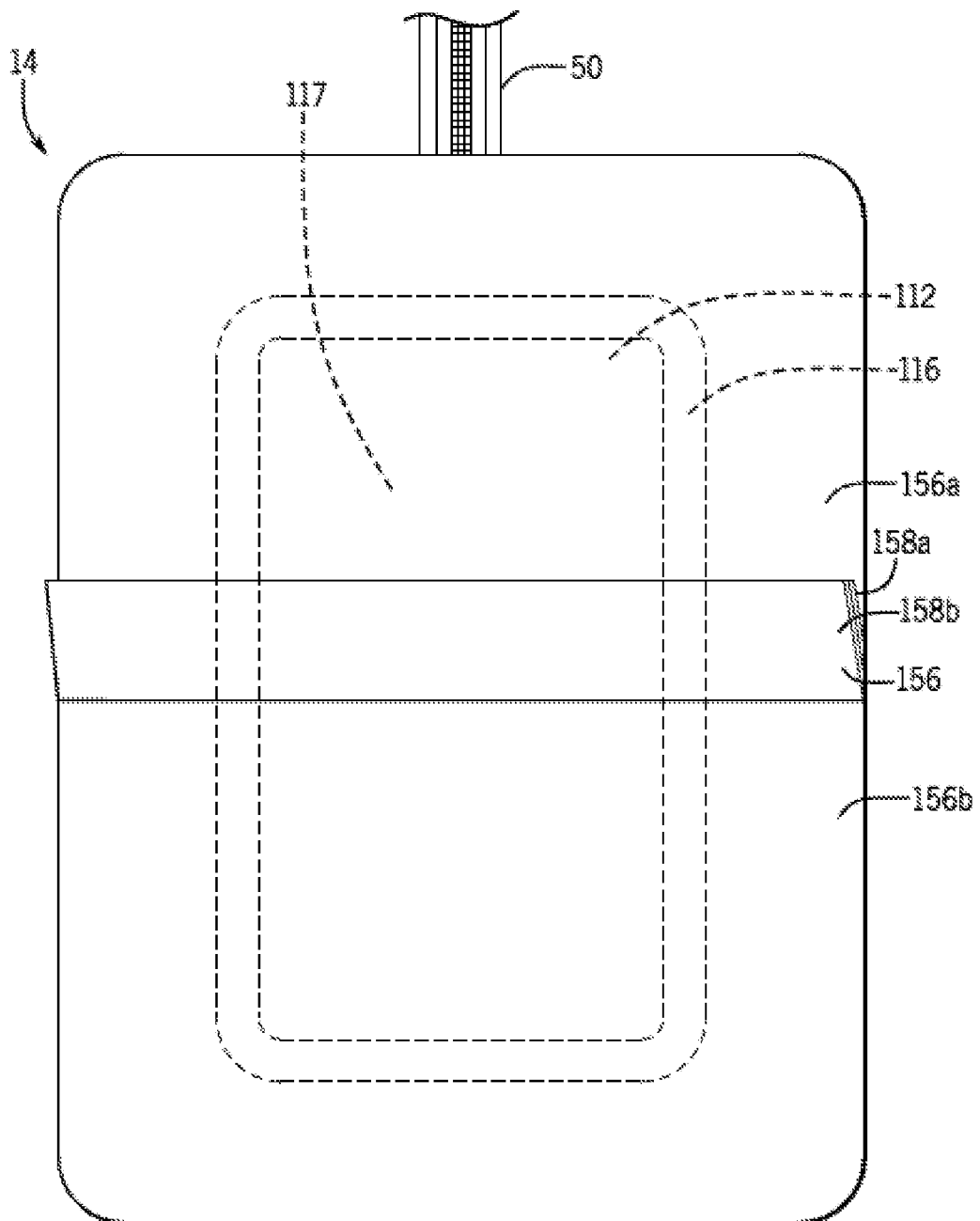


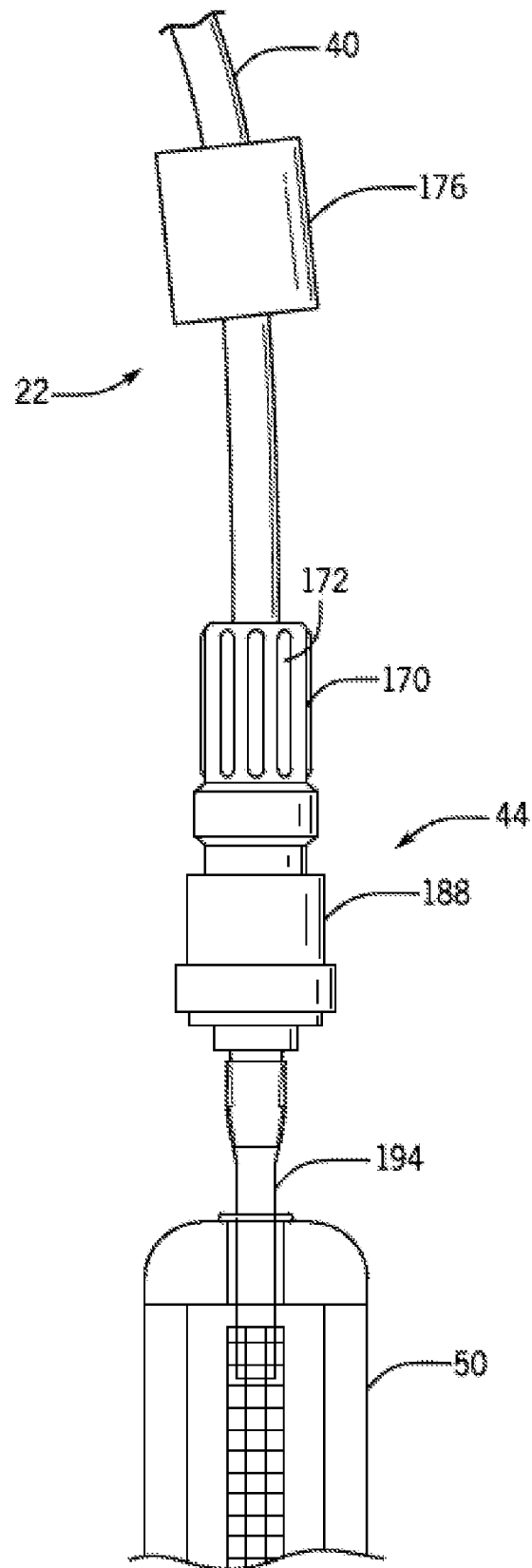
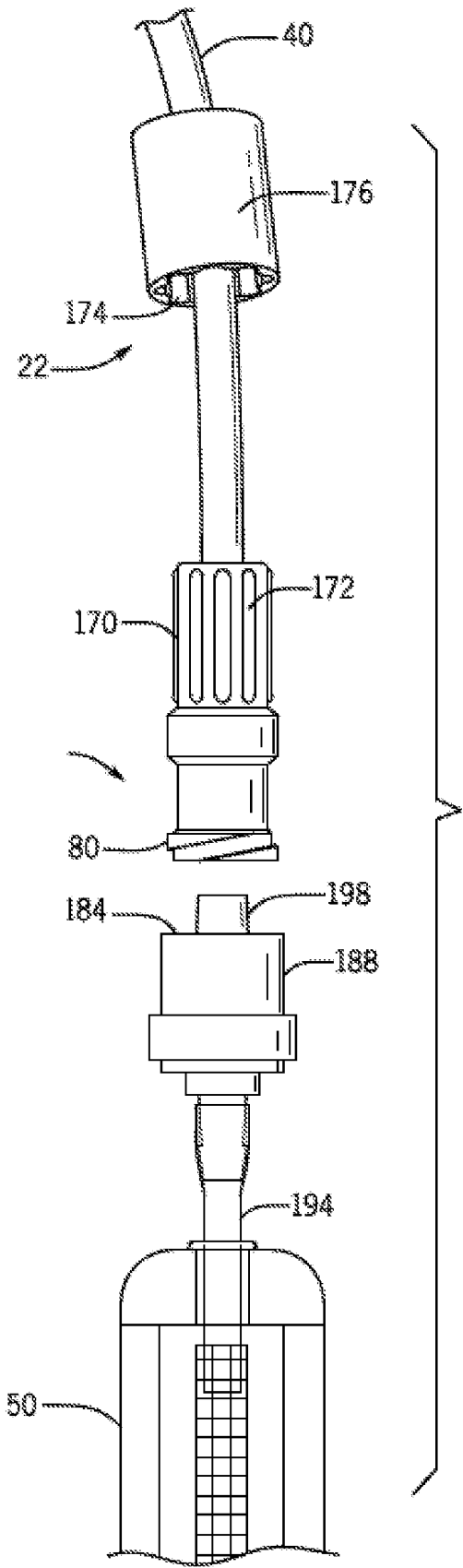
FIG. 7

FIG. 8



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US17/31817

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5-11, 29-39 and 42-47
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US17/31817

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 13/02; 13/00; A61M 1/00 (2017.01)

CPC - A61F 13/022, 13/00068, 13/0216; A61M 1/0056, 1/0086, 1/0088

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 2010/0069863 A1 (OLSON, JS) March 18, 2010; figures 1-3; paragraphs [0004], [0008], [0019], [0027], [0031]-[0033], [0063], [0041]-[0042], [0052]-[0054], [0056], [0059]	22, 24/22, 25/22 ----- 23, 24/23, 25/23, 26, 27, 28/26, 28/27, 40-41
Y	US 2011/0276016 A1 (TSAI, ML) November 10, 2011; paragraph [0035]	23, 24/23, 25/23
Y	US 2015/0351970 A1 (SMITH & NEPHEW PLC) December 10, 2015; figures 1A-B; paragraph [0003], [0017], [0019]; claim 28	26, 27, 28/26, 28/27, 40, 41
Y	US 2013/0296816 A1 (GREENER, B) November 7, 2013; figure 2; paragraphs [0088], [0093]	41
A	US 2015/0182677 A1 (SMITH & NEPHEW PLC) July 2, 2015; figures 1, 2A-C, 3A-B; paragraphs [0006], [0011]-[0012], [0105], [0107], [0111], [0116], [0118], [0167]	1-4, 12-21
A	US 2015/0057625 A1 (KCI LICENSING, INC.) February 26, 2015; figures 1, 9; paragraph [0006], [0034], [0066]-[0068], [0070]-[0071]	1-4, 12-21
A	US 2010/0036333 A1 (SCHENK, III, AA et al.) February 11, 2010; figure 3; paragraph [0027]	48
A	US 2013/0267918 A1 (PAN, L et al.) October 10, 2013; figure 16; paragraph [0050]	48

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

14 July, 2017 (14.07.2017)

Date of mailing of the international search report

11 AUG 2017

Name and mailing address of the ISA/

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