

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**

**[0008a]** In one aspect, provided herein is 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;
- 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; and
- a pressure dispersion layer in contact with the backing layer;

wherein the dressing comprises an envelope structure formed by joined peripheral portions of the pressure dispersion layer and the wound contact layer, and

wherein the at least one layer of absorbent material is disposed within the envelope structure

**[0008b]** In one aspect, provided herein is 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, a pressure dispersion layer in contact with the backing layer, and at least one layer of absorbent material between the wound contact layer and the backing layer, wherein the dressing comprises an envelope structure formed by joined peripheral portions of the pressure dispersion layer and the wound contact 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;

- 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; and

- an indicator member positioned between the backing layer and the pump.

**[0008c]** In one aspect, provided herein is 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 a plurality of layers 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;

- 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;

- a pressure dispersion layer in contact with the backing layer;

- a thermoplastic spun lace layer connected to the pressure dispersion layer; and

- a nonwoven spun lace layer connected to the wound contact layer;

wherein the dressing is shaped to form an envelope structure via joined peripheral portions of the pressure dispersion layer and the wound contact layer; and

wherein the plurality of layers of absorbent material are disposed within an interior cavity of the envelope structure.

**[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 example, 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

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 examples, 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.

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 examples 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

## 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 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;
  - 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; and
  - a pressure dispersion layer in contact with the backing layer;wherein the dressing comprises an envelope structure formed by joined peripheral portions of the pressure dispersion layer and the wound contact layer, and  
wherein the at least one layer of absorbent material is disposed within the envelope structure.
2. The wound exudate management system of claim 1, wherein the one-way valve is connected to one of the pump and the tube.
3. The wound exudate management system of claim 1, wherein the pressure dispersion layer comprises a reticulated foam, a polyester foam or a polyurethane foam.
4. The wound exudate management system of claim 1, wherein the at least one layer of absorbent material comprises about eight layers of absorbent material.
5. The wound exudate management system of claim 1, wherein the at least one layer of absorbent material comprises chemically modified cellulosic fibers.
6. The wound exudate management system of claim 1, wherein the at least one layer of absorbent material comprises one or more fenestrations.
7. The wound exudate management system of claim 1, wherein the wound contact layer comprises chemically modified cellulosic fibers.

8. The wound exudate management system of claim 1, wherein the wound contact layer comprises reinforced stitching.
9. The wound exudate management system of claim 1, further comprising an indicator member.
10. The wound exudate management system of claim 1, wherein the backing layer has a Moisture Vapor Transmission Rate (MVTR) of at least about 10,000 g/m<sup>2</sup> per 24 hours.
11. The wound exudate management system of claim 1, wherein the backing layer comprises a port.
12. The wound exudate management system of claim 1, further comprising an adhesive layer.
13. The wound exudate management system of claim 1, further comprising a thermoplastic spun lace layer.
14. The wound exudate management system of claim 1, further comprising a nonwoven spun lace layer.
15. 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, a pressure dispersion layer in contact with the backing layer, and at least one layer of absorbent material between the wound contact layer and the backing layer, wherein the dressing comprises an envelope structure formed by joined peripheral portions of the pressure dispersion layer and the wound contact 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;
  - 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; and
  - an indicator member positioned between the backing layer and the pump.

16. The wound exudate management system of claim 15, wherein the dressing comprises an envelope structure formed by joined peripheral portions of (i) a pressure dispersion layer in contact with the backing layer and (ii) the wound contact layer.

17. The wound exudate management system of claim 16, wherein the at least one layer of absorbent material is disposed within the envelope structure.

18. The wound exudate management system of claim 15, wherein the indicator member is capable of absorbing exudate.

19. The wound exudate management system of claim 18, wherein the indicator member comprises gel-forming fibers.

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 a plurality of layers 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;

- 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;

- a pressure dispersion layer in contact with the backing layer;

- a thermoplastic spun lace layer connected to the pressure dispersion layer; and

- a nonwoven spun lace layer connected to the wound contact layer;

wherein the dressing is shaped to form an envelope structure via joined peripheral portions of the pressure dispersion layer and the wound contact layer; and

wherein the plurality of layers of absorbent material are disposed within an interior cavity of the envelope structure.