

(12) **DEMANDE DE BREVET CANADIEN**
CANADIAN PATENT APPLICATION

(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2017/03/06

(87) Date publication PCT/PCT Publication Date: 2017/09/14

(85) Entrée phase nationale/National Entry: 2018/09/04

(86) N° demande PCT/PCT Application No.: EP 2017/055225

(87) N° publication PCT/PCT Publication No.: 2017/153357

(30) Priorités/Priorities: 2016/03/07 (US62/304910);
2016/03/07 (US62/304790); 2016/03/09 (US62/305926);
2016/04/26 (US62/327537)

(51) Cl.Int./Int.Cl. *A61F 13/00* (2006.01),
A61F 13/02 (2006.01), *A61M 1/00* (2006.01)

(71) Demandeur/Applicant:
SMITH & NEPHEW PLC, GB

(72) **Inventeurs/Inventors:**
 ASKEM, BEN ALAN, GB;
 GOWANS, JOHN PHILIP, GB;
 HUNT, ALLAN KENNETH FRAZER GRUGEON, GB;
 BEADLE, VICTORIA, GB;
 KELBIE, WILLIAM, GB;
 HESKETH, MARK, GB;
 MUSGRAVE, DAMYN, GB;
 ROBINSON, JOSEPH WILLIAM, GB

(74) **Agent:** BORDEN LADNER GERVAIS LLP

(54) Titre : APPAREILS ET PROCEDES DE TRAITEMENT DE PLAIES AVEC UNE SOURCE DE PRESSION NEGATIVE INTEGREE DANS UN PANSEMENT

(54) Title: WOUND TREATMENT APPARATUSES AND METHODS WITH NEGATIVE PRESSURE SOURCE INTEGRATED INTO WOUND DRESSING

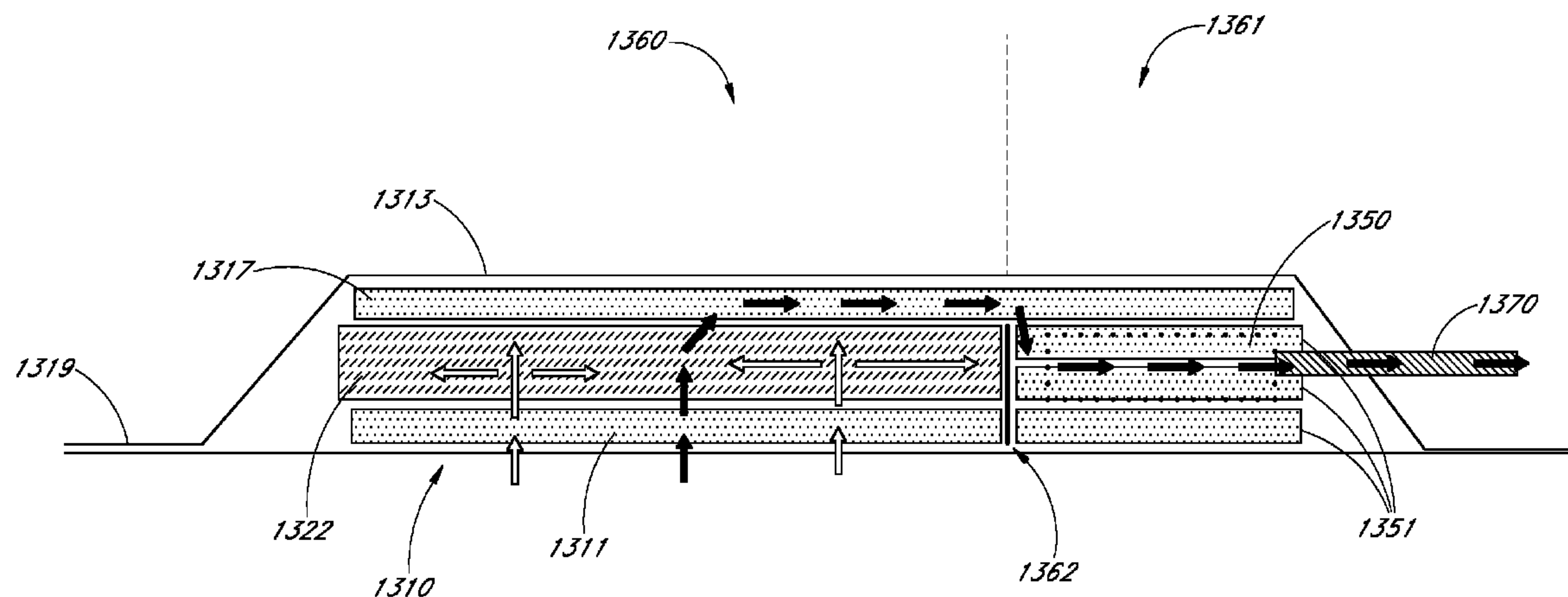
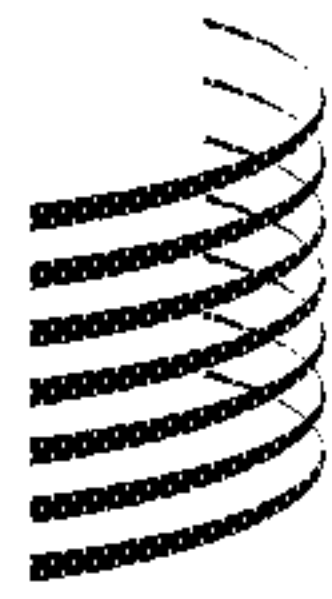


FIG. 14

(57) Abrégé/Abstract:

Disclosed embodiments relate to apparatuses and methods for wound treatment. In some embodiments, a negative pressure source is incorporated into a wound dressing apparatus so that the wound dressing and the negative pressure source are part of an integral or integrated wound dressing structure that applies the wound dressing and the negative pressure source simultaneously to a patient's wound. The negative pressure source and/or electronic components may be positioned between a wound contact layer and a cover layer of the wound dressing. The negative pressure source and/or electronic components may be separated and/or partitioned from an absorbent area of the dressing. A switch may be integrated with the wound dressing to control operation of the wound dressing apparatus. A connector may be direct air from an outlet of the negative pressure source to the environment. A non-return valve may inhibit back flow of air into the wound dressing.

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

(19) World Intellectual Property
Organization
International Bureau(10) International Publication Number
WO 2017/153357 A1(43) International Publication Date
14 September 2017 (14.09.2017)

WIPO | PCT

(51) International Patent Classification:

A61F 13/00 (2006.01) *A61F 13/02* (2006.01)
A61M 1/00 (2006.01)

(21) International Application Number:

PCT/EP2017/055225

(22) International Filing Date:

6 March 2017 (06.03.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/304790	7 March 2016 (07.03.2016)	US
62/304910	7 March 2016 (07.03.2016)	US
62/305926	9 March 2016 (09.03.2016)	US
62/327537	26 April 2016 (26.04.2016)	US

(71) Applicant: **SMITH & NEPHEW PLC** [GB/GB]; 15 Adam Street, London WC2N 6LA (GB).

(72) Inventors: **ASKEM, Ben, Alan**; Smith & Nephew Research Centre York Science Park, Heslington, York YO10 5DF (GB). **GOWANS, John, Philip**; 7 Cannon Tardrew Court Hessle, Hull HU13 9QD (GB). **HUNT, Allan, Kenneth, Frazer, Grurgeon**; Smith & Nephew Research Centre York Science Park, Heslington, York YO10 5DF (GB). **BEADLE, Victoria**; Smith & Nephew Research Centre York Science Park, Heslington, York YO10 5DF (GB). **KELBIE, William**; Smith & Nephew Research Centre York Science Park, Heslington, York YO10 5DF (GB). **HESKETH, Mark**; PA Consulting Services Limited Back Lane, Melbourn Hertfordshire SG8 6DP (GB). **MUSGRAVE, Damyn**; PA Consulting Services Limited Back Lane, Melbourn Hertfordshire SG8 6DP (GB). **ROBIN-**

SON, Joseph, William; PA Consulting Services Limited Back Lane, Melbourn Hertfordshire SG8 6DP (GB).

(74) Agent: **ELLYATT, William**; Smith & Nephew, York Science Park Heslington, York YO10 5DF (GB).

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

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

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: WOUND TREATMENT APPARATUSES AND METHODS WITH NEGATIVE PRESSURE SOURCE INTEGRATED INTO WOUND DRESSING

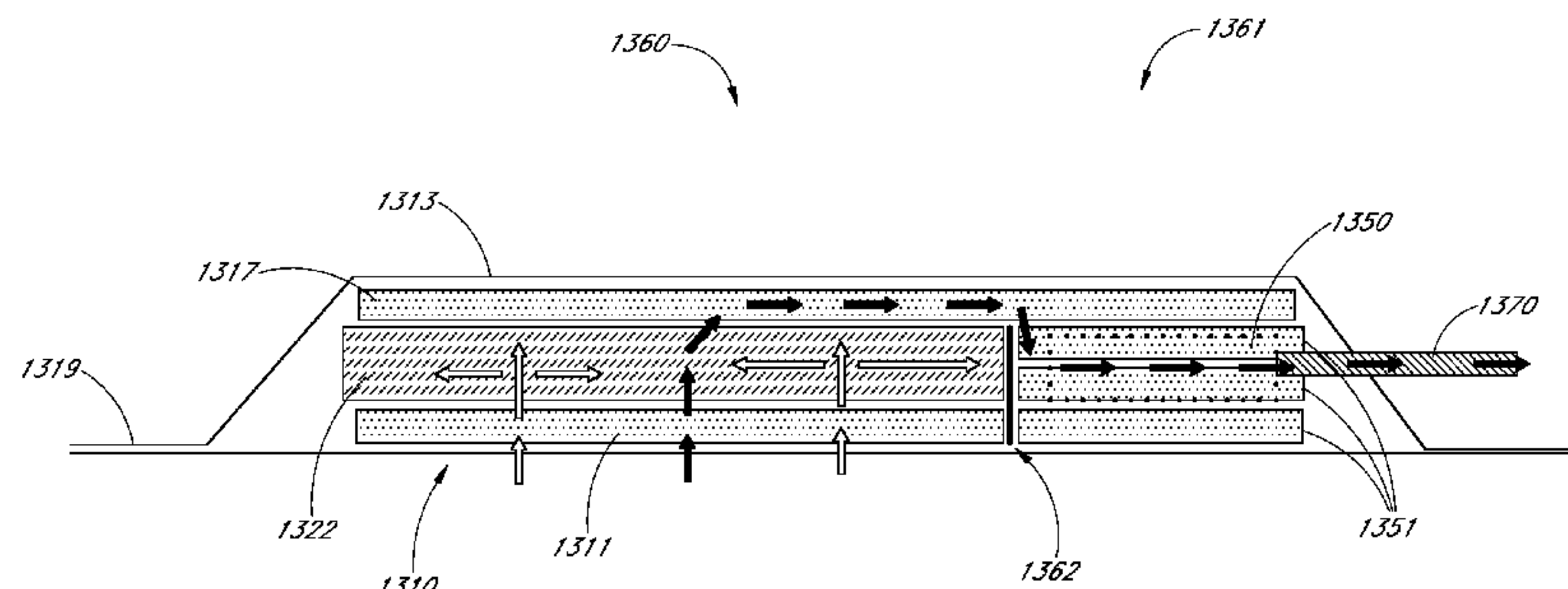


FIG. 14

(57) Abstract: Disclosed embodiments relate to apparatuses and methods for wound treatment. In some embodiments, a negative pressure source is incorporated into a wound dressing apparatus so that the wound dressing and the negative pressure source are part of an integral or integrated wound dressing structure that applies the wound dressing and the negative pressure source simultaneously to a patient's wound. The negative pressure source and/or electronic components may be positioned between a wound contact layer and a cover layer of the wound dressing. The negative pressure source and/or electronic components may be separated and/or partitioned from an absorbent area of the dressing. A switch may be integrated with the wound dressing to control operation of the wound dressing apparatus. A connector may direct air from an outlet of the negative pressure source to the environment. A non-return valve may inhibit back flow of air into the wound dressing.

WO 2017/153357 A1

WHAT IS CLAIMED IS:

1. A wound dressing apparatus comprising:
 - a wound contact layer configured to be positioned in contact with a wound;
 - a first area over the wound contact layer comprising:
 - a lower spacer layer;
 - an absorbent layer;
 - a second area over the wound contact layer comprising a plurality of spacer layers and a negative pressure source and/or electronic components positioned within or between the plurality of spacer layers, wherein the first area is positioned adjacent to the second area and separated by a partition;
 - an upper spacer layer configured to cover the first area and the second area and to allow air to be communicated between the first area and second area around the partition; and
 - a cover layer configured to cover and form a seal over the wound contact layer, the upper spacer layer, the first area, and the second area.
2. The wound dressing apparatus of claim 1, wherein the plurality of spacer layers in the second area comprise a third spacer layer beneath the negative pressure source and/or electronic components and a fourth spacer layer positioned above the negative pressure source and/or electronic components, wherein the fourth spacer layer comprises one or more cutouts or recesses configured to receive the negative pressure source and/or electronic components.
3. The wound dressing apparatus of claim 1, wherein the partition comprises a non-porous dam.
4. The wound dressing apparatus of claim 1, further comprising one or more user interface components configured to allow a user to operate the negative pressure source and/or electronic components.
5. A wound dressing apparatus comprising:
 - a wound dressing configured to be positioned over a wound site;
 - a negative pressure source disposed on or positioned within the wound dressing; and

a switch integrated with the wound dressing configured to control operation of the wound dressing apparatus.

6. The wound dressing apparatus of Claim 5, wherein the switch is at least one of positioned within, disposed on, or embedded in the wound dressing.

7. The wound dressing apparatus of Claim 5, wherein the wound dressing comprises a wound dressing body and a wound dressing border, the wound dressing border extending along at least of a portion of a perimeter defined around the wound dressing body.

8. The wound dressing apparatus of Claim 7, wherein the switch is integrated with the wound dressing body or the wound dressing border.

9. The wound dressing apparatus of Claims 7 or 8, wherein the switch is at least one of positioned within, disposed on, or embedded in the wound dressing body or the wound dressing border.

10. The wound dressing apparatus of any of Claims 7 to 9, wherein the wound dressing body and the wound dressing border comprise a top layer and a bottom layer, the top layer comprising a cover layer and the bottom layer comprising a wound contact layer, the switch being integrated with the wound dressing proximally adjacent at least one of the top layer and the bottom layer.

11. The wound dressing apparatus of any of Claims 5 to 10, wherein the wound dressing body or the wound dressing border comprises a flexiboard layer beneath the switch to dissipate and/or inhibit the transfer of a compression force to the wound site when the switch is actuated.

12. The wound dressing apparatus of any of Claims 5 to 11, wherein the switch is configured to be actuated by pressing the switch in a first direction with a finger.

13. The wound dressing apparatus of Claim 7, wherein the wound dressing further comprises a tab that extends from the wound dressing border, the switch being integrated with the tab.

14. The wound dressing apparatus of Claim 12, wherein the switch is at least one of positioned within, disposed on, or embedded in the tab

15. The wound dressing apparatus of Claims 13 or 14, wherein the tab is configured to be lifted by a user so that the switch can be actuated by the user by applying force to the switch in two opposing directions on opposite or different sides of the tab.

16. The wound dressing apparatus of any of Claims 13 to 15, wherein the wound dressing comprises a joint between the tab and the wound dressing border to facilitate movement of the tab without applying force to the wound dressing body or the wound dressing border, the tab being configured to rotate about the joint when a user moves the tab.

17. The wound dressing apparatus of any of Claims 5 to 16, further comprising one or more indicators configured to indicate one or more statuses of the wound dressing apparatus.

18. The wound dressing apparatus of Claim 17, wherein the one or more indicators comprise one or more visual indicators.

19. The wound dressing apparatus of Claim 18, wherein the one or more visual indicators comprise one or more light emitting diodes (LEDs).

20. The wound dressing apparatus of any of Claims 17 to 19, wherein the one or more indicators are configured to indicate a battery level of the wound dressing apparatus.

21. The wound dressing apparatus of any of Claims 17 to 20, wherein the one or more indicators extend around the switch.

22. The wound dressing apparatus of Claim 21, wherein the one or more indicators circumferentially extend around the switch.

23. The wound dressing apparatus of any of Claims 17 to 22, wherein the switch is positioned in a sub-flush position relative to the one or more indicators to inhibit accidental or inadvertent actuation of the switch.

24. The wound dressing apparatus of any of Claims 5 to 23, wherein the switch is selectively operable by a user to control operation of the negative pressure source.

25. The wound dressing apparatus of any of Claims 5 to 24, wherein the switch is selectively operable by a user to turn on and turn off the negative pressure source.

26. The wound dressing apparatus of any of Claims 5 to 25, wherein the switch is electrically connected to the negative pressure source.

27. The wound dressing apparatus of any of Claims 5 to 26, wherein the negative pressure source is a micro pump.

28. A wound dressing apparatus comprising:
a wound dressing configured to be positioned over a wound site;

a negative pressure source disposed on or positioned within the wound dressing, the negative pressure source comprising an inlet and an outlet, the negative pressure source being configured to apply negative pressure to the wound site via the inlet and being further configured to remove air from the wound dressing via the outlet; and

a connector comprising first and second ends and a flow path therebetween, wherein the first end is in fluid communication with the outlet and the second end is open to an environment outside the wound dressing, wherein a portion of the flow path extends through an opening defined in the wound dressing, the flow path being configured to direct air from the outlet to the environment.

29. The wound dressing apparatus of Claim 28, wherein the opening in the wound dressing is defined on a top layer of the wound dressing.

30. The wound dressing apparatus of Claim 29, wherein the top layer comprises a moisture vapor permeable film.

31. The wound dressing apparatus of Claim 28, wherein the opening in the wound dressing is defined between a top layer and a bottom layer of the wound dressing.

32. The wound dressing apparatus of Claim 28, wherein the opening in the wound dressing is defined through an edge of the wound dressing between a top layer and a bottom layer of the wound dressing.

33. The wound dressing apparatus of Claims 31 or 32, wherein the top layer comprises a moisture vapor permeable film and the bottom layer comprises a wound contact layer.

34. The wound dressing apparatus of any of Claims 28 to 33, wherein the connector comprises a spacer that extends between a first and second portion of the connector, the spacer being configured to resist collapse of the connector when the connector is compressed.

35. The wound dressing apparatus of any of Claims 28 to 34, wherein the first and second portions of the connector comprise the first and second ends of the connector.

36. The wound dressing apparatus of Claims 34 or 35, wherein the spacer is enveloped in a film to form a gas tight seal with the wound dressing.

37. The wound dressing apparatus of Claims 34 or 35, wherein the spacer comprises a length of 3D fabric material.

38. The wound dressing apparatus of Claims 36 or 37, wherein the film is a plastic film.

39. The wound dressing apparatus of any of Claims 36 to 38, wherein the film is Versapore film having a pore size diameter of about 2 μm .

40. The wound dressing apparatus of any of Claims 28 to 39, wherein the connector forms a gas tight seal with the wound dressing.

41. The wound dressing apparatus of any of Claims 28 to 40, wherein the connector forms a gas tight seal with the outlet of the negative pressure source.

42. The wound dressing apparatus of any of Claims 28 to 41, wherein the connector is configured to resist collapse, thereby inhibiting occlusion of the connector when the wound dressing is subjected to compressive forces.

43. The wound dressing apparatus of any of Claims 28 to 42, wherein the connector is configured to inhibit the ingress of water, foreign bodies, dirt, or bacteria through the opening in the wound dressing.

44. The wound dressing apparatus of any of Claims 28 to 43, wherein the wound dressing apparatus further comprises a tube interposed between the outlet and the connector, the tube being coupled to the outlet and the connector.

45. The wound dressing apparatus of any of Claims 28 to 44, wherein the tube is configured to extend the connector such that the connector is positioned outside of the wound dressing after the tube passes through the opening in the wound dressing.

46. A wound dressing apparatus comprising:

- a wound dressing configured to be positioned over a wound site;
- a negative pressure source disposed on or positioned within the wound dressing, the negative pressure source comprising an inlet and an outlet and being operable to apply negative pressure to the wound site; and
- a non-return valve in fluid communication with the outlet, the non-return valve being configured to inhibit back flow of air into the wound dressing.

47. The wound dressing apparatus of Claim 46, wherein the non-return valve is configured to inhibit back flow of air into the wound dressing through the outlet.

48. The wound dressing apparatus of Claims 46 or 47, wherein the non-return valve is connected to the outlet.

49. The wound dressing apparatus of any of Claims 46 or 47, wherein the non-return valve comprises a first end in fluidic communication with the outlet and a second end in fluid communication with an exhaust component, the exhaust component being configured to direct air from the outlet to the environment.

50. The wound dressing apparatus of Claim 49, wherein the first end of the non-return valve is connected to the outlet and the second end of the non-return valve is connected to the exhaust component.

51. The wound dressing apparatus of any of Claims 46 to 50, wherein the non-return valve is at least partially disposed in the outlet.

52. The wound dressing apparatus of any of Claims 46 or 47, further comprising an exhaust system having first and second ends, wherein the exhaust system is interposed between the outlet and the non-return valve such that the first end is connected to the outlet and the second end is connected to the non-return valve.

53. The wound dressing apparatus of any of Claims 46 or 47, further comprising an exhaust system, wherein the non-return valve is at least partially integrated with the exhaust system.

54. The wound dressing apparatus of Claim 52, wherein the non-return valve is at least partially integrated with the exhaust system at an end of the exhaust system.

55. The wound dressing apparatus of any of Claims 46 to 54, wherein the non-return valve is integrated with the wound dressing.

56. The wound dressing apparatus of any of Claims 46 to 55, wherein the non-return valve is positioned within and/or embedded in the wound dressing.

57. The wound dressing apparatus of any of Claims 46 to 56, wherein the non-return valve comprises a size configured to fit within the wound dressing.

58. The wound dressing apparatus of any of Claims 46 to 57, wherein the non-return valve has a height that is less than a thickness of the wound dressing.

59. The wound dressing apparatus of any of Claims 46 to 58, wherein the non-return valve has a low cracking pressure and a low resistance to out flow.

60. The wound dressing apparatus of any of Claims 46 to 59, wherein the non-return valve has a cracking pressure of less than 500 Pa for a nominal flow rate of about 1mL/min through the apparatus.

61. The wound dressing apparatus of any of Claims 46 to 60, wherein the non-return valve has an out flow resistance of less than 30 mL/min as measured with a nominally fixed vacuum of 10.7 kPa below atmosphere.

62. The wound dressing apparatus of any of Claims 46 to 60, wherein the non-return valve provides a resistance to air flowing out of the wound dressing apparatus of less than 100 mL/min as measured with a nominally fixed vacuum of 10.7 kPa below atmosphere.

63. The wound dressing apparatus of any of Claims 46 to 62, wherein the negative pressure source and the non-return valve together allow air to leak into the wound dressing apparatus via the outlet at a negligible rate of less than 2.0 mL/min.

64. The wound dressing apparatus of any of Claims 46 to 63, wherein the non-return valve is a mechanical valve that is self-activated.

65. The wound dressing apparatus of any of Claims 46 to 64, wherein the non-return valve comprises a duckbill valve.

66. The wound dressing apparatus of any of Claims 46 to 65, wherein the non-return valve comprises a reed valve.

67. The wound dressing apparatus of Claim 66, wherein the reed valve comprises a 75 micron thick polyester reed valve.

68. The wound dressing apparatus of Claims 66 or 67, wherein the non-return valve comprises a cavity with an inlet port and an outlet port and a reed at least partially disposed in the cavity.

69. The wound dressing apparatus of any of Claims 46 to 68, wherein the non-return valve comprises a crescent shape.

70. The wound dressing apparatus of Claim 69, wherein the crescent shape is defined by a housing having a first curved surface that intersects a second surface.

71. The wound dressing apparatus of Claim 70, wherein the second surface is flat.

72. The wound dressing apparatus of Claim 70, wherein the second surface is curved, the second surface having a radius of curvature that is greater than a radius of curvature of the first curved surface.

73. The wound dressing apparatus of any of Claims 70 to 72, wherein the second surface is semi-rigid or flexible such that it is configured to conform to a surface of the wound site.

74. The wound dressing apparatus of Claims 67 or 68, wherein the non-return valve comprises a crescent shape, wherein the reed comprises a rectangular shape with circular ends.

75. The wound dressing apparatus of Claims 67 or 68, wherein the non-return valve comprises a crescent shape, wherein the reed includes a curved portion.

76. The wound dressing apparatus of any of Claims 46 to 75, wherein the negative pressure source is a micro pump.

77. The wound dressing apparatus of Claim 76, further comprising a controller configured to control the operation of the micro pump to apply negative pressure to the wound site.