



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

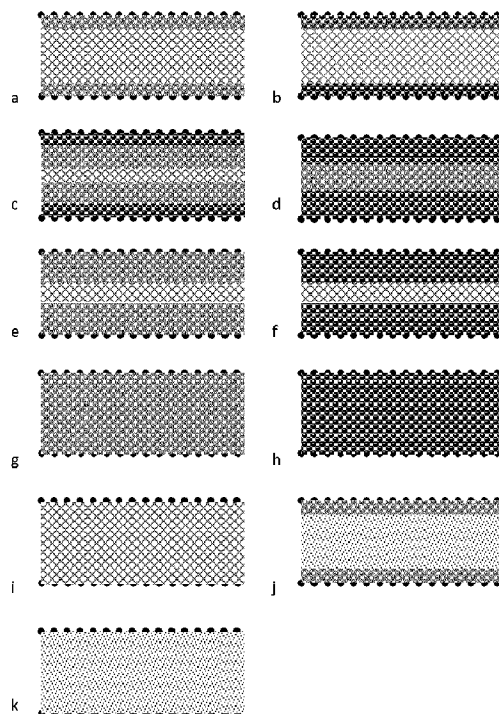
(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2018/07/12
(87) Date publication PCT/PCT Publication Date: 2019/01/17
(85) Entrée phase nationale/National Entry: 2019/12/24
(86) N° demande PCT/PCT Application No.: EP 2018/069015
(87) N° publication PCT/PCT Publication No.: 2019/012069
(30) Priorité/Priority: 2017/07/12 (GB1711183.2)

(51) Cl.Int./Int.Cl. *A61L 15/42* (2006.01),
A61L 15/60 (2006.01)
(71) Demandeur/Applicant:
SMITH & NEPHEW PLC, GB
(72) Inventeurs/Inventors:
BREWSTER, AMY, GB;
CRUMP, ROBERT, GB;
LECOMTE, HELENE ANNE, GB;
STEPHENSON, DAVID, GB;
WRAY, MATTHEW, GB
(74) Agent: BORDEN LADNER GERVAIS LLP

(54) Titre : MATERIAUX ANTIMICROBIENS OU DE SOINS DE PLAIE, DISPOSITIFS ET UTILISATIONS
(54) Title: ANTIMICROBIAL OR WOUND CARE MATERIALS, DEVICES AND USES

Fig. 1a-k Symmetric composite (powder charge) loaded matrix
matrix
matrix with background additive in structural framework
additive within cells, low concentration
additive within cells, high concentration
••••• additive at matrix surface



(57) **Abrégé/Abstract:**

Antimicrobial material which is a composite of a matrix component comprising a flexible hydrophilic polymer foam or fiber matrix comprising two matrix faces providing a release face and a reverse face or two release faces, and therebetween a structural matrix

(57) Abrégé(suite)/Abstract(continued):

framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and a powder charge component comprising antimicrobial additive or wound care additive, wherein said powder charge is comprised at one said release face or both said faces and/or within said cell network wherein said composite is an assembly of preformed matrix component and powder charge component; and asymmetric material which is asymmetric having regard to distribution of said powder charge therein; and material wherein said power charge comprises flowing agent and/or bulking agent and/or binder and wherein said additive and/or flowing agent is co-located with said bulking agent and/or said binder; devices comprising said composite, methods for manufacture thereof comprising assembling said matrix and said powder charge, and use thereof.

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
17 January 2019 (17.01.2019)



(10) International Publication Number
WO 2019/012069 A1

- (51) International Patent Classification:
A61L 15/42 (2006.01) *A61L 15/60* (2006.01)
- (21) International Application Number:
PCT/EP2018/069015
- (22) International Filing Date:
12 July 2018 (12.07.2018)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1711183.2 12 July 2017 (12.07.2017) GB
- (71) Applicant: **SMITH & NEPHEW PLC** [GB/GB]; 15 Adam Street, London WC2N 6LA (GB).
- (72) Inventors: **BREWSTER, Amy**; Smith & Nephew 101 Hessle Road, Hull HU3 2BN (GB). **CRUMP, Robert**; Smith & Nephew 101 Hessle Road, Hull HU3 2BN (GB). **LECOMTE, Helene, Anne**; Smith & Nephew 101 Hessle Road, Hull HU3 2BN (GB). **STEPHENSON, David**; Smith & Nephew 101 Hessle Road, Hull HU3 2BN (GB). **WRAY, Matthew**; Smith & Nephew 101 Hessle Road, Hull HU3 2BN (GB).

(74) Agent: **ELLYATT, William**; Smith & Nephew, 101 Hessle Road, Hull East Yorkshire HU3 2BN (GB).

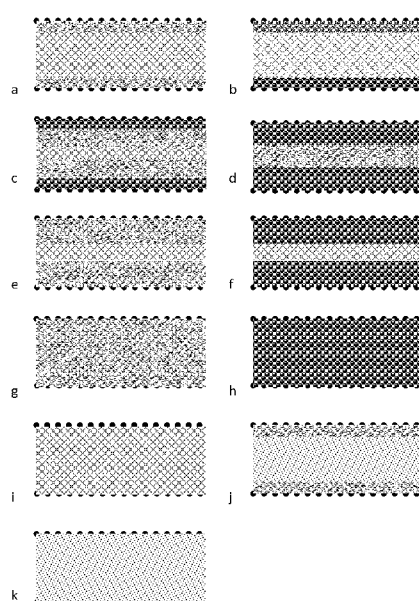
(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, 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).

(54) Title: ANTIMICROBIAL OR WOUND CARE MATERIALS, DEVICES AND USES

Fig. 1a-k Symmetric composite (powder charge) loaded matrix

matrix
matrix with background additive in structural framework
additive within cells, low concentration
additive within cells, high concentration
••••• additive at matrix surface



(57) Abstract: Antimicrobial material which is a composite of a matrix component comprising a flexible hydrophilic polymer foam or fiber matrix comprising two matrix faces providing a release face and a reverse face or two release faces, and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and a powder charge component comprising antimicrobial additive or wound care additive, wherein said powder charge is comprised at one said release face or both said faces and/or within said cell network wherein said composite is an assembly of preformed matrix component and powder charge component; and asymmetric material which is asymmetric having regard to distribution of said powder charge therein; and material wherein said powder charge comprises flowing agent and/or bulking agent and/or binder and wherein said additive and/or flowing agent is co-located with said bulking agent and/or said binder; devices comprising said composite, methods for manufacture thereof comprising assembling said matrix and said powder charge, and use thereof.

WO 2019/012069 A1

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))

ANTIMICROBIAL OR WOUND CARE MATERIALS, DEVICES AND USES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.K. Provisional Application No. 1711183.2 filed on July 12, 2017, which is incorporated by reference in its entirety.

FIELD

[0002] This application discloses antimicrobial or wound care materials and devices, methods for their manufacture, their uses and methods of treatment therewith. The materials and devices comprise antimicrobial additive powder or wound dressing additive powder loaded thereon or therein, such as asymmetrically loaded thereon or therein, for effective release rate, release profile and/or reproducibility of release.

BACKGROUND

[0003] Silver-impregnated antimicrobial wound dressings exist as products, containing a silver salt, notably silver nitrate, silver sulfadiazine or silver sulfate, as the antimicrobial additive, combined with a porous absorbent matrix, such as woven and non-woven fibrous articles or polyurethane foam, which handles the exudate coming from the wound. The silver salt is usually combined into the porous matrix, via a liquid phase solution or suspension. This can be at the time of manufacture of the absorbent matrix itself, for example during the polymerisation reaction of polyurethane foam, where the silver salt is suspended or dissolved in the aqueous reactive phase or from treating an absorbent matrix in a dipping or reactive bath.

[0004] Increasingly there is a need for wound dressings which may remain in place for extended periods between dressing changes, and which deliver a sustained release of antimicrobial silver ion, while still delivering a bolus (up front or rapid) release thereof. This has led to use of low solubility silver salts in wound dressings. However the low solubility of such silver salt limits the quantity of salt that can be introduced by traditional solution manufacturing routes. The bolus release from such limited quantity low solubility salt may not

be high enough to inhibit or kill bacteria and equally the sustained release may be difficult to control.

[0005] Attempts to address these limitations have met with limited success, such as introduction of a combination of dissolved and dispersed silver salt to polyurethane foam during the polymerisation reaction, and introducing silver salt in multiple layers of multi-layered wound dressings, including hydrophilic foam and films.

SUMMARY

[0006] We have now found that these needs may be met by providing antimicrobial material comprising low solubility silver salt that is readily available, that is to say with high effective surface area, readily accessible within a matrix and/or present in high concentration, and/or providing silver salt, regardless of solubility, in differentiated or manipulated availability, that is to say directed to where it is needed within said material for efficient and effective availability for both bolus and sustained release.

[0007] We provide herein antimicrobial material comprising a porous absorbent fiber or foam matrix, said matrix comprising a powder charge of antimicrobial release additive loaded in powder form on and/or within pre-formed matrix. More particularly, we provide herein an antimicrobial wound dressing material comprising a porous absorbent foam matrix, such as a polyurethane (PU) foam matrix, or porous absorbent fibre matrix and a powder charge of antimicrobial species-releasing additive, more particularly iodine-releasing additive or silver ion-releasing additive. Iodine and silver ion are highly effective antimicrobials.

[0008] We moreover provide herein wound dressing material comprising a porous absorbent fiber or foam matrix, said matrix comprising a powder charge of additive asymmetrically loaded in powder form in said pre-formed matrix.

[0009] In an advantage said powder charge is powder form additive charged to a face and/or cells of said matrix and is readily available for antimicrobial release. The powder charge is dry-loaded, that is to say it is loaded onto or within said matrix by means of a dry processing route. The powder charge retains powder form during and after loading. Material herein is imparted with additive property characteristic of the powder charge dry-loaded thereon and/or therein. For example, antimicrobial material herein is of antimicrobial release

profile, such as rapid release and/or high release of antimicrobial, characteristic of the powder charge dry-loaded antimicrobial release additive.

[0010] In an advantage additive may be selected regardless of density or aqueous solubility, for example may be dense or poorly water-soluble and nevertheless be comprised in the herein material in effective amount, for example in antimicrobially effective amount. More particularly additive may be loaded onto foam or fibre matrix such as polyurethane (PU) foam or natural or synthetic fibre matrix, without problems presented by limited solubility or maintaining an unstable suspension of solid in liquid. In an advantage material herein may be characterised by highly reproducible additive loading, such as symmetric or asymmetric additive loading and/or in reproducible additive dose, regardless of matrix thickness or absorbcency.

[0011] In embodiments there is provided herein antimicrobial material which is a composite of

a flexible hydrophilic polymer foam or fibre matrix component comprising two matrix faces providing a release face and a reverse face or two release faces, and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores, also referred herein as cell openings or cell windows, and

a powder charge component comprising antimicrobial additive wherein said additive is antimicrobial species-releasing additive

and wherein said powder charge is comprised at one said release face or both said faces and/or within said cell network.

[0012] Preferably said antimicrobial species is selected from one or more atomic species and one or more diatomic species and combinations thereof.

[0013] Preferably said composite comprises an assembly of pre-formed matrix and pre-formed powder charge, that is to say each of said matrix and said powder charge are pre-formed components assembled in a composite as herein defined, more particularly a composite is an assembly of said matrix in matrix form and said antimicrobial additive in powder form.

[0014] Preferably said powder charge is absent from, or present in incidental or insignificant amount within, said structural matrix framework. Powder charge present in

incidental or insignificant amount within said structural matrix framework is suitably present locally to powder charge comprised at said face or faces and/or within said cell network.

[0015] A network of pores herein may be a tortuous pore network having low aperture and/or low frequency pores or cell openings, or may be a reticulated pore network, i.e. a net-like pore network, having high aperture and/or high frequency pores or cell openings.

[0016] In embodiments said matrix provides a tortuous pore network and said material comprises powder charge within said cell network proximal to said release face or faces and/or in decreasing concentration with increasing depth within said cell network from one or both said faces. For example said matrix resembles a surface loading or depth loading filter. In alternative embodiments said matrix provides a reticulated pore network and said material comprises powder charge uniformly loaded throughout said cell network. For example said matrix resembles a scaffold.

[0017] In embodiments powder charge is retained at said face or faces and/or within said cell network by action of a binder and/or by mechanical retention thereof by tortuosity of pore network and/or by cell size and/or intercell pore size. For example the interconnectivity of the cells is by “windows” between cells which are smaller than the cell size itself, thereby limiting the probability of loaded powder charge from shedding from the cell network and thus from the matrix. This also leads to a high tortuosity within the matrix, which is advantageous to achieve asymmetry in loading, as the powder charge needs to navigate a tortuous path to penetrate the matrix. Example of tortuous cell interconnectivity is illustrated in Figure 3a and Figure 3c in non-limiting manner in context of polyurethane foams, “closed celled” with small interconnecting windows or pores in the cell wall, or “open celled” or reticulated with struts defining pores.

[0018] There is moreover provided herein wound care material comprising
a flexible hydrophilic polymer foam or fibre matrix comprising a wound facing face and a reverse face or two wound facing faces and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

a powder charge comprising a wound dressing additive or combinations thereof,

wherein said matrix provides a tortuous pore network and

wherein said powder charge is comprised at said wound facing face or said reverse face and within said cell network in cells proximal to said face, more particularly in diminishing amount with increasing depth within said network.

[0019] A wound dressing additive herein or combinations thereof, is preferably selected from any of antimicrobial species-releasing additive as hereinbefore or hereinbelow defined, and wound dressing additive selected from antimicrobial, bacterial, bacteriostatic, fireproofing, odour control such as activated charcoal or bentonite, protein-breaking or denaturisation, wicking, conductive, structure-supporting, absorbent such as superabsorbent polymer (SAP), colour or colour masking such as prevention of PU foam yellowing (optical brighteners, oxidation prevention) and the like and combinations with viscosity modifying agents and the like.

[0020] In a first advantage embodiments herein are specific to antimicrobial species-releasing additives and facilitate control of particle size of additive powder such as a silver salt. This is particularly of interest where a particular particle size, for example micron particle size, enhances the release of an antimicrobial species such as silver ions. When liquid phase-loaded, i.e. using wet processing, the particle size of the salt or additive of interest can vary greatly depending on temperature, concentration, and solubility. Change in particle size during processing is avoided in the present invention by keeping powder additive dry during loading onto or into a matrix or finished antimicrobial porous material. Advantages herein may moreover be significant to materials and methods comprising wound dressing additives in general, which are sensitive to particle size or moisture content or hydration or both.

[0021] In a second particular advantage embodiments herein comprise a powder charge of additive, such as antimicrobial additive for example silver salt, located on said matrix face and/or said cell network, thereby readily available for contact with fluid at a locus and for example absorption of said fluid or release of antimicrobial species. The dose of additive used can therefore potentially be reduced, or can be loaded to greater or faster effect, compared to other loading techniques with less readily available additive, for example

introduced at the point of manufacture of the porous matrix. This leads to improvements in safety profile of the material, such as a wound dressing material, without compromising performance or to more effective material, such as antimicrobial material giving higher log reduction of microorganism or potentially able to kill a wider range of microorganisms.

[0022] In a further advantage embodiments herein facilitate admirable dose control, as the basis weight of the porous matrix component does not affect the loading amount. For example this is in contrast to methods in which additive is to be combined at the point of manufacture of the porous matrix.

[0023] In an advantage embodiments herein enable use of dense or sparingly water-soluble additive such as silver sulfate, without the need for liquid-phase or wet processing. Manufacture of material is simple, cost-efficient, and dispenses with the need for large volumes of solvent, with the inherent disposal and processing problems.

[0024] In a further advantage embodiments herein provide high concentration of additive. For example dry-loaded powder may be rapidly, simply and effectively loaded, in any desired concentration. This is in contrast to prior art wet processing methods, i.e. solution / dispersion methods. The present invention is not subject to or affected by solubility limit or unstable suspensions.

[0025] A composite herein may be understood by its ordinary meaning. For example composite may be defined by its theoretical ability to disassemble and recover intact its component parts by reversing its assembly. Powder charge comprised at face and/or within cells of matrix herein retains its pre-assembly identity, and disregarding any retention such as by tortuosity of pore network or embedding in cell surface, is theoretically recoverable by shedding from said face and from said cells by means of said pore network. Likewise matrix retains its pre-assembly identity, and disregarding any embedding, is theoretically recoverable by shedding said powder charge, without need for destruction of matrix fabric, i.e. structural matrix framework.

[0026] Composite antimicrobial material retains the characteristic properties of component pre-formed or prefabricated matrix and of powder charge, such as matrix properties of flexibility or softness and powder charge properties such as release, absorption, solubility or surface area or hydration or water content of individual particles or powder

making up the powder charge. Wet processing typically diminishes matrix properties of softness and flexibility, and particle surface area properties.

[0027] Composite herein is thus distinct from prior art materials comprising a powder dissolved or dispersed into solution, applied to a matrix and dried in situ or mixed into reactive foam components with subsequent matrix formation, whereby in each case the identity of the starting powder is lost or altered. In the latter case, identity of starting matrix would also be lost in theoretical recovery of additive from the structural matrix network.

[0028] A composite herein may be conveniently defined as the intimate combination of said matrix with said powder charge, for example dry-loaded, solid phase-loaded or solid in gas phase-loaded powder charge or the like.

[0029] A cell and cell network herein may be any interconnecting cell, void or free space and network thereof comprised in a structural matrix framework, for example in a polymeric foam or between woven or non-woven fibers. A pore and pore network herein includes any pore, cell-opening or cell window interconnecting adjacent cells, and network thereof. A pore and pore network herein permits fluid (liquid and gas) transmission between cells, and provides a fluid pathway. Preferably said pore network comprises pores of limited aperture and frequency providing non-aligned disposition thereby impeding air transmission in a tortuous fluid pathway.

[0030] An antimicrobial species-releasing additive herein is an additive which may be activated to release antimicrobial species as defined, by a release event comprising contact with moist or aqueous medium. Antimicrobial species-releasing additive or part thereof is therefore soluble or leaches into water, preferably has solubility in excess of 0.15mg/L at 25C. Material and matrix as herein defined is ideally stored away from moisture or aqueous medium, for example packaged in water impermeable packaging. Thereby premature release of antimicrobial species is avoided.

[0031] A powder herein may take its ordinary meaning, and may be understood to denote fine, dry particle(s), including primary particles and agglomerations and aggregates defined as secondary particles. Primary particles, are characterised by particle size or in case of a range of particle sizes, by particle size distribution.

[0032] Agglomerations and aggregates of primary particles, defined as secondary particles, have surface area the same as or similar to cumulative surface area of primary particles. An individual agglomeration, aggregate or secondary particle is thus typically of greater surface area than a corresponding size single primary particle.

[0033] Reference herein to a powder charge is to a charge of powder delivered to and comprised in the matrix. A powder charge may be a non-quantitative charge or may be a quantitative charge. For example a powder charge delivered to matrix may be comprised in material in whole or in part.

[0034] A powder charge may be a batch or discontinuous charge or may be a continuous charge, for example the total charge on or in a discontinuous matrix such as a sheet matrix or a charge per unit volume or area on or in a continuous matrix such as a roll or web of matrix.

[0035] A powder charge of additive may be variously referred herein as powder charge, powder-loaded additive or dry-loaded additive. “Dry-loaded” or “powder-loaded” herein may conveniently be understood to indicate the phase of the powder charge and/or its manner of loading, for example “solid phase-loaded” additive, “solid in gas phase-loaded” additive or the like, and is not intended to be indicative of ambient moisture content.

[0036] A powder charge herein may be loose and flowing or fixed, for example, at least partially embedded in the cell network surface. Importantly however embedding has no effect or incidental effect only on primary particle size.

[0037] In embodiments said material is asymmetric having regard to said additive, wherein powder charge is comprised at one said matrix face, for example a release face or wound facing face, or reverse face and/or within cell network proximal thereto, and is absent from or present in incidental or insignificant amount at other said matrix face and/or within cell network proximal thereto. Said release face may provide more ready antimicrobial release, fluid absorption or the like than said reverse face, whereby said release face may be provided as the microbe facing face, or the primary microbe facing face, for example to be positioned facing towards a wound surface. Said wound facing face or said reverse face may provide more ready fluid absorption, colour masking or other additive property as herein defined.

[0038] Alternatively said material is symmetric having regard to the distribution of additive, wherein said powder charge is comprised at both said faces and/or within said cell network proximal thereto. Said material may provide ready antimicrobial release, fluid absorption, colour masking or the like at either or both matrix faces. Either face may be provided as a microbe facing or wound facing face, for example to be positioned towards a locus such as a wound surface. Said material may thus provide a choice of microbe facing, locus facing or wound facing face.

[0039] In embodiments said powder charge is present at said face or said faces, and is absent from, or present in incidental or insignificant amount within, said cell network and within said structural matrix framework.

[0040] In embodiments said powder charge is present at said face or said faces and within said cell network throughout said matrix.

[0041] Preferably material is asymmetric having regard to additive, wherein said powder charge is present at one or both said faces and within said cell network proximal to one said face. Said powder charge is absent from, or is present in incidental or insignificant amount within, cell network proximal to said reverse face and within said structural matrix framework.

[0042] Alternatively said powder charge is present at both said faces and within said cell network proximal to each said face (symmetric).

[0043] In embodiments material herein presents a choice of antimicrobial release face, wound facing face or the like, i.e. material is non-handed and is adapted for contacting a locus, directly or fabricated in a device, with either face proximal to the locus. Alternatively material herein is handed, and is adapted for contacting a locus, directly or fabricated in a device, with additive-rich face proximal to or remote from the locus.

[0044] Powder charge herein may be uniformly loaded, asymmetrically loaded or loaded in diminishing amount within said cell network, with increasing depth in said matrix, for example may be present in decreasing amount or concentration with increasing distance from the or each said face. Concentration at a face may be in continuous profile or discontinuous profile with concentration or amount within said cell network with the facility to independently manipulate respective concentrations or amounts during assembly thereof.

[0045] Said powder charge may extend to 5% to 100% such as 85% or 50% of the separation between said faces, from one or each said matrix face, for example may extend to 2-6 average sized cell diameters inward from said face or faces.

[0046] In embodiments material herein comprises a powder charge or plurality of powder charges comprising antimicrobial additive and super absorbent polymer (SAP) together or separately

[0047] In embodiments material herein comprises a powder charge or plurality of powder charges, comprising antimicrobial additive or SAP together with a wound dressing additive as hereinbefore defined. A plurality of powder charges may be comprised at same or different face and/or within cell network proximal thereto.

[0048] In embodiments matrix herein comprises same or different additive, for example same or different antimicrobial species releasing additive, impregnated in background content or supplementary content within the structural matrix framework of materials herein, said background or supplementary content being comprised in said pre-formed matrix, that is to say, introduced other than as powder charge to pre-formed matrix. Background additive content remains impregnated and thereby protected from leaching from structural matrix framework during assembly of said matrix and powder charge components into material as herein defined.

[0049] In embodiments powder charge is seated or embedded in said matrix face or faces and/or cell network surface, preferably partially embedded and protruding therefrom. Seating or embedding prevents or limits shedding of powder charge from said matrix face(s) and/or from said cell network.

[0050] Alternatively or additionally material herein may form a laminate together with one or more powder charge-retaining fluid permeable nets. Powder charge provided within a cell network as hereinbefore defined may be moreover retained within cell network as hereinbefore defined by tortuosity thereof or by cell and/or pore size.

[0051] In embodiments material herein comprises additive having solubility less than 100g/L (25°C), more preferably less than 10g/L (25°C). Preferably such additive is present at a face and/or within cell network in concentration in excess of that which might be provided by absorption and drying of said additive from saturated solution.

[0052] In embodiments powder charge herein comprised both at a matrix face and within cell network is provided in respective independently differentiated amounts and concentrations adapted for a required aggregate additive property profile, such as release profile thereof. In an advantage composite material herein provides the facility to independently differentiate or manipulate powder charge comprised respectively at matrix face and cell network during assembly thereof. For example for a given material, the proportion of a powder charge at matrix release face may be greater than, comparable to or less than the proportion thereof within said cell network.

[0053] Matrix or part thereof herein suitably comprises foam matrix selected from natural and synthetic polymer foam such as polystyrene, styrenic polymers, polyvinylchloride, polyvinyl alcohol, polyurethanes, phenolic polymers, silicones, polyolefins, rubbers and elastomer thermoplastic polymers and combinations and copolymers thereof.

[0054] Matrix or part thereof herein suitably comprises fiber matrix selected from woven and non-woven fiber matrix of any natural or synthetic fibre including absorbent and super absorbent fibers such as cellulose, alginate, chitin, chitosan, functionalised derivatives thereof such as rayon and viscose and blends thereof. Matrix may comprise a foam and/or fiber bilayer or multilayer.

[0055] Atomic or diatomic species herein may be charged or uncharged. Antimicrobial atomic species is preferably antimicrobial ion, more preferably antimicrobial cation, most preferably silver cation. Antimicrobial diatomic species is preferably uncharged, more preferably is homonuclear diatomic species such as I₂. Antimicrobial species-releasing additive as hereinbefore defined may release additional antimicrobial species, for example aqueous decomposition forms of iodine.

[0056] Preferably said antimicrobial atom-releasing or diatom-releasing additive is selected from elemental silver, silver salts, silver complexes, caged forms of silver, and caged iodine and combinations thereof, more preferably from silver salts, silver complexes and caged forms thereof, and from caged iodine.

[0057] Preferably therefore there is provided herein antimicrobial material which is a composite of a flexible hydrophilic polymer foam or fiber matrix comprising two matrix faces providing a release face and a reverse face or two release faces, and therebetween a

structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

a powder charge comprising antimicrobial species-releasing additive wherein species is selected from antimicrobial atomic species and antimicrobial diatomic species,

wherein said powder charge is comprised at said face or faces and/or within said cell network, characterised in that said antimicrobial additive is selected from elemental silver, silver complexes, silver salts, caged forms of silver, caged iodine and combinations thereof.

[0058] Preferably silver complexes and silver salts are selected from one or more of colloidal silver, silver zeolite, silver sulfadiazine, silver sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate, and combinations thereof. Preferably caged iodine is selected from cadexomer iodine.

[0059] SAP herein may be selected from known medical grade superabsorbent polymers such as sodium polyacrylate, cross linked CMC or other absorbent functionalised (by carboxylation or sulfonation) cellulose derivatives, cross linked polyethylene oxide and PVA copolymers.

[0060] A powder charge herein may additionally comprise a flowing agent. Flowing agent is comprised together with additive particles within said charge, providing improved powder handling. Preferably additive is co-located with said flowing agent.

[0061] Flowing agent reduces or inhibits additive agglomeration or aggregation and aids in powder charge flow or lubrication and may inhibit caking. Flowing agent may facilitate uniform dosing of additive to a face and may also reduce wastage, cleaning and maintenance of processing equipment. Flowing agent may be a high melting point insoluble powder such as a stearate salt, clay, silica, charcoal or graphite or the like. Flowing agent may have same or different primary particle size as additive herein.

[0062] Material or powder charge herein may comprise a bulking agent comprised as part of said powder charge or as solid melt or partial melt, together with said powder charge, at said matrix face(s) and/or within said cell network at the surface thereof. Preferably additive is co-located with said bulking agent or solid melt or partial melt thereof.

[0063] Bulking agent is a powder diluent and increases volume of powder charge. Bulking agent may facilitate accurate and reproducible dosing of powder charge to and within matrix herein. Bulking agent may be particularly beneficial where dosing accuracy is required. Bulking agent may facilitate in directing powder charge within said cell network, and in particular to a given depth within said network. Bulking agent may be of smaller particle size than additive herein and be comprised to greater depth within the cell network, or of larger particle size than said additive and be comprised at lesser depth within the cell network.

[0064] Bulking agent is water permeable. Water permeability permits fluid transmission with said cell network. Bulking agent may be a low softening or melting point material such as PEG, PVP or the like. Bulking agent is provided together with powder charge component in powder form. Bulking agent comprised in material in melt form may provide binding of powder charge to matrix.

[0065] SAP comprised in powder charge herein may provide bulking agent function during manufacture in addition to absorbent function in material as finished product.

[0066] Material herein may comprise a binder together with said powder charge at said matrix face(s) and/or within said cell network. Binder is comprised as solid melt or partial-melt. Binder is provided in powder form together with powder charge component and may be same as or different to bulking agent as hereinbefore defined. Additive is co-located with said solid melt or partial melt binder.

[0067] Binder herein is non-adhesive at ambient temperatures and softens at elevated temperatures from 20°C to 90°C for example from 30°C to 90°C. A binder adheres to the matrix and to said powder charge by transient softening. Material comprising binder retains fluid permeability properties at matrix face and fluid absorption via matrix face.

[0068] In embodiments herein there is provided material which is a composite of a matrix component

comprising a flexible hydrophilic polymer foam or fiber matrix comprising two matrix faces providing a release face and a reverse face or two release faces, and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

additive, or a powder charge component comprising additive, selected from antimicrobial additive, wound care additive and wound dressing additive, wherein said material or said powder charge additionally comprises flowing agent and/or bulking agent and/or binder

and wherein said additive and said flowing agent and/or bulking agent and/or binder are co-located or said powder charge components are co-located at one said release face or both said faces and/or within said cell network.

[0069] Co-located additive and flowing and/or bulking agent and/or binder may be evidenced by SEM, for example by means of secondary electrons (topography) and backscattered electron, for example as illustrated in Figures 3g) and 3h).

[0070] Additive and/or flowing agent is comprised partially embedded and retained at said face or faces and within said cells by melt-softened co-located bulking agent and/or binder.

[0071] In a further aspect there is provided a method for manufacture of antimicrobial material comprising

providing a flexible hydrophilic polymer foam or fiber matrix component comprising two matrix faces providing a release face and a reverse face or two release faces and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

providing a powder charge component comprising antimicrobial additive wherein additive is antimicrobial species-releasing additive,

contacting said powder charge component and said matrix component

and directing said powder charge to one said release face or both said release faces and/or within said cell network, preferably in proximal to said face or faces.

[0072] In a further aspect there is provided a method for manufacture of wound care material comprising

providing a flexible hydrophilic polymer foam or fiber matrix component comprising a wound facing face and a reverse face or two wound facing faces and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

providing a powder charge component comprising a wound dressing additive or combinations thereof, wherein said matrix provides a tortuous pore network and contacting said powder charge component and said matrix component and directing said powder charge to said wound facing face or said reverse faces and within said cell network in cells proximal to said face, more particularly in diminishing amount with increasing depth within said network.

[0073] Preferably said method is a method for manufacture of antimicrobial material or wound care material as hereinbefore and hereinbelow defined, more preferably is a method for manufacture of material comprising assembling a composite of an matrix component and a powder charge component as hereinbefore and hereinbelow defined.

[0074] Said method may comprise in a preceding, simultaneous or subsequent step melt softening of matrix and/or of a fluid permeable laminating net laid up at said face(s) and/or of a binder provided together with said powder charge as hereinbefore defined. Melt softening embeds or binds said powder charge at said matrix face and/or within said cell network. Additive is co-located with said melt softened binder.

[0075] Degree of softening or net lamination or quantity of binder may determine depth or extent of embedding or binding.

[0076] Providing a powder charge as herein defined comprises selection of additive having regard to solubility thereof, and any flowing agent, bulking agent and binder as hereinbefore defined, and respective amounts thereof having regard to additive particle size and required availability thereof and providing in a powder charge for contacting and directing as defined.

[0077] Primary availability additive is available for primary contact with fluid at a locus, and ready diffusion of antimicrobial species to said locus, ready absorption of fluid from said locus or other wound dressing property. Secondary availability additive is available for secondary contact with fluid progressively absorbed within said cell network from a locus, and for example diffusion of antimicrobial species via said cell network to said locus.

[0078] In embodiments providing a matrix component in said method herein comprises providing matrix having background content or supplementary content of same or different additive comprised within said structural matrix framework. Such background

content additive is available for tertiary contact with fluid progressively absorbed from a locus within said cell network and thence within the structural matrix framework, with diffusion of antimicrobial species from said framework via said cell network to said locus.

[0079] Preferably said method comprises providing said matrix component or an intermediate surface in desired orientation, for example horizontal or inclined with dosing face upward or downward, vertical facing orientations may also be contemplated; and

providing said powder charge in one or more powder charge receptacles such as hoppers, canisters, cassettes, nozzles, release buckets, drums and feed lines from or linking such receptacle(s); and

directing said powder charge by dosing directly to said matrix face or indirectly to said intermediate surface and subsequently contacting said matrix face with any such intermediate surface; wherein

dosing is selected from dusting, powder sprinkling, powder spraying, powder jetting, entraining and depositing on said face or surface.

[0080] Many forms of receptacle are known for example those provided on carousels or conveyors. Release buckets include inverting buckets on an inverting carousel or conveyor, hinged buckets and hopper buckets.

[0081] An intermediate surface may comprise a release liner for dosing and optionally transiently adhering powder charge thereon or a gravure for releasably containing powder charge.

[0082] Directing to both said matrix faces may be simultaneous or sequential by means of one or more said direct or indirect dosing methods. Resulting material may be asymmetric or is preferably symmetric.

[0083] Dosing may be continuous or discontinuous, and by volume or weight of powder charge per matrix face or per unit surface area of said matrix face or per unit volume of said matrix. Dosing includes dosing to a face of a still tacky part-formed matrix, or casting matrix to a dosed release liner.

[0084] In embodiments said method comprises in a preceding step preparing said powder charge including selection of additive or combination thereof, and any flowing agent, bulking agent and/or binder as hereinbefore defined, and respective amounts thereof having

regard to additive particle size and required availability thereof within material herein, and combining with optional blending or mixing and providing in a powder charge and optional bulking agent and/or binder provided therewith, for contacting and directing as defined.

[0085] In embodiments said step of preparing powder charge comprises additionally subjecting said additive or said powder charge to a particle size selection or reduction process. Particle size selection may comprise sieving, centrifugal or cyclone separation by mass, or otherwise isolating a desired particle size or mass fraction from powder as commercially supplied. Said particle size reduction process may be selected according to the required primary or secondary particle size or particle size distribution of additive or powder charge or component thereof. Primary particle size reduction techniques include known bottom up techniques for controlled particle size recrystallization and top down techniques such as milling or grinding. Secondary particle size reduction techniques include top down techniques for de-aggregating or de-agglomerating additive or powder charge, such as grinding or milling.

[0086] In embodiments methods herein comprise micronizing additive or powder charge. Micronising may comprise dry particle collision employing self-collision or collision with other solid particles, for example by use of milling media selected from gaseous and particulate media including high speed jets of gas inert to said additive such as high speed air jet and high speed nitrogen jet, and high density milling beads or balls such as microbeads into which said additive is directed, for example a turbulent bed of high density microbeads, or which are directed at said additive, for example as a jet of said microbeads, as further disclosed in our co-pending U.K. Provisional Application No. 1711179.0, filed July 12, 2017, the contents of which are incorporated herein by reference.

[0087] Examples of known dry milling apparatus and methods using high speed gas jet milling media include DEC (Dietrich Engineering Consultants) Conika dry mill, IKA Pilotina MC dry mill and MC Jetmill and FPS (Food Pharma Systems) Spiral jetmill range.

[0088] Directing to one said face and within said cell network suitably comprises dosing powder charge as hereinbefore defined and simultaneously or subsequently applying translating force thereby translating at least a part thereof within said cell network.

[0089] Translating may be to a distance between said faces. Alternatively translating may be throughout the matrix including said other face. Resulting material may be asymmetric or symmetric.

[0090] Translating force includes physical force applied directly to powder charge, such as needling, or applied indirectly to powder charge via said matrix, for example by mangling or rolling said matrix, thereby displacing powder charge with translating by gravity or suction or like.

[0091] Alternatively translating force comprises a field applied across said matrix dosed with or to be dosed with said powder charge, more particularly a fluidising field disposed so as to fluidise said powder charge or otherwise cause said powder charge to adopt fluid like flow. Fields include alternating electrostatic field (AC electric field), acoustic field, ultrasonic field, aeraulic field, pneumatic field and the like.

[0092] Translating force may be modulated for a given powder charge particle size, matrix porosity and the like in manner to manipulate depth of translation within said cell network or the like.

[0093] In embodiments a method herein includes in a further step differentiating a part of powder charge comprised at said face and a part of powder charge part comprised within said cell network for respective primary availability and secondary availability, in manner to manipulate respective amounts thereof and depth to which secondary availability part is directed within said cell network and/or to said reverse or secondary release face.

[0094] Dosing and applying translating force may be sequential or simultaneous, for example air jetting powder charge to said matrix face with simultaneous or subsequent translation of an amount thereof within said cell network.

[0095] In a further aspect there is provided herein antimicrobial material or wound care material obtained or obtainable by a method herein.

[0096] In a further aspect there is provided herein an antimicrobial device for application to a locus and activation by contact with aqueous medium provided at said locus, said device comprising

- (a) a locus contacting surface or layer and/or
- (b) an opposing non-locus contacting surface or layer together with

(c) an aqueous medium absorbing layer comprised between or in combination with (a) and/or (b)

wherein (c) comprises antimicrobial material as herein defined.

[0097] In a further aspect there is provided a device comprising a wound dressing or part thereof for application to a wound locus and activation by contact with fluid at said wound locus such as wound exudate, said wound dressing comprising

(a) a wound contacting surface or layer and/or

(b) an opposing non-wound contacting surface or layer together with

(c) one or more optional fluid absorbing layers comprised therebetween between or in combination with one thereof

wherein (c) comprises antimicrobial material or wound care material as herein defined.

[0098] Layer or surface (a) may be adhesive or non-adhesive, for example is a conformable elastomeric apertured film.

[0099] Layer or surface (b) is conveniently a breathable top film permitting fluid and air regulation at the locus and providing an antimicrobial barrier, preferably a continuous moisture vapour transmitting conformable polymer film. A layer (b) may comprise a border about the perimeter of material (c).

[0100] Said device may comprise additional layers selected from a masking layer (b') comprised between a layer (b) and a layer (c), a superabsorbent layer (b'') comprised between a layer (b) and a layer (c) and the like.

[0101] Layers may be laminated and/or sealed within a pouch formed by outer layers in a contiguous and co-extensive relationship.

[0102] Material or device herein may be sterile, terminally sterile and/or sealed in moisture and/or microbe impermeable packaging such as a silver foil pouch.

[0103] In a further aspect there is provided herein a method of manufacture of a device herein.

[0104] In embodiments the previously formed individual layers may be formed into a laminate by bonding the layers together in one or more laminating processes. Suitable

bonding methods include heat sealing or adhesive bonding providing the adhesive layer is moisture vapour transmitting.

[0105] In alternative embodiments the foam layer is formed in contact with one or both of the other layers or additional layers. This process may be favoured as it reduces or eliminates the number of special bonding operations.

[0106] In another preferred process the outer conformable film layer is formed on the foam layer for example by spraying a solution of the polymer.

[0107] In a continuous process the wound dressing can be made in the form of a continuous strip which is then cut up into suitable sized dressings.

[0108] Normally the bringing together of the layers will be a lamination process.

[0109] In a preferred process of forming the dressing in which the foam layer is produced in contact with an external layer it is important that the other external layer should be laminated to the expanded foam while the foam is still tacky so as to obtain a good bond. Typically 2.5 minutes to 5 minutes, for example 3 minutes to 3.5 minutes after the foam has been cast is suitable for bringing the foam into contact with the other external layer.

[0110] In a further aspect there is provided a method for treating a locus so as to aid in rendering or maintaining it free from microbes deleterious to the health of said locus which comprises contacting the locus with antimicrobial material or device as herein defined thereby enabling release of antimicrobial species into said material and/or said locus. Preferably such method is a method of treating a wound locus thereby enabling release of antimicrobial species into said wound locus. In an advantage antimicrobial material and device herein release antimicrobial species, notably silver ion, rapidly in high concentration, with release sustained for a required duration, for example up to 7, 8 or 10 days or more.

[0111] In further embodiments there is provided a method for wound care which comprises contacting the wound locus with wound care material or device as herein defined.

[0112] In another aspect, a method of treating a wound is provided. The method comprises placing a wound dressing comprising a loaded wound dressing layer into or over the wound, wherein the loaded wound dressing layer comprises a porous matrix and a powder charge of antimicrobial release additive loaded within the matrix, wherein the powder charge is concentrated at least at a wound facing surface of the porous matrix; wherein the

antimicrobial release additive is activated for the release of an antimicrobial agent into the wound from the wound dressing upon contact with moist or aqueous medium.

[0113] In some embodiments, the method further comprises releasing said antimicrobial agent for more than a day. In some embodiments, the method further comprises releasing said antimicrobial release agent in an amount up to 1.8mg/cm² per day. In some embodiments, the method further comprises allowing wound exudate to contact the loaded wound dressing layer before releasing at least a portion of the antimicrobial agent toward the wound, wherein the antimicrobial agent is configured to diffuse into wound exudate upon contact with wound exudate. In some embodiments, the method further comprises applying negative pressure to the wound dressing. The antimicrobial release additive may be selected from a group consisting of elemental silver, silver salts, silver complexes, caged forms thereof, caged forms of iodine and combinations thereof. The antimicrobial release additive may be selected from a group consisting of silver sulfadiazine, silver zeolite, silver sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate, cadexomer iodine, copper salts and complexes, zinc salts and complexes, gold salts and complexes, chlorhexidine gluconate, polyhexamethylenebiguanide hydrochloride, and combinations thereof. In one embodiment the antimicrobial release additive may be selected from a group consisting of silver sulfadiazine, silver zeolite, silver sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate, cadexomer iodine, and combinations thereof. The antimicrobial agent may comprise silver ion and/or iodine. In some embodiments, the powder charge of antimicrobial additive further comprises super absorbent polymer. The powder charge of antimicrobial release additive may have particle size on the order of 1 micron<D90<30 micron and D50<10 micron. The powder charge of antimicrobial additive may further comprise a flowing agent selected from a group consisting of stearate salt, clay, silica, charcoal, graphite and a combination thereof, and wherein the flowing agent is in particle size less than the antimicrobial release additive. In some embodiments, the wound dressing further comprises an absorbent layer that absorbs wound exudate, and/or a wound contact layer positioned in contact with the wound below the loaded wound dressing layer.

In some embodiments, the wound dressing may further comprise one or more active ingredients in place of, or in addition to the antimicrobial release additive. The active ingredients may for example include powdered growth factors and small active organic molecules (useful for debridement e.g., collagenase, or useful for promoting healing response e.g. MMP-inhibitors), topical oxygen delivery compounds (e.g. variants on haemoglobin), and any other organic or inorganic bacteriostatic, antibacterial, antiseptic or antimicrobial agent.

If the disclosed technology is in the form of a slurry, active For example the active ingredients in a slurry may exclude the growth factors, MMP-inhibitors, collagenase, haemoglobin variants.

[0114] In another aspect, a wound dressing is provided. The wound dressing comprises:

a loaded wound dressing layer comprising:

a porous matrix comprising a wound facing face and a reverse face; and
a powder charge of antimicrobial release additive loaded within the matrix, wherein the powder charge decreases in amount with increasing distance from at least the wound facing face.

[0115] In some embodiments, the matrix comprises polymer foam, fibrous matrix and/or a hydrophilic polymer. The antimicrobial release additive may comprise elemental silver, silver salts, silver complexes, caged forms thereof, caged forms of iodine and combinations thereof. The antimicrobial release additive may be selected from a group consisting of silver sulfadiazine, silver zeolite, silver sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate, cadexomer iodine and combinations thereof. The antimicrobial release additive may be in an amount of $1.4\text{mg}/\text{cm}^2$ to $4\text{mg}/\text{cm}^2$ at the wound facing face. In some embodiments, the wound dressing may further comprise a wound contact layer below the loaded wound dressing layer, a cover layer over the loaded wound dressing layer, a fluidic connector configured to connect the cover layer to a source of negative pressure, and/or an absorbent layer over the loaded wound dressing layer. The absorbent layer may comprise superabsorbent particles. In some embodiments, the powder charge further comprises superabsorbent polymer. In some embodiments, the powder charge of antimicrobial release

additive may have a particle size of the order of 1 micron<D90<30 micron and D50<10 micron. In some embodiments, the powder charge may further comprise a flowing agent selected from a group consisting of stearate salt, clay, silica, charcoal, graphite and a combination thereof, and wherein the flowing agent is in particle size less than the antimicrobial release additive. In some embodiments, the matrix comprises a plurality of cells and wherein the antimicrobial release additive is at least partially embedded within said cells.

[0116] Variations and modifications of these embodiments will occur to those of skill in the art after reviewing this disclosure. The foregoing features and aspects may be implemented, in any combination and sub-combinations (including multiple dependent combinations and sub-combinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

[0117] Further areas of applicability of the disclosed devices and methods will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating particular embodiments, are intended for purposes of illustration only and are not intended to limit the scope of the disclosure or any of the claims that may be pursued.

BRIEF DESCRIPTION OF THE DRAWINGS

[0118] The foregoing and other objects and advantages will be appreciated more fully upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numbers refer to like parts throughout. These depicted embodiments are to be understood as illustrative and not limiting in any way:

[0119] Figures 1a-k illustrate variants of symmetric material herein;

[0120] Figure 2 illustrates by cross-section SEM, prior art point of manufacture loaded polyurethane foam;

[0121] Figures 3(a)-(h) illustrate by diagram and cross section SEM tortuous pore network types, asymmetric loading of polymer foam herein;

[0122] Figures 4a-o illustrate variants of asymmetric material herein;

- [0123] Figures 5a-d illustrate wound dressing formats comprising material herein;
- [0124] Figures 6 and 7 illustrate silver ion release from prior art multilayer dressings and multilayer dressings herein;
- [0125] Figure 8 illustrates release of silver ion from a reverse face herein;
- [0126] Figure 9 demonstrates release of silver ion pre and post sterilisation;
- [0127] Figure 10 illustrates silver release from different multilayer dressing formats herein;
- [0128] Figure 11 is a schematic diagram of an example of a negative pressure wound therapy system;
- [0129] Figure 12A illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing capable of absorbing and storing wound exudate;
- [0130] Figure 12B illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing capable of absorbing and storing wound exudate;
- [0131] Figure 12C illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing capable of absorbing and storing wound exudate;
- [0132] Figure 12D illustrates a cross section of an embodiment of a fluidic connector connected to a wound dressing;
- [0133] Figures 13A-13D illustrates an embodiment of a wound treatment system employing a wound dressing capable of absorbing and storing wound exudate to be used without negative pressure;
- [0134] Figure 13E illustrates a cross section of an embodiment of a wound treatment system employing a wound dressing capable of absorbing and storing wound exudate to be used without negative pressure;
- [0135] Figures 14A-14B illustrate an embodiment of a wound dressing incorporating the source of negative pressure and/or other electronic components within the wound dressing;

[0136] Figure 14C illustrates an embodiment of layers of a wound dressing with the pump and electronic components offset from the absorbent area of the dressing;

[0137] Figure 15A illustrates an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing with a wrapped around spacer layer, the wound dressing capable of absorbing and storing wound exudate;

[0138] Figure 15B illustrates a cross sectional view of an embodiment of a negative pressure wound treatment system employing a flexible fluidic connector and a wound dressing with a wrapped around spacer layer, the wound dressing capable of absorbing and storing wound exudate;

[0139] Figure 15C illustrates an embodiment of a negative pressure wound treatment system employing a wound dressing capable of absorbing and storing wound exudate;

[0140] Figure 16A illustrates another embodiment of a wound dressing in cross-section;

[0141] Figure 16B illustrates a perspective view of an embodiment of a wound dressing including an obscuring layer and viewing windows;

[0142] Figure 17 is a schematic diagram of a section of an example of a wound dressing;

[0143] Figure 18 is a schematic diagram of an example of a support layer;

[0144] Figure 19A is a schematic diagram of a section of another example of a wound dressing;

[0145] Figure 19B is a perspective view of the wound dressing of Figure 19A;

[0146] Figure 20 is a schematic diagram of a further example of a wound dressing;
and

[0147] Figure 21 is a schematic diagram of a yet further example of a wound dressing.

DETAILED DESCRIPTION

[0148] Embodiments disclosed herein relate to apparatuses and methods of treating a wound with or without reduced pressure, including optionally a source of negative

pressure and wound dressing components and apparatuses. The apparatuses and components comprising the wound overlay and packing materials, if any, are sometimes collectively referred to herein as dressings.

[0149] Preferred embodiments disclosed herein relate to wound therapy for a human or animal body. Therefore, any reference to a wound herein can refer to a wound on a human or animal body, and any reference to a body herein can refer to a human or animal body. The term “wound” as used herein, in addition to having its broad ordinary meaning, includes any body part of a patient that may be treated using negative pressure. It is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured or where trauma causes a contusion, or any other superficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, abdominal wounds or other large or incisional wounds, either as a result of surgery, trauma, sterniotomies, fasciotomies, or other conditions, dehiscent wounds, acute wounds, chronic wounds, subacute and dehiscent wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like.

[0150] As used herein a chronic wound is one that does not heal in an orderly set of stages and in a predictable amount of time the way most wounds do; wounds that do not heal within three months are often considered chronic. For example, a chronic wound may include an ulcer such as a diabetic ulcer, a pressure ulcer (or pressure injury), or venous ulcer.

[0151] Treatment of such wounds can be performed using negative pressure wound therapy, wherein a reduced or negative pressure can be applied to the wound to facilitate and promote healing of the wound. It will also be appreciated that the wound dressing and methods as disclosed herein may be applied to other parts of the body, and are not necessarily limited to treatment of wounds. Other embodiments do not utilize negative pressure for the treatment of wounds or other parts of the body.

[0152] Material or matrix component as herein defined is fluid absorbent, more particularly absorbent for aqueous fluids such as body fluids for example wound fluids and

components thereof. Material or matrix component is liquid, gas and vapour permeable, for example permeable to said aqueous fluids, moisture and air. When applied to a locus, material aids in regulating moisture and air circulation at a locus. Said material suitably provides a moist environment such as a moist wound environment. Preferably material or matrix component are hydrocellular, i.e. characterised by an ability to create a moist environment and absorb high amounts of fluid. A hydrocellular wound dressing material is characterised by an ability to create a moist wound healing environment and absorb high amounts of exudate.

[0153] Material or matrix component herein is a shaped or cast continuous or discontinuous body such as a block, layer, slab, mattress, sheet, strip, web or a roll thereof or the like, of regular or irregular shape. Material and matrix herein are non-particulate.

[0154] Flexible material or matrix herein is herein is both conformable and elastically extensible. Flexible material or matrix herein may be conformed to a surface, such as a shaped surface, for example irregular or regular, static or mobile. For example material or matrix may be conformable to a surface of a body part or wound surface or the like and dynamically conform to changes resulting from movement, skin drag, stretch, flex and the like. Such material or matrix may attain and retain a shape or profile with or without the aid of adhesive or other restraint.

[0155] Material herein is suitably for use to inhibit or kill microbes selected from bacteria, yeast and fungi, thus is selected from antifungal, antibacterial, antiyeast, and in particular fungicidal, bactericidal and yeasticidal, fungistatic, bacteriostatic and/or yeastistatic and combinations. For the avoidance of doubt antimicrobial species-releasing additive herein is other than the antibiotic class of antimicrobials.

[0156] Antimicrobial material is envisaged for contact with aqueous media, such as aqueous fluid, at said locus, such as waste fluid, contaminated fluid, body fluid such as wound fluid and the like. A particularly suitable locus is moist.

[0157] Antimicrobial material may be medical material such as wound care material, dental material, personal care material, hygiene or sanitation material such as clothing material or upholstery material, food industry material, packaging material or the like. Material may be for use directly or comprised within a device.

[0158] Thus for example silver salts and/or wound care additive advantageous for wound dressings, are combined as a dry powder with porous matrix useful to wound dressing. The resulting material composite may then be used in the manufacture of a wound care device such as a wound dressing for application to a moist wound locus which may be exuding or non-exuding.

[0159] In embodiments said material applied to a wound locus absorbs exudate and particulate matter from the surface of granulating wounds and, as the material becomes moist, antimicrobial species such as ionic silver or diatomic and ionic iodine species is released. The material thus has the dual effect of cleansing the wound and exerting an antimicrobial action.

[0160] In an advantage asymmetric antimicrobial material herein is adapted for contacting a locus at risk of infection by microbes with the matrix release face i.e. antimicrobial-rich side of the material proximal to the locus, for example a wound, so that the maximum amount of antimicrobial additive is near and is most readily available where it is needed.

[0161] In an advantage asymmetric wound care material herein is adapted for contacting a wound with the wound facing face which may be additive-rich or additive-poor side of the material proximal to the wound, for example so that the additive is positioned where it is needed.

[0162] In an advantage symmetric antimicrobial or wound care material presents a choice of locus or wound contacting face, i.e. material is non-handed and is adapted for contacting a locus, directly or fabricated in a device, with either release face or additive-rich side of the material proximal to the locus or wound.

[0163] Figures 1a-h and j illustrate symmetric material variants herein comprising powder charge at both matrix faces and within matrix cell network. It should be noted that additive may be absent from said face or faces where this disrupts adhesion in a laminar device with additional layers, or at a locus such as a wound. Matrix may for example be treated to prevent powder charge loading at a face or faces, for example by removing a thin surface layer from said matrix or selecting a slice of matrix omitting a matrix face. Variants herein with or without face loaded additive may comprise: a) uniform low concentration within cell network

proximal to said faces for example within a few cells from each face; b) uniform high concentration within cell network proximal to said faces for example within a few cells from each face; c) and d) decreasing high to low high concentration within cell network proximal to said faces, for example to a few cells from each face, in case of c) to just short of mid-cell network depth, and in case of d) to mid depth; e) uniform high concentration within cell network proximal to said faces to just short of mid-matrix depth from each face; f) uniform low concentration within cell network proximal to said faces to just short of mid-matrix depth from each face; g) low concentration throughout cell network; h) high concentration throughout cell network. Figure 3i) illustrates symmetric variant comprising powder charge at both faces only. Figures 3j) and 3k) illustrate variants of 3b) and 3i) wherein matrix component prior to assembly comprises background content of additive such as same or different antimicrobial additive, comprised within the matrix structural framework.

[0164] Figure 2 illustrates figuratively matrix cell and pore architecture a) providing a tortuous pore network herein and b) providing a reticulated cell network or pore network herein, and c) cross section SEM of matrix providing a tortuous pore network herein. Matrix type a) and c) may provide asymmetric material herein having powder charge asymmetrically loaded or loaded in diminishing concentration within cell network herein. Matrix type b) may provide symmetric material herein having powder charge symmetrically loaded within cell network herein. Both matrix types may provide symmetric or asymmetric material loaded at said face or faces.

[0165] Figure 3a is a cross-section SEM of prior art point of manufacture polyurethane foam comprising silver sulfate (bright spots) provided in the aqueous phase of the polymerisation reaction, and comprised throughout the structural polyurethane framework.

[0166] Figures 3b and 3c illustrate antimicrobial polyurethane foam matrix herein providing a tortuous pore network, comprising powder charge of silver sulfate (bright spots) at a foam face and within cell network. It can be seen that the powder charge has concentrated proximal to the matrix face to which charge is dosed. There is penetration of the silver sulfate, concentrated in cell network up to 1mm depth, in the 2mm thick foam and (3c) foam/fiber laminate. There are some silver salt particles deeper in the structure, but these are incidental to the concentration proximal to the dosing and release face.

[0167] Figures 4a-o illustrate asymmetric material variants herein. Figures 4a-h, j and l illustrate asymmetric variants comprising powder charge at one matrix face and within cell network, and it should be noted that additive may be absent from said face or faces where this disrupts adhesion in a laminar device with additional layers, or at a locus such as a wound, as described in context of Figure 1 above. Variants herein with or without face loaded additive may comprise: a) uniform low concentration within cell network proximal to release face to a few cells depths from said face; b) uniform high concentration within cell network proximal to said face to a few cells from said face; c) decreasing high to low concentration within cell network proximal to said face to a few cells from said face; d) uniform low concentration within cell network proximal to release face to mid-matrix depth from said face; e) uniform high concentration within cell network proximal to said face to mid-matrix depth from said face; f) decreasing high to low concentration within cell network proximal to said face to mid-matrix depth from said face; g) high concentration within cell network proximal to said face and low concentration throughout remainder of cell network to reverse face; h) high concentration within cell network to mid-matrix depth and low concentration throughout remainder of cell network to reverse face. Figures 4j) and 4k) illustrate asymmetric variants comprising powder charge at said face only. Figure 4j) and 4k) illustrate variants of 2b) and 2i) wherein matrix component prior to assembly comprises background content of additive such as same or different additive, comprised within the matrix structural framework. Figure 4l illustrates variant 4a) with powder charge comprised at both said faces and within cell network proximal to one said face.

[0168] Material herein may comprise powder charge within cell network proximal to a face to any desired depth from said face, for example from two mean cell diameters therefrom to mid- or full-matrix depth, for example 5% up to 50% or 85% or 100%, such as 10% or 20% up to 50% or 85% or 100% of said cell network depth or matrix depth; or 0.2 mm or 0.3 mm or 0.4 mm or 0.5 mm up to 1mm or 2mm or 3mm or 4mm in material or matrix of 1mm or 2mm or 3mm to 6mm or 7mm or 1cm in depth, that is to say 1mm or 2mm or 3mm to 6mm or 7mm or 1cm separation of respective faces; or from 0.5 mm or 1cm up to 2cm in material or matrix of 1cm to 4cm in depth, that is to say 1cm to 4cm separation of respective faces.

[0169] Material herein may be conditioned post-assembly, for example dried, equilibrated, stored or packaged, sterilised and the like, with no effect or incidental effect on powder charge or on additive property such as release profile thereof. In an advantage antimicrobial material herein may be thus conditioned, for example sterilised, with release profile corresponding to unconditioned, for example unsterilized, pre-assembly powder charge. Such effect, if any, may therefore be taken into consideration in determining amount of powder charge, dosing and/or directing thereof.

[0170] Material herein may be sterile or non-sterile, preferably terminally sterile or non-terminally sterile, for example may be sterilised by steam, gamma radiation, x-ray or electron beam or ethylene oxide. As shown in Figure 9, ionic silver release is comparable for matching samples of material composite assembled from same powder charge and same matrix, one thereof not sterilised and the other thereof ethylene oxide sterilised.

[0171] Material herein suitably has moisture content less than 10% (wt.), preferably less than 8% (wt.), preferably less than 5% (wt.). Additive or powder charge herein typically has loss on drying for 4 hours in vacuum oven at 50°C of less than or equal to 0.5wt%, such as less than or equal to 0.4 wt% or 0.3 wt% prior to or after loading in matrix herein.

[0172] Matrix component herein may have thickness of 0.5mm to 20mm, more suitably 0.8mm to 15mm, preferably 1mm to 12mm, for example 2mm, 3mm, 4mm, 5mm or 6mm. but may be of lesser or greater thickness if desired.

[0173] Matrix component may have cell size of 30 micron to 1000 micron, such as 30 micron to 700 micron or 300 micron to 1000 micron. A porous foam matrix component herein preferably has cell size in the range 50 micron to 500 micron, for example 200 micron – 250 micron in average diameter.

[0174] Matrix herein may have 20% to 70% of the total surface area of cells as openings. Matrix may be of very high free internal volume, e.g. of the order of 70% to 90%. Matrix may have any desired cell network and pore network architecture. The microstructures of polyurethane (PU) foams range from foams with small circular holes in the centre of the pore surfaces providing resistance to air flow across the foam, as illustrated for example in Figure 2a, to reticulated low density “open pore” foams, where no pore surfaces remain, as

illustrated for example in Figure 2b, providing free air flow across the foam. Corresponding fiber matrix ranges from matrix with misaligned voids, cells herein, between fibres and misaligned pores interconnecting said voids, said matrix providing resistance to air flow across the matrix to matrix with aligned voids between fibres and aligned pores interconnecting said voids, providing free air flow across the matrix. Matrix herein may be characterised by air resistance between faces thereof as a function of cell network and/or pore network tortuosity, including factors such as the size of pores in cell surfaces, their orientation and spacing, the cell size, and the fraction of cell surfaces that contain pores. The air flow resistance of PU foams is thought to be a function of the area of the largest pores in the cells and of linked paths between large pores.

[0175] In embodiments material comprising additive at a matrix face and within cell network thereof comprises matrix of high air flow resistance and/or low air transmission between faces and/or a high tortuosity pore network, wherein material is asymmetric as hereinbefore defined. Preferably high tortuosity polymer foam or fiber matrix herein is selected from hydrocellular polymer foams and fiber matrices intended for use in wound care applications, more preferably polyurethane foam and combinations thereof, super absorbent fiber fleeces and cellulosic fiber fleeces and the like.

[0176] Such matrix component is commercially available or may be manufactured by techniques as known in the art and includes fiber matrix comprised in TENCEL™ fibres (Durafiber™), polyurethane foam matrix (Allevyn™ and Allevyn Ag™), cellulose matrix (Post-op™), cotton leno-weave gauze fabric (Bactigras™), and absorbent rayon/polyester matrix (Acticoat™), all available from Smith & Nephew, Inc., and MepilexR and MepilexR Ag, available from Moelnlycke Health Care. Fiber matrix such as cellulose superabsorbent air laid is commercially available (Glatfelter).

[0177] Matrix component may comprise a combination of fiber and foam, for example a combination of hereinbefore commercially available fiber such as superabsorbent fiber and foam matrices, or commercially available combinations such as MepilexR Border (and Ag) which comprises a laminated bilayer of polyurethane foam and superabsorbent fibers.

[0178] Polyurethane foam matrix component may be manufactured as disclosed, for example in EP0059049, and in EP1964580, both of which disclose the option to

incorporate antibacterial agents into proto foam prior to polymerising. Polyurethane foam component may be manufactured by reacting a hydrophilic isocyanate terminated polyether pre-polymer with water, aqueous liquid or aqueous surfactant, and casting into or onto a mould or liner such as a shaped liner and optionally drying. Matrix component may be the finished product or may be part-finished product, premixed and cast in situ in the method herein to a mould or liner dosed with powder charge as hereinbefore defined. High tortuosity pore network polyurethane foam herein may be manufactured for example by mixing 100 parts by weight of isocyanate such as Hypol FHP2000, 2001, 3000, 3001, 2002 or 2000HD with 0.3 to 7 parts by weight of surfactant or mixtures of surfactants and 30 to 300 parts by weight of water and the foaming mixture cast onto a surface. Typical foaming mixtures have a cream time of about 20 secs., a rise time of about 250 secs and a cure time or about 400 secs.

[0179] Silver ion releasing additive is suitably comprised in material herein or assembled with matrix component herein in an amount of 0.05mg to 3.5mg or 0.05mg to 4mg silver ion/cm² of material as herein defined, such as 0.1mg to 3.5mg or 4mg silver ion/cm² of material as herein defined or 0.2mg to 3.5mg or 4mg silver ion/ cm² material as herein defined. Material may comprise additive such as silver sulfate in amount in excess of 1.4 mg/cm² up to 4 mg/cm² such as in the range 1.75 mg/cm² to 3.5 mg/cm².

[0180] Antimicrobial additive is suitably characterised by species release profile, i.e. amount of species as hereinbefore defined released with time, such as amount released into 50mL of aqueous media given as mg/cm² of material per unit time as known in the art. In embodiments release profile is rapid onset, i.e. bolus release, within 24 hours, thereafter maintaining a sustained steady state secondary release for duration up to 10 days, for example up to 7 or 8 days.

[0181] Antimicrobial additive may provide a required Minimum Bactericidal Concentration (MBC) or Minimum Inhibitory Concentration (MIC) of antimicrobial during the lifetime of material or at specific time intervals from activation. MBC is given as a measure of concentration of a given antimicrobial species in a given fluid, as mg species/mL fluid.

[0182] For example MBC may be 0.4mg - 50 mg silver ion/ 50mL wound fluid or simulated wound fluid or aqueous medium or 0.7mg – 2mg iodine /mL, depending on the microbe in question, the media chosen, the test set-up, and ease of kill.

[0183] Release may be obtained with material comprising silver salt such as sulfate providing an equivalent calculated as mg salt / cm² antimicrobial material, for a given material having given absorption for example thickness etc. Preferably MBC is achieved and surpassed as rapidly as possible.

[0184] Methods for determining ion release are for example according to ASTM E2149 (microbiology testing) with modifications as known in the art. ASTM E2149 allows for the ability to evaluate many different types of materials and devices, and a wide range of microorganisms. Materials and devices can be subject to a wide variety of physical/chemical stresses or manipulations and the test allows for versatility of testing the effect of contamination due to such things as hard water, proteins, blood, serum, various chemicals and other contaminants.

[0185] Powder charge herein comprises additive herein which is commercially available and may be comprised as supplied in powder charge or may be processed, for example by drying, by particle size reduction such as selection of a desired particle size grade thereof, or by methods known in the art.

[0186] In embodiments herein powder charge or additive has weight loss on drying (L.O.D) less than 2%.

[0187] L.O.D is suitably determined in a sample of powder charge or additive herein as weight loss during 4 hours in vacuum oven at 50°C or in non-vacuum oven at 105°C, of less than 2%, such as less than 1% or of less than 0.5%, such as less than 0.4% or less than 0.3% or less than 0.2% or 0.1%.

[0188] L.O.D as defined permits accurate dosing of additive or powder charge thereof, without additional or variable moisture content in said dosed amount.

[0189] L.O.D may be determined as powder charge or additive. Alternatively L.O.D may be determined as material comprising additive and includes loss of moisture from the matrix and from the additive. Material humidity varies with atmospheric conditions and may be determined and decoupled in suitable manner.

[0190] Preferably powder charge comprises additive having particle size and distribution thereof compatible with matrix component and manufacturing requirements, such as matrix component cell size and pore size and dosing requirements. Particle size for a highly

soluble salt such as silver nitrate may be selected for compatibility with matrix cell and pore size and manufacturing requirements such as dosing, for example may be of the order of 50-1000 micron, for example 50 – 200 micron such as 100 micron compatible with 200 micron cell size matrix. Additive for loading in a matrix herein may have particle size distribution of the order of 8 micron<D90<115 micron or 4 micron<D50<60 micron or 1 micron<D90<30 micron. In a particular advantage additive has particle size distribution of D50<10 micron.

[0191] Additive may be provided in any suitable particle size and particle size distribution as commercially available, as supplied additive or by particle size reduction, suitably micronisation by methods known in the art or novel methods disclosed herein and in our copending unpublished U.K. Provisional Application No. 1711179.0, filed July 12, 2017, the contents of which are incorporated herein by reference.

[0192] Preferably additive is micronized, said micronizing according to novel methods of our co-pending unpublished U.K. Provisional Application No. 1711179.0, filed July 12, 2017, the contents of which are incorporated herein by reference, for example comprising providing additive or powder charge and dry micronization thereof by particle collision selected from gas phase self-collision and collision with fluidised solid particles, such as contacting with gaseous or particulate milling force such as high speed air jet or high density milling beads or microbeads.

[0193] Powder charge may comprise flowing agent as hereinbefore defined selected from fumed silica, stearate salts, activated charcoal, clays such as bentonite, montmorillonite, micas. Flowing agent may be medically compatible.

[0194] Flowing agent is provided in powder charge as hereinbefore defined as small particle size powder in range as hereinbefore defined for additive. In case of low solubility additive as hereinbefore defined, flowing agent may have particle size of the order D50<10 micron for example comprised in powder charge together with additive of low micron particle size for example having particle size distribution D50<10 micron.

[0195] Flowing agent may be present in an amount up to 20wt % such as 0.5-8 wt.% or 0.5-4 wt.%, e.g. 2 wt.%. Amount depends on nature of agent chosen and is chosen such as not to reduce matrix porosity, affect flex/suppleness on softening.

[0196] Flowing agent may provide additional function. For example charcoal has additional function as odour control agent or as colouring agent masking matrix discoloration in case of light sensitivity of silver salt or absorption of coloured aqueous media such as wound fluids, blood. Powder charge may comprise bulking agent selected from inert organic polymers such as PEG. Bulking agent may be present in an amount up to 80wt % such as 10-80 wt% or 20-80 wt%, e.g. 25 wt% or 50wt% or 75 wt%. Bulking agent assists in ensuring low variation in processing accuracy on dosing.

[0197] Bulking agent may have particle size less than, same as or in excess of additive particle size, in range as hereinbefore defined for additive. A particularly useful particle size in case of low solubility additive as hereinbefore defined is in the range 50 to 100 micron for example 80 micron.

[0198] One or more further additives may be provided in said matrix component as herein defined or comprised in said powder charge, for example selected from wound dressing additives as hereinbefore defined.

[0199] Fluid permeable laminating net inhibits shedding of additive from material herein. A suitable laminating net may be a porous polymeric sheet or net, commonly used to interface and adhere adjacent layers in a wound dressing. Extruded polymeric meshes, non-wovens or melt blown polymer variants are known such as polyamide, polyester or polyethylene for example DelnetTM, Delpore[®], Stratex[®] and Naltex[®] (Delstar).

[0200] Fluid permeable laminating net is heat laminatable at elevated temperature such as 150 - 170°C.

[0201] Methods for directing additive to a face known in the art as hereinbefore defined include for example:

- i) dosing powder charge to a face of said matrix; or
- ii) dosing powder charge to a liner, such as a silicone surface or silicone coated surface or to a melt polymer film and contacting with a cast matrix, suitably by casting foam matrix mixture or fiber matrix mixture to said liner, applying a cast foam or fiber matrix at a face thereof to said liner or applying said liner to a cast foam or fiber matrix face.

[0202] For example a liner providing a powder charge “reservoir” and the matrix face “receiver” are brought together in a batch wise or continuous process whereby powder charge transfers from liner to the matrix face on contact. A liner may be a belt having thereon a thin layer of powder charge or may be a tacky or non tacky or melt polymer film or laminating net that can be heat-laminated onto the matrix face. Matrix may be a belt or layer of matrix.

[0203] A liner may be a continuous liner in the form of a closed loop conveyor belt positioned in a vertical plane below a hopper, canister or reservoir of powder charge and having pockets presented alternately upright and inverted, to receive powder charge from said hopper, canister or reservoir, and dose to matrix positioned therebelow.

[0204] Methods suitably use belt systems or stamp printing systems for example using gravures as known in the art of manufacturing for bringing two surfaces together or transfer coating a surface. Such methods are known for example in the context of organic powder applications for example dry powder coating processes for making durable coatings such as of organic dyes or inorganic sintering materials.

[0205] Matrix may be freshly cast and thereby tacky, or powder charge may comprise a medically-accepted adhesive powder or soft tacky gel. Thereby powder charge may be securely retained at said face.

[0206] Matrix may be heated, simultaneously with or subsequent to dosing powder charge, to cause melt softening of matrix face or binder optionally comprised in powder charge or of commercially available melt polymer liner or laminating net, as hereinbefore described, laid over said face.

[0207] For example the method may comprise dosing as hereinbefore defined and thereafter applying heat and/or pressure such as by contact or laminating plate, to secure melt polymer liner or laminating net to said matrix face.

[0208] Dosing powder charge to a face of a matrix i) or to a liner ii) is for example by air-spraying, sprinkling or dusting dry powder onto the liner or the face of the matrix. Air-spraying, sprinkling or dusting may be from a hopper, canister or reservoir of powder charge. Powder charge is fluidised or fluid flow induced by entraining in an air jet or by flowing or pouring from a hopper or like reservoir.

[0209] Powder charge may be dosed according to ii) and loosely retained or supported at matrix release face for subsequent or simultaneous translation within cell network as hereinbefore and hereinbelow defined.

[0210] Methods for translation known in the art or as described herein include for example dosing to a face and translation within cell network by I) physical force or II) – V) excitation field/field force as hereinbefore defined such as by:

[0211] I) mangling or needling for example by techniques known for interlocking or meshing non-woven fibres to form a matrix. Mangling suitably comprises applying a roller or other force translating across said release face, optionally with a liner therebetween, or said reverse face. Needling suitably comprises inserting one or more fine projections within said matrix to cause penetration and thereby translating powder charge within cell network thereof;

[0212] II) aeraulic field, such as air jetting powder charge to said matrix face with simultaneous translation of an amount thereof within said cell network. Air jet is applied to said face in the direction of said cell network. Air jetting may be from a hopper, canister or reservoir of powder charge. Powder charge is fluidised by entraining in an air jet. For example an air gun with hopper, canister or line feed to a reservoir entrains powder charge with air and sprays at a matrix face, preferably from one or more spray heads, which may have adjustable aperture. A hopper, canister or line feed may include a metering device to meter a predetermined dose of powder charge. A spray gun may be automated or robotically operated with facility to spray at desired rate across a matrix face. Alternatively air spraying may be by dry powder techniques as known for example in US 2017098818, the contents of which are incorporated herein by reference. Air spray apparatus is for example available at Nordson.com;

[0213] III) high-intensity air-jet for example using air jet techniques as hereinbefore defined, operated at air jet velocity and/or jet contact area sufficient to direct fluidised powder charge within the cell network. Preferably said method comprises fluidising dosed powder charge by means of a plurality of co-aligned air jets or an air jet diffuser head directed to a matrix face. An air jet diffuser head may comprise diffusion outlet surface area corresponding to matrix face surface area or a portion thereof, and said diffusion head may be

aligned facing said matrix face perpendicular or at an angle thereto at suitable separation such as 1mm to 5mm separation or more. Said diffusion head may be recessed within a hood located about said matrix face or diffuser head or may be sealed together with said matrix within a powder charge containment means such as a vacuum bag, thereby containing powder charge at the matrix face. Vacuum may draw powder charge within said matrix, in symmetric loading case of a reticulated matrix herein or in face loading in case of a tortuous pore network collapsed under application of vacuum. In an advantage fluidisation by air jet diffuser allows for minimal turbulence and minimal loss of powder charge.

[0214] High intensity air-jet may comprise a hopper, canister or reservoir for powder charge, whereby dosing and directing within a matrix may be simultaneous;

[0215] IV) alternating electrostatic field for example alternating current electric field force applied across said matrix perpendicular to said faces, optionally by commercially available impregnation service provided by Fibroline SA. The method operates a system of 2 face to face electrodes connected to an alternative high tension generator, the electrodes protected by dielectric material and spaced apart by a distance suitable to allow passage of the matrix therebetween. Matrix may be passed between said electrodes at a rate from 10m/min to in excess of 300 m/min, either as continuous matrix such as a roll, or as discontinuous sections or lengths of matrix conveyed between said electrodes on suitable conveying apparatus. The Fibroline D-Preg, S-Preg or T-Preg method may be selected according to scale and dimensions of material required, and quantities and concentrations of powder charge to be provided thereon. The T-Preg method may be selected for manufacture of material comprising low powder charge concentrations or employing low powder charge volumes. The method is disclosed in US2016/0228909 the contents of which are incorporated herein by reference.

[0216] US2016/0228909 discloses optimisations to achieve a deep impregnation of powder charge across a substrate, and demonstrates a uniform impregnation across the thickness of a substrate of powder dosed at one face. With reference to Figure 3b and 3c, powder charge comprising silver sulfate was dosed to release face shown as lowermost and uppermost in respective figures, and directed in cell network closest to the dosing face. There is penetration of the salt, but mostly in the first 1mm of the 2mm thick foam. There are some silver sulfate particles deeper in the matrix, but this is in incidental concentration compared to

that within cell network proximal to the dosing face. This is of advantage in the herein material comprising antimicrobial species-release additive;

[0217] V) An alternative excitation field may be a vibration excitation field as described in US2016/0228909 generated by a series of freely rotating bars in place of electrodes, said bars of polygonal cross section having their diameter selected according to the thickness of matrix and rate of advance of said matrix into and through said field. Said bars apply a variable pressure on the matrix, generating vibrations therein and fluidising powder charge dosed to a face thereof, said fluidised charge directed thereby within matrix cell network.

[0218] In embodiments fluidising may be by powder excitation in a field selected from alternating electrostatic field (AC electric field), acoustic field, ultrasonic field, aeraulic field, pneumatic field and the like as hereinbefore defined. Preferably the method comprises dosing powder charge to a matrix face as hereinbefore defined and exciting powder charge by applying an excitation field to said face. Preferably an excitation field is applied perpendicular to said face. The field may be applied continuously or discontinuously. Continuous field may be applied to matrix passed continuously through the field as a continuous sheet or roll, or as discrete pieces.

[0219] An excitation field/field force such as II) – V) above, is suitably applied for duration sufficient to fluidise and translate powder charge within cell network herein. Fluidisation and translation is rapid. Suitable duration is less than a minute, for example 3 seconds to 30 seconds such as 5, 10, 15, 20 or 30 seconds. Excitation field is preferably non turbulent.

[0220] In a preferred embodiment there is provided herein a method for manufacture of asymmetric material as hereinbefore defined comprising a flexible hydrophilic polymer foam or fiber matrix component comprising two matrix faces providing and therebetween a structural matrix framework defining a network of cells having a cell network surface and pore network and

a powder charge component as hereinbefore defined

comprising dosing said powder charge to said release face and applying an excitation field to fluidise said powder charge and direct within said cell network

wherein said powder charge is comprised within said cell network proximal to said release face in decreasing concentration with increasing depth within said cell network and wherein said powder charge is present in incidental amount at said reverse face and in cell network proximal to said reverse face

characterised in that said matrix provides a tortuous pore network.

[0221] Preferably said matrix component comprises a foam matrix having a superabsorbent fiber matrix laminated at said foam matrix reverse face and/or said powder charge comprises super absorbent polymer together with said antimicrobial additive.

[0222] Preferably said method comprises laminating a melt polymer laminating net to said release face.

[0223] Material herein may be for use selected from the management of wounds; hygiene and sterilisation of articles including medical and dental articles and point of use sterilisation; hygiene and sterilisation of personal care preparations and articles such as sanitary pads, diapers, cosmetics; hygiene and sterilisation of food or of fluids, including air and water, or systems for their preparation and generation such as food preparation or packaging plants, ventilation systems, water management systems; and in particular such uses for which preventing or combatting microbial infection is beneficial.

[0224] The material may be for application to wounds which carry a risk of presence of, contamination by or infection with microbes harmful to the health of said wound or of a subject, particularly selected from bacteria, yeast and fungi and combinations thereof.

[0225] Wound management includes management of shallow granulating wounds, chronic and acute exudative wounds, full and partial thickness wounds, exuding wounds, infected wounds, malignant wounds, surgically dehiscent wounds, first and second degree burns, donor sites, fungating wounds and the like. Wounds for which the hereinbefore defined material has particular use include for example ulcers and pressure sores such as pressure ulcers, leg ulcers and diabetic foot ulcers; surgical wounds; trauma wounds; partial thickness burns; skin flap and skin graft donor site wounds; tunnelling and fistulae wounds; wounds left to heal by secondary intent; and wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided, cavity wounds, sinus and open wounds.

[0226] Asymmetric material herein is useful in providing a wound facing face or release face, such as additive-rich or additive-poor for example a silver-rich face, or choice of silver rich faces for positioning facing the locus or wound, so that the maximum amount of antimicrobial species is readily available for release near where it is needed or maximum amount of wound dressing additive is proximal to or remote from the wound.

[0227] Material herein may be suitable for combatting Gram positive bacteria and/or Gram negative bacteria, for example Gram positive bacteria selected from Staphylococcus such as Staph. aureus, Staph. epidermidis and MRSA, Streptococcus, Enterococcus, Corynebacterium and Clostridium such as C. difficile, also Peptostreptococcus, Lactobacillus, Propionibacterium, Bifidobacterium and Actinomyces and/or Gram negative bacteria selected from proteobacteria such as Enterobacteriaceae for example, Escherichia coli, Salmonella, Shigella, Pseudomonas such as Pseudomonas aeruginosa, Proteus, Klebsiella, also Legionella, Hemophilus, Neisseria, Acinetobacter such as A. baumannii, Bacteroides, Prevotella, Fusobacterium, Porphyromonas and the cyanobacteria and spirochaetes.

[0228] Material herein is particularly useful in combatting one or more microbes encountered in a wound environment, for example Gram negative aerobic bacteria such as Pseudomonas aeruginosa, Gram positive bacteria such as Staphylococcus aureus, more particularly MRSA (methicillin resistant Staphylococcus aureus) also known as ORSA (oxacilin resistant Staphylococcus aureus), anaerobic bacteria such as Bacteroides fragilis, yeast such as Candida albicans and fungi such as Aspergillus brasiliensis.

[0229] A device as hereinbefore defined may be a medical or dental sponge or wipe, or together with additional functional materials is a wound dressing.

[0230] In preferred devices herein, layer (a) and/or (b) are independently selected from silicone, polyurethane and the like.

[0231] A device herein may comprise same or different antimicrobial or wound care material as hereinbefore defined provided in a plurality of layers, for example 2 or 3 layers of asymmetric material may provide strata of additive within said device.

[0232] In this embodiment a device may comprise material herein fabricated in a commercially available wound dressing format for example in format of the ALLEVYN™

range of dressings, OPSITETM and OPSITETM POST-Op Visible, PICOTM, Algisite, DurafiberTM, the Mepilex range of dressings, and the like.

[0233] Figure 5 illustrates wound dressing formats including antimicrobial material herein. In Figures 5a and 5b are illustrated dressings comprising layers (a), (b) and (c) above. In Figure 5b, layers are held together by heat laminating outer layers (a) and (c) at the borders thereof. Figure 5c shows variant 5b including additional layers (b') and (b'') above. Figure 5d illustrates a variant of Figure 5a, comprising a foam and fiber matrix bilayer. The bilayer may constitute a bilayered antimicrobial material as hereinafter defined comprising a bilayer matrix component with powder charge component as hereinafter defined. Alternatively the bilayer may constitute independent antimicrobial material layers either or both comprising a matrix component with powder charge component as hereinbefore defined.

[0234] A packaged device herein is suitably packaged in a water proof pouch such as an aluminium foil pouch.

[0235] In a further aspect there is provided herein a method of manufacture of a device herein.

[0236] In embodiments the previously formed individual layers may be formed into a laminate by bonding the layers together in one or more laminating processes. Suitable bonding methods include heat sealing or adhesive bonding providing the adhesive layer is moisture vapour transmitting.

[0237] In alternative embodiments the foam layer is formed in contact with one or both of the other layers or additional layers. This process may be favoured as it reduces or eliminates the number of special bonding operations.

[0238] In another preferred process the outer conformable film layer is formed on the foam layer for example by spraying a solution of the polymer.

[0239] In a continuous process the wound dressing can be made in the form of a continuous strip which is then cut up into suitable sized dressings.

[0240] Normally the bringing together of the layers will be a lamination process.

[0241] In a preferred process of forming the dressing in which the foam layer is produced in contact with an external layer it is important that the other external layer should be laminated to the expanded foam while the foam is still tacky so as to obtain a good bond.

Typically 2.5 minutes to 5 minutes, for example 3 minutes to 3.5 minutes after the foam has been cast is suitable for bringing the foam into contact with the other external layer.

[0242] A method of treatment as hereinbefore defined is for treating a locus such as a wound. A suitable locus for treatment is moist or comprises aqueous fluid. Antimicrobial species release is activated into said locus or wound on contact with moisture or aqueous fluid. A suitable wound is exuding.

[0243] Preferably the method of treatment herein comprises additionally securing material or device herein in position in contact with said locus or wound. Suitably securing means is sufficiently robust to retain material or device in position for the required duration, for example 7, 8 or 10 days or more. Securing may be by adhesion to said locus, such as skin surrounding said wound, of locus contacting face such as wound contacting face, or of cover layer or of a further adhesive layer or strips or a bandage applied over said material or device.

[0244] Embodiments herein are illustrated as follows with reference to examples which are non-limiting thereof.

EXAMPLES

Comparative Example 1 Preparation of PU foam point of manufacture (P.O.M.) loaded with silver sulfate

Example CE1.1: P.O.M. loaded (aqueous)

[0245] PU foam sample comprising silver sulfate (Alfa Aesar, as supplied 40-70 micron) was prepared using a variant of method of EP0059049 Example 8, replacing aqueous silver sulfadiazine solution with aqueous silver sulfate solution:

[0246] Silver sulfate (1.5g) was blended with a high speed shear mixer into a Brij 72 emulsion (30g as a 2.5% aqueous solution) .

[0247] The mixed emulsion-additive was added to Hypol 2002 (20 g) in a beaker and mixed by stirring with a metal spatula and then with a mechanical stirrer until the Hypol was uniformly dispersed (approximately 20 seconds) and cast to a shaped liner to produce foam with equivalent loading dose (TS) of 1.9 mg/cm². In SEM images of the resulting material, shown in Figure 2a and 2b, silver sulfate (bright spots) is seen loaded in pores (dark grey against grey cross sectioned structural matrix framework or grey cross sectioned cell

surface) throughout the 2mm thick foam showing loading of particles precipitated from solution in sub-micron size.

Example CE1.2: P.O.M. loaded (aqueous suspension)

[0248] PU foam comprises silver sulfate loaded within the structural matrix framework from a combined solution suspension of silver sulfate combined in the aqueous phase of the polyurethane foam polymerisation reaction, as disclosed in European Patent EP1964580.

Comparative Example 2 Preparation of Multi-layer dressing compositions

Example CE1.1D (P.O.M. loaded (aqueous))

[0249] Foam of Comparative Example CE1.1 was provided together as corresponding CE1.1D with breathable top film and adhesive wound contact layer in multi-layer dressing composition formats.

Example CE1.2D (P.O.M. loaded (aqueous suspension))

[0250] Commercially available MepilexR Border Ag (Moelnlycke Health Care) is multilayer dressing CE1.2D (format of Figure 5c), comprising hydrocellular PU foam layer manufactured using methodology of Example CE1.2 (P.O.M loaded (aqueous suspension)) source of silver sulfate unknown, together with superabsorbent fibre layer, PU breathable top film and gentle adhesive wound contact layer with equivalent loading dose (TS) of 1.3 mg/cm². Silver sulfate is comprised as part precipitated / part suspension derived particles within the PU foam structural matrix framework throughout the depth of the foam in one population including 15 micron particles and a second population of approx. 1 micron fines as supplied 40-70 micron.

Example 1.1 Preparation of micronized additive

[0251] Silver sulfate (40-70 micron, Alfa Aesar), a very dense silver salt, d=5, was introduced into the inlet of air jet milling apparatus (Dietrich Engineering Consultants, Conika dry mill). Settings were adjusted (injection and grinding line gas pressures and silver sulfate

feed rate) to reduce the median particle size to 1 – 10 micron. Powder charge was obtained in a number of grades.

[0252] Grade of samples of micronized silver sulfate was measured by Malvern Mastersizer after sonicating a dispersion of the powder in methanol, for example as follows:

D50 ~ 3 micron;

D50 ~ 6 micron;

D50 ~ 14 micron.

[0253] Micronized silver sulfate was also assessed for particle size distribution, by methods disclosed herein, for example as follows:

average 1.6 (0.4-5.3) micron;

average 1.9 micron (0.7 – 5 micron).

Example 1.2 Preparation of Powder Charge

[0254] Powder charge was prepared from silver sulfate as supplied or micronized silver sulfate from Example 1.1, alone or combined in different combinations with PEG 3350 (bulking agent, 80 micron) and/or fumed silica (flowing agent <1 micron) and/or charcoal (secondary additive), for example as in Table 1:

Ag ₂ SO ₄ additive/ micron	Fumed silica flowing agent/ %w/w Ag ₂ SO ₄	PEG bulking agent/ %w/w Ag ₂ SO ₄	Charcoal additive/ %w/w Ag ₂ SO ₄
40			
40		25, 50, 75	
40	0.5	50	
40	0.5	50	3
6	0.5, 2		
6		50	

6	0.5	50	
6		50	3, 5, 8
6*		50	

Example 2 Preparation of PU foam composite (powder charge) loaded

[0255] Samples of ALLEVYN range polyurethane foam (2mm thickness), or *bilayer laminate with superabsorbent fibre fleece, were provided to Fibroline SA, together with powder charge from Example 1, dosed to a gravure.

[0256] Fibroline SA performed assembly of antimicrobial material in a number of samples at different equivalent loading doses (TS):

Ex.2.1 – 2.4: 1.6 mg/cm² and (micronized) 0.8 mg/cm², 1.1 mg/cm², 1.4 mg/cm²;

using proprietary methodology as referenced in for example US2016/0229890 as follows: Powder charge dosed to the release face of matrix, or to a gravure laid onto or under matrix; AC electrostatic field applied to the dosed matrix resulting in the penetration of the powder charge into the cell network of the PU foam proximal to the dosed release face.

[0257] Samples comprising flowing agent and/or bulking agent dosed accurately to foam surface, with acceptable amounts (ideally none) remaining on dosing gravure. Samples comprising flowing agent loaded more efficiently than samples without.

[0258] Material was heated to soften matrix and/or bulking agent comprised in powder charge, thereby seating silver sulfate particles in cell walls.

[0259] In SEM images of the resulting material, shown in Figure 3c, 3d and 3e, 3f, silver sulfate (bright spots) is seen loaded in pores (dark grey against grey cross sectioned structural matrix framework or grey cross sectioned cell surface). In Figure 3c, the tortuosity of pore network is illustrated. Figures 3d) – 3h) are SEM images of material loaded with micronized silver sulfate. In Figures 3d, 3e and 3f is seen the resulting asymmetric powder charge loading, translated to a depth of 1mm within the 2mm thick foam with concentration of silver sulfate decreasing with increasing depth. In Figures 3g (secondary electrons

(topography)) and 3h backscattered electron (brighter zone = heavier element, here silver)) is seen the co-located softened bulking agent and seated/embedded silver sulfate.

Example 3 Preparation of multi-layer dressing compositions

[0260] Foams of Ex.2.1-2.4 were provided as the corresponding Ex.2.1D-2.4D in a variety of multi-layer commercial dressing composition formats as illustrated in Figure 5:

ALLEVYN Gentle Border: 5b

ALLEVYN Life: Figure 5c

ALLEVYN Gentle: 5b, no border

ALLEVYN Life Non-Bordered : 5c, no border

Example 4 Silver Release Performance

[0261] Silver release was determined for multilayer compositions CE1.1D, CE1.2D and Ex.2.1D – Ex.2.4D using methodology herein described, i.e. amount released into 50mL of aqueous media given as mg/cm² of material per unit time. Release was cumulative with the same media sampled over 7 days, leading to slow saturation of that particular fluid. Results are shown in Figure 6.

[0262] All 3 multilayer composition types, P.O.M (aqueous), P.O.M (aqueous suspension) and composite (powder charge) loaded showed a bolus release in the first 6 hours, then reached steady state, with release continuing beyond 170 hours. Ex.2D samples showed higher bolus and higher sustained release, at lower equivalent loading dose in Figure 6 as follows:

silver-release from dressings of Ex.2.2D and Ex.2.3D surpassed, at lower loading (TS = total silver element), that of CE1.2D;

silver-release from dressings of Ex.2.1D surpassed, at lower loading (TS), that of CE2.1D.

Example 5 Silver Release Performance daily challenge

[0263] Silver release was also determined in the same manner as Example 4 but by daily challenge, replenishing release media on a daily basis. Results shown in Figure 7,

illustrate the silver-release performance of dressing of Ex.2.4D (micronized composite (powder charge) loaded)) surpassed, at comparable loading (TS), CE1.2D (P.O.M loaded (aqueous suspension)) up to day 4, and thereafter gave comparable release up to day 7.

[0264] Example 4 and Example 5 demonstrate increased availability of additive loaded within cells, and in asymmetric loading within cell network close to where it is needed, proximal to the release face, as further demonstrated in Example 6.

[0265] Example 4 also demonstrates the superior release achieved with increased particle surface area, from micronized particles (Figure 6).

Example 6 Release face

[0266] Asymmetric material was prepared according to Example 2 in high loading of micronized silver sulfate for experimental purpose only, with TS approx. 3mg/cm². Material was assembled in two dressings:

Ex. 6.1D: silver-rich side (i.e. loading and release face) proximal to wound contacting layer;

Ex. 6.2D: silver-poor face (i.e. reverse face) proximal to wound contacting layer.

[0267] Release of silver was measured over 7 days from the wound contacting face of both dressings using the method of Example 4, results are shown in Figure 8 in which:

[0268] Dressing 6.1D gave exceedingly high silver release. This demonstrated that release can be adapted at will by increasing loading in the materials and methods herein, in contrast to solubility limited prior art materials and methods;

[0269] Dressing 6.2D gave negligible release from the dressing composition, silver ion was retained within the dressing and rendered the dressing antimicrobial but had minimal effect on the release locus, which would typically be a wound bed. This demonstrated that total silver content, loaded strategically at wound contacting face in asymmetric materials using asymmetric methods herein, is more readily available for release into the wound bed and may provide enhanced silver release or may facilitate provision of silver salt in reduced amount within material or a dressing.

Example 7 Sterilisation

[0270] Example 2 samples were coated with silicone wound contact layer, cut into 2x2cm squares, assembled with layers according to Figure 5c herein, and sealed at elevated temperature for lamination, and 3 of each sample sterilised by ethylene oxide cycle and ionic silver determined against corresponding non sterilised samples. Results shown in Figure 9 illustrate that sterilisation did not affect ionic silver.

Example 8 Silver Release Performance different dressing composition format

[0271] Different multilayer compositions Ex.2D were compared for silver ion release using the method of Example 4. The results shown in Figure 10 demonstrate bolus and sustained silver ion release is upheld in multilayer compositions of different formats.

[0272] Samples were successfully tested against *S.aureus* and *P.aeruginosa*.

Visualisation of Additive Surface Enrichment

[0273] In some embodiments, after said powder charge is dosed or loaded to said matrix as described herein, said matrix may exhibit heterogeneous spatial distribution of said powder charge and/or said additive. In some embodiments, for example as shown in Figure 4, the highest enrichment of the powder charge and/or said additive may be present at one or more foam surface (e.g. the locus contacting face, the wound contacting face) and gradually decreases with increasing depth, subsurface into the bulk foam.

[0274] The surface enrichment of the loaded additive, such as silver sulfate, may be visualised in 2-dimensions using backscatter Scanning Electron Microscopy (b-SEM) of planar cross-sectioned surfaces across the depth of the foam and in 3-dimensions using high resolution (instrument used must be capable of better than 35 micron spatial resolution) micro-focussed X-ray Computed Tomography (μ -XCT). The use of both visualisation techniques may be beneficial, because of the limits of spatial resolution of micro-focused X-ray Computed Tomography instruments. The matrix and loaded additive can be simultaneously visualised by both b-SEM and by μ -XCT.

[0275] In some embodiments, a 2-dimensional visualisation method such as micro Raman spectroscopy could be employed to map the spatial distribution of the loaded additive

across a planar cross-sectioned surface of the foam. The polyurethane foam and the silver sulfate can be simultaneously mapped by micro Raman spectroscopy.

[0276] In some embodiments, a 2-dimensional visualisation method such as micro X-ray Fluorescence (μ -XRF) could be employed to map the spatial distribution of silver and sulphur (elemental constituents of silver sulfate) across a planar cross-sectioned surface of the foam, where such an elemental map is overlaid upon a macroscopic optical image of the mapped area (the polyurethane foam cannot be mapped by μ -XRF).

Quantification of Additive Surface Enrichment

[0277] Quantification of the extent of the additive enrichment can be achieved by means of image analysis based on greyscale segmentation (brightness of backscatter signal) of b-SEM images. Areas of interest located at different foam depths in the cross-sectional images can be analysed to obtain a 2D percentage area coverage of silver sulfate (silver sulfate yields brighter contrast than polyurethane foam in b-SEM images).

[0278] Quantification of the extent of silver sulfate enrichment can be achieved by means of image analysis based on greyscale segmentation (X-ray opacity) of μ -XCT images. Volumes of interest located at different foam depths in the 3-dimensional image datasets can be analysed to obtain a 3D percentage area occupation of silver sulfate within each subsequently deeper volume of interest (silver sulfate yields higher X-ray opacity than polyurethane foam in μ -XCT images).

Example 9 Silver distribution within PU foam with composite (powder charge) loaded

[0279] Another four asymmetric materials were prepared according a method similar to Example 2 in loading of silver sulfate for experimental purpose only. In these examples, a polyurethane (PU) foam layer was dry-impregnated with silver sulfate powder (approximately 1-2 mg/cm² as silver). During the impregnation process, a powder binder (e.g., polyethylene glycol, PEG) can be added, as well as small quantities of activated charcoal and fumed silica. In addition, the silver can be milled to reduce its particle size, or used unmilled as supplied by the manufacturer.

[0280] Materials such as these samples can be imaged through the cross section of PU foam samples in order to identify the effect of the presence of binder, and of milled or unmilled silver, on:

- The depth of penetration of the silver particulates into the foam;
- Whether there is a segregation of particles during impregnation (PEG particles are larger than silver sulfate particles) leading to a difference in the distribution of silver sulfate through the depth of the foam (e.g. more surface concentration in one case vs the other).

[0281] The four foam samples were as follows:

AD – a polyurethane foam with 2mm thickness, with 48 wt% dry-milled silver sulfate, 48 wt% PEG100k, 3 wt% charcoal, 1 wt% silica. Silver dose was ranged 0.76-0.88 mg/cm²;

AC – a polyurethane foam with 2mm thickness, with 48 wt% unmilled silver sulfate, 48 wt% PEG100k, 3 wt% charcoal, 1 wt% silica. Silver dose was ranged 0.67-0.88 mg/cm²;

AE – a polyurethane foam with 2mm thickness, with 96 wt% dry-milled silver sulfate, 3 wt% charcoal, 1 wt% silica. Silver dose was ranged 2.31-2.59 mg/cm²;

AB – a polyurethane foam with 2mm thickness, with 96 wt% unmilled silver sulfate, 3 wt% charcoal, 1 wt% silica. Silver dose was ranged 1.68-1.96 mg/cm².

[0282] The particle size distribution for the dry-milled silver sulfate was about 2 micron <D10<about 5 micron, about 5 micron<D50<about 10 micron, about 10 micron<D90<about 18 micron. The particle size distribution for the unmilled silver sulfate was about 10 micron <D10<about 25 micron, about 30 micron<D50<about 60 micron, about 50 micron<D90<about 90 micron. In some embodiments, milled silver sulfate can have a particle size distribution of: 4 micron <D10<5 micron, 8 micron<D50<11 micron, 16 micron<D90<19 micron, and unmilled silver sulfate can have a particle size distribution of 10 micron<D10<15 micron, 20 micron<D50<40 micron, 40 micron<D90<95 micron.

[0283] In the above samples, the PEG foam samples contain 2 ½ to 3 ½ times less silver sulfate than the non-PEG foam samples. Samples can be analyzed using SEM images, micro-CT images, or any other suitable technique.

[0284] Figure 4m illustrates X-ray transmission images acquired from the dry-impregnated silver sulfate foam samples described above, with the dark areas showing the silver sulfate. The milled silver sulfate foam samples had a more defined silver sulfate distribution which was consistent with the nodes arranged in a checkerboard pattern observed on the supplied foams. In contrast, the unmilled silver sulfate foam samples had a relatively more random silver sulfate distribution (see the plan view transmission images shown in Figure 4m). There is some indication of unmilled sample AB having a higher silver sulfate concentration at the nodes, but this is not as distinct as the milled samples. The cross-sectional X-ray transmission images show the silver sulfate penetrated into the foams to differing depths, as discussed below. Accordingly, in some embodiments powder charge may be loaded in a random distribution, and in other embodiments powder charge may be loaded to provide a pattern, such as a checkerboard pattern.

[0285] Figure 4n illustrates SEM images of cross-sectional view of each of the asymmetric material acquired by a method described herein, and Figure 4n illustrates micro-focused X-ray Computed Tomography (μ -XCT) images of each of the asymmetric material acquired by a method described herein. Cross-sectional images for the milled samples were acquired approximately through the center of a node. As shown in Figures 4n-o, in some embodiments, the silver sulfate may be impregnated in multiple pyramidal shapes, with the base of the pyramid being at the surface of a node and the point of the pyramid being further in to the foam (e.g., 0.4mm to 0.8mm into the foam). In some embodiments, silver sulfate may be distributed more randomly, as shown in the unmilled samples, where the bulk on unmilled silver sulfate appears to be randomly distributed about 0.4mm to about 0.8mm into the foam. In some embodiments, silver sulfate may be distributed throughout the whole foam, but to a much lesser concentration than on the loaded surface. In some embodiments, more than 50%, 70%, or 80% of silver sulfate may be present within 0.8mm from a surface of the foam. As shown in Figure 4o, The bulk of the silver sulfate in the non-PEG foam samples went into the foam to a depth of about 0.8mm, and in contrast the bulk of the silver sulfate in the PEG foam samples went into the foam to a depth of about 0.4mm. For all of the four foam samples, silver sulfate particles were observed throughout the whole foam but to a much lesser extent than on the surface of the impregnated foam. Accordingly, in some embodiments

powder charge may be loaded with a bulk (or any of the percentages above) of the particles being provided within a specified distance of the surface of matrix, for example, within about 0.4mm or about 0.8mm.

Negative Pressure Wound Therapy (NPWT)

[0286] It will be understood that embodiments of the present disclosure are generally applicable to use in topical negative pressure ("TNP") therapy systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema; encouraging blood flow and granular tissue formation; removing excess exudate and may reduce bacterial load (and thus infection risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems may also assist on the healing of surgically closed wounds by removing fluid and by helping to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

[0287] As is used herein, reduced or negative pressure levels, such as -X mmHg, represent pressure levels relative to normal ambient atmospheric pressure, which can correspond to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of -X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760-X) mmHg. In addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g., -40 mmHg is less than -60 mmHg). Negative pressure that is "more" or "greater" than -X mmHg corresponds to pressure that is further from atmospheric pressure (e.g., -80 mmHg is more than -60 mmHg). In some embodiments, local ambient atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg.

[0288] The negative pressure range for some embodiments of the present disclosure can be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg. Note that these pressures are relative to normal ambient atmospheric pressure, which can be

760 mmHg. Thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively, a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively, a pressure range of over approximately -100 mmHg, or even -150 mmHg, can be supplied by the negative pressure apparatus.

[0289] In some embodiments of wound closure devices described herein, increased wound contraction can lead to increased tissue expansion in the surrounding wound tissue. This effect may be increased by varying the force applied to the tissue, for example by varying the negative pressure applied to the wound over time, possibly in conjunction with increased tensile forces applied to the wound via embodiments of the wound closure devices. In some embodiments, negative pressure may be varied over time for example using a sinusoidal wave, square wave, or in synchronization with one or more patient physiological indices (e.g., heartbeat). Examples of such applications where additional disclosure relating to the preceding may be found include U.S. Patent No. 8,235,955, titled "Wound treatment apparatus and method," issued on August 7, 2012; and U.S. Patent No. 7,753,894, titled "Wound cleansing apparatus with stress," issued July 13, 2010. The disclosures of both of these patents are hereby incorporated by reference in their entirety.

[0290] Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in International Application No. PCT/IB2013/001469, filed May 22, 2013, published as WO 2013/175306 A2 on November 28, 2013, titled "APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY," International Application No. PCT/IB2013/002060, filed on July 31, 2013, published as WO2014/020440, entitled "WOUND DRESSING," the disclosures of which are hereby incorporated by reference in their entireties. Embodiments of the wound dressings, wound treatment apparatuses and methods described herein may also be used in combination or in addition to those described in US Patent No. 9,061,095, titled "WOUND DRESSING AND METHOD OF USE," issued on June 23, 2015; and U.S. Application Publication No. 2016/0339158, titled "FLUIDIC CONNECTOR FOR NEGATIVE PRESSURE WOUND THERAPY,"

published on November 24, 2016, the disclosures of which are hereby incorporated by reference in its entirety, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings.

[0291] Additionally, some embodiments related to TNP wound treatment comprising a wound dressing in combination with a pump or associated electronics described herein may also be used in combination or in addition to those described in International Publication No. WO 2016/174048 A1, entitled “REDUCED PRESSURE APPARATUSES”, published on November 3, 2016, the entirety of which is hereby incorporated by reference. In some of these embodiments, the pump or associated electronic components may be integrated into the wound dressing to provide a single article to be applied to the wound.

Multi-Layered Wound Dressings

[0292] Any multi-layered wound dressings may incorporate or comprise a loaded matrix as hereinbefore described. Such wound dressings may incorporate a loaded matrix layer, composite or laminate including the loaded matrix. For example, a loaded foam layer including a powder charge/additive-loaded polyurethane (PU) material as described previously herein and illustrated in Figures 1-10 may be incorporated into a multi-layered wound dressing. As described previously herein, the powder charge or additive loaded onto the polyurethane (PU) material may be configured to be activated to release chemical species, for example, antimicrobial species by contact with moist or aqueous medium. Accordingly, the loaded matrix may be configured to release, for example, antimicrobial species upon contact with moist or aqueous medium, for example wound exudate. To facilitate release and diffusion of antimicrobial species into the wound, the loaded matrix may be placed proximate to the wound within the wound dressing.

[0293] In some embodiments, there is provided a method to treat a wound or locus. The method may include placing a multi-layered wound dressing having a loaded matrix, such as a fiber or foam layer including a powder charge/additive as described herein, over the wound, such that the wound dressing touches the wound. Examples of such wound dressings were described above and are further described hereinafter. The wound dressing

may be adhered to healthy skin around the wound. The method may further include allowing wound exudate to reach and/or touch the loaded matrix layer. In some embodiments, negative pressure may be applied to the wound dressing, such that wound exudate is suctioned into the wound dressing. In some embodiments, the wound exudate may be diffused or wicked into the wound dressing. In some embodiments, any moist or aqueous medium other than wound exudate may be provided to the wound dressing. Upon contact with moist or aqueous medium, either provided by wound exudate or not, the loaded matrix layer may release antimicrobial species as described herein previously. At least a portion of the released antimicrobial species may be released into the wound, for example by diffusion. In some embodiments, the antimicrobial species may be silver ions. In some embodiments, the antimicrobial species may be released to the wound for a prolonged duration, for example, up to a day, five days, seven days or 10 days or more. In some embodiments, the silver ion may be released up to $0.1\text{mg}/\text{cm}^2$ per day, up to $1.2\text{mg}/\text{cm}^2$ per day, up to $1.8\text{mg}/\text{cm}^2$ per day or more.

Multi-Layered Wound Dressings for NPWT

[0294] Figure 11 illustrates an example of a negative pressure wound therapy system 700. The system includes a wound cavity 710 covered by a wound dressing 720, which can be a dressing according to any of the examples described herein. The dressing 720 can be positioned on or inside the wound cavity 710 and further seal the wound cavity so that negative pressure can be maintained in the wound cavity. For example, a film layer of the wound dressing 720 can provide substantially fluid impermeable seal over the wound cavity 710. In some embodiments, a wound filler, such as a layer of foam or gauze, may be utilized to pack the wound. The wound filler may include a loaded matrix as hereinbefore described. For example, in a traditional negative pressure wound therapy system utilizing foam or gauze, such as the Smith & Nephew RENASYS Negative Pressure Wound Therapy System utilizing foam (RENASYS-F) or gauze (RENASYS-G), the foam or gauze may be replaced with or may be supplemented with a loaded matrix layer, composite or laminate as described above. When supplementing a foam or gauze layer or other wound packing material, the loaded

matrix layer, composite or laminate may either be separately inserted into the wound or may be pre-attached with the wound packing material for insertion into the wound.

[0295] A single or multi lumen tube or conduit 740 connects the wound dressing 720 with a negative pressure device 750 configured to supply reduced pressure. The negative pressure device 750 includes a negative pressure source. The negative pressure device 750 can be a canisterless device (meaning that exudate is collected in the wound dressing and/or is transferred via the tube 740 for collection to another location). In some embodiments, the negative pressure device 750 can be configured to include or support a canister. Additionally, in any of the embodiments disclosed herein, the negative pressure device 750 can be fully or partially embedded in, mounted to, or supported by the wound dressing 720.

[0296] The conduit 740 can be any suitable article configured to provide at least a substantially sealed fluid flow path or pathway between the negative pressure device 750 and the wound cavity 710 so as to supply reduced pressure to the wound cavity. The conduit 740 can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable rigid or flexible material. In some embodiments, the wound dressing 720 can have a port configured to receive an end of the conduit 740. For example, a port can include a hole in the film layer. In some embodiments, the conduit 740 can otherwise pass through and/or under a film layer of the wound dressing 720 to supply reduced pressure to the wound cavity 710 so as to maintain a desired level of reduced pressure in the wound cavity. In some embodiments, at least a part of the conduit 740 is integral with or attached to the wound dressing 720.

[0297] Figures 12A-B illustrate embodiments of a negative pressure wound treatment system 10 employing a wound dressing 100 in conjunction with a fluidic connector 110. Additional examples related to negative pressure wound treatment comprising a wound dressing in combination with a pump as described herein may also be used in combination or in addition to those described in US Patent No. 9,061,095, which is incorporated by reference in its entirety. Here, the fluidic connector 110 may comprise an elongate conduit, more preferably a bridge 120 having a proximal end 130 and a distal end 140, and an applicator 180 at the distal end 140 of the bridge 120. The system 10 may include a source of negative pressure such as a pump or negative pressure unit 150 capable of supplying negative pressure. The pump may comprise a canister or other container for the storage of wound exudates and

other fluids that may be removed from the wound. A canister or container may also be provided separate from the pump. In some embodiments, such as illustrated in Figures 12A-12B, the pump 150 can be a canisterless pump such as the PICO™ pump, as sold by Smith & Nephew. The pump 150 may be connected to the bridge 120 via a tube 190, or the pump 150 may be connected directly to the bridge 120. In use, the dressing 100 is placed over a suitably-prepared wound, which may in some cases be filled with a wound packing material such as foam or gauze as described above. The applicator 180 of the fluidic connector 110 has a sealing surface that is placed over an aperture in the dressing 100 and is sealed to the top surface of the dressing 100. Either before, during, or after connection of the fluidic connector 110 to the dressing 100, the pump 150 is connected via the tube 190 to the coupling 160, or is connected directly to the bridge 120. The pump is then activated, thereby supplying negative pressure to the wound. Application of negative pressure may be applied until a desired level of healing of the wound is achieved.

[0298] As shown in Figure 12C, the fluidic connector 110 preferably comprises an enlarged distal end, or head 140 that is in fluidic communication with the dressing 100 as will be described in further detail below. In one embodiment, the enlarged distal end has a round or circular shape. The head 140 is illustrated here as being positioned near an edge of the dressing 100, but may also be positioned at any location on the dressing. For example, some embodiments may provide for a centrally or off-centered location not on or near an edge or corner of the dressing 100. In some embodiments, the dressing 100 may comprise two or more fluidic connectors 110, each comprising one or more heads 140, in fluidic communication therewith. In a preferred embodiment, the head 140 may measure 30mm along its widest edge. The head 140 forms at least in part the applicator 180, described above, that is configured to seal against a top surface of the wound dressing.

[0299] Figure 12D illustrates a cross-section through a wound dressing 100 similar to the wound dressing 10 as shown in Figure 12B and described in International Patent Publication WO2013175306 A2, which is incorporated by reference in its entirety, along with fluidic connector 110. The wound dressing 100, which can alternatively be any wound dressing embodiment disclosed herein or any combination of features of any number of wound dressing embodiments disclosed herein, can be located over a wound site to be treated. The

dressings 100 may be placed as to form a sealed cavity over the wound site. In a preferred embodiment, the dressing 100 comprises a top or cover layer, or backing layer 220 attached to an optional wound contact layer 222, both of which are described in greater detail below. These two layers 220, 222 are preferably joined or sealed together so as to define an interior space or chamber. This interior space or chamber may comprise additional structures that may be adapted to distribute or transmit negative pressure, store wound exudate and other fluids removed from the wound, and other functions which will be explained in greater detail below. Examples of such structures, described below, include a transmission layer 226 and an absorbent layer 221.

[0300] As used herein the upper layer, top layer, or layer above refers to a layer furthest from the surface of the skin or wound while the dressing is in use and positioned over the wound. Accordingly, the lower surface, lower layer, bottom layer, or layer below refers to the layer that is closest to the surface of the skin or wound while the dressing is in use and positioned over the wound.

[0301] As illustrated in Figure 12D, the wound contact layer 222 can be a polyurethane layer or polyethylene layer or other flexible layer which is perforated, for example via a hot pin process, laser ablation process, ultrasound process or in some other way or otherwise made permeable to liquid and gas. The wound contact layer 222 has a lower surface 224 and an upper surface 223. The perforations 225 preferably comprise through holes in the wound contact layer 222 which enable fluid to flow through the layer 222. The wound contact layer 222 helps prevent tissue ingrowth into the other material of the wound dressing. Preferably, the perforations are small enough to meet this requirement while still allowing fluid to flow therethrough. For example, perforations formed as slits or holes having a size ranging from 0.025 mm to 1.2 mm are considered small enough to help prevent tissue ingrowth into the wound dressing while allowing wound exudate to flow into the dressing. In some configurations, the wound contact layer 222 may help maintain the integrity of the entire dressing 100 while also creating an air tight seal around the absorbent pad in order to maintain negative pressure at the wound.

[0302] Some embodiments of the wound contact layer 222 may also act as a carrier for an optional lower and upper adhesive layer (not shown). For example, a lower

pressure sensitive adhesive may be provided on the lower surface 224 of the wound dressing 100 whilst an upper pressure sensitive adhesive layer may be provided on the upper surface 223 of the wound contact layer. The pressure sensitive adhesive, which may be a silicone, hot melt, hydrocolloid or acrylic based adhesive or other such adhesives, may be formed on both sides or optionally on a selected one or none of the sides of the wound contact layer. When a lower pressure sensitive adhesive layer is utilized may be helpful to adhere the wound dressing 100 to the skin around a wound site. In some embodiments, the wound contact layer may comprise perforated polyurethane film. The lower surface of the film may be provided with a silicone pressure sensitive adhesive and the upper surface may be provided with an acrylic pressure sensitive adhesive, which may help the dressing maintain its integrity. In some embodiments, a polyurethane film layer may be provided with an adhesive layer on both its upper surface and lower surface, and all three layers may be perforated together.

[0303] A transmission layer 226 can be located above the wound contact layer 222. In some embodiments, the transmission layer can be a porous material. As used herein the transmission layer can be referred to as a spacer layer and the terms can be used interchangeably to refer to the same component described herein. This transmission layer 226 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer 226 preferably ensures that an open-air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer 226 should preferably remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure. The layer 226 may be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used. The three-dimensional material can comprise a 3D spacer fabric material similar to the material described in International Publication WO 2013/175306 A2 and International Publication WO2014/020440, the disclosures of which are incorporated by reference in their entireties.

[0304] The wound dressing 100 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam layer including a powder charge/additive-

loaded polyurethane (PU) material or fibre material as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 100. In some embodiments, the loaded matrix layer may be provided below the transmission layer 226. In some embodiments, the loaded matrix layer may be provided above the wound contact layer 222. In some embodiments, the loaded matrix layer may replace the transmission layer 226, such that the loaded matrix layer is provided between an absorbent layer 221 (described further below) and the wound contact layer 222. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 221, or the absorbent layer 221 can be loaded with powder charge as described above. In some embodiments, the wound dressing 100 does not have the wound contact layer 222, and the loaded matrix layer may be the lowermost layer of the wound dressing 100. The loaded matrix may have same or substantially similar size and shape with the transmission layer 226 and/or the absorbent layer 221.

[0305] The loaded matrix layer may be constructed to be flexible but stiff enough to withstand negative pressure, such that the loaded matrix is not collapsed excessively and thereby transmits negative pressure sufficiently to the wound when negative pressure is supplied to the wound dressing 100. The loaded matrix layer may be constructed to include sufficient number or size of pores to enable transmission of negative pressure through it. Further, the loaded matrix layer may have suitable thickness to transmit enough negative pressure to the wound. For example, the loaded matrix layer may have a thickness of 1mm to 5mm, 1.5mm to 4mm, or 2mm to 3mm. In some embodiments, the loaded foam matrix may have a thickness of approximately 2mm.

[0306] In some embodiments, the layer 221 of absorbent material is provided above the transmission layer 226. The absorbent material, which can comprise a foam or non-woven natural or synthetic material, and which may optionally comprise a super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site. In some embodiments, the layer 221 may also aid in drawing fluids towards the backing layer 220.

[0307] The material of the absorbent layer 221 may also prevent liquid collected in the wound dressing 100 from flowing freely within the dressing, and preferably acts so as to

contain any liquid collected within the dressing. The absorbent layer 221 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer 221 may typically be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 or Chem-Posite™11C-450. In some embodiments, the absorbent layer 221 may comprise a composite comprising superabsorbent powder, fibrous material such as cellulose, and bonding fibers. In a preferred embodiment, the composite is an air-laid, thermally-bonded composite.

[0308] In some embodiments, the absorbent layer 221 is a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing.

[0309] An aperture, hole, or orifice 227 is preferably provided in the backing layer 220 to allow a negative pressure to be applied to the dressing 100. The fluidic connector 110 is preferably attached or sealed to the top of the backing layer 220 over the orifice 227 made into the dressing 100, and communicates negative pressure through the orifice 227. A length of tubing may be coupled at a first end to the fluidic connector 110 and at a second end to a pump unit (not shown) to allow fluids to be pumped out of the dressing. Where the fluidic connector is adhered to the top layer of the wound dressing, a length of tubing may be coupled at a first end of the fluidic connector such that the tubing, or conduit, extends away from the fluidic connector parallel or substantially to the top surface of the dressing. The fluidic connector 110 may be adhered and sealed to the backing layer 220 using an adhesive

such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The fluidic connector 110 may be formed from a soft polymer, for example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale. In some embodiments, the fluidic connector 110 may be made from a soft or conformable material.

[0310] Optionally, the absorbent layer 221 includes at least one through hole 228 located so as to underlie the fluidic connector 110. The through hole 228 may in some embodiments be the same size as the opening 227 in the backing layer, or may be bigger or smaller. As illustrated in Figure 12D a single through hole can be used to produce an opening underlying the fluidic connector 110. It will be appreciated that multiple openings could alternatively be utilized. Additionally, should more than one port be utilized according to certain embodiments of the present disclosure one or multiple openings may be made in the absorbent layer in registration with each respective fluidic connector. Although not essential to certain embodiments of the present disclosure the use of through holes in the super-absorbent layer may provide a fluid flow pathway which remains unblocked in particular when the absorbent layer is near saturation.

[0311] The aperture or through-hole 228 is preferably provided in the absorbent layer 221 beneath the orifice 227 such that the orifice is connected directly to the transmission layer 226 as illustrated in Figure 12D. This allows the negative pressure applied to the fluidic connector 110 to be communicated to the transmission layer 226 without passing through the absorbent layer 221. This ensures that the negative pressure applied to the wound site is not inhibited by the absorbent layer as it absorbs wound exudates. In other embodiments, no aperture may be provided in the absorbent layer 221, or alternatively a plurality of apertures underlying the orifice 227 may be provided. In further alternative embodiments, additional layers such as another transmission layer or an obscuring layer such as described with reference to Figures 16A-16B and in International Patent Publication WO2014/020440, the entirety of which is hereby incorporated by reference, may be provided over the absorbent layer 221 and beneath the backing layer 220.

[0312] The backing layer 220 is preferably gas impermeable, but moisture vapor permeable, and can extend across the width of the wound dressing 100. The backing layer

220, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way, an effective chamber is made between the backing layer 220 and a wound site where a negative pressure can be established. The backing layer 220 is preferably sealed to the wound contact layer 222 in a border region around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The backing layer 220 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The backing layer 220 preferably comprises two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is preferably moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet. In some embodiments, the moisture vapor permeability of the backing layer increases when the backing layer becomes wet. The moisture vapor permeability of the wet backing layer may be up to about ten times more than the moisture vapor permeability of the dry backing layer.

[0313] The absorbent layer 221 may be of a greater area than the transmission layer 226, such that the absorbent layer overlaps the edges of the transmission layer 226, thereby ensuring that the transmission layer does not contact the backing layer 220. This provides an outer channel of the absorbent layer 221 that is in direct contact with the wound contact layer 222, which aids more rapid absorption of exudates to the absorbent layer. Furthermore, this outer channel ensures that no liquid is able to pool around the circumference of the wound cavity, which may otherwise seep through the seal around the perimeter of the dressing leading to the formation of leaks. As illustrated in Figures 12C-12D, the absorbent layer 221 may define a smaller perimeter than that of the backing layer 220, such that a boundary or border region is defined between the edge of the absorbent layer 221 and the edge of the backing layer 220.

[0314] As shown in Figure 12D, one embodiment of the wound dressing 100 comprises an aperture 228 in the absorbent layer 221 situated underneath the fluidic connector 110. In use, for example when negative pressure is applied to the dressing 100, a wound

facing portion of the fluidic connector may thus come into contact with the transmission layer 226, which can thus aid in transmitting negative pressure to the wound site even when the absorbent layer 221 is filled with wound fluids. Some embodiments may have the backing layer 220 be at least partly adhered to the transmission layer 226. In some embodiments, the aperture 228 is at least 1-2 mm larger than the diameter of the wound facing portion of the fluidic connector 11, or the orifice 227.

[0315] In particular for embodiments with a single fluidic connector 110 and through hole, it may be preferable for the fluidic connector 110 and through hole to be located in an off-center position as illustrated in Figure 12C. Such a location may permit the dressing 100 to be positioned onto a patient such that the fluidic connector 110 is raised in relation to the remainder of the dressing 100. So positioned, the fluidic connector 110 and the filter 214 may be less likely to come into contact with wound fluids that could prematurely occlude the filter 214 so as to impair the transmission of negative pressure to the wound site.

[0316] Similar to the embodiments of wound dressings described above, some wound dressings comprise a perforated wound contact layer with silicone adhesive on the skin-contact face and acrylic adhesive on the reverse. In some embodiments, the wound contact layer may be constructed from polyurethane, polyethylene or polyester. Above this bordered layer sits a transmission layer. Above the transmission layer, sits an absorbent layer. The absorbent layer can include a superabsorbent non-woven (NW) pad. The absorbent layer can over-border the transmission layer by approximately 5mm at the perimeter. The absorbent layer can have an aperture or through-hole toward one end. The aperture can be about 10 mm in diameter. Over the transmission layer and absorbent layer lies a backing layer. The backing layer can be a high moisture vapor transmission rate (MVTR) film, pattern coated with acrylic adhesive. The high MVTR film and wound contact layer encapsulate the transmission layer and absorbent layer, creating a perimeter border of approximately 20 mm. The backing layer can have a 10 mm aperture that overlies the aperture in the absorbent layer. Above the hole can be bonded a fluidic connector that comprises a liquid-impermeable, gas-permeable semi-permeable membrane (SPM) or filter that overlies the aforementioned apertures.

Multi-Layered Dressing for Use Without Negative Pressure

[0317] Figures 13A-13D illustrates various embodiments of a wound dressing 500 that can be used for healing a wound without negative pressure. Figure 13E illustrates a cross-section of the wound dressing in Figures 13A-13D, which is similar to the structure of Figure 5c. As shown in the dressings of Figures 13A-13E, the wound dressings can have multiple layers similar to the dressings described with reference to Figures 12A-D except the dressings of Figures 13A-E do not include a port or fluidic connector. The wound dressings of Figures 13A-E can include a cover layer 501 and an optional wound contact layer 505 as described herein. In some embodiments, the cover layer 501 may be permeable to moisture and/or air. The wound dressing can include various layers positioned between the wound contact layer 505 and cover layer 501. For example, the dressing can include one or more absorbent layers or one or more transmission layers as described herein with reference to Figures 12A-D.

[0318] As shown in Figures 13A-13E, the dressing 500 includes a perforated wound contact layer 505 and a top film 501. Further components of the wound dressing 500 include a foam layer 504, such as a layer of polyurethane hydrocellular foam, of a suitable size to cover the recommended dimension of wounds corresponding to the particular dressing size chosen. An optional layer of activated charcoal cloth (not shown) of similar or slightly smaller dimensions than layer 504 may be provided to allow for odour control. An absorbent layer 502, such as a layer of superabsorbent air-laid material containing cellulose fibres and a superabsorbent polyacrylate particulates, is provided over layer 504, of dimensions slightly larger than layer 504, and allows allow for an overlap of superabsorbent material and acts as leak prevention. A masking or obscuring layer 503, such as a layer of three-dimensional knitted spacer fabric, is provided over layer 502, providing protection from pressure, while allowing partial masking of the top surface of the superabsorber where coloured exudate would remain. In this embodiment this is of smaller dimension (in plan view) than the layer 502, to allow for visibility of the edge of the absorbent layer, which can be used by clinicians to assess whether the dressing needs to be changed.

[0319] The wound dressing 500 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 500. In some embodiments, the loaded matrix layer

may be provided below the cover layer 501. In some embodiments, the loaded matrix layer may be provided above the wound contact layer 505. In other embodiments, the dressing 500 may not include the wound contact layer 505, such that the loaded matrix layer may be the lowermost layer and be configured to touch the wound surface. In some embodiments, the loaded matrix layer may be provided below the foam layer 504. In some embodiments, the loaded matrix layer may replace the foam layer 504.

[0320] As described previously herein, a loaded matrix, and for example a loaded foam including an antibacterial powder charge/additive-loaded polyurethane (PU) material, may be incorporated into commercially available dressings, such as ALLEVYN™ foam, ALLEVYN™ Life, ALLEVYN™ Adhesive, ALLEVYN™ Gentle Border, ALLEVYN™ Gentle, ALLEVYN™ Ag Gentle Border, ALLEVYN™ Ag Gentle. In some embodiments, the wound dressing 500 may include the cover layer 501 and the loaded foam layer placed below the cover layer 501 and configured to be placed over the wound, similarly with the wound dressing format described previously herein in relation to Figure 5a. The loaded foam layer may include an adhesive such that the foam layer may be attached to healthy skin around the wound. In some embodiments, the wound dressing 500 may include the cover layer 501, the wound contact layer 505 and the loaded foam layer sandwiched therebetween, similarly with the wound dressing format described previously herein relation to Figure 5b. In some embodiments, the wound dressing 500 may include the cover layer 501, the absorbent layer 502, the loaded foam layer below the absorbent layer 502, and the wound contact layer 505, similarly with the wound dressing format described previously herein relation to Figure 5c.

[0321] Further details regarding wound dressings that may be combined with or be used in addition to the embodiments described herein, are found in U.S. Patent No. 9,877,872, issued on January 30, 2018, titled “WOUND DRESSING AND METHOD OF TREATMENT,” the disclosure of which are hereby incorporated by reference in its entirety, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings.

Multilayered Wound Dressing with an Integrated Source of Negative Pressure

[0322] In some embodiments, a source of negative pressure (such as a pump) and some or all other components of the TNP system, such as power source(s), sensor(s), connector(s), user interface component(s) (such as button(s), switch(es), speaker(s), screen(s), etc.) and the like, can be integral with the wound dressing. Additionally, some embodiments related to wound treatment comprising a wound dressing described herein may also be used in combination or in addition to those described in International Application WO 2016/174048 and International Patent Application PCT/EP2017/055225, filed on March 6, 2017, entitled “WOUND TREATMENT APPARATUSES AND METHODS WITH NEGATIVE PRESSURE SOURCE INTEGRATED INTO THE WOUND DRESSING,” the disclosure of which is hereby incorporated by reference in its entirety herein, including further details relating to embodiments of wound dressings, the wound dressing components and principles, and the materials used for the wound dressings and wound dressing components.

[0323] In some embodiments, the pump and/or other electronic components can be configured to be positioned adjacent to or next to the absorbent and/or transmission layers in the wound dressing so that the pump and/or other electronic components are still part of a single apparatus to be applied to a patient with the pump and/or other electronics positioned away from the wound site. Figures 14A-14B illustrates a wound dressing incorporating the source of negative pressure and/or other electronic components within the wound dressing. Figures 14A-14B illustrates a wound dressing 1200 with the pump and/or other electronics positioned away from the wound site. The wound dressing can include an electronics area 1261 and an absorbent area 1260. The dressing can comprise a wound contact layer (not shown) and a moisture vapor permeable film or cover layer 1213 positioned above the contact layer and other layers of the dressing. The wound dressing layers and components of the electronics area as well as the absorbent area can be covered by one continuous cover layer 1213 as shown in Figures 14A-14B.

[0324] The electronics area 1261 can include a source of negative pressure (such as a pump) and some or all other components of the TNP system, such as power source(s), sensor(s), connector(s), user interface component(s) (such as button(s), switch(es), speaker(s), screen(s), etc.) and the like, that can be integral with the wound dressing. For example, the electronics area 1261 can include a button or switch 1211 as shown in Figure

14A-14B. The button or switch 1211 can be used for operating the pump (e.g., turning the pump on/off).

[0325] The absorbent area 1260 can include an absorbent material 1212 and can be positioned over the wound site. The electronics area 1261 can be positioned away from the wound site, such as by being located off to the side from the absorbent area 1260. The electronics area 1261 can be positioned adjacent to and in fluid communication with the absorbent area 1260 as shown in Figures 14A-14B. In some embodiments, each of the electronics area 1261 and absorbent area 1260 may be rectangular in shape and positioned adjacent to one another.

[0326] In some embodiments, additional layers of dressing material can be included in the electronics area 1261, the absorbent area 1260, or both areas. In some embodiments, the dressing can comprise one or more spacer or transmission layers and/or one or more absorbent layers positioned above the contact layer and below the wound cover layer 1213 of the dressing.

[0327] The dressing can comprise a wound contact layer (not shown), a transmission layer (not shown), an absorbent layer 1212 over the transmission layer, a moisture vapor permeable film or cover layer 1213 positioned above the wound contact layer, transmission layer, absorbent layer, or other layers of the dressing. The wound contact layer can be configured to be in contact with the wound. The wound contact layer can include an adhesive on the patient facing side for securing the dressing to the surrounding skin or on the top side for securing the wound contact layer to a cover layer or other layer of the dressing. In operation, the wound contact layer can be configured to provide unidirectional flow so as to facilitate removal of exudate from the wound while blocking or substantially preventing exudate from returning to the wound. The one or more transmission layers assist in distributing negative pressure over the wound site and facilitating transport of wound exudate and fluids into the wound dressing. In some embodiments, the transmission layer can be formed at least partially from a three-dimensional (3D) fabric. Further, an absorbent layer (such as layer 1212) for absorbing and retaining exudate aspirated from the wound can be utilized. In some embodiments, a superabsorbent material can be used in the absorbent layer 1212. In some embodiments, the absorbent includes a shaped form of a superabsorber layer.

The wound dressing layers of the electronics area and the absorbent layer can be covered by one continuous cover layer 1213. In some embodiments, the cover layer can include a moisture vapor permeable material that prevents liquid exudate removed from the wound and other liquids from passing through, while allowing gases through.

[0328] Figure 14C illustrates an embodiment of layers of a wound dressing with the pump and electronic components offset from the absorbent area of the dressing. As illustrated in Figure 14C, the dressing can include a wound contact layer 1310 for placing in contact with the wound. Lower spacer or transmission layers 1311 and 1311' are provided above the wound contact layer 1310. In some embodiments, the transmission layer 1311 can be a separate layer from spacer layer 1311' as shown in Figure 14C. The lower transmission layers 1311 and/or 1311' can assist in distributing pressure evenly to the wound surface and/or wicking fluid away from the wound. An absorbent layer 1322 can be positioned above the lower transmission layer 1311. A dressing layer 1351 can include cutouts or recesses 1328 for embedding the electronic components 1350 within the layer 1351. In some embodiments, the cutouts or recesses 1328 can be sized and shaped to embed a pump 1327, power source 1326, and/or other electronic components. In some embodiments, the layer 1351 can include multiple spacer or transmission layers stacked together. In some embodiments, the layer 1351 can include multiple spacer or transmission layers pieced together to surround the electronic components 1350. An upper transmission layer 1317 can be provided above the absorbent layer 1322, layer 1351, and/or electronic components 1350.

[0329] The wound dressing 1200, 1300 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing. In some embodiments, the loaded matrix layer may be provided below the transmission layer 1311. In some embodiments, the loaded matrix layer may be provided below the wound contact layer 1310. In some embodiments, the loaded matrix layer may replace the transmission layer 1311, 1311' such that the loaded matrix layer is provided between an absorbent layer 1322 and the wound contact layer 1310. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 1212, 1322, or the absorbent layer 1212, 1322 can be loaded with powder charge as described

above. In some embodiments, the loaded matrix layer may be the lowermost layer of the wound dressing. The loaded matrix layer may have same or substantially similar size and shape with the transmission layers and/or the absorbent layers hereinbefore described.

[0330] The loaded matrix layer may be constructed to be flexible but stiff enough to withstand negative pressure, such that the loaded foam is not collapsed excessively and thereby transmits negative pressure sufficiently to the wound when negative pressure is supplied to the wound dressing 1200. The loaded matrix layer may be constructed to include sufficient number or size of pores to enable transmission of negative pressure through it. Further, the loaded matrix layer may have suitable thickness to transmit enough negative pressure to the wound. For example, the loaded matrix layer may have a thickness of 1mm to 5mm, 1.5mm to 4mm, or 2mm to 3mm. In some embodiments, the loaded matrix layer may have a thickness of approximately 2mm.

[0331] A cover layer or backing layer 1313 can be positioned over the upper transmission layer 1317. The backing layer 1313 can form a seal to the wound contact layer 1310 at a perimeter region enclosing the transmission layers 1311, 1311', and 1317, the absorbent layer 1322, layer 1351, and electronic components 1350. In some embodiments, the backing layer 1313 can be a flexible sheet of material that forms and molds around the dressing components when they are applied to the wound. In other embodiments, the backing layer 1313 can be a material that is preformed or premolded to fit around the dressing components as shown in Figure 14C.

Multi-Layered Wound Dressings for NPWT with a Wrapped Around Transmission Layer

[0332] Figure 15A illustrates an embodiment of a TNP wound treatment device comprising a wound dressing. As stated above, the wound dressing 400 can be any wound dressing embodiment disclosed herein or have any combination of features of any number of wound dressing embodiments disclosed herein. For example, the wound dressing 400 may be similar to a PICO single unit dressing available from Smith & Nephew as described previously. The wound dressing 400 and associated system may also be similar to the system described in Figures 12A-12D previously. Embodiments of the wound dressings, wound dressing components, wound treatment apparatuses and methods described herein and with

reference to Figures 15A-15C may also be used in combination or in addition to those described in International Publication No. WO 2017/114745 A1, published July 6, 2017, titled "NEGATIVE PRESSURE WOUND THERAPY APPARATUS," the disclosure of which is hereby incorporated by reference in its entirety.

[0333] The dressing 400 may be placed over a wound, and a port 460 (which together with conduit 401 may form a fluidic connector as described with respect to Figures 12A-12D) may be used to provide negative pressure from a vacuum source to the wound. In the embodiment shown in Figure 12A the dressing 400 may be provided with at least a portion of the conduit 401 pre-attached to the port 460. For example, the port/conduit combination may be a flexible suction adapter as described herein with reference to Figures 12A-12D. In some embodiments, the pre-attached conduit 401 can connect to a conduit extension, for example, a tubing (not shown). Preferably, the dressing 400 is provided as a single article with all wound dressing elements (including the port 460 and conduit 401) pre-attached and integrated into a single unit. The wound dressing 400 may then be connected, via the conduit 401 and/or conduit extension, to a source of negative pressure such as the pump as described with reference to Figures 12A-12D.

[0334] The cover layer 430, 320, which can be more clearly seen in Figure 15B-15C, can be formed of substantially fluid impermeable material, such as film. The cover layer 430, 320 can be similar to the cover layer or backing layer described in Figures 12A-12D previously. The film may be transparent, such that from the top view of Figure 15A, other layers underneath the cover layer are also visible. The cover layer can include an adhesive for securing the dressing to the surrounding skin or a wound contact layer. The dressing can utilize a wound contact layer 440, 322 and an absorbent layer 450, 321 within the dressing. The wound contact layer and the absorbent layer can be similar to the wound contact layer and absorbent layers described in Figures 12A-12D previously. The wound contact layer can be configured to be in contact with the wound. The wound contact layer can include an adhesive on the patient facing side for securing the dressing to the surround skin or on the top side for securing the wound contact layer 440, 322 to a cover layer 430, 320 or other layer of the dressing. In operation, in some embodiments the wound contact layer can be configured to provide unidirectional flow so as to facilitate removal of exudate

from the wound while blocking or substantially preventing exudate from returning to the wound. Further, an absorbent layer (such as layer 450, 321) for absorbing and retaining exudate aspirated from the wound can be utilized. In some embodiments, the absorbent layer can include an absorbent material, for example, a superabsorbent material or other absorbent material known in the art. In some embodiments, the absorbent layer can include a shaped form of a superabsorber layer with recesses or compartments for the pump, electronics, and accompanying components. In some embodiments, the wound dressing can include multiple absorbent layers.

[0335] The absorbent material 450 as shown in Figure 15A which may be a foam or non-woven natural or synthetic material and which may optionally include or be super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site and draws those fluids towards a cover layer 430. The material of the absorbent layer can be similar to the absorbent material described with reference to Figures 12A-12D. The material of the absorbent layer also prevents liquid collected in the wound dressing from flowing in a sloshing manner. The absorbent layer 450 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer.

[0336] In some embodiments, the absorbent layer 450 is a layer of non-woven cellulose fibers having super-absorbent material in the form of dry particles dispersed throughout. Use of the cellulose fibers introduces fast wicking elements which help quickly and evenly distribute liquid taken up by the dressing. The juxtaposition of multiple strand-like fibers leads to strong capillary action in the fibrous pad which helps distribute liquid. In this way, the super-absorbent material is efficiently supplied with liquid. Also, all regions of the absorbent layer are provided with liquid.

[0337] The wicking action also assists in bringing liquid into contact with the upper cover layer to aid increase transpiration rates of the dressing.

[0338] The wicking action also assists in delivering liquid downwards towards the wound bed when exudation slows or halts. This delivery process helps maintain the transmission layer or lower spacer layer and lower wound bed region in a moist state which

helps prevent crusting within the dressing (which could lead to blockage) and helps maintain an environment optimized for wound healing.

[0339] In some embodiments, the absorbent layer 450 may be an air-laid material. Heat fusible fibers may optionally be used to assist in holding the structure of the pad together. It will be appreciated that rather than using super-absorbing particles or in addition to such use, super-absorbing fibers may be utilized according to certain embodiments of the present invention. An example of a suitable material is the Product Chem-Posite™ 11 C available from Emerging Technologies Inc (ETi) in the USA.

[0340] Optionally, according to certain embodiments of the present invention, the absorbent layer 450 may include synthetic stable fibers and/or bi-component stable fibers and/or natural stable fibers and/or super-absorbent fibers. Fibers in the absorbent layer may be secured together by latex bonding or thermal bonding or hydrogen bonding or a combination of any bonding technique or other securing mechanism. In some embodiments, the absorbent layer is formed by fibers which operate to lock super-absorbent particles within the absorbent layer. This helps ensure that super-absorbent particles do not move external to the absorbent layer and towards an underlying wound bed. This is particularly helpful because when negative pressure is applied there is a tendency for the absorbent pad to collapse downwards and this action would push super-absorbent particle matter into a direction towards the wound bed if they were not locked away by the fibrous structure of the absorbent layer.

[0341] The absorbent layer 450 may comprise a layer of multiple fibers. Preferably, the fibers are strand-like and made from cellulose, polyester, viscose or the like. Preferably, dry absorbent particles are distributed throughout the absorbent layer ready for use. In some embodiments, the absorbent layer comprises a pad of cellulose fibers and a plurality of super absorbent particles. In additional embodiments, the absorbent layer is a non-woven layer of randomly orientated cellulose fibers.

[0342] Super-absorber particles/fibers may be, for example, sodium polyacrylate or carbomethoxycellulose materials or the like or any material capable of absorbing many times its own weight in liquid. In some embodiments, the material can absorb more than five times its own weight of 0.9% W/W saline, etc. In some embodiments, the material can absorb more than 15 times its own weight of 0.9% W/W saline, etc. In some embodiments, the

material is capable of absorbing more than 20 times its own weight of 0.9% W/W saline, etc. Preferably, the material is capable of absorbing more than 30 times its own weight of 0.9% W/W saline, etc.

[0343] Preferably, the particles of superabsorber are very hydrophilic and grab the fluid as it enters the dressing, swelling up on contact. An equilibrium is set up within the dressing core whereby moisture passes from the superabsorber into the dryer surrounding area and as it hits the top film the film switches and the fluid vapor starts to be transpired. A moisture gradient is established within the dressing to continually remove fluid from the wound bed and ensure the dressing does not become heavy with exudate.

[0344] The absorbent layer 450 can include at least one through hole. The through hole can be located so as to underlie the suction port as described with reference to Figure 12D. A single through hole can be used to produce an opening underlying the port 460 (not shown in Figure 15B). It will be appreciated that multiple openings could alternatively be utilized. Additionally, should more than one port be utilized according to certain embodiments of the present invention one or multiple openings may be made in the super-absorbent layer in registration with each respective port. Although not essential to certain embodiments of the present invention the use of through holes in the super-absorbent layer provide a fluid flow pathway which is particularly unhindered and this is useful in certain circumstances.

[0345] Use of one or more through holes in the absorption layer 450 also has the advantage that during use if the absorbent layer contains a gel forming material, such as superabsorber, that material as it expands to absorb liquid, does not form a barrier through which further liquid movement and fluid movement in general cannot pass. In this way each opening in the absorbent layer provides a fluid pathway between the lower transmission or spacer layer and the upper transmission or spacer layer to the wound facing surface of the filter and then onwards into the interior of the port.

[0346] These layers can be covered with one layer of a film or cover layer 430. The cover layer can include a filter that can be positioned over the absorbent layer, or a filter may be incorporated in the port 460 as described in International Application Publication No. WO 2013/175306 A2, U.S. Publication No. US2011/0282309, and U.S. Publication No.

2016/0339158 the entirety of which is hereby incorporated by reference. As shown in Figure 7A gas impermeable, but moisture vapor permeable, cover layer 430 extends across the width of the wound dressing. The cover layer may be similar to the cover layer or backing layer described with reference to Figure 12A-12D. The cover layer 430, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way an effective chamber is made between the cover layer and a wound site where a negative pressure can be established. The cover layer 430 is sealed to the wound contact layer 440 in a border region 410 around the circumference of the dressing, ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The cover layer 430 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The cover layer 430 typically comprises two layers: a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet.

[0347] The cover layer can include an aperture within the cover layer for providing fluid communication with a source of negative pressure or pump. The filter can be positioned in communication with the aperture in the wound cover 430. The aperture in the wound cover 430 can be covered by a port 460. In some embodiments, the port 460 connects to a conduit for communication with a negative pressure source or pump. The port 460 can include a filter 420 provided to cover the aperture in the cover layer 430. In some embodiments, the filter 420 can be integral to the port 460. The filter 420 can include hydrophobic material to protect the pump and/or other components from liquid exudates. The filter 420 can block fluids while permitting gases to pass through. In some embodiments, the filter can be similar to the filter or filter system described in Figures 12A-12D previously. In some embodiments, the aperture in the cover layer 430 and the port 460 provide fluid communication between the wound dressing and a pump. In some embodiments, the pump, electronics, switch and battery can be positioned at a remote location from the dressing. In some embodiments, the pump, electronics, switch and battery can be positioned on top of the

first cover layer and a second filter and second cover layer can be alternative or additionally used. For example, the second filter can be constructed from antibacterial and/or antimicrobial materials so that the pump can exhaust gases into the atmosphere. The second filter can also help to reduce noise produced by the pump.

[0348] Negative pressure can be lost at the wound bed when free absorbent capacity remains in the dressing. This can occur because some or all of the pores in the filter are blocked with liquid or particulates. In some embodiments, solutions are utilized to allow the full capacity of the dressing absorbent layer to be utilized whilst maintaining the air path between the source of negative pressure and the wound bed.

[0349] In dressing embodiments that utilize a cover layer directly over the absorbent layer the dressing can have a void underneath the filter which can fill with liquid, thus blocking the filter pores and preventing air flow to the wound bed. A spacer layer or transmission layer 490 can be used to provide a fluid flow path above the absorbent layer 450 preventing the blocking of the port 460. In some embodiments, the transmission layer 490 in the dressing can be provided above and below the absorbent layer. The transmission layer can be incompressible and maintain a path for fluid flow between the source of negative pressure and the wound bed, via the filter. In some embodiments, the transmission layer can encapsulate or wrap around the absorbent layer as shown in Figure 15A and 15B. The wrapped transmission layer can provide an uninterrupted length of transmission material from the filter 420 to the wound bed. The transmission layer can traverse the length of the top surface of the absorbent layer and wrap around at least one side of the absorbent layer and traverse the length of the bottom surface (wound facing surface) of the absorbent layer. In some embodiments, the transmission layer can wrap around two sides of the absorbent layer as shown in Figure 15A.

[0350] In some embodiments, the transmission layer can be utilized to assist in distributing negative pressure over the wound site and facilitating transport of wound exudate and fluids into the wound dressing.

[0351] A lower portion of the transmission layer 490 of porous material can be located above the wound contact layer and below the absorbent layer and wrapped around the edges of the absorbent layer. As the transmission layer is wrapped around at least one edge of

the absorbent layer, the transmission layer has an upper portion of the transmission layer that can be positioned between the cover layer and the absorbent layer. As used herein the edge of the absorbent layer or the dressing refers to the sides of the material that are substantially perpendicular to the wound surface and run along the height of the material.

[0352] In some embodiments, the transmission layer can be a porous layer. This spacer layer, or transmission layer 490 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing as described with reference to Figure 12D. In particular, the transmission layer 490 ensures that an open-air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer should remain open under the typical pressures that will be applied during negative pressure wound therapy as described previously, so that the whole wound site sees an equalized negative pressure. The transmission layer 490 may be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used. Other materials, such as those described previously herein, could of course be utilized.

[0353] The wound dressing 400 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 400. In some embodiments, the loaded matrix layer may be provided below the transmission layer 490. In some embodiments, the loaded matrix layer may be provided above the wound contact layer 440. In some embodiments, the loaded matrix layer may replace all or part of the transmission layer 490, for example such that the loaded matrix layer wraps around the edges of the absorbent layer 450 (described further below) and the wound contact layer 440. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 450, or the absorbent layer 450 can be loaded with powder charge as described above.

[0354] The loaded matrix layer may be constructed to be flexible but stiff enough to withstand negative pressure, such that the loaded matrix is not collapsed excessively and thereby transmits negative pressure sufficiently to the wound when negative pressure is

supplied to the wound dressing 400. The loaded matrix layer may be constructed to include sufficient number or size of pores to enable transmission of negative pressure through it. Further, the loaded matrix layer may have suitable thickness to transmit enough negative pressure to the wound. For example, the loaded foam layer may have a thickness of 1mm to 5mm, 1.5mm to 4mm, or 2mm to 3mm. In some embodiments, the loaded matrix layer may have a thickness of approximately 2mm.

[0355] Providing the transmission layer between the port and the absorbent layer prevents fluid or exudate removed from the wound from blocking the port and/or filter within the port. There can be some free particles in the hole of the absorbent layer positioned below the filter. The loose free particles in the hole can gel and block the hole and/or filter area. Therefore, the upper transmission layer can keep the superabsorber particles clear from the filter and allow the dressing to fill completely. In some embodiments, the transmission layer wrapped around the absorbent layer allow the port to be located at any location with respect to gravity. The transmission layer positioned above the absorbent layer can eliminate the concerns of the fluid or exudate removed from the wound from blocking the port and/or filter within the port on the section of the absorbent layer that is filled first.

[0356] As shown in Figure 15C, a wound dressing 300 can include a wound contact layer 322. The wound contact layer 322 can be similar to the wound contact layer 225 described with reference to Figure 12D. In some embodiments, the wound contact layer 322 can be a double-face coated (silicone-acrylic) perforated adhesive wound contact layer. A transmission layer 326a and absorbent layer 321 can be provided similar to the dressing described with reference to Figure 12D but the transmission layer 326a over-borders the absorbent layer. The wound dressing 300 can include a second transmission layer 326b between the absorbent layer and the backing layer that over-borders the absorbent layer. The first and second transmission layers 326a and 326b can over-border the absorbent layer by 5 mm at the perimeter. This can be the reverse of the cut geometry in the dressings as described previously. In some embodiments, there is no through-hole or aperture in the absorbent layer 321 or second transmission layer 326b. In some embodiments, the hole in the absorbent layer could be disadvantageous because it could become filled with superabsorbent particles or other material and block the filter in the standard dressing. A backing layer 320 sits over the

second transmission layer 326b and the backing layer can include an orifice 327 that allows connection of the fluidic connector to communicate negative pressure to the dressing. In some embodiments, the first and second transmission layer 326a, 326b can include a 3D fabric.

[0357] The wound dressing 300 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 300. In some embodiments, the loaded matrix layer may be provided below the first transmission layer 326a. In some embodiments, the loaded matrix layer may be provided above the wound contact layer 322. In some embodiments, the loaded matrix layer may replace the first transmission layer 326a. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 321, or the absorbent layer 321 can be loaded with powder charge as described above.

[0358] The loaded matrix layer may be constructed to be flexible but stiff enough to withstand negative pressure, such that the loaded matrix is not collapsed excessively and thereby transmits negative pressure sufficiently to the wound when negative pressure is supplied to the wound dressing 300. The loaded matrix layer may be constructed to include sufficient number or size of pores to enable transmission of negative pressure through it. Further, the loaded matrix layer may have suitable thickness to transmit enough negative pressure to the wound. For example, the loaded matrix layer may have a thickness of 1mm to 5mm, 1.5mm to 4mm, or 2mm to 3mm. In some embodiments, the loaded matrix layer may have a thickness of approximately 2mm.

Multi-Layered Wound Dressings for NPWT with an Obscuring Layer

[0359] Figure 16A illustrates a cross-section through a wound dressing 2100 similar to the wound dressing of Figures 12A-12D according to an embodiment of the disclosure. The wound dressing 2100, which can alternatively be any wound dressing embodiment disclosed herein including without limitation wound dressing 110 or any combination of features of any number of wound dressing embodiments disclosed herein, can be located over a wound site to be treated. The dressing 2100 may be placed to as to form a

sealed cavity over the wound site. In a preferred embodiment, the dressing 2100 comprises a backing layer 2140 attached to a wound contact layer 2102, similar to the cover layer and wound contact layer described with reference to Figures 12A-12D. These two layers 2140, 2102 are preferably joined or sealed together so as to define an interior space or chamber. This interior space or chamber may comprise additional structures that may be adapted to distribute or transmit negative pressure, store wound exudate and other fluids removed from the wound, and other functions as described herein. Examples of such structures, described below, include a transmission layer 2105 and an absorbent layer 2110, similar to the transmission layer and absorbent layer described with reference to Figures 12A-12D.

[0360] A layer 2105 of porous material can be located above the wound contact layer 2102. This porous layer, or transmission layer, 2105 allows transmission of fluid including liquid and gas away from a wound site into upper layers of the wound dressing. In particular, the transmission layer 2105 preferably ensures that an open-air channel can be maintained to communicate negative pressure over the wound area even when the absorbent layer has absorbed substantial amounts of exudates. The layer 2105 should preferably remain open under the typical pressures that will be applied during negative pressure wound therapy as described above, so that the whole wound site sees an equalized negative pressure.

[0361] In some embodiments, the layer 2105 may be formed of a material having a three-dimensional structure. For example, a knitted or woven spacer fabric (for example Baltex 7970 weft knitted polyester) or a non-woven fabric could be used.

[0362] A layer 2110 of absorbent material is provided above the transmission layer 2105. The absorbent material, which comprise a foam or non-woven natural or synthetic material, and which may optionally comprise a super-absorbent material, forms a reservoir for fluid, particularly liquid, removed from the wound site. In some embodiments, the layer 2100 may also aid in drawing fluids towards the backing layer 2140.

[0363] With reference to Figure 16A, a masking or obscuring layer 2107 can be positioned beneath at least a portion of the backing layer 2140. In some embodiments, the obscuring layer 2107 can have any of the same features, materials, or other details of any of the other embodiments of the obscuring layers disclosed herein, including but not limited to having any viewing windows or holes. Examples of wound dressings with obscuring layers

and viewing windows are described in International Patent Publication WO2014/020440, the entirety of which is incorporated by reference in its entirety. Additionally, the obscuring layer 2107 can be positioned adjacent to the backing layer, or can be positioned adjacent to any other dressing layer desired. In some embodiments, the obscuring layer 2107 can be adhered to or integrally formed with the backing layer. Preferably, the obscuring layer 2107 is configured to have approximately the same size and shape as the absorbent layer 2110 so as to overlay it. As such, in these embodiments the obscuring layer 2107 will be of a smaller area than the backing layer 2140.

[0364] The material of the absorbent layer 2110 may also prevent liquid collected in the wound dressing 2100 from flowing freely within the dressing, and preferably acts so as to contain any liquid collected within the absorbent layer 2110. The absorbent layer 2110 also helps distribute fluid throughout the layer via a wicking action so that fluid is drawn from the wound site and stored throughout the absorbent layer. This helps prevent agglomeration in areas of the absorbent layer. The capacity of the absorbent material must be sufficient to manage the exudates flow rate of a wound when negative pressure is applied. Since in use the absorbent layer experiences negative pressures the material of the absorbent layer is chosen to absorb liquid under such circumstances. A number of materials exist that are able to absorb liquid when under negative pressure, for example superabsorber material. The absorbent layer 2110 may typically be manufactured from ALLEVYN™ foam, Freudenberg 114-224-4 and/or Chem-Posite™11C-450. In some embodiments, the absorbent layer 2110 may comprise a composite comprising superabsorbent powder, fibrous material such as cellulose, and bonding fibers. In a preferred embodiment, the composite is an air-laid, thermally-bonded composite.

[0365] An orifice 2144 is preferably provided in the backing layer 2140 to allow a negative pressure to be applied to the dressing 2100. A suction port 2150 is preferably attached or sealed to the top of the backing layer 2140 over an orifice 2144 made into the dressing 2100, and communicates negative pressure through the orifice 2144. A length of tubing may be coupled at a first end to the suction port 2150 and at a second end to a pump unit (not shown) to allow fluids to be pumped out of the dressing. The port may be adhered and sealed to the backing layer 2140 using an adhesive such as an acrylic, cyanoacrylate, epoxy, UV curable or hot melt adhesive. The port 2150 is formed from a soft polymer, for

example a polyethylene, a polyvinyl chloride, a silicone or polyurethane having a hardness of 30 to 90 on the Shore A scale. In some embodiments, the port 2150 may be made from a soft or conformable material.

[0366] Preferably the absorbent layer 2110 and the obscuring layer 2107 include at least one through hole 2145 located so as to underlie the port 2150. Of course, the respective holes through these various layers 2107, 2140, and 2110 may be of different sizes with respect to each other. As illustrated in Figure 16A a single through hole can be used to produce an opening underlying the port 2150. It will be appreciated that multiple openings could alternatively be utilized. Additionally, should more than one port be utilized according to certain embodiments of the present disclosure one or multiple openings may be made in the absorbent layer and the obscuring layer in registration with each respective port. Although not essential to certain embodiments of the present disclosure the use of through holes in the super-absorbent layer may provide a fluid flow pathway which remains unblocked in particular when the absorbent layer 2110 is near saturation.

[0367] The aperture or through-hole 2144 is preferably provided in the absorbent layer 2110 and the obscuring layer 2107 beneath the orifice 2144 such that the orifice is connected directly to the transmission layer 2105. This allows the negative pressure applied to the port 2150 to be communicated to the transmission layer 2105 without passing through the absorbent layer 2110. This ensures that the negative pressure applied to the wound site is not inhibited by the absorbent layer as it absorbs wound exudates. In other embodiments, no aperture may be provided in the absorbent layer 2110 and/or the obscuring layer 2107, or alternatively a plurality of apertures underlying the orifice 2144 may be provided.

[0368] The backing layer 2140 is preferably gas impermeable, but moisture vapor permeable, and can extend across the width of the wound dressing 2100. The backing layer 2140, which may for example be a polyurethane film (for example, Elastollan SP9109) having a pressure sensitive adhesive on one side, is impermeable to gas and this layer thus operates to cover the wound and to seal a wound cavity over which the wound dressing is placed. In this way an effective chamber is made between the backing layer 2140 and a wound site where a negative pressure can be established. The backing layer 2140 is preferably sealed to the wound contact layer 2102 in a border region 2200 around the circumference of the dressing,

ensuring that no air is drawn in through the border area, for example via adhesive or welding techniques. The backing layer 2140 protects the wound from external bacterial contamination (bacterial barrier) and allows liquid from wound exudates to be transferred through the layer and evaporated from the film outer surface. The backing layer 2140 preferably comprises two layers; a polyurethane film and an adhesive pattern spread onto the film. The polyurethane film is preferably moisture vapor permeable and may be manufactured from a material that has an increased water transmission rate when wet.

[0369] In some embodiments, the absorbent layer 2110 may be of a greater area than the transmission layer 2105, such that the absorbent layer overlaps the edges of the transmission layer 2105, thereby ensuring that the transmission layer does not contact the backing layer 2140. This provides an outer channel 2115 of the absorbent layer 2110 that is in direct contact with the wound contact layer 2102, which aids more rapid absorption of exudates to the absorbent layer. Furthermore, this outer channel 2115 ensures that no liquid is able to pool around the circumference of the wound cavity, which may otherwise seep through the seal around the perimeter of the dressing leading to the formation of leaks.

[0370] The wound dressings 2100 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 2100. In some embodiments, the loaded matrix layer may be provided below the transmission layer 2105. In some embodiments, the loaded matrix layer may be provided above the wound contact layer 2102. In some embodiments, the loaded matrix layer may replace the transmission layer 2105, such that the loaded matrix layer is provided between an absorbent layer 2110 (described further below) and the wound contact layer 2102. In some embodiments, the loaded matrix layer may be the lowermost layer of the wound dressing 2100. The loaded matrix may have same or substantially similar size and shape with the transmission layer 2105 and/or the absorbent layer 2110. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 2110, or the absorbent layer 2110 can be loaded with powder charge as described above.

[0371] The loaded matrix layer may be constructed to be flexible but stiff enough to withstand negative pressure, such that the loaded matrix is not collapsed excessively and

thereby transmits negative pressure sufficiently to the wound when negative pressure is supplied to the wound dressing 2100. The loaded matrix layer may be constructed to include sufficient number or size of pores to enable transmission of negative pressure through it. Further, the loaded matrix layer may have suitable thickness to transmit enough negative pressure to the wound. For example, the loaded matrix layer may have a thickness of 1mm to 5mm, 1.5mm to 4mm, or 2mm to 3mm. In some embodiments, the loaded matrix layer may have a thickness of approximately 2mm. [0386] Figure 16B illustrates a view of an embodiment of a wound dressing with a waisted portion, an obscuring layer, and viewing windows. Figure 16B illustrates a perspective view of an embodiment of a wound dressing 1400. The wound dressing 1400 preferably comprises a port 1406. The port 1406 is preferably configured to be in fluid communication with a pump, and may include a tube or conduit pre-attached to the port. Alternatively, negative pressure can be supplied to the wound dressing through other suitable fluidic connectors, including but not limited to the fluidic connectors of the type described below in Figures 12A-12D.

[0372] The wound dressing 1400 can be constructed similar to the embodiments of Figure 16A above, and may comprise an absorbent material 1402 underneath or within a backing layer 1405. Optionally, a wound contact layer and a transmission layer may also be provided as part of the wound dressing 1400 as described above with reference to Figure 16A. The absorbent material 1402 can contain a narrowed central or waisted portion 1408 to increase flexibility and conformability of the wound dressing to the skin surface. The backing layer 1405 may have a border region 1401 that extends beyond the periphery of the absorbent material 1402. The backing layer 1405 may be a translucent or transparent backing layer, such that the border region 1401 created from the backing layer 1405 can be translucent or transparent. The area of the border region 1401 of the backing layer 405 can be approximately equal around the perimeter of the entire dressing with the exception of the narrowed central portion, where the area of the border region is larger. One will recognize that the size of the border region 1401 will depend on the full dimensions of the dressing and any other design choices.

[0373] As illustrated in Figure 16B, provided at least at the top of or over the absorbent layer 1402 and under the backing layer 1405 may be an obscuring layer 1404 that

optionally has one or more viewing windows 1403. The obscuring layer 1404 may partially or completely obscure contents (such as fluids) contained within the wound dressing 1400 and/or the absorbent material (i.e., within the absorbent material 1402 or under the backing layer 1405). The obscuring layer may be a colored portion of the absorbent material, or may be a separate layer that covers the absorbent material. In some embodiments, the absorbent material 1402 may be hidden (partially or completely), colored, or tinted, via the obscuring layer 1404, so as to provide cosmetic and/or aesthetic enhancements, in a similar manner to what is described above. The obscuring layer is preferably provided between the topmost backing layer 1405 and the absorbent material 1402, although other configurations are possible. The cross-sectional view in Figure 16A illustrates this arrangement with respect to the masking or obscuring layer 2107. Other layers and other wound dressing components can be incorporated into the dressing as herein described.

[0374] The obscuring layer 1404 can be positioned at least partially over the absorbent material 1402. In some embodiments, the obscuring layer 1404 can be positioned adjacent to the backing layer, or can be positioned adjacent to any other dressing layer desired. In some embodiments, the obscuring layer 1404 can be adhered to or integrally formed with the backing layer and/or the absorbent material.

[0375] As illustrated in Figure 16B, the obscuring layer 1404 can have substantially the same perimeter shape and size as the absorbent material 1402. The obscuring layer 1404 and absorbent material 1402 can be of equal size so that the entirety of the absorbent material 1402 can be obscured by the obscuring layer 1404. The obscuring layer 1404 may allow for obscuring of wound exudate, blood, or other matter released from a wound. Further, the obscuring layer 1404 can be completely or partially opaque having cut-out viewing windows or perforations.

[0376] In some embodiments, the obscuring layer 1404 can help to reduce the unsightly appearance of a dressing during use, by using materials that impart partial obscuring or masking of the dressing surface. The obscuring layer 1404 in one embodiment only partially obscures the dressing, to allow clinicians to access the information they require by observing the spread of exudate across the dressing surface. The partial masking nature of this embodiment of the obscuring layer enables a skilled clinician to perceive a different color

caused by exudate, blood, by-products etc. in the dressing allowing for a visual assessment and monitoring of the extent of spread across the dressing. However, since the change in color of the dressing from its clean state to a state containing exudate is only a slight change, the patient is unlikely to notice any aesthetic difference. Reducing or eliminating a visual indicator of wound exudate from a patient's wound is likely to have a positive effect on their health, reducing stress for example.

[0377] In some embodiments, the obscuring layer can be formed from a non-woven fabric (for example, polypropylene), and may be thermally bonded using a diamond pattern with 19% bond area. In various embodiments, the obscuring layer can be hydrophobic or hydrophilic. Depending on the application, in some embodiments, a hydrophilic obscuring layer may provide added moisture vapor permeability. In some embodiments, however, hydrophobic obscuring layers may still provide sufficient moisture vapor permeability (i.e., through appropriate material selection, thickness of the obscuring layer), while also permitting better retention of dye or color in the obscuring layer. As such, dye or color may be trapped beneath the obscuring layer. In some embodiments, this may permit the obscuring layer to be colored in lighter colors or in white. In the preferred embodiment, the obscuring layer is hydrophobic. In some embodiments, the obscuring layer material can be sterilizable using ethylene oxide. Other embodiments may be sterilized using gamma irradiation, an electron beam, steam or other alternative sterilization methods. Additionally, in various embodiments the obscuring layer can be colored or pigmented, e.g., in medical blue. The obscuring layer may also be constructed from multiple layers, including a colored layer laminated or fused to a stronger uncolored layer. Preferably, the obscuring layer is odorless and exhibits minimal shedding of fibers.

[0378] The absorbent layer 1402, itself may be colored or tinted in some embodiments, however, so that an obscuring layer is not necessary. The dressing may optionally include a means of partially obscuring the top surface. This could also be achieved using a textile (knitted, woven, or non-woven) layer without openings, provided it still enables fluid evaporation from the absorbent structure. It could also be achieved by printing an obscuring pattern on the top film, or on the top surface of the uppermost pad component, using an appropriate ink or colored pad component (yarn, thread, coating) respectively.

Another way of achieving this would be to have a completely opaque top surface, which could be temporarily opened by the clinician for inspection of the dressing state (for example through a window), and closed again without compromising the environment of the wound. Additionally, Figure 16B illustrates an embodiment of the wound dressing including one or more viewing windows 1403. The one or more viewing windows 1403 preferably extend through the obscuring layer 1404. These viewing windows 1403 may allow visualization by a clinician or patient of the wound exudate in the absorbent material below the obscuring layer. Figure 16B illustrates an array of dots (e.g., in one or more parallel rows) that can serve as viewing windows 1403 in the obscuring layer 1404 of the wound dressing. In a preferred embodiment, two or more viewing windows 1403 may be parallel with one or more sides of the dressing 1400. In some embodiments, the one or more viewing windows may measure between 0.1 mm and 20 mm, preferably 0.4 mm to 10 mm, and even more preferably, 1 mm to 4 mm. The viewing windows 1403 may be cut through the obscuring layer 1404 or may be part of an uncolored area of the obscuring layer 1404 and therefore may allow visualization of the absorbent material 1402. The one or more viewing windows 1403 can be arranged in a repeating pattern across the obscuring layer 1404 or can be arranged at random across the obscuring layer. Additionally, the one or more viewing windows can be a circular shape or dots. Preferably, the one or more viewing windows 1403 are configured so as to permit not only the degree of saturation, but also the progression or spread of fluid toward the fluid port 1406, as in some embodiments, dressing performance may be adversely affected when the level of fluid has saturated the fluid proximate the port 1406. In some embodiments, a “starburst” array of viewing windows 1403 emanating around the port 1406 may be suitable to show this progression, although of course other configurations are possible. In some embodiments, the viewing windows 1403 correspond to the area of the absorbent material 1402 that is not covered by the obscuring layer 1404. As such, the absorbent material 1402 is directly adjacent the backing layer 1405 in this area. Since the obscuring layer 1404 acts as a partial obscuring layer, the viewing windows 1403 may be used by a clinician or other trained user to assess the spread of wound exudate throughout the dressing. In some embodiments, the viewing windows 1403 can comprise an array of dots or crescent shaped cut-outs. For example, an array of dots as viewing windows 1403 are illustrated in Figure 16B in which the

array of dots are arranged in an 5×2 array. Additionally, in some embodiments, the dot pattern can be distributed evenly throughout the obscuring layer and across the entire or substantially the entire surface of the obscuring layer. In some embodiments, the viewing windows 1403 may be distributed randomly throughout the obscuring layer. Preferably, the area of the obscuring layer 1404 uncovered by the one or more viewing windows 1403 is balanced to as to minimize the appearance of exudate while permitting the inspection of the dressing 1400 and/or absorbent material 1402. In some embodiments, the area exposed by the one or more viewing windows 1403 does not exceed 20% of the area of the obscuring layer 1404, preferably 10%, and even more preferably 5%.

[0379] The viewing windows 1403 may take several configurations. In some embodiments, the viewing windows 1403 may comprise an array of regularly spaced uncolored dots (holes) made into the obscuring layer 1404. While the dots illustrated here are in a particular pattern, the dots may be arranged in different configurations, or at random. The viewing windows 1403 are preferably configured so as to permit a patient or caregiver to ascertain the status of the absorbent layer, in particular to determine its saturation level, as well as the color of the exudate (e.g., whether excessive blood is present). By having one or more viewing windows, the status of the absorbent layer can be determined in an unobtrusive manner that is not aesthetically displeasing to a patient. Because a large portion of the absorbent layer may be obscured, the total amount of exudate may therefore be hidden. As such, the status and saturation level of the absorbent layer 1402 may therefore present a more discreet external appearance so as to reduce patient embarrassment and visibility and thereby enhance patient comfort. In some configurations, the one or more viewing windows 1403 may be used to provide a numerical assessment of the degree of saturation of the dressing 1400. This may be done electronically (e.g., via a digital photograph assessment), or manually. For example, the degree of saturation may be monitored by counting the number of viewing windows 1403 which may be obscured or tinted by exudate or other wound fluids.

[0380] In some embodiments, the absorbent layer 1402 or the obscuring layer 1404, in particular the colored portion of the absorbent layer, may comprise (or be colored because of) the presence of an auxiliary compound. The auxiliary compound may in some embodiments be activated charcoal, which can act to absorb odors. The use of antimicrobial,

antifungal, anti-inflammatory, and other such therapeutic compounds is also possible. In some embodiments, the color may change as a function of time (e.g., to indicate when the dressing needs to be changed), if the dressing is saturated, or if the dressing has absorbed a certain amount of a harmful substance (e.g., to indicate the presence of infectious agents). In some embodiments, the one or more viewing windows 1403 may be monitored electronically, and may be used in conjunction with a computer program or system to alert a patient or physician to the saturation level of the dressing 1400.

Multi-Layered Wound Dressing with a Support Layer

[0381] Figure 17 shows an example of a multi-layer wound dressing 3100. The wound dressing 3100 includes a liquid impermeable film layer 3102 located at the top of the wound dressing 3100. In use, the film layer 3102 is the top layer of the wound dressing 3100, most distal from a wound site. The film layer 3102 is also gas and vapour permeable to allow for evaporation of fluid or wound exudate from the wound dressing 3100, and help prevent maceration of the wound. In this example, the film layer 3102 is formed from a polyurethane blend, though other suitable materials may include other polymeric materials, for example polyethylene, or polypropylene.

[0382] An absorbent layer 3108 underlies the film layer 3102. The absorbent layer 3108 has a fibrous structure for absorbing exudate from a wound site. In this example, the absorbent layer 3108 includes superabsorbent fibres. The absorbent layer 3108 also includes other fibres. In this example, the absorbent layer includes superabsorbent fibres, viscose fibres and polyester fibres. In this example, the absorbent layer 3108 includes around 40% superabsorbent fibres, 40% viscose fibres, and 20% polyester fibres. In other examples, the absorbent layer may include around 0-50% superabsorbent fibres, 0-100% viscose fibres and 0-50% polyester fibres. Suitable superabsorbent fibres include crosslinked acrylate copolymer fibres that are partially neutralized to sodium salt however other superabsorbent fibres are available. The absorbent layer 3108 may be manufactured using a needling process in which the fibres are mechanically tangled together. In other examples, the absorbent layer 3108 may include other ratios of superabsorbent, viscose and polyester fibres. For example, the absorbent layer may include around 50% superabsorbent fibres, 35% viscose fibres and 20%

polyester fibres. Alternatively, the absorbent layer may include 40% superabsorbent fibres and 60% viscose fibres. The film layer 3102 is located over the absorbent layer 3108 so that wound exudate collected in the absorbent layer 3108 can evaporate out of the wound dressing 3100 through the film layer 3102.

[0383] A support layer 3106 is located between the film layer 3102 and the absorbent layer 3108. The support layer 3106 helps to reinforce the structure of the absorbent layer 3108 and thereby reduce shrinkage of the wound dressing 3100. The support layer 3102 also helps to provide extra mechanical strength to the film layer 3102 to reduce or prevent wrinkling of the film layer 3102 over time. The mechanical strength also reduces the chance of the dressing deforming or rolling up causing a pressure point. Aptly, the support layer 3106 is configured to have a tensile strength from 0.05 to 0.06 Nm to provide mechanical strength to the surrounding layers (e.g. the film layer 3102 and the absorbent layer 3108) without compromising the flexibility of the wound dressing 3100. The support layer 3106 may have a thickness of from 50 to 150 μm . Aptly, the support layer 3106 may have a thickness of around 100 to 110 μm .

[0384] The wound dressing 3100 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 3100. In some embodiments, the loaded matrix layer may be provided below the cover layer 3102. In some embodiments, the loaded matrix layer may be provided below the absorbent layer 3108. In some embodiments, the loaded matrix layer may be the lowermost layer of the wound dressing 3100. The loaded foam may have same or substantially similar size or shape with the cover layer 3102 and/or the absorbent layer 3108. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 3108, or the absorbent layer 3108 can be loaded with powder charge as described above.

[0385] Referring to Figure 18, the support layer 3106 includes a net 3200 configured to reduce shrinkage of the wound dressing 3100. Aptly, the net 3200 is configured to reduce shrinkage of the absorbent layer 3108 and/or the film layer 3102 to help reduce wrinkling of the film layer 3102. In this example, the net 3200 has a substantially hexagonal

(or honeycomb) structure 3204 including a plurality of substantially triangular shaped apertures 3202 extending therethrough. The hexagonal structure 3204 is formed from a plurality of dots (or bosses) 3206 joined by polymer strands 3208. The dots 3206 are substantially evenly spaced with respect to each other. Each dot forms a vertex of the hexagonal pattern in the structure 3204. Each dot 3206 is joined to six surrounding dots 3206 by polymer strands 3208. That is, six polymer strands 3208 extend from each dot 3206 and each connect to a respective surrounding dot 3206 to form the hexagonal structure 3204 having triangular shaped apertures 3202 between the polymer strands 3208. Each of the triangular shaped apertures 3202 may have an area A of from 0.005 to 0.32 mm². This allows liquid vapour from a wound to pass freely through the apertures, whilst still providing sufficient strength to the support layer 3106. It can also be said that the structure 3204 is a structure comprising a plurality of strands or struts that are joined to form a plurality of triangles. In this example the triangles tessellate in rows. It will be appreciated that the strands or struts may be arranged in other formations, for example squares, diamonds or rectangles with different geometries and therefore differing open areas.

[0386] In this example, the support layer 3106 is located directly adjacent the absorbent layer 3108. As such, the support layer 3106 can effectively provide additional mechanical strength to fibres in the top surface of the absorbent layer 3108. This can help prevent movement of the fibres and reduce shrinking of the absorbent layer 3108. Aptly, the support layer 3106 is bonded to the fibres in the top surface of the absorbent layer 3108. This can help to lock the fibres in position and prevent or reduce any movement. In this example, the support layer 3106 further includes a bonding layer for heat laminating the net 3200 to the absorbent layer 3108. The support layer 3106 is thus heat laminated to fibres in the absorbent layer 108 via the bonding layer.

[0387] The bonding layer contained within the net has a lower melting temperature than the net 3200 so that the support layer 3106 can be heat laminated to the absorbent layer 3108 whilst maintaining the structure of the net 3200. The bonding layer can be formed from a low melting point polymer, for example a low melting point ethylene-vinyl acetate, whilst the net 3200 may be formed from a high-density polyethylene, which melts at a higher temperature than the bonding layer. Other polymers having a lower melting point than the net

3200 may also be suitable. For example the bonding layer may be a separate layer or alternatively include an ethylene-acrylate or thermoplastic polyurethane based adhesive. The net 3200 and the bonding layer can be coextruded to form the support layer 3106. Aptly, the bonding layer is extruded with a similar structural shape to the net 3200, so that the apertures 3202 in the net 3200 are not obstructed by the bonding layer. This helps to ensure that exudate the absorbent layer 3108 can pass through the support layer and evaporate out of the wound dressing 3100 through the film layer 3102.

[0388] Figures 19A-B illustrate another example of a multi-layered wound dressing 3300. The wound dressing 3300 includes a film layer 3302, support layer 3306 and absorbent layer 3308, the same as the film layer 3102, support layer 3106 and absorbent layer 3108 described in relation to Figure 17. The wound dressing 3300 also includes a first adhesive layer 3304, located between the film layer 3302 and the support layer 3306, for attaching the film layer 3302 to the support layer 3306. The first adhesive layer 3304 is a hot melt adhesive applied to a wound facing side (underside) of the film layer 3302. Aptly, the first adhesive layer 3304 is pattern coated onto the film layer 3302, to include holes, so that gas and liquid vapour can pass through holes in the first adhesive layer 3304. In other examples the film layer 3302 may be laminated (e.g. heat laminated) directly onto the support layer 3306 without the need for an adhesive layer 3304 in between. In this example, the wound dressing 3300 also includes a foam layer 3312, which is a fluid transport layer. The foam layer 3312 is located under the absorbent layer 3306. The foam layer 3312 acts to draw fluid away from a wound site and transport the fluid to the absorbent layer 3308. The foam layer may be formed from an open cell polyurethane foam and other options are available, as will be recognised by those skilled in the art.

[0389] An adhesive web layer 3310 is located between the foam layer 3312 and the absorbent layer 3108 to adhere the foam layer 3312 to the absorbent layer 3308. The adhesive web layer may be formed from bicomponent polypropylene/polyethylene fibres. Such bicomponent fibres are known in the art, so for brevity will not be discussed in detail. The adhesive web layer 3310 includes a plurality of apertures extending therethrough to allow for passage of exudate from the foam layer 3312 to the absorbent layer 3108.

[0390] The wound dressing 3300 also includes a wound contact layer 3320, which includes a perforated film 3316. The perforated film 3316 is located under the foam layer 3312 and helps to prevent the wound dressing 3100 from attaching to the wound as the wound heals. For example, where the wound dressing 3300 includes the foam layer 3112, the perforated film 316 can prevent new tissue from growing into cells of the foam layer 3312. In other examples, the foam layer 3312 may not be present and the perforated film 3316 can help prevent fibres of the absorbent layer 3308 from becoming embedded in the wound. Perforations in the perforated film 3316 are aptly substantially uniformly distributed and are of suitable size to allow passage of exudate into the wound dressing 3300, e.g. with holes having a diameter of 1-2.5 mm. The perforated film 3316 is aptly formed from polyurethane. The wound contact layer 3320 may also include an adhesive 3318 located under the perforated film 3316 (i.e. on the wound facing side of the perforated film 3316) for adhering the wound dressing 3300 to the skin. In this case the adhesive is silicone 3318 and is aptly spread onto the underside of the perforated film with a coat weight of around 30-200 g/m². In some other examples, an additional attachment element, for example bandages, strips of tape, or compression bandages may be used to secure the wound dressing 3300 to the patient.

[0391] The top side of the perforated film 3316 (i.e. the side distal from the wound) may be coated with a further adhesive layer 3314. The further adhesive layer 3314 adheres the wound contact layer 3320 to the foam layer 3312. Aptly, the further adhesive layer 3314 may be an acrylic adhesive, though other suitable adhesives may also be used. In other examples the wound contact layer 3320 may be laminated (e.g. heat laminated) directly to the foam layer 3312, without the need for the further adhesive layer 3314 in between.

[0392] The wound dressing 3300 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressing 3300. In some embodiments, the loaded matrix layer may be provided below the cover layer 3302. In some embodiments, the loaded matrix layer may be provided between the absorbent layer 3308 and the wound contact layer 3320. In some embodiments, the loaded matrix layer may be provided between the foam layer 3312 and the wound contact layer 3320, and thus adhered to the adhesive layer 3314. In some

embodiments, the loaded matrix layer can supplement or replace the absorbent layer 3308 and/or foam layer 3312, or the absorbent layer 3308 and/or the foam layer 3312 can be loaded with powder charge as described above. The loaded matrix may have same or substantially similar size or shape with the cover layer 3302 and/or the absorbent layer 3308.

[0393] In another example, as shown in Figure 20, the film layer 3502 may have a larger surface area than the remainder of the wound dressing 3500 so that it extends further outwardly than the other layers of the wound dressing. The wound-facing (underside) of the film layer may be coated with a pressure sensitive adhesive 3504 (or other suitable adhesive) for sticking the dressing to the patient around the wound periphery. The pressure sensitive adhesive 3504 may also adhere the film layer 3502 to the support layer 3506 of the wound dressing 3500. The wound dressing may also include an absorbent layer 3508, adhesive web layer 3510, foam layer 3512, further adhesive layer 3514 and wound contact layer 3520. Each of the layers in this example may be similar to corresponding layers described above in relation to Figures 19A and 19B, so for brevity will not be described again in detail.

[0394] In a further example, as shown in Figure 21, both the wound contact layer 3620 and the film layer 3602 may extend beyond the remaining layers of the wound dressing 3600. The wound contact layer 3620 and the film layer may be adhered together around the periphery (e.g. via an adhesive layer 3604), so that the remaining layers of the wound dressing are sandwiched between the wound contact layer 3620 and the film layer 3602. In other words, the support layer 3606, the absorbent layer 3608, the adhesive web layer 3610, and the foam layer 3612 may be sealed within a cavity 3622 between the film layer 3602 and the wound contact layer 3620. In this example, a further adhesive layer 3614 adheres the foam layer 3612 to the wound contact layer 3620, though in other examples the further adhesive layer 614 may not be required. Each of the layers in this example may be similar to corresponding layers described above in relation to Figures 19A and 19B, so for brevity will not be described again in detail.

[0395] The wound dressing 3600 in this example may be manufactured similarly to the wound dressing 3300, but with the film layer 3602 and the wound contact layer 3620 being laminated together around the periphery (e.g. via the adhesive layer 3604) to sandwich the remaining layers between the film layer 3602 and the wound contact layer 620.

Alternatively, the film layer 3602 may be directly laminated around the periphery (e.g. heat laminated) to the wound contact layer 3620, without the need for the additional adhesive layer 3604.

[0396] In similar fashion with the wound dressing 3300 described in relation to Figures 19A-19B, the wound dressings 3500 and 3600 may incorporate or comprise a loaded matrix as hereinbefore described. For example, a loaded foam or fibre layer including a powder charge/additive as described previously herein and illustrated in Figures 1-10 may be incorporated into the wound dressings 3500 and 3600. For example, the loaded matrix layer may be provided between the absorbent layer and the wound contact layer. In some embodiments, the loaded matrix layer may be provided between the foam layer and the wound contact layer, and thus adhered to the adhesive layer. In some embodiments, the loaded matrix layer can supplement or replace the absorbent layer 3508 and/or the foam layer 3512, or the absorbent layer 3508 and/or the foam layer 3512 can be loaded with powder charge as described above. The loaded foam may have same or substantially similar size or shape with the cover layer, the absorbent layer and/or the foam layer 3312.

[0397] Although the wound dressings 3300, 3500, 3600 have been described having several adhesive layers, one or more of these layers may not be present. For example, the perforated film itself may be formed from a hot melt adhesive material so that it can be directly heat laminated onto the foam layer, in which case the further adhesive layer may not be needed. In another example, the adhesive web layer may not be present if the foam and absorbent layers are adhered in another way. For example, the foam and absorbent layers may be directly chemically bonded together. Similarly, the first adhesive layer may not be needed. For example, if the support layer includes an adhesive material, or if the film layer itself is formed from a hot melt adhesive then the film layer and the support layer may be directly adhered together.

[0398] In another example, the wound dressing may be provided without the foam layer. The foam layer helps to transport exudate away from the wound. However in some cases, and depending on the severity of a wound, the absorbent layer may sufficiently draw exudate from the wound without the need for the foam layer.

[0399] Although in the examples described above, the support layer is heat laminated to the absorbent layer via a bonding layer, other laminating techniques may be suitable. For example, the bonding layer may include a pressure sensitive adhesive. In this case, heat may not be required to laminate the support layer and adhesive layer together.

[0400] Although in the example described above, the net layer has been described as having a substantially hexagonal shaped structure, other geometric structures may also be suitable. With other geometric structures, the apertures may also have different geometric shapes.

[0401] In another example, the wound dressing may include more than one support layer to provide support to other layers in the wound dressing. For example, a first support layer may be located between the liquid impermeable film layer and the absorbent layer, and a further support layer may be located between the absorbent layer and the fluid transport layer (foam layer). This may help to support the absorbent layer from both sides to further reduce shrinking of the absorbent layer.

[0402] Any of the examples described herein may be adapted for use with a negative pressure system (sometimes referred to as a reduced pressure system) including a source of negative pressure, such as a negative pressure pump. For example, the film layer may include a negative pressure interface, such as a port, to which a negative pressure supply tube may be connected. The supply tube may be connected to a negative pressure source so that, in use, the negative pressure source applies a negative pressure to the wound dressing between the film layer and the wound to help draw wound exudate away from the wound and into the absorbent layer of the dressing.

Terminology

[0403] Depending on the embodiment, certain operations, acts, events, or functions of any of the processes described herein can be performed in a different sequence, can be added, merged, or left out altogether (such as not all are necessary for the practice of the processes). Moreover, in certain embodiments, operations, acts, functions, or events can be performed concurrently, such as through multi-threaded processing, interrupt processing,

or multiple processors or processor cores or on other parallel architectures, rather than sequentially.

[0404] The processing of the various components of the illustrated systems can be distributed across multiple machines, networks, and other computing resources. In addition, two or more components of a system can be combined into fewer components. Various components of the illustrated systems can be implemented in one or more virtual machines, rather than in dedicated computer hardware systems and/or computing devices. Likewise, the data repositories shown can represent physical and/or logical data storage, including, for example, storage area networks or other distributed storage systems. Moreover, in some embodiments the connections between the components shown represent possible paths of data flow, rather than actual connections between hardware. While some examples of possible connections are shown, any of the subset of the components shown can communicate with any other subset of components in various implementations.

[0405] Any patents and applications and other references noted above, including any that may be listed in accompanying filing papers, are incorporated herein by reference. Aspects of the disclosure can be modified, if necessary, to employ the systems, functions, and concepts of the various references described herein to provide yet further implementations.

[0406] Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0407] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other

forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For example, the actual steps or order of steps taken in the disclosed processes may differ from those shown in the figure. Depending on the embodiment, certain of the steps described above may be removed, others may be added. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

[0408] Although the present disclosure includes certain embodiments, examples and applications, it will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments or uses and obvious modifications and equivalents thereof, including embodiments which do not provide all of the features and advantages set forth herein. Accordingly, the scope of the present disclosure is not intended to be limited by the described embodiments, and may be defined by claims as presented herein or as presented in the future.

[0409] Conditional language, such as “can,” “could,” “might,” or “may,” unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, or steps. Thus, such conditional language is not generally intended to imply that features, elements, or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, or steps are included or are to be performed in any particular embodiment. The terms “comprising,” “including,” “having,” and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term “or” is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term “or” means one, some, or all of the elements in the list. Likewise the term “and/or” in reference to a list of two or more items, covers all of the

following interpretations of the word: any one of the items in the list, all of the items in the list, and any combination of the items in the list. Further, the term “each,” as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term “each” is applied. Additionally, the words “herein,” “above,” “below,” and words of similar import, when used in this application, refer to this application as a whole and not to any particular portions of this application.

[0410] Conjunctive language such as the phrase “at least one of X, Y, and Z,” unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require the presence of at least one of X, at least one of Y, and at least one of Z.

[0411] Language of degree used herein, such as the terms “approximately,” “about,” “generally,” and “substantially” as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms “approximately”, “about”, “generally,” and “substantially” may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount. As another example, in certain embodiments, the terms “generally parallel” and “substantially parallel” refer to a value, amount, or characteristic that departs from exactly parallel by less than or equal to 15 degrees, 10 degrees, 5 degrees, 3 degrees, 1 degree, or 0.1 degree.

[0412] Any of the embodiments described herein can be used with a canister or without a canister. Any of the dressing embodiments described herein can absorb and store wound exudate.

[0413] The scope of the present disclosure is not intended to be limited by the description of certain embodiments and may be defined by the claims. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

WHAT IS CLAIMED IS:

1. Material which is a wound care material comprising
a flexible hydrophilic polymer foam or fibre matrix comprising a wound facing face and a reverse face or two wound facing faces and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and
a powder charge comprising a wound dressing additive or combinations thereof,
wherein said matrix provides a tortuous pore network and
wherein said powder charge is comprised at said wound facing face or said reverse face and within said cell network in cells proximal to said face, more particularly in diminishing amount with increasing depth within said network.
2. Material as claimed in claim 1 wherein wound dressing additive or combinations thereof, is selected from any of antimicrobial species-releasing additive as hereinbefore or hereinbelow defined, and wound dressing additive selected from antimicrobial, bacterial, bacteriostatic, fireproofing, odour control such as activated charcoal or bentonite, protein-breaking or denaturation, wicking, conductive, structure-supporting, absorbent such as superabsorbent polymer (SAP), colour or colour masking such as prevention of PU foam yellowing (optical brighteners, oxidation prevention).
3. Material as claimed in claim 1 or 2 wherein said powder charge is present at one or both said faces, and is absent from, or present in incidental or insignificant amount within, said cell network and within said structural matrix framework.
4. Material as claimed in any of claims 1 to 3 wherein said powder charge is present at one or both said faces and within said cell network proximal to said face or faces and is absent from or present in incidental or insignificant amount within said structural framework.
5. Material as claimed in any of claims 1 to 2 and 4 wherein said powder charge is present at both said faces and within said cell network proximal to one said release face (asymmetric) and is absent from, or present in incidental amount within cell network proximal to said reverse face and said structural framework.

6. Material as claimed in any of claims 1 to 2 and 4 to 5 wherein said powder charge is asymmetrically loaded or loaded in diminishing amount with increasing depth within said matrix.

7. Material as claimed in any of claims 1 to 2 and 4 to 6 wherein said powder charge extends to 5% to 50% of the separation between said faces, from the or each said release face, for example to 2-6 average sized cell diameters inward from said face or faces.

8. Material as claimed in any of claims 1 to 7 comprising a powder charge or plurality of powder charges comprising antimicrobial additive and super absorbent polymer (SAP) together or separately.

9. Material as claimed in any of claims 1 to 8 comprising a powder charge or plurality of powder charges, comprising antimicrobial additive or SAP together with a wound dressing additive as defined in claim 3 wherein a plurality of powder charges are comprised at same or different face(s) and/or within cell network proximal thereto.

10. Material as claimed in any of claims 1 to 9 wherein matrix comprises same or different additive impregnated in background content or supplementary content within the structural matrix framework, wherein said background or supplementary content is comprised in said pre-formed matrix.

11. Material as claimed in any of claims 1 to 10 formed as a laminate together with one or more powder charge-retaining fluid permeable nets.

12. Material as claimed in any of claims 1 to 11 wherein matrix or part thereof comprises a foam matrix selected from natural and synthetic polymer foam such as polystyrene, styrenic polymers, polyvinylchloride, polyvinyl alcohol, polyurethanes, phenolic polymers, silicones, polyolefins, rubbers and elastomer thermoplastic polymers and combinations and copolymers thereof.

13. Material as claimed in any of claims 1 to 12 wherein matrix or part thereof comprises a fiber matrix selected from woven and non-woven fiber matrix of cellulose, alginate, chitin, chitosan, functionalised derivatives thereof such as rayon and viscose and blends thereof.

14. Material as claimed in any of claims 1 to 13 wherein antimicrobial atomic species-releasing additive is selected from elemental silver, silver salts, silver complexes and caged forms thereof and combinations thereof.

15. Material as claimed in any of claims 1 to 14 wherein antimicrobial atomic species-releasing additive is selected from silver sulfadiazine, silver zeolite, silver sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate and combinations thereof.

16. Material as claimed in any of claims 1 to 15 wherein diatomic species comprises iodine, for example caged iodine, such as cadexomer iodine.

17. Material as claimed in any of claims 1 to 16 wherein superabsorbent polymer is selected from sodium polyacrylate, cross linked CMC or other absorbent functionalised (by carboxylation or sulfonation) cellulose derivatives, cross linked polyethylene oxide and PVA copolymers.

18. Material as claimed in any of claims 1 to 17 comprising additive having particle size of the order of $1\text{ micron} < D_{90} < 30\text{ micron}$ and $D_{50} < 10\text{ micron}$.

19. Material as claimed in any of claims 1 to 18 wherein powder charge comprises flowing agent selected from stearate salt, clay, silica, charcoal or graphite and a combination thereof in particle size less than additive particle size.

20. Material as claimed in any of claims 1 to 19 comprising water permeable bulking agent and/or binder as part of said powder charge or as solid melt or partial melt, together with said powder charge, at said matrix face(s) and/or within said cell network, selected from PEG and PVP and a super absorbent polymer as defined in claim 18.

21. Material which is a composite of a matrix component comprising a flexible hydrophilic polymer foam or fiber matrix comprising two matrix faces providing a release face and a reverse face or two release faces, and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and additive, or a powder charge component comprising additive, selected from antimicrobial additive, wound care additive and wound dressing additive, wherein said

material or said powder charge additionally comprises flowing agent and/or bulking agent and/or binder

and wherein said additive and said flowing agent and/or bulking agent and/or binder are co-located or said powder charge components are co-located at one said release face or both said faces and/or within said cell network, preferably wherein additive and/or flowing agent is comprised partially embedded and retained at said face or faces and within said cells by melt-softened co-located bulking agent and/or binder.

22. Method for manufacture of material as claimed in any of claims 1 to 21.

23. Method for manufacture of material comprising

a flexible hydrophilic polymer foam or fiber matrix component comprising two matrix faces providing a release face and a reverse face or two release faces and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

a powder charge component comprising antimicrobial species-releasing additive wherein species is selected from one or more antimicrobial atomic species and one or more antimicrobial diatomic species,

said method comprising providing said matrix component and

providing said powder charge component,

contacting said powder charge component and said matrix component

wherein said contacting comprises directing said powder charge to one said release face or both said release faces and/or within said cell network proximal to said face or faces.

24. Method for manufacture of material which is wound care material comprising

a flexible hydrophilic polymer foam or fiber matrix component comprising a wound facing face and a reverse face or two wound facing faces and therebetween a structural matrix framework defining a network of cells having a cell network surface and therein a network of pores or cell openings, and

a powder charge component comprising a wound dressing additive or combinations thereof, wherein said matrix provides a tortuous pore network said method comprising

providing said matrix component and
providing said powder charge component,
contacting said powder charge component and said matrix component
and directing said powder charge to said wound facing face or said reverse
faces and within said cell network in cells proximal to said face, in diminishing amount
with increasing depth within said network.

25. Method as claimed in claim 23 or 24 which comprises in a preceding, simultaneous or subsequent step melt softening of matrix and/or of a fluid permeable laminating net laid up at said face(s) and/or of a binder provided with said powder charge as defined in any of claims 1 to 22 thereby embedding or binding said powder charge at said matrix face and/or within said cell network.

26. Method as claimed in any of claims 23 to 25 which comprises providing said matrix component or an intermediate surface in desired orientation, for example horizontal or inclined with dosing face upward or downward; and

providing said powder charge in one or more hoppers, canisters, cassettes, nozzles or release buckets; and

directing by dosing said powder charge directly to said matrix face or indirectly to said intermediate surface and subsequently contacting said matrix face with any such intermediate surface, wherein dosing is selected from dusting, powder sprinkling, powder spraying, powder jetting or depositing.

27. Method as claimed in any of claims 23 to 26 comprising in a preceding step preparing said powder charge including selection of additive, and any flowing agent, bulking agent and/or binder, and respective amounts thereof having regard to additive particle size and required availability thereof, combining with optional blending or mixing and providing in a powder charge for contacting and directing as claimed said step additionally comprising subjecting said additive or said powder charge to a particle size selection process comprising sieving or mass separation or particle size reduction process comprising micronising.

28. Method as claimed in any of claims 23 to 27 wherein directing to one said face and within said cell network comprises dosing powder charge directly or indirectly thereto and

simultaneously or subsequently applying translating force thereby translating at least a part thereof within said cell network.

29. Method as claimed in any of claims 23 to 28 wherein translating force includes physical force applied directly to powder charge, such as needling, or applied indirectly to powder charge via said matrix, for example by mangling or rolling said matrix, thereby displacing powder charge with translating by gravity or suction or like.

30. Method as claimed in any of claims 23 to 29 wherein translating force comprises a field applied across said matrix dosed with or to be dosed with said powder charge, disposed so as to fluidise said powder charge or otherwise cause said powder charge to adopt fluid like flow, wherein a field is selected from alternating electrostatic field (AC electric field), acoustic field, ultrasonic field, aeraulic field, pneumatic field and the like.

31. Method as claimed in any of claims 23 to 30 which includes in a further step differentiating powder charge part at face and powder charge part within cell network for respective primary availability and secondary availability, in manner to manipulate respective amounts thereof and distance to which secondary availability part is directed within said cell network and/or to said reverse or secondary release face.

32. Material obtained or obtainable by a method as claimed in any of claims 22 to 31.

33. Device for application to a locus and activation by contact with aqueous medium provided at said locus, said device comprising

- (a) a locus contacting surface or layer and/or
 - (b) an opposing non-locus contacting surface or layer together with
 - (c) an aqueous medium absorbing layer comprised between or in combination with (a) and/or (b)
- wherein (c) comprises material as claimed in any of claims 1 to 21 or 32.

34. A device comprising a wound dressing or part thereof for application to a wound locus and activation by contact with fluid at said wound locus such as wound exudate, said wound dressing comprising

- (a) a wound contacting surface or layer and/or
- (b) an opposing non-wound contacting surface or layer together with

(c) one or more optional fluid absorbing layers comprised therebetween between or in combination with one thereof

wherein (c) comprises antimicrobial material or wound care material as claimed in any of claims 1 to 24 or 35.

35. Antimicrobial device as claimed in any of claims 33 and 34 wherein layer or surface (a) is an adhesive or non-adhesive conformable elastomeric apertured film.

36. Antimicrobial device as claimed in any of claims 33 to 35 wherein layer or surface (b) is a breathable top film permitting fluid and air regulation at the locus and providing an antimicrobial barrier, preferably a continuous moisture vapour transmitting conformable polymer film.

37. Antimicrobial device as claimed in any of claims 33 to 36 comprising additional layers selected from a masking layer (b') comprised between a layer (b) and a layer (c), and a superabsorbent layer (b'') comprised between a layer (b) and a layer (c).

38. Antimicrobial material or device as claimed in any of claims 1 to 21 and 32 or 33 to 37 which is sterile, terminally sterile and/or sealed in moisture and/or microbe impermeable packaging.

39. A method for manufacturing a device as claimed in any of claims 33 to 38.

40. A method for treating a locus so as to aid in rendering or maintaining it free from microbes deleterious to the health of said locus which comprises contacting the locus with antimicrobial material or device as claimed in any of claims 1 to 22 and 32 or 33 to 38 thereby enabling release of antimicrobial species into material and/or said locus.

41. Method as claimed in claim 40 which is a method of treating a wound locus thereby enabling release of antimicrobial species into said wound locus rapidly in high concentration, with sustained release thereof for a required duration.

42. A method for wound care which comprises contacting a wound locus with wound care material or device as claimed in any of claims 1 to 22 and 32 or 33 to 38.

43. Material or device as claimed in any of claims 1 to 22 and 32 or 33 to 38 for use in applications to a locus selected from the management of wounds; hygiene and sterilisation of articles including medical and dental articles and point of use sterilisation; hygiene and sterilisation of personal care preparations and articles such as sanitary pads,

diapers, cosmetics; hygiene and sterilisation of food or of fluids, including air and water, or systems for their preparation and generation such as food preparation or packaging plants, ventilation systems, water management systems; and in particular such uses for which preventing or combatting microbial infection is beneficial.

44. A method of treating a wound, comprising:

placing a wound dressing comprising a loaded wound dressing layer into or over the wound, wherein the loaded wound dressing layer comprises a porous matrix and a powder charge of antimicrobial release additive loaded within the matrix, wherein the powder charge is concentrated at least at a wound facing surface of the porous matrix;

wherein the antimicrobial release additive is activated for the release of an antimicrobial agent into the wound from the wound dressing upon contact with moist or aqueous medium.

45. The method according to Claim 44, further comprising releasing said antimicrobial agent for more than a day.

46. The method according to Claim 44 or 45, further comprising releasing said antimicrobial release agent in an amount up to $1.8\text{mg}/\text{cm}^2$ per day.

47. The method according to any of Claims 44-46, further comprising:

allowing wound exudate to contact the loaded wound dressing layer before releasing at least a portion of the antimicrobial agent toward the wound, wherein the antimicrobial agent is configured to diffuse into wound exudate upon contact with wound exudate.

48. The method according to any of Claims 44-47, further comprising:

applying negative pressure to the wound dressing.

49. The method according to any of Claims 44-48, wherein the antimicrobial release additive is selected from a group consisting of elemental silver, silver salts, silver complexes, caged forms thereof, caged forms of iodine and combinations thereof.

50. The method according to any of Claims 44-49, wherein the antimicrobial release additive is selected from a group consisting of silver sulfadiazine, silver zeolite, silver

sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate, cadexomer iodine and combinations thereof.

51. The method according to any of Claims 44-46, wherein the antimicrobial agent comprises silver ion.

52. The method according to any of Claims 44-46, wherein the antimicrobial agent comprises iodine.

53. The method according to any of Claims 44-52, wherein the powder charge of antimicrobial additive further comprises super absorbent polymer.

54. The method according to any of Claims 44-53, wherein the powder charge of antimicrobial release additive has particle size on the order of $1\text{ micron} < D_{90} < 30\text{ micron}$ and $D_{50} < 10\text{ micron}$.

55. The method according to any of Claims 44-54, wherein the powder charge of antimicrobial additive further comprises a flowing agent selected from a group consisting of stearate salt, clay, silica, charcoal, graphite and a combination thereof, and wherein the flowing agent is in particle size less than the antimicrobial release additive.

56. The method according to any of Claims 44-55, wherein the wound dressing further comprises an absorbent layer that absorbs wound exudate.

57. The method according to any of Claims 44-56, wherein the wound dressing further comprises a wound contact layer positioned in contact with the wound below the loaded wound dressing layer.

58. A wound dressing, comprising:

a loaded wound dressing layer comprising:

a porous matrix comprising a wound facing face and a reverse face; and
a powder charge of antimicrobial release additive loaded within the matrix, wherein the powder charge decreases in amount with increasing distance from at least the wound facing face.

59. The wound dressing of Claim 58, wherein the matrix comprises polymer foam.

60. The wound dressing of Claim 58, wherein the matrix comprises a fibrous matrix.

61. The wound dressing of any one of Claims 58-60, wherein the matrix comprises a hydrophilic polymer.

62. The wound dressing of any one of Claims 58-61, wherein the antimicrobial release additive comprises elemental silver, silver salts, silver complexes, caged forms thereof, caged forms of iodine and combinations thereof.

63. The wound dressing of any one of Claims 58-61, wherein the antimicrobial release additive selected from a group consisting of silver sulfadiazine, silver zeolite, silver sulfate, silver carbonate, silver chloride, silver nitrate, silver oxide, silver phosphate, silver citrate, silver acetate, silver lactate, cadexomer iodine and combinations thereof.

64. The wound dressing of any one of Claim 58-63, wherein the antimicrobial release additive is in an amount of $1.4\text{mg}/\text{cm}^2$ to $4\text{mg}/\text{cm}^2$ at the wound facing face.

65. The wound dressing of any one of Claims 58-64, further comprising a wound contact layer below the loaded wound dressing layer.

66. The wound dressing of any one of Claims 58-65, further comprising a cover layer over the loaded wound dressing layer.

67. The wound dressing of any one of Claims 58-66, further comprising a fluidic connector configured to connect the cover layer to a source of negative pressure.

68. The wound dressing of any one of Claim 58-67, further comprising an absorbent layer over the loaded wound dressing layer.

69. The wound dressing of Claim 68, wherein the absorbent layer comprises superabsorbent particles.

70. The wound dressing of any one of Claims 58-69, wherein the powder charge further comprises superabsorbent polymer.

71. The wound dressing of any one of Claims 58-70, wherein the powder charge of antimicrobial release additive has a particle size of the order of $1\text{ micron} < D_{90} < 30\text{ micron}$ and $D_{50} < 10\text{ micron}$.

72. The wound dressing of any one of Claims 58-71, wherein the powder charge further comprises a flowing agent selected from a group consisting of stearate salt, clay, silica, charcoal, graphite and a combination thereof, and wherein the flowing agent is in particle size less than the antimicrobial release additive.

73. The wound dressing of any one of Claims 58-72, wherein the matrix comprises a plurality of cells and wherein the antimicrobial release additive is at least partially embedded within said cells.

Fig. 1a-k Symmetric composite (powder charge) loaded matrix

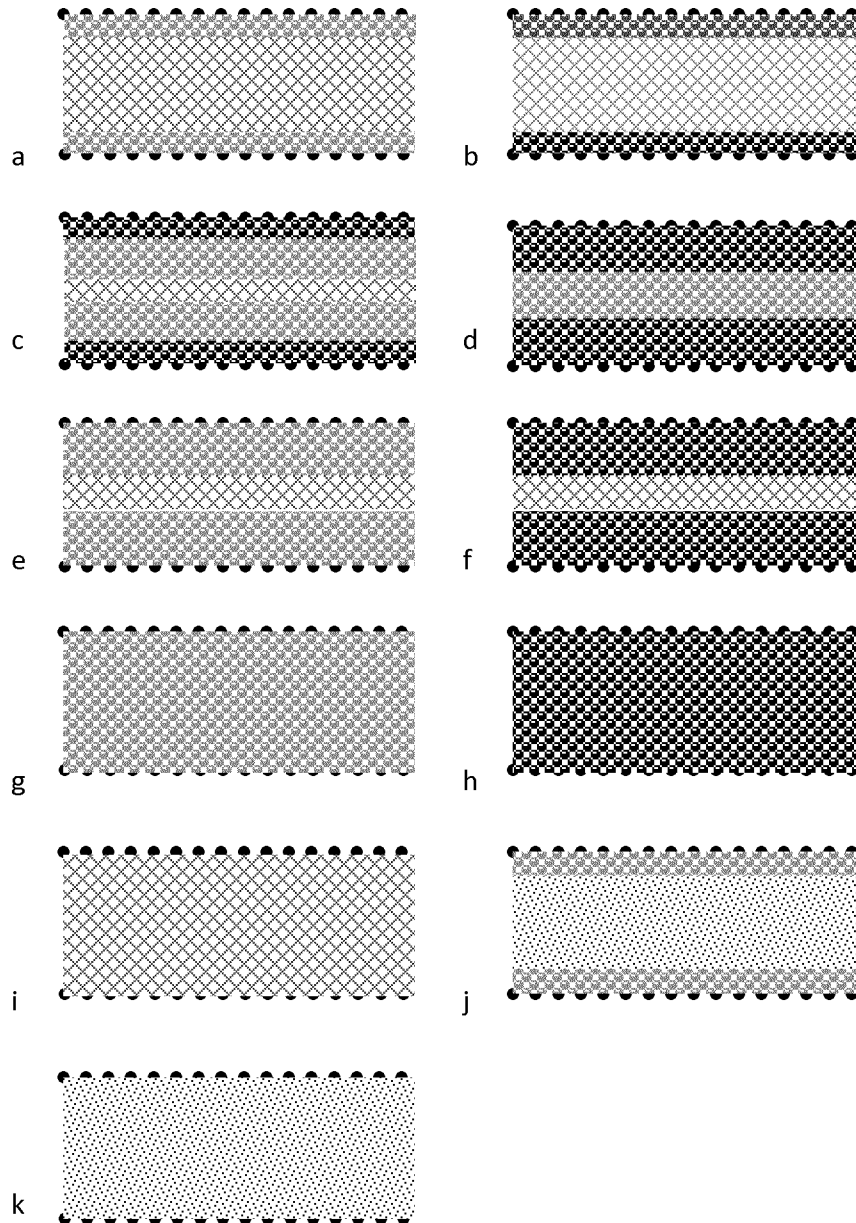
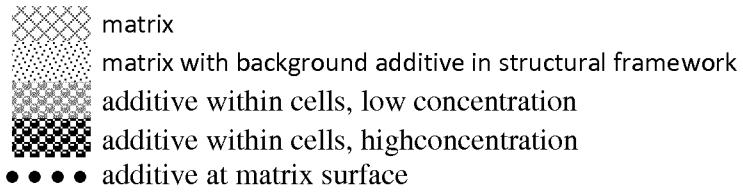


Fig. 2 SEM P.O.M (aqueous) loaded PU foam (CE1.1)

a) 40-70micron

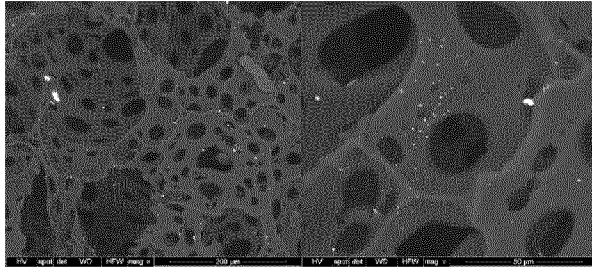
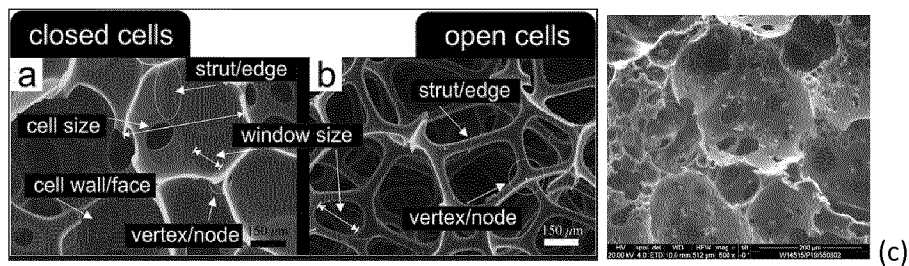
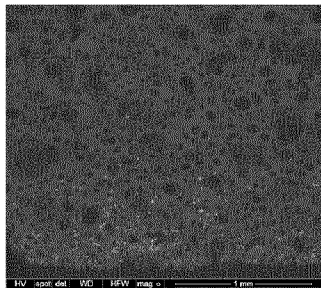


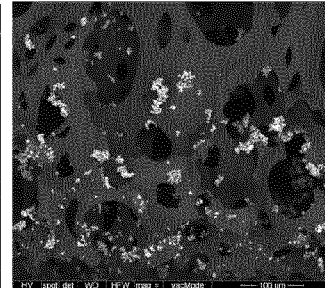
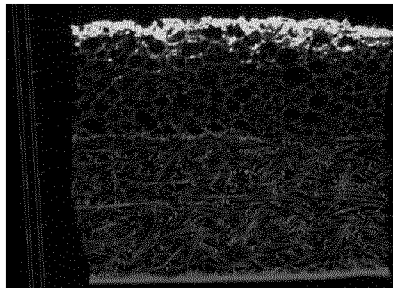
Fig. 3 (a) closed cell and pore network; (b) open (reticulated net-like) cell and pore network (Kranzlin and Niederberger, Mater. Horiz., 2015,2, 359-377); (c) – (h) SEM composite (powder charge) loaded (Ex.1 tortuous network)



(d) foam



(e) foam fiber laminate (f)



co-location of PEG (g) and silver sulfate (h)

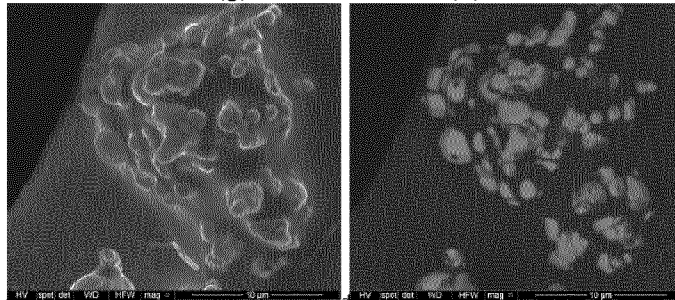
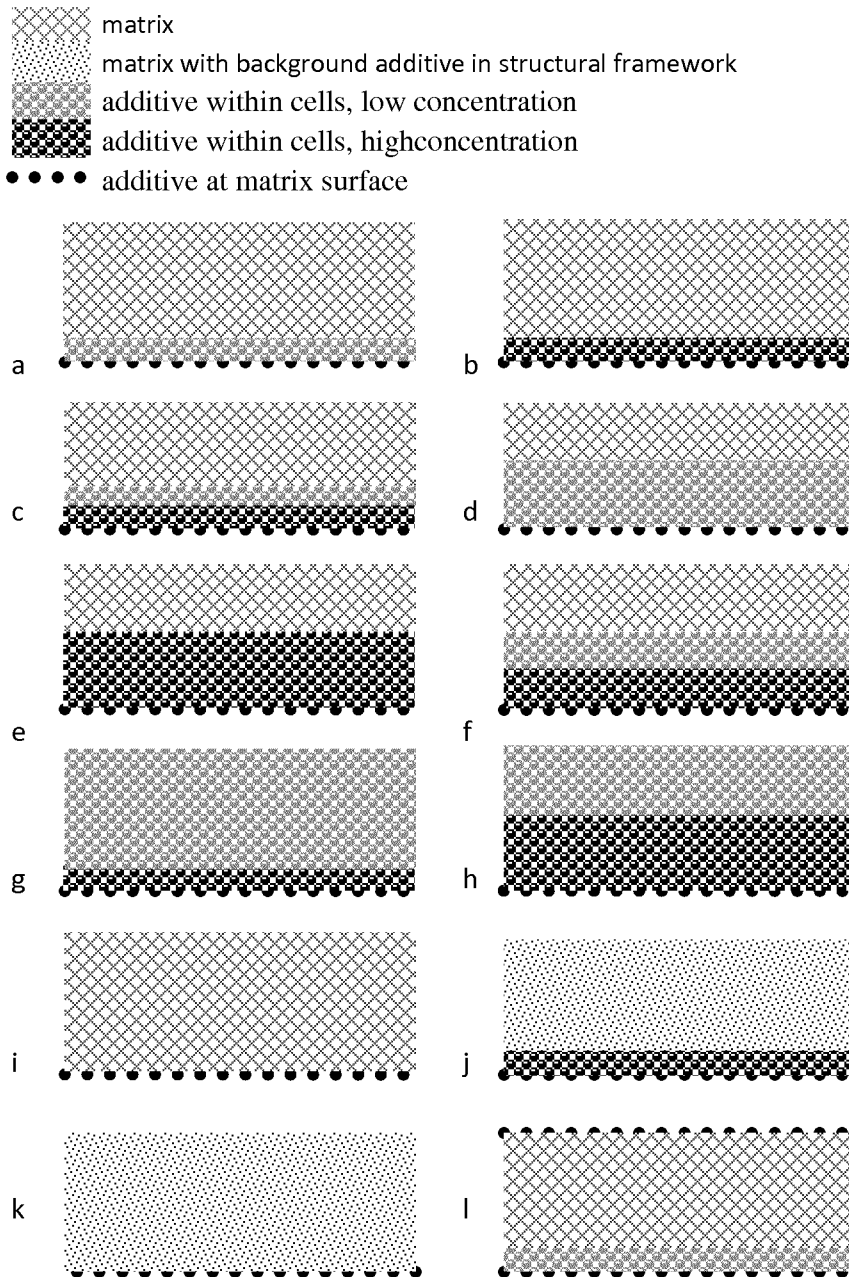
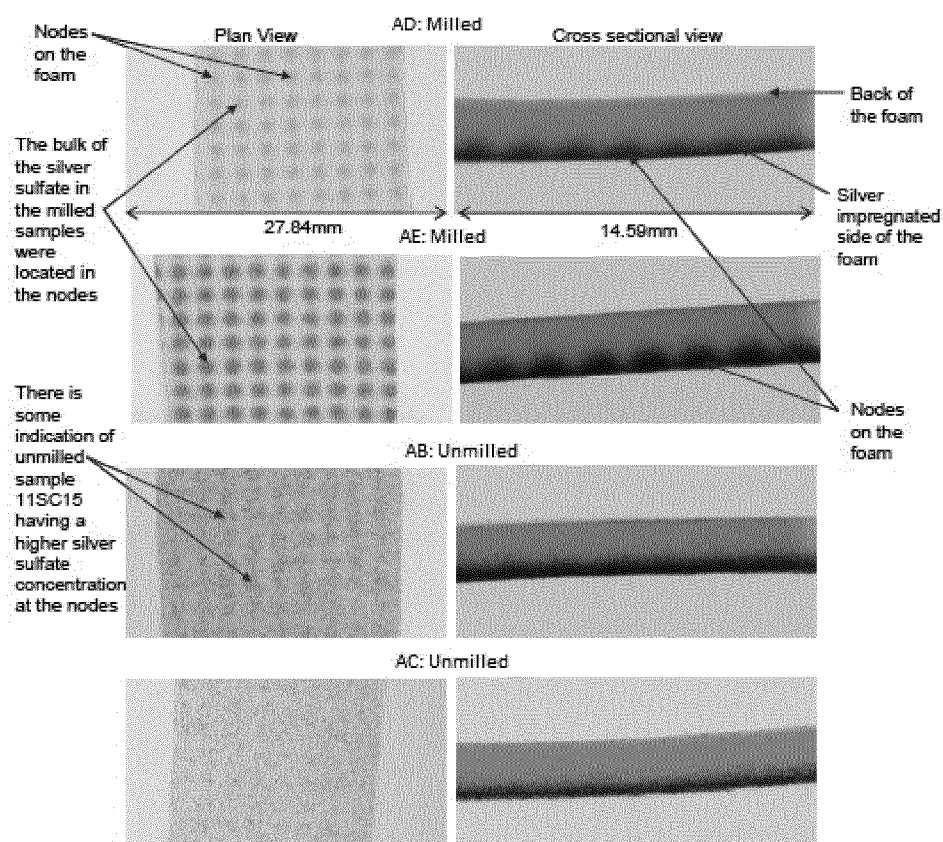


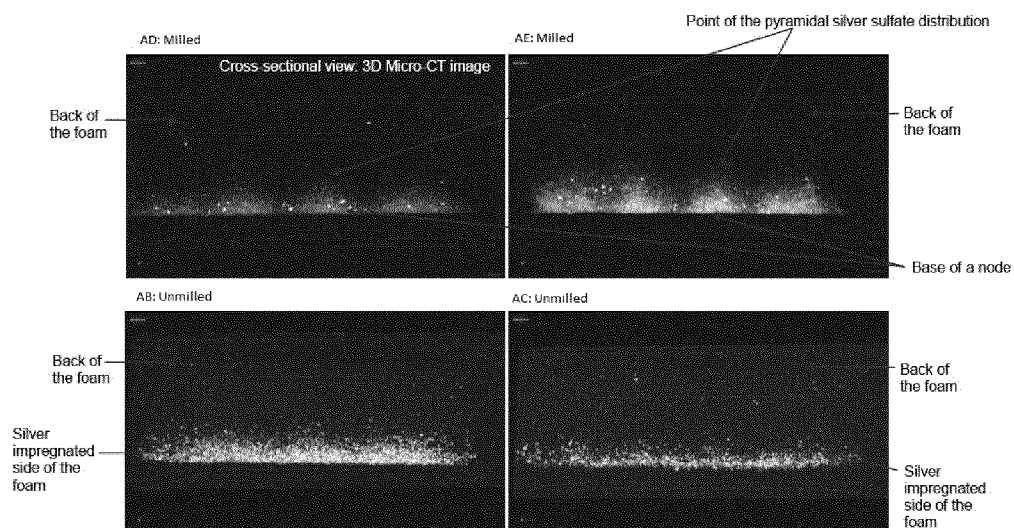
Fig. 4a-o Asymmetric composite (powder charge) loaded matrix



m



n



O

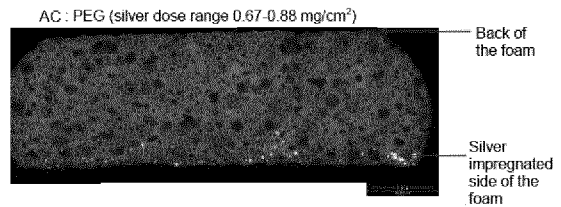
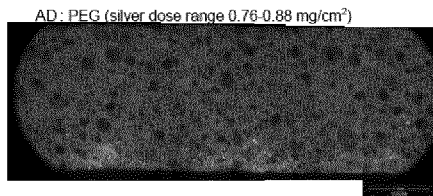
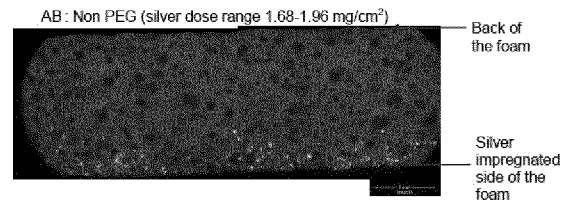
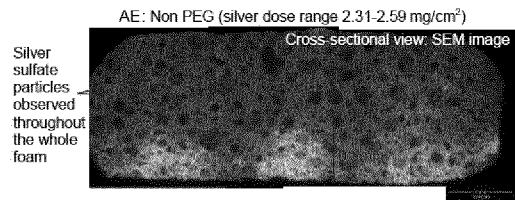
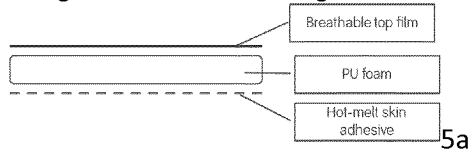
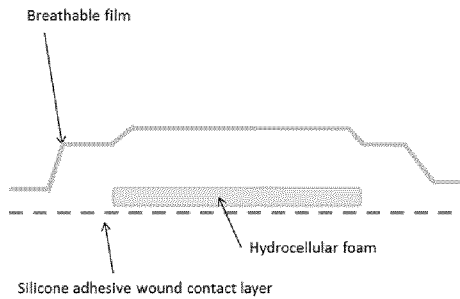


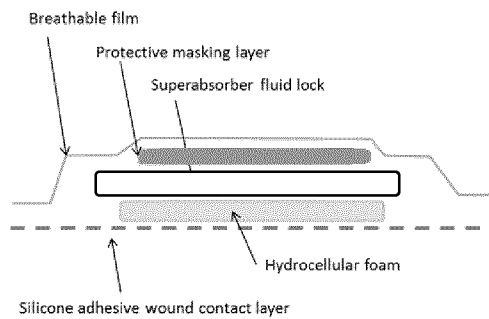
Fig. 5a-d: Wound dressing formats including composite (powder charge) loaded matrix ("foam")



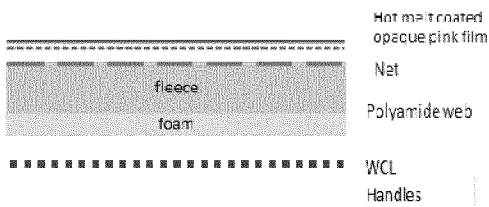
5a



5b



5c



5d

Fig. 6

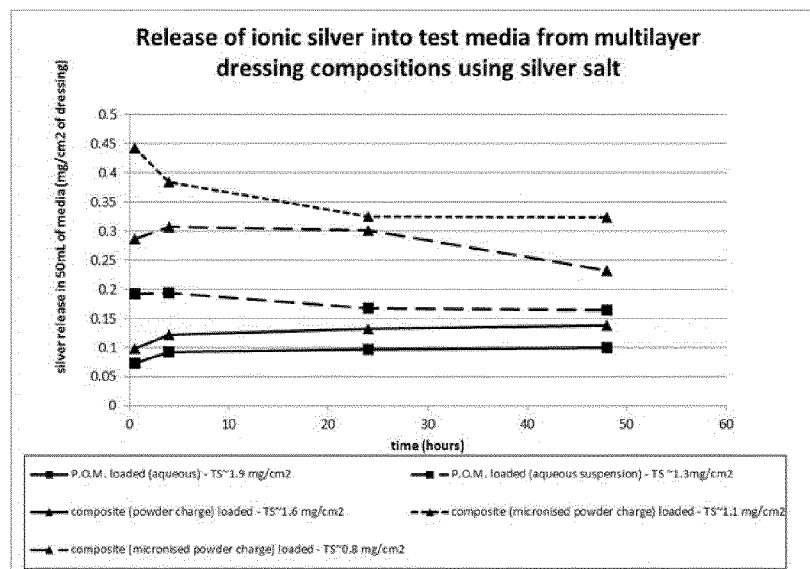


Fig. 7

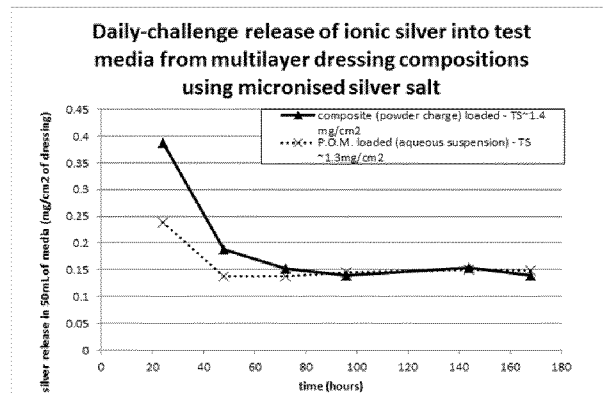
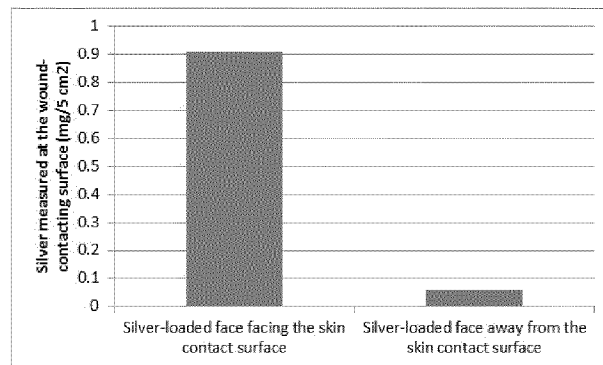


Fig. 8 Release from composite (powder charge) loaded material in experimentally high asymmetric (TS approx 3 mg/cm²)



loading

Fig. 9

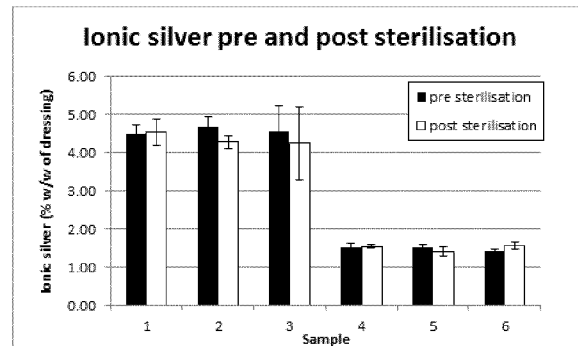
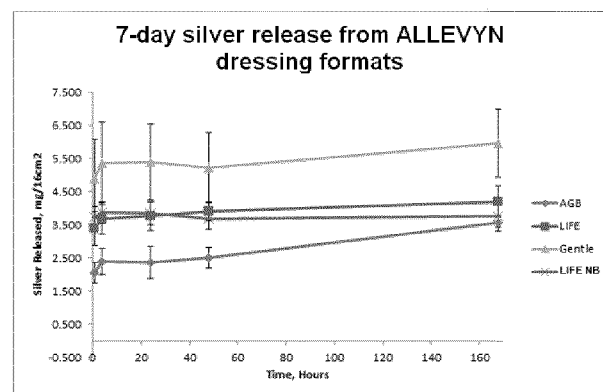
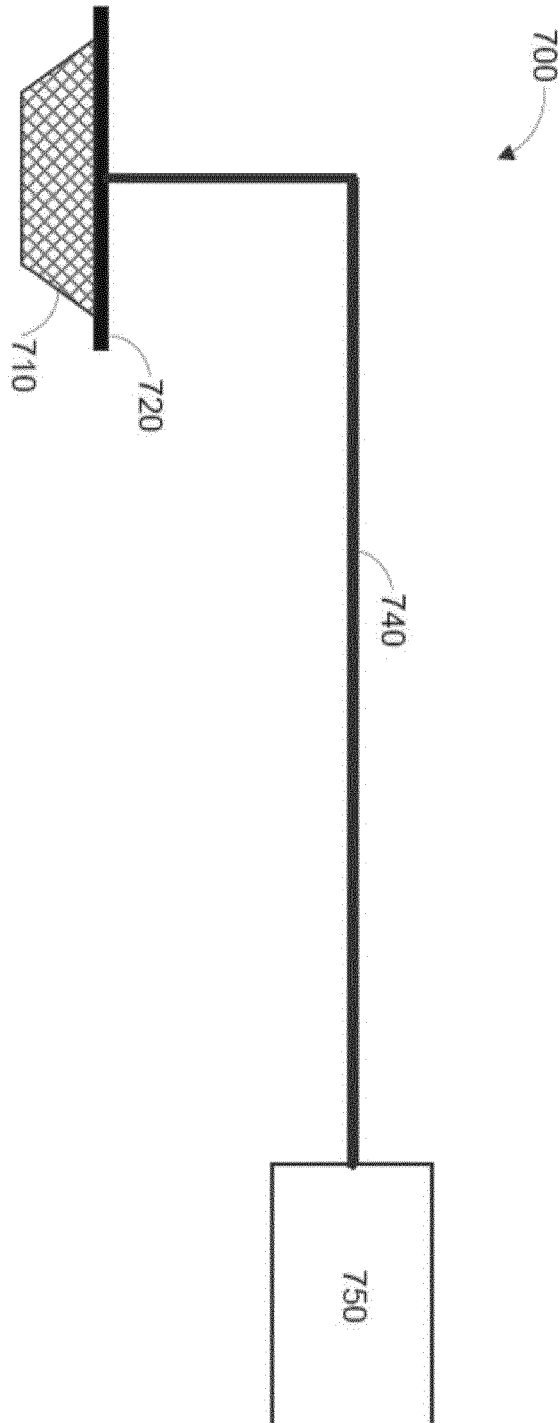


Fig. 10



*FIG. 11*

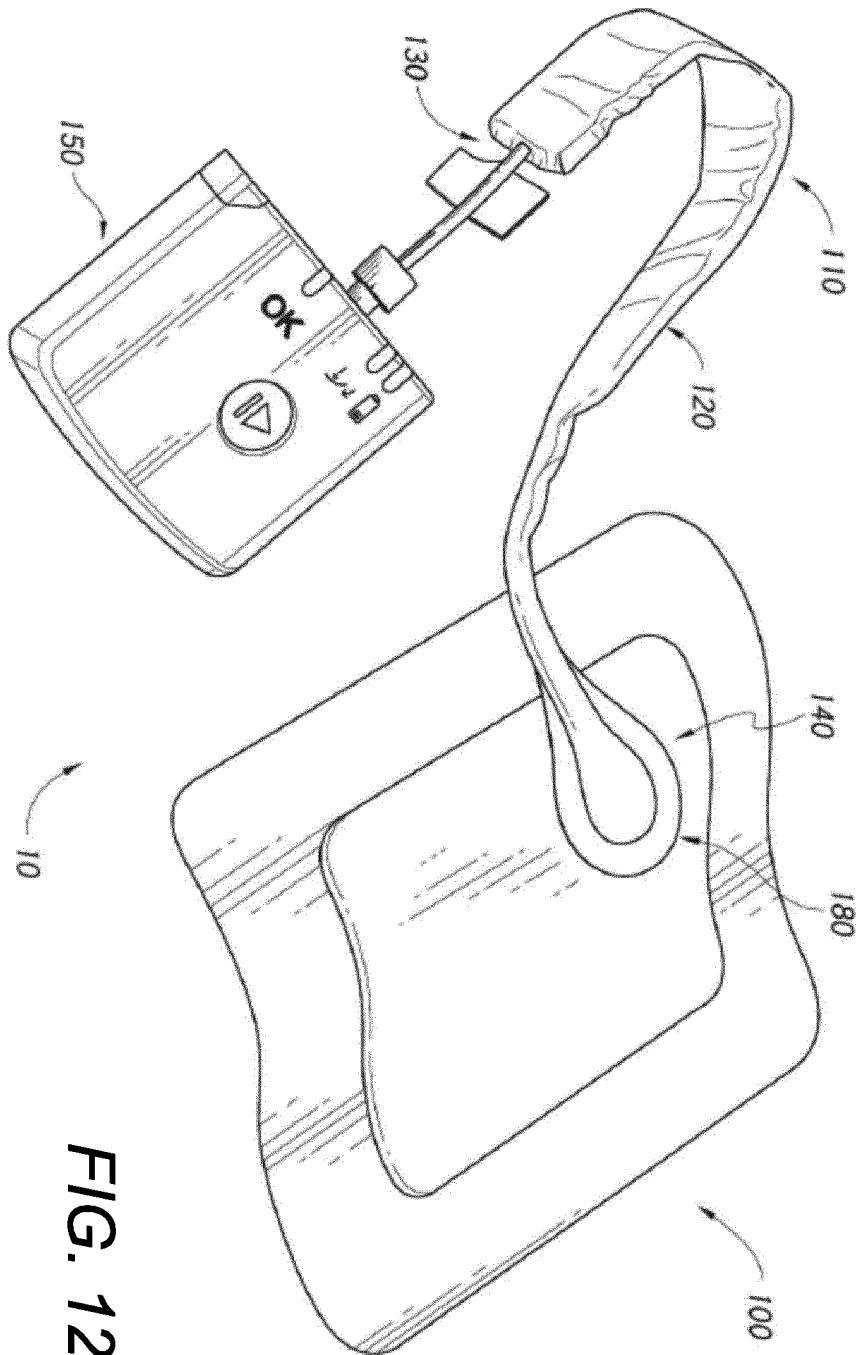
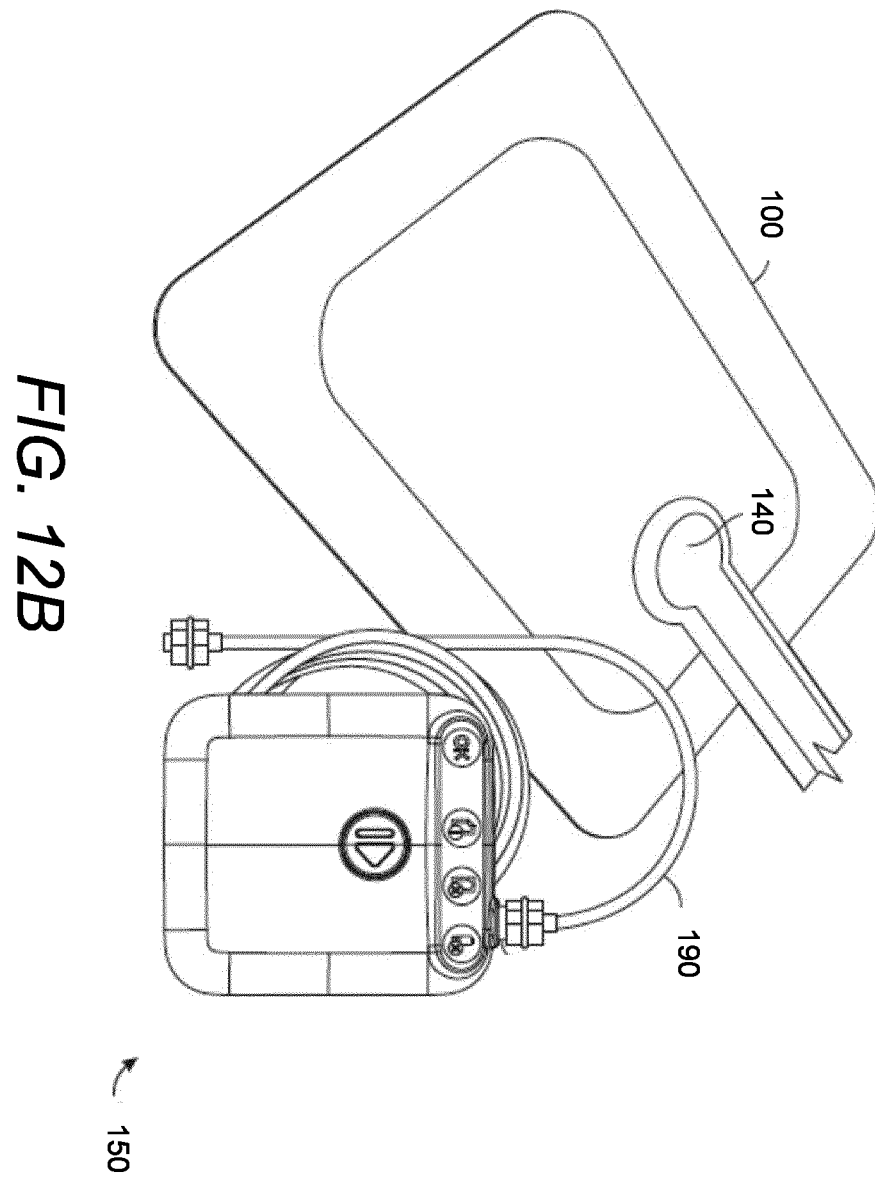


FIG. 12A



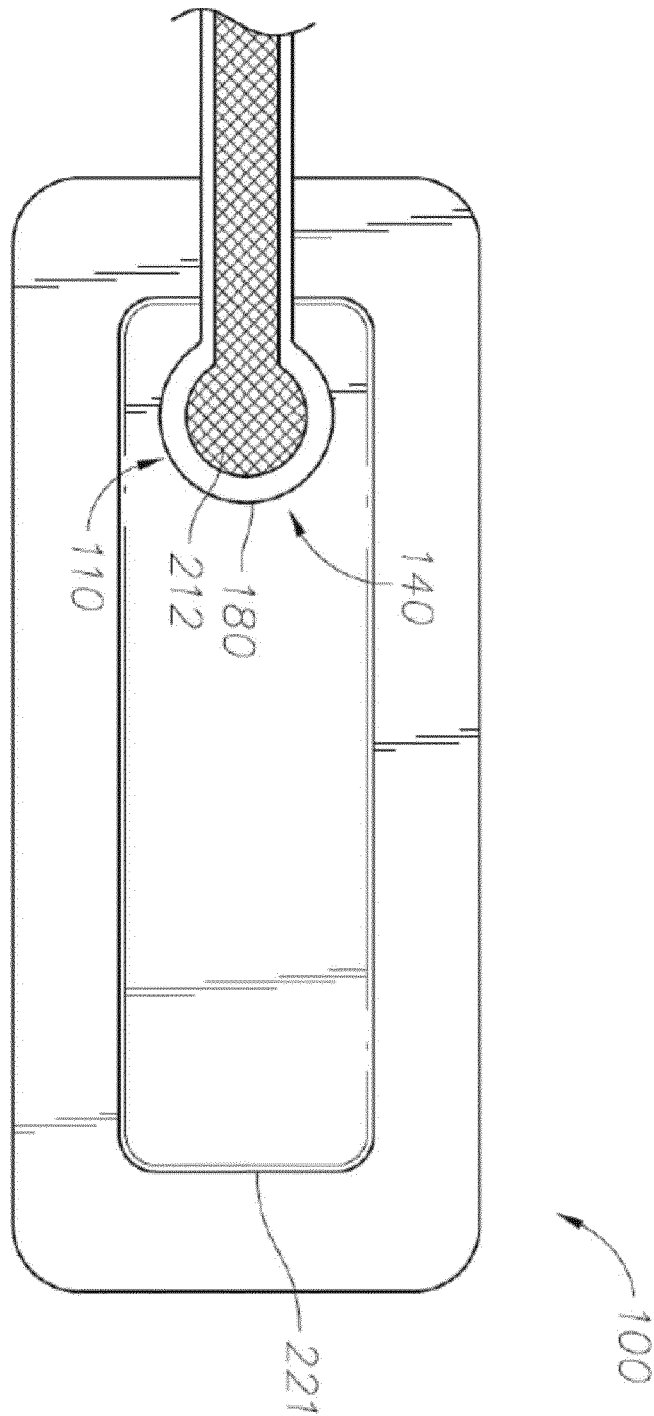


FIG. 12C

12/25

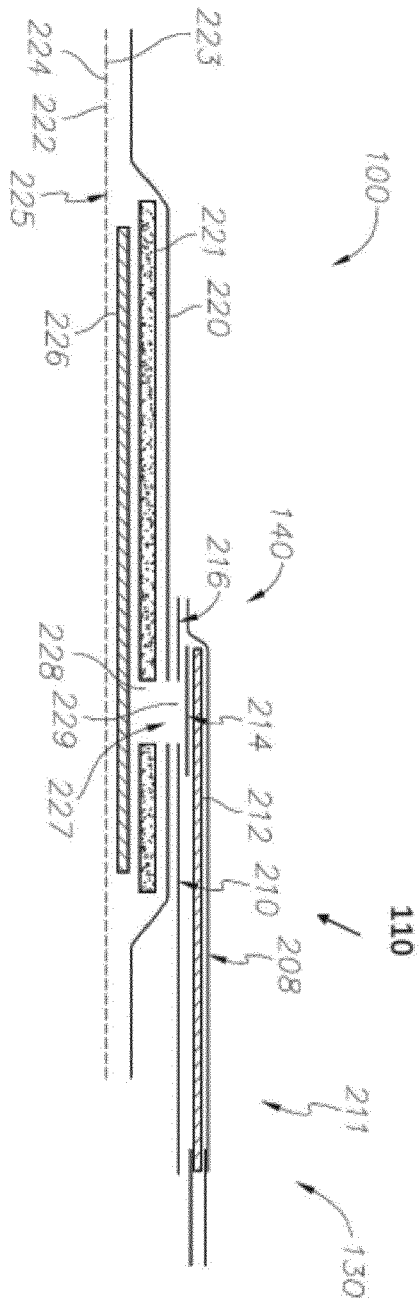


FIG. 12D

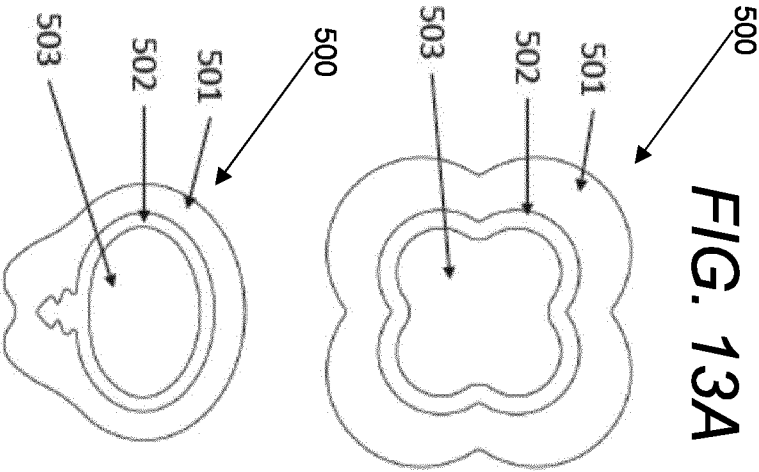


FIG. 13C

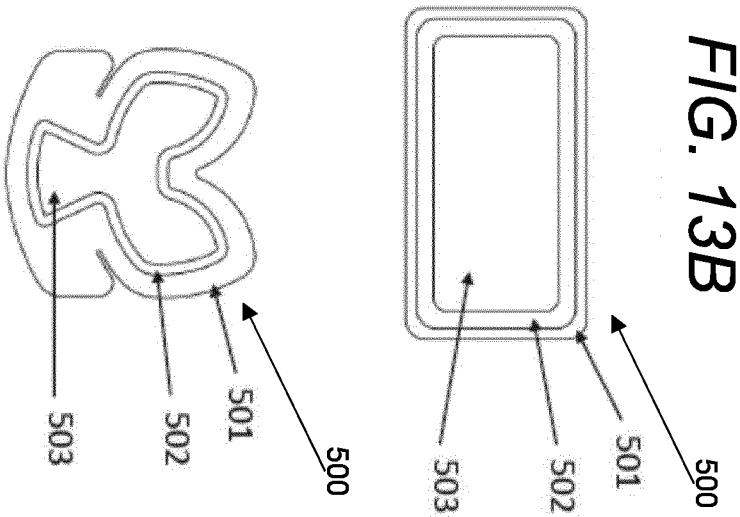
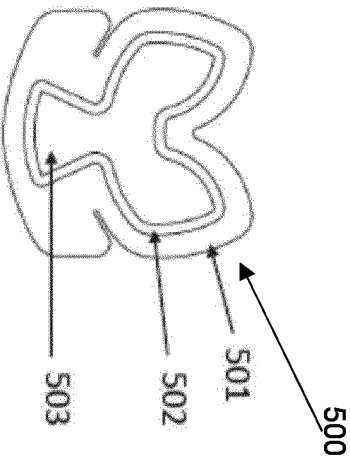


FIG. 13D



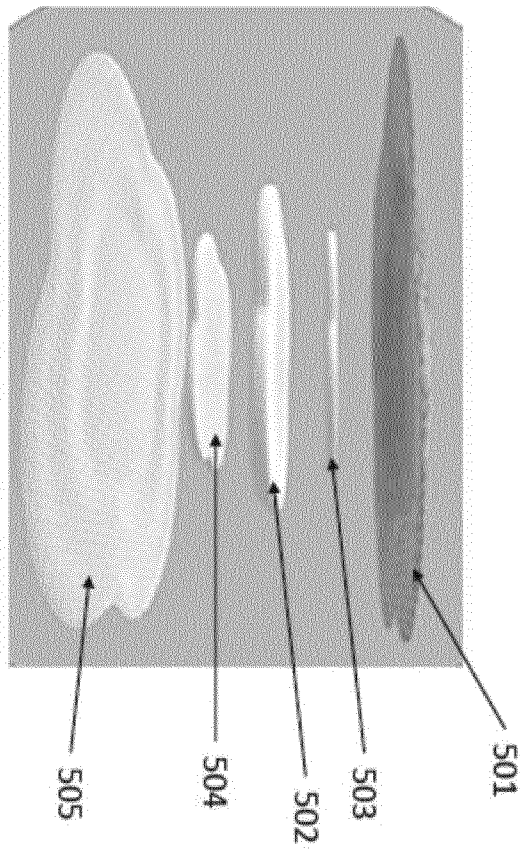
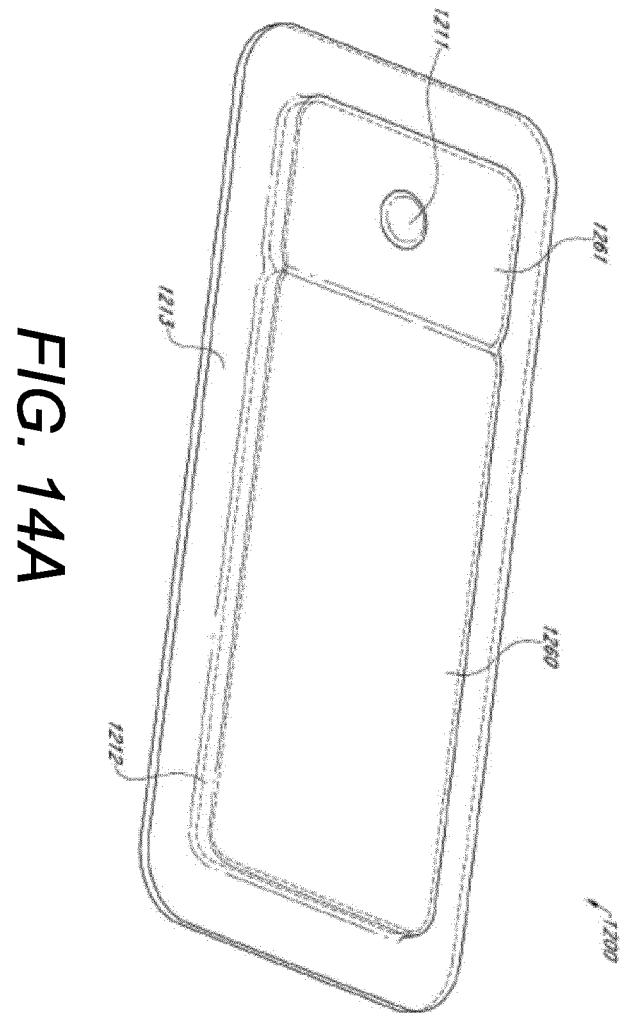


FIG. 13E



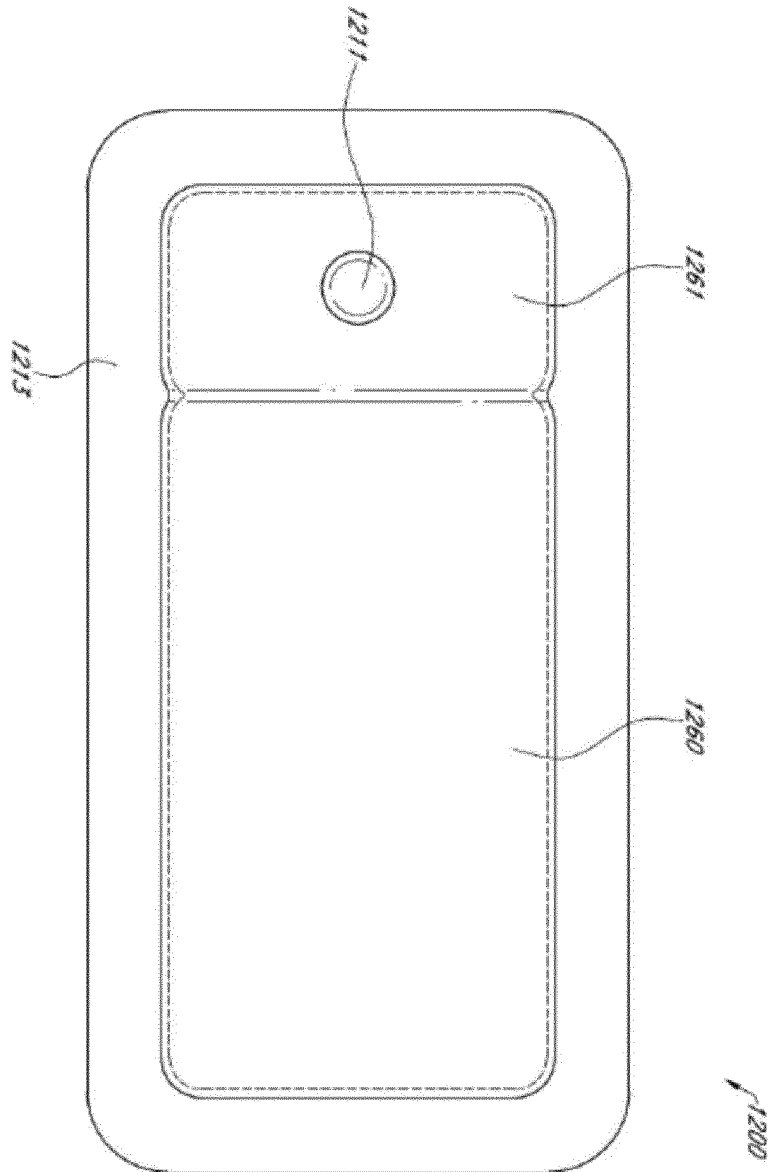
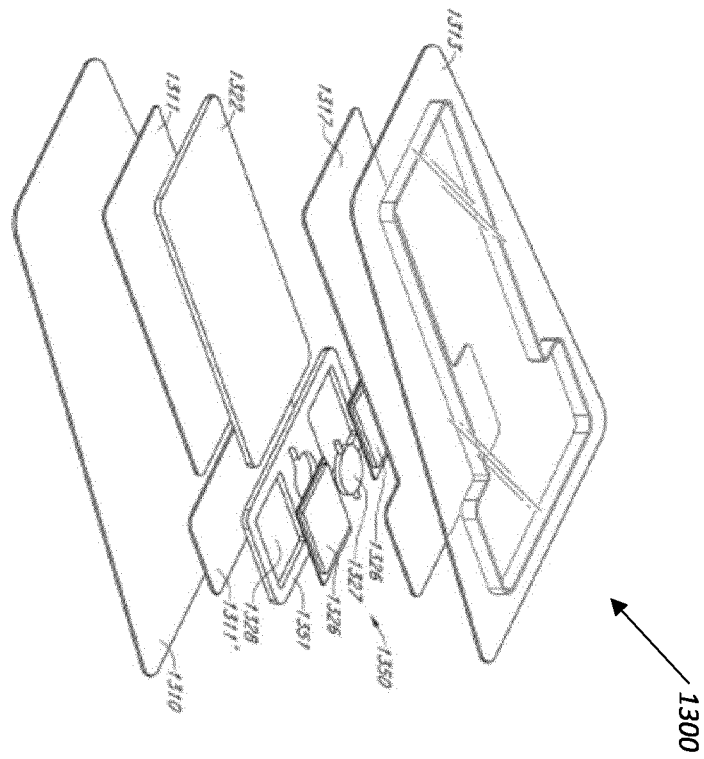


FIG. 14B

FIG. 14C



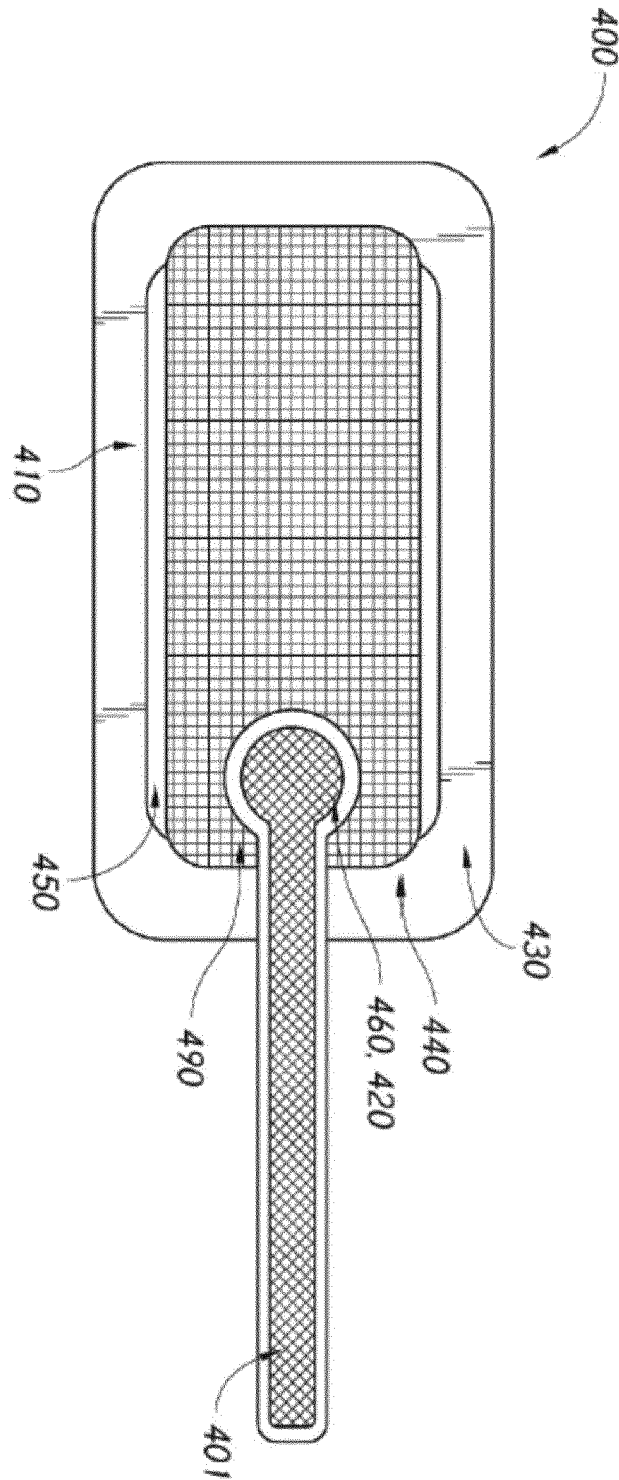
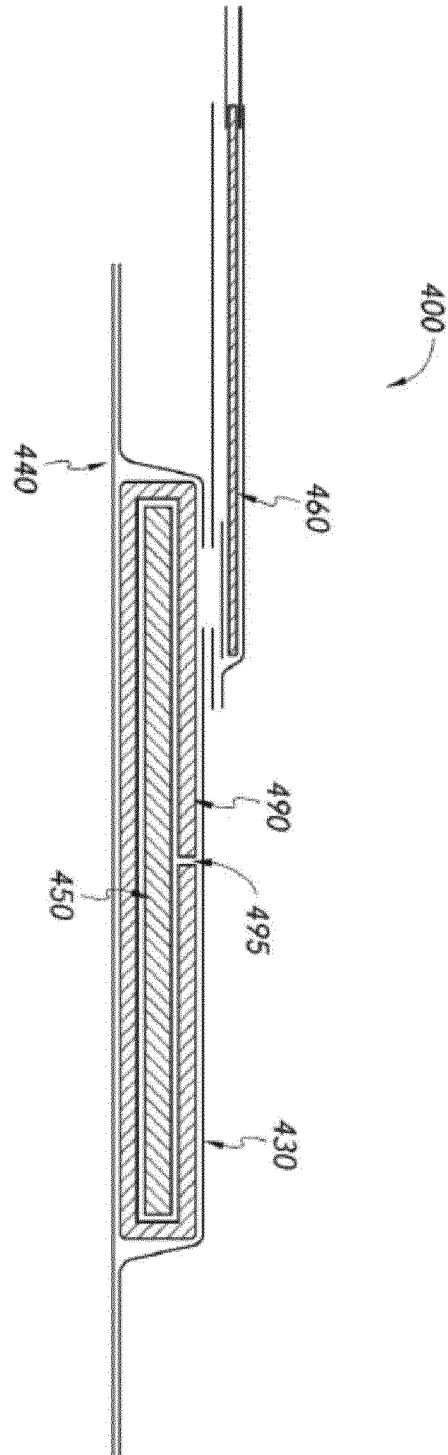
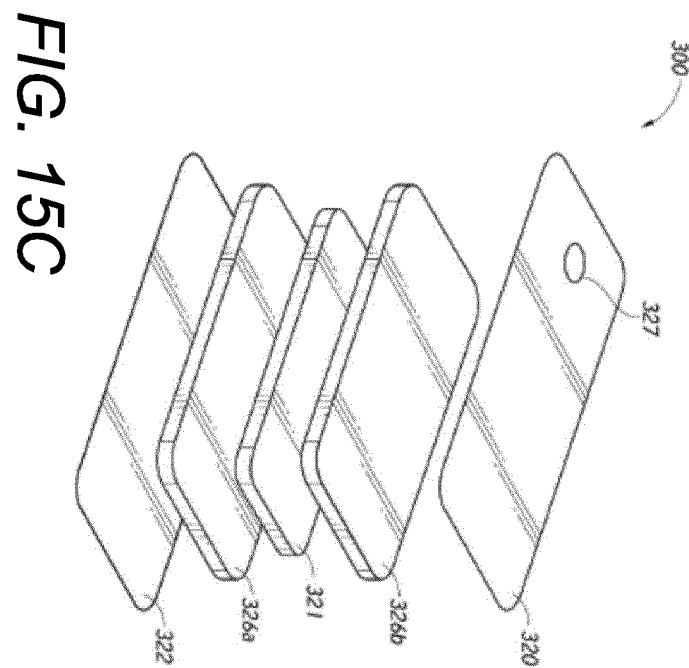
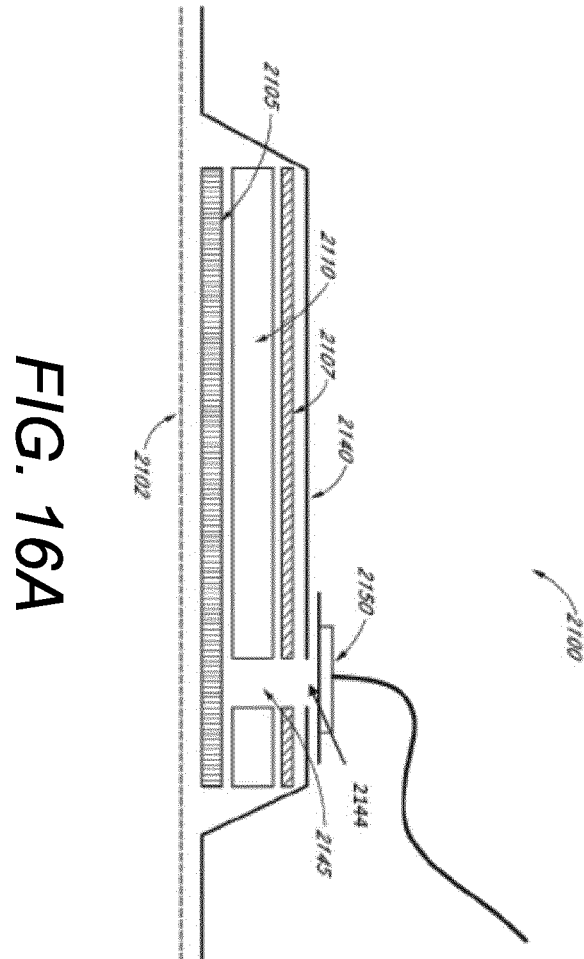
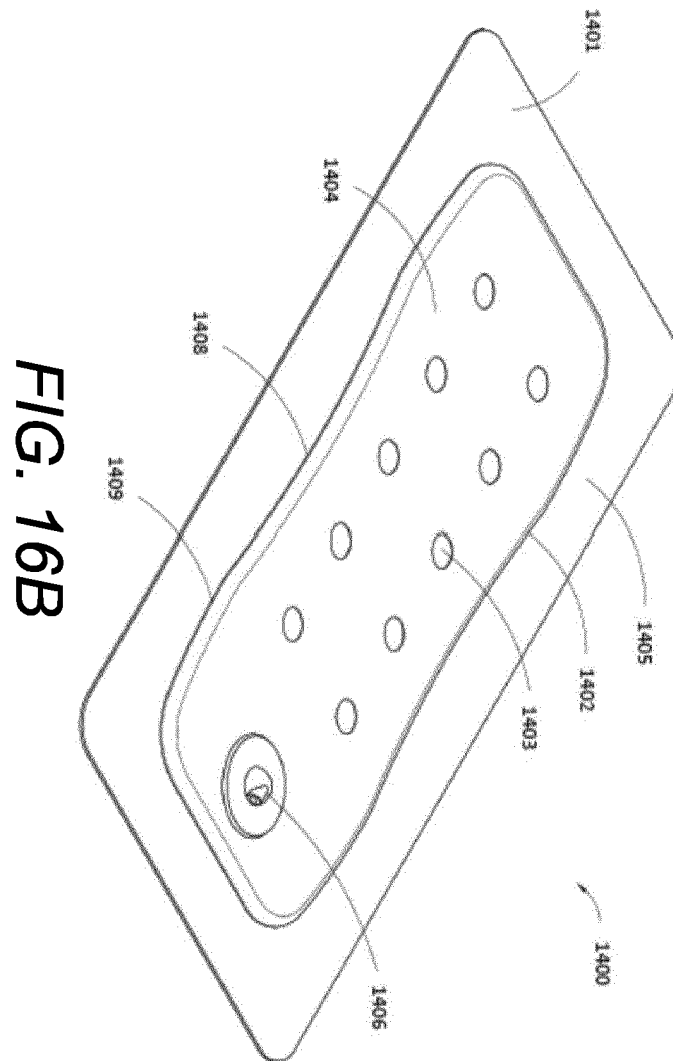


FIG. 15A

**FIG. 15B**







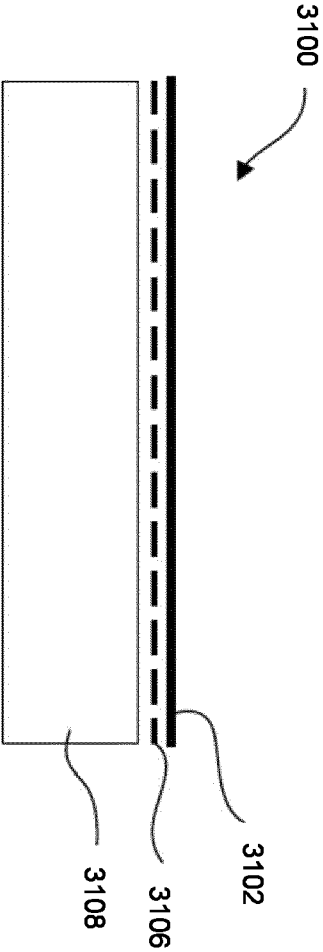


FIG. 17

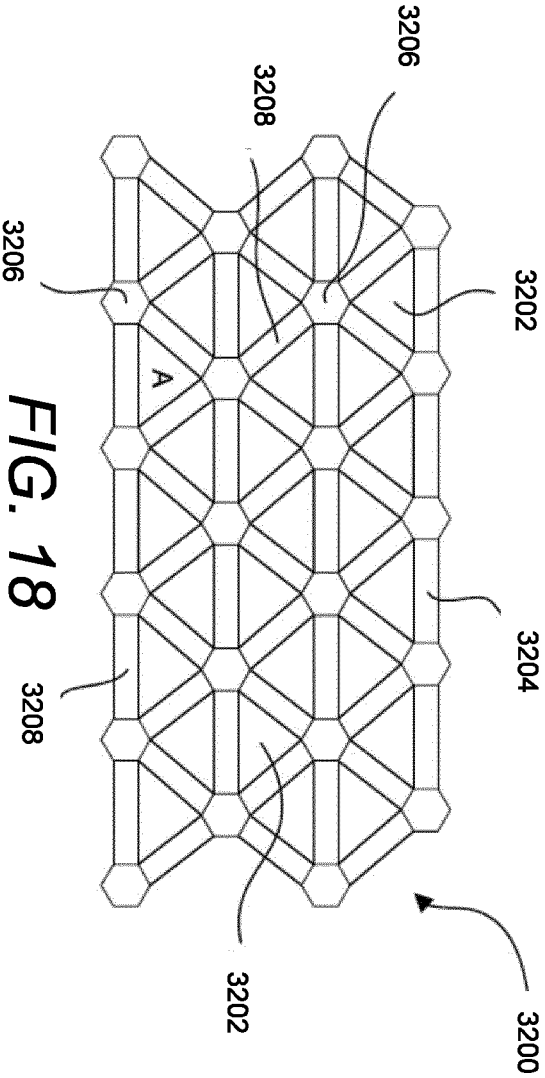
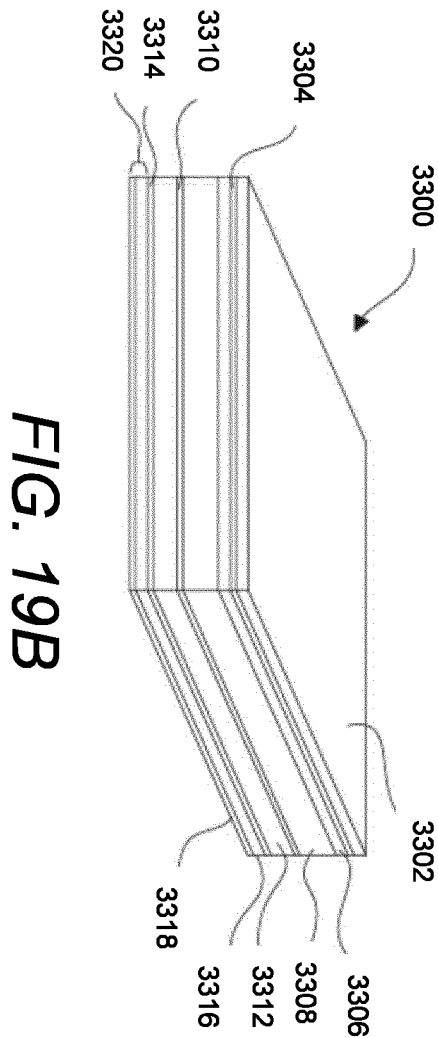
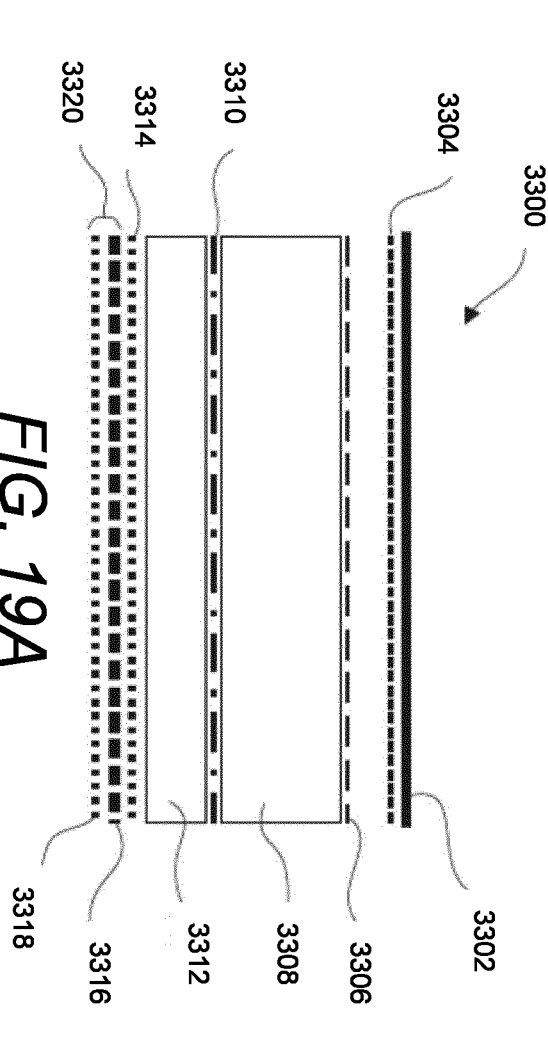


FIG. 18



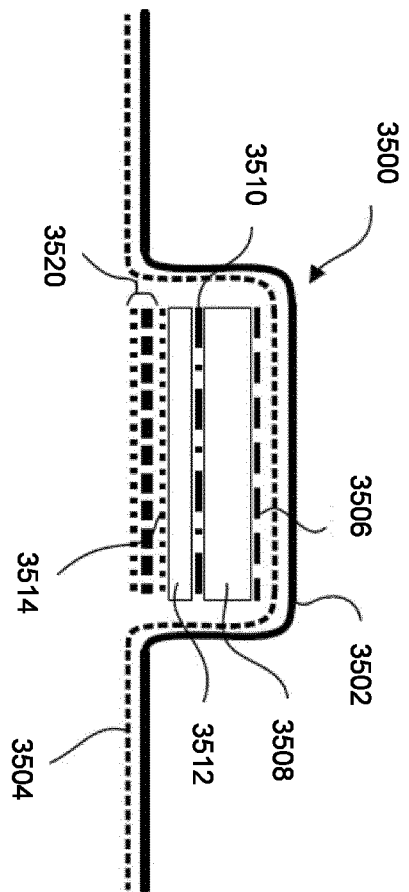


FIG. 20

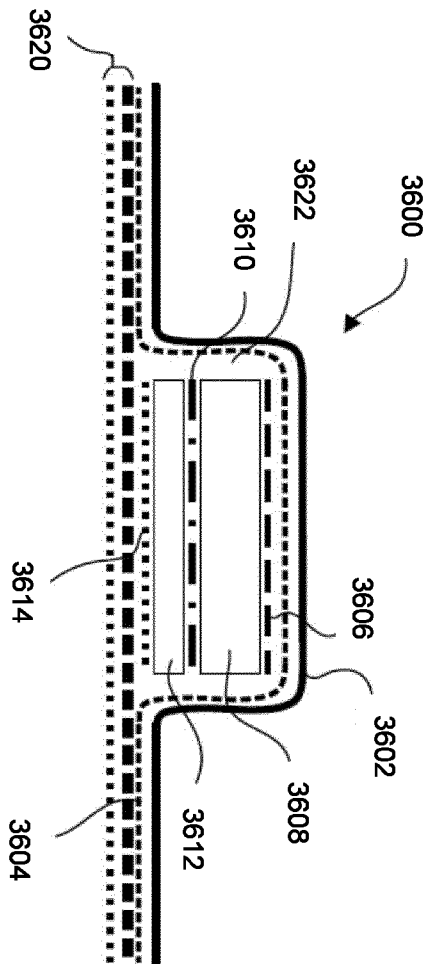


FIG. 21

Fig. 1a-k Symmetric composite (powder charge) loaded matrix

