(12) UK Patent Application (19) GB (11) 2468905 (13) A

(43) Date of A Publication 29.09.2010

(21) Application No: 0905226.7

(22) Date of Filing: 27.03.2009

(71) Applicant(s):
Brightwake Limited
(Incorporated in the United Kingdom)
Sidings Road, Lowmoor Industrial Estate,
Kirkby-in-Ashfield, NOTTINGHAM, NG17 7JZ,
United Kingdom

(72) Inventor(s):
Stephen Cotton

(74) Agent and/or Address for Service:
AdamsonJones
BioCity Nottingham, Pennyfoot Street, Nottingham,
NG1 1GF, United Kingdom

(51) INT CL:
A61F 13/00 (2006.01)

(56) Documents Cited:
WO 2009/071938 A1 **WO 2009/071928 A1**
WO 2008/021212 A3 **US 5470625 A**
US 20080009812 A1

(58) Field of Search:
INT CL **A61F**
Other: **EPODOC, WPI**

(54) Title of the Invention: **Wound packing material**
Abstract Title: **Wound packing element**

(57) A wound packing element 1 comprising a three-dimensional textile material with sealed edges 6. The element 1 can be used for packing a wound cavity e.g. for negative pressure wound therapy (NPWT). The element 1 may be compressible. The edges 6 of the element may be sealed by heat or ultrasonics. More than one wound element 1 may be used in a layered assembly.

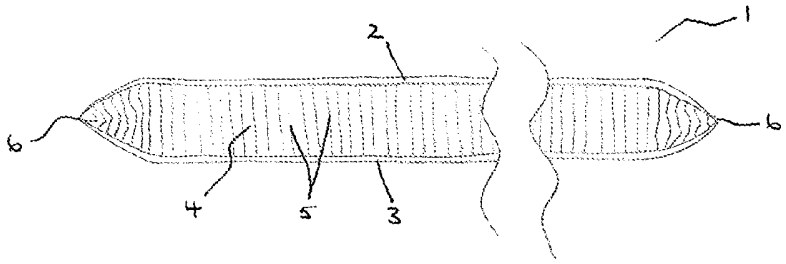

FIGURE 1

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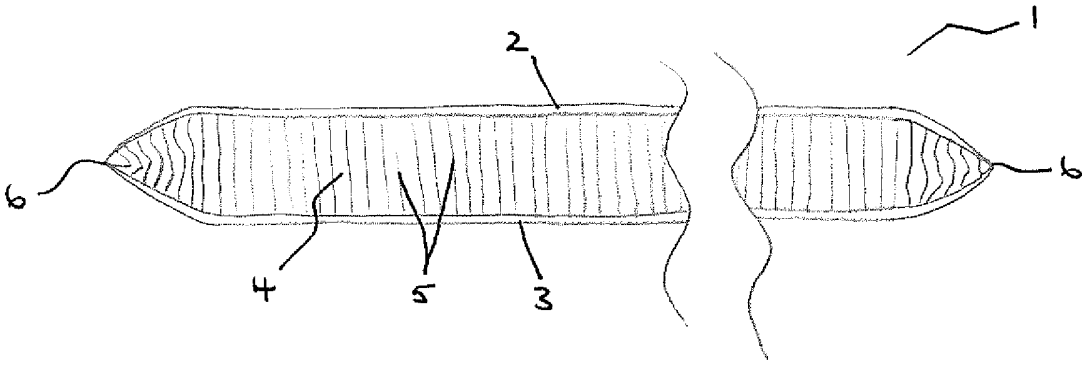

FIGURE 1

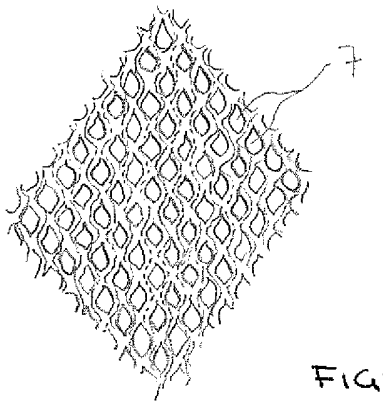

FIGURE 2

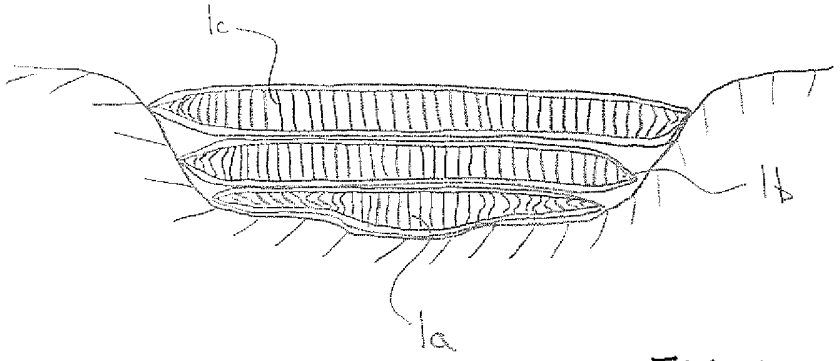

FIGURE 3

Title – Wound packing material

Field of the Invention

This invention relates to the packing of wound cavities. More specifically, the invention relates to wound packing elements, to layered assemblies of wound packing elements, and to their use for packing wound cavities. The invention has particular utility in negative pressure wound therapy.

Background of the Invention

Vacuum-assisted closure, also called negative pressure wound therapy (NPWT), is a technique designed to promote the formation of healthy granulation tissue, and may be used to enhance healing in chronic, acute and hard-to-heal wounds. In large, open wounds, a packer is required to fill the wound cavity and to support and aid the positioning of a drainage tube. An occlusive dressing is used to cover the wound bed and form a seal or gasket beneath which the vacuum is formed. The dressing must be adhered to viable dermal tissue surrounding the wound and pinched around the drainage tube to ensure a proper seal. Negative pressure is then applied and the wound fluid is collected. If a suitable packer is not utilised, the dressing is sucked into the wound cavity and thus does not form an effective seal.

The wound packer must be non-adhesive and porous, and must contact the entire wound. Currently, open cell foams or gauzes are used to pack the wound cavity in NPWT.

When gauze is used, it is typically applied as a single layer, a drain is placed on the gauze and then a second piece of gauze is placed over the drain, creating a “gauze-sandwich”. The gauze may be impregnated, eg with antimicrobials.

More commonly, foams are used as packing materials in NPWT. Examples of commercially available foams include polyurethane foam (black) and polyvinylalcohol (PVA) (white) foam. PVA foam has smaller pores compared to polyurethane foam and, because of its higher density, requires higher negative pressures than PVA to work effectively. The choice of foam depends on the application; for example, the more porous polyurethane foam is more commonly used on larger or deeper wounds. A combination of polyurethane and PVA foam can be used, depending on the desired result. Foams are usually cut to fit the size and shape of the wound. More than one piece of foam can be used if necessary. However, each piece of foam must come into contact with another piece of foam to achieve uniform compression when negative pressure is applied.

The current choice of packing materials suitable for NPWT is limited.

Furthermore, there are difficulties and risks associated with the packing materials that are currently available. For example, it is not always easy to cut the packing to fit the size and shape of the wound bed. The packing may stick to the wound, causing pain to the patient during dressing. There is also a risk that a piece of foam or gauze fibre will become detached and remain in the wound, leading to a foreign body reaction or the formation of an abcess. Foam materials, in particular, do not permit the ready flow of air, and are subject to clogging with wound exudate.

There has now been devised an alternative packing material, for use in NPWT, that overcomes or substantially mitigates the above-mentioned and/or other disadvantages of the prior art.

Brief Summary of the Invention

According to a first aspect of the invention, there is provided a wound packing element comprising a three-dimensional textile material with sealed edges.

In large wounds, wound packing elements may be stacked or layered upon each other in order to fill the wound cavity. Alternatively, a wound packing element may be rolled, folded or crumpled to fit a wound cavity.

Thus, according to a second aspect of the invention, there is provided a wound packing comprising a layered assembly of two or more wound packing elements, wherein the wound packing elements comprise a three-dimensional textile material with sealed edges.

In a further aspect of the invention there is provided the use of one or more wound packing elements for packing a wound cavity, wherein the one or more wound packing elements comprises a three-dimensional textile material with sealed edges.

In a yet further aspect of the invention, there is provided a method for packing a wound cavity, which method comprises placing within the wound cavity a wound packing element comprising a three-dimensional textile material with sealed edges.

In a yet further aspect of the invention, there is provided a method for packing a wound cavity, which method comprises forming a layered assembly of wound packing elements, wherein some or all of the wound packing elements comprise a three-dimensional textile material with sealed edges.

The methods of the invention are particularly useful for packing a wound cavity in negative pressure wound therapy.

By “three-dimensional textile material” is meant in the context of the invention a textile material with a structure such that the textile material has a substantial thickness, ie the textile material is bulky in the dimension that is transverse to the plane of the textile material. Generally, such a textile material will be compressible, such that its thickness may be reduced

substantially, eg by a factor of 2 or more, by the application of mechanical force.

The three-dimensional textile material is preferably a knitted textile material.

The three-dimensional textile material is preferably a "double-faced" or "spacer" fabric. Spacer fabrics comprise two distinct face layers of fabric joined together by a connecting layer. The connecting layer most commonly has the form of connecting pile threads that extend between the two outer face layers. The two outer face layers may be the same or different. Most preferably, each face layer will have a knitted structure with a regular array of openings. The size and/or arrangement of the openings in the two face layers may be the same or different.

The connecting layer comprises threads, eg monofilaments or yarns, that connect the two face layers. Typically the spacer fabric is knitted such that the connecting threads are arranged substantially perpendicular to the two face layers. The distance between the two face layers, ie the thickness of the spacer fabric, is determined by the length of the connecting threads. The properties of the spacer fabric may also be varied by appropriate choice of the type of connecting thread and by varying the density of the connecting threads.

Preferably the connecting threads are of a continuous filament, mono-filament or multi-filament, textured or un-textured (eg BCF) or long staple spun yarn made from synthetic fibre, eg polyamide, polyester or viscose, or natural fibre (eg cotton), or a blend of synthetic and/or natural fibre.

The three-dimensional textile material may be laminated on the face, back or both sides with a perforated plastic film or a permeable non-woven material, or may be incorporated into a bag of such material. This may improve the non-adherent or filtration properties of the three-dimensional textile material and prevent any shedding of fibres.

Spacer fabrics are currently used in a variety of industries including medical, healthcare and hygiene areas. The current use of spacer fabrics in medical applications is limited, however, to external application to the skin, eg as a bandage or support, or as coverings, eg as a mattress cover. For example, current medical applications of spacer fabrics that are of particular interest are in bandaging or dressings, use in orthopaedic medicine, and use for preventing bedsores.

The use of spacer fabrics, or any other three-dimensional fabrics, for packing a wound cavity or, more specifically, for packing a wound cavity in negative pressure wound therapy, has not previously been disclosed.

The wound packing element according to the invention is advantageous primarily because of the ready flow of air through the textile material. This characteristic is particularly useful for applications in negative pressure wound therapy. The construction of the textile material is easily varied to achieve the desired permeability for a particular application. In particular, the spaces within the textile material provide excellent air permeability, which may be controlled by varying the size of the space (ie the thickness) and the density or pile relative to the fabric area. In addition, the outer face layers may be knitted with a varying degree of open or close knit.

Three-dimensional textile materials, and in particular spacer fabrics, have temperature regulating properties, moisture-transporting ability, are compression resistant and have good surface resistance. Again, the extent of these properties can be controlled by the fabric construction.

The structure of spacer fabrics is especially beneficial for wound packing applications because air and moisture flow is enabled without the packing becoming clogged by wound exudates.

The wound packing elements according to the invention are highly conformable, and this is advantageous because a wound packing should fit the contours of wound cavity as closely as possible. Moreover, the wound packing elements may be produced with varying rigidity/conformability, as required for a particular application, eg if compression is required.

Further advantages include the biocompatibility and resilience of the wound packing elements of the invention. They have a considerable shelf-life prior to use, they do not degrade in the body and can be removed without breaking up and leaving fragments in the wound cavity.

The wound packing elements of the invention are additionally advantageous because they are comfortable for use. In particular, they are soft, cushioning and lightweight.

The wound packing elements of the present invention and the layered assembly of said wound packing elements allow an even distribution of pressure to be achieved. This is particularly important in negative pressure wound therapy, for which the wound packing elements of the present invention and the layered assembly of said wound packing elements may provide significant improvements over current packing materials.

Detailed Description of the Invention

The three-dimensional textile materials used in the present invention may be manufactured from a variety of materials, depending on *inter alia* the absorption properties desired. In most cases it is desirable for the wound packing element to be non-adhesive, so that it is easily removed from the wound without causing pain or aggravating the wound tissue. It is thus preferable for the outer face layers to be made from synthetic yarns, eg acrylic, nylon or polyester.

Where the three-dimensional textile material is a spacer fabric, the outer face layers, which may be made from the same or different material, may be made from the same material or different material to the connecting threads.

Preferably the connecting threads are made from polyamide, polyester, viscose or natural fibres such as cotton.

The three-dimensional textile material may be impregnated or coated with one or more active agents. Active agents may be used, for example, to facilitate and accelerate healing of the wound, to prevent or reduce malodour, to minimise pain, and/or to prevent or counteract infection. In particular, the three-dimensional textile material may be impregnated with an antimicrobial agent.

Three-dimensional textile materials suitable for use in the present invention preferably have a thickness of at least 1mm, more preferably at least 1.5mm, more preferably at least 2mm and most preferably at least 3mm. Three-dimensional textile materials suitable for use in the present invention preferably have a thickness of up to 60mm, more preferably a thickness of up to 20mm, more preferably a thickness of up to 15mm, and most preferably a thickness of up to 10mm. Accordingly, three-dimensional textile materials suitable for use in the present invention preferably have a thickness in the range of 1mm to 60mm, more preferably 1.5mm to 20mm, more preferably 2mm to 15mm and most preferably 3mm to 10mm.

The wound packing element according to the present invention is supplied to the user in a pre-cut form with sealed edges. It is desirable to seal the edges to prevent loss of fibres, to prevent/minimise irritation and discomfort, and to minimise attachment of the packing element, eg by cellular infiltration/ingrowth and tissue integration.

For the above reasons, it is similarly desirable to avoid the protrusion of connecting threads from the surface of the two outer face layers.

The edges of the three-dimensional textile material may be sealed by any technique known in the art that is suitable for the type of fabric concerned. Most commonly, the edges of the textile material may be sealed using heat or ultrasonics. For example, the three-dimensional textile material may be hot cut, and in particular hot press cut, thereby fusing the two outer face layers together and creating a heat seal. In certain cases a seal may be created without the use of a heating element, eg by press-cutting the textile material, if the pressure applied is sufficient to fuse the face layers together, or by sewing of the edges, eg over-locking the edges.

In embodiments of the invention in which a wound packing is constructed by forming a layered assembly of wound packing elements, the wound packing may be supplied to the user as a composite product or, as more commonly, the wound packing elements may be supplied as individual products and applied separately to fill the wound cavity.

The wound elements of the present invention (and any composite product) may be supplied as a sterilised product, or sterilised before use.

The production of spacer fabrics, for use in the present invention, is possible on weft knitting machines, eg dial and cylinder, v-bed and purl machines, and on warp knitting machines, eg Raschel machines.

Weft-knitted spacer fabrics may be produced in which loops formed across the width of the fabric create an inelastic structure offering high levels of compression and support. Warp-knitted fabrics offer greater flexibility and elasticity due to the formation of loops along the length of the fabric.

Raschel machines are thought to have the greatest production capabilities at the present time, compared to the above-mentioned knitting machines, due to greater range in yarn tex, higher production speeds, and the ability to adjust the distance between the two needle bars giving greater opportunity for

spacer thickness. In particular, Raschel machines produce both outer layers simultaneously on their own needle beds, and thus it is possible for the front and back to use different yarns and have completely different structures.

Raschel machines that are suitable for producing spacer fabric for use in the present invention include machines supplied by KARL MAYER Textilmaschinenfabrik GmbH, Brühlstraße 25, 63179 Obertshausen, Germany. Specific machines that may be suitable include those supplied by Karl Mayer under the names RD4N and RD6N.

Embodiments of the invention will now be described in greater detail, by way of illustration only, with reference to the accompanying drawings, in which

Figure 1 is a cross-sectional view, schematic and not to scale, of a wound packing element according to the invention;

Figure 2 is a fragmentary view of the surface of the wound packing element of Figure 1, showing a pattern of openings in the knitted structure; and

Figure 3 is a cross-sectional view, schematic and not to scale, of a wound packing comprising a layered assembly of the wound packing elements of the type shown in Figure 1.

Referring first to Figure 1, a wound packing element according to the invention is generally designated 1. The wound packing element 1 comprises an upper face layer 2, a lower face layer 3, and a connecting layer 4 which comprises connecting threads 5 that extend between the upper face layer 2 and lower face layer 3.

At the edges of the wound packing element 1, the upper face layer 2, the lower face layer 3 and the connecting layer 4 are fused together to create a seal 6. The connecting threads 5 are collapsed or flattened as the upper face layer 2 and lower face layer 3 approach each other at the sealed edge 6.

Figure 2 shows the knitted structure of the upper face layer 2 of the wound packing element 1 shown in Figure 1, with a regular array of openings 7.

The lower face layer 3 shown in Figure 1 may have the same knitted structure as the upper face layer 2 or a different knitted structure. In some embodiments, the lower face layer 3 has a different knitted structure, for example with smaller openings.

Figure 3 shows three wound packing elements 1a,1b,1c of different sizes, which are layered or stacked inside a wound cavity. The wound packing elements are selected according to their size and shape in order to entirely fill the cavity, following the contours of the cavity walls as closely as possible.

Claims

1. A wound packing element comprising a three-dimensional textile material with sealed edges.

2. A wound packing element as claimed in Claim 1, wherein the thickness of the three-dimensional textile material may be reduced by a factor of 2 or more by the application of mechanical force.

3. A wound packing element as claimed in Claim 1 or Claim 2, wherein the three-dimensional textile material is a spacer fabric.

4. A wound packing element as claimed in any preceding claim, wherein the three-dimensional textile material has a thickness of at least 1mm, more preferably at least 1.5mm, more preferably at least 2mm and most preferably at least 3mm.

5. A wound packing element as claimed in any preceding claim, wherein the three-dimensional textile material has a thickness of up to 60mm, more preferably a thickness of up to 20mm, more preferably a thickness of up to 15mm, and most preferably a thickness of up to 10mm.

6. A wound packing element as claimed in any preceding claim, wherein the three-dimensional textile material has a thickness in the range of 1mm to 60mm, more preferably 1.5mm to 20mm, more preferably 2mm to 15mm and most preferably 3mm to 10mm.

7. A wound packing element as claimed in any preceding claim, wherein the edges of the three-dimensional textile material are sealed using heat.

8. A wound packing element as claimed in any one of Claims 1 to 6, wherein the edges of the three-dimensional textile material are sealed using ultrasonics.

9. A wound packing comprising a layered assembly of two or more wound packing elements as claimed in any preceding claim.

10. Use of one or more wound packing elements as claimed in any one of Claims 1 to 8, for packing a wound cavity.

11. A method for packing a wound cavity, which method comprises placing within the wound cavity a wound packing element as claimed in any one of Claims 1 to 8.

12. A method for packing a wound cavity, which method comprises forming a layered assembly of wound packing elements, wherein some or all of the wound packing elements comprise a three-dimensional textile material with sealed edges.

Application No:	GB0905226.7	**Examiner:**	Dr Matthew Parker
Claims searched:	1-9	**Date of search:**	26 February 2010

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-9	WO2009/071938 A1 (SMITH), see especially Figures 4 and 5
X	1-9	WO2009/071928 A1 (SMITH), see page 5, line 32, to page 6, line 10
X	1-9	WO2008/021212 A3 (PAYLOAD), see especially Figure 4B
X	1-9	US2008/0009812 A1 (REISINGER), see wound filler 11
X	1-9	US5470625 A (PERRAULT), see column 2, lines 38-50

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61F

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
A61F	0013/00	01/01/2006