(19) DANMARK

(10) DK/EP 2293752 T3

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: *A 61 F 13/00 (2006.01)*

(45) Oversættelsen bekendtgjort den: **2016-08-15**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2016-06-29**

(86) Europæisk ansøgning nr.: **09742356.0**

(86) Europæisk indleveringsdag: **2009-05-08**

(87) Den europæiske ansøgnings publiceringsdag: **2011-03-16**

(86) International ansøgning nr.: **GB2009001138**

(87) Internationalt publikationsnr.: **WO2009136160**

(30) Prioritet: **2008-05-08 GB 0808376**

(84) Designerede stater: **AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK TR**

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(54) Benævnelse: **SÅRBANDAGE**

(56) Fremdragne publikationer:
WO-A1-93/11805
DE-U1- 20 118 880
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DESCRIPTION

[0001] This invention relates to a wound dressing, in particular to ribbon or strip dressing of the type composed of gel forming fibres in the form of a woven or non woven layer or layers. In particular the invention relates to dressings comprising gel forming fibres used in the treatment of sinus or cavity wounds or post-operative wounds.

[0002] It is known to use carboxymethylated cellulosic materials in situations where a high degree of exudate absorption is required. For example, WO 93/12275 describes the production of various absorbent products capable of absorbing many times their own weight of water. This causes the carboxymethylated fibres to form a gel. WO 94/16746 and WO 00/01425 describe the use of carboxymethylated Lyocell materials in wound dressings where the advantages of gel formation in preventing adherence and therefore reducing wound damage and pain on removal are discussed. US 5 807 295 A discloses a medical bandaging material, for example, for use as a wound dressing, soft-tissue support bandage, brace or orthopaedic splinting bandage, comprises two superposed layers of, for example, a woven, knitted or non-woven material spaced apart by strands of mono-filamentary or fibrous layers. The interstitial spaces may be filled with a hardenable resin and/or pharmacologically active agent. WO 93/11805 A1 discloses biomaterials comprised of biodegradable, biocompatible, and bioabsorbable composite membranes for use in surgery for the guided regeneration of tissues. The composite membranes are comprised of threads embedded in a matrix, wherein both the matrix and the threads can be comprised of esters of hyaluronic acid, used singly or in combination, or esters of hyaluronic acid in combination with esters of alginic acid or other polymers. US2007042024 A1 discloses a material for use as a wound dressing, the material being in the form of a roll and comprising gel forming fibers and the material having lines of longitudinal stitching.

[0003] Known wound dressings comprising gel forming fibres are essentially flat, rectangular and fairly small, typically 20cm X 15cm. The usefulness of such dressings is limited in respect of sinus or cavity wounds due to difficulty in removing the dressing from such a wound. The gel-forming fibres gel on absorption of exudate and consequently lose tensile strength once in a gelled state. This presents a problem when the dressing needs to be removed as removal generally is done by pulling the ribbon out of the wound from one end of the ribbon. The loss of tensile strength means that the dressing fragments on removal and has to be removed in many pieces or by flushing.

[0004] However it would be desirable to bring the advantages of gel forming fibre dressings to cavity wounds by having the dressings available in a strip form with sufficient tensile strength to enable the dressing to be removed in one piece from the wound once it has gelled and to be removed in one piece regardless of which part of the dressing is grasped in the removal.

[0005] It is known to form ribbon dressings with a reinforcing scrim in order to improve the tensile strength of the dressing. There are however disadvantages in doing so. The scrim detracts from the absorbency of the dressing and can create a physical barrier to absorption. The scrim also renders the dressing opaque which means that the wound and surrounding skin cannot be observed once the dressing is in situ.

[0006] It is known to increase the tensile strength of bandages by stitching the bandage along its length with one or more lines of stitching. However when longitudinal stitching is applied to a thin strip it gives strength only in the stitching direction and restricts how the dressing can be removed.

[0007] The present invention therefore seeks to provide an improved wound dressings which mitigates the problems associated with ribbon dressings in cavity or sinus wounds.

[0008] We have now found that it is possible to improve the tensile strength of strip dressings in a dry or wet (gelled) state.

[0009] Accordingly the invention provides a wound dressing comprising a layer in the form of a strip characterised in that the strip comprises gel forming fibres, the strip having longitudinal lines of stitches formed from a thread and transverse lines of stitches formed from a thread, where the thread is nylon, Tencel, polyolefin, polyurethane, polyester or cellulosic and the wound dressing is for use in cavity wounds or sinus wounds.

[0010] The longitudinal stitching is longitudinal in that it is generally parallel to the long dimension of the strip.

[0011] The transverse stitching is transverse in that it joins the longitudinal lines of stitches together and in some embodiments is generally perpendicular to the long dimension of the strip.

[0012] The thread may be a single filament or multiple filament yarn or a staple fibre yarn. The thread is nylon, Tencel,

polyolefin, polyurethane, polyester or cellulosic. The thread can be impregnated with an active agent for example with an antimicrobial agent.

[0013] Such dressings are suited to treating sinus or cavity wounds, post operative or surgical wounds or any wound that needs to be packed.

[0014] The longitudinal stitching preferably passes through the whole thickness of the strip and can be visible on both sides of the strip. The transverse stitching may also pass through the whole thickness of the strip or may be present on one side only of the strip or both.

[0015] By gel forming fibres is meant hygroscopic fibres which upon the uptake of wound exudate become moist slippery or gelatinous and thus reduce the tendancy for the surrounding fibres to adhere to the wound. The gel forming fibres can be of the type which retain their structural integrity on absorbtion of exudate or can be of the type which lose their fibrous form and become a structureless gel. The gel forming fibres are preferably spun sodium carboxymethylcellulose fibres, chemically modified cellulosic fibres, pectin fibres, alginate fibres, chitosan fibres, hyaluronic acid fibres, or other polysaccharide fibres or fibres derived from gums. The cellulosic fibres preferably have a degree of substitution of at least 0.05 carboxymethyl groups per glucose unit. The gel forming fibres preferably have an absorbency of at least 2 grams 0.9% saline solution per gram of fibre (as measured by the free swell method).

[0016] Preferably the gel forming fibres have an absorbency of at least 10g/g as measured in the free well absorbency method, more preferably between 15g/g and 25g/g.

[0017] The dressing may for instance comprise non gel forming fibres and in particular may comprise lycra or other elastic fibre.

[0018] The dressing may be in the form of 0.5, 1, 2 or more metre lengths and be approximately 0.5 cm to 10cm wide, preferably from 0.5cm to 5cm wide. The longitudinal lines of stitching may be from 1mm to 10mm apart and are parallel to a long edge of the strip. Preferably, the longitudinal lines of stitching are from 2mm to 5mm apart. The lines of longitudinal stitching may be a lock stitch and may typically be crochet or chain stitch but other stitch patterns may also be used. The rows of transverse stitching may be from 1 to 10mm apart and preferably from 2 to 5mm apart. The transverse lines of stitches may be a pattern stitch and may be crocheted or may be a basting stitch between two layers of superposed gel forming fibres. Preferably, the lines of stitching are made in a thread such as Tencel. The transverse stitches serve to link adjacent longitudinal lines of stitches together to add strength to the dressing in a transverse direction. The transverse lines of stitches are preferably made in columns between pairs of adjacent longitudinal lines of stitches with stitch free gaps between the columns to allow a roll of stitched gelling fabric to be slit in the gaps. This allows strips to be formed without creating loose ends of transverse stitching at the edges of the strip. The transverse lines of stitching may be finished at the edges of the strip to reduce fraying.

[0019] Preferably the transverse stitching is made in a continuous zig zag between longitudinal lines of stitching. The lines of transverse stitching may be in the form of a continuous zig zag that extends in the columns between the longitudinal lines of stitching. The transverse lines of stitching can be perpendicular to the longitudinal stitching as in the case of a zig zag castellated pattern or at an angle to it as in a continuous zig zag angled pattern. The transverse lines of stitches may be stitched through the strip. The transverse lines of stitches may extend between the longitudinal lines of stitches and join them together.

[0020] Preferably the dressing comprises at least two longitudinal lines of stitching joined by a transverse line of stitching that runs in a column between the longitudinal lines. This allows the dressing to be slit from a roll with minimal loose ends of thread. More preferably the dressing comprises at least four longitudinal lines of stitching arranged as two or more pairs of lines where the longitudinal lines of stitching in each pair are joined by a transverse line of stitching in the form of a column. This arrangement allows the user to further cut the dressing in the stitch free gap between the pairs of longitudinal lines of stitching to create a narrower ribbon. The dressing comprises a second strip, superposed over the first strip wherein the longitudinal lines of stitches join the two strips together.

[0021] The dressing may comprise one or more medicaments. For example, an antimicrobial agent, or an antibiotic, or an anaesthetic on an antiinflammatory agent, or a skin protective agent, or an odour absorbing agent. The dressing may be treated with a source of silver to give antimicrobial properties to the dressing.

[0022] Carboxymethylation can be achieved, for example, by sequential or simultaneous treatment of the cellulosic material with a strong alkali, such as aqueous sodium hydroxide, and monochloroacetic acid or a salt thereof. The appropriate reaction conditions will depend upon the composition of the fabric and the degree of carboxymethylation required and will be readily apparent to the person skilled in the art. They may be identical or similar to those described in WO 93/12275, WO 94/16746 or

WO 00/01425 to which the reader is directed for further detail.

[0023] Desirably the carboxymethylation is carried out in the presence of industrial methylated spirits (IMS), and IMS is preferably also used in a subsequent washing step, suitably along with water, as a cleaner and steriliser. The degree of carboxymethylation is desirably such that upon absorption of exudate the fibres at the skin-contacting surface of the bandage form a gel.

[0024] The dressing may be used as part of a composite dressing.

[0025] In a further aspect the invention provides a method of manufacturing a wound dressing for use in cavity or sinus wounds characterised in that the method comprises the steps of:

1. (i) forming a roll of fabric comprising gel forming fibres;
2. (ii) stitching the roll with lines of longitudinal stitching;
3. (iii) stitching the roll with transverse stitching; and
4. (iv) slitting the roll in a longitudinal direction to form strips.

[0026] The roll of fabric may be formed by making a non-woven web of gel forming fibres. The roll of fabric may be formed by knitting a roll of gel forming fibres. The non-woven web may be made by hydroentangling a web of Lyocell fibres and carboxymethylating the so formed web. The method comprises the further step of superposing a second strip on the first strip before the strips are stitched together.

[0027] Preferably the transverse stitching is made in columns joining the longitudinal lines of stitching so that stitch free gaps are created between the columns. In this way a ribbon can be slit from the roll in the gaps so that minimal loose ends occur at the edges of the strip which could otherwise be lost into the wound. Preferably the columns of transverse stitches are secured so that there are no loose threads in the gaps between the columns and the edges of the ribbon or strip have no loose ends. Preferably the columns of transverse stitches are a continuous line of stitching which zig zags between the longitudinal lines of stitches. In this way the columns have stitch free gaps in the space between the columns which allow the roll to be slit into strips with no loose ends at their edges.

[0028] The lines of transverse stitching may be made in columns less than the width of the roll. The roll may be slit between the columns of transverse stitching so that the strip has no loose thread at its edges. The dressing may comprise at least two longitudinal lines of stitching. Preferably the dressing has several pairs of lines of longitudinal stitching with the lines in each pair joined by transverse stitching in a castellated pattern to create stitch free gaps between adjacent pairs of joined longitudinal lines of stitches. This allows the dressing to be cut into thinner ribbons by the user.

[0029] Use of a strip fabric in the manufacture of a wound dressing, the strip comprising gel forming fibres and having lines of longitudinal stitching and lines of transverse stitching for use in the treatment of cavity or sinus wounds.

[0030] Preferred embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a view of a layer of gel forming fibres in the form of a roll with longitudinal lines of stitching joined by transverse lines of stitching in the form of an angular zig zag prior to slitting.

Figure 2 is a view of a layer of gel forming fibres in the form of a roll with longitudinal lines of stitching and transverse lines of stitching in the form of a castellated pattern prior to slitting.

[0031] Figure 1 shows a non woven roll of gel-forming fibres made by a needle felting carding technique to form a web. Optionally the roll can have an antimicrobial material incorporated into it and in particular silver by the method described in WO 02/43743. The roll is stitched in the longitudinal direction with lines of stitching in Tencel yarn. The longitudinal lines of stitches are supplemented by transverse lines of stitching in the form of continuous, angular zig zags which extend between adjacent longitudinal lines of stitches. In this way stitch free gaps are left between columns of longitudinal stitching. The roll is slit in the longitudinal direction in the stitch free gaps to form ribbons.

[0032] Figure 2 shows a non woven roll similar to that shown in Figure 1 except that the continuous zig zag of transverse stitches is made in a castellated pattern between the longitudinal lines of stitches and joins them together. The roll is slit in the longitudinal

direction in the stitch free gaps to form ribbons.

[0033] Preferred embodiments of the invention will now be described with reference to the following examples:

Example 1

Dressing A

[0034] A wound dressing was made from a roll of gel forming fibres as described for the dressing of Figure 1. The roll had lines of longitudinal stitching spaced 5mm apart. The column width was 2.5cm. Ribbons were cut from each roll by slitting in a longitudinal direction at the gaps between the columns in the transverse stitching.

Dressing B

[0035] An alternative wound dressing was made by superposing two rolls of gel forming fibres as described for Dressing A and stitching as described for Dressing A.

Dressing C

[0036] An alternative wound dressing was made by eliminating the transverse stitching of Dressing A.

Dressing D

[0037] Was formed from 100gsm Aquacel a non woven dressing made from fibres of carboxy methyl cellulose ex ConvaTec.

[0038] Test samples were cut from the stitched rolls to have the dimensions 25mm wide by 100mm long for the wet samples and 25mm wide by 75mm long for the dry samples. The tensile strength of the gelled and dry samples were measured in the longitudinal and transverse direction in the following manner.

Dry Tensile Testing

[0039] Samples were conditioned at 20°C ± 2°C and 65% 4RH for a minimum period of 24 hours. The samples were secured in the pneumatic jaws of a Zwick U.T.M. fitted with a 100N load cell. The sample was elongated at a speed of 100mm/min until a 75% reduction in the samples' maximum force was measured.

Wet Tensile Testing

[0040] Samples were conditioned at 20°C ± 2°C and 65% ± 4RH for a minimum period of 24 hours. 2ml of a sodium and calcium chloride solution BP was dispensed via a pipette onto the centre of the sample and left for a period of 1 minute. The sample was secured within the pneumatic jaws of a Zwick U.T.M. fitted with a 100N load cell. The sample was elongated at a speed of 100mm/min until a 75% reduction in the samples' maximum force was measured.

[0041] The results are given below.

Property	Dry Tensile		Wet Tensile	
Measurement	MD N/cm	TD N/cm	MD N/cm	TD N/cm
Dressing D	5.33	16.19	**0.16**	**0.42**
Dressing B	8.04	20.82	**4.51**	**4.39**

Property	Dry Tensile		Wet Tensile	
Measurement	MD N/cm	TD N/cm	MD N/cm	TD N/cm
Dressing C	13.51	15.75	**8.00**	**0.44**
Dressing A	12.19	30.78	**8.05**	**4.45**

[0042] These results show the improvement in tensile strength in transverse stitched samples.

Example 2

[0043] Dressing A was used to pack a tracking wound. On removal from the wound the ribbon dressing was fully hydrated with wound fluid yet had maintained its structure. The dressing was easily removed from the wound in one piece.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO9312275A [0002] [0022]
- WO9416746A [0002] [0022]
- WO0001425A [0002] [0022]
- US5807295A [0002]
- WO9311805A1 [0002]
- US2007042024A1 [0002]
- WO0243743A [0031]

Patentkrav

1. Sårbandage omfattende et lag i form af et bånd kendetegnet ved, at båndet omfatter geldannende fibre, hvilket bånd har langsgående stinglinjer, der er dannet af en tråd og tværgående stinglinjer, der er dannet af en tråd, hvor tråden er nylon, Tencel, polyolefin, polyurethan, polyester eller cellulose, og sårbandagen er beregnet til anvendelse i kavitetssår eller sinussår.

2. Sårbandage ifølge krav 1 kendetegnet ved, at de langsgående stikningslinjer er fra 1 mm til 10 mm fra hinanden og er parallelle med en lang kant af båndet.

3. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at bandagen omfatter et andet bånd, der er lagt over det første bånd, hvor de langsgående stinglinjer samler de to bånd med hinanden.

4. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de tværgående stinglinjer er stukket gennem båndet.

5. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de tværgående stinglinjer strækker sig mellem stingenes langsgående linjer og samler dem med hinanden.

6. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de geldannende fibre er udvalgt fra gruppen af: spundne cellulosefibre, kemisk modificerede cellulosefibre, pectinfibre, alginatfibre, chitosanfibre, hyaluronsyrefibre, andre polysaccharidfibre og fibre afledt af gummi.

7. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de tværgående stikningslinjer er afsluttet ved kanterne af båndet for at reducere optrævling.

8. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de tværgående stikningslinjer er i form af en kontinuerlig zigzag, der strækker sig i kolonnerne mellem de langsgående stikningslinjer.

9. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at bandagen anvendes som en del af en kompositbandage.

10. Sårbandage ifølge et hvilket som helst af de foregående krav kendetegnet ved, at bandagen omfatter mindst to langsgående stikningslinjer.

11. Fremgangsmåde til fremstilling af en sårbandage som i krav 1, til anvendelse i kavitets- eller sinussår kendetegnet ved, at fremgangsmåden omfatter følgende trin:

(i) dannelse af en stofrulle omfattende geldannende fibre;

(ii) stikning af rullen med langsgående stikningslinjer;

(iii) stikning af tullen med tværgående stikningslinjer og

(iv) opskæring af rullen i langsgående retning for at danne bånd.

12. Fremgangsmåde ifølge krav 11 kendetegnet ved, at stofrullen er dannet ved at fremstille en ikke-vævet bane af geldannende fibre.

13. Fremgangsmåde ifølge krav 11 kendetegnet ved, at stofrullen er dannet ved strikning af en rulle af geldannende fibre.

14. Fremgangsmåde ifølge krav 12 kendetegnet ved, at den ikke-vævede bane er fremstillet ved hydrosammenfiltring af en bane af lyocellfibre og carboxymethylering af den således dannede bane.

15. Fremgangsmåde ifølge et hvilket som helst af de foregående krav kendetegnet ved, at fremgangsmåden omfatter det yderligere trin med behandling af bandagen med en sølvkilde for at tilføre bandagen antimikrobielle egenskaber.

16. Fremgangsmåde ifølge et hvilket som helst af de foregående krav kendetegnet ved, at de tværgående stikningslinjer er lavet i kolonner, der er mindre end rullens bredde.

17. Fremgangsmåde ifølge krav 16 kendetegnet ved, at rullen opskæres mellem kolonnerne af tværgående stikning, således at båndet ikke har nogen løs tråd ved dets kanter.

18. Fremgangsmåde ifølge krav 13 kendetegnet ved, at fremgangsmåden omfatter det yderligere trin med: overlejring af et andet bånd på det første bånd, før båndene stikkes sammen.

19. Anvendelse af et stofbånd i fremstillingen af en sårbandage som i krav 1, hvilket bånd omfatter geldannende fibre og har langsgående stikningslinjer og tværgående stikningslinjer til anvendelse i behandlingen af kavitets- eller sinussår.

DRAWINGS

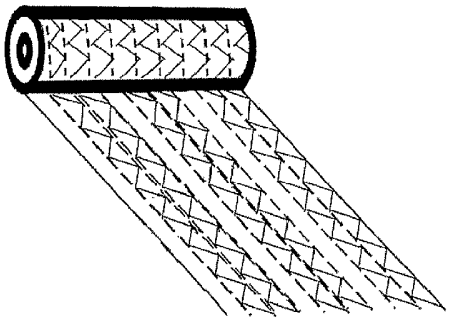

FIGURE 1

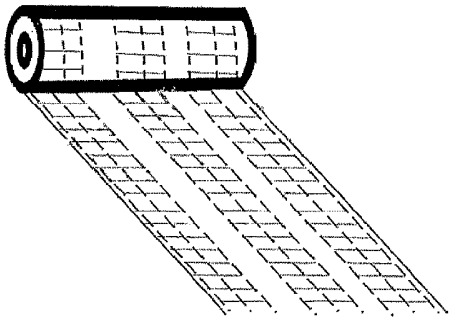

FIGURE 2