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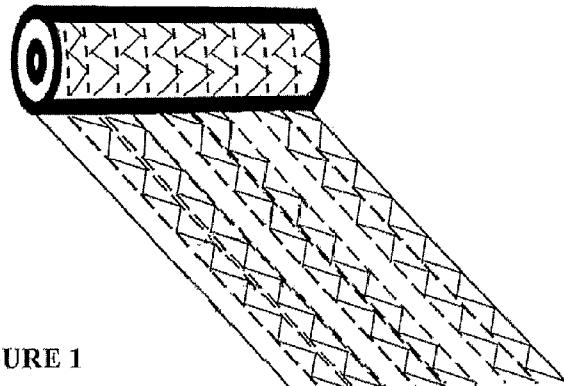


FIGURE 1

(57) Abstract: A wound dressing comprising a layer in the form of a strip and comprising gel forming fibres, the strip having longitudinal lines of stitches formed from a thread and transverse lines of stitches formed from a thread.

WOUND DRESSING

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 5 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.

It is known to use carboxymethylated cellulosic materials in situations 10 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 15 materials in wound dressings where the advantages of gel formation in preventing adherence and therefore reducing wound damage and pain on removal are discussed.

Known wound dressings comprising gel forming fibres are essentially 20 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 25 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.

30 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.

5

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 10 renders the dressing opaque which means that the wound and surrounding skin cannot be observed once the dressing is in situ.

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 15 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.

The present invention therefore seeks to provide an improved wound dressings which mitigates the problems associated with ribbon dressings 20 in cavity or sinus wounds.

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

25 Accordingly the invention provides a wound dressing comprising a layer in the form of a strip and comprising gel forming fibres, the strip having longitudinal lines of stitches formed from a thread and transverse lines of stitches formed from a thread.

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

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.

- 5 The thread may be a single filament or multiple filament yarn or a staple fibre yarn. The thread can be cellulosic, lycra, nylon, polyester or polyurethane. The thread can be impregnated with an active agent for example with an antimicrobial agent.
- 10 Such dressings are suited to treating sinus or cavity wounds, post operative or surgical wounds or any wound that needs to be packed.

15 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.

20 By gel forming fibres is meant hygroscopic fibres which upon the uptake of wound exudate become moist slippery or gelatinous and thus reduce the tendency for the surrounding fibres to adhere to the wound. The gel forming fibres can be of the type which retain their structural integrity on absorption 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.

25 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).

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.

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

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 10 wide. The longitudinal lines of stitching may be from 1mm to 10mm apart and preferably 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 15 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 20 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 25 ends of transverse stitching at the edges of the strip.

25

Preferably the transverse stitching is made in a continuous zig zag between longitudinal lines of stitching. The transverse lines of stitching can be perpendicular to the longitudinal stitching as in the case of a zig 30 zag castellated pattern or at an angle to it as in a continuous zig zag angled pattern.

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 5 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 10 narrower ribbon.

The dressing may comprise one or more medicaments. For example, an antimicrobial agent, or an antibiotic, or an anaesthetic or an anti-inflammatory agent, or a skin protective agent, or an odour absorbing 15 agent.

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 20 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.

25

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 30 absorption of exudate the fibres at the skin-contacting surface of the bandage form a gel.

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:

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

10 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 15 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 20 which allow the roll to be slit into strips with no loose ends at their edges.

25 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.

30 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.

5 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.

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 10 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 15 stitch free gaps to form ribbons.

20 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 25 ribbons.

25 Preferred embodiments of the invention will now be described with reference to the following examples:

Example 1**Dressing A**

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

10 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

15 An alternative wound dressing was made by eliminating the transverse stitching of Dressing A.

Dressing D

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

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

Samples were conditioned at 20°C ± 2°C and 65% 4RH for a minimum
30 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.

5 Wet Tensile Testing

Samples were conditioned at $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $65\% \pm 4\text{RH}$ 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 10 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.

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
Dressing C		13.51	15.75	8.00	0.44
Dressing A		12.19	30.78	8.05	4.45

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

Example 2

- 5 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.

CLAIMS

1. A wound dressing comprising a layer in the form of a strip and comprising gel forming fibres, the strip having longitudinal lines of 5 stitches formed from a thread and transverse lines of stitches formed from a thread.
2. The wound dressing of claim 1 for use in cavity wounds or sinus wounds.
- 10 3. The wound dressing as claimed in claim 1 or claim 2 characterised in that the longitudinal lines of stitching are from 1mm to 10mm apart and are parallel to a long edge of the strip.
- 15 4. The wound dressing as claimed in any preceding claim characterised in that the dressing comprises a second strip, superposed over the first strip wherein the longitudinal lines of stitches join the two strips together.
- 20 5. The wound dressing as claimed in any preceding claim characterised in that the transverse lines of stitches are stitched through the strip.
- 25 6. The wound dressing as claimed in any preceding claim characterised in that the transverse lines of stitches extend between the longitudinal lines of stitches and join them together.
- 30 7. The wound dressing as claimed in any preceding claim characterised in that the gel forming fibres are selected from the group of spun cellulose fibres, chemically modified cellulosic fibres, pectin fibres,

alginate fibres, chitosan fibres, hyaluronic acid fibres, other polysaccharide fibres and fibres derived from gums.

8. A wound dressing as claimed in any preceding claim characterised
5 in that the thread is nylon, Tencel, polyolefin, polyurethane, polyester or
cellulosic.

9. A wound dressing as claimed in any preceding claim characterised
10 in that the transverse lines of stitching are finished at the edges of the
strip to reduce fraying.

10. A wound dressing as claimed in any preceding claim characterised
in that the lines of transverse stitching are in the form of a continuous zig
zag that extends in columns between the longitudinal lines of stitching.

15 11. A wound dressing as claimed in any preceding claim characterised
in that the dressing is used as part of a composite dressing.

20 12. A wound dressing as claimed in any preceding claim characterised
in that the dressing comprises at least two longitudinal lines of stitching.

13. A method of manufacturing a wound dressing for use in cavity or
sinus wounds characterised in that the method comprises the steps of:

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

30 14. A method as claimed in Claim 13 characterised in that the roll of
fabric is formed by making a non woven web of gel forming fibres.

15. A method as claimed in Claim 13 characterised in that the roll of fabric is formed by knitting a roll of gel forming fibres.

16. A method as claimed in Claim 14 characterised in that the non woven web is made by hydroentangling a web of Lyocell fibres and carboxymethylating the so formed web.

17. A method as claimed in any preceding claim characterised in that the method comprises the further step of treating the dressing with a source of silver to give antimicrobial properties to the dressing.

18. A method as claimed in any preceding claim characterised in that the lines of transverse stitching are made in columns less than the width of the roll.

15
19. A method as claimed in claim 18 characterised in that the roll is slit between the columns of transverse stitching so that the strip has no loose thread at its edges.

20. 20. A method as claimed in claim 13 characterised in that the method comprises the further step of:

superposing a second strip on the first strip before the strips are stitched together.

25 21. Use of a strip of 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 or post operative wounds.

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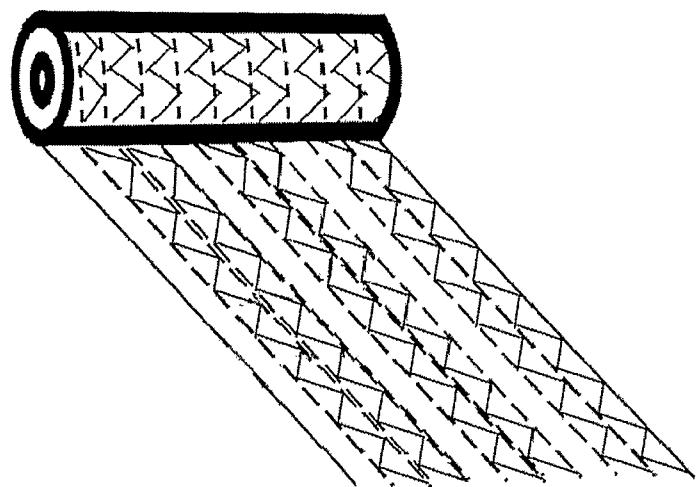


FIGURE 1

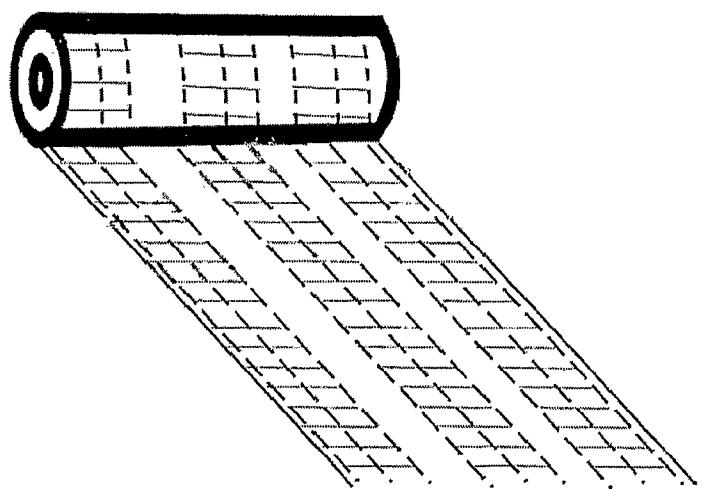


FIGURE 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001138

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 807 295 A (HUTCHEON STEVEN DAVID [GB] ET AL) 15 September 1998 (1998-09-15) column 1, line 51 - line 53 column 2, line 26 - column 3, line 36 column 6, line 23 - column 27, line 42; figures 1-5 ----- WO 93/11805 A1 (M U R S T [IT]) 24 June 1993 (1993-06-24) page 3, line 29 - page 4, line 23; figure 2; example 27 ----- US 2007/042024 A1 (GLADMAN JUNE M [GB] ET AL) 22 February 2007 (2007-02-22) the whole document -----	1-13,15, 17-21 1-2,5-7, 11-12 1-21 -/-
A		

Further documents are listed in the continuation of Box C.

See patent family annex.

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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

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Westberg, Erika

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/001138

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 201 18 880 U1 (RUNGE ALEXANDER [DE]) 24 January 2002 (2002-01-24) page 2, line 13 – line 30 page 3, line 7 – line 21 -----	1-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/001138

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 5807295	A	15-09-1998		AT 166222 T AU 698463 B2 AU 2081495 A CA 2186781 A1 CN 1148799 A DE 69502600 D1 DE 69502600 T2 DK 752839 T3 EP 0752839 A1 ES 2118004 T3 WO 9526698 A1 JP 9510901 T		15-06-1998 29-10-1998 23-10-1995 12-10-1995 30-04-1997 25-06-1998 10-09-1998 08-03-1999 15-01-1997 01-09-1998 12-10-1995 04-11-1997
WO 9311805	A1	24-06-1993		AT 185699 T AU 669148 B2 BG 61596 B1 BG 98862 A CA 2126087 A1 DE 69230182 D1 DE 69230182 T2 DK 625056 T3 EP 0625056 A1 ES 2141145 T3 FI 942895 A GR 3032451 T3 HU 68706 A2 IT 1254170 B JP 7502431 T JP 3277212 B2 KR 100252192 B1 NO 942329 A NZ 246576 A RO 111200 B1 US 5622707 A		15-11-1999 30-05-1996 30-01-1998 31-05-1995 24-06-1993 25-11-1999 31-08-2000 27-03-2000 23-11-1994 16-03-2000 18-08-1994 31-05-2000 28-07-1995 11-09-1995 16-03-1995 22-04-2002 01-06-2000 17-08-1994 27-07-1997 30-07-1996 22-04-1997
US 2007042024	A1	22-02-2007		AU 2006264691 A1 CA 2613225 A1 EP 1904011 A1 WO 2007003905 A1 JP 2008544794 T		11-01-2007 11-01-2007 02-04-2008 11-01-2007 11-12-2008
DE 20118880	U1	24-01-2002		NONE		