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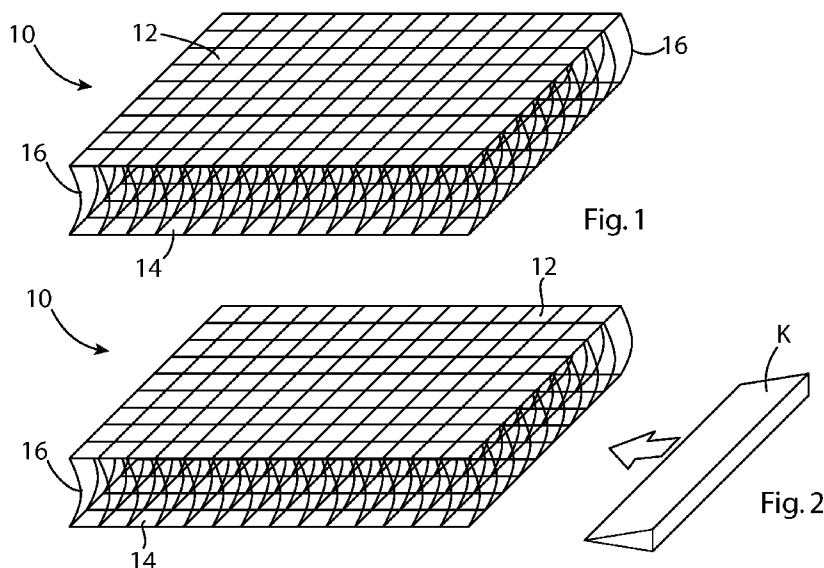
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(54) Title: A self adhering surgical fabric and method of manufacturing same



(57) Abstract: The present invention provides a self adhering surgical fabric and a method of manufacturing same, which fabric may be used as a scaffold, support or closure member in various surgical procedures in order to reduce surgical time and complexity, the method involving the steps of forming a first layer of material, forming a second layer of material, joining the first and second layers in spaced parallel relationship to one another with an array of connecting yarns, and cutting the connecting yarns to separate the first layer and the second layer such that both retain a length of each spacer yarn projecting from a face of the respective layer of material.



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**A self adhering surgical fabric
and method of manufacturing same**

5 Field of the invention

This invention relates to a self adhering surgical fabric and a method of manufacturing same, which fabric may be used as a scaffold, support or closure member in various surgical procedures in order to reduce surgical time and
10 complexity.

Background of the invention

15 Surgical fabrics or meshes are commonly used in various surgical procedures to provide a permanent or temporary support to organs or other tissue while a particular surgical procedure is performed, for example a hernia repair, pelvic organ prolapse, wound closure, surgical incision closure, vessel puncture site closure, AAA/TAA endovascular grafting to inhibit migration, and integration into
20 oesophageal or biliary covered stents to inhibit migration. The meshes are conventionally manufactured from a polymer and may be inorganic or biological, and are often a bioabsorbable material such that the mesh can be left in situ and will be absorbed into the surrounding tissue over time in order to avoid the requirement for further surgery to remove the mesh.

25

The mesh is conventionally sutured into position, or retained with a biocompatible adhesive or the like, which procedures add time and complexity to the overall procedure. If the mesh is not fixed in position migration can occur, which can result in secondary complications for example intestinal obstruction in the case of an
30 oesophageal stent.

It is therefore an object of the present invention to address the above-mentioned problem.

Summary of the invention

According to the present invention there is provided a method of manufacturing a
5 self adhering surgical fabric comprising the steps of:
forming a first layer of material;
forming a second layer of material;
joining the first and second layers in spaced parallel relationship to one another with
an array of connecting yarns;
10 and cutting the connecting yarns to separate the first layer and the second layer
such that both retain a length of each spacer yarn projecting from a face of the
respective layer of material.

Preferably, the method comprises weaving the first layer and/or the second layer.
15

Preferably, the method comprises knitting the first layer and/or the second layer.

Preferably, the method comprises cutting the connecting yarns using heat and/or
mechanical action.
20

Preferably, the method comprises cutting the connecting yarns using a hot knife.

Preferably, the method comprises forming a head on each connecting yarn at a free
end formed when the connecting yarn is cut.
25

Preferably, the method comprises forming the head simultaneously with cutting the
connecting yarn.

Preferably, the method comprises orienting the connecting yarn perpendicularly to
30 the first and/or the second layer.

Preferably, the method comprises orienting the connecting yarn non-perpendicularly
to the first and/or the second layer.

Preferably, the method comprises interweaving the connecting yarn with the first and/or the second layer.

Preferably, the method comprises forming the first and/or second layer from a
5 polymer.

According to a second aspect of the present invention there is provided a self
adhering surgical fabric comprising one half of a layered fabric comprising a first
layer of material, a second layer of material initially joined in parallel spaced
10 relationship to the first layer of material by an array of connecting yarns which are
then cut to separate the first layer and the second layer, each of which layers retain
a length of each connecting yarn projecting from a face of the layer of material.

Preferably, the first layer and/or the second layer are formed from a woven material.
15

Preferably, the first layer and/or the second layer are formed from a knitted material.

Preferably, each connecting yarn comprises a head at a free end of the yarn formed
when the connecting yarn is cut.
20

Preferably, each connecting yarn is oriented perpendicularly to the face of the layer
of material.

Preferably, each connecting yarn is oriented non perpendicularly to the face of the
25 layer of material.

Preferably, the first layer and/or the second layer are formed from one or more
polymers.

30

Brief description of the drawings

The present invention will now be described with reference to the accompanying
drawings, in which:

Figure 1 illustrates a knitted dual layered fabric with connecting yarns extending between the two layers;

- 5 Figure 2 illustrates the layered fabric of Figure 1 and showing a knife positioned to cut through the middle of the connecting yarns to form two surgical fabrics according to the invention;

Figure 3 illustrates a cross sectional view of Figure 2;

10

Figure 4 illustrates a self adhering surgical fabric according to the invention as formed from either half of the cut layered fabric of Figures 2 and 3;

Figure 5 illustrates a cross sectional view of Figure 4;

15

Figure 6a illustrates the surgical fabric of Figures 4 and 5 with a flat hot platen tool being advanced towards the tops of the connecting yarns to form heads thereon;

20 Figure 6b illustrates the surgical fabric with a hot platen tool with spike shaped depressions being advanced towards the tops of the yarns;

Figure 6c illustrates the surgical fabric with a hot platen tool with dome-shaped depressions being advanced towards the tops of the yarns; and

- 25 Figure 7 illustrates a cross sectional view of the surgical fabric with protruding connecting yarns having a dome or mushroom shaped head or barb formed at the free end of each connecting yarn.

30 Detailed description of the drawings

Referring now to the accompanying drawings there is illustrated a layered fabric, generally indicated as (10), which comprises a first layer of material (12) and a second layer of material (14) in parallel spaced relationship to one another, and

connected together by an array of connecting yarns (16) extending between the layers (12), (14). The connecting yarns (16) may extend perpendicularly from one or both of the layers (12), (14) or may extend at an angle to one or both of the layers (12), (14). The first layer (12) and/or the second layer (14) may be formed as
5 a woven material or as a knitted material, or any other suitable construction. A woven material is produced by orienting yarns along both X and Y axes, that is by arranging a series of warp yarns adjacent one another and interspersing or interweaving weft yarns. The resulting material often tends to offer minimal compliance, depending on the yarn or combination of yarns utilised. It will be
10 appreciated that the physical characteristics of the yarns and the weave may be varied to provided particular desired characteristics such as flexibility, porosity, etc.

The first and/or second layers of material (12), (14) may be constructed from monofilament, multifilament or ring spun yarns of regenerated silk, nylon/high
15 tension nylon, PET/high tension PET, UHMWPE, LCP (liquid crystal polymer) or any other suitable material. Where a multifilament is utilised this may be heat set in a twisted condition or not. The layers of material (12), (14) may also be constructed from resorbable polymers, for example PLA, PLLA, PGA, PLGA, Polycaprolactone or Polydioxanone. In a preferred embodiment illustrated the yarns utilised in the
20 construction of the layers of material (12), (14) can range from 5 to 500 denier.

Referring to Figures 2 and 3, once the layered fabric (10) has been constructed, the method according to the present invention then involves separating the first layer of material (12) from the second layer of material (14) by cutting through the
25 connecting yarns (16) such that a portion of each connecting yarn (16) remains attached to both the first layer (12) and to the second layer (14), either of which then define a self adhering surgical fabric (110) according to the invention and as illustrated in Figures 4 to 7. In a preferred embodiment of the method a knife K, which may be heated, is used to cut through the connecting yarns (16) to form the
30 two portions of self adhering fabric (110).

The self adhering surgical fabric (110) comprises a substrate (112) from which projects an array of yarns (116) which function as anchors or hooks which allow the surgical fabric (110) to self adhere to tissue or the like, thereby avoiding the

requirement for suturing or otherwise securing the self adhering fabric (110) into position at a surgical site or the like. Traditionally such surgical meshes are required to be sutured or adhered into place, and by avoiding this additional step the self adhering surgical fabric (110) of the present invention reduces the time and complexity of the surgical operation and as a result can improve patient healing response. Potential surgical applications for the self adhering surgical fabric (110) include fixation to treat pelvic organ prolapse, wound closure, surgical incision closure, vessel puncture site closure, AAA/TAA endovascular grafts to inhibit migration, and integration into oesophageal or biliary covered stents to inhibit migration.

In order to improve the self adherence of the surgical fabric (110) the free end of each of the connecting yarns (116) may be shaped to define a head or barb (118) which will increase the grip generated when the yarns (116) engage with the target tissue. The heads (118) may be formed simultaneously with cutting of the connecting yarns (16) by the knife K, which may be heated in order to partially melt the free end of each connecting yarn (16) as it is cut, thereby deforming the free end of the connecting yarn (16) to form the head (118). Alternatively as illustrated in Figures 6a, 6b and 6c the method of forming the self adhering surgical fabric (110) of the present invention may also include the step of engaging a hot platen P1, P2 or P3 against the free end of each of the yarns (116) in order to melt and deform the free end to form the head (118). The platen P1 comprises a flat contact surface to engage against the yarns (116), while the platens P2 and P3 incorporate a spiked and a domed contact surface in order to generate a barbed or mushroom shaped head (118) when pressed into engagement with the yarns (116). It will of course be appreciated that any other functional alternative may be employed in order to form the shaped heads (118).

It will also be appreciated that the two halves of the layered fabric (10) once separated from one another by the action of the knife K cutting the connecting yarns (116), can be utilised as a self adhering surgical fabric (110) according to the invention.

The invention is not limited to the embodiment described herein but can be amended or modified without departing from the scope of the present invention.

Claims

1. A method of manufacturing a self adhering surgical fabric comprising the steps of:
5 forming a first layer of material;
forming a second layer of material;
joining the first and second layers in spaced parallel relationship to one another with an array of connecting yarns;
and cutting the connecting yarns to separate the first layer and the second
10 layer such that both retain a length of each spacer yarn projecting from a face of the respective layer of material.
2. A method according to claim 1 comprising weaving the first layer and/or the
15 second layer.
3. A method according to claim 1 or 2 comprising knitting the first layer and/or
the second layer.
4. A method according to any preceding claim comprising cutting the
20 connecting yarns using heat and/or mechanical action.
5. A method according to claim 4 comprising cutting the connecting yarns using
a hot knife.
- 25 6. A method according to any preceding claim comprising forming a head on
each connecting yarn at a free end formed when the connecting yarn is cut.
7. A method according to claim 6 comprising forming the head simultaneously
with cutting the connecting yarn.
30
8. A method according to any preceding claim comprising orienting the
connecting yarn perpendicularly to the first and/or the second layer.

9. A method according to any preceding claim comprising orienting the connecting yarn non-perpendicularly to the first and/or the second layer.
10. A method according to any preceding claim comprising interweaving the connecting yarn with the first and/or the second layer.
11. A method according to any preceding claim comprising forming the first and/or second layer from one or more polymers.
12. A self adhering surgical fabric comprising one half of a layered fabric which comprises a first layer of material, a second layer of material initially joined in parallel spaced relationship to the first layer of material by an array of connecting yarns which are then cut to separate the first layer and the second layer, each of which layers retain a length of each connecting yarn projecting from a face of the layer of material such as to define the surgical fabric.
13. A self adhering surgical fabric according to claim 12 in which the first layer and/or the second layer are formed from a woven material.
14. A self adhering surgical fabric according to claim 12 or 13 in which the first layer and/or the second layer are formed from a knitted material.
15. A self adhering surgical fabric according to any of claims 12 to 14 in which each connecting yarn comprises a head at a free end of the yarn formed when the connecting yarn is cut.
16. A self adhering surgical fabric according to any of claims 12 to 15 in which each connecting yarn is oriented perpendicularly to the face of the layer of material.
17. A self adhering surgical fabric according to any of claims 12 to 15 in which each connecting yarn is oriented non perpendicularly to the face of the layer of material.

18. A self adhering surgical fabric according to any of claims 12 to 17 in which the first layer and/or the second layer are formed from one or more polymers.

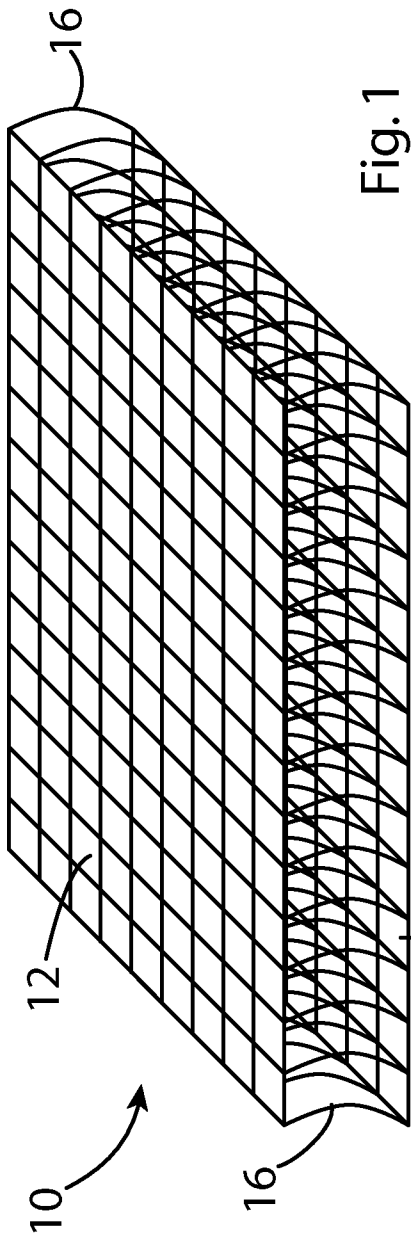


Fig. 1

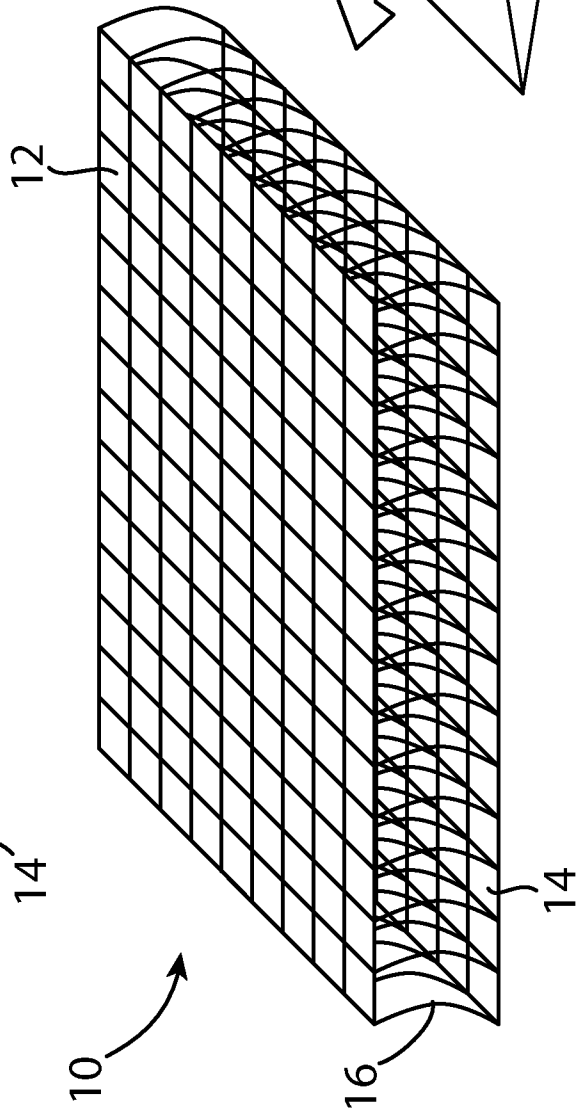


Fig. 2

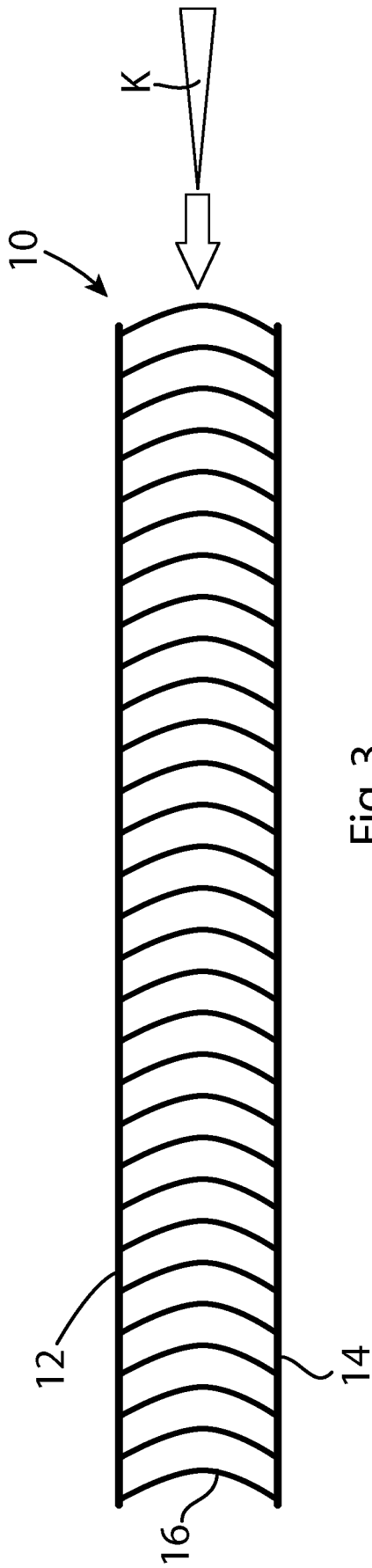


Fig. 3

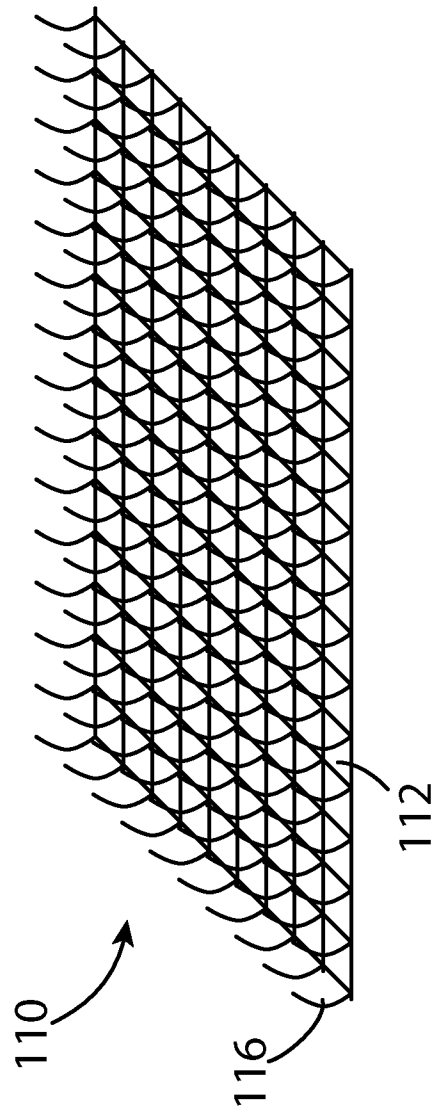


Fig. 4

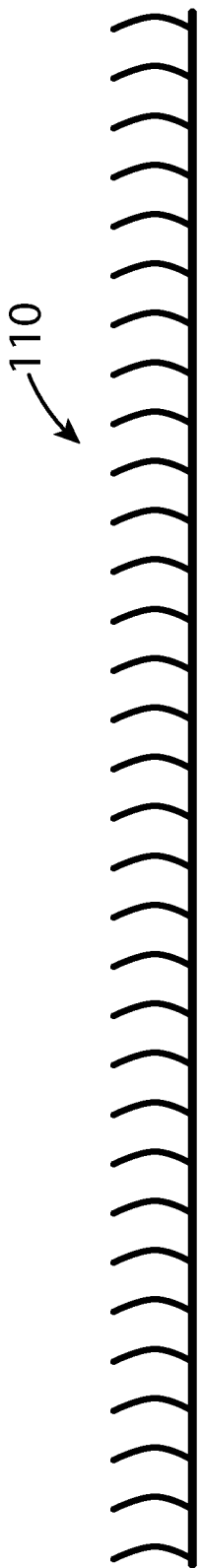


Fig. 5

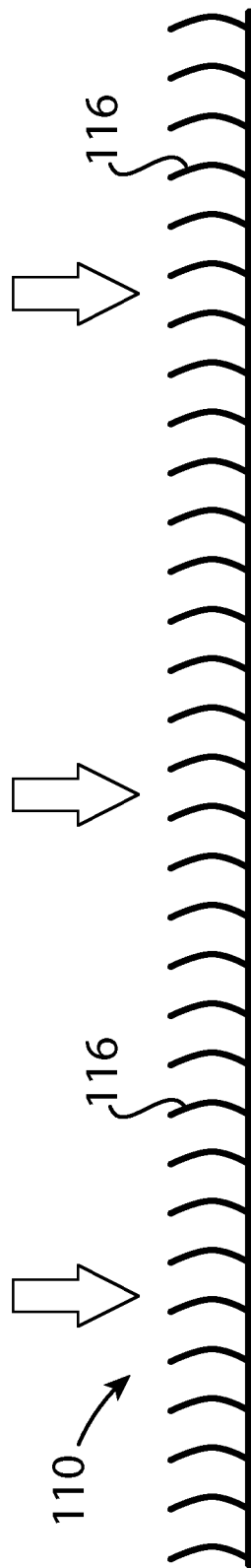
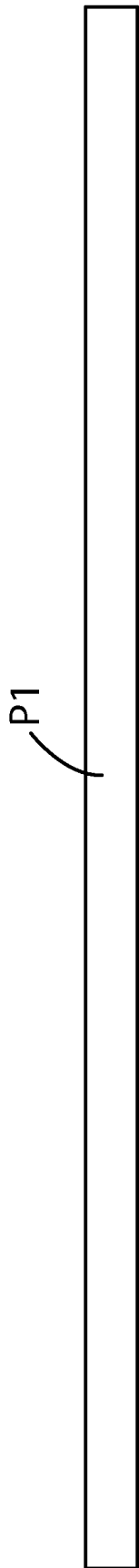


Fig. 6a

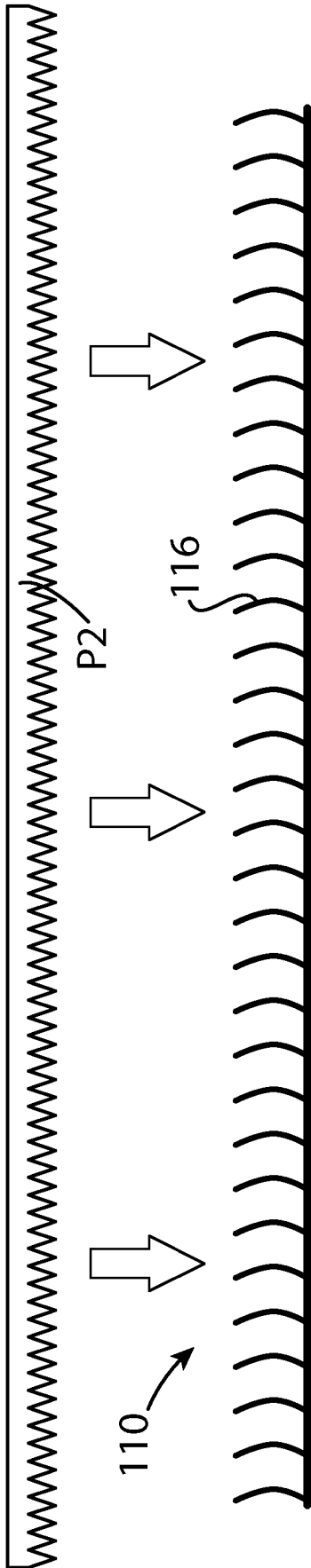


Fig. 6b

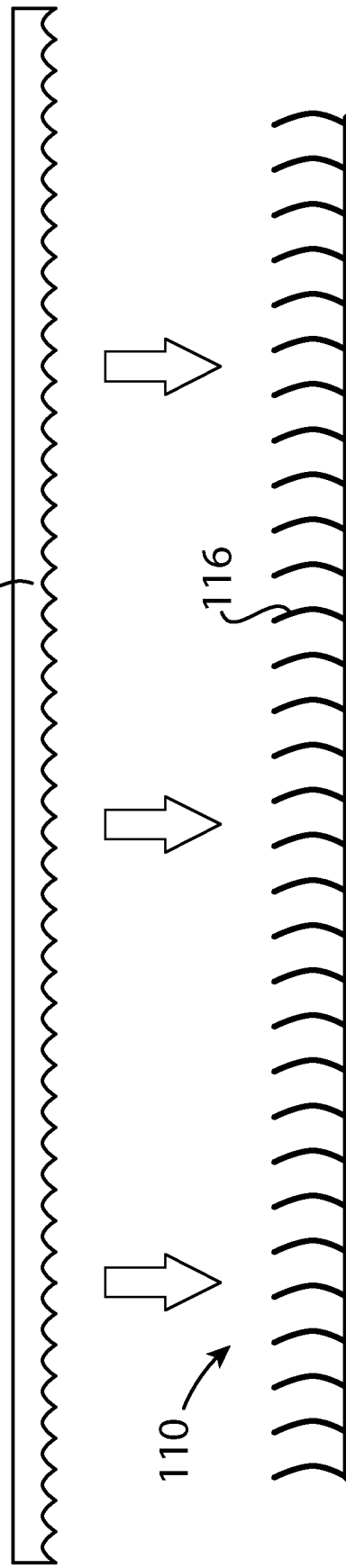


Fig. 6c



Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/086241

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61L31/04 A61L31/06 A61L31/14 D03D11/00 D03D27/08
 D03D27/10
 ADD.
 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)
 A61L D03D

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 practicable, search terms used)
 EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2010/139340 A1 (INST TEXTIL & FASERFORSCHUNG [DE]; SEIBOLD JUERGEN [DE]; MUELLER ERHAR) 9 December 2010 (2010-12-09) page 3, lines 17-20 page 7, line 29 - page 8, line 30 claims	12-14,18
X	WO 93/10731 A1 (KENSEY NASH CORP [US]) 10 June 1993 (1993-06-10) page 8, lines 10-33 claims	12,15-18
X	US 1 313 037 A (C ADAMS) 12 August 1919 (1919-08-12) page 1, lines 9-36 page 1, lines 57-99	1,2,4, 8-10,12, 13
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search 22 March 2019	Date of mailing of the international search report 29/03/2019
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Van den Bulcke, H
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/086241

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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