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(54) Title: WOUND DRESSING AND HEADGEAR

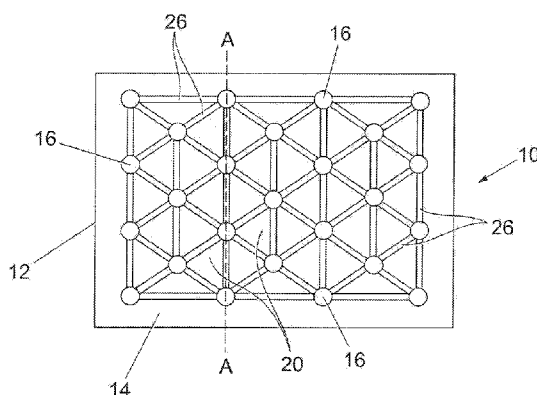


Fig. 1

(57) Abstract: A wound dressing comprising a sealed enclosure having at least one compartment; a plurality of spaced apart pillar-like structures positioned within the at least one compartment; and means for evacuating air from the at least one compartment, wherein the evacuation of air from the at least one compartment causes a reduction in the distance between at least two of the pillar-like structures.

WOUND DRESSING AND HEADGEAR

The present invention relates to a wound dressing, in particular, to an improved wound dressing for reducing post-operative swelling of a body part of a human or animal patient, or for controlling blood loss from wounds.

The invention also relates to a method for reducing post-operative swelling of a body member of a human or animal patient, or for controlling blood loss from wounds.

Post-operative swelling results from the accumulation of bodily fluid around an operation wound. Post-operative swelling cannot be eliminated altogether because following an operation the wound needs a blood supply to enable healing which inevitably results in some leakage and, hence, swelling.

Since swelling can hinder recovery and in some cases lead to further complications, it is always an issue that is sought to be minimised.

The control of blood loss, especially following a serious accident, is of great importance as excessive loss of blood can hamper recovery leading to medical complications or even fatality.

The use of bandages is known in the art in order to minimise post-operative swelling or to control blood loss. The use of bandages is appealing since they are generally versatile in that they can be readily adapted for use on different body members and on wounds of different sizes.

30

However when used as an aid for minimising post-operative swelling, bandages can be bulky and cumbersome. This is especially the case in relation to head injuries where most of the bandage employed does not come into contact with the wound but rather is around the head merely holding a small part of the bandage against the wound. Moreover, wounds need to be checked periodically, to ensure that there is not excessive leakage of fluid from the wound. Generally, bandages are disposed of when a wound is checked and this is wasteful.

10 There are a number of devices known in the art directed at minimising post-operative swelling in patients undergoing surgery on the head.

WO2005/097022 discloses a post-operative head dressing comprising a rigid cap adapted to fit over the head of a patient, and a liner. The liner is a network of tubes of resilient material connected to a single opening through which gas may be introduced to pressurise the liner network. The liner expands against the cap to squeeze the head.

GB 2435833 discloses a post-operative head dressing comprising a cap adapted to fit over the head of a patient. The cap is a patchwork of compartments of airtight flexible material which are evacuated during use, whereby atmospheric pressure compresses the flexible material. The compartments are filled with beads, preferably polystyrene beads, so that, on air evacuation, the cap not only becomes rigid, but also gently pressed against the scalp to inhibit post-operative swelling and/or bleeding from head wounds.

According to a first aspect of the invention there is provided a wound dressing comprising a sealed enclosure having at least one compartment; a plurality of spaced apart pillar-like structures positioned within the at

least one compartment; and means for evacuating air from the at least one compartment, wherein the evacuation of air from the at least one compartment causes a reduction in the distance between at least two of the pillar-like structures.

5

The reduction in the distance between at least two of the pillar-like structures has the effect of reducing the overall length of the bandage resulting in the exertion of pressure by the dressing to the wound in use thus restricting the amount of swelling that may occur. The present invention thus provides an improved wound dressing that stems swelling and bleeding of a wound.

10

The pillar-like structures may be formed from any suitable material. Ideally the pillar-like structures are formed from either a rubber based material, a silicon based material or an elastomeric polymer.

15

Preferably the pillar-like structures are spaced apart from each other in a predetermined arrangement.

By arranging the pillar-like structures in a predetermined arrangement, the way in which pressure can be exerted onto a body member when air is evacuated from the compartment can be controlled. For example, arrangement of the pillar-like structures in long thin parallel strips will result in greater reduction along one axis than another.

20

Conveniently the pillar-like structures are evenly spaced within the compartment. By having the pillar-like structures evenly spaced from each other, an equal reduction in the distance between adjoining pillar-like structures will take place, hence resulting in the application of uniform

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pressure across a body part once air has been evacuated from the compartment.

5 Preferably the pillar-like structures are cylindrical columns, however, the pillar-like structures may be formed of columns having any suitable cross-sectional geometry. For example, the pillar-like structures could be triangular, rectangular, hexagonal etc in cross-section.

10 Advantageously each pillar-like structure is connected to a neighbouring pillar-like structure by a connecting member in order to define a lattice-like structure.

15 Connecting the pillar-like structures to a neighbouring structure removes the need for re-adjusting the positions of the structures relative to each other after use, as is generally required in the prior art dressings mentioned above that incorporate bead structures.

20 The connecting members may be integrally formed with the pillar-like structures. Alternatively the connecting members may be bonded with the pillar-like structures.

Preferably the sealed enclosure comprises a first and second film layer.

25 The first and second film layers may be formed of any suitable material. Ideally the first and second film layers are formed from a vacuum formable material such as PVC.

30 Preferably the first and second film layers are bonded together around their edges to define the sealed enclosure. The pillar-like structures are thus retained between the first and second film layers

The first and second film layers may be bonded together by any suitable means, for example the film layers may be heat sealed, ultrasonically welded or glued together.

5

Preferably the plurality of pillar-like structures are moveably retained between the first and second film layers.

10 Preferably the plurality of pillar-like structures are retained in position between the first and second film layers by connection to the first and/or second film layer.

15 The pillar-like structures may be retained in position between the first and second film layers by any suitable means, for example by a heat seal, an ultrasonic weld or glue.

Preferably the plurality of pillar-like structures are integrally formed with at least one of the film layers.

20 Preferably a portion of the first film layer is adapted to be drawn into the space between the at least two pillar-like structures when air is evacuated from the compartment. As the first film layer is drawn into the space the dimensions of the wound dressing are reduced, causing a reduction in the distance between the at least two pillar-like structures.

25

Preferably the wound dressing further comprises a frame portion for attaching the dressing to a head of a patient.

30 Conveniently the frame portion comprises a securing band for securing the dressing onto the head of a patient.

Preferably the frame portion comprises means for adjusting the working length of the securing band.

- 5 The means for adjusting the working length of the securing band allows the wound dressing to be used with different size heads.

Preferably the means for adjusting the working length of the securing band comprises a pawl and ratchet mechanism.

10

The pawl and ratchet mechanism may be a self limiting pawl and ratchet mechanism of the type known in the art.

- 15 Preferably the means for adjusting the size of the securing band comprises a clip adjuster.

Preferably the frame portion further comprises a retaining member which is adapted, in use, to restrict the removal of the wound dressing independently of the securing band.

20

Preferably the frame portion comprises a flexible plastic material.

The flexible plastic material is preferably a thermoplastic material, ideally an acrylonitrile butadiene styrene (ABS) or a polypropene (PB).

25

Preferably the means for evacuating air from the at least one compartment comprises a vacuum release valve.

- 30 The means for evacuating air from the at least one compartment may further comprise a non-return valve in order to prevent the regression of

air into the at least one compartment during the evacuation of air from the compartment.

- 5 Preferably the wound dressing further comprises means for introducing air into the at least one compartment. The means for introducing air into the at least one compartment may be in the form of a hand pump or an inlet valve connectable to a compressor.

10 According to a second aspect of the invention there is provided a method of reducing post-operative swelling of a body member of a human or animal patient, or for controlling blood loss from wounds comprising the steps of:

- 15 a) applying to the body member or wound a dressing formed by a sealed enclosure having at least one compartment and a plurality of spaced apart pillar-like structures; and
- b) applying pressure onto the body member or wound by reducing the spacing between at least one pair of pillar-like structures by
20 evacuating the at least one compartment of air.

25 According to a third aspect of the invention there is provided a headgear comprising a head covering portion and a frame portion comprising a securing band, wherein the frame portion further comprises at least one retaining member positioned on a side of the headgear which, in use, restricts the removal of the headgear independently of the securing band.

The third aspect of the invention thus enables a headgear to be secured on the head of a user without the need of a chin strap as securement of

the headgear will be provided by the securing band and the at least one retaining member.

5 There now follows a description of preferred embodiments of the invention, by way of non-limiting example, with reference being made to the accompanying drawings, in which:

10 Figure 1 is a plan view of a first embodiment of a wound dressing according to the invention;

Figure 2 is a cross-sectional view of the wound dressing of Figure 1 taken along line A-A in Figure 1;

15 Figure 3a is a schematic view of a section of the wound dressing of Figure 1 showing the spacing between two pillar-like structures prior to evacuation of air from the compartment;

20 Figure 3b is a schematic view of the section shown in Figure 3a following the evacuation of air from compartment;

Figure 4 is a schematic view showing the application of a wound dressing according to the invention applied to an arm of a patient;

25 Figure 5 is a perspective view of a second embodiment of a wound dressing according to the invention in the form of a head wound dressing; and

Figure 6 is a partial side rear view of the wound dressing of Figure 5.

Referring to Figures 1 and 2, a first embodiment of a wound dressing (10) according to the invention is shown. The wound dressing (10) comprises a sealed enclosure (12) having at least one compartment (14); a plurality of spaced apart pillar-like structures (16) positioned within the at least one compartment (14); and means for evacuating air from the at least one compartment (not shown).

The sealed enclosure (12) comprises a first film layer (22) and a second film layer (24) which are sealed together around their edges to define the sealed enclosure (12). The first and second film layers (22, 24) may additionally be bonded together at various points in order to define one or more further compartments within the sealed enclosure (12).

The first and second film layers (22, 24) are made of PVC material and are heat sealed to one another to define the sealed enclosure (12) and/or compartments.

The pillar-like structures (16) (hereinafter referred to as 'pillars') are substantially cylindrical in shape and are connected to a neighbouring structure by means of a connecting member (26). In this arrangement the pillars (16) and the connecting members (26) define a lattice-like structure. In a preferred embodiment, the pillars are made from a silicon based material and the connecting members (26) are made of a resilient material such as a flexible plastic material.

The pillars (16) may be moveably retained between the first and second film layers (22, 24) or may be retained in position between the film layers (22, 24) by connection to the first and/or second film layer.

The means for evacuating air from the at least one compartment is in the form of a vacuum release valve (not shown) having a non-return valve in order to prevent regression of air into the at least one compartment during evacuation of air from the compartment (14).

5

Referring to Figures 3a and 3b, when air is evacuated from the compartment (14), a portion of the first film layer (22) and a portion of the second film layer (24) are pulled into the space (20) between two adjoining pillars (16) (as best seen in Figure 3b). As the film layers (22, 24) are pulled into the space (20) by the vacuum left by the evacuation of air therefrom, the overall surface area of the wound dressing (10) is reduced causing a reduction in the spacing between the adjoining pillars (16).

10

As the adjoining pillars (16) are drawn towards one another, the connecting members (26) are caused to flex inwardly into the space (20).

15

The film layers (22, 24) provide a controlled and self-limiting decrease in length of the wound dressing (10) in one or two axis as air is expelled.

When air is reintroduced into the compartment (14), the pillars (16) are returned to their original spacing due to the resiliency of the connecting members (26) causing the connecting members (26) to straighten and hence push the pillars (16) away from each other.

20

The pillars (16) are spaced apart from each other in a predetermined arrangement depending on requirements. That is to say the shape and spacing of the lattice elements (i.e. the pillars (16) and connecting members (26)) will determine how the wound dressing (10) changes when a vacuum is applied. For example, if the pillars (16) are arranged in a

25

series of long thin strips that are parallel to one another there will be a greater reduction along the transverse axis than the longitudinal axis.

5 The wound dressing (10) further comprises means for introducing air into the at least one compartment (not shown) which may be in the form of a hand pump or an inlet valve connectable to a compressor.

10 Referring to Figure 4, a wound dressing according to a first embodiment of the invention is shown applied to an arm of a patient in order to reduce post-operative swelling of the arm of a patient.

15 The wound dressing is first positioned around the post-operative wound and secured in place by a suitable means such as a band, a strap, VELCRO[®], tape or the like. Pressure is then applied onto the body member to constrict swelling of the body member by evacuating the at least one compartment of air. As described above, evacuation of air results in the film layers (22, 24) being pulled down into the space (20) between the pillars (16) results in the pulling of the pillars (16) closer together and a reduction of the overall dimensions of the wound dressing
20 (10).

25 Referring to Figure 5, a second embodiment of a wound dressing according to the invention is shown. The wound dressing (100) is in the form of a head wound dressing and comprises a head covering portion (102) and a frame portion (104) for attaching the dressing to a head of a patient.

30 The head covering portion (102) is a similar construction to the wound dressing (10) described above and the same reference numerals have been used to identify identical features.

The frame portion (104) comprises a securing band (106) for securing the dressing (100) to the head of a patient and a pair of restraining members (114) positioned on opposite sides of the dressing (100) and located so as to be positioned on either side of a patient's head when worn.

The components of the frame portion (104) are produced from a flexible plastic in order to allow them to conform comfortably around the head whilst being rigid enough not to stretch and allow the wound dressing (100) to be able to be unwilling pulled off the head.

The securing band (106) is adapted to run circumferentially around the head of a patient. In the embodiment shown, the securing band (106) comprises two band members (108) each adapted to run from the forehead of user, along the temple and down such that it finishes below the occipital lobe to provide a secure hold.

The frame portion (104) further comprises means for adjusting the active length of the securing band (106). In the embodiment shown, the dressing (100) comprises a first means for adjusting the active length of the securing band (106) located at the front of the wound dressing (100) and a second means for adjusting the active length of the securing band (106) located at the rear of the wound dressing (100).

The front adjusting means is a pawl and ratchet mechanism (110) coupled to a first end of the two band members (108). The pawl and ratchet mechanism includes a knob (126) for adjusting the tension of a frontal section of the securing band (106).

Referring to Figure 6, the rear adjusting means is a clip adjuster (112) of a kind similar to that known in the art. The clip adjuster (112) comprises a plurality of eyelets (118) positioned proximate a second end of each band member (108). The eyelets (118) are adapted to receive a corresponding projection (120) located on a mounting member (122). The number of eyelets (118) and corresponding projections (120) determine the number of adjustment positions that may employed to increase the tension of a rearward section of the securing band (106). In the embodiment shown each band member (108) comprises four eyelets (118). As shown in Figure 6, the mounting member (122) may incorporate a plurality of receiving loops (124) in which the ends of the band members (118) may be securely tucked away.

Each restraining member (114) is adapted to fit around an ear of a user. In the embodiment shown, a first end of the restraining member (114) is connected to the securing band (106) at a location proximate a front end of the wound dressing (100) and a second end is connected to securing band (106) proximate the rear end of the wound dressing (100).

The restraining members (114) act to restrict the removal of the headgear independently of the securing band (106) and together with the securing band (106) allow the wound dressing (100) to be secured on the head without the use of a chin strap or obscuring the ears.

While the frame structure of the wound dressing (100) has been described with particular reference to use in a headgear for use in reducing post-operative swelling of a head wound, or for controlling blood loss from head wounds, the unique frame structure described above may be incorporated in a headgear where securement of the headgear to the head of a user is required. For example the frame structure may be incorporated into a

safety or protective helmet in order to provide a helmet without a chin strap.

5 All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/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 and/or steps are mutually exclusive.

10 Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar
15 features.

The invention is not restricted to the details of any foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying
20 claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

Claims

1. A wound dressing comprising a sealed enclosure having at least one compartment; a plurality of spaced apart pillar-like structures positioned within the at least one compartment; and means for evacuating air from the at least one compartment, wherein the evacuation of air from the at least one compartment causes a reduction in the distance between at least two of the pillar-like structures.
2. A wound dressing according to Claim 1 wherein the pillar-like structures are evenly spaced within the compartment.
3. A wound dressing according to anyone of the preceding claims wherein the pillar-like structures are cylindrical columns.
4. A wound dressing according to anyone of the preceding claims wherein each pillar-like structure is connected to a neighbouring pillar-like structure by a connecting member in order to define a lattice-like structure.
5. A wound dressing according to any one of the preceding claims wherein the sealed enclosure comprises a first and second film layer.
6. A wound dressing according Claim 5 wherein the first and second film layers are bonded together around their edges to define the sealed enclosure.
7. A wound dressing according to Claim 5 or 6 wherein the plurality of pillar-like structures are moveably retained between the first and second film layers.

8. A wound dressing according to Claim 5 or 6 wherein the plurality of pillar-like structures are retained in position between the first and second film layers by connection to the first and/or second film layer.
- 5 9. A wound dressing according to Claims 5 or 6 wherein the plurality of pillar-like structures are integrally with at least one of the film layers.
- 10 10. A wound dressing according to any one of Claims 5 to 9 wherein a portion of the first film layer is adapted to be pulled into the space between the at least two pillar-like structure to the reduce the distance between the at least two pillar-like structure.
- 15 11. A wound dressing according to anyone of the preceding claims further comprising a frame portion for attaching the dressing to a head of a patient.
- 20 12. A wound dressing according to Claim 11 wherein the frame portion comprises a securing band for securing the dressing onto the head of a patient.
13. A wound dressing according to Claim 12 wherein the frame portion comprises means for adjusting the working length of the securing band.
- 25 14. A wound dressing according to Claim 13 wherein the means for adjusting the working length of the securing band comprises a pawl and ratchet mechanism.
15. A wound dressing according to Claim 13 or 14 wherein the means for adjusting the size of the securing band comprises a clip adjuster.

16. A wound dressing according to any one of Claims 11 to 15 wherein the frame portion further comprises a restraining member.

5 17. A wound dressing according to anyone of Claims 11 to 16 wherein the frame portion comprises a flexible plastic material.

18. A method of reducing post-operative swelling of a body member of a human or animal patient, or for controlling blood loss from wounds comprising the steps of:

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a) applying to the body member or wound a dressing formed by a sealed enclosure having at least one compartment and a plurality of spaced apart pillar-like structures; and

15

b) applying pressure onto the body member or wound by reducing the spacing between at least one pair of pillar-like structures by evacuating the at least one compartment of air.

19. A method as claimed in Claim 17 wherein the dressing is a dressing
20 according to any one of Claims 1 to 16.

20. A headgear comprising a head covering portion and a frame portion comprising a securing band, wherein the frame portion further comprises at least one retaining member positioned on a side of the headgear which, in use, restricts the removal of the headgear independently of the securing band.
25

21. A wound dressing as hereinbefore described with reference to and/or illustrated in the accompanying drawings.

30

22. A method of reducing post-operative swelling of a body member of a human or animal patient, or for controlling blood loss from wounds as hereinbefore described with reference to and/or illustrated in the accompanying drawings.

5

23. A headgear as hereinbefore described with reference to and/or illustrated in the accompanying drawings.

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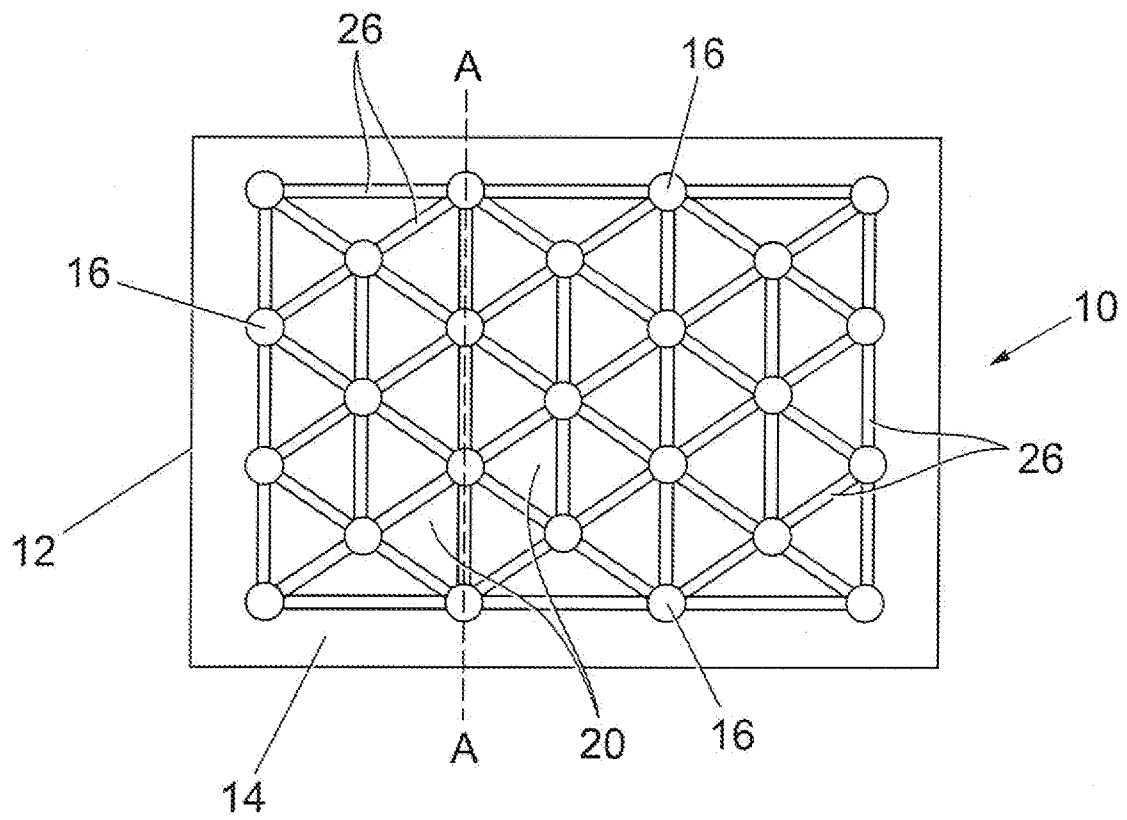


Fig. 1

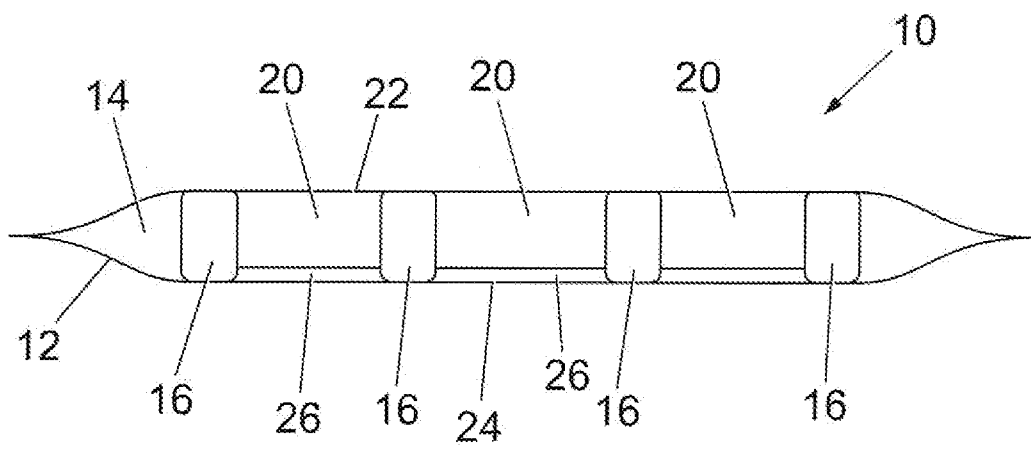


Fig. 2

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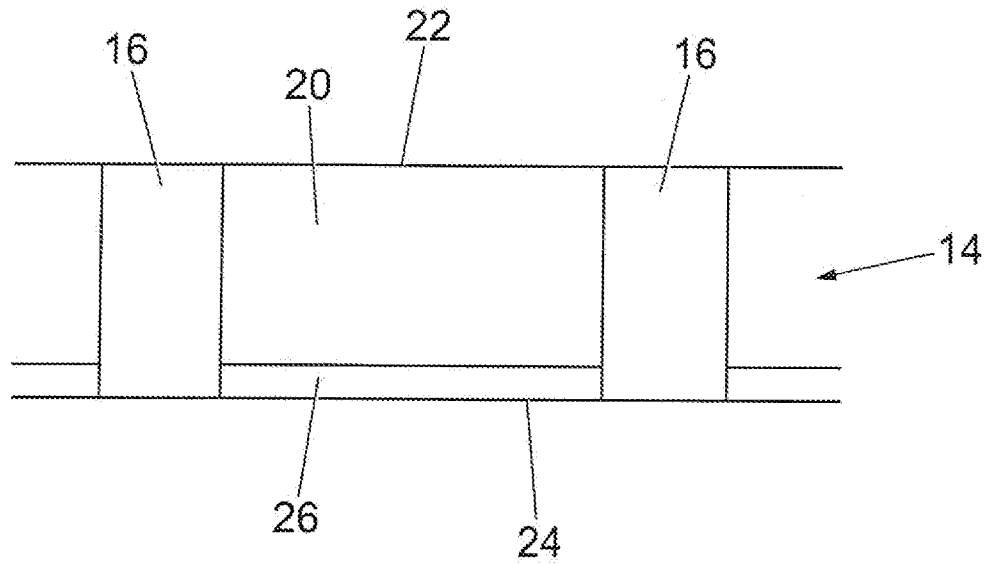


Fig. 3a

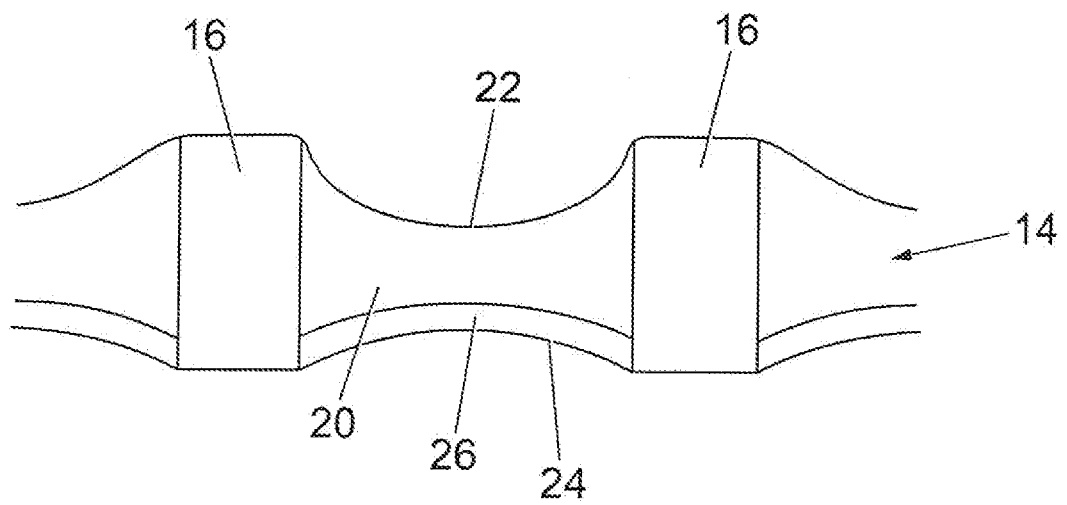


Fig. 3b

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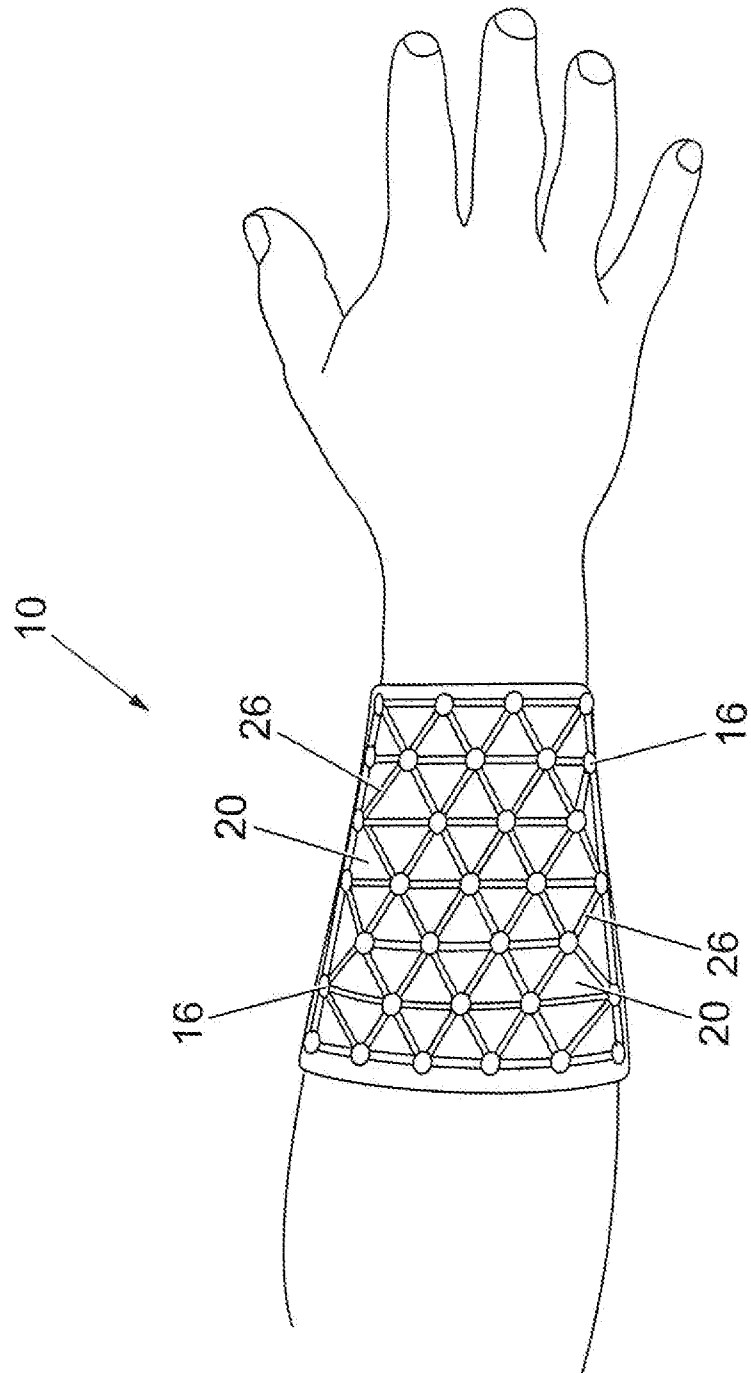


Fig. 4

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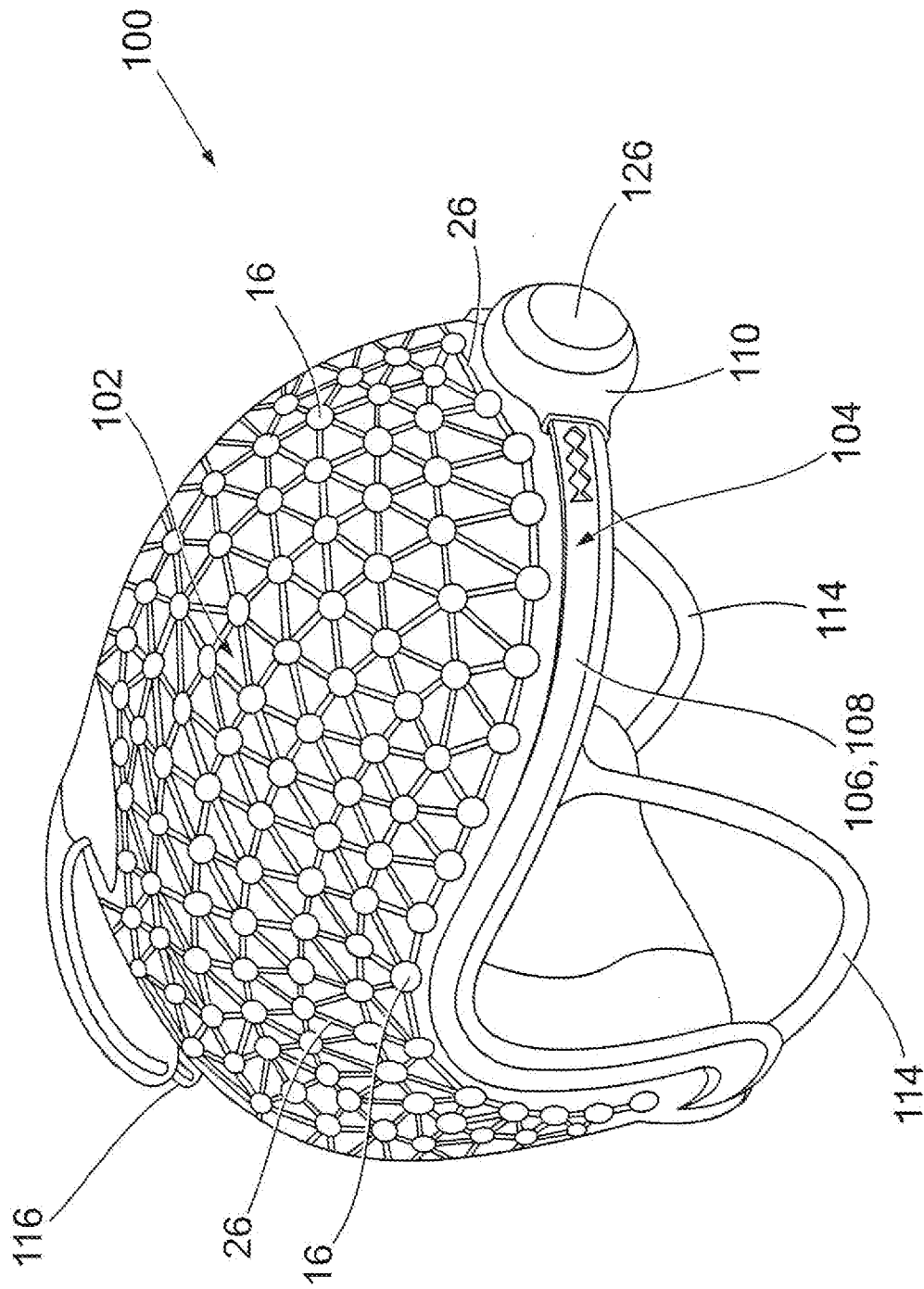


Fig. 5

5 / 5

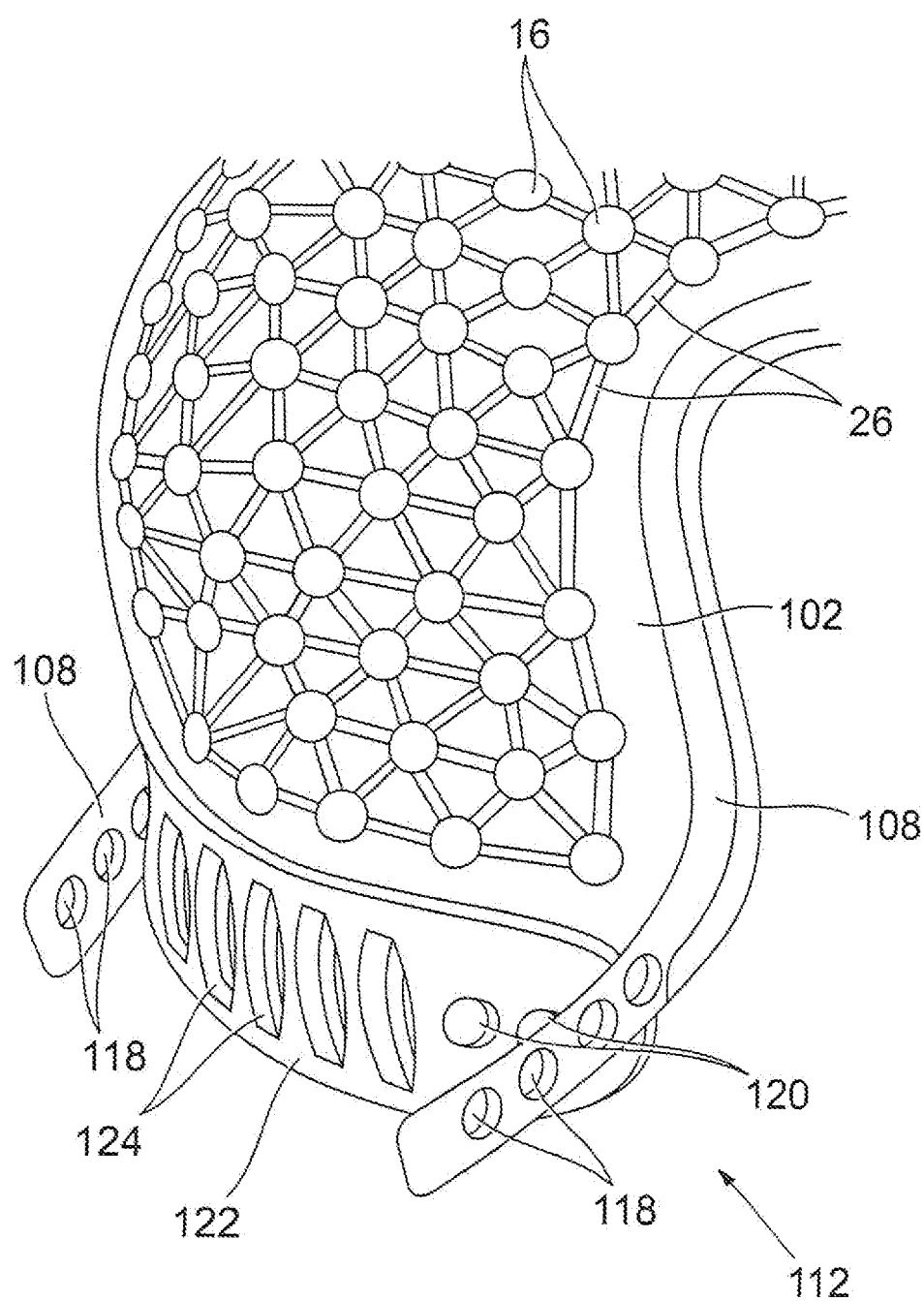


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/050688

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	WO 2005/097022 A1 (TIMOTHY JAKE [GB]) 20 October 2005 (2005-10-20) cited in the application	20,23
A	page 8, line 6 - page 9, line 24 -----	1-17,21
X	GB 2 435 833 A (TIMOTHY JAKE [GB]) 12 September 2007 (2007-09-12) cited in the application	1-17, 20-21,23
	page 2, line 33 - page 4, line 13 page 6, line 10 - line 16 -----	
A	US 2003/212357 A1 (PACE EDGAR ALAN [US]) 13 November 2003 (2003-11-13) the whole document -----	1-17, 20-21,23



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

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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.

& document member of the same patent family

Date of the actual completion of the international search

12 October 2009

Date of mailing of the international search report

21/10/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Westberg, Erika

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 18-19, 22

Claims 18, 19 and 22 define a method of reducing post-operative swelling of a body member of a human or animal patient, or for controlling blood loss from wounds. Such a method is considered as a method of treatment of the human or animal body by therapy. Therefore the subject-matter of claims 18, 19 and 22 is considered by this Authority to be covered by the provisions of Rule 39(iv) PCT and Article 17(2)(a)(i) PCT. Consequently no international search will be carried out on the subject-matter of claims 18, 19 and 22.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2009/050688

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-19, 22
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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