(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 June 2009 (11.06.2009)

PCT

(10) International Publication Number
WO 2009/071938 A1

(51) International Patent Classification:
A61F 13/02 (2006.01) *A61M 27/00* (2006.01)
A61M 1/00 (2006.01)

(21) International Application Number:
PCT/GB2008/051134

(22) International Filing Date:
28 November 2008 (28.11.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0724040.1 8 December 2007 (08.12.2007) GB

(71) Applicant *(for all designated States except US)*: **SMITH & NEPHEW PLC** [GB/GB]; 15 Adam Street, London WC2N 6LA (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **HALL, Kristian** [GB/GB]; 20 Barton Drive, Hessle, Hull HU13 0HN (GB).

(74) Agent: **BOAKES, Jason, Carrington**; Harrison Goddard Foote, 106 Micklegate, York YO1 6JX (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(54) Title: WOUND PACKING MEMBERS

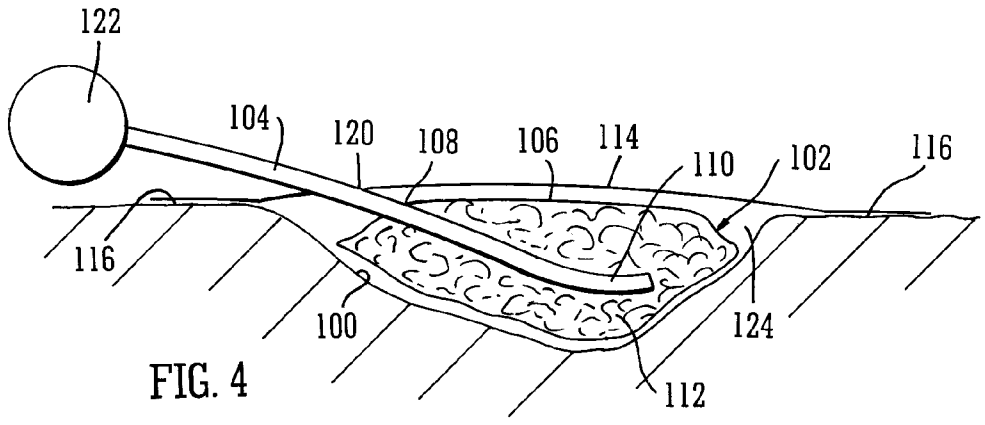


FIG. 4

(57) Abstract: A wound packing unit (10) and a method of using such in the treatment of a wound is described, the wound packing unit comprising a resilient, fluid absorbent material contained within a porous bag member (12), the porous bag member being made of a material which is non-adherent to the wound.

WO 2009/071938 A1

WOUND PACKING MEMBERS

The present invention relates to members for filling a volume of a wound particularly, though not exclusively, during topical negative pressure (TNP) therapy.

In recent years TNP therapy had become increasingly important in the field of improved treatment of wounds by making the healing thereof faster and more controlled.

The basic principle of TNP therapy is to create a closed cavity over the wound itself by means of a thin, flexible sealing film adhered to the patient's sound skin surrounding the wound; admitting one end of an aspirant conduit into the closed cavity, the conduit being sealed to the flexible film, for example; and connecting a distal end of the aspirant conduit to a vacuum source such as an electrically driven vacuum pump, for example, to create a pressure lower than the surrounding ambient atmospheric pressure within the wound cavity. As is known to the skilled person the lower pressure creates many beneficial therapeutic effects on the wound including increased blood flow to the wound and faster formation of granulation tissue, for example. There are very many variations on this basic principle of TNP therapy.

The types of wounds treated by TNP therapy generally range from quite small at about $5cm^2$ to very large traumatic wounds and burns of no particular maximum dimension. Such wounds may also have significant depth and therefore, significant volume. It is necessary to control the way in which a wound heals. For example, the wound should heal from the base up and close in from the edges desirably in a uniform manner. In particular it is desirable that the wound does not close over and form an occluded cavity in the flesh which is extremely undesirable from the patient's point of view as such form sites for infection.

To prevent the formation of occluded cavities during TNP therapy, the wound is usually packed with a filler which desirably has some resilience or "bounce" to resist the compressive forces created during TNP therapy by outside ambient atmospheric pressure bearing down on the wound due to the vacuum created in the wound cavity. The purpose of the filler is to keep the surrounding edges of the wound apart so that they cannot grow over and form a cavity. The filler may also perform the function of providing fluid flow channels between the wound and the filler or through the filler in order to provide a uniform reduced pressure distribution over the surface area of the

wound and to promote efficient aspiration of exudate fluids away from the wound surface and generally into a remote waste receptacle associated with the aspirant conduit.

As noted above there are very many variations on the basic TNP therapy principle and to illustrate how complex TNP therapy may be reference is made to the documents described below and which are of common ownership herewith.

In our co-pending International patent application, WO 2004/037334, apparatus, a wound dressing and a method for aspirating, irrigating and cleansing wounds are described. In very general terms, this invention describes the treatment of a wound by the application of topical negative pressure (TNP) therapy for aspirating the wound together with the further provision of additional fluid for irrigating and/or cleansing the wound, which fluid, comprising both wound exudates and irrigation fluid, is then drawn off by the aspiration means and circulated through means for separating the beneficial materials therein from deleterious materials. The materials which are beneficial to wound healing are recirculated through the wound dressing and those materials deleterious to wound healing are discarded to a waste collection bag or vessel.

In our co-pending International patent application, WO 2005/04670, apparatus, a wound dressing and a method for cleansing a wound using aspiration, irrigation and cleansing wounds are described. Again, in very general terms, the invention described in this document utilises similar apparatus to that in WO 2004/037334 with regard to the aspiration, irrigation and cleansing of the wound, however, it further includes the important additional step of providing heating means to control the temperature of that beneficial material being returned to the wound site/dressing so that it is at an optimum temperature, for example, to have the most efficacious therapeutic effect on the wound.

In our co-pending International patent application, WO 2005/105180, apparatus and a method for the aspiration, irrigation and/or cleansing of wounds are described. Again, in very general terms, this document describes similar apparatus to the two previously mentioned documents hereinabove but with the additional step of providing means for the supply and application of physiologically active agents to the wound site/dressing to promote wound healing.

The content of the above references is included herein by reference.

In spite of the self evident growing complexity of TNP therapy in general the field of wound fillers, which are a vital element in the therapy has changed or improved very little over the years that TNP therapy has been developing. Aside from complicated and expensive inflatable bags, most of the fillers in use are based either on foam or on cotton gauze. Foam fillers are usually cut with scissors to the required shape (of the wound) by a clinician. However both foams and gauzes have the disadvantage that the cell or pore size is often too large and often results in growing tissue growing into the cells and adhering the foam to the wound causing further damage and trauma to the wound and patient on removal. When gauze is used as a filler, however, clinicians are instructed to "fluff up" the gauze to increase its volume which can cause problems in that the actual form of the gauze as packed into wounds is very variable. A further disadvantage with both foams and gauze when cut to fit wounds is that of debris. Gauze in particular is prone to shedding fibres and particles and when cut, these inevitably find their way into the wound and become occluded therein which can lead to later infection.

It is an object of the present invention to overcome or mitigate some of the disadvantages of known wound fillers.

According to a first aspect of the present invention there is provided a wound packing unit comprising a resilient, fluid absorbent material contained within a porous bag member, the porous bag member being made of a material which is non-adherent to the wound.

The resilient, fluid absorbent material may be any suitable known material such as gauze, foams and the like which are known for use in wound packing.

The porous bag member may be any suitable material known to be non-adherent to a wound and especially to new growing tissue. As noted above, one of the problems of using known gauzes and foams for wound packing or filling materials is that the pore sizes of the material often leads to in-growth of granulation tissue into the pores and which may be damaged on changing a wound dressing and also causing pain to the patient. The size of surface porosity of the bag member may be such that growing tissue does not grow into the surface pores and thus does not create a mechanical connection thereto. The material from which the porous bag member may be formed may be a suitable plastics sheet or net material such as EVA, PU, PP, PE, silicone, carbomethoxy cellulose, polyacrylate, for example.

The plastics sheet may comprise nets, woven materials, non-woven fibrous sheet, foams, electrospun nano fibres, for example, from a wide variety of different materials such as those noted above, for example.

A required porosity may be endowed in the case of sheet film material by perforating the sheet with any desired pattern or form of perforations.

The wound packing unit may be made from two sheets of suitable material having substantially coterminous outer shapes, for example, and be welded together at their outer peripheries so as to contain the resilient absorbent material in the cavity so formed. The bag member may comprise two sheets of material joined at their peripheries to form a pocket therein to receive the resilient, fluid absorbing material therein.

In one embodiment the sheets from which the wound packing units are made may be circular, for example.

The wound packing unit according to the present invention may be used as a general, stand-alone wound filling medium in the context of a dressing used for the treatment of any type of wound. Furthermore, the wound filling unit as defined is not used in a sub-divided form by, for example, cutting into a smaller member. A particular advantage of using the wound packing units as one or more units to fill a wound without cutting as with known wound packing materials such as gauze and foam on their own is that there is no shedding of particles due to cutting and consequently no occluded particles in the wound which may lead to infection.

Whilst the wound packing unit may be used singly or in a plurality thereof as general wound filling member(s) in any dressing where suitable, the wound packing unit according to the present invention may advantageously be used as part of a wound dressing in TNP therapy. In such a dressing, the wound packing unit or plurality of them may be used to pack the wound and, the most basic form of TNP therapy, a covering film or drape adhered over the wound to the patient's sound flesh surrounding the wound in order to form a closed or sealed cavity over the wound, and an aspirant conduit connected to a vacuum source being admitted to the so-formed wound cavity.

When used as part of a dressing in TNP therapy the sheet material may desirably be textured so as to form channels in the surface adjacent the wound surface to further enhance the generation of an even negative pressure distribution over the surface of the wound and to enhance the flow and drainage of wound exudate to an aspirant conduit so that it may be aspirated from the wound vicinity into a remotely located waste receptacle. Whilst the filling of the bag member may be an absorbent material able to absorb wound exudate, it is nevertheless beneficial that as much of the exudate as possible is aspirated to a waste receptacle. In this way risk of infection due to build up of exudate may be minimised.

In one embodiment of a porous bag member according to the present invention the textured surface may comprise an array of hexagonal indentations or depressions in the bag material surface effectively producing a three-dimensional surface structure, each indentation or depression having a perforation at its centre to allow fluid flow, both gaseous and liquid, over both surfaces of the bag member, i.e. between the wound surface and bag surface and between the bag surface and filling. A suitable material from which the bag member may be made may be a vacuum formed plastics sheet material such as, for example, EVA film which is soft and non-adherent to a wound surface.

The bag member may have any desired surface topography and formations which are conducive to wound surface therapy.

When used in TNP therapy, the bag member may have an aspirant conduit having a drain portion affixed during manufacture with its drain end inside the bag member and surrounded by the resilient absorbent filling. In this way time may be saved applying a TNP dressing and also the correct positioning of the aspirant conduit may be ensured.

The resilient absorbent filling material within the bag member may also be provided with antimicrobial additives such as silver, for example, to reduce or control bacterial load so as to control infection.

The resilient absorbent material filling of the wound packing unit may also advantageously be provided with other biologically active components in addition to or in substitution of silver, such as antimicrobial compounds e.g. silver containing species, iodine, guanidines, biguanidines etc., analgesics e.g. aspirin, ibuprofen etc.,

anaesthetics e.g. amethocaine, lignocaine etc., growth factors e.g. VEGF PDGF, vasodilators e.g. NO, sildenafil, histamine etc. for example. Other examples of suitable active components may be found in WO 2005/105180 the content of which is included herein by reference.

The sheet material of the wound packing units according to the present invention may optionally be soaked or coated in a non-adherent gel such as, for example, a petroleum gel an example of which is Cuticerin (trade mark), silicone gel or a hydrogel.

As with the filling the sheet material forming the porous bag member may also be treated with silver for antimicrobial purposes etc.

The resilient, fluid absorbent material within the porous bag member or the porous bag member itself may be formed from laminated material so as to provide a texture to the wound packing member unit. Such laminated material may have a “quilted” type of texture where two layers of material may be welded together in a pre-determined pattern with a layer of a resilient material such as an open cell polymer foam, for example, between. The two outer material layers of the laminate may be provided with an array of pores in predetermined fashion to permit ingress of exudate. Some cells formed by a laminating procedure may be left unperforated so as to provide resilience by virtue of compressing the air trapped inside unperforated pockets or cells so formed.

A porous bag member may be formed from two layers of laminated material as described above. Furthermore, a wound packing unit so formed may also further comprise resilient, fluid absorbent material therebetween.

The types of sealing film drapes generally used to form the overlying wound sealing medium in TNP dressings usually have a coating of adhesive over the whole surface of the film. Therefore, it may be desirable to place a second sheet of non-adhesively coated film between the sealing film drape and the wound packing unit of the present invention so that when the sealing drape is removed as the first step of a dressing change the wound packing unit is not torn from the wound with it.

According to a second aspect of the present invention there is provided a method for packing a wound cavity comprising the steps of; forming a wound packing unit by

enclosing a resilient absorbent material within a porous bag member, the porous bag member being made of a material which is non-adherent to the wound.

In order that the present invention may be more fully understood examples will now be described by way of illustration only with reference to the accompanying drawings, of which:

Figures 1A and 1B show a cross section through a bag member of a wound packing unit made from embossed EVA material and a detail thereof, respectively;

Figures 2A and 2B show a plan view of the embossed pattern of the material of the bag member of Figure 1 and a cross section therethrough, respectively;

Figure 3shows a photograph of two examples of wound packing units according to the present invention;

Figure 4 shows a schematic cross section of one embodiment of a wound packing unit incorporated into a TNP therapy dressing; and

Figure 5 which shows a second embodiment of a wound packing unit incorporated into a TNP therapy dressing.

Referring now to the drawings and where the same features are denoted by common reference numerals.

Figure 1 shows a cross section through a wound packing unit 10 comprising a bag member 12 and a filing 14 of a resilient, fluid absorbent material. The bag member is made from thin, embossed EVA material sheet 15, a small enlarged area of which is shown at Figure 1B, and comprises two circular sheet portions 16, 18 which are RF welded 20 around their peripheries. The two sheets are partially welded around their peripheries, filled with the suitable resilient and absorbent filing material 14 such as gauze, foam, chipped foam or non woven, and then the remainder of the periphery is welded so as to form a completely sealed wound packing unit apart from the porosity of the sheets 16, 18 themselves. Thus, the wound packing unit 10 also forms a resilient and fluid absorbing medium with which to pack wounds being treated.

The bag member 12 is manufactured from a thin flexible plastics material such as EVA, for example and which has a vacuum-formed textured surface 50. The surface topography comprises an array of hexagons 52 having a central perforation 54 in each hexagon (although not all indentations may be perforated). The individual hexagons are separated by channels 56 as shown in Figures 2A and 2B. Figure 2B shows the contour of the hexagonal indentations from a side view. In the illustrated embodiment the hexagons 52 are 2.6 mm across the flats, the central perforations 54 are 0.6mm in diameter and the depth of the hexagonal indentations from the planar surface is 1.05mm. However, these dimensions are merely exemplary of one embodiment of a bag member according to the present invention and dimensions may vary according to the needs of a particular wound in other embodiments.

Although the example of the wound filling device described above is stated to be made with circular sheets of material, it is of course merely exemplary and the bag 12 may be made to any required shape and size to suit a particular wound shape and size or a range of wound shapes and sizes.

The wound packing unit described above may be used to fill any general wound and Figure 3 shows two examples of wound packing units; the larger one being approximately 10 cm in diameter and the smaller one approximately 5 cm in diameter.

Figure 4 shows a schematic cross section through a wound 100 being treated with TNP therapy. The wound 100 has a wound packing unit 102 as described with reference to Figures 1 and 2 and is provided as an entity complete with an aspirant conduit 104 which is incorporated in and sealed to the bag member 106 at 108 where it passes through. The end drain portion 110 of the conduit 104 is embedded in and wrapped with the filling material 112 of the wound packing unit. A sealing drape 114 is adhered to the patient's sound flesh 116 around the border of the wound 100. The sealing drape 114 is provided with a coating of pressure sensitive adhesive (not shown) over the surface which is to be adhered to the patient and the conduit 104 where it passes through the sealing drape is sealed to the drape by means of the drape being pinched around the conduit itself at 120. The conduit 104 is connected to a vacuum source 122 such as an electric vacuum pump, for example. The vacuum source may also be associated with a waste receptacle (not shown) in known manner and to which wound exudate from the wound 100 may be aspirated. The closed volume beneath the sealing drape 114 forms a wound cavity 124 which is subject to a negative pressure as created by the vacuum source 122. Outside

ambient atmospheric pressure bears down upon the wound packing unit 102 so as to compress it and hold the sides/edges of the wound apart to prevent them growing over and forming an occluded cavity in the wound.

The embodiment 200 shown in Figure 5 is similar to that of Figure 4 except that the conduit 202 is placed in the wound 204 separately from the wound packing unit 206. In essence this embodiment works in a similar manner to that of Figure 4.

Both the embodiments of Figures 4 and 5 work in essentially the same manner in that the vacuum created in the wound cavity is evenly distributed by virtue of the perforations and channels in the embossed material forming the bag member thus, allowing fluid access to and from all parts of the wound surface. The perforations and channels allow transport of wound exudate both over the wound surface and also through the interior of the wound packing unit towards the aspirant conduit in each case.

Throughout the description and claims of this specification, the words “comprise” and “contain” and variations of the words, for example “comprising” and “comprises”, means “including but not limited to”, and is not intended to (and does not) exclude other moieties, additives, components, integers or steps.

Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

Features, integers, characteristics, compounds, chemical moieties or groups described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith.

CLAIMS

1. A wound packing unit comprising a resilient, fluid absorbent material contained within a porous bag member, the porous bag member being made of a material which is non-adherent to the wound and characterised in that the porous bag member is formed from a laminated material.
2. A wound packing unit according to claim 1 wherein the resilient, fluid absorbent material is selected from the group comprising: gauze; foams and non woven materials.
3. A wound packing unit according to either claim 1 or claim 2 wherein the porous bag member material is a sheet or net material
4. A wound packing unit according to any one preceding claim wherein the material from which an outer surface of the porous bag member is formed may is selected from the group comprising: EVA, PU, PP, PE, silicone, carbomethoxy cellulose and polyacrylate.
5. A wound packing unit according to claim 3 wherein the sheet material is selected from the group comprising: perforated and embossed sheet, woven materials, non-woven fibrous sheet, foams and electrospun nano fibres.
6. A wound packing unit according to claim 5 wherein the sheet material is coated in gel.
7. A wound packing unit according to claim 5 wherein the sheet material is coated in silver.
8. A wound packing unit according to any one preceding claim wherein the resilient, fluid absorbent material is treated with silver.
9. A wound packing unit according to any one preceding claim wherein the resilient, fluid absorbent material is treated with biologically active components.
10. A wound packing unit as claimed in any one preceding claim further having combined therewith a conduit for use in topical negative pressure therapy.
11. A wound packing unit as claimed in any one preceding claim wherein the bag member comprises two sheets of material joined at their peripheries to form a pocket therein to receive the resilient, fluid absorbing material therein.
12. A wound packing member according to any one preceding claim wherein the laminated material comprises a foam material between two outer layers.
13. A wound packing unit according to either claim 12 wherein the laminated material comprises a predetermined pattern of cells or pockets.

14. A wound packing unit according to claim 13 wherein the cells or pockets are formed by welding together of the two outer layers.

15. A wound packing unit according to claim 13 or claim 14 wherein the bag material has a quilted texture.

16. A wound packing unit according to any one of claims 13 to 15 where some cells are unperforated.

17. A wound packing unit substantially as hereinbefore described with reference to the accompanying description and Figures 1 to 3; or Figure 4; or Figure 5 of the drawings.

18. A method for packing a wound cavity comprising the steps of; forming a wound packing unit by enclosing a resilient absorbent material within a porous bag member, the porous bag member being made of a material which is non-adherent to the wound and characterised in that the porous bag member is formed from a laminated material.

19. A method according to claim 18 wherein the wound cavity is treated by topical negative pressure therapy.

20. A method for packing a wound cavity substantially as hereinbefore described with reference to the accompanying description and Figures 1 to 3; or Figure 4; or Figure 5 of the drawings.

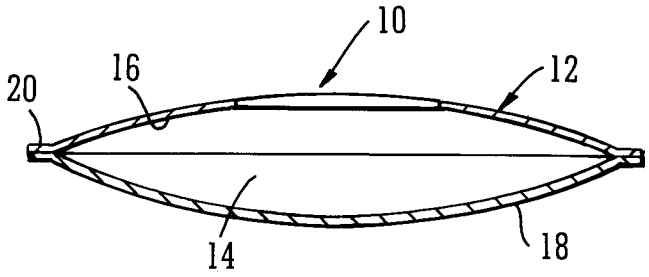


FIG. 1A

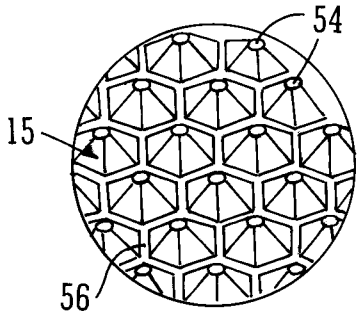


FIG. 1B

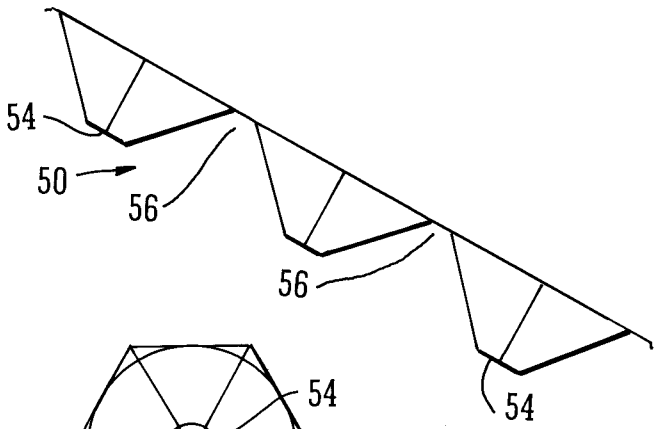


FIG. 2B

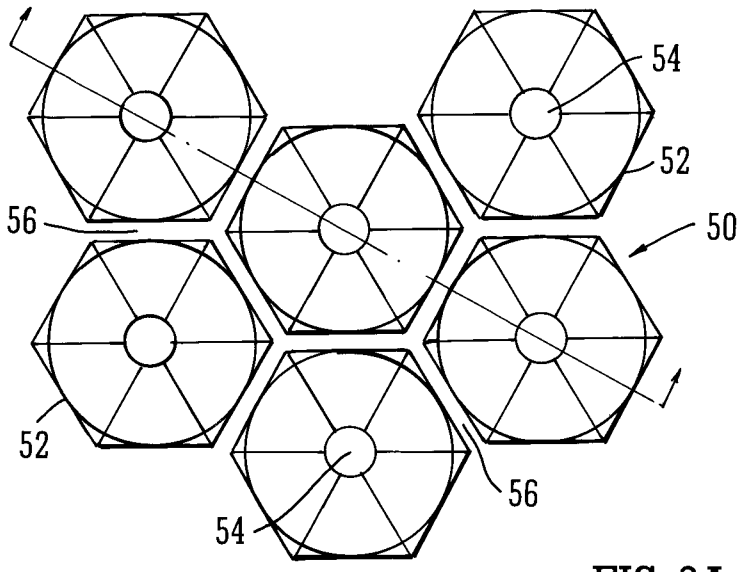


FIG. 2A

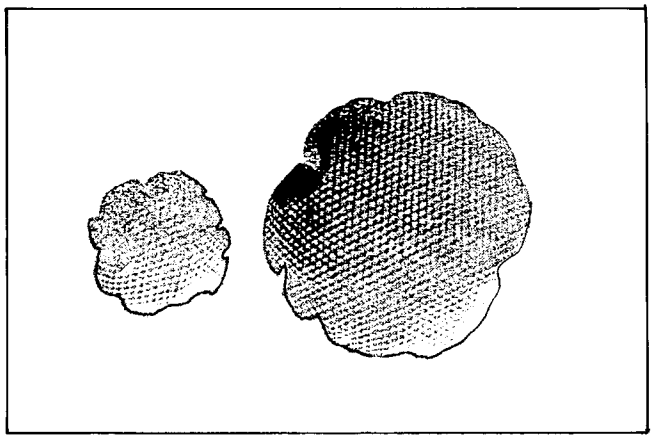


FIG. 3

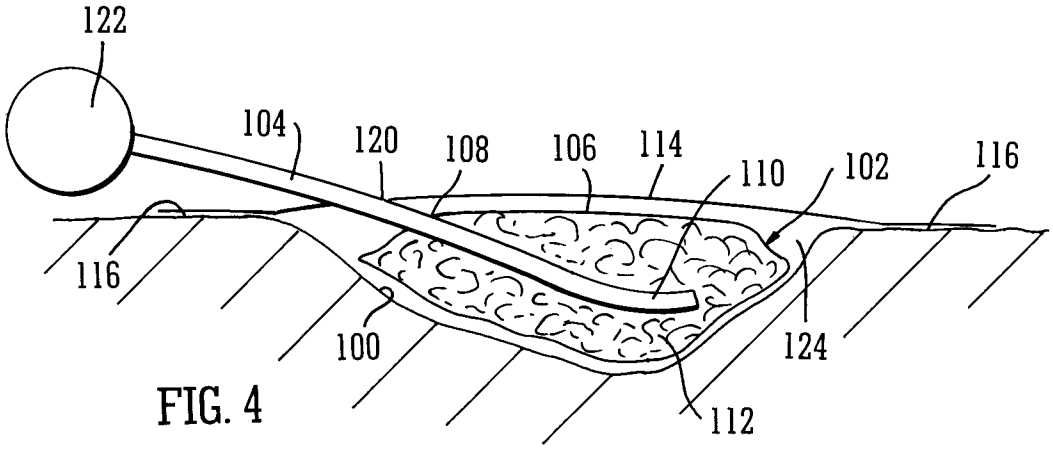


FIG. 4

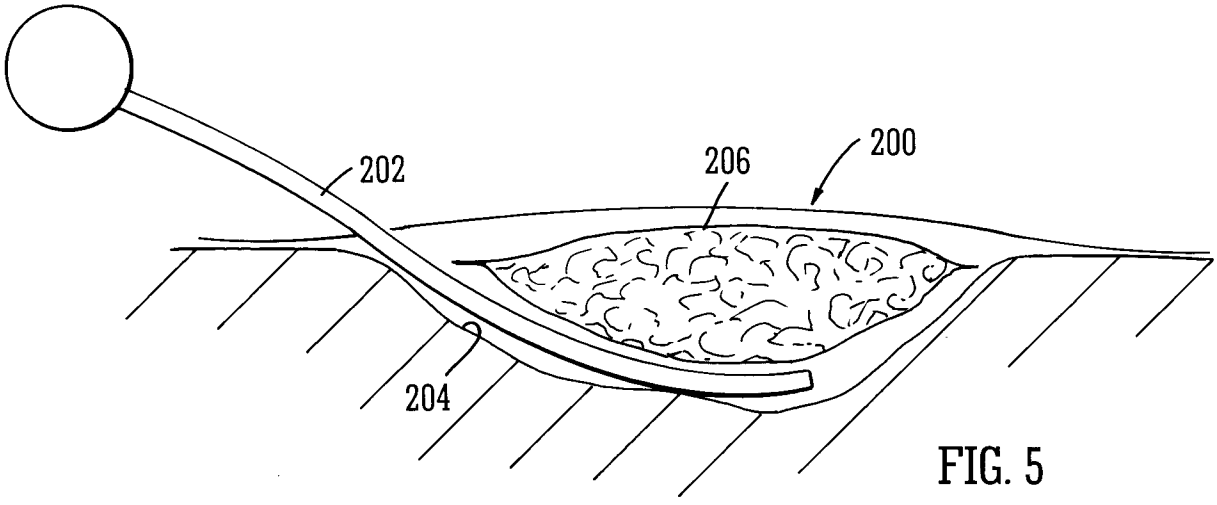


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/051134

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/02
ADD. A61M1/00 A61M27/00

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 A61M

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 Y	WO 2006/089551 A (COLOPLAST AS [DK]; GUNDERSEN BOERGE [DK]) 31 August 2006 (2006-08-31) page 15, line 31 - page 16, line 15; figure 4 page 9, line 27 - page 10, line 4 page 13, line 15 - page 14, line 9	1-5,7-9, 11 6,10, 12-16
Y	WO 95/03018 A (SMITH & NEPHEW [GB]; WEBB JULIAN [GB]; REED CHRISTOPHER IAN [GB]; SMIT) 2 February 1995 (1995-02-02) page 19, lines 8-16 page 15, lines 27-32; figures 1,2	6,12-16
Y	DE 20 2004 018245 U1 (RIESINGER BIRGIT [DE]) 7 July 2005 (2005-07-07) abstract; figure 1	10

☐ 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	Date of mailing of the international search report
25 March 2009	03/04/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Böttcher, Stephanie

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2008/051134

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. [X] Claims Nos.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Claims 18-20 relate to a method for treatment of the human or animal body by therapy

2. [X] Claims Nos.: 17
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:

see FURTHER INFORMATION sheet PCT/ISA/210

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 allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, 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 reportcovers 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.

Continuation of Box II.1

Claims Nos.: 17-20

Rule 39.1(iv) PCT - Claims 18-20 relate to a method for treatment of the human or animal body by therapy

---

Continuation of Box II.2

Claims Nos.: 17

Claim 17 relies, in respect of the technical features of the invention, on references to the description and drawings, contrary to the provisions of Rule 6 PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2008/051134

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006089551 A	31-08-2006	EP 1855630 A1	21-11-2007
		US 2008171958 A1	17-07-2008
WO 9503018 A	02-02-1995	AT 179319 T	15-05-1999
		AU 686644 B2	12-02-1998
		AU 7193294 A	20-02-1995
		CA 2167579 A1	02-02-1995
		DE 69418197 D1	02-06-1999
		DE 69418197 T2	14-10-1999
		DK 710095 T3	08-11-1999
		EP 0710095 A1	08-05-1996
		ES 2133563 T3	16-09-1999
		JP 9502367 T	11-03-1997
		NZ 268653 A	24-10-1997
		US 5633007 A	27-05-1997
DE 202004018245 U1	07-07-2005	AT 390941 T	15-04-2008
		AU 2005309089 A1	01-06-2006
		CA 2589312 A1	01-06-2006
		CN 101065158 A	31-10-2007
		DK 1814609 T3	04-08-2008
		EP 1814609 A1	08-08-2007
		WO 2006056294 A1	01-06-2006
		ES 2304730 T3	16-10-2008
		US 2008119802 A1	22-05-2008