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(54) Title: WOUND DRESSING DEVICE, ASSEMBLY AND METHOD

(57) Abstract: The present disclosure provides a device, method and assembly for use in wound treatment. Specifically disclosed is a wound dressing device; an assembly, e.g. in the form of a kit-of-parts, which comprises the device as one of its components; and a method of wound dressing and a use wherein said device is a key component. The device comprises a cavity defined by concave walls surrounded by lips configured for attachment to skin in a fluid tight manner and a closure removably fixed to the lips and sealing the cavity. The assembly also comprises, as other of its components a device for introducing blood into the cavity after it is fixed over a wound to permit the blood to clot over the wound within said cavity. In use, the clotting mold device is fixed on top of a wound, and blood is introduced into the mold space to permit the blood to clot within the mold space to thereby form a blood clot over the wound.

WOUND DRESSING DEVICE, ASSEMBLY AND METHOD

TECHNOLOGICAL FIELD

This disclosure is in the field of wound treatment and concerns a wound dressing device, assembly and method.

BACKGROUND

Chronic wounds and skin ulcers are a serious medical condition and effective wound treatment approaches is a recognized medical need.

US 9,180,142 discloses a wound treatment procedure by which blood is coagulated and the so-formed blood clot is applied onto a wound with a dressing material.

GENERAL DESCRIPTION

The present disclosure concerns wound treatment through the use of a blood clot. Specifically provided by this disclosure is a wound dressing device and assembly (e.g. in the form of a kit-of-parts for use in the currently disclosed wound treatment) for forming a blood clot, a method for preparing a blood clot-comprising wound dressing, and a method for dressing the wound therewith.

The blood clot that is formed and used according to this disclosure is typically formed from blood of the same subject whose wound is to be dressed by the teaching of this disclosure, withdrawn from the subject in any manner acceptable in medical practice for blood withdrawal. However, the use of blood from a different source, e.g. blood obtained from a blood bank, is also contemplated in accordance with this disclosure.

Three aspects are provided by this disclosure: one concerns a wound dressing device; the other concerns an assembly, e.g. in the form of a kit-of-parts, which comprises said device as one of its components; and the third concerns a method of wound dressing and a use wherein said device is a key component.

All three aspects center around the formation of a blood clot, *in situ*, onto a wound, as part of the wound dressing procedure. In other words, the blood, still in liquid state, is brought into contact with the wound and is induced to clot while at least partially in contact with the wound to be dressed therewith. All three aspects are encompassed in the following description by the term "*wound dressing procedure*".

The method comprises fixing a device of the kind disclosed herein, on top of the wound, the device defining with the wound an enclosed space which serves as a mold (cast) for clotting blood on top of the wound. This space will be referred to herein as a "*mold space*".

The device comprises a cavity or depression surrounded by lips configured for attachment to skin in a fluid tight manner. The cavity or depression may have walls that may be generally concave, polygonal or any other suitable shape. In some embodiments, the cavity is shallow, namely, it has a depth relatively smaller than the overall area confined by the walls.

The lips typically define narrow flat surfaces that when brought into contact with the skin, should be relatively level and smooth to permit fluid tight attachment to the skin. By an embodiment of this disclosure, the lips may carry an adhesive that will ensure fluid tight attachment to the skin.

In addition, in some embodiments, the adhesive may be applied onto the skin or onto the lips, prior to attachment. At times, according to this embodiment, at least a portion of the lips may have a rough surface onto which the adhesive is applied prior to fixation onto the skin. It is also possible, by other embodiments of this disclosure, to fit a two-sided adhesive strip onto the lips or the skin to be used as means for attachment. By still another embodiment, the attachment may be by means of an adhesive tape fitted over the device's lips and the surrounding skin portions for tight association throughout the blood clot formation process.

By other embodiments, the attachment of the lips to the skin may be by forming a vacuum within the mold space, by forcing the device (and hence the lips) against the skin by hand, by the use of an elastic band, adhesive tape or other means for tight forcing of the device against the skin.

The wound's surface area confined between the lips may have different shapes and sizes to suit wounds of different shapes and sizes. Thus, the wound dressing procedure may also involve selection of a device of the proper shape and size to permit the lips to be placed on skin portions surrounding the wound's boundaries. In some embodiments, the device is flexible or pliable to permit its shaping and/or stretching to a desired shape and wound surface area to be confined between the lips.

The device may also comprises a closure that is removably attached to the lips and seals the cavity until use. The closure may be useful for maintaining sterility of the cavity and for holding elements, such as a coagulant initiator and/or scaffold matrix within the cavity. The closure may, for example, be a film made of plastic, foil, a combination thereof, etc. that is pealed from the opening of the cavity (the lips) prior to fixation onto the skin.

according to the wound dressing procedure disclosed herein, once the lips are firmly fixed to skin portions surrounding the wound, a mold space is formed, which, as noted above, is defined between the surface of the wound and the cavity's walls. Blood, typically whole blood, can then be introduced into the mold space and permitted to clot within the mold space to form a blood clot over the wound. The blood clot is maintained over the wound for a time period. This time period may vary and is typically several hours, several days or several weeks, e.g. 1 day, 2-6 days, 1 week, 2-4 weeks, and at times even longer, as well as for any period of time in-between than that indicated. In some embodiments, the blood clot may be maintained over the wound for the entire healing process of several weeks to several month. In some embodiments the wound treatment comprises periodical refreshing procedures that comprises removal of an existing blood clot from the wound and then forming a new blood clot on the wound in a manner as described above. The time period between a blood clot formation over a wound and the performance of a refreshing procedure may be, for example, 1 day, 2-6 days, 1 week, 2-4 weeks, etc., as well as for any period of time in-between than that indicated. The entire wound healing procedure may involve several consecutive refreshing procedures.

The device's walls may be made from a variety of materials. Typically, in order to permit monitoring the blood introduction and the clot formation, the walls or parts thereof are transparent.

Introduction of the blood involves, by one embodiment, piercing the wall with a needle and then injecting blood into the mold space through the needle. Optionally, this introduction is preceded by a second piercing of the wall on an adjacent or different location, to thereby form a vent aperture to permit release of excess pressure during blood introduction. By other embodiments, the walls may comprise a venting valve which, *a priori*, is sealed and opened before the blood introduction and/or a port for introducing the blood into the mold space.

By one embodiment, the device is removed after the blood clot is formed. To facilitate easy removal, e.g. without severing the integrity of the formed blood clot, the walls are preferably made of or coated with a material to which a blood clot does not adhere. By another embodiment, the device or part thereof remains *in situ* after the blood clot is formed and serves as part of the wound dressing.

In the case where the device is removed after clot formation, a dressing material, for example, gauze, plaster or bandage, may be fitted over the blood clot to protect and secure the blood clot in place. The wound dressing procedure, by some embodiments, may make use of a scaffold matrix combined with and brought into contact with the blood prior to its clotting, so as to become integrated with the thus formed blood clot. The scaffold matrix supports the clot and assists in maintaining the clot's structural integrity. The scaffold matrix may, by one embodiment, be an independent element fitted onto the wound, prior to said fixing of the device onto the skin; by another embodiment, the scaffold matrix may be comprised within the cavity, e.g. *a priori* comprised therein or introduced into the cavity before fixing the device onto the wound. The scaffold matrix may, for example, be a 2-domesional or 3-dimensional matrix, may be a porous material, may have a netlike structure; may be made of a polymeric material such as plastic, may be made out of natural or synthetic fibers or made out of a woven or non-woven cloth, e.g. gauze.

In order to ensure controlled coagulation, the blood may be contacted with one or combination of coagulation initiators, namely, one or more substances (synthetic or naturally occurring) that promotes/activates blood coagulation. In some embodiments, the coagulation initiator is kaolin. When using a coagulation initiator, coagulation of blood may involve, for example, mixing the blood with kaolin shortly before introduction into the mold space. Alternatively, the coagulation initiator may *a priori* be present within

the cavity; for example, attached to the walls or incorporated into a scaffold matrix, placed within or a priori comprised within the cavity or further, separately introduced into the mold space (e.g. by injection) before or after introduction of the blood. In addition or alternatively, the coagulation initiator may be incorporated into a scaffold matrix that is fitted onto the wound, prior to fixing of the device over the found.

In some embodiments, the coagulation initiator is independently stored, e.g. as a powder, granulate or liquid in a separate container and subsequently mixed with the blood upon introduction into the mold space or applied onto the scaffold matrix prior to or after introducing the blood. By still another alternative, the coagulation initiator may be applied directly onto the wound as a first step in the wound treatment procedure.

The wound dressing assembly or kit of this disclosure comprises a clotting mold device of the kind specified above. In addition, according to some embodiments, the assembly or kit may comprise other elements or devices required for the *in situ* formation of the blood clot on the wound, e.g. a syringe for introducing blood into the cavity. The assembly or kit may comprise also a dressing material for applying over the blood clot formed over the wound.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to better understand the subject matter that is disclosed herein and to exemplify how it may be carried out in practice, embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig 1 shows a wound dressing device according to an embodiment of this disclosure.

Fig. 2 shows the wound dressing device after removal of the closure and applied onto the skin.

Figs. 3A and 3B show, respectively, two steps of introducing blood into the mold space.

Fig. 4 shows the wound dressing device with blood still in liquid form with the device secured by adhesive tape to the skin.

Fig. 5 shows the blood clot with the device partially ruptured prior to removal.

Fig. 6 shows the blood clot on the skin after its formation and after the device has been removed.

DETAILED DESCRIPTION OF EMBODIMENTS

The invention will now be illustrated with reference to embodiments shown in the annexed Figures. It should be noted that these Figures are pictures from a test trial on skin without a wound, to demonstrate the wound dressing procedure of this disclosure.

The device **100** shown in **Fig. 1** includes generally concave walls **102** that form a cavity **104** defined between lips **106** that are generally flat. The opening defined between the lips is sealed by a removable closure **108** which is a laminate/film fitted onto lips **106**. After removal of closure **108**, the device **100** is placed onto skin, an adhesive remaining after removal of the closure causes it to adhere to the skin. A device **100** fixed to a subject's skin is shown in Fig. 2.

Also shown in **Fig.1** is a scaffold matrix **112** placed within the cavity, the scaffold matrix holds a coagulation initiator **110**.

Turning now to **Figs. 3A-3B**, steps of introducing blood, typically whole blood into the mold space are shown. Specifically, blood withdrawn from the subject or alternatively taken from a blood bank, is injected with a needle **120** into the mold space formed between the walls **102** and underlying portion of the skin or wound. According to this non-limiting embodiment, upon introduction into the mold space, the blood is mixed with the coagulation initiator **110** *a priori* present in the cavity. The needle **120** first pierces the walls of the device and then injects the blood contained in the syringe (not seen).

In some other embodiments, the blood is pre-mixed with a coagulation initiator, such as Kaolin, that is provided in a separate container (not shown), or the coagulation initiator is introduced into the mold space separately, either before, during or after the blood introduction.

As can also be seen in **Figs 1-3B** the walls of the device are transparent to permit monitoring the introduction and subsequent blood clotting.

The device is then allowed to remain attached to the skin with the blood held within the mold space for a time at least until the blood has clotted. Such time may range

from several days, to one or more weeks, The device can be secured to the skin by use of an adhesive strip **130**, as seen in **Fig. 4**.

After a period of time, a blood clot is formed and the walls of the device can then be cut away, as seen in **Fig. 5**; and, after removal, a blood clot **140** remains on top of the skin, as seen in **Fig. 6.** Where the procedure will be performed over a wound, the blood clot will cover the wound and a dressing material, which may be conventional dressing material, such as gauze or bandage, will be applied over the clot for protecting the wound and securing the clot in place.

CLAIMS:

1. A clotting mold device comprising a cavity for holding blood, the cavity being defined by concave walls surrounded by lips configured for attachment to skin in a fluid tight manner and a closure removably fixed to the lips and sealing the cavity.

2. The clotting mold device of claim 1, wherein the lips comprise an adhesive or are configured for receiving adhesive for permitting fixation of said lips onto skin portions.

3. The clotting mold device of claim 1 or 2, comprising a scaffold matrix within said cavity.

4. The clotting mold device of claim 3, wherein said scaffold matrix is selected to become integrated within a blood clot formed within said cavity.

5. The clotting mold device of claim 2 or 3, wherein said scaffold matrix is a gauze.

6. The clotting mold device of any one of claims 1 to 5, wherein at least a portion of said concave walls are pierceable by a needle.

7. The clotting mold device of any one of claims 1 to 6, comprising in said cavity a coagulation initiator.

8. The clotting mold device of claim 7, wherein said coagulation initiator is incorporated into a scaffold matrix that is comprised within said cavity.

9. A method for dressing a wound, comprising:

fixing a clotting mold device on top the wound,

said device comprises a cavity surrounded by lips that are configured for attachment to skin in a fluid tight manner, and

said fixing comprising attaching the lips to skin portions surrounding the wound to thereby form a mold space defined between the wound and the cavity;

introducing blood into the mold space and permitting the blood to clot within the mold space to thereby form a blood clot over the wound; and

maintaining the blood clot over the wound for a wound-healing period.

10. The method of claim 9, wherein said fixing comprise adhering the lips onto said skin portions.

11. The method of claim 10, wherein the lips comprises said adhesive or said adhesive is fitted onto said lips or onto said skin portions prior to said fixing.

12. The method of claim 9, wherein said fixing comprises forming a vacuum within the mold space.

13. The method of any one of the claims 9 to 12, comprising combining the blood clot with a scaffold matrix prior to blood clot formation, such that said scaffold matrix becomes integrated within the formed blood clot.

14. The method of claim 13, wherein said scaffold matrix is fitted onto the wound prior to said fixing.

15. The method of claim 14, wherein said scaffold matrix is comprised within said cavity.

16. The method of any one of claims 9 to 15, comprising

following formation of the blood clot, removing said device off the wound; and

fixing a dressing material, e.g. gauze, over the blood clot.

17. The method of any one of claims 9 to 16, wherein said introducing comprises:

piercing the walls by a needle; and

injecting blood into said mold space through the needle.

18. The method of any one of claims 9 to 17, wherein the blood is whole blood.

19. The method of any one of claims 9 to 18, comprising contacting the blood with a coagulation initiator.

20. The method of claim 19, wherein said coagulation initiator is characterized by one of the following

is mixed with the blood prior to said introducing,

is a priori present in the cavity,

is added into said mold space prior to or after said introducing, and

is incorporated into a scaffold matrix that is comprised within said cavity or fitted onto the wound prior to said fixing.

21. The method of any one of claims 9 to 20, wherein

said device comprises a closure, removably fixed to the lips and sealing the cavity,

said closure is removed prior to said fixing.

22. A wound dressing assembly, comprising

a clotting mold device comprising a cavity defined by concave walls surrounded by lips configured for attachment to skin in a fluid tight manner, and

a device for introducing blood into the cavity after it is fixed over a wound to permit the blood to clot over the wound within said cavity.

23. The wound dressing assembly of claim 22, wherein the device comprises a closure removably fixed to the lips and sealing the cavity.

24. The wound dressing assembly of claim 22 or 23, comprising a blood-coagulation initiator.

25. The wound dressing assembly of any one of claims 22 to 24, wherein the clotting device comprises a closure, e.g. in the form a film, removably fixed to the lips and sealing the mold space.

26. The wound dressing assembly of any one of claims 22 to 25, wherein the lips have an adhesive for adhesion to skin.

27. The wound dressing assembly of any one of claims 22 to 26, comprising a scaffold matrix configured for integration within the formed blood clot.

28. The wound dressing of assembly of claim 27, wherein the scaffold matrix is comprised within said cavity.

29. The wound dressing assembly of any one of claims 22 to 28, comprising one or both of

a syringe and a needle for piercing the walls and injection of the blood into the cavity, and

a dressing material for fixing over the blood clot.

30. The wound dressing assembly of any one of claims 22 to 29, wherein said coagulation initiator

is in a form of a powder, granulate or solution suitable for mixing with the blood or for applying directly onto the wound,

being a priori present in the cavity,

being incorporated into a scaffold matrix that is comprised within said cavity or intended for placement onto the wound prior to said attachment.

31. The wound dressing assembly of any one of claims 22 to 30, wherein the walls of the cavity comprise one or both of

a vent that is *a priori* sealed, for removal of excess pressure during introduction of the blood into the enclosure, and

a port for introducing blood into the mold space.

32. The wound dressing assembly of any one of claims 22 to 31, wherein the enclosure is made of a material to which a blood clot does not adhere.

33. The wound dressing assembly of any one of claims 22 to 32, wherein the walls is made of a material to which a blood clot does not adhere.

34. The wound dressing assembly of any one of claims 22 to 33, wherein at least a portion of the walls is transparent.

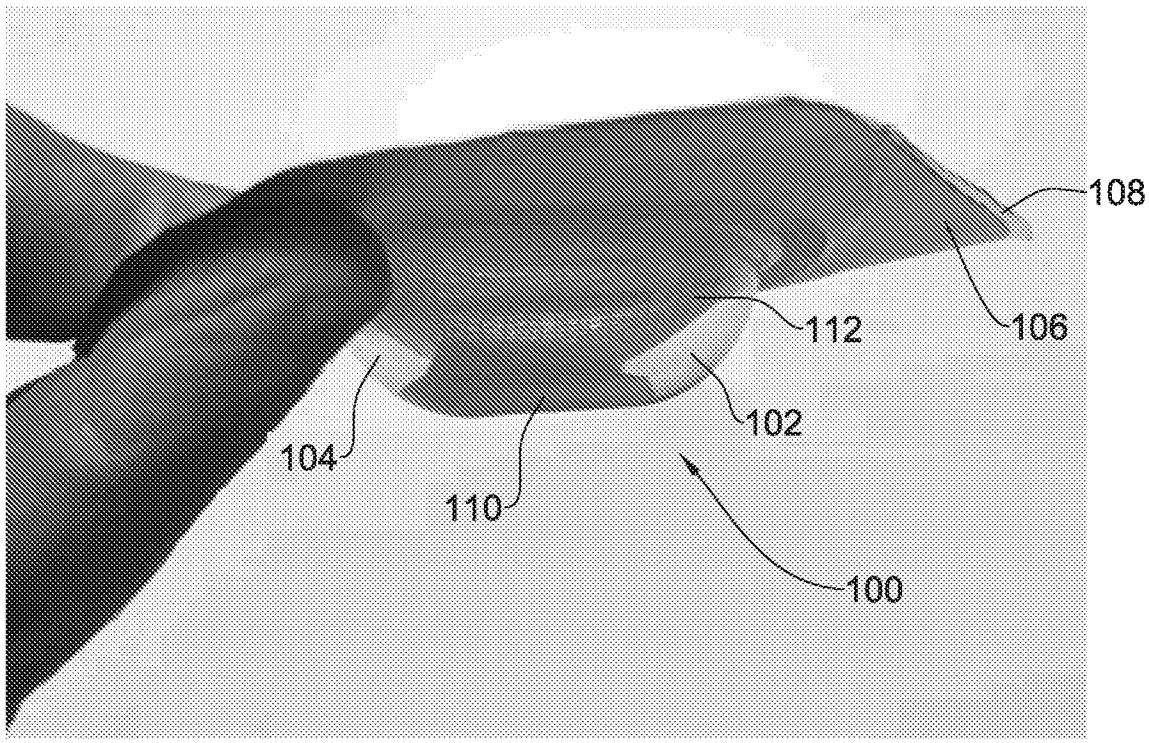


Figure 1

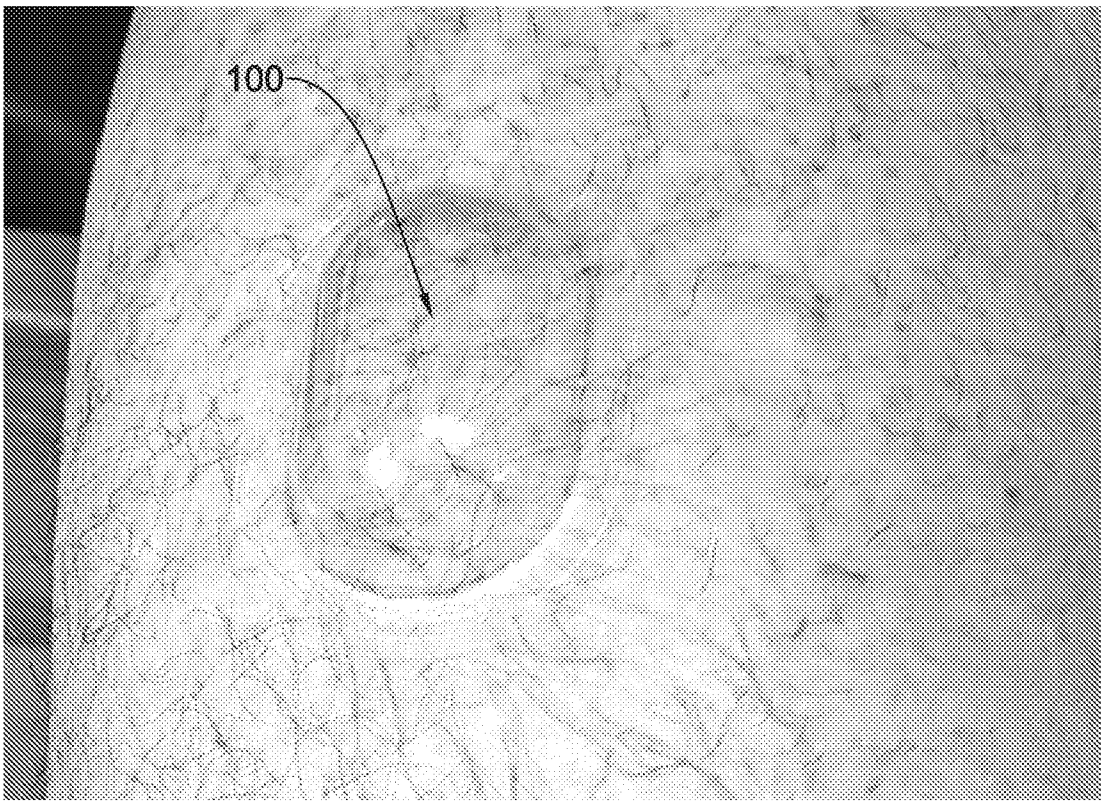


Figure 2

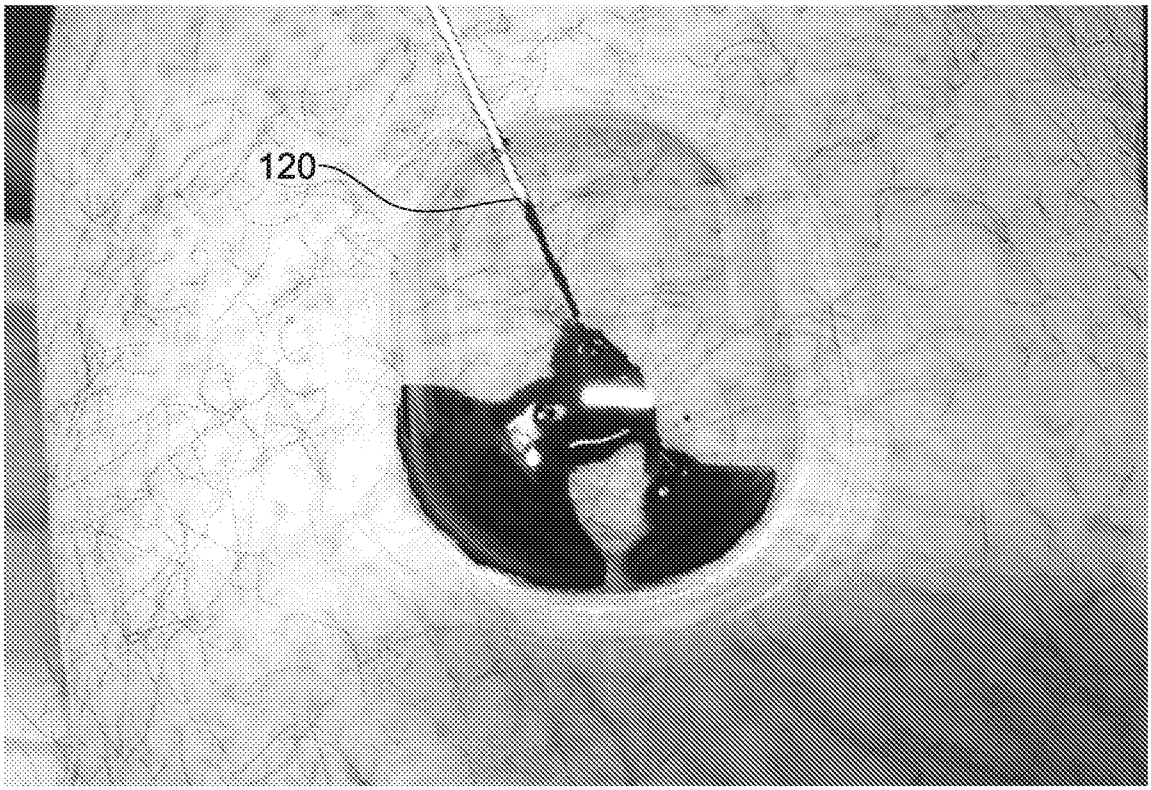


Figure 3A

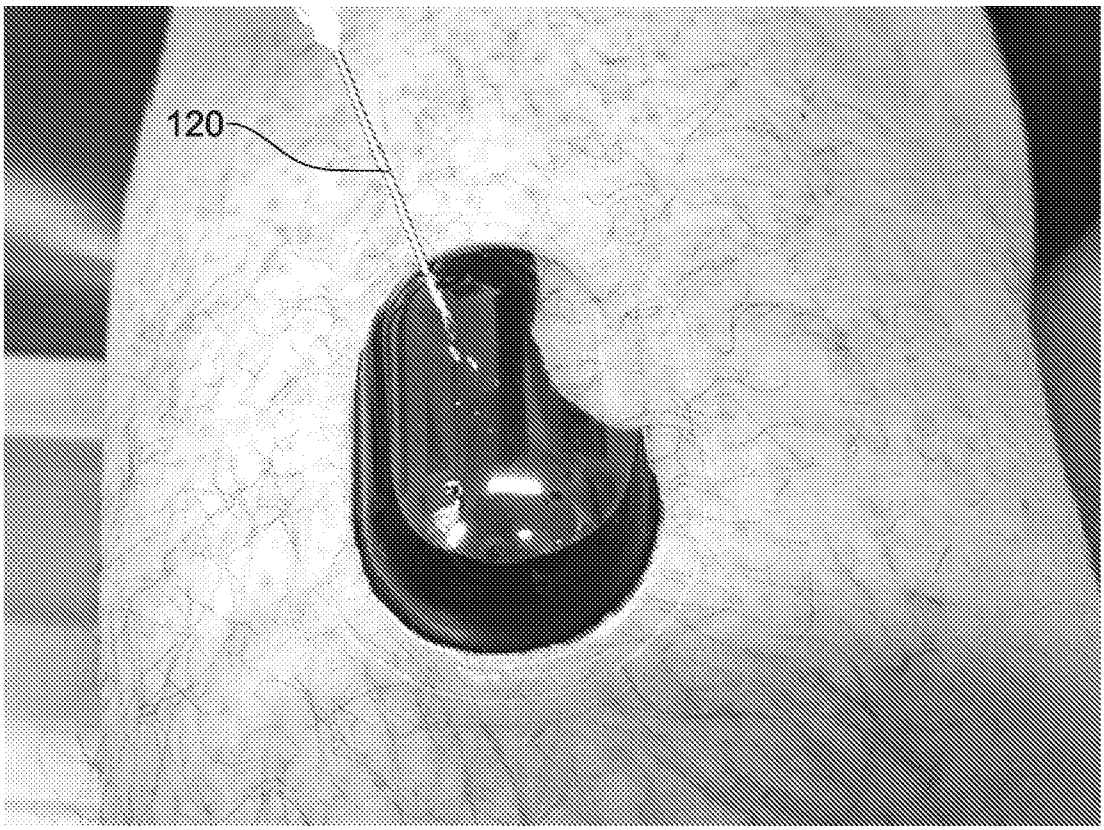


Figure 3B



Figure 4

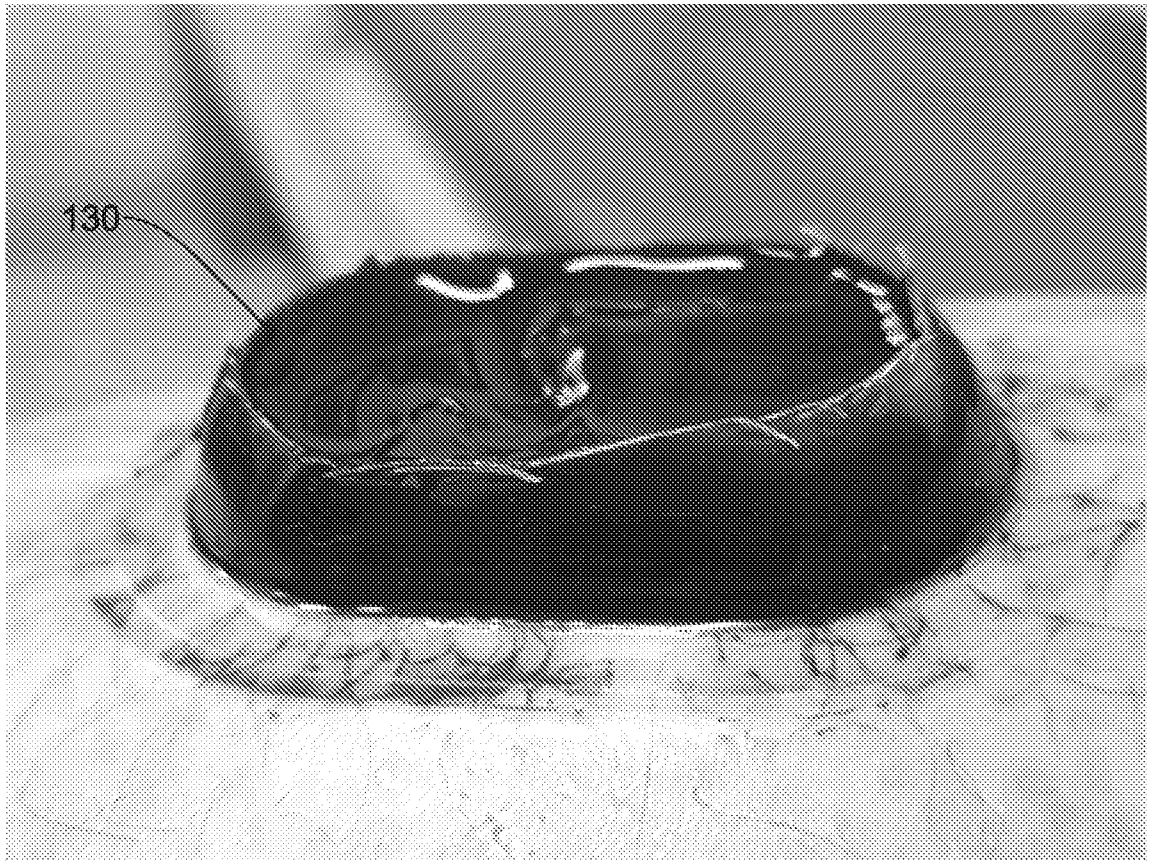


Figure 5

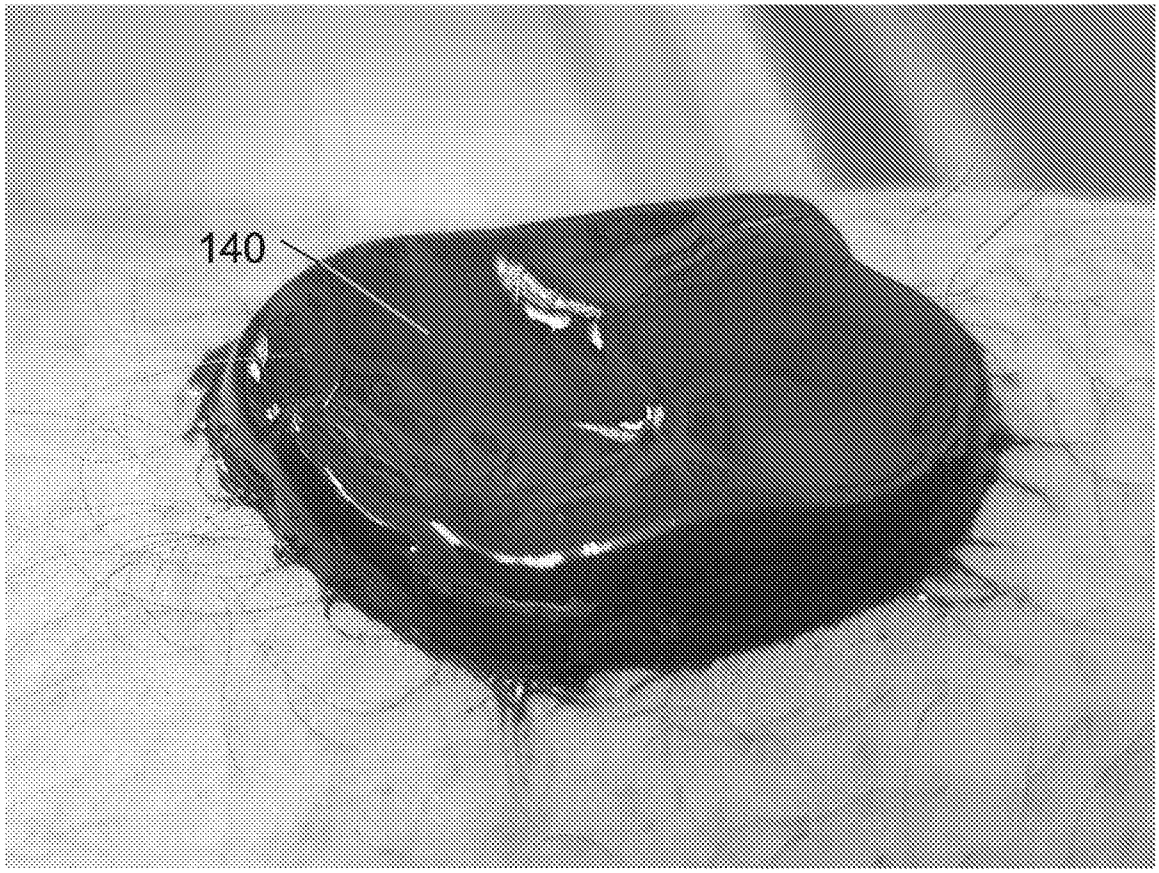


Figure 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2018/051049

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/02 A61M35/00 A61L15/40 A61F13/00
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)
A61F A61L 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 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	US 2012/179121 A1 (CARSON JAMES E [US]) 12 July 2012 (2012-07-12)	1,2
Y	abstract figures 1-5 paragraphs [0003] - [0006], [0015] - [0018], [0021], [0022] claims 1,2,5	3-8, 22-34

X	US 6 096 943 A (MAIWALD DIANE C [US]) 1 August 2000 (2000-08-01)	1,2,6
Y	abstract figures 1-8 column 1, lines 5-22 column 1, line 64 - column 2, line 28 column 3, line 28 - column 5, line 8	3-8, 22-34

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[X] Further documents are listed in the continuation of Box C.

[X] 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 application or patent 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
13 December 2018	20/12/2018

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	Schmitt-Humbert, C

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2007/055205 A1 (WRIGHT CLIFFORD A [US] ET AL) 8 March 2007 (2007-03-08) abstract figures 2-10 paragraphs [0003], [0006], [0008] - [0010], [0024] - [0032], [0038], [0043] - [0046], [0048]	1-8, 22-34 3-8, 22-34
A	Anonymous: "Telfa Dressings Datacard", , 28 March 2002 (2002-03-28), XP055533497, Retrieved from the Internet: URL:http://www.dressings.org/Dressings/telfa.html [retrieved on 2018-12-12] the whole document	1-8, 22-34
A	R. W. Farndale ET AL: "The role of collagen in thrombosis and hemostasis", Journal of Trhombosis and Haemostasis, 1 January 2004 (2004-01-01), pages 561-573, XP055533667, Retrieved from the Internet: URL:https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1538-7836.2004.00665.x [retrieved on 2018-12-12] abstract	1-8, 22-34
A	Monica . Sanandam ET AL: "CHITOSAN BANDAGE FOR FASTER BLOOD CLOTTING AND WOUND HEALING", International Journal of Advanced Biotechnology and Research, 1 January 2013 (2013-01-01), pages 47-50, XP055533663, Retrieved from the Internet: URL:https://www.researchgate.net/profile/Kiran_Shejale/publication/263244625_CHITOSAN_BANDAGE_FOR_FASTER_BLOOD_CLOTTING_AND_WOUND_HEALING/links/0046353a41cedb3fdf000000/CHITOSAN-BANDAGE-FOR-FASTER-BLOOD-CLOTTING-AND-WOUND-HEALING.pdf?origin=publication_detail [retrieved on 2018-12-12] abstract	1-8, 22-34
Y	US 2015/044272 A1 (KUSHNIR ALON [IL] ET AL) 12 February 2015 (2015-02-12) figures 6a,6B, 10,13 paragraphs [0094] - [0106], [0142] - [0147], [0183] - [0187], [0251] - [0261]	3-8, 22-34

3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2018/051049

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.: 9-21
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 9-21 relate to a method of dressing a wound and thus refer to method of treatment of the human body. Claims 9-21 cover subject-matter considered by this Authority to be covered by the provision of Rule 39.1(iv) PCT.Said claims have not been searched.

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 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 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.

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Information on patent family members

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