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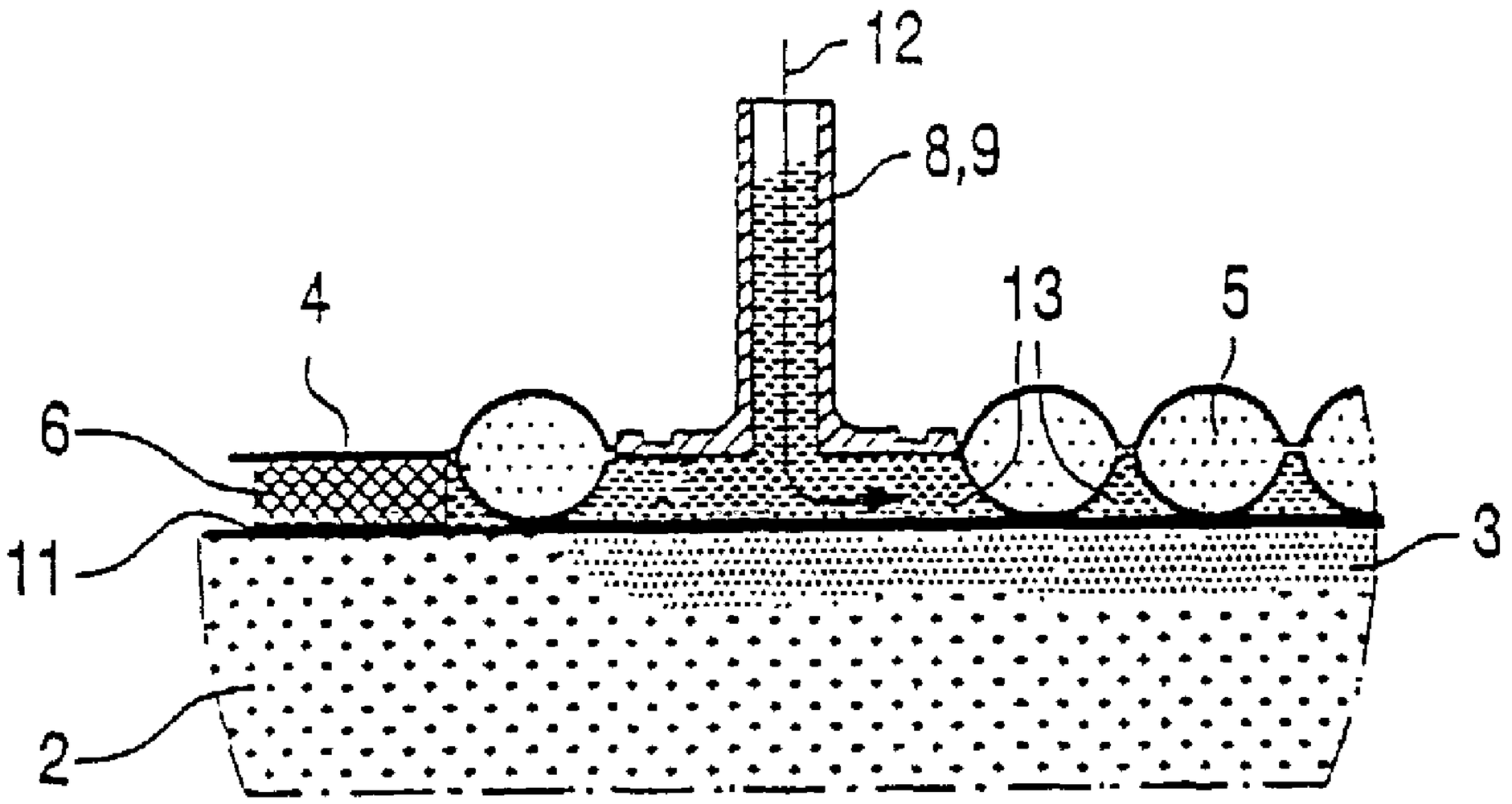
(54) Title: DEVICE FOR TREATING A WOUND IN A SKIN OF A PATIENT



(57) Abrégé/Abstract:
A device (1, 14, 15, 18) for treating a wound (3) in the skin (2) of a patient by exposing the wound to a medium which stimulates the healing process, which device comprises at least one wall (4) which can be connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound (3) so as to form an at least substantially fluid-tight space (13) between the wound (3) and the wall (4), a fluid inlet (8) for introducing said medium into said space (13), and a fluid outlet (9), wherein the wall area that is to cover the wound (3) is provided with spacers (5) extending towards the wound (3), which spacers (5) are intended to rest on the wound (3) so as to keep at least part of the wall (4) spaced from the wound (3).

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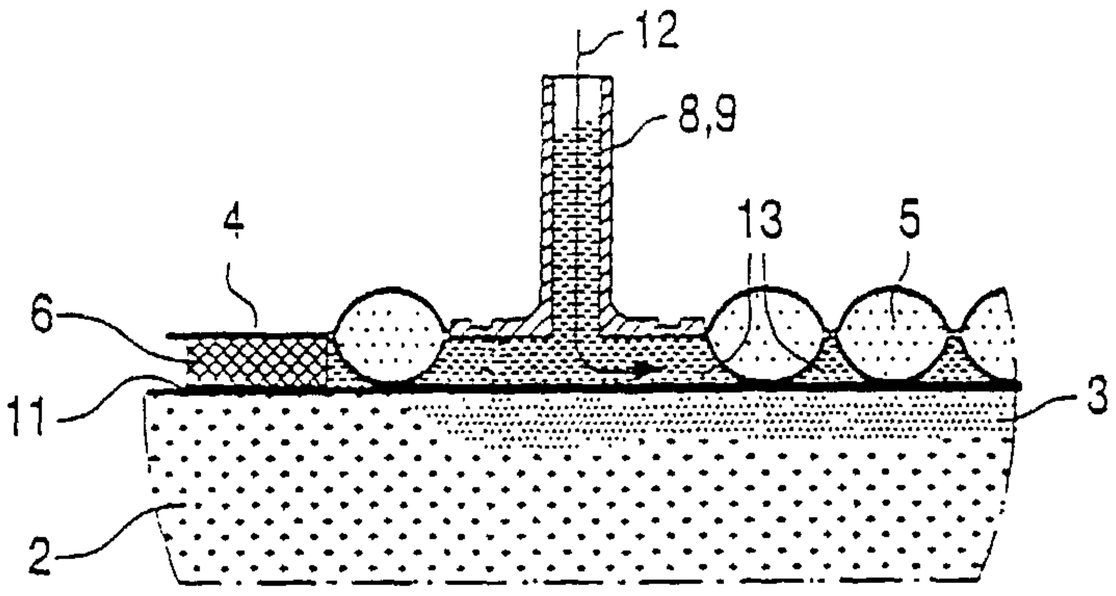
(54) Title: DEVICE FOR TREATING A WOUND IN A SKIN OF A PATIENT



(57) Abstract: A device (1, 14, 15, 18) for treating a wound (3) in the skin (2) of a patient by exposing the wound to a medium which stimulates the healing process, which device comprises at least one wall (4) which can be connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound (3) so as to form an at least substantially fluid-tight space (13) between the wound (3) and the wall (4), a fluid inlet (8) for introducing said medium into said space (13), and a fluid outlet (9), wherein the wall area that is to cover the wound (3) is provided with spacers (5) extending towards the wound (3), which spacers (5) are intended to rest on the wound (3) so as to keep at least part of the wall (4) spaced from the wound (3).

WO 03/070135 A3

DEVICE AND METHOD FOR TREATING A WOUND IN THE SKIN OF A PATIENT

The invention relates to a device for treating a wound in the skin of a patient by exposing the wound to a medium which stimulates the healing process, which device comprises at least one wall which can be connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound so as to form an at least substantially fluid-tight space between the wound and the wall, a fluid inlet for introducing said medium into said space, and a fluid outlet. The invention also relates to a device for treating a wound in the skin of a patient by applying a negative pressure on said wound, which device comprises at least one wall which can be connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound so as to form an at least substantially fluid-tight space between the wound and the wall, and a fluid outlet for removing fluid from said space.

Such a device is known from WO 01/93793. The device that is disclosed therein is very effective for treating burns, decubitus wounds, wounds resulting from diabetes and the like, in which the skin is damaged or has been removed altogether over a relatively large area. The wall of the device consists of a transparent PET cover, which is kept spaced from the wound by a layer of foam which is placed on the skin surrounding the wound. Preferably, a mixture of ozone and oxygen is introduced as a healing medium into the space between the wound and the wall during a treatment. It has appeared that the additional and/or simultaneous

introduction of distilled water into the space has a strong stimulating effect on the healing process of wounds. As described in EP 0 620 720 the application of a negative pressure on the wound reduces the bacterial density in the wound, and thereby the healing of the wound is also substantially improved. Also removal of superfluous wound fluid through the fluid outlet , often containing bacteria, is supportive to a faster healing process.

Because a inlet or an outlet opening can be easily provided in the wall of the device, and it can be even advantageous to make several opening provisions across the surface of the device which can be opened by the user depending on his needs, a fluid inlet and an fluid outlet in the pre-use state of the device according to the invention must be also understood as opening provisions or even spaces in the wall where the user can make an opening himself.

An important limitation of the known devices is the maximum dimension of the wound that can be treated in this manner. Although the device of WO 01/93793 is flexible to a certain extend and can be adapted to the dimension of the skin surface to be treated, the PET cover will come into contact with the wounds in the case of larger wounds in spite of the presence of the surrounding layer of foam that acts as a spacer element, which leads to adhesion between the cover and the wound. As a result, the area where said adhesion takes place cannot be reached by the medium and very painful damage to the healing skin can easily occur upon removal of the device. In addition, micro-organisms may form in the area where the adhesion takes place, which microorganisms will delay or even counteract the healing process of the wound.

Consequently, the known devices can only be used with wounds of limited dimension.

The object of the invention is to provide a device for treating a wound in the skin of a patient which does not have any limitations as regards the dimension of the wound, and consequently it is in principle capable of comprising practically the entire skin area of a patient without the above-described this advantageous effects occurring, or in any case to a smaller extent. Another object of the invention is to provide a device which is easy to use, which can be produced in a simple and inexpensive manner, which is comfortable to the patient and/or which has a significant stimulating effect on the healing process.

In order to accomplish that objective, the wall area that is to cover the wound is provided with spacers extending towards the wound, which spacers are intended to rest on the wound so as to keep at least part of the wall spaced from the wound. The spacers prevent the wall from adhering to the wound, so that the healing medium can reach the entire wound, or that alternatively a negative fluid pressure can be applied to the entire wound surface and/or wound fluids can be sucked out of the entire wound area.

Preferably, the spacers are arranged a regular distance apart. Preferably, the spacing between the respective centres of the spacers ranges from 8 to 18 mm, preferably it is about 12 mm. In this way a proper balance is found between preventing the occurrence of adhesion between the wound and the wall on the one hand and limiting the wound area on which the spacers rest on the other hand.

Preferably, the wall is made of a flexible material capable of adapting itself to the shape of a respective part of the body. Preferably, the wall is furthermore at least partially made of a transparent material, preferably PVC, polyethylene or silicones so as to enable inspection of the wound during the treatment. Preferably, the spacers themselves are likewise made of these materials, because these materials generally cause little allergic reaction and exhibit poor-adhesion to the wound.

In one preferred embodiment, the spacers are made up of at least one compartment which can be filled with a fluid. Each compartment is preferably fitted with a valve so as to make it possible to fill the compartment with the fluid under pressure and close it. It is especially preferred for the wall and the compartment to be made up of two layers of a foil whose surfaces are bonded together in part, with the parts of the foil that are not bonded together forming the compartment. In a first preferred embodiment, the compartment comprises substantially parallel, tubular sub-compartments. In this way an air mattress-like yet flexible structure is formed which can be placed over the wound and under which the medium has sufficient freedom to reach all the locations of the wound, or fluid can be sucked from the entire surface area of the wound.

In a second embodiment, the compartment comprises substantially square, rectangular, triangular or circular sub-compartments. This gives the device a greater degree of flexibility, enabling it to adapt itself to the shape of the body. Another advantage of the invention is the fact that the air can flow from one sub-compartment to another upon

shifting of the patient's weight, as a result of which the pressure on the wound will remain within certain bounds.

In order to enable treatment of large parts of the body in one go in a manner which is simple and relatively comfortable for the patient, the wall is preferably in the form of at least part of a garment, such as a shirt, a pair of trousers, a sleeve, a trouser-leg, a glove and/or a sock, so as to be able to cover a large part of the body. Said parts can be made in various body sizes.

In order to obtain easy adhesion to the skin and effect a substantially fluid-tight seal, the part of the wall that is to come into contact with the skin tissue is preferably provided with adhesive tape, which preferably has a thickness of 1 - 10 mm, more preferably about 3 mm.

The invention also relates to a system for treating a wound on the skin of a patient by exposing the wound to an ozone mixture, which system comprises a device as described above, as well as a device for feeding the ozone mixture to the fluid inlet and/or discharging the ozone mixture from the fluid outlet . Preferably, the device is adjusted so that, in use, a sub-atmospheric pressure prevails in the space between the wall and the wound, for example as a result of the medium being pumped from the outlet by the device. Said sub-atmospheric pressure causes the spacers to exert a pressure on the wound, which helps possible donor skin to adhere to the underlying skin of the patient. Said sub-atmospheric pressure furthermore causes certain bacteria in the skin that retard the healing process to migrate to the surface, where they can be removed with rinsing water.

The invention also relates to a method for treating a wound in the skin of a patient wherein the wound is exposed to a medium which stimulates the healing process, wherein at least one wall is connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound so as to form an at least substantially fluid-tight space between the wound and the wall, and wherein said medium is introduced into said space through a fluid inlet , and removed from said space through a fluid outlet , and wherein the wall area that covers the wound is provided with spacers extending towards the wound, which spacers rest on the wound keeping at least part of the wall spaced from the wound. In a preffered embodiment of the invention said medium comprises ozon. Other mediums can of course be applied too, such as distilled water for just washing the wound, or drug containing mediums.

Furthermore the invention relates to a method for treating a wound in the skin of a patient by applying a negative pressure on said wound, wherein at least one wall is connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound so as to form an at least substantially fluid-tight space between the wound and the wall, wherein fluid is removed from said space through a fluid outlet , and wherein the wall area that covers the wound is provided with spacers extending towards the wound, which spacers rest on the wound keeping at least part of the wall spaced from the wound.

The invention also relates to a method for treating a wound in the skin of a patient, wherein the above mentioned method wherein the wound is exposed to a medium which stimulates the healing process and the above mentioned method wherein a

negative pressure is applied on said wound, are alternatingly applied. Hereby often a unexpectedly high pace of wound healing can be achieved.

The invention will be explained in more detail hereinafter by means of embodiments illustrated in the figures, in which like aspects are indicated by like numerals, and in which:

Figure 1 is a top plan view of a first embodiment of a wound treating device;

Figure 2 is a sectional view along the line II-II of the wound treating device of Figure 1;

Figure 3 shows a detail of the longitudinal sectional view of Figure 2;

Figure 4 is a top plan view of a second embodiment of a wound treating device;

Figure 5 is a front elevation of a third embodiment of a wound treating device; and

Figure 6 is a top plan view of a fourth embodiment of a wound treating device.

Figure 7 is a top plan view of a fifth emodiment of a wound treating device.

According to Figures 1, 2 and 3, a wound treating device 1 which is placed on the skin 2 over a burn 3 in a patient's skin 2 comprises a transparent wall 4 which is made of two

substantially rectangular parts of a flexible PVC foil, the surfaces of two respective sides of which are bonded together in part. The surface of the foil which comes into contact with the wound 2 is provided with a surface structure impressed therein, which helps to prevent the foil from adhering to the wound 2. The bonded-together areas of the PVC foils are configured to form an internal and inflatable continuous tubular compartment which extends into parallel tubular sub-compartments 5 in the wall 4. The wall 4 that is formed in this way is very similar to an inflatable air mattress. Said tubular compartment is provided with a plastic filling aperture 7 with a throttling valve at one end so as to make it possible to fill said "mattress" with air. In an alternative embodiment, the device comprises several separate compartments, which can each be separately filled.

A foam rubber adhesive tape 6 comprising an adhesive layer 11, which has a thickness of about 3 mm, is arranged along the circumference of the wall 4 so as to place the wall 4 over the wound 3 and attach it to the adjoining skin 2 in a substantially liquid-tight manner. The wall 4 is furthermore provided with at least one inlet opening 8 and at least one outlet opening 9 in the form of a plastic inlet and outlet, respectively, which may be identical for that matter. The openings 8, 9 are located between two sub-compartments 5, so that in principle open connections between the surrounding atmosphere and the space 13 between the wound 3 and the wall 4 are formed.

In use, the wound treating device 1 is placed over the wound and the adhesive tape 6 is adhered to the surrounding skin 2 via the adhesive layer 11. The compartment 5 is filled with

air and closed by means of the valve 10. A feed line and a discharge line are connected to the inlet opening 8 and the outlet opening 9, respectively. Said lines are connected to a feeding device for distilled water as well as to an ozone generator. The feeding device is so adjusted that a sub-atmospheric pressure will prevail in the space 13 during the treatment. Said sub-atmospheric pressure causes the sub-compartments 5 to be pressed against the wound, resulting in an improved adhesion of donor skin to the underlying tissue, amongst other things. Clinical tests have shown that treatment for about 20 minutes every day or every other day for a few weeks to a few months, for example, leads to a significantly improved effect as regards the healing of the patient's skin in comparison with the treatment methods that have been usual so far.

Figure 4 is a view of a second embodiment of a wound treating device 14, the difference with a first embodiment being the fact that the tubular sub-compartments have been substituted for square sub-compartments 5. Said sub-compartments 5 are made by bonding the foils of the wall 4 together along the sides of the sub-compartments 5, with the four corner points forming openings through which air can flow to adjoining sub-compartments. Such a structure is known from flexible containers for producing ice cubes. The advantage of this structure in comparison with the first embodiment is that this device is flexible in two directions, allowing it to adapt more easily to the shape of the body. To that end, various rectangular parts as shown in Figure 1 can be interconnected by means of the adhesive tape, or larger parts configured to conform to the shape of the body can be made. In Figures 5 and 6, two embodiments of wound treating devices

15, 18 in the form of a garment are shown by way of example.

Figure 5 shows a similar wound treating device 15 in the form of a shirt 16 for treating wounds (burns) on the upper body. Although only one inlet opening 8 and one outlet opening 9 are shown, openings 8, 9 may be present at various locations in practice so as to effect a proper distribution of the treating medium over the skin 2. The shirt 16 comprises one or more a fluid-tight closures 17, which enable easy putting on and taking off of the shirt 16. Adhesive tape 6 to be adhered to the skin 2 is arranged along the edges of the skirt 16. Since a sub-atmospheric pressure will prevail in the space 13 under the shirt 16 during use, the shirt 16 will properly remain in position.

Figure 6 shows a wound treating device 18 in the form of a glove 19 for treating wounds (burns) on a person's hand. The glove 19, too, is provided with a fluid-tight closure 20, so that it can be put on and taken off without any difficulty and without causing damage to the skin 2. It will be understood that many variations to the two embodiments that are shown herein are possible for treating wounds at various locations on a person's body.

Figure 7 shows a wound treatment device 14 which is very similar to the device of Figure 4, the difference being the fact that there is only a fluid outlet opening 9, and no fluid inlet opening. Of course is possible to close the fluid inlet opening 8 of the device of Figure 4, or to use both, or even more openings to remove fluid from the space 13 between the wound (3) and the wall (4). In this way the device can be used to apply a negative pressure to the wound and remove

possible wound fluids. As described in EP 0 620 720 the application of a negative pressure reduces the bacterial density in the wound, and thereby the healing of the wound is substantially improved.

CLAIMS

1. A device (1, 14, 15, 18) for treating a wound (3) in the skin (2) of a patient by exposing the wound to a medium which stimulates the healing process, which device comprises at least one wall (4) which can be connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound (3) so as to form an at-least substantially fluid-tight space (13) between the wound (3) and the wall (4), a fluid inlet (8) for introducing said medium into said space (13), and a fluid outlet (9), **characterized in that** the wall area that is to cover the wound (3) is provided with spacers (5) extending towards the wound (3), which spacers (5) are intended to rest on the wound (3) so as to keep at least part of the wall (4) spaced from the wound (3).

2. A device (1, 14, 15, 18) for treating a wound (3) in the skin (2) of a patient by applying a negative pressure on said wound, which device comprises at least one wall (4) which can be connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound (3) so as to form an at least substantially fluid-tight space (13) between the wound (3) and the wall (4), and a fluid outlet (9) for removing fluid from said space (13), **characterized in that** the wall area that is to cover the wound (3) is provided with spacers (5) extending towards the wound (3), which spacers (5) are intended to rest on the wound (3) so as to keep at least part of the wall (4) spaced from the wound (3).

3. A device (1, 14, 15, 18) according to claim 1 or 2,

characterized in that the spacers (5) are arranged a regular distance apart.

4. A device (1, 14, 15, 18) according to claim 1, 2 or 3, **characterized in that** the spacing between the respective centres of the spacers (5) ranges from 8 to 18 mm, preferably it is about 12 mm.

5. A device (1, 14, 15, 18) according to any one of the preceding claims 1 - 4, **characterized in that** the wall (4) is made of a flexible material capable of adapting itself to the shape of a respective part of the body.

6. A device (1, 14, 15, 18) according to any one of the preceding claims 1 - 5, **characterized in that** the wall (4) is at least partially made of a transparent material, preferably PVC, polyethylene or silicones so as to enable inspection of the wound (3).

7. A device (1, 14, 15, 18) according to any one of the preceding claims 1 - 6, **characterized in that** the spacers (5) are made up of at least one compartment which can be filled with a fluid.

8. A device (1, 14, 15, 18) according to claim 7, **characterized in that** each compartment (5) is fitted with a valve so as to make it possible to fill the compartment (5) with the fluid under pressure and close it.

9. A device (1, 14, 15, 18) according to claim 7 or 8, **characterized in that** the wall (4) and the compartment

(5) are made up of two layers of a foil whose surfaces are bonded together in part, with the parts of the foil that are not bonded together forming the compartment (5).

10. A device (1, 14, 15, 18) according to any one of the preceding claims 7 - 9, **characterized in that** the compartment comprises substantially parallel, tubular sub-compartments (5).

11. A device (1, 14, 15, 18) according to any one of the preceding claims 7 - 10, **characterized in that** the compartment (5) comprises substantially square, rectangular, triangular or circular sub-compartments (5).

12. A device (1, 14, 15, 18) according to any one of the preceding claims 1 - 11, **characterized in that** the spacers (5) are made of PVC, polyurethane or silicones.

13. A device (1, 14, 15, 18) according to any one of the preceding claims 1 - 12, **characterized in that** the wall (4) is preferably in the form of at least part of a garment, such as a shirt (16), a pair of trousers, a sleeve, a trouser-leg, a glove (19) and/or a sock, so as to be able to cover a large part of the body.

14. A device (1, 14, 15, 18) according to any one of the preceding claims 1 - 13, **characterized in that** the part of the wall (4) that is to come into contact with the skin tissue is provided with adhesive tape (6).

15. A device (1, 14, 15, 18) according to claim 14, **characterized in that** said adhesive tape (6) has a thickness of 1 - 10 mm, preferably about 3 mm.

16. A system for treating a wound (3) on the skin (2) of a patient by exposing the wound (3) to an ozone mixture, which system comprises a device (1, 14, 15, 18) according to any one of the preceding claims as well as a device for feeding the ozone mixture to the fluid inlet (8) and/or discharging the ozone mixture from the fluid outlet (9).

17. A system for treating a wound (3) on the skin (2) of a patient by applying a negative pressure to said wound (3), which system comprises a device (1, 14, 15, 18) according to any one of the preceding claims as well as a device for discharging fluid from the fluid outlet (9).

18. A system according to claim 16 or 17, **characterized in that** the device is adjusted so that, in use, a sub-atmospheric pressure prevails in the space (13) between the wall (4) and the wound (3).

19. A method for treating a wound (3) in the skin (2) of a patient wherein the wound is exposed to a medium which stimulates the healing process, wherein at least one wall (4) is connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound (3) so as to form an at least substantially fluid-tight space (13) between the wound (3) and the wall (4), and wherein said medium is introduced into said space (13)

through a fluid inlet (8), and removed from said space (13) through a fluid outlet (9), and wherein the wall area that covers the wound (3) is provided with spacers (5) extending towards the wound (3), which spacers (5) rest on the wound (3) keeping at least part of the wall (4) spaced from the wound (3).

20. A method according to claim 19, wherein said medium comprises ozon.

21. A method for treating a wound (3) in the skin (2) of a patient by applying a negative pressure on said wound, wherein at least one wall (4) is connected in an at least substantially fluid-tight manner to skin tissue surrounding the wound (3) so as to form an at least substantially fluid-tight space (13) between the wound (3) and the wall (4), wherein fluid is removed from said space (13) through a fluid outlet (9), and wherein the wall area that covers the wound (3) is provided with spacers (5) extending towards the wound (3), which spacers (5) rest on the wound (3) keeping at least part of the wall (4) spaced from the wound (3).

22. A method according to claim 19 or 21, wherein the spacers (5) are arranged a regular distance apart.

23. A method according to claim 19 or 21, wherein the spacing between the respective centres of the spacers (5) ranges from 8 to 18 mm, preferably it is about 12 mm.

24. A method according to claim 19 or 21, wherein the wall

(4) is made of a flexible material capable of adapting itself to the shape of the respective part of the body.

25. A method according to claim 19 or 21, wherein the wall (4) is at least partially made of a transparent material, preferably PVC, polyethylene or silicones so as to enable inspection of the wound (3).

26. A method according to claim 19 or 21, wherein the spacers (5) are made up of at least one compartment which is filled with a fluid, such as air.

27. A method according to claim 26, wherein each compartment (5) is fitted with a valve which closes the the compartment (5) after it is filled with the fluid under pressure.

28. A method according to claim 26, wherein the wall (4) and the compartment (5) are made up of two layers of a foil whose surfaces are bonded together in part, with the parts of the foil that are not bonded together forming the compartment (5).

29. A method according to claim 26, wherein the compartment comprises substantially parallel, tubular sub-compartments (5).

30. A method according to claim 19 or 21, wherein the compartment (5) comprises substantially square, rectangular, triangular or circular sub-compartments (5).

31. A method according to claim 19 or 21, wherein the spacers (5) are made of PVC, polyurethane or silicones.

32. A method according to claim 19 or 21, wherein the wall (4) is in the form of at least part of a garment, such as a shirt (16), a pair of trousers, a sleeve, a trouser-leg, a glove (19) and/or a sock, covering a large part of the body.

33. A method according to claim 19 or 21, wherein said part of the wall (4)is bonded to the skin tissue with adhesive tape (6).

34. A method according to claim 33, wherein said adhesive tape (6) has a thickness of 1 - 10 mm, preferably about 3 mm.

35. A method for treating a wound (3) in the skin (2) of a patient, wherein the method according to claim 19 and the method according to claim 21 are alternatingly applied.

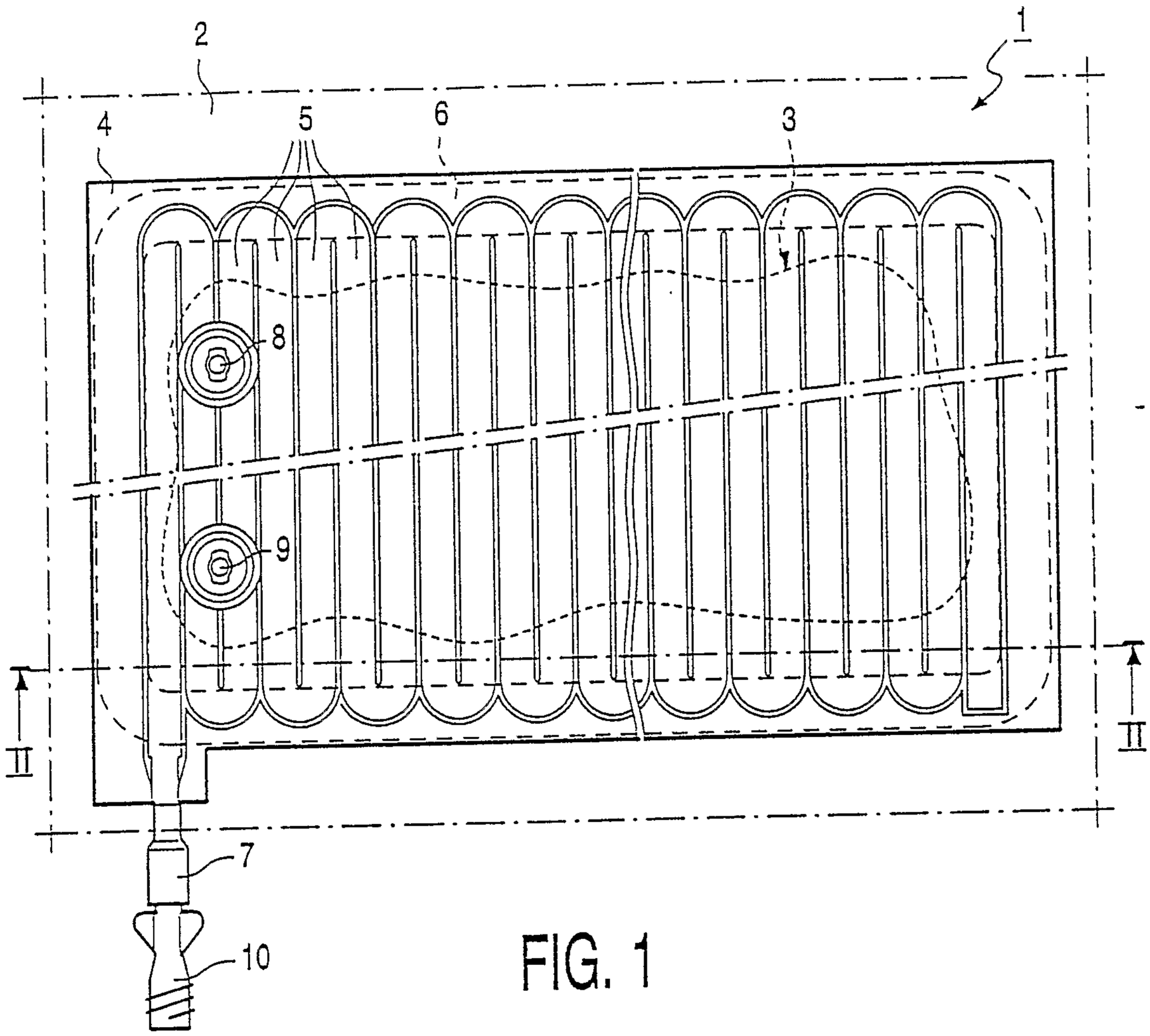


FIG. 1

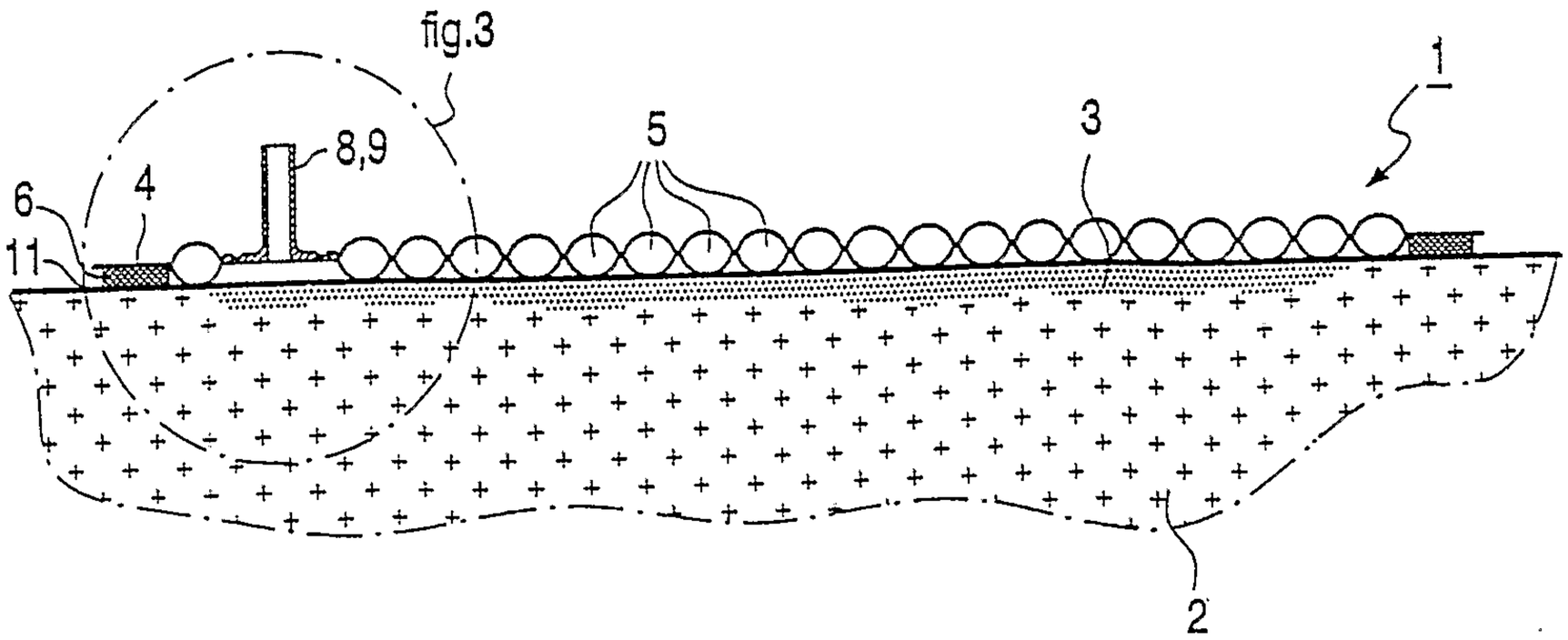


FIG. 2

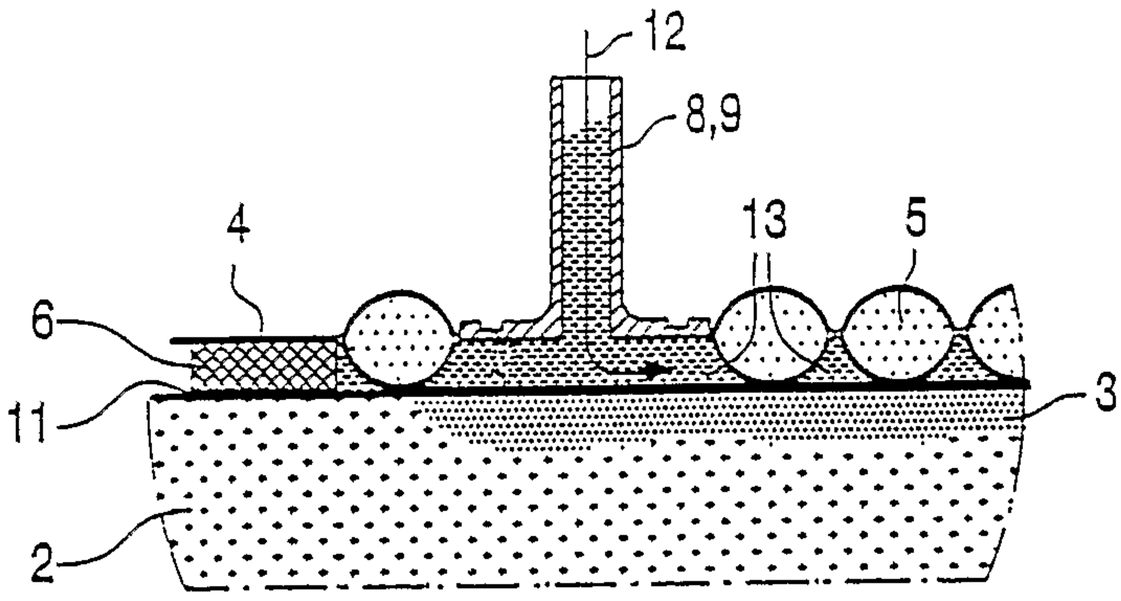


FIG. 3

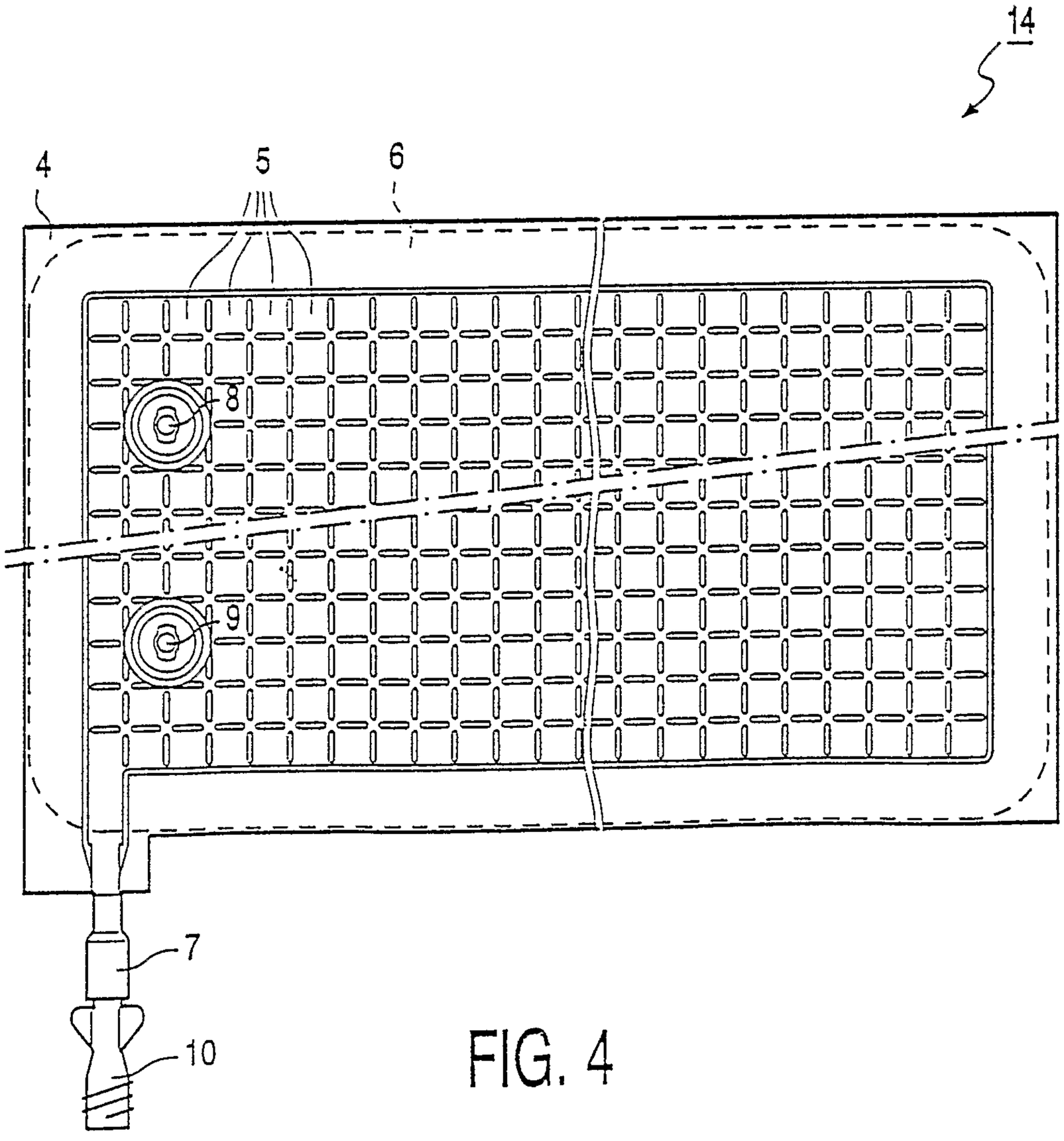


FIG. 4

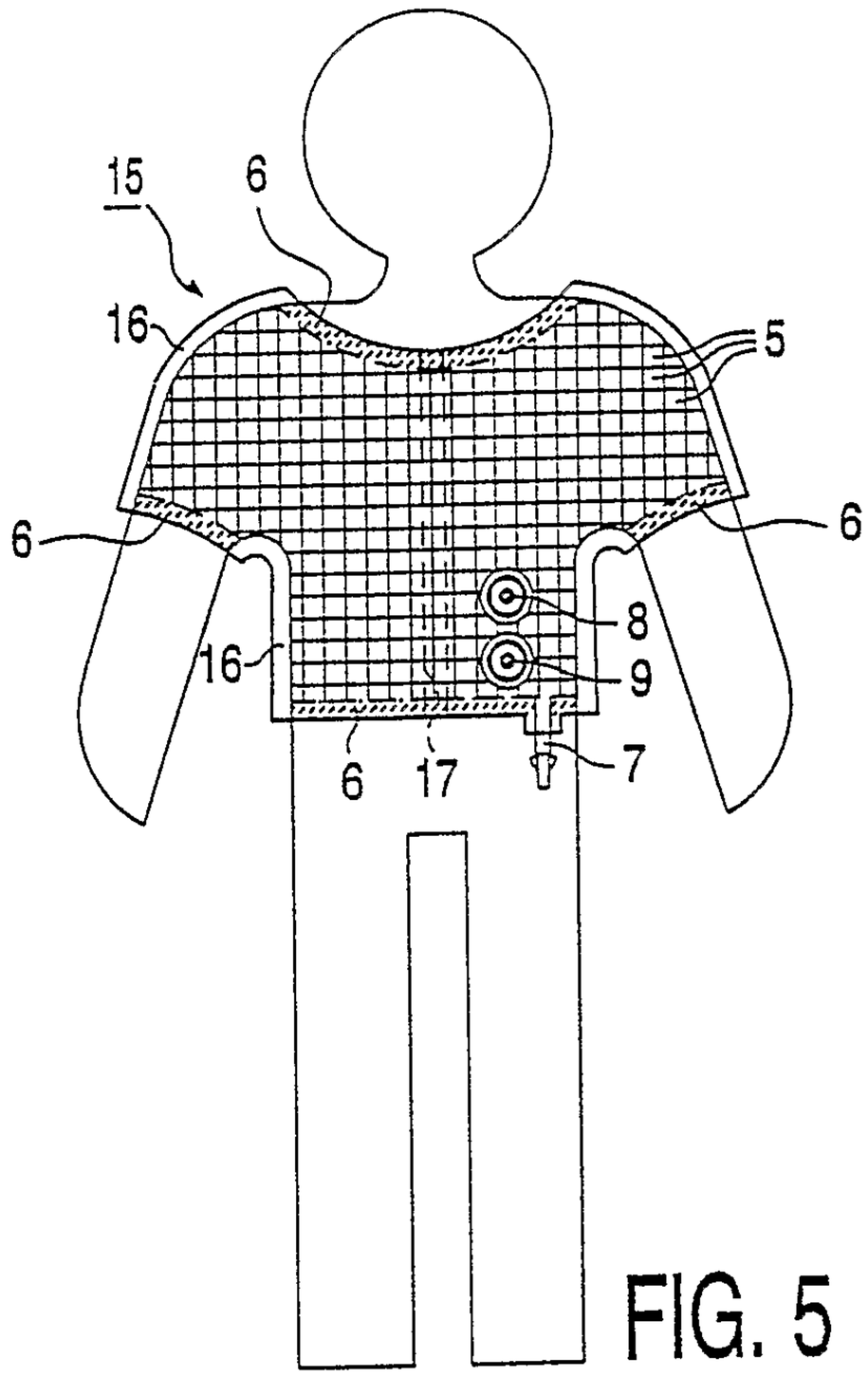


FIG. 5

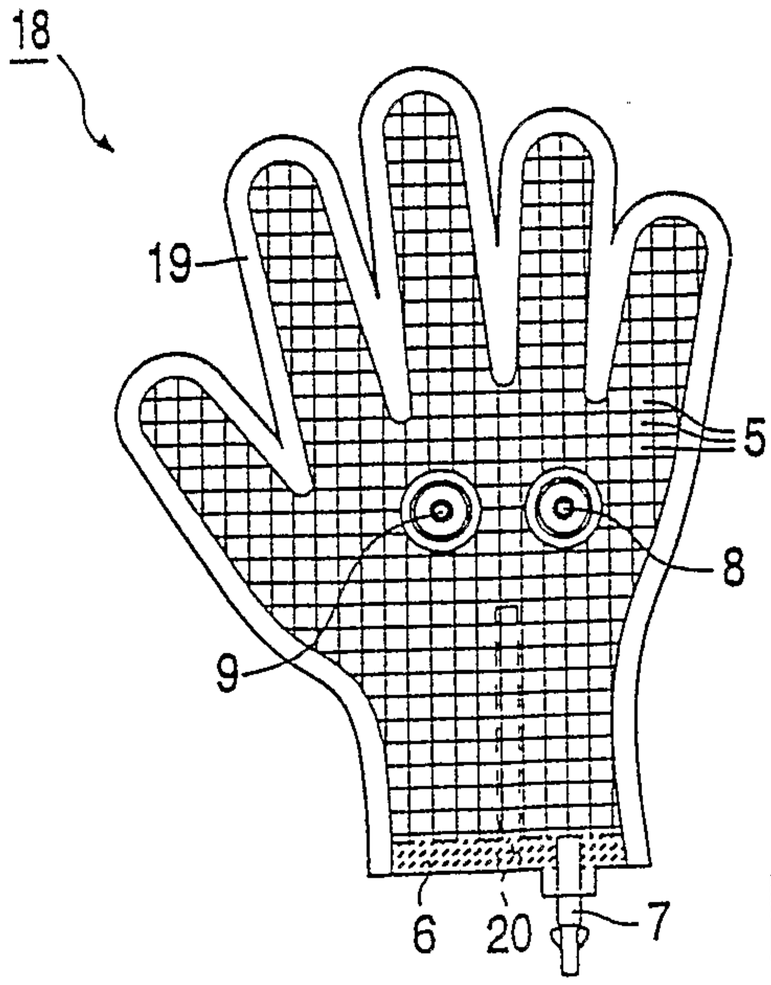


FIG. 6

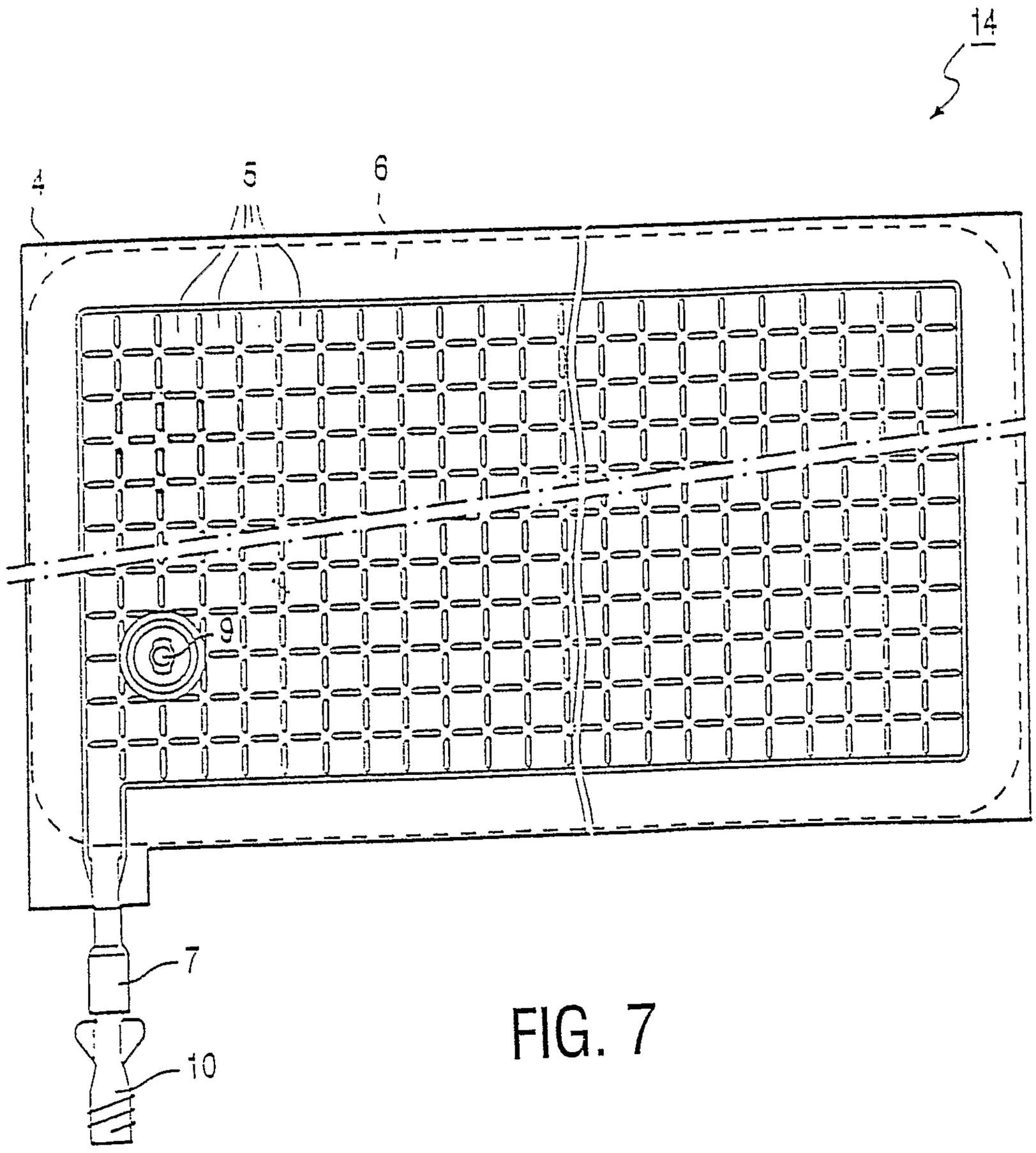
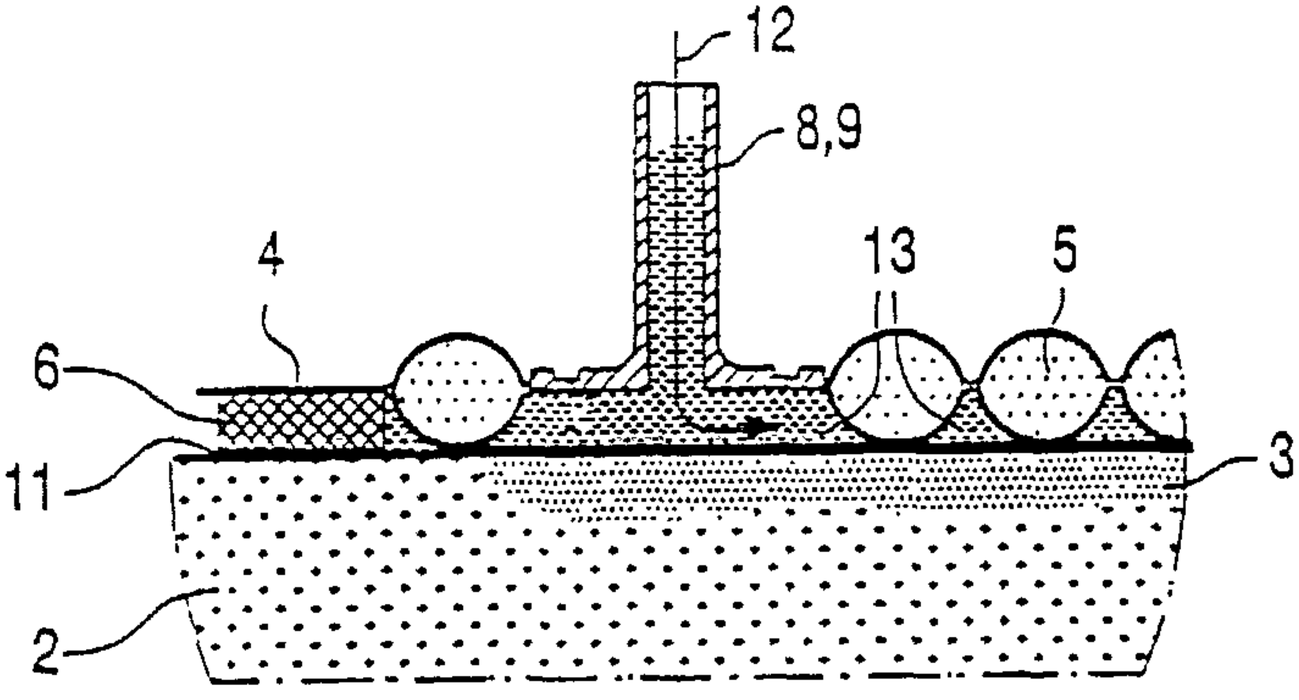


FIG. 7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