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- (54) Benævnelse: **FORBINDINGSMATERIALE TIL ET PUNKTUR- ELLER INFUSIONSSTED, SÆRLIG TIL HÆMODIALYSE**
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Description

The invention relates to the medical or veterinary field.

5 The invention more particularly concerns a dressing for a puncture or infusion site.

The term "puncture" as used here refers to the operation by which a substance, generally liquid, is removed from a body part
10 of a human or an animal.

An example of a puncture is blood sampling, a common procedure allowing laboratory tests to be conducted on a blood sample taken by venous, capillary, or arterial puncture. The hypodermic
15 needle used for blood sampling is often connected to vacuum tubes (for example the Vacutainer®, marketed by the firm Becton Dickinson).

The term "infusion" as used here refers to the operation by which a substance, generally liquid, is introduced into a cavity
20 or into the blood vessels of the body of a human or an animal.

An example of infusion is intravenous infusion, a common parenteral infusion technique allowing the dropwise
25 administration of drugs, liquids, or blood products into the veins, generally a peripheral vein of the upper extremity. In particular, intravenous infusion allows the administration of solutes to correct blood volume.

30 The term "puncture or infusion site" as used here refers to an area of the skin of the body of a human or an animal through which a puncture or infusion device passes (in particular a needle, a catheter, or a cannula).

35 The term "dressing for a puncture or infusion site" as used here refers to a protective device covering the wound formed by the puncture or injection site.

The invention relates more particularly to the medical or veterinary use of a vascular puncture or infusion site, for example needle/catheter infusions or short intravenous devices of the Cathlon® type (PTFE cannulas).

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The invention relates still more particularly to the field of haemodialysis.

10 It is common to withdraw or inject fluids or to administer drugs to a patient or an animal using a tube attached to a needle or a catheter. It is estimated that approximately 80% of hospitalised patients undergo treatment administered by intravenous catheter.

15 For the puncture or the infusion, a device is inserted through the skin (a hypodermic needle, catheter, or cannula).

For example, butterfly needles are used for transfusions, particularly for drawing blood. These needles take their name
20 from the fact that they are provided with a manual pinching area in the shape of butterfly wings. Folding the wings together allows a good grip and facilitates insertion of the needle under the skin. Once the needle is in place, the wings ordinarily rest on the skin, and an adhesive strip is placed on these wings and
25 on the skin in order to prevent extraction of the needle. Examples of butterfly needles can be found in the U.S. patents issued under the following numbers: 2725058, 3064648, 3640275, 4194504, 4300553, 4627842, 5108376, 5149328, and 6270480.

30

In some patients, peripheral catheters are chronically used. This is the case in particular in patients suffering from acute or chronic renal insufficiency and treated by haemodialysis or extra-renal purification.

35

Three types of vascular access are predominantly used in haemodialysis: arteriovenous fistulas (AVF), arteriovenous prostheses or grafts, and central venous catheters (CVC).

AVFs are anastomoses created surgically in order to connect an artery and a vein in a patient, ordinarily in the forearm or arm, and most often between a radial or humeral artery and its homonymous vein. This anastomosis makes it possible to increase the blood flow in said vein.

The needle that brings the patient's blood to the dialysis unit is referred to as the artery, and the one that returns the blood to the patient is referred to as the vein.

When the needle is withdrawn from a blood vessel or a dialysis fistula, several risks must be taken into account: the risk of haemorrhage, the risk of blood spray, the risk of contamination of health care personnel, the risk of a hematoma, and the risk of bacterial contamination.

The risk of haemorrhage is quite considerable for certain patients suffering from acute or chronic renal insufficiency and under haemodialysis treatment. During haemodialysis, an anticoagulant is in fact often used to limit the risks of blockage of the capillary lumina due to thrombosis. At the end of the dialysis session, any haemorrhage from the puncture site may have a fatal outcome for the patient.

The risks of blood spray and contamination are considerable, and the spread of AIDS and hepatitis, among other blood-borne contagious diseases, has only led to increased fear of this risk. According to a circular of the General Health Delegation dated 20 April 1998 (which can be accessed at <http://www.sante.gouv.fr>) concerning the prevention of infectious agents borne by the blood or biological fluids during treatment at health care establishments, accidental exposure to blood (AEB) is defined as *"any contact with blood or a biological fluid containing blood and involving either breakage of the skin or spraying onto an (ocular) mucous membrane or damaged skin"*. The risk of transmission of infectious diseases on AEB in haemodialysis is currently greatest for the hepatitis C virus because of its

prevalence in haemodialysis patients. The average risk of transmission of HIV after exposure to the blood of a patient infected with HIV is estimated at 0.32%. The risk of transmission of HBV from an infected patient is very high: between 2% and 40%. This high contagion rate is connected with the very large amount of the virus present in the blood and the biological fluids (between 1 million and 1 billion viral particles per ml). According to the RAISIN report (monitoring of accidental exposure to blood in French health care establishments in 2005, available at <http://www.invs.sante.fr>), the majority of cases of accidental exposure to blood occur when a needle is withdrawn through the skin. According to the AEB-Raisin network report, for the years 2013-2014, the rate of AEB per 100 beds was approximately 6%, with AEBs occurring in 20% of cases due spraying, particularly during withdrawal of a needle through a patient's skin.

For haemodialysis sessions in AVFs, the moment at which there is the greatest risk of contamination by blood spray is that of compression, mainly at the time of withdrawal of the needle. In fact, the haemostatic compress may be incorrectly positioned on the puncture site, in particular in AVFs with high blood flow or aneurysmal areas.

At the end of a dialysis session, at the time of disconnection, there is a risk of bacterial contamination, generally staphylococcal. This risk is increased at the time of compression of the puncture sites or during recurrence of bleeding after the dialysis session.

The wound formed during each dialysis session presents specific characteristics.

First, this wound occurs in a small area, in a repeated manner, with large-diameter needles. A haemodialysis session lasts about four hours and must be carried out three times a week. The needles used to puncture the AVF are of large calibre, having an internal diameter typically ranging from 1.6 to 2 mm.

Second, in principle, the skin surrounding the puncture or infusion site in the AVF is non-exudative and non-secretory, as only blood can be present, with post-dialysis bleeding being a known complication. Some patients remain at risk even after manual compression for thirty minutes (Perera et al. A novel use of 2 octyl-cyanoacrylate controlling post haemodialysis site haemorrhage, The Journal of Emergency Medicine, 44 Vol. 2, pp. 467-468, 2013). Haemostasis is achieved within a varying period of time, on the order of 15 to 20 minutes according to Schwab et al., Prevention of haemodialysis fistula thrombosis. Early detection of venous stenosis, Kidney International, 36, pp. 707-711 (1989), and could be reduced to approximately 3 minutes by local administration of thrombin according to Varizi, Topical thrombin and control of bleeding from the fistula puncture sites in dialyzed patients, Nephron 24, pp. 254-256 (1979). The use of poly- β -1 $\rightarrow$ 4-N-acetylglucosamine has been reported to allow compression times on the order of 1 to 14 minutes (US 8992453, page 4, lines 44-54). In dialysis patients with an AVF with a high blood flow rate, the effect of anticoagulants is such that the bleeding time at the puncture site can extend to 30 minutes (cf. WO 2004/060245 page 1, 3rd paragraph), and even 45 minutes, after the dialysis session (cf. WO 03/099143, page 1, lines 11-20). There are a large number of patents and patent applications for compression dressings intended to provide a solution for these bleeding times (cf. for example US 2004/0092999, WO 99/08723, US 2005/0256438, WO 2007/044647, WO03/099143, US 5891074, US 20060155235, US 3490448, and US 6316686).

Third, the wound occurs in a deformed area. Indeed, the creation of an AVF strongly alters the appearance of the patient's forearm by creating aneurysmal areas.

Moreover, dialysis patients are often elderly, which has consequences due to the sensitivity of their skin to dressings.

The measures taken in haemodialysis units in order to limit the risks of AEB and haemorrhage are not standardised.

Disconnection protocols in particular are not uniform, as multiple parameters are taken into account: patient autonomy, the physical capacity of the patients, which allows them to be involved in their care to different degrees, fragility of the skin of patients, most of whom are elderly, the presence or absence of aneurysmal areas, administration of anticoagulant drugs of the acetylsalicylic acid type or anti-vitamin-K agents, or anti-inflammatories.

The blood flow in the AVF, as well as the presence of excessively high pressure due to stenosis of the vascular access, can combine to prolong compression time.

Several techniques are known from the prior art for preventing the above-described risks of AEB and haemorrhage.

The means allowing haemostasis to be achieved in an AVF can be classified into four categories:

- manual compression,
- mechanical devices combining a spring mechanism (fistula pressure clamp), cf. for example CN 203169258,
- strips for compression by tightening,
- pads comprising a compress loaded with a haemostatic agent (gelatine, collagen, chitosan, cellulose oxide, kaolin, zeolite), cf. for example Bachtell et al., Treatment of dialysis access puncture wound bleeding with chitosan dressings, Dialysis and transplantation, 2006, pp. 1-6.

According to an extremely common technique that allows haemostasis to be achieved in an AVF, a compress, a pad, or cotton is placed at the puncture site, and manual pressure is applied to this compress or this cotton, with one or more adhesive strips keeping the compress or the cotton in place

after the manual pressure is released.

The applicant has found that this common technique involves several difficulties.

5

In dialysis patients with an AVF having heavy blood flow, the effect of anticoagulants is such that the bleeding time at the puncture site may extend to 45 minutes after the dialysis session (cf. document WO 03/099143 page 1, lines 11 à 20). Maintaining
10 pressure on the AVF for such a long time is tedious and tiring. People suffering from neurodegenerative diseases (Parkinson's, Parkinsonian syndrome, Alzheimer's) may not be able to maintain manual pressure at the puncture site. The same applies to patients who are agitated or depressed, epileptic, or suffering
15 from chorea or patients suffering from convulsions for various reasons.

It is necessary to regularly check that bleeding has stopped at the puncture or injection site, which makes it necessary to
20 remove the compress or the cotton. This check may cause a blood spray, with the risk of contamination of the health care personnel, or else a haemorrhage, in particular when the patient is agitated or in dialysis patients who must simultaneously compress the venous access and the arterial access of the AVF.
25 Bleeding may occur during compression of the puncture site, making it necessary to change the compress, as the presence of blood conceals the puncture site. Regular checking that bleeding has stopped by partially or completely removing the compress may cause adhesion of the haemostatic or non-haemostatic compress
30 to the puncture site, with a risk of detachment of the platelet plug.

The document US 2004/0092999 describes a latex elastic cuff to which a rubber or latex hemispherical part is glued, this cuff
35 being able to be used as a tourniquet prior to venous puncture and facilitating haemostasis after the puncture, with the rubber part compressing the puncture site through a compress. The rubber part described in this prior document makes it possible

to avoid applying manual pressure at the puncture site. However, the use of this cuff does not make it possible to avoid the risks of blood spray or haemorrhage when the compression part is removed in order to check the puncture site. The dressings described in the documents WO 99/08723 and US 2005/0256438 have the same drawbacks. The same applies to the compression haemorrhage dressing for AVFs described in the document WO 03/099143.

The document US 5891074 describes a compression dressing comprising an absorbent polymer foam placed opposite the puncture or injection site. The absorbent polymer foam is for example a polyurethane foam marketed by the company Avitar under the brand name Hydrasorb®. In a variant, a part made of spring steel or a polymer material such as polycarbonate, polyethylene, or polyurethane is placed in direct contact with the skin. The dressing described in the document US 5891074, like a large number of dressings proposed in the prior art, is intended to automatically apply pressure to the puncture or infusion site instead of manual application.

Beyond the haemostatic agents cited in the document US 2006/0155235, a large number of chemical agents for promoting haemostasis are known in the prior art (based on gelatine, collagen, cellulose oxide, and chitosan). Bachtell et al. (Treatment of dialysis access puncture wound bleeding with chitosan dressings, Dialysis & Transplantation, November 2006) describe the use of a haemostatic dressing marketed by the company HemCon, this dressing making it possible to reduce to a few minutes the compression time on the AVF required to achieve haemostasis. The dressings proposed by the company HemCon have been widely used in emergency contexts. Such dressings, marketed for example under the name HemCon Chito-Flex®, contain haemostatic agents (derived from chitosan, cf. <http://www.fda.gov>). These dressings have the drawback of concealing the puncture site, which cannot be visually monitored while compressing the cutaneous bleeding site.

The present inventor developed a dressing for an arteriovenous fistula that makes it possible to significantly reduce bleeding time at the end of dialysis (cf. Boulanger et al., Evaluation of post-puncture bleeding time of arteriovenous fistulas with Iris® bandage, J Vasc Access 2014, pp. 102-107). This dressing is marketed under the band name Iris and makes it possible to reduce the post-dialysis compression time of arteriovenous fistulas.

The present inventor found that certain patients always show prolonged post-dialysis bleeding times despite the use of the best techniques available. Prolonged post-dialysis bleeding is a frequent and severe complication that impairs the quality of life of patients and prolongs the duration of dialysis sessions, thus placing a particular demand on medical personnel at the end of the dialysis session.

The object of the invention is to provide a solution to the problems presented above.

In particular, the object of the invention is to provide a device making it possible to dress a puncture or injection site, with this device not having the drawbacks of those known in prior art and providing increased protection against AEB, haemorrhages, and bacterial contaminations, particularly but not exclusively for vascular dialysis access sites.

For this purpose, according to a first aspect, a dressing is proposed for a puncture or infusion site comprising a sheet of micro-perforated polymeric material, with a first face of this sheet being covered with a pressure-sensitive adhesive, the opposite face of this sheet being non-adhesive, the dressing comprising a strip of material attached to the non-adhesive face of the sheet of polymeric material, and this strip of material being compressible and impermeable. The sheet of micro-perforated polymeric material is provided with perforations having a diameter of less than 0.5 mm.

During the movement of withdrawing a needle for a puncture or infusion site, in particular at the end of dialysis, the application of the adhesive sheet to this puncture or injection site and around this site may lead to the formation of a direct
5 air passage between the adhesive sheet and the skin of the patient, with this direct passage being the imprint of the volume occupied by the needle. The application of manual pressure to the compressible and impermeable strip of material makes it possible to close this direct passage and to prevent the creation
10 of a depression in this passage when the needle is completely withdrawn.

Advantageously, the compressible and impermeable strip of material forms a frame. This arrangement allows the dressing to
15 be used in various orientations.

According to various embodiments, the dressing has the following characteristics, which may optionally be combined:

- 20 • the compressible and impermeable strip of material is of expanded polymer, or of a cellulose based or polyethylene vinyl acetate based nonwoven material;
- the compressible and impermeable strip of material is of
25 polyethylene foam;
- the sheet of micro-perforated polymeric material is transparent, translucent or semi-transparent;
- 30 • the sheet of micro-perforated polymeric material is of polyethylene provided with an acrylic adhesive;
- the perforation density of the sheet of micro-perforated polymeric material is on the order of one hundred per square
35 centimetre.

According to a second aspect, an infusion, drainage, or catheterisation kit is proposed, comprising a dressing such as

set forth above and a needle or a cannula or a catheter or a drain.

5 The use of a dressing as set forth above is proposed as a dressing for an arteriovenous fistula (AVF).

Other objects and advantages of the invention will become apparent in light of the following description of embodiments with reference to the attached drawings, in which:

10

- Fig. 1 is a perspective view of a patient's forearm provided with an AVF, with a butterfly needle being in place in this AVF;

15

- Fig. 2 is a view analogous to that of Fig. 1 showing the first step of the process;

- Fig. 3 is a view analogous to Figs. 1 and 2 showing a second step of the process

20

- Fig. 4 is a top view of a dressing according to an embodiment;

- Fig. 5 is a side view of the dressing of Fig. 4.

25

The following refers to Figs. 1 to 3.

30

Fig. 1 shows the forearm 1 of a patient with an AVF. For simplification purposes, a single needle remains in place in this AVF. As the person skilled in the art will understand, the procedure described with reference to the figures is applied successively to both the venous needle and the arterial needle.

35

In the attached figures, the needle is of the butterfly type. It is nevertheless understood that the procedure described also concerns needles without wings, as well as catheters (for example of the Cathlon® type), or also cannulas.

The AVF, the first indication vascular access and the one most

widely used in dialysis patients, causes the appearance of aneurysmal areas 2, visible in the figures, with the skin being considerably deformed in the vicinity of the AVF. The AVFs are often short, such that the two arterial and venous needles must
5 be placed close to each other. The use of fixing strips can cause repeated irritation of the skin, favouring the development of excoriations that are particularly likely to cause bacterial contamination. The fistulas may be kept active for very many years, and the skin of some dialysis patients shows little
10 flexibility, is thin, and is fragile because of age.

In a first step, shown in Fig. 2, the needle 3 is withdrawn and an adhesive strip 4 is placed at the puncture site. This adhesive strip 4 is transparent, semi-transparent or translucent.

15 Advantageously, this adhesive strip 4 is permeable to liquids, for example micro-perforated.

Advantageously, this adhesive strip 4 contains haemostatic
20 compounds, for example mixed with the adhesive.

In a third step, shown in Fig. 3, a compress can be applied with pressure against the adhesive strip 4 at the level of the puncture site, the needle 3 being completely withdrawn.

25 The pressure on the compress can then be relaxed, and visual inspection of the haemostasis can be carried out. It should be noted that the adhesive strip 4 does not need to be removed, so the puncture site remains covered during visual inspection of
30 the haemostasis. The risks of AEB are thus eliminated, as are the risks of bleeding associated with removal of the platelet plug.

An adhesive strip, for example of the type marketed under the
35 brand name Tegaderm®, can then be placed on top of the compress or on top of the adhesive strip 4.

The implementation of this process makes it possible to sharply

reduce the compression time at the puncture sites of AVFs.

In the applicant's experience, the mechanisms resulting in this quite sharp reduction in compression time could be as follows.

5

In a first phase, after the adhesive strip covering the puncture site is put into place, the blood coming from the puncture site does not flow under the adhesive strip 4 and remains confined. This confinement phase varies in duration depending on the total
10 blood hydration status: the greater the extent of the patient's hyperhydration, the longer this first phase lasts. The duration of this first phase is increased by taking vitamin K or in the presence of a platelet anomaly. The duration of this first phase also increases when puncture of the AVF is carried out in an
15 aneurysmal area or near the anastomosis. The duration of this first phase may be reduced by exerting pressure on the anastomosis for about two minutes.

In a second phase, shorter than the first, the blood is strained
20 by passing through the adhesive strip 4, which is permeable to liquid, and the serum is absorbed by the compress. The concentration of formed elements increases in the blood present at the puncture site because of this straining and this absorption of the serum. The viscosity of the blood present at
25 the puncture site increases. The perforations of the adhesive strip 4 are progressively obstructed by viscous blood.

The implementation of the process also makes it possible to sharply reduce the risks of resumption of bleeding.

30

In the experience of the applicant, the mechanisms leading to this reduction in risk of resumption of bleeding could be as follows.

35 The confinement and the straining of the blood flowing from the puncture site leads to the creation of small scabs. Therefore, when the compress is removed, the risk of detachment of these scabs is reduced.

The semi-permeable transparent sterile adhesive strip 4 protects the vascular puncture site and leaves it visible at all times, without the risk of blood spray or direct sticking of the compress to the puncture site.

We will now refer to Figs. 4 and 5, which illustrate an embodiment of a dressing allowing the use of the process described with reference to Figs. 1 to 3.

The dressing 10 shown in Figs. 4 and 5 comprises a first part 11 forming said adhesive strip 4. Advantageously, a peelable sheet 12 covers the adhesive face of this first part 11. In an embodiment, the peelable sheet 12 is based on siliconized polyester and is thin, for example on the order of 0.05 mm.

Advantageously, the adhesive strip 4 is semi-permeable and allows the diffusion of at least some blood components from the puncture site to a compress placed opposite the adhesive strip 4.

In an advantageous embodiment, the adhesive strip is made of flexible polymeric material or coated fabric, and is advantageously completely transparent, translucent or semi-transparent.

The flexibility of the dressing allows it to follow the contours of the skin, including in the vicinity of the aneurysmal areas of the AVFs. Advantageously, the material forming the adhesive strip, and optionally all of the dressing 10, can be extended in at least one longitudinal direction, and even more advantageously, in both the longitudinal and transverse directions. The dressing 10 is therefore even more adaptable to the various curves of the patient's body.

Perforation of the adhesive strip 4 is advantageously carried out by implementing a process comprising the following steps:

- application of glue to the face of the film to be made adhesive, for example a polyethylene (PE) film, particularly a low-density PE film measuring 60 μm in thickness, with the adhesive being acrylic-based, with a thickness of about 30 μm ;

5

- application of a liner covering the glued face;

- perforation of the film, for example by hot needling, according to a square or diamond-shaped mesh pattern, in one or two passes, with the density of the holes advantageously being on the order of 110 per square centimetre;

10

- removal of the protective film and placement of a peelable strip.

15

Advantageously, the perforations intended for straining are micro-perforations obtained without removing material, for example by needling.

20

Advantageously, the adhesive strip 4 is elastic and perforation is carried out with the adhesive strip under tension, such that the micropores are substantially closed after the tension of the strip is released. On placement of the dressing, the manual stretching of the adhesive strip 4 causes these micropores to

25

The dressing comprises a frame 13 of flexible material. The frame may be square, rectangular, or oval in shape. Advantageously, the frame 13 is composed of foam, for example polyethylene foam. In other embodiments, the frame 13 is composed of cellulose-based nonwoven material or is based on polyethylene vinyl acetate.

30

Before being withdrawn, the needle occupies a space between the skin and the adhesive strip 4, with this space being capable of forming a short path for the passage of blood coming from the puncture site. The present inventor has found that in order to eliminate this risk, it is advantageous to apply manual pressure

35

to the frame 13 above the needle during its withdrawal.

Advantageously, the frame 13 and the adhesive strip 4 do not contain latex, thus preventing allergic reactions to this compound.

By way of example, the dressing 10, seen in a top view, has a substantially rectangular shape with rounded edges and has a length equal to about 40 mm and a width equal to about 35 mm.

The frame 13 delimits a substantially square central window 14 measuring about 20 mm per side. The thickness of the frame 13 is on the order of 1.5 to 2 mm.

The dressing 10 just described presents numerous advantages.

The present inventor has found that the risks of accidental exposure to blood were sharply reduced on disconnection of the venous and arterial lines at the end of the dialysis session.

Indeed, in most patients, only a single droplet of blood appeared, forming at the point of passage of the needle, with this extremely small amount of blood being absorbed by the compress placed on the dressing and the compression time being a few dozen seconds. In a few rare patients, for example in the case of stenosis of the AVF or cardiac arrhythmia, blood flow may take place in the form of a small jet, but this flow is broken by the presence of the micro-perforated adhesive strip. The dressing allows visual inspection of any prolonged bleeding without the risk of spray.

The present inventor has found that compression times at the end of the dialysis session were sharply reduced.

The frame 13 can also play a role in protecting the puncture or injection site against pressure and shocks, maintaining a space between the skin and the patient's clothing. Optionally, a compress may be kept in place in the window 14 defined by the frame 13.

Patentkrav

1. Forbindingsmateriale (10) til et punktur- eller
infusionssted, hvilket materiale omfatter en folie af
5 mikroperforeret polymermateriale, idet en første overflade af
denne folie er dækket med et trykfølsomt klæbemiddel, idet den
modsatte overflade er ikke-klæbende, kendetegnet ved, at det
omfatter et bånd af materiale, der er fastgjort på den ikke-
klæbende overflade af folien af polymermateriale, idet dette
10 bånd af materiale er komprimerbart og uigennemtrængeligt, og
folien af mikroperforeret polymermateriale er forsynet med
perforeringer med en diameter under 0,5 mm.
2. Forbindingsmateriale (10) til et punktur- eller
15 infusionssted ifølge krav 1, kendetegnet ved, at båndet af
komprimerbart og uigennemtrængeligt materiale danner en ramme
(13).
3. Forbindingsmateriale (10) til et punktur- eller
20 infusionssted ifølge krav 1 eller 2, kendetegnet ved, at båndet
af komprimerbart og uigennemtrængeligt materiale er fremstillet
af ekspanderet polymer eller et ikke-vævet materiale på basis
af cellulose eller på basis af polyethylenvinylacetat.
- 25 4. Forbindingsmateriale (10) til et punktur- eller
infusionssted ifølge krav 3, kendetegnet ved, at båndet af
komprimerbart og uigennemtrængeligt materiale er fremstillet af
polyethylenskum.
- 30 5. Forbindingsmateriale (10) til et punktur- eller
infusionssted ifølge et hvilket som helst af kravene 1 til 4,
kendetegnet ved, at folien af mikroperforeret polymermateriale
er gennemsigtig, gennemskinnelig eller halvgennemsigtig.
- 35 6. Forbindingsmateriale (10) til et punktur- eller
infusionssted ifølge krav 5, kendetegnet ved, at folien af
mikroperforeret polymermateriale er fremstillet af polyethylen
forsynet med et acryl-klæbemiddel.

7. Forbindingsmateriale (10) til et punktur- eller
infusionssted ifølge krav 6, kendetegnet ved, at
perforationsdensiteten af folien af mikroperforeret
5 polymermateriale ligger i størrelsesordenen hundrede pr.
kvadratcentimeter.

8. Perfusions-, drænings- eller katetersæt, der omfatter et
forbindingsmateriale (10) ifølge et hvilket som helst af de
10 foregående krav og en nål eller en kanyler eller et kateter eller
et dræn.

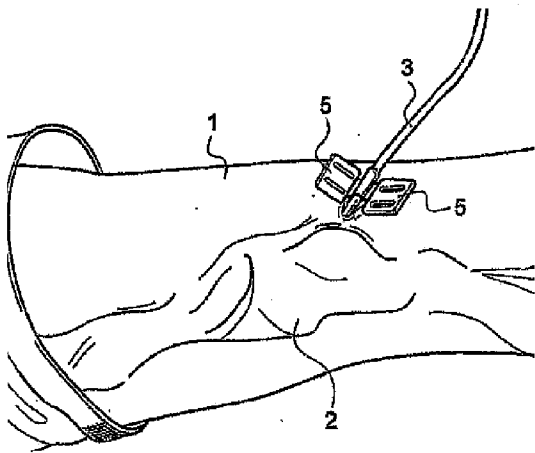


Fig.1

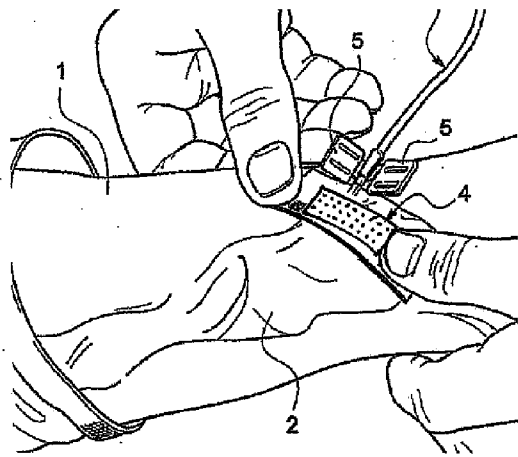


Fig.2

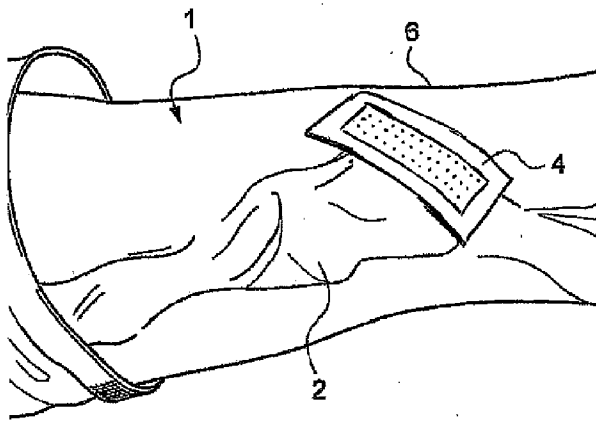


Fig.3

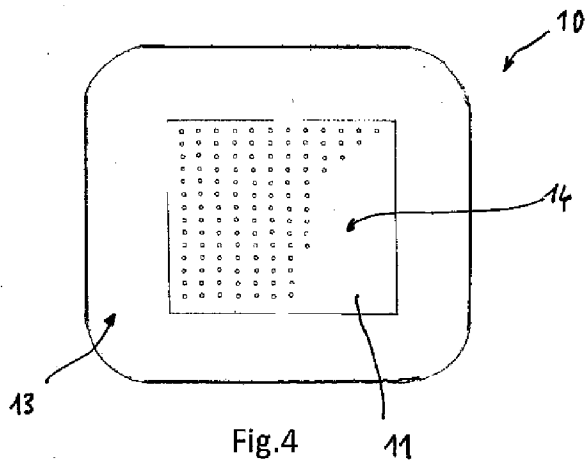


Fig.4

