

**A METHOD FOR INSERTING A PUNCTURE DEVICE ON A SKIN OF A
SUBJECT USING A SKIN COVER UNIT**

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 63/508,077, filed June 14, 2023, the disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present disclosure relates to an ultrasonically transparent surgical skin cover unit for use when inserting a puncture device, such as a cannula, electrode or probe, into a human body, for example into a vein or artery. In particular, procedures involving an ultrasonic device for visualization of the exact location for the puncturing with the puncture device are provided.

BACKGROUND OF THE INVENTION

[0003] When a cannula is inserted into a part of a body, for example a blood vessel of an arm or leg, the insertion can be optimized by visualizing the blood vessel and the cannula using ultrasonic visualization.

[0004] U.S. Patent No. 9,393,381 discloses a skin cover unit for this purpose. The skin cover unit includes an ultrasonically transparent window, made of polymer film, which is glued onto the skin at the puncture site and onto which an ultrasonic probe is placed for imaging the puncture site during insertion of the cannula. Typically, for

better contact between the ultrasonic probe and the polymer film of the base, a gel is used between the probe and the film. In order to properly separate the probe from the puncturing site and for preventing gel to flow to the puncturing site, an upstanding wall is provided in extension of the base, separating the window from the puncturing site. The film for the window is relatively stiff and enables an upstanding wall to be in a position upright to the window. Optionally, the unit includes a gel-removing layer on top of the window for removing the gel-removing layer together with the gel from the window after ultrasonic visualization.

SUMMARY OF THE INVENTION

[0005] This disclosure provides an improved skin cover unit for ultrasonic-assisted control when inserting a cannula or other puncture device at a puncturing site on the skin, for example for injection or blood draws. This objective is achieved with a surgical skin cover unit and its use as explained in greater detail in the following.

[0006] In an embodiment, the skin cover unit includes a base and a wall in extension of the base and connected to the base by a bending region located at a proximal end of the base for bending the wall into an angled orientation relatively to the base. The base includes an ultrasonically transparent flexible sheet extending to a distal end of the cover unit. The base includes a stabilizing but also flexible frame. The frame, together with the ultrasonically transparent flexible sheet, defines an ultrasonically transparent window. The ultrasonically transparent window extends all the way to the distal end of the cover unit. That is, the frame is open-ended at the distal end of the cover unit.

[0007] In an embodiment, a method for inserting a puncture device through a skin of a subject includes applying the skin cover unit onto a skin of the subject at a puncture site; imaging an anatomical structure and/or the puncture device under the skin of the

subject at the puncture site or near the puncture site in a distal direction using an ultrasonic probe on a top side of the base; and inserting the puncture device at the puncture site.

[0008] In an embodiment, a method for inserting a puncture device through a skin of a subject includes applying a skin cover unit onto a skin of the subject at a puncture site; imaging an anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in a distal direction using an ultrasonic probe on a top side of the cover unit; inserting the puncture device at the puncture site; and imaging the anatomical structure and/or the puncture device under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a top view of a prior art skin cover unit in a bent configuration.

[0010] FIG. 2A is a top view of a skin cover unit according to embodiments of the disclosure.

[0011] FIG. 2B illustrates a cross-sectional view of a skin cover unit in a bent configuration according to embodiments of the disclosure.

[0012] FIG. 3A is a cross-sectional view of the skin cover unit before bending according to embodiments of the disclosure.

[0013] FIG. 3B is a cross-sectional view of the skin cover unit after bending the stabilizer according to embodiments of the disclosure.

[0014] FIG. 3C is a cross-sectional view of the skin cover unit after bending the wall relative to the base according to embodiments of the disclosure.

[0015] FIG. 4A is a perspective view of the skin cover unit in a flat configuration before removal of parts of the cover sheet according to embodiments of the disclosure.

[0016] FIG. 4B is a perspective view of the skin cover unit in a flat configuration during removal of a parts of the cover sheet according to embodiments of the disclosure.

[0017] FIG. 4C is a perspective view of the skin cover unit in a bent configuration before final attachment of the stabilizer according to embodiments of the disclosure.

[0018] FIG. 5A is a cross-sectional view of the cover unit in a flat configuration before being applied to the skin of the subject according to embodiments of the disclosure.

[0019] FIG. 5B is a cross-sectional view of the cover unit in a flat configuration after being applied to the skin of the subject according to embodiments of the disclosure.

[0020] FIG. 6A is a cross-sectional view of the skin cover unit in a flat configuration with the stabilizer bent according to embodiments of the disclosure.

[0021] FIG. 6B is a cross-sectional view of the skin cover unit after application to the skin of the subject with the wall in a bent configuration relative to the base according to embodiments of the disclosure.

[0022] FIG. 7 is a cross-sectional view of a further embodiment of a stabilizer according to embodiments of the disclosure.

[0023] FIG. 8 is a cross-sectional view of the skin cover unit similar to FIG. 6B with an added gel-removal strip according to embodiments of the disclosure.

[0024] FIG. 9A is a cross-sectional view of the skin cover unit similar to FIG. 8 with the gel-removal strip extending underneath the stabilizer for removal of the stabilizer together with the gel-removal strip according to embodiments of the disclosure.

[0025] FIG. 9B is a cross-sectional view of the skin cover unit in a flat configuration after removal of the gel-removal strip and the stabilizer.

DETAILED DESCRIPTION OF THE INVENTION

[0026] While conventional skin cover units allow ultrasonic-assisted control when inserting a cannula or other puncture device at a puncturing site on a subject's skin for e.g., blood draws or injection, they may not provide adequate ultrasonic-assisted control when the cannula or other puncture device is relatively long. A conventional skin cover unit may provide ultrasonic-assisted control in the lateral direction when a relatively long cannula or other puncture device is used. However, the conventional skin cover unit does not provide adequate ultrasonic-assisted control in the longitudinal direction when a relatively long cannula or other puncture device is used, because the distal end of the skin cover unit can block the ultrasonic scan. Even when a relatively shorter cannula or other puncture device is used, it may be necessary for the user to place the conventional skin cover unit at a more precise location to avoid this ultrasonic scan blockage.

[0027] FIG. 1 is an illustration of such a conventional skin cover unit 1. The skin cover unit 1 includes a base 2 and a wall 3 in extension of the base 2. The skin cover unit 1 also includes a tab 31 on the distal end. The wall 3 is connected to the base 2 by a bending region 4 for orienting the wall 3 into an angled orientation relatively to the base 2. The base 2 includes a stabilizing frame 5 and an ultrasonically transparent flexible sheet 6, typically a polymer film, on or within the frame 5, or at least partially within the frame, for ultrasonic investigation of the insertion site (not shown) by an ultrasonic probe (not shown). The flexible sheet 6 is attached to and supported by the frame 5. Further, the flexible sheet 6 includes an adhesive layer (not shown) on the bottom side of the flexible sheet 6 for gluing the base 2 onto the skin (not shown) of

the subject. The frame 5 creates an ultrasonically transparent window 30. The distal part 5' of the frame 5 sets the limit of the ultrasonically transparent window 30 in the longitudinal direction.

[0028] Here, when a relatively long cannula (e.g., a cannula longer than the longitudinal length of the ultrasonically transparent window 30 of the skin cover unit 1) is used in conjunction with the skin cover unit 1, the distal part of the frame 5 of the cover unit 1, due to not being ultrasonically transparent, can block the sonographic view of the relatively long cannula and the anatomical structure around the end of the relatively long cannula. Even when shorter cannulas are used, this prior art skin cover unit 1 requires a more precise application to the skin because the distal part of the frame 5 of the cover unit 1 can prevent the ultrasonic scan if it is placed too close to the puncture site.

[0029] Accordingly, there is a need to improve ultrasonic-assisted control when inserting a cannula or other puncture device at a puncturing site on the skin.

[0030] In accordance with the present disclosure, using a skin cover unit having an open-ended configuration on the distal end provides an unblocked sonographic view even of a relatively long cannula and the anatomical structure around the end of the cannula. Also, precise application of the skin cover unit is less of an emphasis due to this open-ended configuration.

[0031] As used throughout the disclosure, the term “proximal” refers to the direction towards the puncture site. Conversely, the term “distal” refers to the direction away from the puncture site. The distal direction typically corresponds to the direction of penetration of the cannula or puncture device into the skin.

[0032] As used throughout the disclosure, the term “lateral” refers to the direction perpendicular to the proximal-distal direction. The term “longitudinal” refers to the proximal-distal direction.

[0033] As used throughout the disclosure, the term “puncture site” refers to the exact location where the cannula (typically having a diameter ranging from 0.6 to 2.1 mm) or another puncture device penetrates the skin of the subject and the vicinity thereof. For example, the puncture site can include an area having a radius of equal to or less than 0.5 mm, equal to or less than 1 mm, equal to or less than 1.5 mm, equal to or less than 2 mm, equal to or less than 3 mm, equal to or less than 4 mm, equal to or less than 5 mm, equal to or less than 6 mm, equal to or less than 7 mm, equal to or less than 8 mm, equal to or less than 9 mm, equal to or less than 10 mm, equal to or less than 15 mm, or equal to or less than 20 mm, or any radius therebetween, relative to the exact location where the cannula or other puncture device penetrates the skin of the subject. For purposes of the disclosure, the skin cover unit is not penetrated by the cannula or any other puncture device. Therefore, a skin cover unit located “at a puncture site” does not mean that any portion of the skin cover unit directly covers the exact location of the skin where the cannula or other puncture device is penetrating. After penetration, a portion of the skin cover unit may cover and secure the cannula or other puncture device to prevent dislodgement of the cannula or other puncture device. At the puncture site, the skin cover unit may or may not be in direct contact with the skin.

[0034] Although the disclosure exemplifies insertion of a cannula or catheter as the puncture device, it also encompasses insertion of different types of puncture devices, for example an electrode for nerve stimulation, a transducer for recording electric signals from nerves, or a cannula or catheter for injection of steroids or anesthesia for nerve blocks. A further use of the skin cover unit is insertion of a probe for analysis of chemical agents, for example oxygen, metabolites, or drugs.

[0035] The imaging of the anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in the distal direction

using the ultrasonic probe on the top side of the base/cover unit; the inserting of the puncture device at the puncture site; and the imaging of the anatomical structure and/or the puncture device under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe, can be conducted in any order and can be, at any given moment, conducted simultaneously.

[0036] In an embodiment, the imaging of the anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in the distal direction using the ultrasonic probe on the top side of the base/cover unit can be conducted first, the inserting of the puncture device at the puncture site can be conducted second (the first step is not required to be ceased when conducting the second step), and the imaging of the anatomical structure and/or the puncture device under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe can be conducted third (the first and/or second steps are not required to be ceased when conducting the first and/or second steps).

[0037] In an embodiment, the inserting of the puncture device at the puncture site can be conducted first, the imaging of the anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in the distal direction using the ultrasonic probe on the top side of the base/cover unit can be conducted second (the first step is not required to be ceased when conducting the second step), and the imaging of the anatomical structure and/or the puncture device under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe can be conducted third (the first and/or second steps are not required to be ceased when conducting the first and/or second steps).

[0038] In an embodiment, the inserting of the puncture device at the puncture site can be conducted first, the imaging of the anatomical structure and/or the puncture device

under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe can be conducted second (the first step is not required to be ceased when conducting the second step), and the imaging of the anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in the distal direction using the ultrasonic probe on the top side of the base/cover unit can be conducted third (the first and/or second steps are not required to be ceased when conducting the first and/or second steps).

[0039] FIG. 2A is an illustration of a skin cover unit 101 according to embodiments of the disclosure. The skin cover unit 101 includes a base 102 and a wall 103 in extension of the base 102. The base 102 and the wall 103 can be made of a single component or be made of different components. The skin cover unit 101 also includes a tab 131 on one side of the distal end. The wall 103 is connected to the base 102 by a bending region 104 for orienting the wall 103 into an angled orientation relatively to the base 102. The base 102 includes a stabilizing frame 105 and an ultrasonically transparent flexible sheet 106, typically a polymer film, on or within the frame 105, or at least partially within the frame, for ultrasonic investigation of the insertion site 120 by an ultrasonic probe 119. The flexible sheet 106 is attached to and supported by the frame 105. Further, the flexible sheet 106 includes an adhesive layer 107 on a first side of the flexible sheet 106 for gluing the base 102 onto the skin 108 of the subject. The frame 105 creates an ultrasonically transparent window 130. The distal part of the frame 105 does not exist such that the limit of the ultrasonically transparent window 130 in the longitudinal direction is the distal end of the flexible sheet 106.

Advantageously, a relatively long cannula can be used by guidance of an unobstructed sonographic view of the relatively long cannula and the anatomical structure around the tip of the relatively long cannula, as such cannula is typically inserted into relatively larger and/or relatively deeper veins. In comparison with standard cannula

or catheter lengths of 2 to 6 cm, the relatively long cannula or catheter may have non-limiting lengths of about 6 to about 8 cm, about 8 to about 15 cm, or about 15 to about 25 cm, or any length therebetween.

[0040] Typically, the wall 103 is made of a polymer film, paper sheet, or a dressing textile or a combination thereof. For transport, typically, the wall 103 is provided in longitudinal extension of the base 102, such that the base 102 and wall 103 are packed in a flat condition. Alternatively, the base 102 and the wall 103 can be folded onto each other into a compact double layer configuration which has to be unfolded for use.

[0041] When the skin cover unit 101 is unpacked from a package, the wall 103 is folded into an angled, typically perpendicular or largely perpendicular orientation, relative to the base 102 in order to provide the wall 103 in upstanding orientation relative to the skin 108. This folding is done before or after gluing the base 102 onto the skin 108.

[0042] The frame 105 can be made of materials including, but not limited to, woven, knitted, or non-woven fabric, plastic, rubber, paper, silicone, or combinations thereof.

[0043] The ultrasonically transparent flexible sheet 106 can be made of materials including, but not limited to, rubber, paper, silicone, plastics, or combinations thereof. Non-limiting examples of plastics include polyurethane or elastomeric polyesters (e.g., polyethylene (PE), polyethylene terephthalate (PET)). The ultrasonically transparent flexible sheet 106 is to be understood as a sheet that has sufficient elasticity and resiliency for the sheet to be able to follow the movements of the skin and remain attached. For example, the flexible sheet 106 has a thickness in the range of about 10 to about 45 microns.

[0044] The wall 103 can be made of materials including, but not limited to, woven, knitted, or non-woven fabric, plastic, rubber, paper, silicone, or combinations thereof.

[0045] The skin cover unit 101 can have a width ranging from about 1 to about 20 cm, about 2 to about 15 cm, about 3 to about 12.5 cm, about 4 to about 10 cm, about 5 to about 8 cm, or any width therebetween. Preferably, the skin cover unit 101 has a width ranging from about 4 to about 10 cm. The skin cover unit 101 can have a length ranging from about 1 to about 30 cm, about 3 to about 25 cm, about 5 to about 20 cm, about 6 to about 15 cm, about 7.5 to about 12 cm, or any length therebetween. Preferably, the skin cover unit 101 has a length ranging from about 6 to about 15 cm. The skin cover unit 101 can have a thickness for each layer ranging from about 1 to about 3000 microns, about 1 to about 2000 microns, about 1 to about 1000 microns, about 1 to about 500 microns, about 1 to about 250 microns, about 5 to about 100 microns, about 10 to about 45 microns, or any thickness therebetween. Preferably, the skin cover unit 101 has a thickness for each layer ranging from about 10 to about 45 microns.

[0046] In FIG. 2B, the flexible sheet 106 is shown as placed on the frame-side that is remote from the skin 108, however, it could alternatively be provided inside the frame 105 or between the frame 105 and the adhesive layer, facing the skin 108. If the flexible sheet 106 is placed below the frame, the flexible sheet 106 can be provided with the adhesive layer 107 in order to glue the flexible sheet to the skin 108. If the flexible sheet 106 is placed on the frame 105 as illustrated in FIG. 2B, the frame 105 could also be provided with the adhesive layer 107 in order to glue the frame to the skin 108. At the beginning of the puncture procedure, the site to be punctured is located, washed, or disinfected.

[0047] The flexible sheet 106 typically made of flexible polymer film is attached to and supported by the frame 105. The flexible sheet 106 is ultrasonically transparent. For example, the material of the frame 105 is thicker and more mechanically stable and rigid than the flexible sheet 106. The stable frame 105 allows the flexible sheet

106 being provided thin and flexible for bending easily with the skin and rest tightly against the skin for good ultrasound transmission. That is, the stable frame 105 supports the flexible sheet 106 such that the flexible sheet 106 can be positioned on the skin 108 of the subject without forming wrinkles and without adhering to itself. The stable frame 105 may assist in having the wall 103 maintained at an angle relative to the base 102; however, it is preferable to have a stabilizer 109 at the bending region 104 to maintain the angled orientation. Typically, the flexible sheet 106 is also light transparent in order to allow inspection of the puncture site by the eye and/or a camera for patient care.

[0048] In an embodiment, the ultrasonically transparent flexible sheet 106, for example polymer film, is glued to the skin 108 with an adhesive 107 that provides a good contact for ultrasonic transmission from the flexible sheet 106 and into the skin 108. However, this is not strictly necessary. For example, if the sheet 106 is made of a thin polymer film, the film itself may readily attach to the skin 108 and follow the contour of the skin 108 even without glue. The principle is similar to the attachment properties of kitchen wrap film. However, for such thin and flexible film, a stable frame 105 is an advantage in that the stable frame 105 gives the necessary stability for not only holding the film but also the wall 103, and the film can be made sufficiently thin for good skin contact.

[0049] As a further alternative, only the frame 105 is provided with adhesive on the skin-adjacent side, and the flexible sheet is merely resting against the skin 108. Some polymer films are readily attaching to the skin even without glue and have sufficient ultrasonic transmission for the investigation.

[0050] On a bottom side of the base 102, there is provided an adhesive layer 107 for gluing the base onto the skin 108 of the subject. The opposite, top side of the base 102 is configured to be in contact with the ultrasonic probe 119 for visualization of the

insertion area adjacent (and in the distal direction) to the base 102 when inserting the puncture device into the skin 108.

[0051] In order to provide a good contact between the ultrasonic probe 119 and the flexible sheet 106 of the base 102, it is often advantageous to use an ultrasonic fluid, typically a gel 114. This gel 114 is applied to the ultrasonically transparent flexible sheet 106 prior to the ultrasonic investigation and then removed again. For example, the gel 114 is wiped off after use of the ultrasonic probe 119. Alternatively, a gel-removal strip, which is also ultrasonically transparent, is provided on top of the flexible sheet 106 and forms part of the base 102. This gel-removal strip is then taken off and removed from the ultrasonically transparent flexible sheet 106 together with the gel 114 such that wiping off the gel 114 from the base is avoided. For example, the gel-removal strip extends under at least part of the stabilizer 109, for example under the entire stabilizer 109, for by manual removal of the gel-removal strip from the flexible sheet 106 also removing the stabilizer 109.

[0052] Furthermore, the skin cover 101 unit may include a stabilizer 109, in or at the bending region 104. The stabilizer 109 is configured for maintaining the angled orientation, for example perpendicular orientation, between the wall 103 and the base 102 only by a stabilizing action of the stabilizer 109, for example when the skin cover unit 101 is positioned on top of a flat straight skin surface. In an embodiment, the stabilizer 109 is positioned outside the ultrasonically transparent window 130. Optionally, the stabilizer 109 or part of the stabilizer 109 is positioned along a perimeter of the ultrasonically transparent window 130. In an embodiment, the stabilizer 109 is provided on the frame 105 and on the wall 103 for stabilizing the orientation of the wall 103 relatively to the frame 105.

[0053] The stabilizer 109 can be made of materials including, but not limited to, polyester, polyethylene terephthalate (PET), polyethylene, polyamide (e.g., nylon), paper (typically coated), or combinations thereof.

[0054] The stabilizer 109 is provided at or near the bending region 104, which typically is the region where the wall 103 is connected to the base 102. For example, the stabilizer 109 is in itself bendable so that the base 102 and wall 103 can be manually bent about the bending region 104 from a planar or collapsed configuration into a bent configuration where the wall 103 is angled relative to the base 102, for example angled perpendicular to the base 102. However, once the wall 103 is bent relative to the base 102 into the angled orientation, for example perpendicular orientation, the stabilizer 109 maintains the angled orientation between the wall 103 and the base 102. Typically, the bending of the wall 103 relative to the base 102 about the bending region 104 is along a bending line.

[0055] In an embodiment, the stabilizer 109 is non-resiliently bendable and configured for adopting and maintaining a selectable bending condition when being bent for thereby maintaining a selected orientation of the wall 103 relative to the base 102. When the non-resilient stabilizer 109 is bent into the selected bent configuration it maintains this bent configuration. For example, the stabilizer 109 includes a metal foil with non-resilient bending properties. Optionally, the stabilizer 109 is provided as a non-resiliently bendable hinge, for example a non-resilient bendable polymer sheet or metal foil, that is adopting and maintaining a selectable bending condition when being bent for thereby maintaining a selected orientation of the wall 103 relative to the base 102.

[0056] In an embodiment, the stabilizer 109 is bent into a collapsed double-layer configuration during manufacturing and supplied in the collapsed position where the base 102 is abutting the wall 103. It is then at least partially unbent in use.

Alternatively, the stabilizer 109 is not bent during manufacturing and supplied in the unbent configuration, typically flat configuration, which is then bent for use.

[0057] In FIGS. 2A and 2B, the stabilizer 109 is illustrated as an angled profile with two legs 111A and 111B, of which one leg 111A is glued with a first stabilizer-adhesive 110A to the wall 103 and the other leg 111B is glued with a second stabilizer-adhesive 110B to the base 102, thus maintaining the angled orientation between the wall 103 and the base 102.

[0058] In case that the flexible sheet 106 is provided on the upper side of the frame 105, which is the side remote from the side with the adhesive 107, the stabilizer 109 would be attached to the flexible sheet 106 on that portion of the flexible sheets that is itself attached to the frame. If the flexible sheet 106 is only provided within the frame 105, the stabilizer would be attached to the frame 105 directly, instead, as the frame at least partially surrounds the flexible sheet 106. The stabilizer 109 would be attached to the frame if the flexible sheet 106 is provided between the frame 105 and the skin 108, as the frame 105 in this case is attached to the opposite, upper side of the flexible sheet 106. In either case, the stabilizer is attached to the frame, either directly or through the film on the frame. Various embodiments and variations of the principle are possible.

[0059] The upstanding wall 103 is provided with a wall adhesive layer 117 covered by a cover sheet 118, the use of which is explained in more detail in the following, especially in connection with FIGS. 5A, 5B, 6A, and 6B.

[0060] As illustrated in FIG. 2A, the stabilizer 109 is provided as two separate bent strips, one on either side of the flexible sheet 106. Each strip has the first leg 111A attached to the wall and the second leg 111B attached to the frame 105 at the perimeter of the sheet 106 and outside the sheet 106, where the sheet 106 covers the ultrasonically transparent window 130.

[0061] Alternatively, the stabilizer 109, has a second leg 111B fastened to the frame 105 on either side of the frame 105. However, the leg 111A that is attached to the wall 103 stretches across the wall 103 from one side edge of the wall to the opposite side edge of the wall 103. The configuration of the stabilizer in this embodiment resembles a C-shape.

[0062] As illustrated in FIGS. 2A and 2B, the flexible sheet 106 extends around the bending region 104 with a minor part 106' of the flexible sheet 106 so that the minor part 106' is bent upwards together with the wall 102.

[0063] In an alternative embodiment, the sheet 106 is not bent upwards with the wall 102 but has a perimeter at the stabilizer 109 at the bending region 104. In this case, the sheet 106 is only provided flat against the skin.

[0064] As a further alternative embodiment, the configuration of the wall 103 and base 102 with a frame 105 can be combined with the stabilizer 109 strips of FIG. 2A.

[0065] In all cases, the stabilizer 109 is outside that part of the base 102 that is used for ultrasonic investigation.

[0066] It should be mentioned that the stabilizer 109 can be attached to the base 102 and the wall 103 from the onset and then bent into an angled configuration, which is then maintained due to the non-resilient material of the stabilizer 109, for example metal.

[0067] Alternatively, one leg 111A of the stabilizer 109 is fastened to the wall 103 and the other leg 111B is not yet fastened to the base 102, or vice versa, but is only fastened to the base, or respectively the wall, once the orientation between the wall and the base has been adjusted. Options of this principle are explained in greater detail below.

[0068] FIG. 3A illustrates a possible package and transport condition of the cover unit 101. The wall 103 is oriented in flat extension of the base 102. The adhesive layer

107 for gluing on the skin is covered by a removable cover sheet 112, typically a paper sheet. The two legs 111A and 111B of the stabilizer 109 are folded together, and configured for unfolding, as illustrated in FIG. 3B. The second stabilizer-adhesive 110B is covered by a further cover sheet 113, typically further paper sheet, which is removed from the second stabilizer-adhesive 110B, such as illustrated in FIG. 3B. Once, the cover unit 101 as per FIG. 2A is removed from its package (not shown) and the further cover sheet 113 is removed from the second stabilizer-adhesive 110B, the wall 103 is bent about the bending region 104 into an angled orientation relatively to the base 102, and the second stabilizer-adhesive 110B is subsequently attached to the base 102, which stabilizes the orientation of the wall 103 relatively to the base 102, such as illustrated in FIG. 3C. For attachment to the skin 108, the cover sheet 112 is removed, and the adhesive layer 107 of the base 102 is glued to the skin 108. This is preferably done before bending the wall 103 relatively to the base 102 but can also be done after bending the wall 103.

[0069] In an embodiment, the cover unit 101 is removed from the subject after the ultrasonic investigation and insertion of a puncture device, especially a cannula insertion or, alternatively, insertion of other puncture device, for example electrode or probe. In other situations, the cover unit 101 remains on the skin 108 of the subject even after the investigation and insertion of the puncture device, for example cannula. In the latter case, the wall 103 can, in principle, be removed from the base 102, for example by cutting it off. Alternatively, the wall 103 is bent onto the base 102 and remains there. For these situations, the wall 103 does not need to be provided with adhesive 117 in contrast to the illustrations in FIGS. 2B, 5A, 5B, 6A, and 6B.

[0070] However as explained in more detail in the following, the wall 103 is optionally glued onto the skin 108 after the ultrasonic investigation and insertion of the cannula or other puncture device into the skin 108. Thus, although the adhesive

layer 107 is shown in FIG. 2B as only extending along the base 102, it also can be provided under the wall 103. Such embodiments are illustrated in FIGS. 2B, 5A, 5B, 6A, and 6B, and are described in more detail in the following.

[0071] FIGS. 4A, 4B, and 4C illustrate a sequence of preparatory steps from the just-unpackaged condition to the bent configuration. In FIG. 4A, the cover unit 101 is in flat, straight configuration just after unpacking. The wall 103 is in straight extension of the base 102. The base 102 is not yet transparent, as it is covered by a cover sheet (not shown) on its skin-adjacent side. However, once such cover sheet is removed, as illustrated in FIG. 4B, the transparent flexible sheet 106 is clearly visible inside the frame 1015. The further cover sheet 113 is visible in FIG. 4A, and in the process of removal in FIG. 4B. After removal of the further cover sheet 113, two flaps 111B', corresponding to the second leg 111B of FIG. 2B, are visible in FIG. 4C. These two flaps 111B' are two portions of the stabilizer 109 and provided at each of two opposite edges 115 A, 115B of the wall 103 for fastening the two flaps 111B' to two opposite parts 105A, 105B of the frame 105 of the base 102. Once, these flaps 111B' are glued onto the base 102, the wall 103 is fixed in orientation relatively to the base 102, as illustrated in FIG. 2A.

[0072] In some embodiments, the wall 103 includes a slot 116 extending from an end of the wall 103 towards the base 102. As best seen in FIG. 2A, the slot 116 has a bottom 116' which is near the bending region 104 and close to the flexible sheet 106. In some embodiments, a slit is provided in the wall material, and the slot 116 can then be provided by pressing apart the two adjacent opposite edges of the slit.

[0073] Alternatively, the slot 116 is provided with a suitable width to ease insertion of the puncture device. As illustrated in FIGS. 2B, 5A, 6A and 6B, the wall 103 includes a first wall side 103A with an adhesive 117 for also gluing the wall 103 to the skin 108 of the subject and for locating the cannula inside the slot 116 while the

wall 103 is glued to the skin 108 of the subject. The adhesive 117 is covered by a wall cover sheet 118. Once, the wall cover sheet 118 is removed, the first side 103A of the wall 103 can also be glued to the skin 108 of the subject by the adhesive 117.

[0074] In an embodiment, the wall cover sheet 118 is kept on the adhesive 117 of the first wall side 103A while it is used as an upstanding wall 103 adjacent to the insertion site, while the wall 103 is bent relatively to the base 102. Selectively, the wall cover sheet 118 is then removed from the adhesive 117 and the wall 103 glued to the subject's skin 108 after insertion of the puncture device in order to accommodate the puncture device inside the slot after gluing. Alternatively, the wall cover sheet 118 of the adhesive 117 on the wall 103 is removed together with the wall cover sheet 112 of the adhesive 107 of the base 102, and the wall 103 and base 102 are glued onto the skin of the subject before ultrasonic investigation.

[0075] In the initial form, the adhesive 117 of the first wall side 103A is covered by a wall cover sheet 118 in order for the user to keep the wall cover sheet 118 on the adhesive 117 of the first wall side 103A while using the wall 103 in upstanding configuration, stabilized by the stabilizer 109, for safe ultrasonic investigation adjacent to the insertion site 119, as explained above and as illustrated in FIGS. 2B and 6B, while the wall 103 is bent in the bending region 1014 relatively to the base 102.

[0076] The user can then select removing the wall cover sheet 118 from the adhesive 117 and gluing also the wall 103 to the subject's skin 108 after insertion of the puncture device, especially a cannula, into the skin 108, such that the puncture device 123, especially a cannula, is located inside the slot 116. For the latter case, the stabilizer 109 has to be deactivated, for example by cutting it or by partial detachment from the base 102 or the wall 103. In the embodiment with the stabilizer legs flaps

111B, these are decoupled from the base 102 or frame 103 or both for the de-activation. Alternatively, the stabilizer 109 is cut for deactivation.

[0077] As an alternative, the user can selectively glue the wall 103 as well as the base 102 to the skin 108 of the subject and insert the puncture device, especially a cannula, into the skin 108 through the slot 118 while performing the ultrasonic investigation with the probe 119 through the base 102. In this case, the cover unit 101 is used in straight condition and the wall 103 is not used in upstanding configuration.

[0078] The flat configuration of the cover unit 101 with both the wall 103 and the base 102 being glued to the skin is illustrated in FIG. 5B. In this illustration, the stabilizer 109 has not been activated but remained in the transport condition.

[0079] When starting with the straight transport condition of the skin cover unit 101, as illustrated in FIG. 5A, the user has several options. As a first option, the user can remove the cover sheets 112 and 118 and glue the skin cover unit 101 onto the skin 108 of the user while the skin cover unit 101 is in straight condition, such as illustrated in FIG. 5B. As a second option, the user can remove the cover sheet 113 from the stabilizer 109 and bend the stabilizer 109 into the angled orientation, as illustrated in FIG. 6A and then raise the wall 103 into the upstanding configuration as in FIGS. 2B and 6B. After ultrasonic investigation, the user may optionally lay down the wall 103 onto the skin 108, similar to the configuration of FIG. 5B.

[0080] In these ways, the cover unit 101 is has multiple functions. On the one hand, it preserves the function of the prior art and, on the other hand, it adds the function of the upstanding wall 103 which is stabilized by the stabilizer 109 in case that the skin 108 surface is relatively flat.

[0081] FIG. 7 illustrates a further embodiment of a stabilizer 109. The stabilizer 109 is fastened to a first point or region 121A on the wall 103 and a second point or region 121B on the base 102, for example on the frame 105, where both points or regions

121A, 121B are remote from the bending region 104. The stabilizer 109 connects these two remote points or regions 121A, 121B, thus forming a stable triangular configuration between the two points or regions 121A, 121B and the bending region 104.

[0082] Although, the upstanding wall 103 is illustrated as having a perpendicular orientation relatively to the base 102, this is not strictly necessary, as the angle between the wall 103 and the base 102 can be adjusted to other angles, for example in the range of 45-135 degrees.

[0083] Optionally, in order to ease removal of the gel, a gel-removal strip 122, see FIG. 8, is provided on top of the flexible sheet 106. This gel-removal strip 122 is also ultrasonically transparent and is taken off and removed from the ultrasonically transparent flexible sheet 106 together with the gel such that wiping off the gel from the flexible sheet 106 is avoided.

[0084] FIG. 9A is a sketch similar to FIG. 8A but with the gel-removal strip 122 extending underneath the second leg 111B of the stabilizer 109 in order for the stabilizer 109 to be removed together with the gel-removal strip 122 when the user pulls off the gel-removal strip 122 from the surface of the flexible sheet 106. For this, the adhesive 110A of the first leg 111 A of the stabilizer 109 is pulled off the upstanding wall 103. Once the stabilizer 109 is removed, the upstanding wall 103 can be laid flat down on the skin 108 and glued to the skin 108 by the adhesive 117, once the wall cover sheet 118 for covering adhesive 117 has been removed. This situation is illustrated in FIG. 9B. The puncture device 123 then extends through the slot 116 and through the skin 108 into the underlying tissue.

[0085] It is pointed out that the gel-removal strip 122 could also extend underneath the adhesive 110A and first leg 111A of the stabilizer 109 a distance up the upstanding wall 103. In this case the gel-removal strip 122 extends entirely under the

stabilizer 109 and endures that the entire stabilizer is removed together with the gel-removal strip 122.

[0086] The stabilizer 109 can be made of materials including, but not limited to, polyester, polyethylene terephthalate (PET), polyethylene, polyamide (e.g., nylon), paper (typically coated), or combinations thereof.

[0087] EXAMPLES

[0088] Specific embodiments will now be demonstrated by reference to the following examples. It should be understood that these examples are disclosed solely by way of illustrating the invention and should not be taken in any way to limit the scope of the present invention.

[0089] EXAMPLE 1

[0090] A skin cover device in accordance with embodiments of the disclosure, such as that shown in FIGS. 2A-2B, is applied to a subject. The skin cover device, in a flat configuration, is unpacked from a package. The base is adhered to the subject's skin. Subsequently, the wall, including a stabilizer, is bent to maintain an angle relative to the base. A gel is applied on a gel-removal strip on top of the flexible sheet of the base. A cannula having a length of 6 to 10 cm is inserted into the subject's skin while an ultrasonic probe positioned on top of the gel-removal strip and in contact with the gel is used to monitor the insertion of the cannula and location of the veins. After insertion is complete, ultrasonic monitoring is ceased and the gel-removal strip is removed. A wall cover sheet covering the bottom side of the wall is removed then the wall was unbent to be adhered to the subject's skin.

WHAT IS CLAIMED IS:

1. A method for inserting a puncture device through a skin of a subject comprising:

applying a cover unit onto the skin of the subject at a puncture site, the cover unit comprising:

a base comprising:

a first adhesive layer on a bottom side of the base;

an ultrasonically transparent flexible sheet extending to a distal end of the cover unit; and

a frame, which, together with the ultrasonically transparent flexible sheet, defines an ultrasonically transparent window, the ultrasonically transparent window extending to the distal end of the cover unit, the frame being open-ended at the distal end of the cover unit; and

a wall being connected to the base via a bending region located at a proximal end of the base;

imaging an anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in a distal direction using an ultrasonic probe on a top side of the base; and

inserting the puncture device at the puncture site.

2. The method of claim 1, further comprising:

imaging the anatomical structure and/or the puncture device under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe.

3. The method according to claim 1 or 2, further comprising:
bending the bending region to have the wall in an angled orientation relative to the base.
4. The method according to any one of claims 1-3, further comprising:
applying a gel on the top side of the base before the imaging of the anatomical structure; and
removing the gel after the inserting of the puncture device.
5. The method of claim 4, wherein the cover unit further comprises an ultrasonically transparent gel-removal strip covering the ultrasonically transparent flexible sheet on the top side of the base.
6. The method of claim 5, further comprising:
removing the ultrasonically transparent gel-removal strip from the base.
7. The method according to any one of claims 1-6, further comprising:
disinfecting the puncture site.
8. The method according to any one of claims 1-7, wherein, in the bending step, an angle between the wall and the base ranges from 45 to 135 degrees.
9. The method according to any one of claims 1-8, wherein the cover unit further comprises a stabilizer located at or near the bending region, the stabilizer being capable of maintaining the angled orientation between the wall and the base.

10. The method of claim 9, wherein the stabilizer is a bendable sheet comprising a first stabilizer part being fixed to the wall and a second stabilizer part being fixed to the base.

11. The method of claim 9, wherein the cover unit comprises two stabilizers, each stabilizer located at or near each lateral end of the bendable region.

12. The method of claim 9, wherein the cover unit further comprises an ultrasonically transparent gel-removal strip covering the ultrasonically transparent flexible sheet on the top side of the base, wherein the ultrasonically transparent gel-removal strip extends under at least part of the stabilizer.

13. The method of claim 12, further comprising:
applying a gel on the top side of the ultrasonically transparent gel-removal strip before the imaging of the anatomical structure; and
removing the ultrasonically transparent gel-removal strip from the base after the inserting of the puncture device such that the gel and the stabilizer are also removed.

14. The method according to any one of claims 1-13, wherein the wall comprises a slot extending from a proximal end of the wall towards the base, wherein the slot is capable to position the puncture device after the inserting of the anatomical structure.

15. The method of claim 14, wherein the wall further comprises a second adhesive layer on a bottom side of the wall.

16. The method of claim 15, further comprising:
unbending the bending region such that at least part of the second adhesive layer is in contact with the skin of the subject and the puncture device is positioned in the slot.
17. The method of claim 15, wherein the wall further comprises a wall cover sheet on a bottom side of the second adhesive layer.
18. The method of claim 17, further comprising:
removing the wall cover sheet; and
unbending the bending region such that at least part of the second adhesive layer is in contact with the skin of the subject and the puncture device is positioned in the slot.
19. A method for inserting a puncture device through a skin of a subject comprising:
applying a cover unit onto the skin of the subject at a puncture site;
imaging an anatomical structure and/or the puncture device under the skin of the subject at the puncture site or near the puncture site in a distal direction using an ultrasonic probe on a top side of the cover unit;
inserting the puncture device at the puncture site; and
imaging the anatomical structure and/or the puncture device under the skin of the subject beyond the distal end of the cover unit in the distal direction using the ultrasonic probe,
wherein the cover unit comprises an ultrasonically transparent window extending to the distal end of the cover unit.

20. A cover unit, comprising:
- a base, comprising:
 - a first adhesive layer on a bottom side of the base;
 - an ultrasonically transparent flexible sheet extending to a distal end of the cover unit; and
 - a frame, which, together with the ultrasonically transparent flexible sheet, defines an ultrasonically transparent window, the ultrasonically transparent window extending to the distal end of the cover unit, the frame being open-ended at the distal end of the cover unit; and
 - a wall being connected to the base via a bending region located at a proximal end of the base.
21. The cover unit of claim 20, further comprising an ultrasonically transparent gel-removal strip covering the ultrasonically transparent flexible sheet on the top side of the base.
22. The cover unit according to claim 20 or 21, further comprising a stabilizer located at or near the bending region, the stabilizer being capable of maintaining the angled orientation between the wall and the base.
23. The cover unit of claim 22, wherein the stabilizer is a bendable sheet comprising a first stabilizer part being fixed to the wall and a second stabilizer part being fixed to the base.

24. The cover unit of claim 22, wherein the cover unit comprises two stabilizers, each stabilizer located at or near each lateral end of the bendable region.

25. The cover unit of claim 22, further comprising an ultrasonically transparent gel-removal strip covering the ultrasonically transparent flexible sheet on the top side of the base, wherein the ultrasonically transparent gel-removal strip extends under at least part of the stabilizer.

26. The cover unit according to any one of claims 20-25, wherein the wall comprises a slot extending from a proximal end of the wall towards the base, wherein the slot is capable to position the puncture device after the inserting of the anatomical structure.

27. The cover unit of claim 26, wherein the wall further comprises a second adhesive layer on a bottom side of the wall.

28. The cover unit of claim 27, wherein the wall further comprises a wall cover sheet on a bottom side of the second adhesive layer.