

thereto and another glue or other fixing material also may be applied. This adhesion layer can be at the bottom side of the base element, i.e. between the base element and the skin. The adhesion layer can also be around the base element covering the edge of the base element and the skin. An example of a fixation means whereby the edges of the base element are fixed to the skin by providing a tape 154 over the edge and the surrounding skin is illustrated in FIG. 1. The base element 110 has a slit 112 for holding a tube on a second side 113 opposite to the first side 111. The base element 110 is made of waterproof material. At least part of the base element 110 is made of a deformable material 111, 113. In embodiments of the present invention also the form may be selected for providing a good adaptability to the body underneath. The thickness (H_b) may for example be at his thickest near the slit 112 and gets thinner towards the edges, as illustrated in FIG. 5. This results in so-called deformable wings. These wings adjust more easily to the body shape than thicker portions. The exemplary embodiments in the figures show a wing shaped base element 110. Embodiments of the present invention are however not limited thereto. In one example, the soft material is ethylene propylene diene monomer rubber (EPDM rubber). One example of a shape and dimensions of the base element that may be used are indicated in FIG. 4 and FIG. 5. In embodiments of the present invention the length L_b of the base element may for example be between 10mm and 150mm, for example between 50mm and 100mm, for example 74.4 mm. In embodiments of the present invention the width W_b of the base element may for example be between 20mm and 200mm, for example between 80mm and 120mm, for example 101 mm. In embodiments of the present invention the maximum height H_b of the base element may be between 4mm and 20mm, for example between 8mm and 12mm, for example 8.9 mm.

The medical device 100 also comprises a top element 120. The top element 120 typically may have a deformable first side 121. This deformable first side 121 can be deformed such that a waterproof sealing between the base element 110 and the top element 120 can be realized. In one example according to an embodiment of the present invention where the base element 110 is wing shaped, the deformable first side 121 of the top element 120 is deformable to provide a waterproof sealing with the wing shaped top element 110.

Moreover the top element 120 has a protrusion 122 for closing the slit 112, e.g. when a catheter tube or infusion line is present therein, when the top element 120 is mounted on the base element 110. The top element 120 typically is made of waterproof material. The dimensions and shape of an exemplary top element are indicated in FIG. 2 and FIG. 3. In embodiments of the present invention the length L_m of the top element may be between 15mm and 50mm, for example between 25mm and 30mm, for example be 28.6 mm. In embodiments of the present invention the width W_m of the top element may for example be between 10mm and 80mm, for example between 25mm and 35mm, for example be 31.6 mm. In embodiments of the present invention the height H_m of the top element, comprising the protrusion may for example be between 10mm and 40mm, for example between 15mm and 20mm, for example be 17.8 mm.

When mounted, the base element 110 is fixed against the body, the catheter exit site of the foil 150 is in between the base element 110 and the top element 120, and the catheter tube or infusion line is

in the slit of the base element. The protrusion 122 pushes against the tube thereby realizing a first sealing preventing water to enter alongside the tube. The inside diameter of the slit 112 is adapted towards the outside diameter of the tube such that the tube fits tightly in the slit 112 preventing water to enter the sealed volume where the catheter is injected. In embodiments of the present invention at least a first portion of the element forming the slit 112 is made of hard material 114. The hard material is shaped such that the catheter tube or infusion line fits tightly with the slit. Also at least a first portion of the protrusion 122 is made of hard material fitting tightly with the opposite side of the tube when mounted. When deforming and gluing the base element 110 to the body only the deformable first side 111 will deform. The parts of the slit 112 made of hard material will not deform and therefore their shape will remain matching with the shape of the tube. This provides a first sealing element for avoiding liquid to enter the sealed volume between the slit 112 and the catheter tube or infusion line. The hard material enables a good fit between the tube and the slit 112 and guarantees that the shape does not change when deforming the base element 110. Instead of being adapted for a cylindrical tube the slit might be adapted for holding various shaped tubes. The hard material of the slit guarantees a constant pressure of the slit 112 on the tube. The fact that a first portion of the slit and protrusion is made in more hard material allows to accurately position and fix the catheter tube or infusion line.

A second portion of at least one of the base element and the top element is made of a soft deformable material. The soft deformable material provides an additional sealing for the catheter. Furthermore it also guarantees a waterproof sealing between the body and the base element 110 and between the base element 110 and the top element 120. In some specific embodiments the part of the slit made of hard material 114 is embedded in the soft deformable material. This can be realized by overmolding. By embedding the hard material in the soft material the waterproof connection between the hard material and the soft material is ensured. For realizing the top element 120 overmolding is also a possibility as process for realizing a combined hard/soft structure.

Sealing may be provided via sealing rings in the slit and/or at the protrusion. Such rings may be appropriate in width and thickness for providing additional sealing. In some embodiments, one or more sealing rings may be present in both the base element, e.g. in the slit, and in the top element, e.g. at the protrusion so that additional sealing is created at all sides of the tube.

The foil 150 for sealing the catheter application area also may be considered part of the medical device, although embodiments are not limited thereto and may only relate to the sealing component providing a catheter feed through.

The foil 150 may have a high moisture vapor transmission rate such that vapor can leave the sealed volume. The latter prevents that the sealed volume gets humid because of sweating. In one example, the foil 150 is a polyurethane foil with a thickness of about 40 μm . The thickness of the foil may be selected so that the foil is sufficiently strong for avoiding tearing when the different components are handled. The area of the foil should be sufficient to cover the injection area, including the dressings already applied on the exit site. It thereby is an advantage that dressings already applied can be kept dry and therefore need not to be replaced after washing, bathing or showering. This saves time and materials. In one example

Claims

- 1.- A medical device (100) suitable for assisting in liquid proof shielding of a catheter application area on the body of a living creature, the device comprising
 - a base element (110) having a deformable first side (111) such that the base element is tightly placeable on a body area near the catheter application area, and a deformable second side (113) opposite the first side (111) such that the device can adapt to a body shape of the body
 - a top element (120) having a deformable first side (121) connectable with the second side (113) of the base element (110),
 one of the base element (110) or the top element (120) being an element comprising a slit (112) for holding a catheter tube or infusion line and the other element comprising a protrusion (122) for closing the slit and for forming a feedthrough for the catheter when the elements are connected, wherein a first portion of the element forming the slit (112) and the protrusion (122) is made of a first material and shaped for tightly fitting the catheter when it is in position and wherein the element forming the slit (112) and/or the protrusion (122) comprises a second portion formed in a second material, the second material being more soft and deformable than the first material, the second portion being adjacent the first portion and being arranged so as to form a further liquid sealing element for the catheter.
- 2.- A medical device according to claim 1, wherein the first portion of the element is embedded in the second portion of the element.
- 3.- A medical device according to any of the previous claims, the device furthermore comprising a foil (150) for covering the catheter application area, the foil comprising a catheter exit site placeable between the base element (110) and the top element (120).
- 4.- A medical device according to any of the previous claims, wherein the second portion made of the second material is deformable around the catheter tube or infusion line.
- 5.- A medical device (100) according to any of the previous claims, wherein one of the base element or the top element (110, 120) comprises also a second protrusion (123), the first protrusion (122) and the second protrusion (123) being made of the first material and being removable connectable on the other element.
- 6.- A medical device (100) according to any of the previous claims, wherein the top element (120) comprises a holding portion (124) for holding the top element (120) during manipulation.
- 7.- A medical device (100) according to claim 6, wherein the top element (120) comprises a first holding portion (124) and a second holding portion (125) for holding the top element (120) and wherein the first holding portion and the second holding portion are configured for, when pushing the holding portions simultaneously with respect to each other, opening the removable connection.
- 8.- A medical device (100) according to any of the previous claims, wherein the device furthermore comprises an adhesive material at one or more of the first side (111) of the base element (110), the second side (113) of the base element (110), the first side of the top element (120) such that the adhesive material assists in providing a liquid proof sealing.