

Description:

Device for immobilization

The invention relates to a device for immobilization according to the pre-characterizing features of claim 1. Here, in medical sense, "immobilization" means especially fixing, immobilizing, compression and/or positioning of the human body or human body parts (legs, arms), in particular also fixation of medical target devices, markers and/or surgical instruments for image-guided, minimally invasive surgical procedures, for which patients should be fixed.

In many areas of human medicine or medical research a secure fixation/immobilization or positioning of the patient or body part of the patient or (mechanical) installation of equipment or appliances is necessary. This is very important in the field of diagnostic and therapeutic radiology, radiotherapy or operative/surgical procedures (e.g. neurosurgery), but also in pre- or post-operative care.

Implementing of computer technology in diagnosis and therapy demands on accuracy and repeatability are increased both in fixing a stereotactic frame system at humans and in the fixation of the body itself. Comfort, speed of application, mobility and costs play a significant role, wherein an invasive fixation (by screws etc.) should be avoided in any possible case.

So-called non-invasive fixation equipment is known as prior art:

a) Immobilization of the body with straps or sleeves:

The patient's body lies on a foam pad and belts across the body fix the patient on this surface. Here, the disadvantage is that strong strain of the belts may cause pressure areas, offsets and skin swelling (inhomogeneous pressure distribution, in particular at the edges of taut bands or belts).

b) Fixation by formwork:

Here, the patient is placed on a kind of "air mattress", which is filled with foam beads. By evacuating the air in the mattress, it is solidified by juxtaposing the foam beads. The vacuum mattress is adjusted in a first step and then further evacuated in a second step. The disadvantage is that the "mattress" commonly guarantees though restraint, but not an exact fixation. If the patient is uncooperative, sufficient immobilization is practically impossible. In addition, wrinkling or excessive pressing may often lead to pressure points and tissue injury, especially with anaesthetized patients.

c) Vacuum fixation system:

In vacuum fixation systems, vacuum is applied to the body. By sucking the air at the patient's skin a good fixation may be created. Here, the disadvantage is that the vacuum pump has to run permanently. In addition, the vacuum system is relatively complex, so bad in handling and transport. In procedures requiring low sterility or even high sterility the air flow of the vacuum pump may cause a risk (germs). Further, high fixing forces are hardly possible because of long-lasting pressure injuries (e. g. hypoperfusion, bruising etc.) to occur. In case of failure of the vacuum, the fixation is abruptly lost, so that a risk to the patient may occur or the (surgical/radiological) intervention must be stopped or repeated.

Other techniques such as rails, plastic molding, plaster, etc. have similar drawbacks. In addition, these methods are still associated with considerable financial and time expenditure and are therefore used only for long-term applications.

Thus, the invention is based on the object to provide a device for fixing, which avoids the mentioned disadvantages, has a simple structure and is gentle to the patient on application. Moreover, the device should enable exact placement of calibration points (so-called markers) and/or target devices and/or other medical equipment (as instrument holders, MR coil (-s), etc.) and facilitate optimum access to operation areas.

This object is solved by an apparatus having the features of claim 1. Advantageous embodiments are subject of the dependent claims.

An important feature is a consolidated non-woven fabric, enabling a stable fixing on the human body as the non-woven fleece engage with the micro hook-and-loop fastener ("micro Velcro"). The non-woven fabric is strengthened or consolidated by controlled stretching or pre-stretching winding on a roll, thus having a defined tensile strength to serve as counter element for such a micro Velcro. Usually application of a hook-and-loop fastener has symmetrical "double" hook elements and counter elements, but here the non-woven fabric forms the counter-acting loops for the hooks. The edge regions of the fabric strip are rather compliant, in contrast to stiff belts so that damage to the skin of the patient may be excluded. The more or less (cross-) elasticity of non-woven fleece perfectly adapts to the contour of the patient to allow optimal pressure distribution such that pressure peaks are avoided. Thus, the patient's body can be fixed in relation to a base plate of an examination or operating table and harmless compression of the body is achieved by applying slight pressure. As a side effect, this compression can also be used before, during and/or after the treatment, f. i. by inserting a wound compress between fleece and a wound/surgery region, thereby forming a

wound compression. Thus, unlike belts or bands with Velcros, no longer two cooperating Velcro elements are needed; rather, the consolidated non-woven fleece acts as one connecting element, in which the hooks of the one-sided micro Velcro engage (in releasable manner). Thus, cost of such a device for fixation of the human body or parts of the body is very low, since practically only the commercially available inexpensive non-woven fleece forms a fastener-half being a disposable product for each patient. In this manner of a bandage the device is easy to use and the hygienic requirements are complied with. If necessary (e. g. for direct contact with the wound/the operational area), the fleece may be used in a sterile way.

The micro Velcro is preferably designed as a flexible foil with mushrooms and/or hooks as fasteners for the non-woven fleece. In this case, this foil is affixed as a strip with its back side (opposite to the hook side) on the side surface of a surgical table to serve as a stable anchorage. Such a micro Velcro fastener is preferably made of polypropylene (PP) or polyamide (PA) prepared to be cleaned in a simple manner. The hook-side of the micro Velcro film has relatively small (sub-millimeter) hooks, so that cleaning solutions are sucked-into the hook-side by capillary effect to cause a complete disinfecting of the micro Velcro. Classic Velcro or hook tapes do not have this property; they are not easy to disinfect and have, up to now, a very limited use in hospitals - especially in the operating room or sterile areas with high hygienic requirements. The counter element of the inventive fixing member, namely the non-woven fleece is usually configured as (sterile) disposable so that it can be easily disposed after skin contact similar to a gauze bandage.

The non-woven fabric or fleece is mostly formed as strip and can be used to create an access port as surgical site to a body part (e. g. puncture opening) by perforations or regular cuts (e. g. of 1 cm diameter on each 10 cm length in the longitudinal direction). This allows to place the non-woven fabric to the intended surgical site and then to fasten it on both ends. Alternatively, the non-woven fleece may have an oblong recess whose length is longer than the body spanning part of the non-woven fabric and the width of which is enough to perform an operation at a desired, exaggerated body part. The available mounting surface of the non-woven fabric is not reduced by the recess, such that the holding characteristics of the micro Velcro are not reduced. Here, the non-woven fleece is preferably unwound from a roll or coil and preferably cut to length, individually (e. g. by usual scissors etc.). However, the non-woven fabric may have pre-formed perforations, f. i. provided each meter in length or greater distance (slightly longer than the width between the micro Velcros) as desired separation points. The fleece strips may also overlap or be placed in several layers; thus, mechanical strain can be "individually" adjusted by each non-woven strip, whereby different parts of the

body can be compressed to different extents and fixed. The advantage of multiple, overlapping and/or superposed fleece strips is also a safety aspect, as it is possible to ensure that the immobilization of the patient is not lost by dissolving one or more bands. In addition to the strip-like form it's also possible to design cloth or vest-like versions of the non-woven fabric, having the advantage of even faster and simpler handling.

The consolidated non-woven fabric has high strength in tensioning direction (longitudinal direction of the strip) and lower strength or elasticity in the transverse direction (strip width) to conform perfectly to the patient's body. The fleece consolidation or strengthening can be carried out by various methods, as explained in WIKIPEDIA under "non-wovens", in particular by so-called needle fleeces. It is important that the non-woven fabric remains breathable and thus gentle on the patient. In addition, so-called markers and/or reinforcements may be integrated in the non-woven fabric.

As mentioned, the micro hook fastener may be attached to the edge regions of an examination or operating table, in particular in movable form in profiles along the edges or bonded at the table. In this case standard profiles can be used, such as used for operating tables, examination tables, CT or MRI tables, etc.. In addition, the micro Velcro can be provided in the form of patches with adhesive strips or attached to fixation accessories (head shell, vacuum pads etc.) or glued thereto. Such fixing members can also include an additional device, in particular a marker or target device, preferably attached by at least one adapter plate which may have Velcro elements or an adhesive layer, as well. Thus, even the outer or top side of the non-woven fabric can be used for anchoring, too.

After fixing and sterile covering a surgical intervention (possibly with robot support) can be performed in an operating window, wherein the above-cited markers for imaging or surgical navigation are reproducibly mounted. As the non-woven fabric provide to a large-scale, ergonomic fixing, high holding forces are generated with maximum comfort. The adhesive forces can be further increased if a skin-friendly adhesive spray or a thin, double-sided tape applied to the non-woven fabric in the contact region towards the patient. Further, soft human tissue can be fixed, f. i. to keep it away from radiation beams.

Embodiments are described with reference to the drawing. The figures show in:

- Fig. 1 the attachment of a device for immobilization,
- Fig. 2 an enlarged detailed view of the device, and
- Fig. 3 setting-up/fitting of additional devices.

The device for immobilization or fixation of the human body or of body parts consists of at least one fixing element 1 on the body (shown in hatched lines, here for example, a cross section of a human back resting on a cushion pad 4b) (FIG. 1). This positioning is done with a consolidated non-woven 2, which is applied to the skin and tensioned to the left and right of the pad 4b to be fixed to a respective micro Velcro 3 (by engaging to the hooks in the micrometer range, according to the above designation "micro"). The non-woven fabric 2 has preferably a strip-like design and is especially wound on a coil or roll. 6 The non-woven fleece 2 has high tensile strength in its mounting direction L (usually transverse to the longitudinal axis of the body), but is relatively elastic in the transverse direction Q thereof. An adapter plate 5a may be attached to the outside of the fixing element 1 in order to anchor a marker 5 (or other accessories) in a stable and reproducible manner (see Fig. 3). The fixing element is preferably attached to a base plate of an examination or operating table 4 via at least one profile 4a, f. i. a rounded groove guide. Some of these fixing elements 1 can be located at the human back, with distance from one another, such that several corresponding operation areas are formed.

Fig. 2 is a greatly enlarged view of the connection between the non-woven fabric 2 and the micro Velcro 3, wherein plural T-formed hooks 3a in the micrometer range, (small mushroom or hook shape of these fasteners 3a is applicable, as well) engage with with the fibers of the non-woven fabric 2 like claws. As shown in Fig. 1, right side, a second micro Velcro 3 can be bonded to the right side of the operating table 4 (lateral to the patient) in the manner of an adhering tape to be adhered. Likewise, such a "patch" can be glued to the side of the patient support 4b, depending on the position of the fixated body part, e.g. in the shoulder area and/or the hips and/or in the leg area, etc.. The fibers of the non-woven fabric 2 are mainly directed in the longitudinal direction L, thus ensuring high tensile strength. The right side of Fig. 2 indicates an adhesive layer 7 beside the micro Velcro 3 (i. e. towards the patient) to be preferably applied as by spraying shortly before fixing. This can increase the sticking or immobilization forces or keep way soft tissue from of the surgical area (cf. access port or opening 2a in Fig. 3).

As shown in FIG. 3 in cross section, such an opening 2a is provided for a puncture in the lumbar region (and in the strip-like non-woven fabric 2). Thus, the treating physician or medical person can fix any region of the body (whole human body or just body parts) as required. This results in universal adapting to operating tables and a simple fixing of surgical equipment and markers. It's also possible to add pads below the non-woven fabric 2 (increasing comfort), wherein the non-woven fabric 2 enables the skin to "breathe", in contrast to conventional bands or collars, such that even prolonged use will not cause

irritating. To sum up, body parts are immobilized with a defined pressure and at very low cost, wherein the proposed device can also be used with a device based on adhesive forces (cf. Applicant's DE 20 2011 005 573). This principle of micro hook-and-loop fasteners 3, wherein the loops are formed by the non-woven fleece 2 can also apply for fixing the above-mentioned adapter plate 5a, as indicated in Fig. 3. The underside of the adapter plate 5a can also be provided with micro Velcro (i.e. the half of micro hooks) to be anchored on the outside ("loops") of the strained non-woven fabric 2. The non-woven fleece 2 may also cross above the adapter plate 5a for additional fixation. This also applies to other medical accessories, such as MR coils or pressure sensors for detecting (respiratory) patient motion, which are securely fixed by the non-woven fabric 2 close to the body (like a second skin).

Claims:

1. A device for immobilization of the human body or of body parts, in particular for attachment of medical target devices, markers or surgical Instruments for image-guided, minimally invasive surgery, with at least one fixing element (1) to be positioned on the body surface, characterized in that the fixing element (1) comprises a consolidated non-woven fabric (2) which is fastened to a micro Velcro (3).
2. Device according to claim 1, characterized in that the micro Velcro (3) has a flexible film with connecting elements (3a) in the form of mushrooms or hooks for engagement with the non-woven fabric (2).
3. Device according to claim 1 or 2, characterized in that the micro Velcro (3) is made of polypropylene (PP) or polyamide (PA).
4. Device according to one of claims 1 to 3, characterized in that the non-woven fabric (2) is a strip or cloth, in particular with at least one access opening (2a) to a body part.
5. Device according to one of claims 1 to 4, characterized in that the non-woven fabric (2) can be unwound from a roll (6), preferably to be cut to length at perforations.
6. Device according to one of claims 1 to 5, characterized in that the non-woven fabric (2) has high tensile strength in the longitudinal direction (L) and is formed resilient in the transverse direction (Q).
7. Device according to one of claims 1 to 6, characterized in that the non-woven fabric (2) is formed as a sterile disposable article.
8. Device according to one of claims 1 to 7, characterized in that markers and/or reinforcements are integrated in the non-woven fabric (2)
9. Device according to one of claims 1 to 8, characterized in that the micro Velcro (3) is fastened at edge regions of an examination or operating table (4), in particular in profiles (4a) along the edges in moveable manner, or is adhered to the table (4) and/or a patient support (4b).

10. Device according to one of claims 1 to 9, characterized in that at least one additional device, in particular a target device (5) or elements for imaging can be fixed to the fixing element (1), preferably by means of at least one adapter plate (5a), which also carries hook-like connecting elements (3a).

11. Device according to one of claims 1 to 10, characterized in that an adhesive layer (7) is applied to the non-woven fleece (2), in particular in the form of a skin-compatible spray adhesive or thin double-sided adhesive tape.