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(54) Benævnelse: **Fisteladapteranordning**

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Description

The present invention relates to a fistula adapter device for the management of enteroatmospheric fistulas on the open abdomen.

Prior art

The Utility Model DE 20 2011 101 620 U1 discloses a fistula drainage for the management of enteroatmospheric fistulas using vacuum therapy for wound treatment. A device for the management of fistulas is also known from the document US 2008/0287892 A1.

Summary of the invention

The object of the present invention is to make available a fistula adapter device of a modular structure, which is universally adaptable to individual fistula shapes, which does not require a vacuum and which thus avoids the danger of additional wound injuries and also the danger of secondary fistula formations, such that the patient does not experience any additional pain.

Moreover, the fistula adapter device is also intended to be particularly flexible and as easy as possible to handle during use by the medical personnel treating the fistulas.

These objects are achieved by a fistula adapter device according to Claim 1.

Accordingly, the fistula adapter device for the management of enteroatmospheric fistulas without vacuum assistance comprises a tube which serves to remove the fistula liquid and which is of variable height and/or variable cross-sectional area, a rim which is arranged at one end of the tube and serves as a wound contact surface of variable cross-sectional area or contact area, and/or a gel layer as fistula support surface or adjoining fistula contact surface, and an endpiece which is arranged at

the other end of the tube and serves for sealing and/or coupling to other medical instruments or devices, for example a stoma bag or a liquid collection vessel.

The gel layer is understood to be a three-dimensional viscous, elastic or semi-solid mass which is malleable and which, when pushed onto the fistula or upon contact with the fistula with low mechanical stress, bears tightly on or adjoins the latter and thus adapts individually to the fistula geometry without further injuring the wound and/or without new fistulas being formed. The gel layer can be of organic or inorganic material.

Furthermore, the gel layer inherently has an adhesive effect, or the gel layer is adhesive, such that the otherwise customary application of an additional vacuum, for example in the context of vacuum therapy, in particular for precise placement and tight application, is not necessary. This is advantageous for the patient, since application of a vacuum is at least in many cases perceived as uncomfortable or even as painful.

Moreover, the gel layer is preferably formed from a medically approved organic or inorganic gel, in particular from a biocompatible gel.

Alternatively or in addition to the gel layer, the rim, as wound contact surface or as adapter to the wound, has an adjustable variable cross-sectional area, in order to be able to be placed individually, flexibly and over a large area on the wound.

The rim arranged on the tube surrounds one end of the tube as a laterally protruding planar structure, comparable to the brim of a hat, and has a flexible symmetrical or asymmetrical shape.

By virtue of the adjustable variable height and/or adjustable variable cross-sectional area of the tube for removing the fistula liquid and/or the adjustable variable cross-sectional area or contact surface of the rim, the fistula adapter device can be used particularly flexibly by the medical personnel.

In one embodiment according to the invention, the tube for removing the fistula liquid is a telescopic tube. The telescopic tube consists of a plurality of cylindrically tapering, parallel-guided tubes or hollow cylinders which can be pulled out linearly up to the stop at a maximum extension length and can be pushed back into one another again.

In an alternative embodiment according to the invention, the tube for removing the fistula liquid is a bellows. A bellows is understood here to be an elastic tube that folds up like an accordion. To prevent the backflow of the fistula liquid, the fistula adapter device preferably has, arranged in the tube and/or in the endpiece, at least one nonreturn valve, if appropriate with a pump action.

According to the invention, the tube and the rim are produced from a flexible material, preferably from a standard elastomer or from a thermoplastic elastomer.

Examples of standard elastomers here are natural rubber or silicone rubber or silicone elastomers such as methyl vinyl silicone rubber (VQM), fluorosilicone rubber (FMQ), but also styrene butadiene rubber (SBR), isoprene rubber (IR), ethylene propylene diene rubber (EPDM), polynorbornene (PNR), acrylonitrile butadiene rubber (NBR), butyl rubber (IIR), chlorobutadiene rubber, acrylate rubber (ACM), fluorine rubber (FPM), ethylene acrylate rubber (AEM) or butadiene rubber (BR).

The thermoplastic elastomers include block copolymers and also elastomer alloys or polyblends. These include, for example, non-cross-linked or cross-linked thermoplastic elastomers based on olefins (TPE-O, TPE-V), thermoplastic elastomers based on urethanes (TPE-U), thermoplastic polyester elastomers or thermoplastic copolyesters (TPE-E), styrene block copolymers (TPE-S), thermoplastic copolyamides (TPE-A), blends based on acrylate, blends based on fluorine rubber and other thermoplastic vulcanizates.

At least the wound-side surfaces of the rim and/or the (fistula-liquid-side) inner surfaces of the tube are advantageously of a medically approved material and in particular are biocompatible.

On account of the material and/or the shape, the rim has a particularly good adhesive effect, i.e. is particularly adhesive, which is especially advantageous for precise placement without slipping, and at the same time the wound is subject to low mechanical stress.

The endpiece, in particular as a further adapter of the fistula adapter device, is advantageously produced from a thermoplastic. The thermoplastics include, for example, acrylonitrile butadiene styrene (ABS), polyamides (PA), polylactate (PLA), polymethyl methacrylate (PMMA), polycarbonate (PC), polyethylene terephthalate (PET), polyethylene (PE), polypropylene (PP), polystyrene (PS), polyetheretherketone (PEEK).

In this case, at least the (fistula-liquid-side) inner surfaces of the endpiece, in particular for other medical instruments or devices, for example a stoma bag or a liquid collection vessel, are advantageously of a medically approved material and in particular are biocompatible.

The biocompatibility of the medical materials and products is certified in accordance with ISO 10993 1-20.

The tube and the rim can be produced from the same material, in particular from the same (thermoplastic) elastomer, in order to simplify the production process and the later disposal of the fistula adapter device.

According to the invention, the rim is designed to be more flexible than the tube, in particular in order to reduce the mechanical stress on the wound. The particularly flexible design is preferably achieved either via the correspondingly more flexible material or via the corresponding geometry, for example

a smaller thickness. In this case, the tube is preferably produced from a comparatively stiff(er) material in order to ensure particularly stable removal of the fistula liquid.

For particularly good or optimal wound control, at least the rim and the optional gel layer of the fistula adapter device are designed to be transparent, in particular through a corresponding choice of the materials.

In a preferred embodiment of the fistula adapter device, wound additives are added to the rim and the optional gel layer. Wound additives are understood here to mean additions of medicaments and/or agents that promote wound healing.

In order to lengthen the intervals between replacement of the fistula adapter device, antimicrobial additives are preferably added to the rim, the optional gel layer, the tube and/or the endpiece.

An antimicrobial additive is understood here to mean a substance which reduces the ability of microorganisms to reproduce, or reduces their infectivity, or kills them off or inactivates them. The antimicrobial additives include antibiotics against bacteria, and the antimycotics against fungi and pathogenic yeasts. Furthermore, all antiparasitics are counted among the antimicrobial substances, and these in turn include the anthelmintics against parasitic worms and the antiprotozoals against pathogenic amoebas. In addition to these substance groups, which serve for direct specific therapy, the antimicrobial additives also include all disinfectants. In addition to the pathogens mentioned above, these can also inactivate viruses.

For storage or transport of the fistula adapter device, at least the gel layer of the fistula adapter device is preferably covered with a peelable film and is thereby in particular fixed to the rim. At the same time, a corresponding film can provide overall protection against environmental influences such as dirt,

moisture, light and/or heat. Directly before the fistula adapter device is used to manage the fistulas, this film can be easily removed by the medical personnel by simply being peeled off.

To increase the stability while at the same time maintaining the flexibility of the gel layer preferably used, in particular after the aforementioned fixing film and/or protective film has been peeled off, the gel layer preferably comprises as gel a polymer which is (further) cross-linked or strengthened by the action of moisture, light, in particular UV light, and/or heat.

To simplify the handling of the fistula adapter device for the medical personnel, the outer visible side of the tube and/or the outer visible side of the rim is provided with height markings, cross-sectional area markings or contact surface markings, for example by concentric circles with millimetre information, for example as an optical cutting aid or setting aid with respect to the height or the cross section.

Brief description of the drawings

Figures 1a and 1b each show a schematic fistula adapter device with a different height of the tube (not true to scale).

Implementation of the invention

The subject matter of the invention is explained in more detail below using an example, without restricting the invention.

Figures 1a and 1b each show a fistula adapter device 1 for the management of enteroatmospheric fistulas (not shown) without vacuum assistance, a flexible tube 2 for removing the fistula liquid and with a variable height H2 and a variable cross-sectional area Q2, a rim 4 arranged at one end 2a of the tube as a wound contact surface with a variable cross-sectional area or variable contact area QA4, and a gel layer 6 as a fistula support or adjoining fistula contact surface, and an endpiece 8 arranged at the other tube end 2b for sealing and/or coupling

to other medical devices not shown in Figures 1a and 1b, for example a stoma bag or a liquid collection vessel.

The gel layer 6 is preferably formed from a biocompatible gel.

In Figures 1a and 1b, the rim 4, as a wound contact surface or as an adapter for the wound (not shown), has a variable cross-sectional area or contact area QA4, in order to be able to be placed on the wound individually, flexibly and over a large area.

The rim 4 arranged on the tube 2 surrounds the tube end 2a as a laterally protruding planar structure, comparable to the brim of a hat, and has a flexible symmetrical or asymmetrical shape.

On account of the variable height H2 and the variable cross-sectional area Q2 of the tube 2 for removing the fistula liquid and the variable cross-sectional area or contact area QA4 of the rim 4, the fistula adapter device 1 can be used particularly flexibly and individually by the medical personnel.

According to the invention, the tube 2 for removing the fistula liquid is a telescopic tube (not shown in Figures 1a and 1b) or alternatively a bellows. Figures 1a and 1b show the same design with only a differently set variable height H2 of the tube 2, namely with Figure 1a showing a variant of the tube 2 that is set longer in terms of height, and Figure 1b showing a variant of the tube 2 that is set shorter in terms of height.

In order to prevent the backflow of the fistula liquid, the fistula adapter device 1 preferably has, arranged in the tube 2, nonreturn valves 10, possibly with a pump action, as is shown in Figure 1a.

The tube 2 and/or the rim 4 are advantageously produced from a standard elastomer or a thermoplastic elastomer. At least the wound-side surfaces 4a of the rim 4 and the fistula-liquid-side

inner surfaces 2c of the tube 2 are advantageously biocompatible.

On account of the material and/or the shape, the rim 4, like the gel layer, has a particularly good adhesive effect, i.e. is particularly adhesive, which is particularly advantageous for precise placement without slipping and at the same time places little mechanical stress on the wound. The endpiece 8, in particular as a further adapter of the fistula adapter device 1, is advantageously produced from a thermoplastic.

In this case, at least the inner surfaces 8a of the endpiece 8 on the fistula liquid side are advantageously biocompatible, in particular for other medical devices (not shown), for example a stoma bag or a liquid collection vessel.

The tube 2 and the rim 4 can be produced from the same material, in particular from the same (thermoplastic) elastomer, in order to simplify the production process and the later disposal of the fistula adapter device 1.

According to the invention, the rim 4 is designed to be more flexible than the tube 2, in particular in order to reduce the mechanical stress on the wound. The particularly flexible design is preferably achieved either via the correspondingly more flexible material or via the corresponding geometry, for example a smaller thickness. In this case, the tube 2 is preferably produced from a comparatively stiff(er) material in order to ensure particularly stable removal of the fistula liquid.

For particularly good or optimal wound control, the rim 4 and the gel layer 6 of the fistula adapter device 1 are designed to be transparent, in particular through a corresponding choice of the materials.

In a preferred embodiment of the fistula adapter device 1, at least the rim 4 is provided with at least one wound additive 12.

Wound additives are understood here as additions of medicaments and/or agents that promote wound healing.

In order to lengthen the intervals between replacement of the fistula adapter device 1, antimicrobial additives (not shown) are preferably added to the rim 4, the gel layer 6, the tube 2 and/or the endpiece 8.

For storage or transport of the fistula adapter device 1, at least the gel layer 6 of the fistula adapter device 1 is preferably covered with a peelable film (not shown) and is thereby in particular fixed to the rim 4. At the same time, a corresponding film can provide overall protection against environmental influences such as dirt, moisture, light and/or heat. Directly before the fistula adapter device 1 is used to manage the fistulas, this film can be easily removed by the medical personnel by simply being peeled off.

To increase the stability while at the same time maintaining the flexibility of the gel layer 6, in particular after the aforementioned fixing film and/or protective film (not shown in Figures 1a and 1b) has been peeled off, the gel layer 6 preferably comprises as gel a polymer which is (further) cross-linked or strengthened by the action of moisture, light, in particular UV light, and/or heat.

To simplify the handling of the fistula adapter device 1 for the medical personnel, the outer visible side 2d of the tube 2 and/or the outer visible side 4b of the rim 4 are provided with height markings, cross-sectional area markings or contact surface markings (not shown in Figures 1a and 1b), for example by concentric circles with millimetre information, for example as an optical cutting aid or setting aid with respect to the height or the cross section.

List of reference signs

1	fistula adapter device
2	tube
2a	tube end at the rim (4)
2b	tube end at the endpiece (8)
2c	inner surfaces of the tube (2)
2d	outer visible side of the tube (2)
4	rim
4a	wound-side surfaces of the rim (4)
4b	outer visible side of the rim (4)
6	gel layer
8	endpiece
8a	inner surfaces of the endpiece (8)
10	nonreturn valve
12	wound additive
H2	variable height of the tube (2)
Q2	variable cross section of the tube (2)
QA4	variable cross-sectional area or contact area of the rim (4)

Patentkrav

1. Fisteladabteranordning (1) til behandling af enteroatmosfæriske fistler uden vakuum omfattende en slange (2) til bortledning af fistelvæsken med variabel højde (H2) og/eller variabel tværsnitflade (Q2), en på en slangeende (2a) placeret flange (4) som sårkompresflade med variabel tværsnits- eller kompresflade (QA4) og/eller med et gellag (6) som fistelkompres- eller tilgrænsende fistelkontaktflade og et på den anden slangeende (2b) placeret afslutningsstykke (8) til tætning og/eller tilkobling af andre medicinske anordninger, idet slangen (2) og flangen (4) er fremstillet af et fleksibelt materiale, fortrinsvis af standard-elastomerer eller af termoplastiske elastomerer, idet flangen (4) er mere fleksibel end slangen (2), kendetegnet ved, at slangen (2) er udformet som teleskoprør eller som foldebælg.

2. Fisteladabteranordning (1) ifølge krav 1, hvor der i slangen (2) og/eller i afslutningsstykket (8) er placeret i det mindste en tilbagestrømsventil (10).

3. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor gellaget (6) er dannet af en medicinsk godkendt gel, navnlig er biokompatibelt.

4. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor i det mindste de overflader (4a) på flangen (4), der vender mod såret, og/eller de indvendige flader (2c) på slangen (2) er af et medicinsk godkendt materiale, navnlig er biokompatible.

5. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor afslutningsstykket (8) er fremstillet af termoplast, idet i det mindste de indvendige flader (8a) på afslutningsstykket (8) er af et medicinsk godkendt materiale, navnlig er biokompatible.

6. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor slangen (2) og flangen (4) er fremstillet af samme materiale, navnlig af den samme (termoplastiske) elastomer.

7. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor flangen (4) og det valgfrie gellag (6) er transparente.

8. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor flangen (4) og det valgfrie gellag (6) er blandet med såradditiver (12).

9. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor flangen (4), gellaget (6), slangen (2) og/eller afslutningsstykket (8) er blandet med antimikrobielle additiver.

10. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor gellaget (6) til lagring eller transport er overtrukket med en aftrækkelig folie.

11. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor gellaget (6) som gel omfatter en polymer, som ved påvirkning med fugt, lys, navnlig UV-lys og/eller varme blandes (yderligere) eller bliver fastere.

12. Fisteladabteranordning (1) ifølge et af de foregående krav, hvor slangen (2) på den udvendige synlige side (2d) og/eller flangen (4) på den udvendige synlige side (4b) er forsynet med højde-, tværsnitsflade- eller kompressionsflademarkeringer.

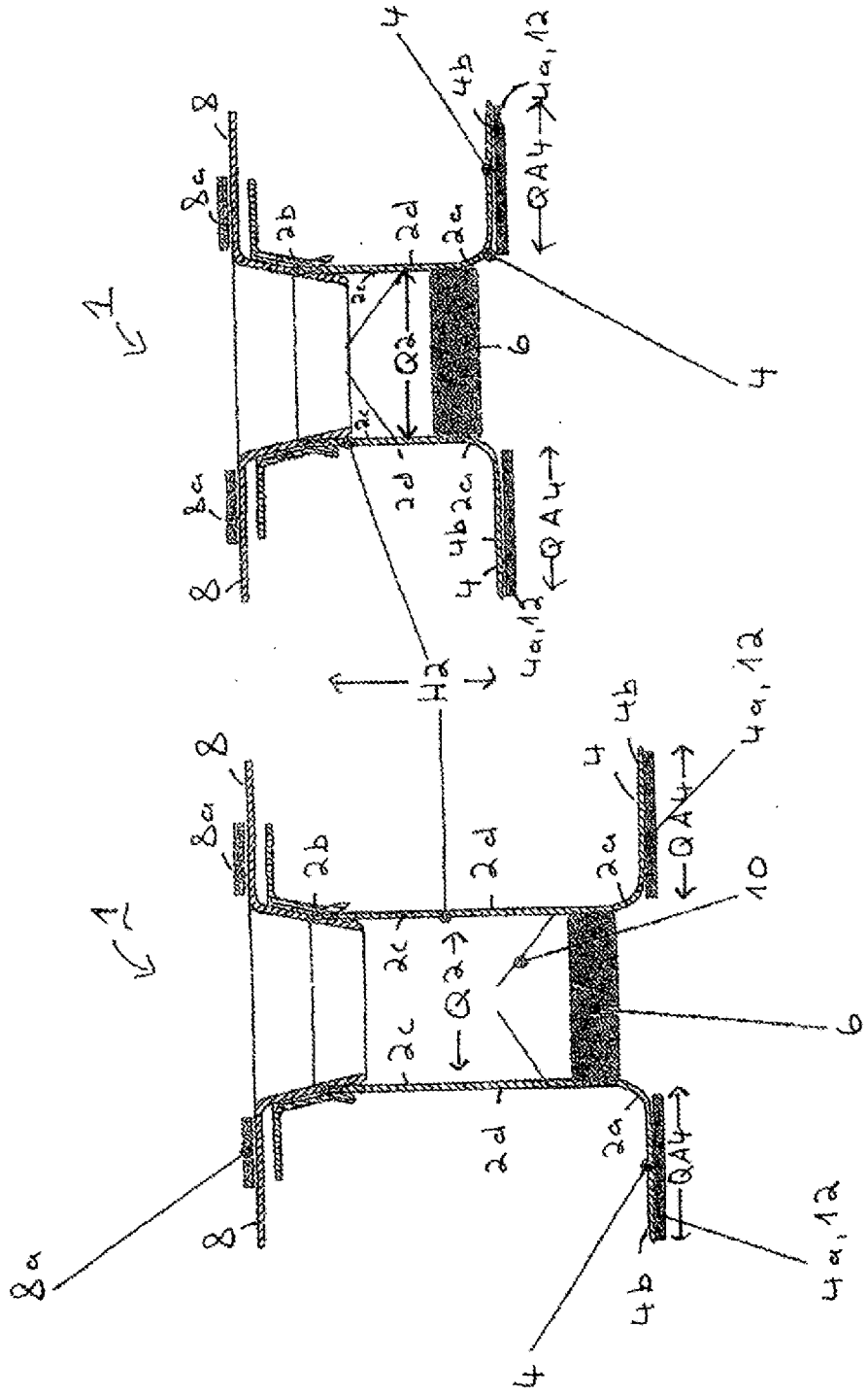

Fig. 1a

Fig. 1b