DESCRIPTION

The invention relates generically to a device to close a wound, more specifically a substantially rectilinear surgical incision, - having two textile stringer tapes, rows of interlocking fastener members disposed thereon, and a sliding clasp completing the sliding clasp fastener, the said sliding clasp fastener having means for adhesive bonding to the skin of a patient or animal along the edges of the wound. In the context of the invention, closure signifies that the device is intended for use to draw the initially gaping edges of a surgical incision together and abutting them to close the wound, and not for use when the wound has been closed by other means. The need for more usual means such as stitching or clamping is specifically excluded.

In the known devices for this purpose (US 35 16 409, DE 34 44 782), the sliding clasp fastener is of a type not usually employed in the textiles field, having specially adapted stringer tapes with an adhesive facing. They have not been adopted in the medical field, because their special manufacture is too costly, the edges of the wound knit with the stringer tapes and/or the interlocking fastener members, and furthermore there is no assurance that wound secretions will be able to escape. The adhesive bond with the skin often fails prematurely. If a special cover strip is attached to the stringer tapes to protect the wound, it cannot be prevented from penetrating into the wound or being pushed together. If it folds up in this way, the edges of the wound

will become misaligned locally, and will knit to form unsightly scars.

Bonding to the skin can be improved by using sliding clasp fasteners specially adapted for wound closure, in which each stringer tape features a row of needle-like pins, which are urged into the skin of the patient or animal along the edges of the wound before closing the sliding clasp fastener; this is complicated, and produces additional wounds and scars. Wound closure within the known prior art requires bringing the edges of the wound together by hand before closing the sliding clasp fastener. For all these reasons, the known devices have hitherto been used exclusively for abdominal wounds (cf. "Neue Zuricher Zeitung", 22nd August 1984 issues; "Hamburger Abendblatt", Whitsun 1984), and only then for the temporary closure of a wound requiring frequent re-opening, for example in cases of peritonitis related to failure of the pancreas. This is further confirmed by the article in "Arch. Surg., Volume 121, pp. 147-152 (February 1986, entitled "Scheduled Reoperations (Etappenlavage) for Diffuse Peritonitis", which refers to the use of ordinary sliding clasp fasteners. The known devices for wound closure and maintaining wound closure during the healing process, as a substitute for or improvement over conventional stitching or clamping, are quite unsuitable.

The object of the invention is to further modify a device of the generic type so that it can be adopted for wound closure and subsequent healing as an improvement over conventional wound closure by stitching or clamping, yet has a simple and easily used construction based on simple initial

components, and is furthermore well adapted to sterilisation. The entire device will obviously require sterilisation by the manufacturer or user, prior to use, and must be stored under correspondingly sterile conditions.

The object is achieved by providing the following combination of features:

1) the sliding clasp fastener has rows of interlocking fastener members and stringer tapes as in the ordinary flexible sliding clasp fasteners used for textile garments, with low-stretch stringer tapes and rows of polyester/polyamide interlocking fastener members resisting compression when interlocked;

2) spacer strips forming a clearance space over the wound are provided on the underside, facing the wound clear of the rows of interlocking fastener members;

3) the means for adhesive bonding consist of adhesive strips with a hypoallergenic adhesive film on the skin-facing side, attached to the stringer tapes and extending laterally beyond the stringer tapes,

the stringer tapes being underlain by the adhesive strips over at least a part of their breadth, and the breadth of the adhesive strips including the overlaps being adapted to withstand the transverse tensile forces set up when the wound is closed by the sliding clasp fastener and the wound edges are compressed together. - Ordinary flexible sliding clasp

fasteners as used for textile garments, with low-stretch stringer tapes and incompressible rows of interlocking fastener members, have been adopted for a very wide range of applications. However, it has always been maintained hitherto, by those versed in the art, that such sliding clasp fasteners are unsuited for use as wound closures and protection during healing (cf. "Surgical use of zippers worries manufacturer", in "China Post", 08 November 1986).

The device of the invention should obviously be so applied that the wound runs substantially exactly under the centreline of the sliding clasp fastener. As a result of the specified combination of features, very uniformly distributed forces are applied to the wound edges by the adhesive strips, after they have been as it were butted together by closing the sliding clasp fastener; the wound edges are held together without zones of overloading, and the interlocked rows of fastener members have as it were a protective action, since they are of incompressible construction, at the same time, the wound edges lie adequately freely in the clearance space, allowing secretions to drain away, admitting air to the wound and both supporting and promoting healing. Furthermore, the provision of the clearance space adequately prevents the entrapment of interlocking members in the healing wound. It is within the scope of the invention to coat the undersides of the rows of interlocking members, and optionally of the stringer tapes also, with a wound-protecting layer of silicone material. Finally, the clearance space also ensures that the sliding clasp can be manipulated to close the wound without

bringing it into harmful contact with the wound edges or encountering any risk of enmeshing the wound edges between the interlocking members when they are interlocked. As a result, the wound edges knit together substantially more neatly and cleanly than wounds closed by stitching or clamping. The healing process is undisturbed, and the appearance of the healed wound is free from the scars associated with stitches or clamps disposed at intervals along the wound. All these advantages are enjoyed more particularly when the wound is placed under slight tension before applying the device of the invention, using hooks at either end, for example, as will be discussed later. Moreover, the same advantages are enjoyed when the device of the invention is applied to an injury wound rather than an elongated surgical incision.

Within the scope of the invention, there are numerous detailed possibilities for the further adaptation and modification of the device as a whole and it various components. In respect of the rows of interlocking fastener members, a preferred embodiment of the invention is characterised in that the rows of interlocking fastener members are made in continuous form from polyamide or polyester, more specifically as monofilaments. The synthetic monofilament should be about 0.5 mm or less in diameter. The attachment of the rows of interlocking fastener members to the stringer tapes is substantially optional, within the context of the invention, but a preferred embodiment of the invention outstandingly providing the advantages already indicated is characterised in that the rows of interlocking fastener

members and the stringer tapes are united by weaving. This method of attaching the rows of interlocking fastener members to the stringer tapes leads to the sliding clasp fastener and the device as a whole acquiring mechanical characteristics in keeping with the described effects, with particular reference to incompressibility and protective effects in the closed postion. In the interlocked position, the rows of interlocking fastener members have a preferred breadth of about 5 mm.

The stringer tapes can be made from the widest variety of materials commonly used in the textiles industry and more particularly the surgical dressings industry. The stringer tapes in a preferred embodiment of the invention are made from polyester or polyamide.

The spacer strips used to form the clearance space over the wound in the device of the invention should generally start 4 to 10 mm off the centreline of the interlocked fastener members, preferably about 7 mm therefrom. The thickness of the spacer strips forming the clearance space over the wound should be between 0.5 and 1.5 mm, preferably about 1 mm. One preferred embodiment of the invention is further characterised in that the spacer strips used to form the clearance space over the wound are adhesive on the skin-facing side, this further improving the described performance of the device of the invention when closing the sliding clasp fastener and when in the closed position.

Secretions often seep from a closed wound. However, this no longer influences the performance of the device of the

invention, since the secretions escape through the clearance space over the wound. A preferred embodiment of the invention with respect to the escape of secretions is further characterised in that, in the zone between the rows of interlocking fastener members and the spacer strips forming the clearance space, the stringer tapes are adapted as drainage zones, for example provided with perforated holes. From the practical viewpoint, a very wide variety of materials can be used for the spacer strips forming the clearance space. However, it is once again preferred to use the materials already found satisfactory in the surgical dressings industry. In this connection, it is preferred under the invention to make the spacer strips forming the clearance space from the elastic adhesive microfoam plaster materials commonly used in the surgical dressings industry. In general, microfoams consist of enclosed cells of polyvinylchloride or polyethylene. The adhesive strips used to secure the stringer tapes along the wound edges can also be made from elastic foam material, more particularly a microfoam plaster material. A single strip can be used as a spacer strip and/or an adhesive strip. The foam strips in question actually behave elastically in a very similar manner to skin. However, it is equally possible to adopt an arrangement whereby the adhesive strips used to secure the stringer tapes along the wound edges are made from surgical gauze strips with an adhesive underside; the latter are relatively rigid in the longitudinal direction, relative to the sliding clasp fastener, but can expand and contract in the transverse

direction. The stringer tapes must obviously be bonded to the adhesive strip. Bonding can be carried out in various ways, including for example adhesive bonding, welding, sewing, stitching or a combination of these methods.

When the device of the invention is applied and the wound is closed in the described manner by closing the sliding clasp fastener, the resulting longitudinal tensile forces set up in the direction of the sliding clasp fastener are preferably diverted rather than transmitted through the adhesive strips to the skin. For this purpose, it is preferred under the invention to provide the stringer tapes with holding loops at the closed and/or the open ends of the sliding clasp fastener, adapted to withstand the longitudinal tensile loads set up when the sliding clasp fastener is respectively closed and/or opened. In both actions, the transverse tensile forces are absorbed by the adhesive strips.

The stringer tapes of the sliding clasp fastener in the device of the invention can be designed as flat strips, to lie in a single plane, so that the rows of interlocking fastener members are as it were held up by the stringer tapes on the skin side. It is however equally possible to use so-called concealed sliding clasp fasteners. This embodiment of the device of the invention is characterised in that the stringer tapes in the vicinity of the rows of interlocking fastener members are folded back into a U-shape, the rows of interlocking fastener members being disposed on the U-shaped fold, and the U-shaped folds contributing to or constituting the thickness of the spacer strips.

The invention will now be described in greater detail, with reference to a schematic drawing of embodiments thereof, purely by way of examples. In the drawing:

Figure 1 is a plan view of a device of the invention,

Figure 2 is a section, on a larger scale than Figure 1, taken on the line A-A through the object of Figure 1,

Figure 3 is a corresponding sectional view to Figure 2 through a differently designed device of the invention,

and

Figure 4 illustrates the closure of a surgical wound with the aid of a device of the invention.

The device shown in the Figures is designed to close a wound, more specifically a substantially rectilinear surgical incision. Its basic construction comprises two textile stringer tapes 1, rows 2 of interlocking fastener members disposed thereon and a sliding clasp 3 completing the sliding clasp fastener 1,2,3, together with means 4 for securing the stringer tapes 1 of the sliding clasp fastener 1,2,3, to the skin of a patient or animal along the wound edges.

A comparative examination of Figures 1 to 3 will show that the sliding clasp fastener 1,2,3 has rows 2 of interlocking fastener members 2 and stringer tapes 1 as in the ordinary flexible sliding clasp fasteners used for textile garments, with low-stretch stringer tapes 1 and rows 2 of interlocking fastener members which resist compression when interlocked. Figures 2 and 3 clearly show that spacer strips

5 forming a clearance space over the wound are provided on the underside, facing the wound clear of the rows 2 of interlocking fastener members. The means for securing the stringer tapes along the wound edges consist of adhesive strips 4 with a hypoallergenic adhesive film on the skin-facing side, attached to the stringer tapes 1. Borders 4a extend laterally beyond the stringer tapes 1. The stringer tapes 1 are underlain by the adhesive strip 4 over at least a part of their breadth, and the breadth of the adhesive strips in contact with the skin is adapted to withstand the transverse tensile forces set up when the wound is closed and whilst it remains closed by the sliding clasp fastener 1,2,3.

In the preferred embodiment of the invention as shown, rows 1 of interlocking fastener members are made in continuous form from a synthetic monofilament of polyamide or polyester for example. The synthetic monofilament should be about 0.5 mm in diameter. Furthermore, the rows 2 of interlocking fastener members are attached to the stringer tapes by weaving. Their breadth in the interlocked position is about 5 mm. The stringer tapes 1 can also be made from polyamide or polyester.

The spacer strips 5 used to form the clearance space over the wound start at a distance of say 4 to 10 mm from the centreline of the interlocked rows 2 of fastener members. In the embodiment shown, the distance is about 7 mm. Moreover, the thickness of the spacer strips 5 forming the clearance space over the wound is between 0.5 and 1.5 mm. In the embodiment shown, the thickness is 1 mm. The spacer strips 5

have an adhesive underface.

Referring particularly to Figures 1 and 4, it will be seen that the stringer tapes 1 are adapted as drainage zones between the rows 2 of interlocking fastener members and the spacer strips 5 forming the clearance space over the wound, and are provided with perforated holes 6 for this purpose.

In the embodiment shown in Figures 1 and 2, the spacer strips 5 used to form the clearance space over the wound are made from the elastic adhesive microfoam materials commonly used in the surgical dressings industry. The microfoam consists for example of polyvinyl chloride cells. The detailed arrangement is such that each stringer tape 1 is underlain by a foam strip 5 which besides the adhesive layer facing the skin has another adhesive layer facing the stringer tapes, at least over the area in contact with the stringer tape, whilst another foam strip is applied to the outward-facing surface of the first foam strip 5, to make the stringer tape 1 non-adhesive in the drainage zone having the perforations 6. The arrangement in Figures 1 and 2 is such that the adhesive strips 4 securing the stringer tapes 1 along the wound edges are also made from elastic foam strip material of the microfoam type. The spacer strips 5 run into the adhesive strips 4. In the embodiment shown in Figure 3, on the other hand, the adhesive strips 4 securing the stringer tapes 1 along the wound edges are made fron surgical gauze strips with an adhesive underside, which are relatively rigid in the longitudinal direction, relative to the sliding clasp fastener 1,2,3, but can expand and contract in the transverse

direction.

In the embodiment shown, the stringer tapes 1 and the adhesive strips 4 are bonded together with adhesive. They could however be secured additionally or alternatively to the adhesive strips by sewing or stitching.

Figure 1 shows that the stringer tapes can be provided at the closed end with a holding loop 7, to withstand the longitudinal tensile loads when the sliding clasp fastener 1,2,3 is being closed; the operator grasps this holding loop 7 when pulling the sliding clasp 3 in the opposite direction to close the wound.

Figure 4 illustrates the procedure used when a substantially rectilinear surgical incision W with initially gaping edges is closed by applying a device of the invention. As Figure 4 shows, the incision W has been stretched longitudinally with the aid of hooks H, thereby narrowing the wound gap. With the sliding clasp fastener 1,2,3 open, one adhesive strip 4 in the device has been applied to the skin alongside the edge R of the narrowed wound, the edge of the spacer strip 5 being at a distance therefrom of about half the breadth of the clearance space between the spacer strips 5. The second adhesive strip 4 has then been applied in a similar manner alongside the other edge R of the narrowed wound. Figure 4 depicts the situation immediately prior to closing the surgical incision W by actuating the sliding clasp. Thus, the surgical incision W will be closed by moving the sliding clasp 3 from the bottom upwards in Figure 4. The wound edges R will be urged together. Furthermore, Figure 4 shows that

the sliding clasp fastener 1,2,3 in the device is about 4 cm longer than the wound W and extends beyond it for about 2 cm at both top and bottom. The adhesive surfaces of the device, intended for bonding it to the skin, are obviously to be protected with foil in the usual manner, the foil being removed immediately prior to applying the device.



PATENT CLAIMS

1. A device to close a wound, more specifically a substantially rectilinear surgical incision, - having

two textile stringer tapes, rows of interlocking fastener members disposed thereon, and a sliding clasp completing the sliding clasp fastener,

the said sliding clasp fastener having means for adhesive bonding to the skin of a patient or animal along the edges of the wound, characterised by the following combination of features:

1) the sliding clasp fastener (1,2,3) has rows (2) of interlocking fastener members and stringer tapes (1) as in the ordinary sliding clasp fasteners used for textile garments, with low-stretch stringer tapes (1) and rows (2) of polyester or polyamide fastener members resisting compression when interlocked;

2) spacer strips (5) forming a clearance space over the wound are provided on the underside, facing the wound clear of the rows (2) of interlocking fastener members;

3) the means for adhesive bonding consist of adhesive strips (4) with a hypoallergenic adhesive film on the skin-facing side, attached to the stringer tapes (1) and extending laterally (at 4a) beyond the stringer tapes (1),

the stringer tapes (1) being underlain by the adhesive strips (4) over at least a part of their breadth, and the breadth of

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the adhesive strips (4) including the overlaps (4a) being adapted to withstand the transverse tensile forces when the wound is closed by the sliding clasp fastener (1,2,3) and the wound edges are compressed together.

2. A device as in Claim 1, characterised in that the rows (2) of interlocking fastener members are made in continuous form from synthetic monofilaments of polyamide or polyester.

3. A device as in Claim 2, characterised in that the synthetic monofilament in the rows (2) of interlocking fastener members is 0.5 mm or less in diameter.

4. A device as in any of Claims 1 to 3, characterised in that the rows (2) of interlocking fastener members and the stringer tapes (1) are united by weaving.

5. A device as in any of Claims 1 to 4, characterised in that in the interlocked position the rows (2) of interlocking fastener members have a breadth of about 5 mm.

6. A device as in any of Claims 1 to 5, characterised in that the stringer tapes (1) are made from polyester or polyamide.

7. A device as in any of Claims 1 to 6, characterised in that the spacer strips (5), used to form the clearance space over the wound, start 4 to 10 mm off the centreline of the interlocked fastener members (2), preferably about 7 mm therefrom.

8. A device as in any of Claims 1 to 7, characterised in that the thickness of the spacer strips (5), used to form the clearance space over the wound, is between

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0.5 and 1.5 mm, preferably about 1 mm.

9. A device as in any of Claims 1 to 8, characterised in that the spacer strips (5), used to form the clearance space over the wound, are adhesive on the skin-facing side.

10. A device as in any of Claims 1 to 9, characterised in that, in the zone between the rows of interlocking fastener members and the spacer strips (5) forming the clearance space, the stringer tapes (1) are adapted as drainage zones, for example provided with perforated holes (6).

11. A device as in any of Claims 1 to 10, characterised in that the spacer strips (5), forming the clearance space, are made as adhesive elastic foam plastic strips of the microfoam plaster type, e.g. consisting of cells of polyvinylchloride or polyethylene.

12. A device as in any of Claims 1 to 11, characterised in that the adhesive strips (4), used to secure the carrier strips along the wound edges, are also made from adhesive elastic foam plastics material in the form of microfoam plasters running into the spacer strips (5).

13. A device as in any of Claims 1 to 11, characterised in that the adhesive strips (4) used to secure the stringer tapes along the wound edges are made from surgical gauze strips with an adhesive underside, and are relatively rigid in the longitudinal direction, relative to the sliding clasp fastener (1,2,3) but capable of expanding and contracting in the transverse direction.

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14. A device as in any of Claims 1 to 13, characterised in that the stringer tapes (1) and the adhesive strips (4) are bonded together by welding and/or adhesive bonding.

15. A device as in any of Claims 1 to 14, characterised in that the stringer tapes (1) and the adhesive strips (4) are bonded together by sewing or stitching.

16. A device as in any of Claims 1 to 15, characterised in that the stringer tapes (1) are provided at the closed and/or open ends of the sliding clasp fastener (1,2,3) with holding loops (7), adapted to immobilise the sliding clasp fastener (1,2,3) during closure and/or opening, and to withstand the longitudinal forces set up when the sliding clasp fastener (1,2,3) is closed and opened.

17. A device as in any of Claims 1 to 16, characterised in that the stringer tapes (1) of the sliding clasp fastener are designed as flat strips, to lie in a single plane, so that the rows (2) of interlocking members are held up by the stringer tapes (1).

18. A device as in any of Claims 1 to 7, characterised in that the stringer tapes in the vicinity of the rows of interlocking members are folded longitudinally back into a U-shape, the rows of interlocking fastener members being disposed on the U-shaped fold, and the U-shaped folds contributing to or constituting the thickness of the spacer strips.