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WOUND SUCTION DEVICE WITH MULTI-LUMEN CONNECTOR

This invention relates to apparatus for applying negative pressure therapy to a wound. Negative pressure therapy is based on the observation that the application of continuous or intermittent suction to an open wound stimulates the rate of healing of the wound, probably by stimulating flow of blood in the zone of statis of the wound. It has now been accepted as a highly effective way of improving the rate of healing of patients suffering from pressure sores, ulcers, partial thickness burns and wounds that fail to heal quickly after an operation.

PCT Application WO 96/05873 describes apparatus for applying negative pressure therapy to a wound including a porous pad connected to a suction line with a collection container interposed between the suction means and the porous pad to collect exudate from the wound. UK Patent Application 9623743.3 (Publication No. 2307180) discloses a development of the apparatus described in the above PCT Application which provides for sensing pressure actually applied to the wound at the wound site. While the equipment described in the above application works effectively, disadvantages can occur in practice when there is a need to disconnect and reconnect the patient to the suction line.

The present invention provides an improved apparatus which includes a convenient system for connecting and disconnecting the suction line to the wound site.

According to one aspect of the present invention there is provided apparatus or applying negative pressure therapy to a wound which comprises a porous pad for application to the wound, a suction tube linking the porous pad to a source of negative

pressure, a container for collecting fluid exudate from the wound interposed between the porous pad and the source of negative pressure and a quick disconnect connector linking a first section of the suction tube leading to the porous pad with a second section leading to the container, said connector comprising two separable and non-interchangeable parts, said second section of the suction tube comprising a multi-lumen tube, one lumen being provided for applying suction to the porous pad and another being provided for monitoring pressure, said multi-lumen tube being fixedly attached at one end to the container and at the other end to one of said separable parts, said one separable part including sealing means whereby the lumens are connected in air-tight manner to said first section of the suction tube.

Preferably, also, the section of tube leading to the porous pad is a multi-lumen tube and is also fixedly attached to the separable connector part and to an adapter which can be sealed to the porous pad.

By the term "fixedly attached" we mean that the components mentioned are joined one to the other in such a way that they cannot be separated without damaging one or both of the joined components. The parts of the connector and the suction tube are generally formed from plastics material and the components can be fixedly joined by welding or adhesively. A convenient way of fixedly attaching the components is by using a mutual solvent for the components.

An advantage of the invention is that the container assembly and fixedly attached suction tube can only be used in conjunction with a correct, matching suction tube section and associated porous pad. Consequently, a proper and effective seal will be

made between the two sections of the lumens for applying suction and the "sensor" lumen in one section will be sealingly connected to the corresponding sensor lumen in the other section or to the "suction" lumen in that section. As a result, the pressure at or close to the wound site can be reliably monitored.

Various other aspects, features and advantages of the present invention will become apparent from the following description and accompanying drawings, in which:-

Figure 1 is a part schematic view of apparatus in accordance with the invention;

Figure 2 shows the two separable parts of the connector with portions of multi-lumen tubes fitted to them;

Figure 3 shows the two halves of the connector fitted together;

Figure 3a is an enlarged portion of the part indicated in Figure 3;

Figures 4 and 5 show views of the two connector halves from various viewpoints;

Figure 6 shows a modification of the connector;

Figures 7, 7a and 7b shows perspective views of a 3-way connector; and

Figures 8a, 8b and 8c show modified forms of the adaptor and systems for sealing the adaptor to a wound site.

Referring to the drawings and, in particular, Figure 1, the apparatus in accordance with the invention comprises a porous pad (1) (e.g. of polymeric, open-celled foam, such as a polyurethane or polyvinyl alcohol foam having interconnected cells), intended for application into or onto a wound to be treated. The porous pad is connected to a source of negative pressure (103) such as a pump or vacuum bottle by a

suction tube (2) and adapter (3) in the manner described generally in our above British Application No. 2307180 and our pending UK Patent Application No. 9819678.5 (Publication No. 2329127. The adapter (3) is preferably constructed in the manner shown in UK Patent Application No. 9819678.5 (Publication No. 2329127 and the porous pad and the adapter (3) are sealed in airtight manner to the wound site, using a surgical drape as described in UK Patent Application No. 2307130 or No. 2329127. Suction tube (2) is fixedly attached at one end (4) to a spout portion (5) of the adapter (3). The end (4) may be sealed and fixed by any suitable means such as welding or adhesive bonding to the spout (5). Conveniently, an adhesive bond may be formed by applying a solvent for the material of the adapter and the suction tube to the outer surface of the tube and inserting the tube into the adapter. The other end of suction tube (2) is connected to a wound exudate container (6) where it is fixedly sealed in airtight manner to the inlet end (7) of the container by suitable means. Suction tube (2) is formed in two parts which are linked by a connector (8). Connector (8) comprises two easily separable parts (9) and (10) which enables the patient to be easily and quickly disconnected from the major part of the apparatus, e.g. for ease of moving the patient for other treatment. The section (11) of the suction tube (1) which links the adapter (3) to the connector half (9) extends fully into the connector half (9) and is sealed therein, e.g. by adhesive bonding or welding. Thus, the section of tube (11) is sealed at both of its ends.

Similarly, the second section of suction tube (12) which links the connector half (10) with the collection container (6) is also sealed into its respective connector half

(10). Thus, no air leaks are possible between the adapter and the connector (8) and between the connector (8) and the container (6). Connector (8) is designed so that the two halves when assembled are locked together in a sealed condition. The construction of the connector will be described in more detail below.

The section (12) of suction tube (2) is a multi-lumen tube having a central lumen for applying suction to the wound site and one or more peripheral lumens for sensing pressure at the wound site. Specific examples of multi-lumen tubes are described in our co-pending British Patent Application No. 9819678.5 (Publication No. 2329127).

Preferably, also, the section (11) is a multi-lumen tube, but this is not essential especially if the section (11) between the connector half (9) and the patient is a relatively short piece. In that case, the pressure sensed at the connector (8) will be essentially the same as the pressure sensed at the wound site.

At the container (6) the central lumen is connected to a tube (20) which is linked by passage (21) to the interior of the container (6). Suction may be applied to the container, e.g. through a tube (22) to apply suction to the wound site. The outer lumen or lumens communicate with a peripheral passage (23) which is connected to a chamber (24). Chamber (24) is linked by a port (25) to a transducer (10) for measuring pressure at the connector (8) or at the wound site (1). A valve (102) may also be connected to the port (25) and can be opened to atmosphere to release or reduce the negative pressure at the wound site. By opening or closing the valve (102) at intervals, intermittent or varying negative pressure can be applied at the wound.

Tube (22) is connected to a source of negative pressure, e.g. pump (103). A pressure sensor (104) is connected to the tube (22) to sense the pressure in the suction line.

The connector is shown in more detail in Figures 2 to 5 of the accompanying drawings.

Referring to Figure 2 it will be seen that the connector half (9) has a shoulder (30) which enters a recess within the connector half (10) and seals against an O-ring (31). Connector half (10) has a projecting tubular part (32) which is dimensioned to enter the central lumen (33) of the multi-lumen tube (11), and in the fully assembled condition of the connector, the enlarged portion (35) seals within the central lumen (33). Connector half (10) has passages (36) which communicate at one end with one or more peripheral lumens (37), and at the other with a space (38) outside the central projection (32).

The two halves (9) and (10) are held together in their closed position by a bayonet-type fitting comprising a projection (39) which engages in a slot (40). The inter-engaging surfaces forming the slot and the projection (39) are such that the two halves are forced together so as to compress the O-ring (31) and force the portion (35) firmly into the inner lumen (33). The position is shown clearly in Figure 3 in the assembled condition. It will be seen that when assembled, the central lumen (33) communicates through the hollow projecting portion (32) between the two portions of the multi-lumen tube and this path is quite separate from the sensor part which connects the lumens (37) in each section of the suction tube.

Suitable materials for manufacturing the tubing include pvc, and suitable materials for manufacturing the connector include pvc, polypropylene and ABS. The tubes may be sealed into the connector halves by means of a solvent glue such as a cyclohexanol glue, or by a UV light curable adhesive composition. In order to prevent the sections (11) and (12) of the multi-lumen tube from leaking when disassembled, clamps (50) may be applied to the tube prior to separating the two halves of the connector.

Figure 6 shows a modification of the connector which provides an automatic sealing effect when the two halves are disconnected. This connector is essentially the same as the connector shown in Figures 2 and 3, and differs by having a rubbery membrane (16) across the central part (33) of the multi-lumen tube or across the whole of the open end of the suction tube portion (11). The projecting part (32) of the connector half (10) is shaped with a needle end (61), which is capable of piercing the rubber membrane (60). The projecting portion (32) has a lateral orifice (62) communicating with its hollow interior. Thus, when the two parts (9) and (10) are brought together, the needle end (61) penetrates the membrane (60) and places the two central lumens of the suction tubes (11) and (12) into communication. The membrane (60) is designed to be a soft material which self-seals when the portion (32) is withdrawn, thus preventing exudate from leaking from the end of the tube (11) when it is disconnected from the connector half (10).

In some circumstances where, for example, a very large wound is being treated, or simultaneous treatment is required perhaps to two sides of one limb, either separate

porous pads will be appropriate, or a very large porous pad will be necessary. In such circumstances, it may be convenient to provide two adapters (5) which are both connected by tubing (11) to a suction device and drainage container (6). In these circumstances, rather than connect the tubing separately to the container, a Y- or T-shaped connector piece may be provided in which two arms are connected to separate tubes (11), leading to separate adapters and the third arm (10) is connected to the collection container. Two Y-shaped connectors are shown in Figure 7. The arms of the Y-shaped connector body piece (100) are each provided with a separable part (80 or 81) which will each connect to a corresponding part fixedly attached to a respective tubing section.

Connector part (80) is attached to a multi-lumen tube section and the other end of the multi-lumen section is sealed to a canister (6). The other connector parts may be fixedly attached to other sections of the suction tube each of which lead to an adapter (3). For a large wound, two adapters may be arranged to apply suction to the same wound. While the sections of suction tube leading from the 'Y' piece to the adapters may be multi-lumen tubes, this is not essential and would require a very complex moulding for the 'Y' piece. Although, in this case, the pressure sensed at the wound site will be the average of the pressures at the two adapters, they will normally be close enough together for the pressure difference to be small. Figures 7A and 7B show the bayonet fitting very clearly.

Figures 8A, 8B and 8C show the arrangement of sealing the adapter assembly to a wound. Figure 8A is a section through the adapter assembly attached to a wound

(200). A porous dressing (1) e.g. of polyurethane foam is packed into the wound cavity and an adapter (3) is pressed against the surface of the dressing. As can be seen from Figures 8A~8C, the underside of the flange 301 of the adaptor is covered with projections (302), which are arranged in a staggered disposition to facilitate flow of fluids from a wide area of the foam pad (1) into the spout (5) of the adapter. The adapter (3) and dressing are sealed into the wound cavity by a thin elastomeric sheet material (303) which is adhered by a tacky pressure-sensitive adhesive to the skin (304) surrounding the wound (200). Sheet material (303) is typically polyurethane film which is coated all over one face with adhesive so that it is bonded to the upper face of flange (301) as well as to the skin of the patient.

Figure 8B is a plan view from above of the adapter showing the surgical drape assembly (305) surrounding the adapter. The drape assembly and the flange of the adapter are transparent so that the projections (302) can be seen. The drape assembly comprises three layers of sheet material as best seen in Figure 8C. The lower-most layer (306) is a release-coated comparatively stiff sheet material which is lightly bonded to the lower, adhesive-coated face of the surgical drape itself (307). The latter material is a very thin, flexible elastomeric material. A strengthening layer (308) of thicker material overlies the drape layer (307). Layers (307) and (308) have holes to permit the spout (5) of the adapter to pass through. In use, the foam pad (1) is placed in the wound, the release layer (306) is removed and the adhesive face of the drape applied to the skin around the pad to produce an airtight seal. Strengthening layer (308) is removed prior to, during or after adhering the drape to the skin. Handling bars (310) of

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thicker material are attached to the ends of the drape layer and to the ends of the strengthening layer to facilitate adhering the drape to the skin and separating the strengthening layer from the drape. After the seal has been achieved, the handling bars can be removed from the drape layer and perforations (311) may be provided for this purpose.

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CLAIMS:

1. Apparatus for applying negative pressure therapy tc a wound which comprises a porous pad for application to the wound, a suction tube linking the porous pad to a source of negative pressure, a container for collecting fluid exudate from the wound interposed between the porous pad and the source of negative pressure and a quick disconnect connector linking a first section of the suction tube leading to the porous pad with a second section leading to the container, said connector comprising two separable and non-interchangeable parts, said second section of the suction tube comprising a multi-lumen tube, a central lumen being provided for applying suction to the porous pad and at least one peripheral lumen being provided for monitoring pressure, said multi-lumen tube being fixedly attached at one end to the container and at the other end to one of said separable parts, said one separable part including sealing means whereby the lumens of the second section can be connected in air-tight manner to said first section via the other separable parts;

said sealing means comprising a projecting part which enters the central lumen of the second section, and at least one peripheral passage which communicates with the peripheral lumen.

2. Apparatus as claimed in claim I in which said first section of the suction tube is also a multi-lumen tube and said separable parts and sealing means individually connect the lumens in the second section with respective lumens in the first section in substantially air-tight manner.

3. Apparatus as claimed in claim 1 or 2 in which the first section of the suction tube is fixedly attached at one end to an adapter having a flange portion for application to said pad and a portion fixedly attached to said first section of the suction tube.

4. Apparatus as claimed in any one of the preceding claims in which the separable parts include respective parts of a bayonet fitting for connection and disconnection.

5. Apparatus as claimed in any one of the preceding claims in which said one separable parts, attached to said section of the suction tube, comprises a further tubular projection adapted to extend into and engage in sealing manner with a lumen of the first section of the suction tube.