

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 February 2009 (05.02.2009)

PCT

(10) International Publication Number
WO 2009/016605 A2

- (51) International Patent Classification:
A61L 15/42 (2006.01) A61M 1/00 (2006.01)
A61F 13/00 (2006.01)
- (21) International Application Number:
PCT/IB2008/053078
- (22) International Filing Date: 31 July 2008 (31.07.2008)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
2007/06398 1 August 2007 (01.08.2007) ZA
- (71) Applicant (for all designated States except US): **BLACK-BEARD, Graham Alan** [ZA/ZA]; Southern Implants Office Park, Building 10 1 Albert Road, 0157 Irene (ZA).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **DE VILLIERS, Malan** [ZA/ZA]; Southern Implants Office Park, Building 10 1 Albert Road, 0157 Irene (ZA). **GRIMSEHL, Karl**

[ZA/ZA]; Southern Implants Office Park, Building 10 1 Albert Road, 0157 Irene (ZA).

(74) Agents: **SPOOR & FISHER** et al.; PO Box 454, 0001 Pretoria (ZA).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,

[Continued on next page]

(54) Title: WOUND CONTACT MEANS FOR A REDUCED PRESSURE WOUND TREATMENT APPARATUS

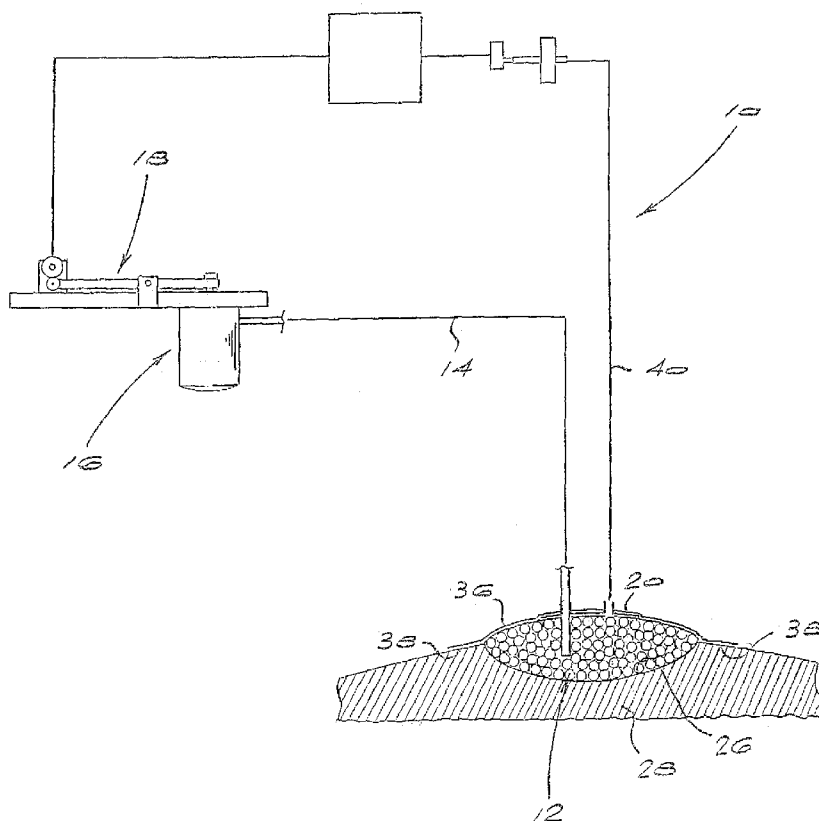


Fig. 1

(57) Abstract: The invention concerns a wound contact means (12) for use in a reduced pressure wound treatment apparatus (10) including a wound contact means locatable on a wound, a vacuum pump (16) and a suction line (14) through which the vacuum pump can apply suction to a wound (26) through the wound contact means in order to draw wound exudate from the wound through the wound contact means. The wound contact means (12) of the invention is characterised in that it includes a mass of discrete particles (24) which are movable relative to one another to enable the mass of particles to be shaped to suit the wound. Furthermore the individual particles are of such shape and rigidity that when the particles are compacted together the particle mass exhibits porosity enabling wound exudate to pass through the mass. Another aspect of the invention concerns a reduced pressure wound treatment apparatus (10) which incorporates the wound contact means (12).

WO 2009/016605 A2



NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- *without international search report and to be republished
upon receipt of that report*

**“WOUND CONTACT MEANS FOR A REDUCED PRESSURE WOUND
TREATMENT APPARATUS”**

BACKGROUND TO THE INVENTION

THIS invention relates to a reduced pressure wound treatment apparatus.

In the treatment of open wounds the application of controlled levels of negative pressure, i.e. a pressure which is reduced with respect to ambient pressure, or suction, has been shown to accelerate wound debridement and to promote healing. It is believed that the applied suction assists in the removal of interstitial fluid from the wound site, thereby decreasing localised oedema and increasing blood flow.

In the co-called V.A.C.® (Vacuum Assisted Closure) system, as described for instance in ZA95/6968, a porous pad of open cell foam material is placed in contact with the wound and a sealing membrane or drape is located over the pad. The drape has an adhesive underside by means of which it can be adhered to the skin of the patient around the outside of the pad, thereby providing a seal. One end of a suction tube is placed in communication with the pad, for instance by sandwiching it between two layers of the pad or by embedding it in the pad. The opposite end of the tube is connected to a canister. A separate vacuum pump is provided to generate a negative pressure in the canister so that wound exudate is drawn from the wound into the canister, where it accumulates.

One disadvantage of the known V.A.C.® -type wound treatment apparatus is the fact that the porous pad tends to become clogged with wound exudate, particularly in a region close to the inlet end of the suction tube. This reduces the suction efficiency of the apparatus. Another disadvantage of the known system is the difficulty which may be encountered in conforming the foam pad to the actual shape of a wound cavity so that the pad adequately fills the wound.

SUMMARY OF THE INVENTION

According to one aspect of the invention there is provided a wound contact means for use in a reduced pressure wound treatment apparatus including wound contact means locatable on a wound, a vacuum pump and a suction line through which the vacuum pump can apply suction to a wound through the wound contact means in order to draw wound exudate from the wound through the wound contact means, characterised in that the wound contact means comprises a mass of discrete particles which are movable relative to one another to enable the mass of particles to be shaped to suit the wound and in that the individual particles are of such shape and rigidity that when the particles are compacted together the particle mass exhibits porosity enabling wound exudate to pass through the mass.

The particles may for instance be rigid or semi-rigid bodies of rounded shape. Preferably they are in the form of spherical balls and may be made of a biocompatible material, possibly silicone.

The particles may be weakly bound together, for example by an adhering material, such as a gel, allowing the particles to move relative to one another, for example by sliding over one another. Alternatively the particles, or groups of particles, are linked to one another by flexible linking means such as cords or strings. The particles, or groups thereof, may for instance be threaded onto one or more cords or strings.

In one version of the invention the particles are provided as an uncontained mass which can be packed into the wound in order to fill it, while in another version, the particles are contained in a flexible, porous container such as a porous bag of net or mesh construction.

The wound contact means of the invention may also comprise a connector positionable on the particle mass and having an opening therein for locating the suction tube in or against the particle mass. The preferred connector has a base member positionable on the particle mass with an opening

-3-

therethrough through which the tube can extend. The connector may also include a further opening therein for locating a pressure sensing tube of the

Still further the wound contact means may comprise a sealing drape which can be placed over the connector and particle mass, the drape having an adhesive underside by means of which it can be adhered to skin around the wound.

According to another aspect of the invention there is provided a reduced pressure wound treatment apparatus comprising a wound contact means, as summarised above, which can be located on a wound, a vacuum pump and a suction line through which the vacuum pump can apply suction to the wound through the wound contact means in order to draw wound exudate from the wound through the wound contact means.

According to yet another aspect of the invention there is provided a method of withdrawing wound exudate from a wound cavity, the method comprising the steps of providing a wound contact means as summarised above, locating the wound contact means in the wound cavity with the mass of particles shaped to conform to and fill the wound cavity, and applying suction to the wound cavity through a suction line, by means of a vacuum pump, thereby to draw wound exudate from the wound cavity through the mass of particles and suction line.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail, by way of example only, with reference to the accompanying drawings in which:

Figure 1 diagrammatically illustrates a reduced pressure wound treatment apparatus incorporating a wound contact means according to the invention; and

Figure 2 shows an enlarged cross-sectional view of the wound contact means seen in Figure 1.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENT

The reduced pressure wound treatment apparatus 10 seen in Figure 1 is described in detail in a copending international patent application entitled "Reduced Pressure Wound Treatment Apparatus" filed simultaneously with the present application by the same applicant. The disclosure of the copending applications is incorporated herein and reference should be made to it for the details.

For present purposes it is pointed out that the apparatus 10 includes a disposable wound contact means 12 according to the present invention, a disposable suction tube 14 extending from the wound contact means 12, a disposable vacuum pump 16, i.e. a pump capable of applying suction to the wound contact means through the suction tube, and a reusable actuator 18 for actuating the vacuum pump. In use, with the vacuum pump actuated and operative to apply to suction to the wound contact means, wound exudate is drawn from the wound into a suction chamber of the pump 16 through the suction tube 14.

The illustrated apparatus also includes a connector 20 for use in connecting the end of the tube intimately to the wound contact means 12. More is said subsequently about the connector 20.

The wound contact means 12 includes a flexible bag 22, in this case made of nylon mesh, and a large number of rigid particles in the form of spherical bodies or balls 24 packed in the bag.

In this example the balls 24 are not connected to one another in any way and so are free to move relative to one another in the bag. This freedom of movement allows the bag, considered as a whole, to assume many

-5-

different shapes. The numeral 26 in Figure 1 indicates an open wound, such as a burn wound or ulcer, in a body part 28 of an injured patient. The bag can be shaped as necessary to conform to the shape of the wound cavity, allowing the bag to be inserted into the cavity, essentially to fill it, with the bag conforming closely and intimately to the uneven wound surfaces.

It will be understood that bags of different size and volume may be provided to enable a selection to be made as to the most appropriate bag for a given wound. Alternatively, the bag may be designed so as to be openable for the purposes of introducing or emptying out balls in order to create the required volume for a particular wound, and may thereafter be closable.

Even when the balls 24 are packed as compactly as possible within the bag, their spherical shapes ensure that the resulting mass has considerable porosity, allowing exudate to pass through the bag when suction is applied. The diameter of the balls is selected accordingly, i.e. the diameter of the balls will be sufficient to ensure that adequate porosity is always present to allow efficient exudate passage.

The invention envisages that shapes other than spherical may be used but in each case the external shape and dimensions of the particles will be selected such that, even in a state of maximum compaction, the mass which they form has sufficient porosity for exudate to pass through.

As shown in Figure 2, the connector 20 includes a flexible base 30 having openings 32 therein and an upstanding, hollow spigot 34 at each opening. The flexibility of the base 30 enables it to conform closely to the exposed surface of the bag 22 once the latter has been appropriately shaped and placed in the wound cavity. The end of the tube 14 passes through one of the spigots 34 and the associated opening 32 into the mass of balls in the bag. If necessary the end of the tube may be designed such that it cannot be blocked by a ball.

-6-

A sealing cover or drape 36 (Figure 1) is placed over the connector 20 and bag 22 with the spigot and suction tube extending through a hole in the cover. The underside of the cover carries an adhesive enabling it to be adhered peripherally, at the position 38, to the patient's skin around the wound site, thereby forming a seal. In use, when the vacuum pump 16 is operative, suction is applied to the wound surfaces through the bag, such that exudate is drawn from the wound to the vacuum pump through the bag and suction tube. The random distribution of the balls within the bag ensures that numerous exudate flow passages are created within the mass, and that such passages will allow suction to be applied substantially over the entire surface area of the wound.

As suction is applied to the bag it can be expected that the balls 24 will be drawn together into a more compacted state. However, as indicated above, the selection of the balls is such that exudate can still pass adequately. It can also be expected that the balls will be drawn into firm contact with the inner end of the suction tube, thereby anchoring that end firmly within the bag during the procedure.

With freely movable balls of adequate diameter there is little chance of the spaces between the balls becoming blocked with exudate. If it is detected that some blockage has taken place, it is in any event perceived that it would be possible to manipulate the bag as necessary to reorganize the balls and eliminate the blockage.

In other embodiments of the invention, not illustrated, the wound contact means may be provided merely by a mass of uncontained particles, preferably spherical balls, which could be filled into the wound in order to provide randomly distributed exudate flow passages. Alternatively uncontained particles could be bound weakly to one another by a lightly adhesive substance such as a gel which would still allow the balls to move relative to one another. In another alternative, the balls or other particles are threaded onto one or more strings or cords, in the manner of beads.

-7-

The flexible strings or particles can then be placed in any desired configuration into the wound cavity.

In each of the above examples the particle mass exhibits considerable conformability to allow it to be shaped to suit the wound site.

Where a bag is used, it is envisaged that the material of which the bag is made could be impregnated with medicaments such as anti-bacterial agents, or with growth agents.

In the illustrated example the connector is placed against the outside of the bag. It is however within the scope of the invention for the connector to be located within the bag, possibly with a length of suction hose attached to the connector and already projecting from the bag. In this event, the projecting length of hose could, for instance, be connected to the remainder of the hose by suitable connectors such as luer connectors.

In the examples described above, the tube 14 projects through the connector 20 into the mass of balls or other particles. In other embodiments, not illustrated, the end of the tube may reside at the surface of the particle mass rather than actually projecting into it. In this case the tube may for instance terminate at the level of the base 30 of the connector 20 as indicated by the broken line 42 in Figure 2.

The connector 20 in the illustrated example also provides the facility for connection of a pressure sensing tube 40, leading to a pressure transducer, as described in the copending patent application referred to above.

CLAIMS

1.

A wound contact means for use in a reduced pressure wound treatment apparatus including wound contact means locatable on a wound, a vacuum pump and a suction line through which the vacuum pump can apply suction to a wound through the wound contact means in order to draw wound exudate from the wound through the wound contact means, characterised in that the wound contact means comprises a mass of discrete particles which are movable relative to one another to enable the mass of particles *to be shaped to suit the wound and in that the individual particles are of such shape and rigidity that when the particles are compacted together the particle mass exhibits porosity enabling wound exudate to pass through the mass.*

2.

A wound contact means according to claim 1 wherein the particles are rigid or semi-rigid bodies of rounded shape.

3.

A wound contact means according to claim 2 wherein the particles are spherical balls.

4.

A wound contact means according to any one of the preceding claims wherein the particles are made of a biocompatible material.

5.

A wound contact means according to claim 4 wherein the particles are made of silicone.

6.

A wound contact means according to any one of the preceding claims wherein the particles are weakly bound together in a manner allowing them to move relative to one another.

7.

A wound contact means according to claim 6 wherein the particles are weakly bound together by an adhering material which allows the particles to slide over one another

8.

A wound contact means according to claim 7 wherein the particles are weakly bound together by an adhering gel.

9.

A wound contact means according to any one of claims 1 to 5 wherein the particles, or groups of particles, are linked to one another by flexible linking means.

10.

A wound contact means according to claim 9 wherein the particles, or groups of particles, are linked to one another by cords or strings.

11.

A wound contact means according to claim 10 wherein the particles are threaded onto one or more cords or strings.

12.

A wound contact means according to any one of the preceding claims wherein the particles are provided as an uncontained mass which can be packed into the wound in order to fill it.

13.

A wound contact means according to any one of claims 1 to 11 wherein the the particles are contained in a flexible, porous container.

14.

A wound contact means according to claim 13 wherein the particles are contained in a porous bag of net or mesh construction.

15.

A wound contact means according to any one of the preceding claims and further comprising a connector positionable on the particle mass and having an opening therein for locating the suction tube in or against the particle mass.

16.

A wound contact means according to claim 15 wherein the connector has a base member positionable on the particle mass and having an opening therethrough through which the tube can extend.

17.

A wound contact means according to claim 15 or claim 16 wherein the connector includes a further opening therein for locating a pressure sensing tube of the reduced pressure wound treatment apparatus.

18.

A wound contact means according to any one of claims 15 to 17 and further comprising a sealing drape which can be placed over the connector and particle mass, the drape having an adhesive underside by means of which it can be adhered to skin around the wound.

19.

A reduced pressure wound treatment apparatus comprising a wound contact means, according to any one of the preceding claims, which can be located on a wound, a vacuum pump and a suction line through which the vacuum pump can apply suction to the wound through the wound contact means in order to draw wound exudate from the wound through the wound contact means.

20.

A method of withdrawing wound exudate from a wound cavity, the method comprising the steps of providing a wound contact means according to any one of claims 1 to 18, locating the wound contact means in the wound cavity with the mass of particles shaped to conform to and fill the wound cavity, and applying suction to the wound cavity through a suction line, by means of a vacuum pump, thereby to draw wound exudate from the wound cavity through the mass of particles and suction line.

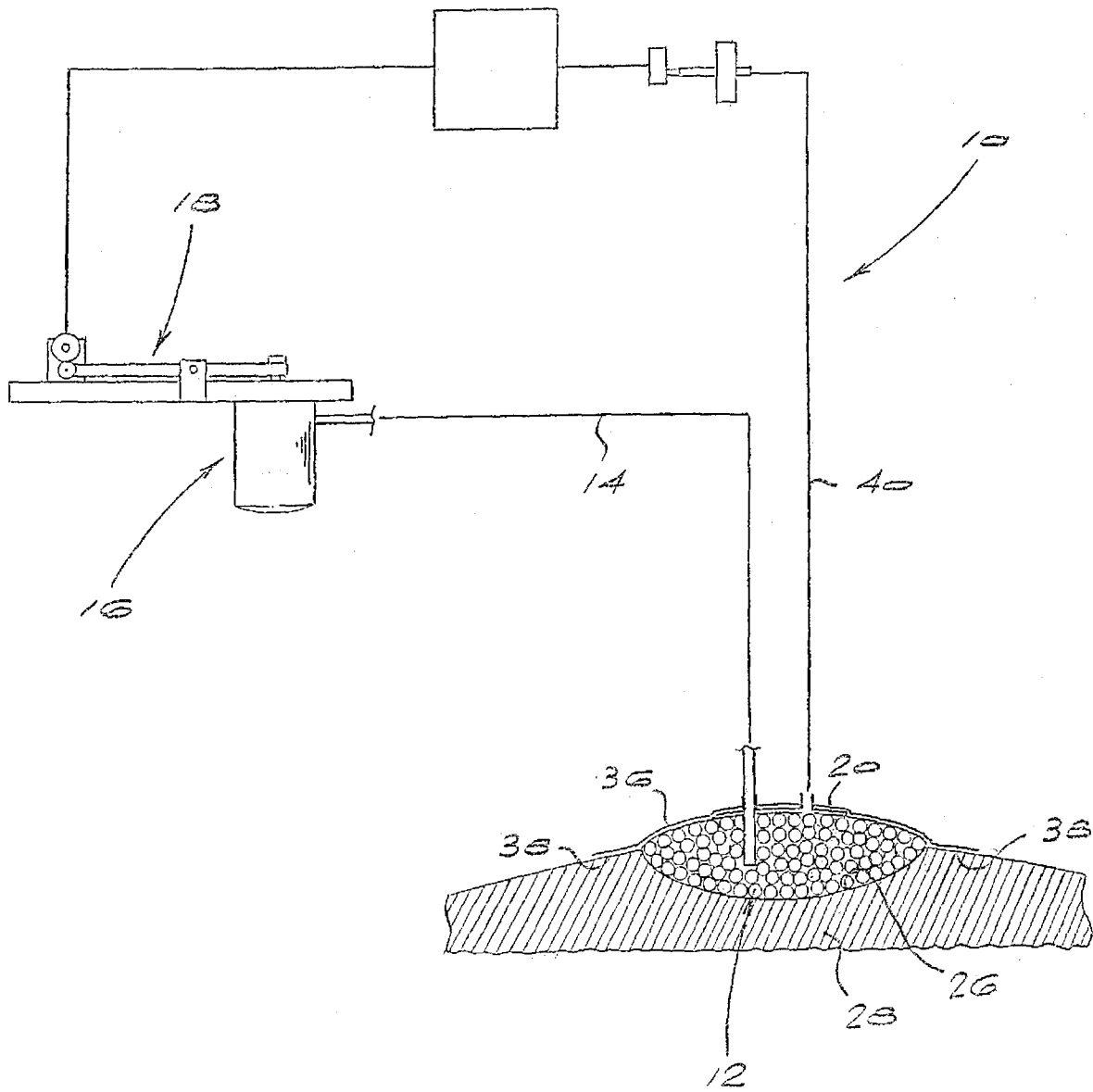


Fig. 1

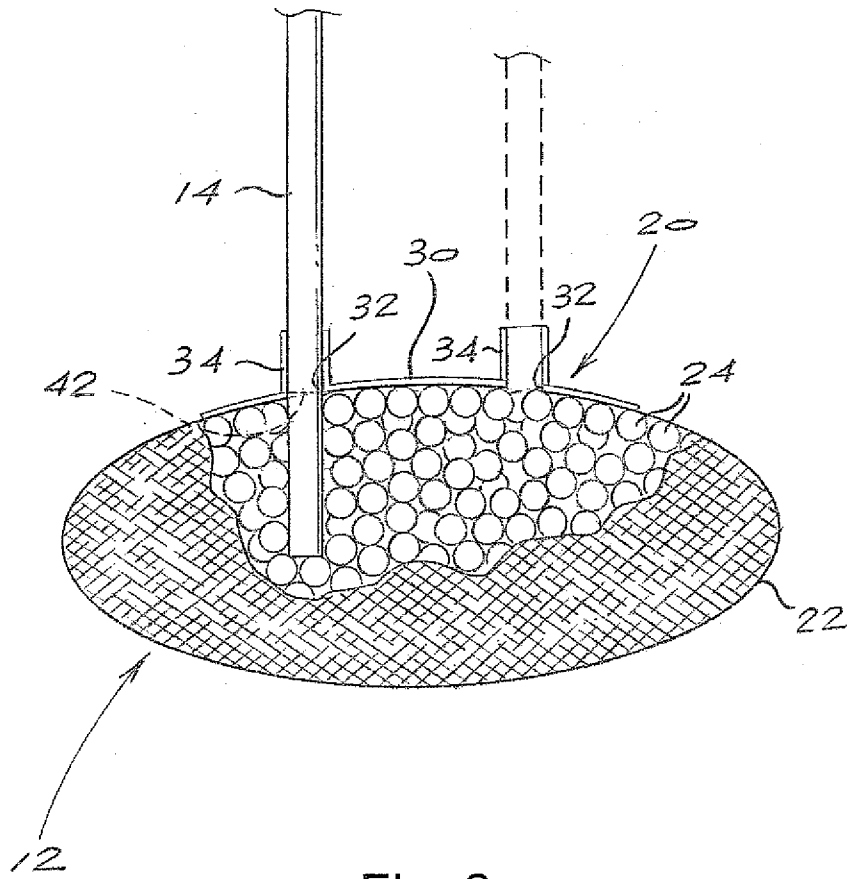


Fig. 2