

(19) AUSTRALIAN PATENT OFFICE

(54) Title
Negative pressure wound treatment dressing

(51)⁶ International Patent Classification(s)
A61M 35/00 20060101ALI2008053
(2006.01) 1BMEP **A61M**
A61F 13/06 (2006.01) 1/00
A61M 1/00 (2006.01) 20060101ALI2008053
A61M 27/00 1BMEP **A61M**
(2006.01) 27/00
A61F 13/00 (2006.01) 20060101ALI2008053
A61M 35/00 1BMEP **A61F**
20060101AFI2007022 13/00
4BMEP **A61F** 20060101ALN200805
13/06 31BMEP
PCT/US2004/023541

(21) Application No: 2004258980

(22) Application Date: 2004 .07 .21

(87) WIPO No: W005/009488

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/489,344	2003 .07 .22	US

(43) Publication Date : 2005 .02 .03

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(56) Related Art
US 2002/0150720
US 6071267

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
3 February 2005 (03.02.2005)

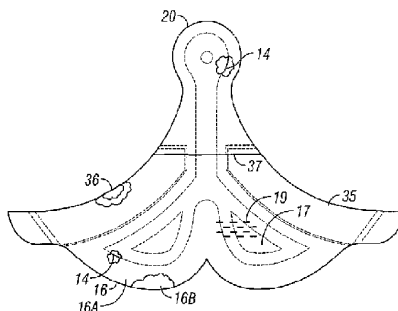
PCT

(10) International Publication Number
WO 2005/009488 A3

- (51) International Patent Classification⁷: **A61M 35/00**
- (21) International Application Number:
PCT/US2004/023541
- (22) International Filing Date: 21 July 2004 (21.07.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/489,344 22 July 2003 (22.07.2003) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 60/489,344 (CON)
filed on 22 July 2003 (22.07.2003)
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, 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, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: **NEGATIVE PRESSURE WOUND TREATMENT DRESSING**



(57) Abstract: A wound treatment dressing for applying negative pressure wound therapy to a wound of an extremity, such as on the heel of a foot. The dressing comprises a fluid manifold (14) positioned within a fenestrated drape (16) to form a contoured occlusive wrapping (10) for placement over a wound on an extremity. A contoured porous pad (26) is placed adjacent or within the wound, such that the contoured pad (26) is enveloped by the occlusive wrapping (10). Flexible tubing (42) is attached to or through a fluid communication port (18), which forms an opening to the outer layer (16b) of the occlusive wrapping (10), so as to allow for fluid communication of negative pressure to the contoured pad (26) from a source of negative pressure (44) connected to an opposite end of the flexible tubing (42). The negative gauge pressure is communicated from the source (44), through the tube (42), through the fenestrations (19) of the occlusive wrapping (10), such that negative gauge pressure is applied to the wound on the extremity. The fluid manifold (14) serves to direct the negative pressure from a position away from the wound site to the contoured pad (26) at the wound site.

**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AI, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SI, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AI, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ,

OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SI, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

- of inventorship (Rule 4.17(iv)) for US only

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
28 April 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

NEGATIVE PRESSURE WOUND TREATMENT DRESSING

[0001] This application claims priority to U.S. Provisional patent application no. 60/489,344 filed under 37 C.F.R. 1.53(b)(2) on July 22, 2003.

FIELD OF THE INVENTION

[0002] This invention relates to the treatment of open, chronic wounds, as well as burns and skin grafts. More specifically this invention relates to dressings for the treatment of wounds to the extremities, such as the heel of a human foot, by means of negative pressure wound therapy.

BACKGROUND OF THE INVENTION

[0003] Negative pressure wound therapy has been utilized for the treatment of open wounds and has been commercialized by Kinetic Concepts, Inc. of San Antonio, Texas, by its proprietary V.A.C.[®] product line. In practice, the application to a wound of negative gauge pressure, commercialized by Assignee or its parent under the designation "Vacuum Assisted Closure[®]" (or "V.A.C.[®]") therapy, typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid, which is often accomplished by means of a polymer foam and occlusive drape dressing in fluid communication with a negative pressure source. In this manner, negative pressure wound therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return. As a result, negative pressure wound therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable.

[0004] Many of these wounds include decubitus and venous stasis ulcers to the lower extremities, especially the foot. Closure of these wounds has been difficult and often times impossible using traditional techniques, such as skin grafting, sharp debridement, or combinations thereof. Failure to close these wounds, which have often been present for several years, can lead to necrotizing of the tissue, and in many cases amputation of the extremity. Use of negative pressure wound therapy has proven highly successful in closing these wounds. However, treatment of the lower extremities with negative pressure wound therapy, especially to wounds of the foot and heel can be difficult, especially considering the nature of the location of the wound. Particular concern arises with maintaining the dressing on the extremity, especially in light of the frequent movement of the foot, and friction often associated with foot coverings, including socks, stockings, and shoes. Of particular concern, is the ability to maintain a negative pressure at the wound site when the dressing is in place, as air leaks may occur during movement of the foot, which can adversely affect the therapy being administered.

[0005] For the foregoing reasons, there is a need for a negative pressure wound treatment dressing system that is capable of maintaining a negative pressure over an extremity that has heretofore been difficult to treat using traditional negative pressure wound therapy dressings. Additionally, there is a need for a negative pressure wound treatment dressing system that is capable of maintaining a negative pressure over a wound which exists in a highly contoured part of the

body, or a portion of the body that undergoes frequent movement or friction against clothing or other outside forces.

[0006] It is therefore an object of the present invention to provide a negative pressure wound treatment dressing system that provides a means for maintaining a negative pressure over a contoured extremity, such as the foot, and more specifically the heel of the foot.

SUMMARY

[0007] In accordance with the foregoing objects, the present invention generally comprises a contoured porous pad positioned within a fenestrated and contoured occlusive wrapping for placement over a wound on an extremity, such as the heel of a human foot. A concave porous pad is placed adjacent or within the wound, such that the concave pad is enveloped by the occlusive wrapping. Flexible tubing is attached to or through an opening of the drape, so as to allow for fluid communication of negative pressure to the concave pad from a source of negative pressure connected to an opposite end of the flexible tubing. The negative gauge pressure is communicated from the source, through the tube, through the fenestrations of the occlusive wrapping, such that negative gauge pressure is applied to the wound on the extremity. The contoured porous pad serves to manifold the negative pressure from a position away from the wound site to the concave pad at the wound site. Such an arrangement allows for the tubing to connect to the dressing of the present invention at a position least likely to be dislodged during normal ambulation of the patient.

[0008] Attachments means are formed on the outer edges of the occlusive wrapping to form an airtight seal over the wound. Such attachment means may be an adhesive coated on the occlusive wrapping for attachment to an intact area of tissue or skin. The adhesive is coated on the perimeter edge of the occlusive wrapping such that a pouch is formed when the occlusive wrapping is secured over the concave pad.

[0009] A collection canister is provided between the negative pressure source and the occlusive drape for collecting any effluents that may be drawn from the wound during application of negative pressure.

[0010] The tubing is connected to the drape and pad through an opening in the drape, or through a flanged tubing connector as has been described in U.S. Patent 6,345,623, entitled "Surgical drape and suction head for wound treatment," to Heaton, et al., which is incorporated herein by reference as though fully set forth. Alternative embodiments allow the tubing to be placed within or embedded in the concave padding.

[0011] The foregoing has outlined some of the more pertinent objects of the present invention. These objects should be construed to be merely illustrative of some of the more prominent features and applications of the invention. Many other beneficial results can be attained by applying the disclosed invention in a different manner or by modifying the invention as will be described. Accordingly, other objects and a fuller understanding of the invention may be had by referring to the following Detailed Description of the Invention, which includes the preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other features and advantages of the invention will now be described with reference to the drawings of certain preferred embodiments, which are intended to illustrate and not to limit the invention, and wherein like reference numbers refer to like components, and in which:

[0013] Figure 1A, is an exploded view of the occlusive wrapping of the present invention.

[0014] Figure 1B, is an orthogonal flat pattern view of the occlusive wrapping of the present invention.

[0015] Figure 2 is an orthogonal view of the fluid manifold of the occlusive wrapping of the present invention.

[0016] Figure 3A is a perspective view of a contoured pad of the present invention.

[0017] Figures 3B and 3C are cross-sectional views of a contoured pad of the present invention.

[0018] Figure 3D is a top plane view of the contoured pad of the present invention.

[0019] Figures 4A-4G are perspective views of the negative pressure wound treatment dressing system, illustrating the steps of applying the dressing system to a wound on the heel of a foot.

[0020] Figure 5 is an orthogonal flat pattern view of the occlusive wrapping of the present invention folded along its center line.

DETAILED DESCRIPTION

[0021] Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention as well as alternate embodiments, the scope of which is limited only by the claims that may be drawn hereto.

[0022] The details of the preferred embodiments of present invention are graphically and schematically illustrated in the accompanying drawings. Like elements in the drawings are represented by like numbers, and any similar elements are represented by like numbers with a different lower case suffix.

[0023] Referring now to Figure 1 in particular, there is illustrated the primary components of the occlusive wrapping **10** of the negative pressure dressing system that operates in accordance with the present invention. The occlusive wrapping **10** consists of a fluid manifold **14** embedded within an

occlusive drape 16. The occlusive drape 16 is preferably made of a clear vapor permeable polyurethane material. The drape 16 is composed of a wound facing layer 16a and an outer layer 16b that are sealed along their periphery to secure the fluid manifold 14 within the wound facing layer 16a and the outer layer 16b of the drape 16. Multiple fenestrations 19 are formed along a wound contact region 17 of the wound facing layer 16a, so as to allow for fluid communication through the fluid manifold 14. The fluid manifold 14 allows for attachment of the fluid communication port 18 at a position away from the wound site. The type of wounds desired to be treated by the present system are often situated at a position that has, at times been difficult to maintain a reduced pressure using traditional negative pressure wound therapy techniques described herein. The occlusive wrapping 10 of the present invention overcomes this difficulty by communicating the negative pressure along the manifold 14, and more particularly the fluid manifold 14 of the occlusive wrapping 10, which is most clearly illustrated in Figure 2.

[0024] Figure 2 illustrates an alternative embodiment of the fluid manifold 14 of the occlusive wrapping 10. The fluid communication port 18 is attached to a receiving site 20, which is most preferably a circular shaped foam section that is approximately the size of the fluid communication port 18. Fluid communicator arms 22 extend distally from the receiving site 20 to the wound contact regions 17. The fluid communicator arms 22 terminate in loops 24, having openings for viewing the wound perimeter. In an alternative embodiment, fluid communicator fingers 24 extend distally from the fluid communicator arms 22.

[0025] A contoured pad 26 as illustrated in Figures 3A-3D is utilized as a wound contact screen to prevent unwanted adhesions, direct fluid away from the wound through pores within the pad 26, and exert contracting forces on the wound margins as negative pressure is applied through the manifold 14 and to the pad 26. The contoured pad 26 and fluid manifold 14 of the occlusive wrapping 10 are preferably made of a porous polymer foam material, such as polyurethane or polyvinyl alcohol foam. The pad 26 is preferably constructed into an elliptical shape as illustrated in Figure 3D, but may also be more symmetrically circular to accommodate more uniform wounds.

[0026] In practice, the contoured pad 26 is trimmed to the areal dimensions of the wound and is placed in the wound, which may be on the heel of a foot, and between the wound and the fluid manifold 14, as illustrated in Figures 4A-4G. The pad 26 may be secured to the wound site by an adhesive strip 28, as shown in Figure 4A, or by other means known in the art. In the preferred embodiment, the adhesive strip is constructed of the same vapor permeable polyurethane material as the occlusive drape 16, having an adhesive coated on one side for securing the strip to the pad 26 and the intact skin surrounding the wound.

[0027] The occlusive wrapping 10 forms a pouch 30 when it is folded along its centerline and the lower edges 31 are bonded together at 33 as shown in Figure 5. In practice, the pouch 30 is placed over the wound and contoured pad 26, as illustrated in Figures 4B and 4C. A fingerhold 36a is provided to facilitate grasping the pouch 30 and holding it in place as the liner 35 is removed to expose an adhesive backing on layer 16b. The edges 32a, 32b of the pouch 30 are brought

into contact with the intact skin surrounding the wound by means of an adhesive backing. A removable liner 35 is pulled off, starting at finger tab 35a, exposing the adhesive, as shown in Figure 4C. The removable liner 35 may be statically adhered to the adhesive backing to protect the adhesive during handling.

[0028] As illustrated in Figure 4D, a second removable liner 37 is adhered to the receiving site 20 to protect the adhesive on the wound facing layer 16a along the receiving site 20 during handling, and which is removed prior to adhesion of the receiving site 20 to a region 40 of intact skin away from the wound site, so as to prevent dislodgement of the fluid communication port 18 during movement of the patient, as shown in Figure 4E. A removable, protective liner 36 may be overlaid on the occlusive drape 16, so as to provide rigidity to the manifold during handling, and which is removed after securing the pouch 30 to the wound site, as shown in Figure 4F.

[0029] A fluid communication port 18 is positioned over the receiving site 20, and is secured in place also by means of an adhesive contact surface on the communication port 18. As known in the art of negative pressure wound therapy, a fluid communication means 42, such as a flexible silicone tube, communicates negative pressure to the wound from a negative pressure source 44, such as a portable pump. A collection canister 46 is positioned in line between the negative pressure source 44 and the fluid communication means 42 to collect any exudates that may be drawn from the wound.

[0030] While the invention has been described herein with reference to certain preferred embodiments, these embodiments have been presented by way

of example only, and not to limit the scope of the invention. Many other variations are possible, which would be obvious to one skilled in the art. Accordingly, the scope of the invention should be identified only in accordance with the claims that follow.

VARIATIONS

It will of course be realised that while the foregoing has been given by way of illustrative example of this invention, all such and other modifications and variations thereto as would be apparent to persons skilled in the art are deemed to fall within the broad scope and ambit of this invention as is herein set forth.

Throughout the description and claims this specification the word "comprise" and variations of that word such as "comprises" and "comprising", are not intended to exclude other additives, components, integers or steps.

What is claimed is:

1. A wound dressing for use under negative pressure, comprising:
 - a contoured pad adapted for placement in a wound;
 - an occlusive wrapping adapted for positioning over and around the contoured pad, wherein said occlusive wrapping comprises a fluid manifold, an occlusive drape surrounding said fluid manifold and bonded to form a pouch for placing over the wound and the contoured pad, and an adhesive on at least an edge of said occlusive drape for sealing said occlusive wrapping to the area surrounding the wound; and
 - a fluid communication port through at least a layer of said occlusive drape for communicating fluid from said fluid manifold to a source of negative pressure.
2. The wound dressing of claim 1, wherein said fluid manifold further comprises fluid communicator arms extending distally from said fluid communication, port.
3. The wound dressing of claims 1 or 2, wherein said occlusive drape is comprised of a wound facing layer and an outer layer.
4. The wound dressing of claim 3, wherein said wound facing layer is fenestrated.
5. The wound dressing of claims 3 or 4, wherein said communicator arm form contiguous loops.
6. The wound dressing of claim 2, wherein said communicator arms further comprise communicator fingers extending distally from said communicator arms.

7. A wound dressing for use under negative pressure, comprising:

a contoured pad adapted for placement in a wound;

an occlusive wrapping adapted for positioning over and around the contoured pad,

wherein said occlusive wrapping comprises a fluid manifold, a clear occlusive drape surrounding said fluid manifold and forming a pouch for placing over the wound and said contoured pad, and an adhesive on at least an edge of said occlusive drape for sealing said occlusive wrapping to the area surrounding the wound;

a fluid communication port through at least a layer of said occlusive drape for communicating fluid from said fluid manifold to a source of negative pressure;

and

wherein said fluid manifold is comprised of a receiving site and fluid communicator arms extending distally from said receiving site, and wherein said communicator arms terminate in loops to allow viewing of the area around the wound through the occlusive drape.

8. The wound dressing of claim 7, wherein said occlusive drape is comprised of a wound facing layer and an outer layer.

9. The wound dressing of claim 8, wherein said wound facing layer is fenestrated.

10. A wound dressing for use under negative pressure, comprising:

a contoured pad adapted for placement in a wound;

an occlusive wrapping adapted for positioning over and around the contoured pad,

wherein said occlusive wrapping comprises a fluid manifold, a clear occlusive drape surrounding said fluid manifold and bonded to form a pouch for placing over the wound and the contoured pad, and an adhesive on at least an edge of said occlusive drape for sealing said occlusive wrapping to the area surrounding the wound;

wherein said fluid manifold is comprised of fluid communicator arms extending distally from said fluid communication port form contiguous loops to allow viewing of the area around the wound through the occlusive drape; and

a fluid communication port through at least a layer of said occlusive drape for communicating fluid from said fluid manifold to a source of negative pressure.

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11. The wound dressing of claim 10, wherein said occlusive drape is comprised of a wound facing layer and an outer layer.

12. The wound dressing of claim 11, wherein said wound facing layer is fenestrated.

13. A wound dressing for use under negative pressure substantially as herein described with reference to the accompanying drawings.

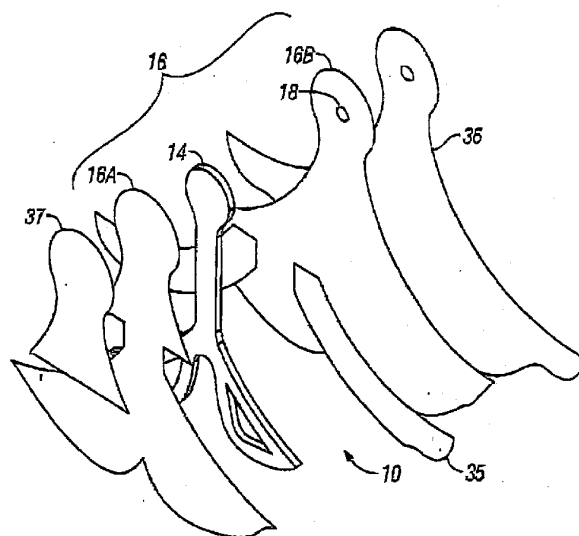


FIG. 1A

AMENDED SHEET

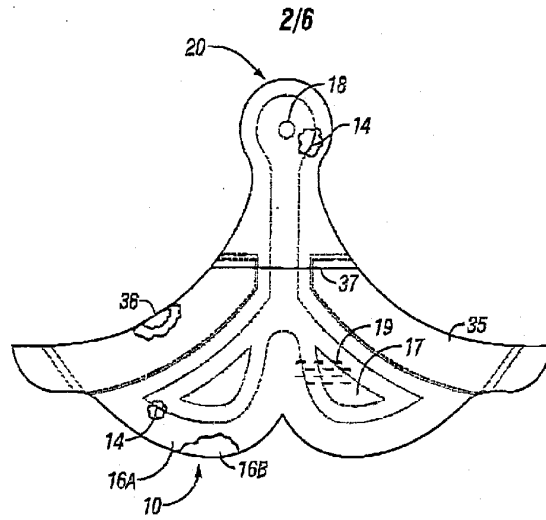


FIG. 1B

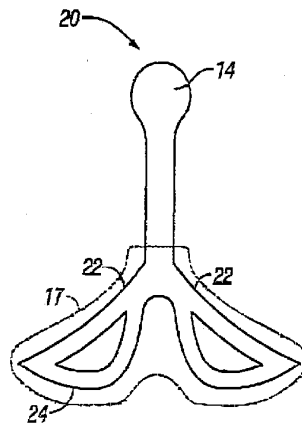


FIG. 2

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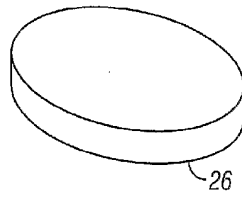


FIG. 3A



FIG. 3B

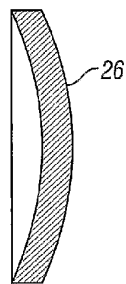


FIG. 3C

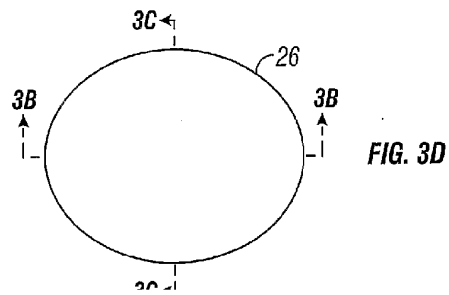


FIG. 3D

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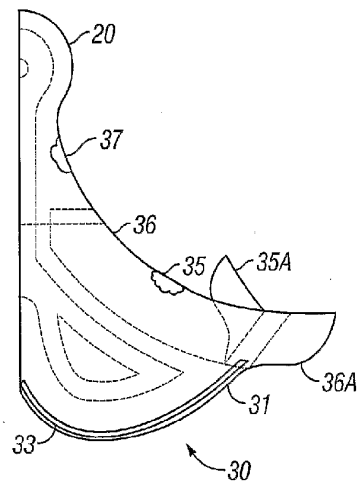


FIG. 5

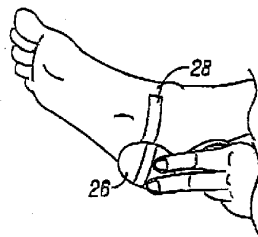


FIG. 4A

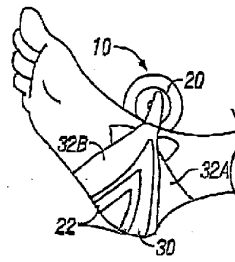


FIG. 4B

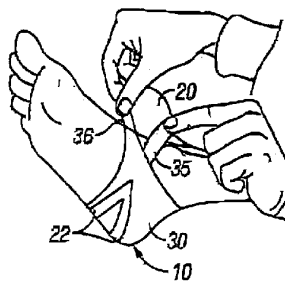


FIG. 4C

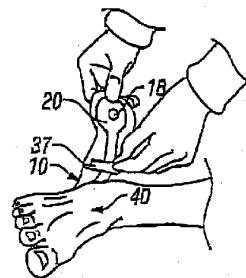


FIG. 4D

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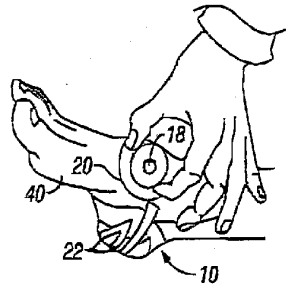


FIG. 4E

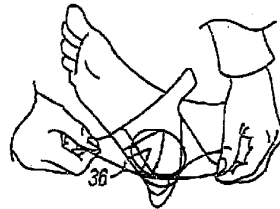


FIG. 4F

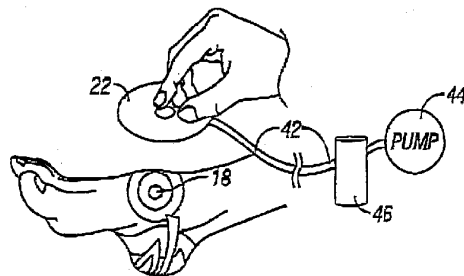


FIG. 4G

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