Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2396218 C 2009/01/27

(11)(21) 2 396 218

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2001/01/03
(87) Date publication PCT/PCT Publication Date: 2001/07/12
(45) Date de délivrance/Issue Date: 2009/01/27
(85) Entrée phase nationale/National Entry: 2002/07/03
(86) N° demande PCT/PCT Application No.: US 2001/000130
(87) N° publication PCT/PCT Publication No.: 2001/049228
(30) Priorité/Priority: 2000/01/03 (US60/174,477)

(51) Cl.Int./Int.Cl. *A61F 13/00* (2006.01), *A61F 13/02* (2006.01), *A61L 15/22* (2006.01)

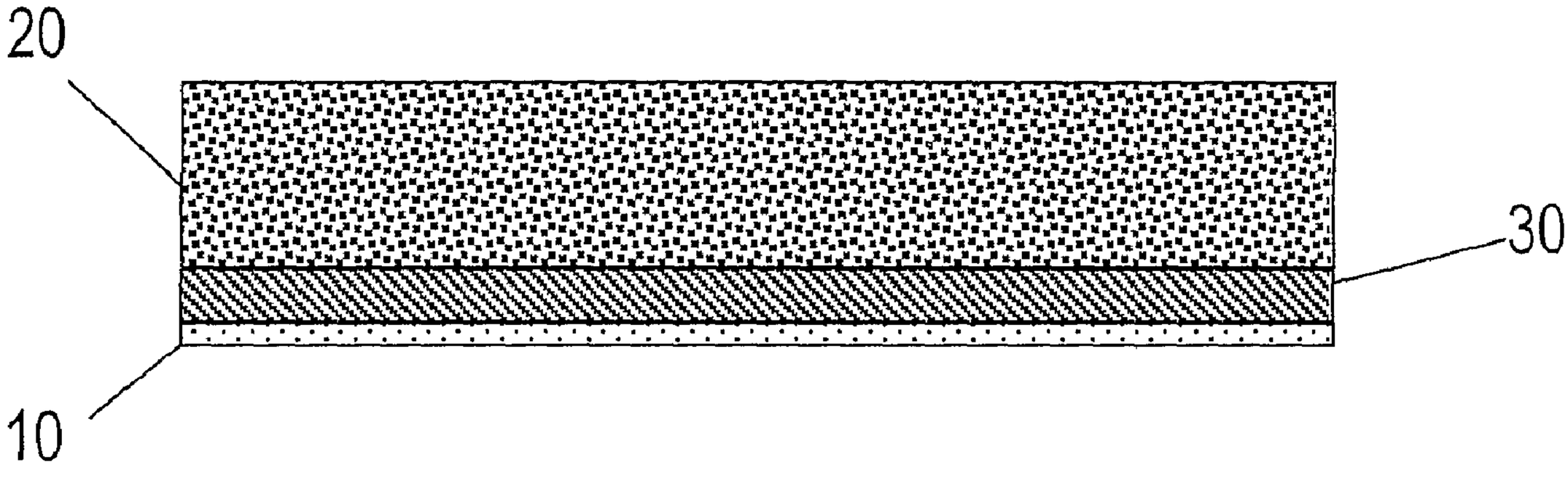
(72) Inventeur/Inventor:
DILLON, MARK E., US

(73) Propriétaire/Owner:
BIOMED SCIENCES, INC., US

(74) Agent: SMART & BIGGAR

(54) Titre : NOUVELLE MATIERE DE PANSEMENT, SON PROCEDE DE FABRICATION ET ARTICLES UTILES PRODUITS A PARTIR DE LADITE MATIERE DE PANSEMENT

(54) Title: NOVEL WOUND DRESSING, PROCESS OF MANUFACTURE AND USEFUL ARTICLES THEREOF



(57) Abrégé/Abstract:
A wound dressing is provided that serves unique dual-purpose role. One surface of the dressing is comprised of a polyurethane foam (20) and the other surface is comprised of a non-adherent thin-film (30) of polydimethylsiloxane and polytetrafluoroethylene interpenetrating polymer networks ("IPN"). With the foam side of the dressing down against the wound, the product provides an adhesive surface for difficult fixation conditions. With the IPN side of the dressing against the wound, the dressing provides non-adherent covering for fragile and sensitive wounds.

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

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 July 2001 (12.07.2001)

PCT

(10) International Publication Number
WO 01/49228 A1

(51) International Patent Classification[7]: A61F 13/00

(21) International Application Number: PCT/US01/00130

(22) International Filing Date: 3 January 2001 (03.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/174,477 3 January 2000 (03.01.2000) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 09/754,010 (CON)
Filed on 3 January 2001 (03.01.2001)

(71) Applicant *(for all designated States except US)*: **BIOMED SCIENCES, INC.** [US/US]; 1111 Hamilton Street, Allentown, PA 18101 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **DILLON, Mark, E.** [US/US]; 6448 Sauerkraut Lane, Menungie, PA 18062 (US).

(74) Agents: **EARLEY, John, F., A.** et al.; Harding, Earley, Follmer & Frailey, 86 The Commons at Valley Forge East, 1288 Valley Forge Road, P.O. Box 750, Valley Forge, PA 19482 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

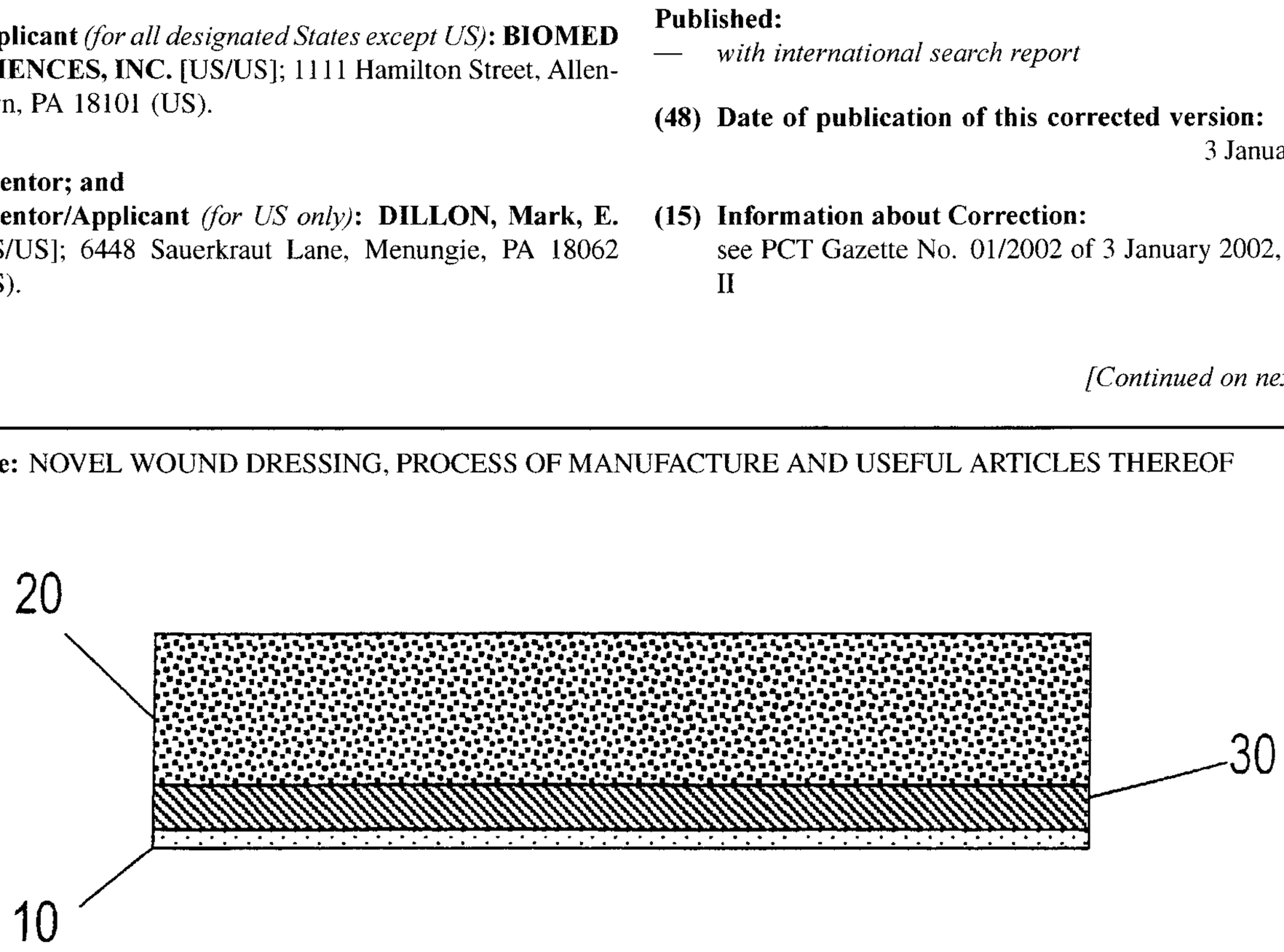
Published:
— *with international search report*

(48) Date of publication of this corrected version:
3 January 2002

(15) Information about Correction:
see PCT Gazette No. 01/2002 of 3 January 2002, Section II

[Continued on next page]

(54) Title: NOVEL WOUND DRESSING, PROCESS OF MANUFACTURE AND USEFUL ARTICLES THEREOF



(57) Abstract: A wound dressing is provided that serves unique dual-purpose role. One surface of the dressing is comprised of a polyurethane foam (20) and the other surface is comprised of a non-adherent thin-film (30) of polydimethylsiloxane and polytetrafluoroethylene interpenetrating polymer networks ("IPN"). With the foam side of the dressing down against the wound, the product provides an adhesive surface for difficult fixation conditions. With the IPN side of the dressing against the wound, the dressing provides non-adherent covering for fragile and sensitive wounds.

WO 01/49228 A1

WO 01/49228 A1

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.

NOVEL WOUND DRESSING, PROCESS OF MANUFACTURE AND USEFUL ARTICLES THEREOF

BACKGROUND OF THE INVENTION

1. Field of the Invention This invention relates to a novel wound dressing design. Particularly, this invention relates to a wound dressing which incorporates two distinct layers, each providing useful features and together providing a novel method of managing a variety of wound types. Ease of use, patient comfort and the cost of care are improved.

2. Description of the Prior Art

In the field of woundcare there exist several general categories of commonly used dressings. Some dressings aggressively adhere to the wound surface. For example, conventional gauze integrates into the wound as healing occurs and eschar forms on the wound surface. Other types of dressings are designed to adhere to the surrounding intact tissue around the wound site, but not

directly to the wound. Examples of this type of dressing include polyurethane films coated with pressure sensitive adhesive. Other types of dressings are designed to be substantially nonadherent. Examples of this type include polyethylene oxide hydrogels, and particularly the material described in U.S. Patent number 4,832,009. The latter example is a dressing made from an interpenetrating polymer network ("IPN") of polytetrafluoroethylene and silicone, and is presently marketed by Bio Med Sciences, Inc. of Allentown, PA as Silon-TSR® Temporary Skin Replacement. Each type of dressing has its advantages and disadvantages, and is indicated for certain wound conditions and user preferences.

There are a wide variety of wound types. Wounds can be categorized as chronic or acute. Examples of chronic wounds include venous stasis ulcers, decubitus ulcers and diabetic ulcers. Examples of acute wounds include burns, skin graft donor sites, skin graft recipient sites, abrasions and the like. The features required for the proper performance of a wound dressing depend on the wound type as well as the location of the wound on the body. For example, non-adherent films minimize disruption of fragile skin during dressing changes, but are not always applicable because of difficulties in

keeping the dressing in position. This is particularly a challenge for skin graft donor sites on the back or buttocks of a patient, where ordinary movement and contact with bedding can easily dislodge the dressing. As a result, adhesive dressings are typically used for this type of wound. An additional example includes the use of absorbent dressings on chronic wounds. Chronic wounds tend to produce copious amounts of exudate which makes the use of thin film dressings difficult since these dressings are generally poor at managing wound fluid.

Even the same wound may require different dressings at different stages of the healing process. A venous stasis ulcer will produce copious amounts of exudate in the early stages of healing. Hydrocolloid dressings are often used on these wounds because of their high absorption capabilities. But as a wound of this type heals, the fragile epithelium can easily be damaged during dressing changes, so a non-adherent dressing may be substituted later in the healing process even if it is not as absorbent.

Bio Med Sciences, Inc. manufactures a thin-film non-adherent dressing made from an interpenetrating polymer network ("IPN") of polytetrafluoroethylene and silicone (Silon-TSR®). The IPN film is flexible and thin (50

microns), thereby providing transparency and good conformity to wound contours. Small fenestrations are cut through the film so that wound fluid can wick away from the wound surface and be collected in a secondary dressing such as gauze. The outer gauze may be changed as required, but the IPN dressing may be left in place until the wound heals or for up to 10 days.

The IPN dressing is well-suited for applications such as laser resurfacing, which is a cosmetic surgery procedure almost exclusively performed on the face. The product's non-adherent and transparent properties provide clinical advantages during the healing process. This product, however, does not perform as well on certain other types of wounds, such as skin graft donor sites and many types of chronic wounds. The non-adherent character of the product is problematic for application on any part of the body where shear forces, such as contact with bedding or other surfaces, may cause the dressing to roll-up or slide off of the wound. This difficulty is particularly acute on lower limbs where the general shape tends to be somewhat conical thereby causing the dressing to slide distally.

The IPN dressing manufactured by Bio Med Sciences, Inc. provides desirable properties with respect to a conformable non-adherent surface for wound coverage.

These features, however, have proved to be problematic with respect to maintaining wound coverage and avoiding dressing roll-up and slippage.

SUMMARY OF THE INVENTION

In an effort to mitigate said problematic characteristics, I have unexpectedly created a dressing with a unique dual-purpose design.

The new dressing comprises a thin layer (50 microns) of the IPN material laminated to a polyurethane foam of approximately 1,500 microns in thickness. This construction has the effect of providing a greater cross-sectional thickness, which tends to be more resistant to roll-up, wrinkling and slippage.

By applying the dressing to the wound site with the IPN surface against the wound surface, the non-adherent advantages of the IPN material are preserved. At the same time, however, the foam layer minimizes any tendency for the dressing to slip, roll-up or wrinkle. Fenestrations are still cut through the IPN material and the foam passes wound exudate through to a secondary dressing.

Unexpectedly, I have discovered that the dressing of this invention is also useful for woundcare when used "up-side-down" with the foam layer against the wound instead of the IPN layer. This serves to provide a

dressing with a higher level of surface adhesion but otherwise similar features. Wound fluid is still wicked from the wound surface to a secondary dressing and slippage or roll-up are still minimized.

An embodiment of this invention provides a single dressing that can offer disparate wound healing features depending on its orientation on the wound surface. This is useful for broadening the range of clinical applications for which either the IPN material or the foam layer could be used individually. This is true for different clinical cases or for the same case at different stages of the healing process.

While the two opposite approaches to wound healing (adhesive/non-adhesive) are commonly found in the field, no product combines these two features in a single dressing by means of simply using it one side up or the other. This provides great utility in the field where the number of products stocked is always minimized to reduce inventory costs. In addition, cost effectiveness is promoted due to consolidated manufacturing and distribution operations. Most importantly, this invention provides a unique dual-purpose dressing for a wide variety of wound types.

According to one particular aspect of the invention, there is provided a dual-purpose wound dressing capable of providing disparate wound healing characteristics to a wound depending on which side of the wound dressing contacts the wound, comprising a multilayered composite structure, the multilayered composite structure having a first wound contacting side having an outer wound contacting surface that has wound healing characteristics and a second wound contacting side having an outer wound contacting

surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure, the multilayered structure including a first layer forming the first wound contacting side of the composite structure, the first layer being a membrane layer, and a second layer forming the second wound contacting side of the composite structure, the second layer being a foam layer.

A use of such a wound dressing is also provided.

A further aspect of the invention provides a method of manufacturing a dual-purpose wound dressing capable of providing disparate wound healing characteristics to a wound depending on which side of the wound dressing contacts the wound, comprising (1) producing a thin film membrane layer, (2) passing said thin film membrane layer through a coating assembly and depositing a layer of an adhesive substance, and (3) causing a foam material to make intimate contact with said adhesive substance to form a multilayered composite wound dressing having a first wound contacting side and a second wound contacting side, the first wound contacting side of the multilayered wound dressing being formed by the thin film membrane layer and the second wound contacting side of the multilayered wound dressing being formed by the foam material.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a cross-sectional view of a preferred embodiment of this invention. The IPN material 10 is bonded to a foam layer 20 by means of silicone elastomer 30.

Figure 2 shows a plan view of a dressing 40 cut from the material of this invention. Fenestrations 50 are cut through the IPN film to provide a means for managing wound exudate.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Turning to the drawings, there is shown the inventive new dressing which comprises a thin layer (50 microns) of IPN material 10 laminated to a polyurethane foam 20 of approximately 1,500 microns in thickness. Preferably, a silicone elastomer 30 is used to bond the IPN material 10 to the polyurethane foam 20. Fenestrations 50 are cut through the IPN film to provide a means for managing wound exudate.

The following examples are not intended to be limiting, as minor variations on these designs and processes would be obvious to those skilled in the art. Likewise, it is believed that other materials could be used to achieve the same dressing design.

Example 1:

A continuous sheet of polydimethylsiloxane and polytetrafluoroethylene IPN was manufactured according to established methods. The film measured approximately 50 microns in thickness. The IPN film was then passed through a knife-over-roll assembly and coated with approximately 200 microns of liquid silicone rubber MDX4-4210 from Dow Corning Corporation of Midland, MI. Soon after the silicone rubber was applied to the IPN material, an open-cell hydrophilic foam (Amrel® Medical Foam from Rynel Limited, Inc. of Boothbay, ME) was laid onto the uncured silicone rubber and the laminate was passed through a tunnel style oven at approximately 150°C for approximately 6 minutes. The resultant material was then fed through a rotary die-cutting apparatus to cut individual dressings from the sheet and to create fenestrations in the IPN film.

Example 2:

The process of Example 1 was repeated with a pigment added to the liquid silicone rubber prior to the lamination process. A blue silicone-based ink (product code R1008-7 from Nusil Technology of Carpinteria, CA) was mixed into the MDX4-4210 at a concentration of 4 percent by weight. Since the IPN material is transparent and the foam is opaque, the blue pigment imparted a soft blue coloration to one side of the dressing. This serves as a visual indicator for differentiating one side of the dressing from the other in the field.

63129-118

CLAIMS:

1. A dual-purpose wound dressing capable of providing disparate wound healing characteristics to a wound depending on which side of the wound dressing contacts the wound, comprising

a multilayered composite structure, the multilayered composite structure having a first wound contacting side having an outer wound contacting surface that has wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure, the multilayered structure including

a first layer forming the first wound contacting side of the composite structure, the first layer being a membrane layer, and

a second layer forming the second wound contacting side of the composite structure, the second layer being a foam layer.

2. The wound dressing of claim 1, further comprising an adhesive layer for joining the first and second layers together.

3. The wound dressing of claim 1 or claim 2, wherein the foam layer comprises a polyurethane material.

4. The wound dressing of any one of claims 1-3, wherein the membrane layer comprises a silicone-containing compound.

5. The wound dressing of claim 2, wherein the adhesive layer comprises a silicone compound.

6. The wound dressing of any one of claims 1-5, wherein the first layer comprises an interpenetrating polymer network of polytetrafluoroethylene and silicone.

7. The wound dressing of any one of claims 1-6, further comprising a pigment for imparting a discernable color to one side of the composite structure.

8. The wound dressing of claim 1, further comprising an adhesive layer for joining the first and second layers together, the first layer being substantially transparent, the second layer being substantially opaque, and the adhesive layer containing a pigment for imparting a discernable color to the first layer of the wound dressing.

9. The wound dressing of any one of claims 1-8, further including fenestrations formed in the first layer.

10. The wound dressing of any one of claims 2, 5 and 8, the adhesive layer being a silicone elastomer.

11. The wound dressing of any one of claims 1-10, the first layer being about 50 microns thick and the second layer being about 1500 microns thick.

12. The wound dressing of any one of claims 1-11, the wound dressing having a cross-section of such thickness as to be resistant to roll-up, wrinkling and slippage.

13. Use of the wound dressing of any one of claims 1-12 for management of any of a variety of wound types.

14. A method of manufacturing a dual-purpose wound dressing capable of providing disparate wound healing characteristics to a wound depending on which side of the wound dressing contacts the wound, comprising (1) producing a thin film membrane layer, (2) passing said thin film membrane layer through a coating assembly and depositing a layer of an adhesive substance, and (3) causing a foam material to make intimate contact with said adhesive substance to form a multilayered composite wound dressing having a first wound contacting side and a second wound contacting side, the first wound contacting side of the multilayered wound dressing being formed by the thin film membrane layer and the second wound contacting side of the multilayered wound dressing being formed by the foam material.

15. The method of claim 14, further including cutting the wound dressing into smaller sized wound dressings.

16. The method of claim 14 or 15, further including creating fenestrations in the membrane layer.

17. The method of any one of claims 14-16, the adhesive substance having a pigment mixed therein.

SMART & BIGGAR

OTTAWA, CANADA

PATENT AGENTS

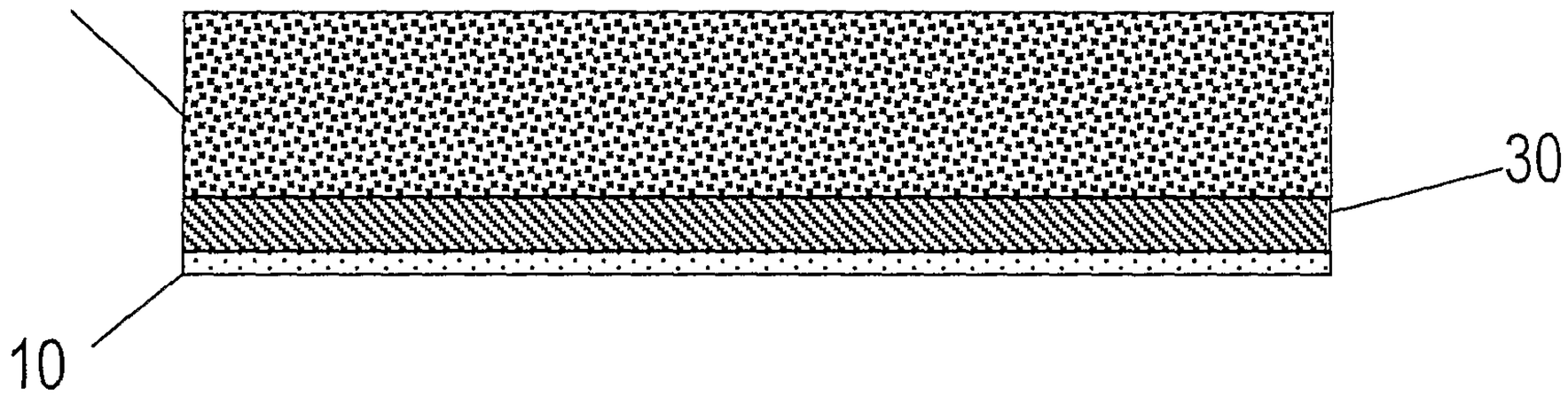


Figure 1

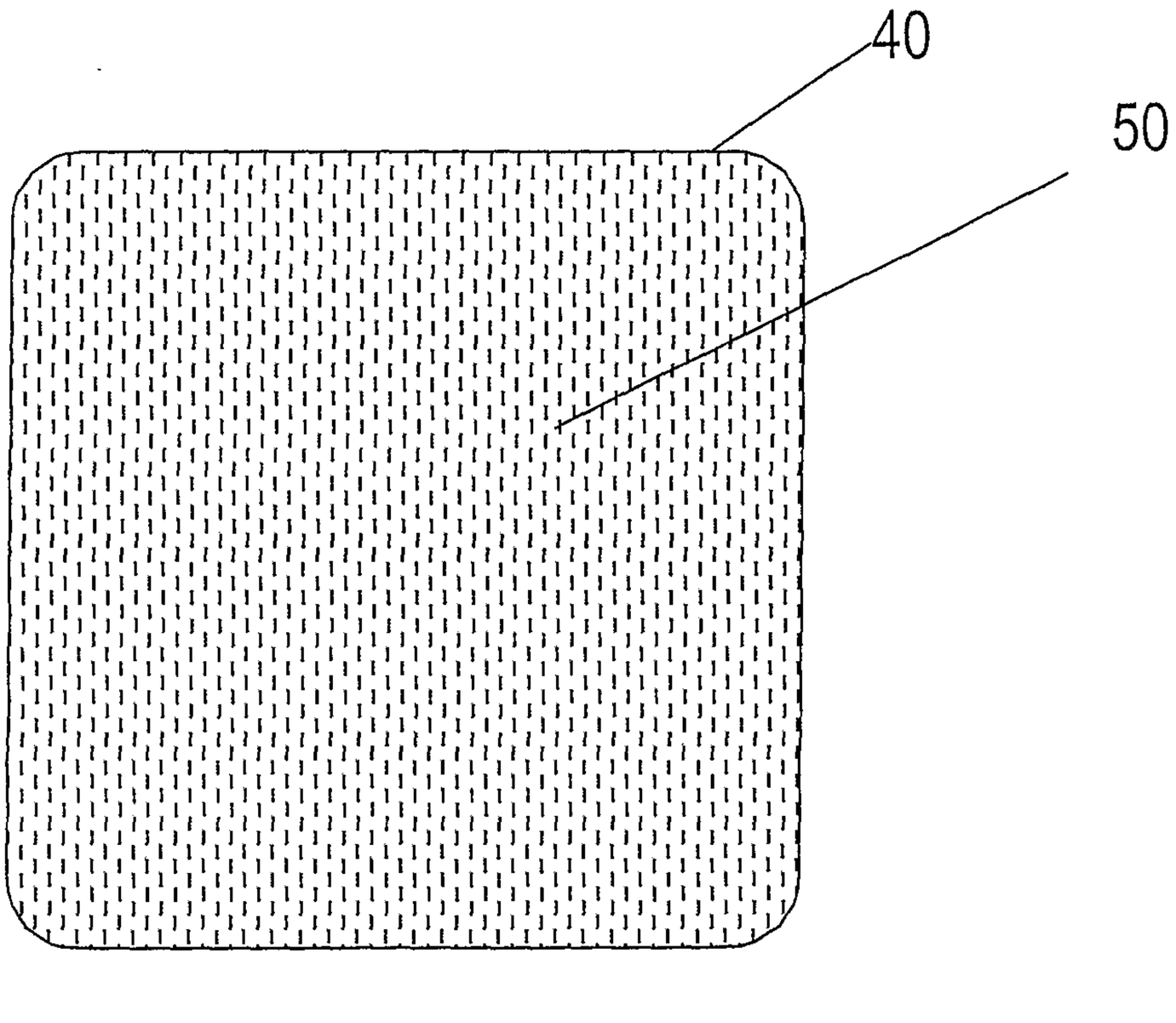
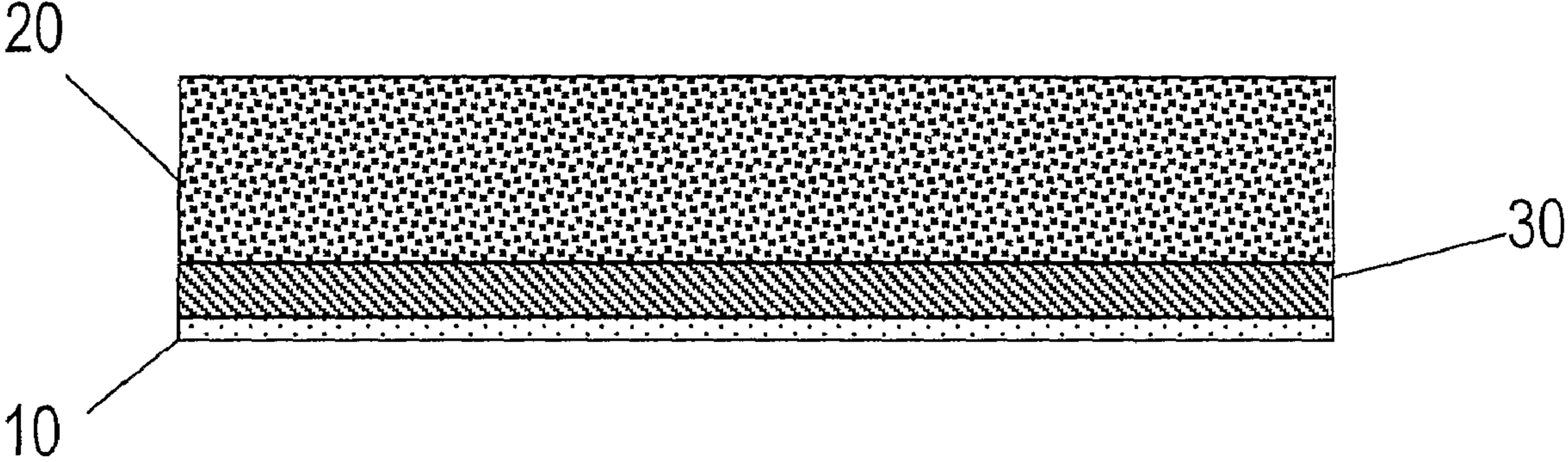


Figure 2


20
30
10