

ESCORRER-URIBE ASOCIADOS
Intellectual Property

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Ac. 05-105909-00006-0000

25 NUCREAZIONE
26 DEPOSITO


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T.P. 68.228

99

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 05-108999-00006-0000

Fecha 2007-10-19 17:00:25 Dep. 2020 NUECREACION
IVA 2 PATENTES Ene: 1 REGDEPOSITO
Ar Solos 8

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 07 - B4,111
FECHA : OCTUBRE 11 DE 2007

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Gr. PAGO
CLARKE MOBY Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	63071675	11/10/2007	27,420,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-04	PRESENTACION DE OBSERVACIONES	
12		MARCAS Y LEMAS COMERCIALES	256,000.00
		TOTAL :	\$ 256,000.00

SON: DOSCIENTOS CINCUENTA Y SEIS MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

2

2896

NO. 15-2000-1008-0000

NIT : 800176089-2

CONSIGNACION

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SOLR: SETENTA Y DOS MIL PESOS

RESPONSABLE : _____

101

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 07 - 81,201
FECHA : OCTUBRE 2 DE 2007

==== CONSIGNACION ====

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMBIA	CONSIGNACION	BANCO POPULAR	030-00110-6	66408802	02/10/2007	18,573,000.00

==== CONCEPTO ====

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-08	PRORROGA DE TERMINOS	72.000.00
		31 PRORROGA DE TERMINOS	72.000.00
		TOTAL :	\$ 72,000.00

SON: SETENTA Y DOS MIL PESOS



RESPONSABLE : _____

4

2896.

ESTA CERTIFICACION DE EXCEDENTE DE PAGO SÓLO PODRÁ SER UTILIZADA
COMO PARTE DE LA CANCELACION DE UNA TARIFA VIGENTE Y NO PODRÁ SER
SUSTITUIDA POR NINGUN RECIBO.

102 p2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

CERTIFICACION DE EXCEDENTE : 07 - 76,558
FECHA : SEPTIEMBRE 21 DE 2007

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	71028042	21/09/2007	10,244,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09	OTROS SERVICIOS DE PROPIEDAD I	
		99 OTROS SERVICIOS ADMINISTRATIVOS	1,000.00
		TOTAL :	\$ 1,000.00

SON: MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

5
2896

ESTA CERTIFICACION DE EXCEDENTE DE PAGO SOLO PODRA SER UTILIZADA
COMO PARTE DE LA CANCELACION DE UNA TARIFA VIGENTE Y NO PODRA SER
SUSTITUIDA POR NINGUN RECIBO.

105 103

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECORRIDO
CORRELACION
POSITO

CERTIFICACION DE EXCEDENTE : 07 - 76,557
FECHA : SEPTIEMBRE 21 DE 2007

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
CLARKE MODET Y CO. COLOMBIA	CONSIGNACION	BANCO POPULAR	050-00110-6	71928042	21/09/2007	10,244,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09	OTROS SERVICIOS DE PROPIEDAD I	
		99 OTROS SERVICIOS ADMINISTRATIVOS	1,000.00
		TOTAL :	\$ 1,000.00

SON: MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

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2896

ESTA CERTIFICACION DE EXCEDENTE DE PAGO SÓLO PODRÁ SER UTILIZADA
COMO PARTE DE LA CANCELACION DE UNA TARIFA VIGENTE Y NO PODRÁ SER
SUSTITUIDA POR NINGUN RECIBO.

109
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

CERTIFICACION DE EXCEDENTE : 07 - 76,556
FECHA : SEPTIEMBRE 21 DE 2007

No. 05-103899-00006-0000
Dep. 2020 NUSCRLACIONE
EX-1 REGDEPOSITO
Folios: 8

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CA. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	71928042	21/09/2007	10,244,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09	OTROS SERVICIOS DE PROPIEDAD 1	
		99 OTROS SERVICIOS ADMINISTRATIVOS	1,000.00
		TOTAL :	\$ 1,000.00

SON: MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

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2896

ESTA CERTIFICACION DE EXCEDENTE DE PAGO SOLO PODRA SER UTILIZADA
COMO PARTE DE LA CANCELACION DE UNA TARIFA VIGENTE Y NO PODRA SER
SUSTITUIDA POR NINGUN RECIBO,

105 105

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

CERTIFICACION DE EXCEDENTE : 07 - 76,555
FECHA : SEPTIEMBRE 21 DE 2007

RECIBO DE PAGO
2020 NUECREACION
REGDEPOSITO
COLOMBIA

**** CONSIGNACION ****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CG. COLOMBIA	CONSIGNACION	BANCO POPULAR	050-00110-6	7102B042	21/09/2007	10,244,000.00

**** CONCEPTO ****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09	OTROS SERVICIOS DE PROPIEDAD	1,000.00
		99 OTROS SERVICIOS ADMINISTRATIVOS	1,000.00
		TOTAL :	\$ 1,000.00

SON: MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

2896

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. **05-108999**

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **575** DE

FECHA **30 DE ABRIL DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA LEY

EXPIRA EL **31 DE JULIO DE 2007**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X

[54] HYDROGEL WOUND DRESSING PRODUCT

[75] Inventors: James V. Carmell; Wayne E. Starnes, both of Cincinnati, Ohio;
Mamuel Velazquez, Castaic, Calif.;
Michael L. Wolf, West Milton, Ohio

[73] Assignee: NDM Acquisition Corp.,
Muncie, Ind.

[21] Appl. No.: 430,188

[22] Filed: Nov. 1, 1989

[51] Int. Cl.: A61F 13/00

[52] U.S. Cl.: 424/443; 128/156;
524/310

[58] Field of Search: 424/28, 132, 443;
260/29.2; 128/156, 132 D; 524/310

[56] References Cited

U.S. PATENT DOCUMENTS

3,526,224	6/1967	Pain	128/155
3,543,750	1/1968	McIntosh	128/155
3,579,028	5/1971	Gander et al.	424/443
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4,236,232	10/1980	Spencer	128/153
4,393,048	7/1981	Mason, Jr. et al.	414/132
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4,657,006	4/1987	Rawlings et al.	128/156
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4,599,244 3/1986 Quarlott et al. 128/156

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146903	3/1986	European Pat. Off.
2347299	4/1975	Fed. Rep. of Germany
2801877	3/1988	PCT Int. Appl.
2331448	6/1989	United Kingdom

OTHER PUBLICATIONS

Smith & Nephew advertisement describing Flexigrid Application System, copyright 1990.
Smith & Nephew Abstract of lecture presented at Advanced Wound Care Symposium, Mar. 12, 1990.

Primary Examiner—Thurman K. Page
Assistant Examiner—William E. Beaton, Sr.
Attorney, Agent, or Firm—Kilworth, Gortman, Hagan & Schaeff

[57] ABSTRACT

A wound dressing product is described which includes a flexible backing member that can be vacuum formed to include a depression. A pressure-sensitive adhesive layer extends across the depression side of the flexible backing member. A hydrogel material is positioned in the depression of the flexible backing member and a release liner extends over the exposed pressure-sensitive adhesive layer and the exposed hydrogel material, which release liner has a selective releasability whereby it can be removed from the wound dressing product intact, leaving a portion of the pressure-sensitive adhesive and the hydrogel material exposed.

6 Claims, 2 Drawing Sheets

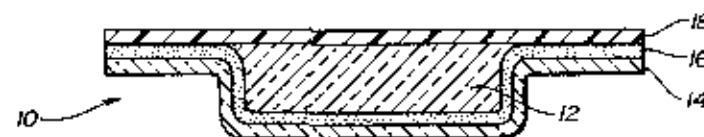


FIG-2

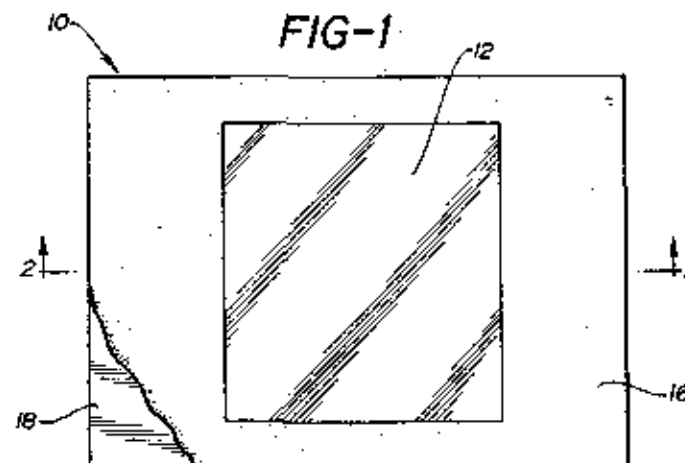


FIG-3

FIG-4

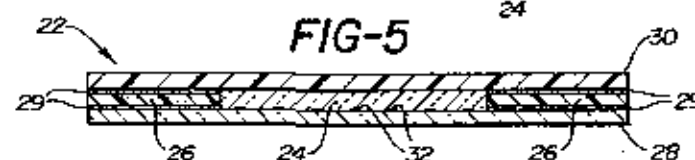
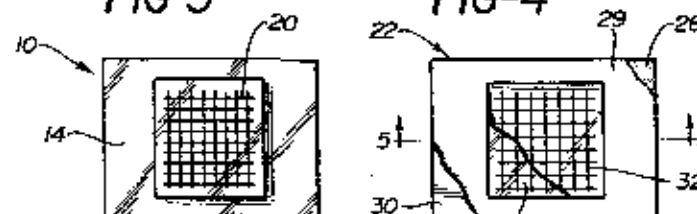


FIG-5

HYDROGEL WOUND DRESSING PRODUCT

BACKGROUND OF THE INVENTION

This invention relates to wound dressings and, more particularly, to a flexible wound dressing product comprising a hydrogel substance. The wound dressing product conforms to a wound site while maintaining the wound in a moist state.

Managing draining wounds such as decubitus ulcers has presented a difficult problem of treatment for the medical profession. The accumulation of wound exudate, such as blood, serum and pus, in the wound cavity of a wound can lead to bacterial growth which can delay healing of the wound. However, it has been difficult to maintain the wounds free of wound excretion to permit them to heal. Conversely, it is often desirable to allow a wound to heal in a slightly moist state as it is believed that this may expedite healing.

Currently, there are several absorbent compression dressings which are comprised of hydrogel materials in powder form. Generally, such dry, powdery hydrogel materials are introduced to an open, draining wound to absorb the exudate from the wound. One such commercially available method of treatment employing dry hydrogel material is the use of Debramaster bands. Debramaster bands are highly hydrophilic and compressible sponges which can be introduced to a wound site to absorb the wound exudate. A drawback of such hydrogel material is that the dry material is forced to clump and form lumps prior to and during introduction of the material to the wound site. The clumping or lumping can also occur after introduction of the material to the wound site and as it absorbs the wound exudate. The lumps or granules are difficult to apply evenly to the wound and, subsequently, are difficult to remove from the wound site without damaging the new tissue that forms at the wound site.

U.S. Pat. No. 4,124,232, issued to Spence on Oct. 7, 1978, teaches the blending of a hydrogel material with a liquid curing agent, such as a polyethylene glycol prior to introducing the gel-like or rubber-like material to a wound. Again, there are drawbacks with such a system, as the system cannot be sterilized by irradiation due to the formation of free radicals within the gel material.

A need has arisen for a wound dressing which can provide a protective covering to the wound while being able to absorb the exudate from the wound. It would be desirable to have a wound dressing which could provide a protective pad over the wound to prevent debris and foreign matter from contaminating the wound and which could cushion the wound against pressure. It would be desirable to have a wound dressing which would not adhere to the new tissue forming in the wound or the exudate being released by the wound. It would be desirable to have a wound dressing which would be transparent to enable observation of the healing process of the wound, but which would shield the wound against bacteria to inhibit infection. It would also be desirable to have a wound dressing which, through selecting a carrier film could either permit moisture so that the wound environment is stabilized with respect to moisture pressure or occlude moisture transfer.

It would also be desirable to provide a wound dressing which could be pre-cut, sterilized, and readily available for application to a draining wound. Such a wound dressing could be readily applied by an attendant without

the need for mixing and applying a paste or gel to an open wound. Such a wound dressing system could save time and expense and insure a uniform, consistent coating. It would further be desirable to have such a wound dressing which could be radiation sterilized as current sterilization techniques are slowing under more and more restrictions and closer scrutiny for environmental reasons.

SUMMARY OF THE INVENTION

The invention herein is directed to a wound dressing which can be manufactured to any desirable size to provide a dressing for any size open, draining wound. The invention herein is directed to a wound dressing which will absorb the exudate from the wound but which will not adhere to the wound. Thus, when it is removed from the wound it will not damage the wound. The wound dressing provides a clear, wet wound dressing which allows visual inspection of the wound without having to remove the dressing.

In particular, the present invention includes a method of treating wounds comprising the step of applying a substantially transparent hydrogel material to a wound site, the hydrogel material comprising from about 15% to about 30% by weight of a polyethylene glycol selected from the group consisting of polyethylene glycol, polyethylene glycol and glycerine, from about 3% to about 14% by weight of an isopropyl alcohol, from about 5% to about 10% by weight of a polyethylene oxide based adhesive, up to about 1% by weight of a salt such as sodium chloride, and the balance water.

In a preferred embodiment of the present invention, the hydrogel composition comprises 15% by weight of the polyethylene glycol, 12% by weight of the isopropyl alcohol, 10% by weight of the polyethylene glycol, 5% by weight of the polyethylene oxide based adhesive, 1% by weight of the salt, and the balance water.

The present invention also discloses a wound dressing product for application to a wound site. The wound dressing product comprises a flexible backing member having a first side and a second side and further having a vacuum formed center portion to define a depression at the first side, a pressure-sensitive adhesive layer extending across the first side of the flexible backing member, a hydrogel material located in the depression of the flexible backing member, and a release liner extending over the exposed pressure-sensitive adhesive layer and the exposed hydrogel material.

A release liner extends over the exposed pressure-sensitive adhesive layer and the exposed hydrogel. The release liner has a selective releasability such that it can be removed from the wound dressing to expose the pressure-sensitive adhesive and the hydrogel. The pressure-sensitive adhesive is exposed along an area which forms a perimeter surrounding the hydrogel.

In a preferred embodiment of the present invention, the flexible backing member comprises a polyurethane film and the pressure-sensitive adhesive comprises an acrylic-based adhesive. Additionally, the wound dressing product further comprises a printed wound size on the flexible backing member overlying the hydrogel material.

Another embodiment of the present invention also discloses a similar wound dressing product. This similar wound dressing product comprises a flexible backing sheet, a perimeter-defining, draining layer on the flex-

FIG-6

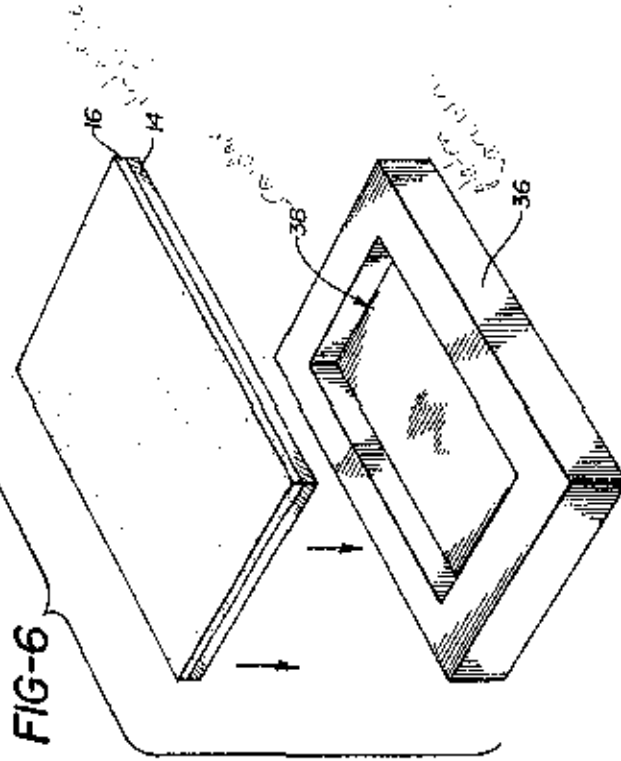
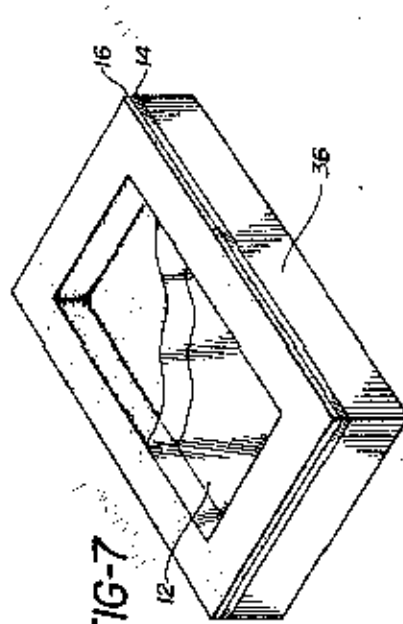


FIG-7



materials described with regard to their embodiment.

The structure for the wound dressing product shown in FIG. 4 is shown in the cross-sectional view of FIG. 5.

With regard to FIGS. 4 and 5, the hydrogel layer 24 is maintained in place on the flexible backing sheet 20 by a pressure-defining damping layer, such as a foam dam 26 which overlies the hydrogel layer 24. The foam dam 26 has a sufficient height to support the hydrogel layer 24 when the hydrogel material is deposited on the flexible backing member 20. The foam dam 26 may be constructed of any suitable material which will be compatible with the body. A preferred material is polyethylene foam. The foam dam 26 may be coated on both of its surfaces with a suitable adhesive 28. The adhesive coated on the initial side may be different than the adhesive on the flexible backing sheet side.

Thus, the adhesive properties for adhering the foam dam 26 to the flexible backing sheet may be different than those for adhering the foam dam 26 to a patient's skin. A release liner 30 may be coated over the exposed hydrogel and foam dam 26 member.

For adhering the wound dressing product 22 to a patient, the foam dam member 26 may be coated with a pressure-sensitive adhesive on its surface facing the release liner 30. The pressure-sensitive adhesive may be applied to the embodiment in FIGS. 1 and 2. The hydrogel material also may act as an adhesive to aid in adhering the wound dressing product 22 to a patient.

The release liner 30 may be any suitable material having release properties for selectively being released from the hydrogel and foam dam without destroying the integrity of the hydrogel or foam dam. As shown in FIG. 4, the flexible backing may be impregnated with a release liner 32. As with the member embodiment, the hydrogel material 24 in the embodiment shown in FIGS. 4 and 5 is a clear hydrogel material which will permit viewing of the wound underneath the hydrogel material 24 when the wound dressing product 22 is in place. The grid or printed wound size 32 permits observation of the wound and monitoring of the changes in size of the wound.

The hydrogel wound dressing product herein provides a benefit not currently realizable in state-of-the-art wound dressings. The hydrogel material is capable of absorbing wound exudate. The hydrogel material is clear and can permit visual observation of the wound.

The hydrogel material retains its integrity such that upon removal of the wound dressing, no gel or wound debris is left in the wound. The hydrogel material has physical properties which permit it to be non-irritatingly removed from a wound. The hydrogel material also conducts the wound against pressure which can be exerted on the outer surface of the wound dressing when the wound dressing is worn by the patient. The hydrogel material herein is also advantageous in that it permits extended wearing of the dressing to a patient due to the vapor absorption that is provided by hydrogel material. The hydrogel material of the present invention has a salt content approximating that of the human body, and this may enhance its ability for extended wearing.

The hydrogel herein is particularly suited for use as part of a wound dressing product. The hydrogel is a water hydrogel, containing more than 30% by weight of water, and is capable of providing some adhesion to the wound dressing product. However, the adhesive property of the hydrogel is not such that it will damage

cell or tissue growth adequately, upon removal of the wound dressing product from the wound. Thus, the hydrogel provides an adhesive tenacity to aid in adhering the wound dressing product to the patient and wound site. The hydrogel exhibits a high degree of fluid absorption and can thereby absorb a sufficiently large quantity of wound exudate.

Another advantage of the hydrogel material herein is that it retains its gel-like integrity even upon removal of the wound dressing product from a wound site. The hydrogel does not leave debris, such as hydrogel particles, in the wound upon removal. The hydrogel material herein exhibits a capability of non-instrumentally releasing from the wound when the wound dressing product is removed from the wound. This non-instrumental release of the hydrogel wound dressing product from the wound does not destroy the new cell tissue forming at the wound site and thereby wound healing is not inhibited when the dressing is removed. The hydrogel material also provides a protective cushioning of the wound due to its gel-like consistency.

A further advantage of the hydrogel herein is its ability to absorb water. It can remain on a wound for relatively long periods of time and, therefore, does not need to be removed frequently. Finally, a special advantage of the hydrogel material herein is that the hydrogel material is not only translucent but also transparent. The hydrogel material is sufficiently clear such that visual inspection of the wound can be performed without having to remove the wound dressing product. Although the hydrogel material does not deleteriously affect the wound when it is removed, it is still highly desirable to avoid removing dressings from a wound site as removal can provide an opportunity for the ingress of bacteria to the wound from the surrounding environment.

Having described the invention in detail and by reference to preferred embodiments thereof, it will be apparent that modifications and variations are possible without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. A wound dressing product comprising:

a flexible backing member having a first side and a second side and further having a depression on said first side;

a pressure-sensitive adhesive layer extending across said first side of said flexible backing member;

a hydrogel material located in said depression of said flexible backing member, said hydrogel material comprising from about 15% to about 30% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of an amphoteric diacyanate cross-linked prepolymer, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water; and

a release liner extending over said exposed pressure-sensitive adhesive layer and said exposed hydrogel material.

2. A wound dressing product comprising:

a flexible backing sheet;

a pressure-defining damping layer on the flexible backing member having a central cavity; and

a hydrogel material comprising from about 15% to about 30% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of an amphoteric diacyanate cross-linked prepolymer, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water; and

a release liner extending over said exposed pressure-sensitive adhesive layer and said exposed hydrogel material.

3. A wound dressing product comprising:

a flexible backing member having a first side and a second side and further having a depression on said first side;

a pressure-sensitive adhesive layer extending across said first side of said flexible backing member;

a hydrogel material located in said depression of said flexible backing member, said hydrogel material comprising from about 15% to about 30% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of an amphoteric diacyanate cross-linked prepolymer, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water; and

a release liner extending over said exposed pressure-sensitive adhesive layer and said exposed hydrogel material.

4. A wound dressing product comprising:

a flexible backing sheet;

a pressure-defining damping layer on the flexible backing member having a central cavity; and

a hydrogel material comprising from about 15% to about 30% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of an amphoteric diacyanate cross-linked prepolymer, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water; and

a release liner extending over said exposed pressure-sensitive adhesive layer and said exposed hydrogel material.

5. A wound dressing product comprising:

a flexible backing sheet;

a pressure-defining damping layer on the flexible backing member having a central cavity; and

a hydrogel material comprising from about 15% to about 30% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of an amphoteric diacyanate cross-linked prepolymer, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water; and

a release liner extending over said exposed pressure-sensitive adhesive layer and said exposed hydrogel material.

diacyanate terminated prepolymer, from about 7% to about 10% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of a polyhydric alcohol, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water.

3. A wound dressing product as claimed in claim 2 wherein said hydrogel comprises:

17% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

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10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

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10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

95% by weight of said polyhydric alcohol based diacyanate terminated prepolymer, from about 7% to about 10% by weight of a polyhydric alcohol, from about 8% to about 14% by weight of a polyhydric alcohol, from about 7% to about 10% by weight of a polyethylene oxide-based diamine, from about 0% to about 1% by weight of a salt, and the balance water.

4. A wound dressing product as claimed in claim 2 wherein said hydrogel comprises:

17% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

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10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

10% by weight of said polyhydric alcohol;

12% by weight of said amphoteric diacyanate terminated prepolymer;

United States Patent [19]
Castellana et al.

[11] **Patent Number:** 5,250,043
 [45] **Date of Patent:** Oct. 5, 1993

[54] **CONTINENT OSTOMATE BANDAGE**

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[21] **Appl. No.:** 394,703

[22] **Filed:** Aug. 16, 1989

[51] **Int. Cl.:** A61F 5/44

[52] **U.S. Cl.:** 604/336; 602/79;
 604/337

[58] **Field of Search:** 604/336, 337, 332, 327,
 604/378, 307, 304; 128/155, 156; 602/60, 79

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 1988 Inventor: Ole R. Jensen Assigned to: E. R. Squibb
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Primary Examiner—Randall L. Green

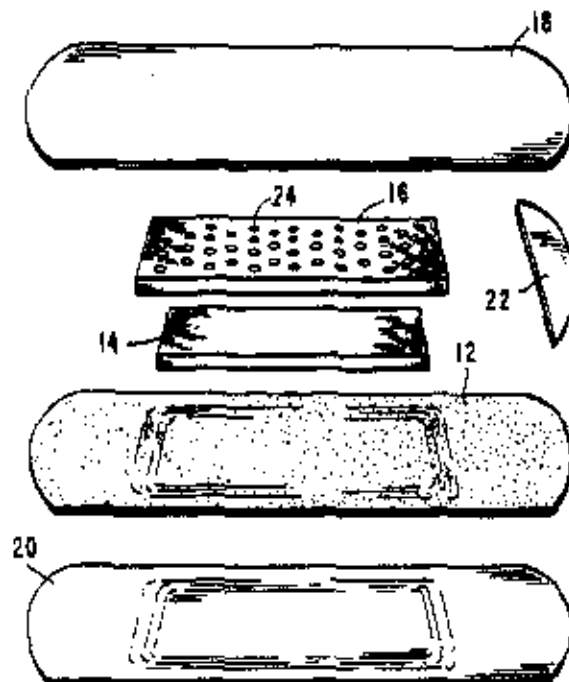
Assistant Examiner—R. Clarke

Attorney, Agent, or Firm—Richard H. Brink; Stephen B.
 Davis

[37] **ABSTRACT**

A bandage including a superabsorbent pad covered by a porous cover pad placed on a thin, flexible hydrocolloid adhesive layer leaving a portion of the adhesive layer around the pads as an adhesive border is disclosed. One side of the adhesive layer is laminated to a polymeric backing or non-woven fabric layer and a protective cover layer is applied over the pads and border portion. The protective cover layer may be silicone coated release paper and the bandage may be subjected to a vacuum thus forming the adhesive layer to the pads resulting in the border portion being substantially coplanar with the exposed surface of the cover pad overlaying the superabsorbent pad.

4 Claims, 3 Drawing Sheets



CONTINENT OSTOMATE BANDAGE

BACKGROUND OF THE INVENTION

The present invention relates to bandages, more particularly, to bandages for applications requiring multiple bandages per day to the same area of the skin.

New surgical procedures today for ostomy care have in some cases eliminated the need for external pouches. A pouch is formed internally by placing a U-bend in the terminal portion of the colon or intestinal track after surgical removal of a portion of the colon. The U-bend ends in a stoma or opening through the abdominal wall in the usual manner but the pouch formed internally by the U-bend is capable of storing a finite amount of discharge. The pouch is emptied four or five times a day by intubation. People who have undergone this type of surgery are often referred to as continent ostomates or ileostomates or urostomates.

The stoma will secrete a certain amount of mucous or discharge which is absorbed by a bandage placed over the stoma. The bandage must be removed and a new bandage applied each time intubation takes place.

A common bandage approach consists of taking a square or rectangular piece of acrylic adhesive, placing a piece of cotton or gauze in the center and placing this over the stoma or, alternatively, taping a piece of cotton or gauze over the stoma. The acrylic adhesive is not particularly friendly to skin upon removal and using this technique four or five times a day often results in skin irritation or even excoriation. A real need exists to provide a bandage for continent ostomates or others such as those suffering with mucous fistulas which bandage will not cause skin irritation, etc. when multiple bandages are used each day to the same area of the skin.

SUMMARY OF THE INVENTION

The present invention is directed to an improved bandage particularly suitable for continent ostomates or others such as those suffering with mucous fistulas. This invention provides a flexible, thin, hydrocolloid adhesive layer having a plastic or non-woven fabric layer affixed to one surface thereof and a superabsorbent pad, smaller than the adhesive layer affixed to the opposite adhesive surface. A porous cover pad covers the superabsorbent pad and leaves a portion of the adhesive layer uncovered to form an adhesive border around the pads.

A protective cover covers the adhesive layer and pads. In one embodiment, the protective cover comprises a plastic cover with a molded cavity having a depth and size to receive the superabsorbent pad and cover pad. Alternatively, the protective cover may be a layer of release paper.

In one embodiment, the hydrocolloid adhesive layer is about eight to twelve mils thick, preferably about ten mils thick, while the plastic or non-woven fabric layer is in the range of 0.5 to 3 mils thick but preferably is a 1 mil thick polyethylene film. The polyethylene layer may be of an opaque color such as flesh colored which may be more aesthetically pleasing and serves to hide blood stains or the like. Also, the polyethylene layer may be embossed.

Preferably, the border portion of the adhesive layer is substantially co-planar with the exposed surface of the cover pad. This can be accomplished by exposing the bandage covered with a layer of release paper to a vacuum. The vacuum removes air from around the pads

and when the vacuum is removed the flexible adhesive layer is pressed up against the edges of the superabsorbent pad and the overlaying cover pad.

The invention further provides for placing a narrow strip of release paper along one edge of the adhesive layer before applying the protective cover or layer of release paper which extends over the strip as well.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top planar view of the bandage of the present invention.

FIG. 2A is a cross sectional view of the bandage of FIG. 1 with protective cover and strip of release paper taken along the lines and arrows 2-2 in FIG. 1 before applying the vacuum while FIG. 2B is the same bandage after vacuum forming.

FIG. 3 is an exploded isometric view of the bandage of FIG. 1.

FIG. 4 is a top planar view of the bandage of FIG. 1 with a layer of release paper partially peeled away.

FIG. 5 is a cross sectional view of the bandage of FIG. 2 with an alternate embodiment protective cover taken along the lines and arrows 2-2 in FIG. 1 with no vacuum forming.

FIGS. 6A and 6B show the bandages of FIG. 2B and 2A, respectively, in cross section applied to the stoma of a user.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring now to the Figures, a bandage designated generally 10 is shown having an adhesive layer 12, a superabsorbent pad 14, a porous cover pad 16 and a protective cover 18. The adhesive layer 12 is a highly flexible, relatively thin, occlusive hydrocolloid adhesive layer with a backing layer 20 of polymeric material attached to one surface thereof.

To make the bandage as flexible as possible, it is desirable to keep the hydrocolloid layer with backing as thin as possible. A thickness of between 5 mils and 15 mils for the layer 12 is suggested. In the preferred embodiment, a thickness of between 8 and 12 mils is used with 10 mils being most preferable. The polymeric or non-woven fabric layer 20 may be between 0.5 mils to 3 mils. Suitable non-woven fabrics for use as layer 20 include polyester fibers, polypropylene fibers, nylon fibers, composite olefin fibers, and cellulose fibers. Preferably, layer 20 is a polymeric film such as polyethylene with 1 mil embossed polyethylene being most preferred. A suitable polyethylene film is sold under the trade name Tefaflex Code XIX available from Clonpay U.S.A. The layer 12 is formed by extruding and is laminated to layer 20. Other polymeric backing films can be selected from the various materials commonly employed in ostomy and medical devices. For example, polyolefins such as polypropylene, ethylene acrylic acids, ethylene vinyl acetates, polyvinylchlorides, polyether sulfones, polyether ketones, polyether urethanes, polyurethanes, etc. can be used.

Unlike prior bandages used by continent ostomates and others requiring like bandages, the preferred adhesive layer 12 of the bandage 10 of this invention is a skin friendly non-acrylic material which is less irritating to the skin. The overall adhesive layer 12 of this invention is flexible and conformable to the body contours of the user and is comfortable for the user.

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Doctora
JIMENA ESCOBAR URIBE
Abogada

ASUNTO	Radicación	05-108999
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	0513
	Folios	05

Patente de Invención

☒

Patente de Modelo de Utilidad

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

Descripción:	Folios: 9 a 23	como se radicó inicialmente
Reivindicaciones:	Folios: 24 a 26	como se radicó inicialmente
Dibujos:	Folios: 27 a 28	como se radicó inicialmente
Prioridad:	Folios: 62 a 91	como se radicó inicialmente
	Numero: PI0404697-8	
	País: Brasil	
	Fecha: 26 de octubre de 2004	

2. Objeto de la invención

Título de la invención

Producto de venda adhesiva y procedimiento de fabricación para un producto de venda adhesiva.

El problema planteado en esta solicitud es no obtener vendas adhesivas donde la película adhesiva en presencia de la almohadilla no se comprima y no genere fuerzas de tracción que tiendan a aflojar la película.

Para solucionar este problema técnico se desarrolla una venda adhesiva caracterizada por tener una cavidad perfilada en la capa inicial de película de plástico en la cual se coloca la almohadilla.

Clasificación internacional de Patentes (IPC) en A61F 13/16.

3. De la solicitud de Patente (según el caso)

Descripción (artículo 28 D. 486)

- Se debe corregir el siguiente error de mecanografía, folio 9 línea 20 "eficiente".

Reivindicaciones (artículo 30 D 486)

- No es claro porque en la reivindicación 1 y varias de sus dependientes, se utiliza dos términos para referirse a la capa inicial como "película estructural (1)" y como "película de plástico 1".
- En la reivindicación 8, no es claro el paso (ii) del método de fabricación de la venda adhesiva, ya que en el paso (i) la capa inicial es revestida por un adhesivo y en el paso (ii) se dice que se coloca una almohadilla sobre la capa inicial, siendo que esta ya esta recubierta con un adhesivo.

Por lo anterior, el capítulo reivindicatorio no cumple con el requisito de claridad de acuerdo al art. 30 de la Decisión 486.

4. Determinación del Estado de la Técnica

- La fecha para determinar el estado de la técnica es el 26 de octubre de 2004, de acuerdo al la fecha de prioridad invocada.
- *Teniendo en cuenta la anterior fecha indicada, se realiza la búsqueda de las anterioridades de la presente solicitud, encontrándose los siguientes documentos relevantes:*

Nº	Documento	Título	Fecha de publicación
D1	US5059424	HYDROGEL WOUND DRESSING PRODUCT	1991-10-22
D2	US5250043	CONTINENT OSTOMATE BANDAGE	1993-10-05

5. Análisis de patentabilidad (según requisito) (artículo 14 D486)

Nivel inventivo (artículo 18 D486)

1) Respecto a la reivindicación 1

La reivindicación 1 dice: "Producto de venda adhesiva caracterizado por el hecho que consiste en: por lo menos una capa inicial de película estructural (1); por lo menos un revestimiento adhesivo (2) asociado con la capa inicial de la película estructural (1); y por lo menos una almohadilla (3); el producto esta caracterizado por el hecho que consiste en una cavidad (6) perfilada por la capa inicial de la película de plástico 1 para la colocación de la almohadilla (3)".

2) Respecto al estado de la técnica:

D1 se refiere a un apósito y su método de fabricación. El apósito comprende un miembro flexible posterior que tiene un primer y segundo lado, y una porción central formada por vacío para definir una depresión en el primer lado; una lamina adhesiva sensible a la presión que se extiende a través del primer lado del miembro flexible posterior; un material hidrogel localizado en la depresión del

miembro flexible; y un lamina de liberación que se extiende sobre la lamina de adhesivo expuesto y el material hidrogel expuesto (Col. 2 líneas 41-50). El material hidrogel es capaz de absorber los exudados de la heridas (Col. 7 líneas 45-46).

D2 se describe vendajes, mas específicamente vendajes para ser utilizados en múltiples aplicaciones el mismo día en la misma área de la piel (Col. 1 líneas 5-7). Esta invención provee una lamina adhesiva flexible, delgada e hidrocoloide, que esta sobre una lamina plástica o no tejida donde se coloca una almohadilla superabsorbente. Una almohadilla porosa recubre la almohadilla superabsorbente y deja una porción de la lamina adhesiva descubierta para formar un borde adhesivo alrededor de la almohadilla. Un recubrimiento protector cubre la lamina de adhesivo y la almohadilla (Col. 1 líneas 40-48). En una forma de realización el recubrimiento protector comprende un recubrimiento plástico que se moldea para obtener una cavidad con una profundidad y un tamaño para recibir la almohadilla superabsorbente y la almohadilla de recubrimiento. Alternativamente el protector de recubrimiento puede ser una lamina de papel de liberación (Col. 1 líneas 50-54).

Análisis de las diferencias con respecto al estado de la técnica:

Características Esenciales	D1 US5059424	D2 US5250043
Producto de venda adhesiva caracterizado por el hecho que consiste en:	(Col. 2 líneas 41-50)	(Col. 1 líneas 5-7)
por lo menos una capa inicial de película estructural (1);	(Col. 2 líneas 27-33)	(Col. 2 líneas 35-38)
por lo menos un revestimiento adhesivo (2) asociado con la capa inicial de la película estructural (1);	(Col. 2 líneas 44-45)	(Col. 2 líneas 35 y 53-55)
y por lo menos una almohadilla (3);	NO	(Col. 2 líneas 34)
el producto esta caracterizado por el hecho que consiste en una cavidad (6) perfilada por la capa inicial de la película de plástico 1 para la colocación de la almohadilla (3)	(Col. 2 líneas 51-53)	NO

3) Estado de la técnica más cercano:

Respecto a la solicitud en estudio D1 es el documento del estado de la técnica más cercano porque describe un apósito que ayuda ha proteger heridas, el cual esta diseñado con una cavidad que sirve para depositar el hidrogel que absorbe los exudados de las heridas.

La solicitud colombiana se diferencia en D1, por tener una almohadilla que se coloca en una cavidad de la venda adhesiva.

Esta diferencia no parece darle un efecto técnico sorprende a esta reivindicación, ya que la almohadilla cumple la función de tocar la herida permitiendo la absorción de los exudados, como el hidrogel utilizado en el apósito de la anterioridad D1.

4) Es así como para un técnico experto en la materia el utilizar una almohadilla o hidrogel en una venda adhesiva (apósito) que sirva para absorber los exudados, no va más allá del progreso normal del estado de la técnica y que simplemente se puede deducir de este. Ya que muchos productos absorbentes de higiene personal tienen como principal componente geles superabsorbente. Además en el estado del arte ya es conocido muchos productos con almohadillas, como se

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puede evidenciar entre otros con D2. Por lo tanto esta reivindicación y sus dependientes carecen de nivel inventivo.

1) Respecto a la reivindicación 8

La reivindicación 8 dice "Método de fabricación de la venda adhesiva:

i) aplicar un revestimiento adhesivo (2) a una capa inicial de la película estructural (1); ii) colocar por lo menos una almohadilla (3) sobre la capa inicial de la película estructural (1); iii) configurar plásticamente por lo menos de manera parcial y bajo presión, por lo menos una cavidad (6) en la capa inicial de la película estructural (1) revestida en el paso (i)".

Análisis de las diferencias con respecto al estado de la técnica:

Características Esenciales	D1 US5059424	D2 US5250043
i) aplicar un revestimiento adhesivo (2) a una capa inicial de la película estructural (1);	(Col. 3 líneas 45-47)	(Col. 2 líneas 53-55)
ii) colocar por lo menos una almohadilla (3) sobre la capa inicial de la película estructural (1);	NO	(Col. 4 líneas 3-5)
iii) configurar plásticamente por lo menos de manera parcial y bajo presión, por lo menos una cavidad (6) en la capa inicial de la película estructural (1) revestida en el paso (i)	(Col. 3 líneas 47-52)	NO

3) Estado de la técnica más cercano:

Respecto a la solicitud en estudio D1 es el documento del estado de la técnica más cercano porque describe el método de fabricación de un apósito diseñado con una cavidad.

La solicitud colombiana se diferencia en D1, por el paso de colocar la almohadilla sobre la película estructural.

Esta diferencia no parece darle un efecto técnico sorprende a esta reivindicación, ya que es obvio que un vendaje deba tener un elemento absorbente para los exudados de las heridas como una almohadilla o cualquier otro elemento equivalente.

4) Es así como para un técnico experto en la materia el paso de colocar una almohadilla sobre una película estructural, no va más allá del progreso normal del estado de la técnica y que simplemente se puede deducir de este, como se evidencia en D2. Por lo tanto esta reivindicación y sus dependientes carecen de nivel inventivo.

7. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

Documento N°	Reivindicaciones afectadas	Requisito que afecta
US5059424	1-14	Nivel Inventivo
US5250043	1-14	Nivel Inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de 60 días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente. Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha
22 ENE. 2009

CONCEPTO TÉCNICO N° 0032	EXAMINADOR TÉCNICO Código N° 202090
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