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As 2558/PCT

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES****E S D**

Ref Expediente No 03-039 887
Solicitud de Patente a nombre de
The Procter & Gamble Company

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad 03-039887 00005 0000
Fec 2008-10-09 14:35:24 Dep 2020 NUECREACIONES
Tra 11 PATENTE/II
Eve 379 FASENACIONAL/II
Act 538 PETICION Folios 2

Yo **JIMENA ESCOBAR URIBE**, identificada como aparece al pie de mi firma, domiciliada en Bogota, en la Carrera 11 A No 94 76 Of 305, obrando como apoderada de la sociedad **The Procter & Gamble Company**, con domicilio en Cincinnati, Ohio, Estados Unidos de America, solicitante de la patente de la referencia, pido a usted que se proceda a examinar si la invencion, cuya patente se tramita en el expediente de la referencia, es patentable

Adjunto al presente memorial el recibo No 06 - 74,357 de septiembre 26 de 2006, por la suma de \$194 000 oo con lo cual queda cubierta la tasa oficial correspondiente a dicho estudio

Señor Superintendente,


JIMENA ESCOBAR URIBE

C C 39 779 452 de Usaquen

T P 68 228

Cod 5376

JEU/ra

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad 03-039887 00005 0000
Fec 2006-10-09 14:35:24 Dep 2020 NUECREACIONES
Tra 11 PATENTE(YI)
Eve 379 FASENACIONALII
Act 538 PETICION
Folios 2

N1 8001 6089

REC BO OFICIA DE CA A 06 4,37
FECHA SEP IEMBRE 26 DE 2006

***** CONSIGNACION *****

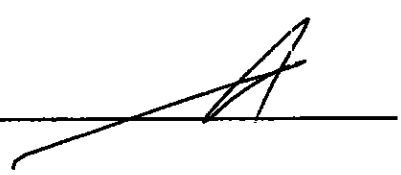
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ESCOBAR URIBE ASOCIADOS	CONS GNACION	BAN O POPULAR	0 0-00 10 6	49044680	26 09/2006	4,403,600 00

***** CONCEPTO *****

CANT	REN IS ICC	CONCEP O	TO AL CONCEPTO
5000 0 0	SOL C TJDES	14 P C AP- I E AMEN DE PATENT BI ID	94,000 00
		TOTA	\$ 194,000 00

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RESPONSABLE



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**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES**

2020

Bogotá D C 19 de julio de 2007

Abogada

Jimena Escobar U

(Apoderado)

Solicitante The Procter & Gamble Company

ASUNTO	Radicación	03 – 39 887
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	1000 8924
	Folios	023

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

- | | | |
|-----|-------------------------|---|
| 1 1 | <u>Descripción</u> | Folios 16 a 39 como se radicó inicialmente |
| 1 2 | <u>Reivindicaciones</u> | 1 a 12 Folios 40 a 44 como se radicó inicialmente |
| 1 3 | <u>Dibujos</u> | Folios 46 a 49 como se radicó inicialmente |
| 1 4 | <u>Proridad</u> | 00 12-12 US 60/255 045 |

2 Objeto de la invención

- Título de la solicitud *Dispositivo de aplicación*
- El objeto de la presente solicitud de patente de invención consiste en un dispositivo de aplicación que comprende un sustrato aplicador un sustrato de liberación y un parche colocado entre ellos para aplicarlo en una superficie destino donde el parche puede llevar una sustancia activa [aunque no se requiere por ejemplo el parche puede ser una gasa estéril] No se requiere tampoco que el parche se emplee en el cuidado de la salud [por ejemplo el parche se puede emplear para reparar un neumático pinchado]

Reivindicaciones 1 a 12 Un dispositivo de aplicación laminar para aplicar un parche intercalado a una superficie destino que comprende los siguientes elementos sustancialmente planos un sustrato aplicador que tiene una lengüeta de agarre que se extiende hacia fuera de este y que tiene una superficie interior un parche que tiene dos superficies y un sustrato de liberación que tiene una lengüeta de agarre que se extiende hacia fuera de este y que tiene una superficie interior En donde la superficie interior del sustrato aplicador tiene un medio adhesivo que fija de manera desprendible una primera superficie del parche a la

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superficie interior del sustrato con lo que se forma una primera unión de desprendimiento a la vez que se forma una combinación de sustrato aplicador – parche que tiene una superficie interior en donde el sustrato de liberación se fija de manera desprendible a la superficie interior de la combinación con lo que se forma una segunda unión de desprendimiento donde la lengüeta del sustrato de liberación está desplazada lateralmente con relación a la combinación donde la resistencia de la primera unión de desprendimiento es superior a la resistencia de la segunda unión de desprendimiento y donde la resistencia de una unión adhesiva entre el medio adhesivo de la segunda superficie del parche y una superficie destino es superior a la resistencia de la primera unión de desprendimiento

El problema planteado en esta solicitud es la necesidad de facilitar el uso de un dispositivo de aplicación para parches de tal manera que al quitar las láminas protectoras del parche el adhesivo de éste no se vea afectado negativamente. Así se requiere que al retirar la primera de las láminas denominada en la solicitud como *sustrato de liberación* no se afecte la superficie del parche que va a entrar en contacto con la superficie destino [denominada superficie *diana*] y que cuando se retire la segunda de las láminas protectoras denominada *sustrato aplicador* se pueda efectuar la operación sin levantar ninguna porción significativa del parche que se ha unido adhesivamente a la superficie destino. Toda la operación debe ser realizada sin que las diferentes acciones del usuario del dispositivo se interfieran obstaculizando de alguna manera el retiro de una de las dos láminas o de ambas y sin que el parche se vea perjudicado. En otras palabras lo importante del objeto de la solicitud es que se puedan desprender los sustratos sin afectar negativamente la superficie activa del parche.

Para solucionar este problema técnico la solicitud en estudio proporciona unas láminas configuradas de manera que las lengüetas de las dos láminas no se superpongan cuando se vayan a emplear y además se distribuyen las resistencias de desprendimiento de cada una de ellas de manera que el desprendimiento tenga que hacerse en un orden particular.

- Clasificación Internacional de Patentes (IPC) A61F 13/02 13/56
B32B 7/06 7/12

3 De la solicitud de Patente

3.1 Descripción (artículo 28 D 486)

- El solicitante debe
 - (1) Modificar la expresión *diana* que aparece a lo largo de la descripción y las reivindicaciones por otra que se ajuste mejor al contexto se sugiere emplear *destino*
 - (2) Introducir la definición de la expresión *activo* –que aparece en la página 20 folio 35- cuando la utilice la primera vez esto es en la página 2 folio 17
 - (3) Modificar la definición de la expresión *fuerza de unión* que aparece en la página 6 folio 21 porque es confusa ya que dice *fuerza de unión significa la cantidad de fuerza con lo cual se mide la fuerza de unión* Lo que carece de sentido por una parte porque lo definido no debe entrar en la definición y por otra parte porque *una cantidad* no sirve para medir no mide

- (4) Modificar también la definición de la expresión *desplazado lateralmente* que aparece en las páginas 7 y 8 folios 22 y 23 porque lo definido no debe aparecer dentro de la definición
 - (5) Corregir las expresiones numéricas defectuosas que aparecen por primera vez en la página 11 folio 26 porque expresiones como 1 cm^2 y 4 cm^2 carecen de significado. Debe consultar la regla 12-c) de la aplicación del Sistema Internacional de unidades (puede consultarla en el sitio web <http://www.sic.gov.co/Estudios/Siu.php>). La primera cifra a la izquierda de la coma decimal tiene como valor posicional el de la unidad en la que se expresa el número. Por ejemplo al decir 34.5 m la cifra 4 indica metros 0.25 N la cifra 0 indica newtons 1.85 m la cifra 1 indica metros y 220 V la cifra 0 indica volts
 - (6) Corregir la expresión *que no incluyendo* que aparece en la página 13 folio 28 porque carece de significado según el contexto
 - (7) Corregir la expresión *maternal continuos que se superpuestos* que aparece en la página 14 folio 29 porque carece de sentido
 - (8) Corregir las unidades defectuosas que aparecen por primera vez en la página 19 folio 34 porque KPa significa kelvin pascuales no kilopascuales que se representa por kPa
 - (9) Sustituir las expresiones *sorción* y *silíce de humo* que aparecen en la página 21 folio 36 por otras que tengan un significado reconocido
 - (10) Aclarar la expresión 0.007M que aparece en la página 23 folio 38 porque M es el símbolo para mega un prefijo para multiplicar la unidad por 10^6
 - (11) Presentar un nuevo juego de dibujos donde se puedan observar claramente las figuras 1 a 3 y donde se suprima la figura 4 -que se refiere a un procedimiento- porque no se reclama ningún procedimiento en el capítulo reivindicatorio y por tanto es superflua
- La descripción no cumple con el requisito de claridad de acuerdo al art. 28 de la Decisión 486

3.2 Reivindicaciones (artículo 30 D 486)

- El solicitante debe
 - (1) Modificar la reivindicación 1 en el sentido de hacerla más concisa porque por ejemplo se enumeran tres elementos y de cada uno de ellos se dice que es *sustancialmente plano* en las definiciones de cada uno de ellos. Se puede decir que son sustancialmente planos antes de entrar a definirlos por separado
 - (2) Aclarar la expresión *en donde el medio adhesivo fija de manera desprendible la primera superficie del parche a la superficie interior del parche* que aparece en la reivindicación 1 porque por una parte no se ha definido antes ninguna *superficie interior* para el parche y por otra parte no se ha divulgado dentro del capítulo descriptivo que el parche tenga dos superficies distintas que se unan entre sí ni que el parche tenga una superficie interior

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- (3) Aclarar la expresión *en donde el sustrato de liberación se fija de manera desprendible a la superficie superior de la combinación* que aparece en la misma reivindicación 1 folio 40 porque por una parte no se ha establecido antes dentro de esta reivindicación que la *combinación* tenga una *superficie superior* y por otra parte si se habia definido antes dentro de esta reivindicación que la *combinación* tiene una *superficie interior* pero no se le da ningun uso a tal superficie
- (4) Modificar la expresion *un borde que no se fina* que aparece en la reivindicación 2 folio 41 porque carece de significado

- El capitulo reivindicatorio no cumple con el requisito de claudad concisión o sustento por la descripción de acuerdo al art 30 de la Decisión 486

4 Determinacion del Estado de la Tecnica

Dado que la fecha de presentación de la primera solicitud de patente de la cual se reivindica prioridad fue el 00-12-12 se buscaron documentos del estado de la tecnica relacionados con fecha de publicación anterior a esta

Durante la busqueda de anterioridades se encontraron los siguientes documentos que forman parte de la familia de patentes del objeto de la presente solicitud solicitud EP 1 359 875 A2 del 03-11-12 y WO 02/47593 A2 del 02-06-20 [citada por el solicitante ver folio 1] Se anexa la copia de la primera pagina del documento EP junto con la copia del Informe de Busqueda Internacional

n °	Documento	Título	Fecha de publicación
D1 ⁽¹⁾	Solicitud EP 0 424 165 A1 cuyos inventores son James V Cartmell y Wayne R Sturtevant quienes le cedieron sus derechos a la NDM Acquisition Corp	Transparent Wound dressing (Una preparación transparente para heridas)	91-04-24
D2 ⁽²⁾	Patente US 5 891 078 cuyos inventores son Chnstina M Trungren Dale E Lanser y Thomas F Hilbert	Sterile adhesive bandage and associated methods (Una venda adhesiva estéril y los métodos para su fabricación)	99-04-06

Estos documentos también se encuentran citados en el Informe de Busqueda Internacional

⁽¹⁾ documento citado por el solicitante como patente US 5 106 629 en la pagina 1 folio 16 se anexan las copias de las páginas pertinentes

⁽²⁾ documento citado por el solicitante en la página 1 folio 16 se anexan las copias de las páginas pertinentes

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NOTA No se realizó una evaluación de los demás requisitos de patentabilidad porque se objetó la claridad de las reivindicaciones. Una vez hayan sido superadas las objeciones establecidas en este Concepto Técnico se podrán hacer los exámenes correspondientes

5 Conclusión

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados negativamente por la falta de claridad de la descripción, los dibujos y las reivindicaciones.

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 sesenta 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 **27 JUL 2007**

CONCEPTO TÉCNICO n ° 1095	EXAMINADOR TÉCNICO Codigo n ° 09
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INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/US 01/48597A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 (A61F13/02)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 424 165 A (NDM ACQUISITION CORP) 24 April 1991 (1991-04-24) cited in the application column 6 line 1 -column 7 line 15 column 8 line 19 -column 9 line 14 claims figures	1
Y	—	2-6 10
Y	US 5 891 078 A (HILBERT SR THOMAS F ET AL) 6 April 1999 (1999-04-06) cited in the application column 9 line 36 -column 10, line 7	2-6 10
A	DE 40 01 380 A (BRENNER WERNER) 25 July 1991 (1991-07-25) the whole document	1,6
	— -/-	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

Special categories of cited documents

- A document defining the general state of the art which is not considered to be of particular relevance
- E⁺ earlier document but published on or after the International filing date
- L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- O⁺ document referring to an oral disclosure, use, exhibition or other means
- P⁺ document published prior to the International filing date but later than the priority date claimed

- T⁺ later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- X⁺ document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- Y⁺ document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- &⁺ document member of the same patent family

Date of the actual completion of the International search

4 February 2003

Date of mailing of the International search report

20/02/2003

Name and mailing address of the ISA

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Authorized officer

Douskas, K

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 01/48597

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C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 788 784 A (HOLLISTER INC) 13 August 1997 (1997-08-13) claims, figures	1,4 6
A	US 5 713 842 A (KAY DENNIS) 3 February 1998 (1998-02-03) column 9 line 61 -column 10 line 12, figures 7-9	1 4 6
A	US 5 994 613 A (CUMMINGS GARY WAYNE ET AL) 30 November 1999 (1999-11-30) column 12, line 40 -column 13, line 10, figure 7	1 4 6
A	EP 0 630 629 A (NDM ACQUISITION CORP) 28 December 1994 (1994-12-28) claims figures	1 4

INTERNATIONAL SEARCH REPORT

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 Application No
 PCT/US 01/48597

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INTERNATIONAL SEARCH REPORT

Inte
al Application No
PCT/US 01/48597

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 667766 B2	04-04-1996
		AU 5644794 A	08-12-1994
		CA 2119731 A1	28-11-1994
		EP 0630629 A1	28-12-1994
		JP 2604542 B2	30-04-1997
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		US 5501661 A	26-03-1996

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Europäisches Patentamt

European Patent Office

Office européen des brevets

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12 11 2003 Bulletin 2003/46

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(21) Application number 01985571 7

(86) International application number
PCT/US01/48597

(22) Date of filing 07 12.2001

(87) International publication number
WO 02/047583 (20.06.2002 Gazette 2002/25)

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(54) APPLICATION DEVICES

(87) This international application for which the EPO is a designated office has not been republished by the EPO according to article 158(1) EPC.

Cette demande internationale pour laquelle l'OEB est office désigné n'a pas été republiée par l'OEB en vertu de l'article 158(1) CBE

Diese internationale Anmeldung, für die das EPA Bestimmungsamt ist, würde, gemäß Artikel 158(1) EPÜ vom EPA nicht wieder veröffentlicht.

EP 1 359 875 A 2



Europäisches Patentamt
European Patent Office
Office européen des brevets



Publication number **0 424 165 A1**

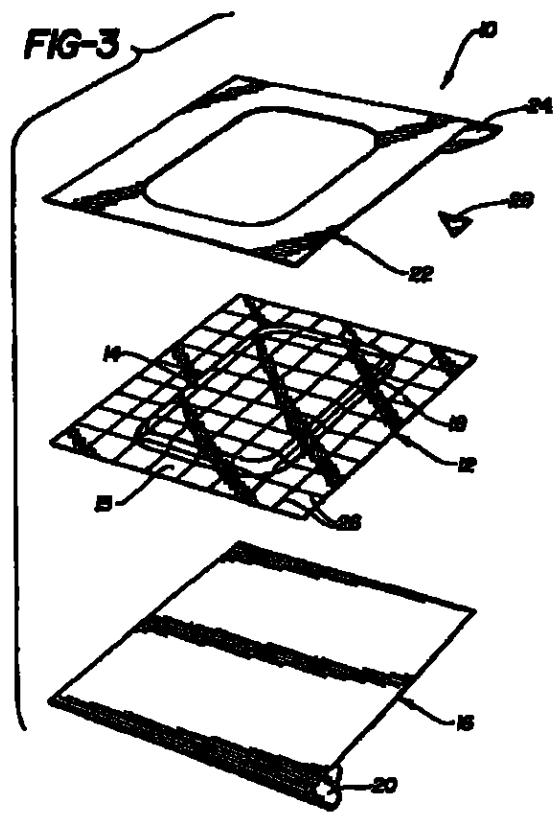
EUROPEAN PATENT APPLICATION

Application number **90311477.5** Int. Cl. **A61F 13/02, A61F 13/00, A61L 15/20**
Date of filing **18.10.90**

Priority 20.10.89 US 424559 Date of publication of application 24.04.91 Bulletin 91/17 Designated Contracting States: AT BE CH DE DK ES FR GB IT LI LU NL SE Applicant: NDM ACQUISITION CORP 90 South 6th Street Minneapolis, Minnesota 55402(US)	Inventor: Cartmell, James V 8275 Rhineway Centerville Ohio 45458(US) Inventor: Sturtevant, Wayne R. 20 South Johanna Drive Centerville Ohio 45458(US) Representative: Warren, Keith Stanley et al BARON & WARREN 18 South End Kensington London W8 5BU(GB)
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Transparent wound dressing.

A flexible transparent wound dressing product (10) contains a clear hydrogel material (18) in a gel-like phase and is comprised of several layers including a wound dressing (12,18), a release layer (16), and a dimensionally stable backing member (22). The dressing comprises a thin-film transparent layer (12) having an adhesive perimeter portion (15) and a center portion (14), and the hydrogel material positioned therein. A grid pattern (26) may be printed on the thin-film transparent layer to permit measurement of a wound. The dimensionally stable backing member is adhesively attached around the perimeter portion of the thin-film transparent layer to help the dressing maintain its shape. When the dressing is applied to a wound the release layer (16) is removed using a tab (20) to expose the hydrogel material. The dressing is then applied to the wound site with the hydrogel material in direct contact with the wound. The dimensionally stable backing member (22) is then removed using a tab (24).



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Directly contacting the wound is the hydrogel material, where it creates a bio-compatible, bacterial protective, fluid absorbing, cushioned skin-like media to facilitate the healing process. The wound dressing product is then securely attached to the healthy skin surrounding the wound site by gently pressing into place the adhesive edge, created by the first adhesive layer of the transparent film. Once the wound dressing product has been placed on the wound site and the adhesive edge of the transparent film has been attached to the healthy skin surrounding the wound site, then the dimensionally stable backing member can be removed, preferably using a tab extending beyond the transparent layer provided with the backing member. The result is a wound dressing product including a transparent wound dressing which allows observation of the wound without removal of the dressing, the wound dressing containing a bio-compatible, non-irritating, fluid absorbing, skin-like media hydrogel material. Conformity and more importantly bacterial protection is improved since there is no "lifting edge" to catch on clothing or bed sheets.

It is an object of the present invention to provide a wound dressing product containing an aqueous hydrogel substance which is particularly advantageous when used to dress exuding wounds such as decubitus ulcers, by providing a skin-like media which is bio-compatible, non-irritating, fluid absorbing and bacterial protective, to provide a wound dressing having improved adhesive and conforming features; to provide a wound dressing which is transparent, thereby allowing medical personnel to observe the healing progression of a wound without removing the wound dressing; to provide a wound dressing which is more flexible and less bulky than existing dressings; to provide a wound dressing which will not adhere to new cell tissue when it is removed; and to provide a wound dressing product with the above features that is pre-cut, sterilized and readily available for application to a wound site.

In order that the invention may be more readily understood, reference will now be made to the accompanying drawings, in which:

Figure 1 is a plan view of the wound dressing product;

Figures 2A and 2B are cross-sectional views of the wound dressing product and the wound dressings respectively of Figure 1 taken along line 2-2;

Figure 3 is an exploded view illustrating the layers which form the preferred embodiment of the wound dressing product; and

Figures 4A through 4D illustrate the preferred method of application of the wound dressing product of the present invention.

The present invention relates to a wound dressing product for application to a wound which includes a wound dressing comprised of a thin-film transparent layer and a hydrogel material. The invention also includes a method of manufacture and a method of application for the disclosed wound dressing product.

The wound dressing product 10 of the present invention is illustrated in Figures 1, 2A, 2B, and 3. Although the wound dressing product 10 is shown in Figure 1 as having a rectangular shape, it may be any of a variety of desirable shapes. The wound dressing product is composed of several layers, as illustrated by the cross-sectional view of Figure 2A and the exploded view of Figure 3.

Referring now to Figure 2A, the wound dressing product 10 is illustrated in cross-section taken along line 2-2 of Figure 1. The wound dressing product 10 includes a thin-film transparent layer 12, preferably of polyurethane, which has a center portion 14 and a perimeter portion 15. The transparent layer 12 has a first side and a second side, the first side being coated with a first adhesive layer 17. A layer of hydrogel material 18 is inserted on the first side of the transparent layer 12 in the center portion 14, thereby defining a center cavity in the center portion 14. The transparent layer 12, the first adhesive layer 17, and the hydrogel material 18 comprise a wound dressing 11, as illustrated in Figure 2B.

The wound dressing product 10 is comprised of the wound dressing 11, a release liner layer 16, a dimensionally stable backing member 22, and a second adhesive layer 23, as illustrated in Figure 2A. The release liner 16, preferably of a silicone-coated sheet material, is adhesively attached to the perimeter portion on the first side of the thin-film transparent layer 12 by means of the first adhesive layer 17. The release liner 16 overlies the hydrogel material 18 located in the center portion of the transparent layer 12 and the perimeter portion 15 of the transparent layer 12. The dimensionally stable backing member 22, has a first side and a second side, the first side of which is attached to the second side of the transparent layer 12 by means of the second adhesive layer 23.

In a preferred embodiment of the present invention, as illustrated in Figures 1 and 3, the wound dressing product 10 includes a first tab extending from a corner of the release liner 16 and extending beyond the transparent layer 12. Additionally, a release element 28 is placed on one corner of the transparent layer 12, between the transparent layer 12 and the dimensionally stable backing member 22, as illustrated in Figure 3. The release element 28 may be adhered along one edge to insure that it maintains its position on the transparent layer 12. A preferred embodiment of

the present invention also includes a tab 24 extending from a corner of the dimensionally stable backing member 22, corresponding to the transparent layer 12 corner placement of the release element 28, and extending beyond the transparent layer 12.

In one embodiment of the present invention a grid pattern 26 can be printed on the transparent thin-film layer 12 of the wound dressing product 10, as illustrated in Figure 1. The grid pattern 26 allows a means for measuring the wound, observing the wound healing process, and noting the changing size of the wound site. Although Figure 1 illustrates a rectangular grid pattern 26, any suitable grid pattern may be incorporated.

The present invention provides a method of manufacturing the wound dressing product 10. In the manufacturing method of the present invention, the release liner 16 and the dimensionally stable backing member 22 are provided, each having a first side and a second side. Additionally, the transparent layer 12 is provided, the transparent layer 12 having a first side and a second side and further having a center portion 14 and a perimeter portion 15, as illustrated in Figures 1 and 2B. The first side of the transparent layer 12 is coated with the first adhesive layer 17 and the first side of the dimensionally stable backing member 22 is coated with the second adhesive layer 23, which is illustrated in Figure 2A. The second side of the transparent layer 12 is then laminated to the first side of the dimensionally stable backing member 22, wherein the second adhesive layer 23 is located between the transparent layer 12 and the dimensionally stable backing member 22, as can be seen in Figure 2A. In a preferred embodiment of the present invention, the dimensionally stable backing member 22 and the second adhesive layer 23 define a center aperture, whereby the backing member 22 and the second adhesive layer 23 surround but do not overlap the center portion 14 of the transparent layer 12, as illustrated in Figure 3.

Once the dimensionally stable backing member 22 is laminated to the transparent layer 12, the release liner 16 is temporarily separated from the transparent layer 12 and a vacuum pressure is applied to the transparent layer 12 to form a cavity in the center portion 14. During the vacuum pressure, a clear gel-like aqueous material 18, preferably a hydrogel, is inserted into the center portion 14 of the thin-film layer. The hydrogel material 18 is adhesively attached to the center portion 14 via the first adhesive layer 17 which coats the transparent layer 12. However, the first adhesive layer remains exposed around the perimeter portion 15. After the hydrogel material 18 has been inserted, the release liner 16 is reapplied to the transparent layer 12.

The hydrogel material 18 includes from about 15% to about 30% by weight of a polyhydric alcohol selected from a group consisting of polypropylene glycol, polyethylene glycol and glycerine, from about 8% to about 14% by weight isophoronedisocyanate terminated prepolymer from about 5% to about 100% by weight polyethylene oxide based diamine up to about 1% by weight of a salt, and the remaining percentage being water. In the preferred embodiment of the present invention, the hydrogel material 18 includes 17% propylene glycol, 12% isophoronedisocyanate terminated prepolymer, 90% polyethylene oxide based diamine, 1% salt, and 81% water. The hydrogel material 18 provides a bio-compatible, non-irritating fluid absorbing bacterial protective cushioning skin-like media over the wound site.

Referring now to Figures 4A-4D, a preferred method of application of the wound dressing product 10 is illustrated in sequence. Figure 4A illustrates how the extending tab 20 can be gripped by the person applying the wound dressing product 10 to begin removal of the release liner 16 and expose the hydrogel material 18 before the wound dressing product 10 is applied to the wound site. In Figure 4B, the wound dressing product 10 has been flipped over so the hydrogel material 18 can contact the wound site 30. The release liner 16 continues to be removed in a rolling motion as the transparent layer 12 is placed over the wound site 30. Once the release liner 16 has been completely removed and the remaining layers of the wound dressing product 10 are properly situated over the wound site 30, the wound dressing product 10 is secured to the wound site 30 by gently pressing into place the first adhesive layer 17 which is exposed on the perimeter portion 15, as illustrated in Figure 4C. Finally, in Figure 4D, the dimensionally stable backing member 22, having a center aperture surrounding the hydrogel material 18, is peeled away from the transparent layer 12 to leave only the wound dressing 11 on the wound site 30.

In a preferred embodiment of the present invention, the first adhesive layer 17 located between the patient's skin and the perimeter portion 15 of the thin-film transparent layer 12, has stronger adhesive qualities than the second adhesive layer 23 located between the dimensionally stable backing member 22 and the transparent layer 12. Such a construction allows removal of the dimensionally stable backing member 22 from the wound dressing 11 while maintaining the adhesion between the perimeter portion 15 and the patient's skin. The release element 28 repels the adhesion created by the second adhesive layer 23 so as to provide a partial separation between the second adhesive layer 23 and the dimensionally stable

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backing member 22 sufficient to begin removal of the dimensionally stable backing member 22 from the wound dressing 11

Once the dimensionally stable backing member 22 has been completely removed, leaving only the release element 28, the thin-film transparent layer 12, and the hydrogel material 18, the release element 28 can be lifted off the transparent layer 12 and disposed of. The result is a wound dressing 11 comprising the thin-film transparent covering 12 having an adhesive perimeter portion which adheres to the healthy skin surrounding the wound site 30 and a center portion 14 containing a wound healing hydrogel material 18.

The wound dressing product 10 of the present invention is particularly advantageous for use on exuding wounds. In particular a special feature of the hydrogel material 18 is that it is sufficiently clear and transparent that visual observation of the wound is possible without removal of the wound dressing 11. Another benefit of the hydrogel material 18 is that it retains its gel-like integrity even upon removal of the wound dressing 11 from a wound site. The hydrogel material 18 does not leave debris in the wound when the wound dressing is removed nor does it adhere to the wound site. The benefit of this feature is that the hydrogel material 18 exhibits a capability of non-traumatically releasing from the wound when the wound dressing 11 is removed, so as not to destroy new cell tissue forming at the wound site. Thus, healing is not inhibited by removal of the dressing 11.

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.

Claims

1. A method of manufacturing a wound dressing product (10) for a wound comprising the steps of: providing a release liner (16), said release liner (16) having a first side and a second side; providing a transparent thin-film layer (12) said transparent layer (12) having a first side and a second side and further having a perimeter portion (15) and a center portion (14); coating said first side of said transparent layer (12) with a first adhesive layer (17); providing a dimensionally stable backing member (22) said dimensionally stable backing member (22) having a first side and a second side; coating said first side of said dimensionally stable backing member (22) with a second adhesive layer (23); laminating said second side of said transparent

layer (12) to said first side of said dimensionally stable backing member (22) wherein said second adhesive layer (23) is located between said transparent layer (12) and said dimensionally stable backing member (22);

applying a vacuum pressure to said center portion (14) of said transparent layer (12) to define a cavity in said center portion (14);

inserting a clear hydrogel material (18) in said cavity in said center portion (14) of said transparent layer (12) during the application of said vacuum pressure thereto; and

laminating said first side of said transparent layer (12) to said first side of said release liner (16) wherein said first adhesive layer (17) is located between said transparent layer (12) and said release liner (16).

2. A method of manufacturing a wound dressing product (10) as claimed in claim 1 characterized in that the step of providing a release liner (16) includes the step of providing a release liner (16) having a first tab (20) extending beyond said transparent layer (12) to facilitate removal of said release liner (16) when the wound dressing product (10) is to be applied to a wound.

3. A method of manufacturing a wound dressing product (10) as claimed in claim 1 or 2, further characterized by the inclusion of the step of printing a grid pattern (26) on said transparent layer (12).

4. A method of manufacturing a wound dressing product (10) as claimed in claim 1, 2 or 3 characterized in that the step of providing a dimensionally stable backing member (22) includes the step of providing a dimensionally stable backing member (22) having a second tab (24) extending beyond said transparent layer (12) to facilitate removal of said dimensionally stable backing member (22) after the wound dressing product (10) has been applied to the wound.

5. A method of manufacturing a wound dressing product (10) as claimed in claim 4, further characterized by the inclusion of the step of positioning a release element (28) between said transparent layer (12) and said backing member (22) adjacent to said second tab (24) thereby further facilitating removal of said dimensionally stable backing member (22) after the wound dressing product (10) has been applied to the wound.

6. A method of manufacturing a wound dressing product (10) as claimed in any preceding claim characterized by the inclusion of the step of providing a dimensionally stable backing member (22) includes the step of providing a dimensionally stable backing member (22) defining a center aperture and wherein the step of laminating said second side of said dimensionally stable backing member (22) includes the step of laminating said

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transparent layer (12) to said backing layer (22) such that said dimensionally stable backing member (22) surrounds but does not overlie said hydrogel material (18) contained in said center portion of said transparent layer (12).

7 A method of manufacturing a wound dressing product (10) as claimed in any preceding claim characterized in that said first adhesive layer (17) has stronger adhesive qualities than said second adhesive layer (23) so as to allow removal of said dimensionally stable backing member (22) from said transparent layer (12) after application of the wound dressing product (10) to the wound while maintaining adhesion between said transparent layer (12) and the skin of a patient.

8. A wound dressing product (10) for a wound comprising
a wound dressing (11) including
a transparent layer (12) having a center portion (14) and an adhesive perimeter portion (15) surrounding said center portion (14) and further having a first side and a second side,
a first adhesive layer (17) coating said adhesive portion positioned on said first side of said transparent layer (12), and
a layer of a hydrogel material (18) positioned on said first side of said transparent layer (12) in said center portion (14);
a release liner (16) overlying said hydrogel material (18) and secured to said first side of said transparent layer (12) by means of said first adhesive layer (17); and
a dimensionally stable backing member (22) having a second adhesive layer (23), said backing member (22) secured to said second side of said transparent layer (12), opposite said first side, by means of said second adhesive layer (23).

9. A wound dressing product (10) as claimed in claim 8, characterized in that said release liner (16) has a first tab (20) extending beyond said transparent layer (12) to facilitate removal of said release liner (16) from said transparent layer (12) when the wound dressing product (10) is to be applied to a wound.

10. A wound dressing product (10) as claimed in claim 8 or 9, characterized in that a grid pattern (26) is printed on said transparent layer (12).

11. A wound dressing product (10) as claimed in claim 8, 9 or 10, characterized in that said dimensionally stable backing member (22) has a second tab (24) extending beyond said transparent layer (12) to facilitate removal of said dimensionally stable backing member (22) after the wound dressing product (10) has been applied to the wound.

12. A wound dressing product (10) as claimed in claim 11, characterized in that a release element (28) is positioned between said transparent layer (12) and said backing member (22) adjacent to said

second tab (24) to further facilitate removal of said dimensionally stable backing member (22) after the wound dressing product (10) has been applied to the wound.

5 13. A wound dressing product (10) as claimed in any one of claims 8-12, characterized in that said dimensionally stable backing member (22) defines a center aperture whereby said dimensionally stable backing member (22) surrounds but does not overlie said hydrogel material (18) contained in
10 said center portion (14) of said transparent layer (12).

14. A wound dressing product (10) as claimed in any one of claims 8-13, characterized in that said transparent thin-film layer (12) comprises a poly-
15 urethane material.

15. A wound dressing product (10) as claimed in any one of claims 8-14, characterized in that said release liner (16) is silicone coated.

20 16. A wound dressing product (10) as claimed in any one of claims 8-15, characterized in that said first adhesive layer (17) comprises a medical grade acrylic adhesive.

17. A method of application of a wound dressing (11) to a wound site, the wound dressing (11) including (1) a transparent layer (12) having an adhesive perimeter portion (15) and a center portion (14) and (2) a hydrogel material (18) contained in the center portion (14) of the transparent
25 layer (12), said wound dressing (11) being provided as a part of a product (10) further including a release liner (16) adhesively attached to a first side of the transparent layer (12) and a dimensionally stable backing member (22) adhesively attached to
30 a second side of the transparent layer (12), comprising the steps of:
partially removing said release liner (16) from said first side of said transparent layer (12) of the wound dressing (11);

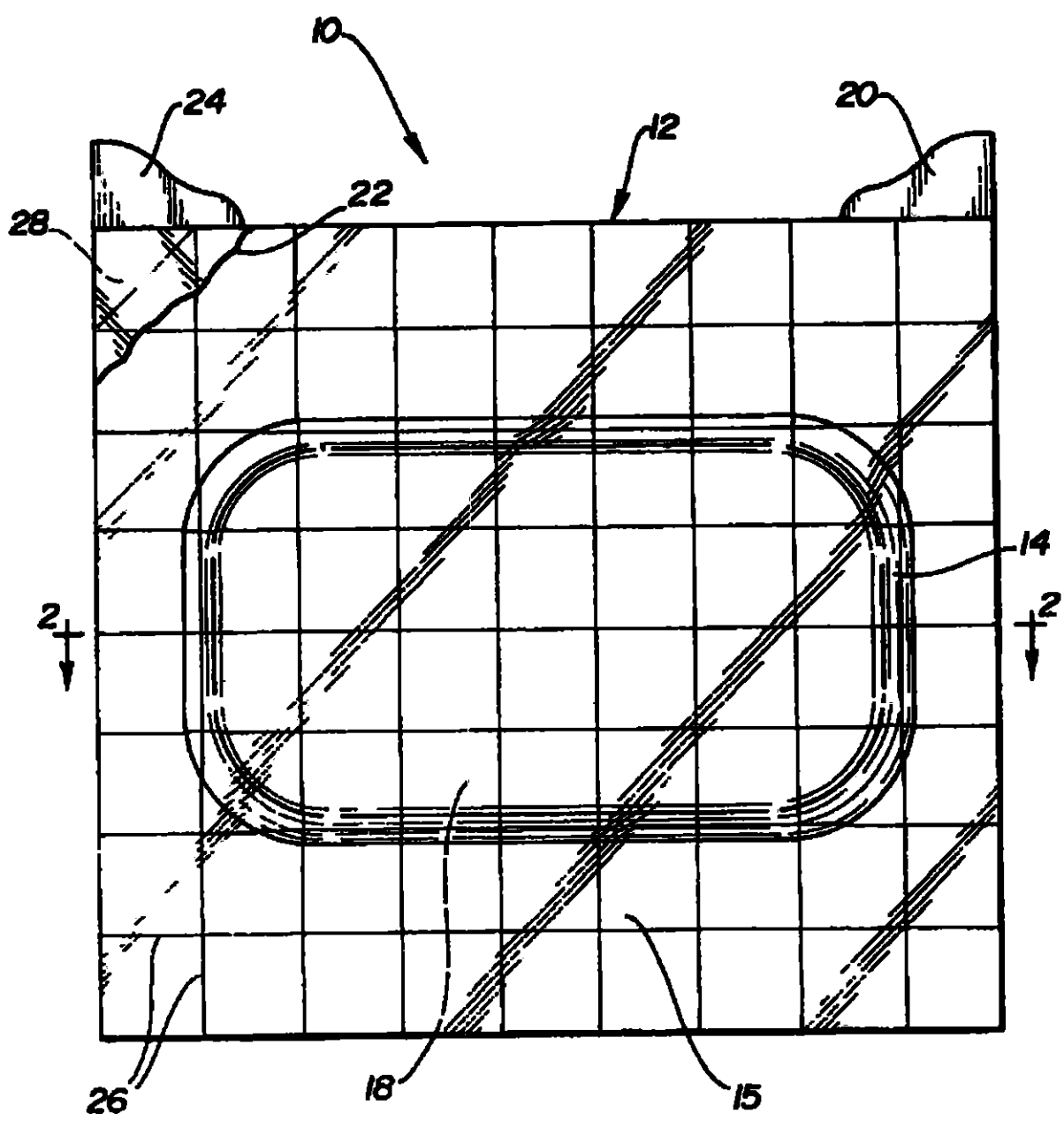
40 applying the wound dressing (11) over the wound site in a rolling motion whereby said hydrogel material (18) directly contacts the wound;
continuing to remove said release liner (16) from said first side of said transparent layer (12) of the wound dressing (11) until said hydrogel substance (18) completely covers the wound site (30);

45 securing the wound dressing (11) to the wound site by pressing said adhesive perimeter portion (15) of said transparent layer (12) gently into place over healthy skin surrounding the wound and
50 removing said dimensionally stable backing member (22) from said second side of said transparent layer (12) after the wound dressing (11) has been applied to the wound.

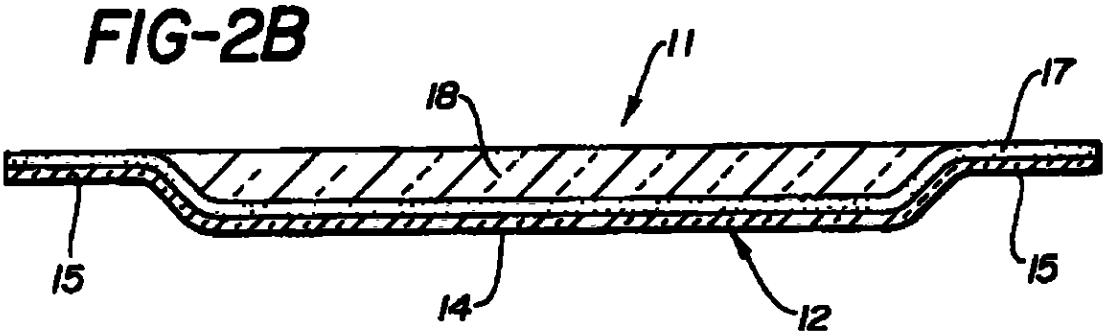
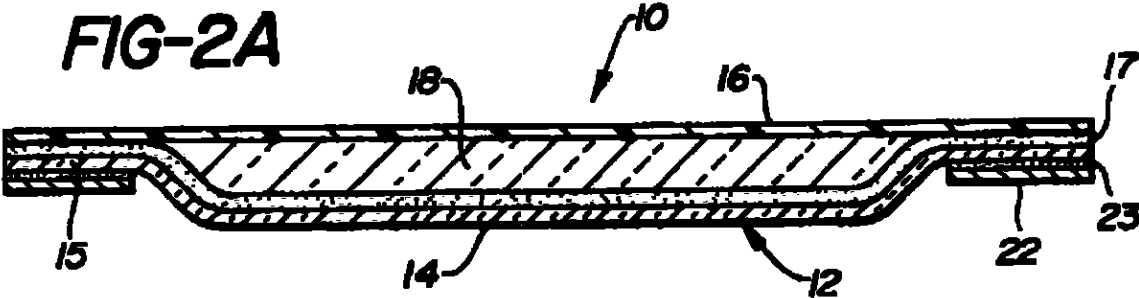
55 18. A method of application of a wound dressing (11) as claimed in claim 17, characterized in that said release liner (16) has a first tab (20) extending beyond said transparent layer (12) to facilitate re-

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FIG-1

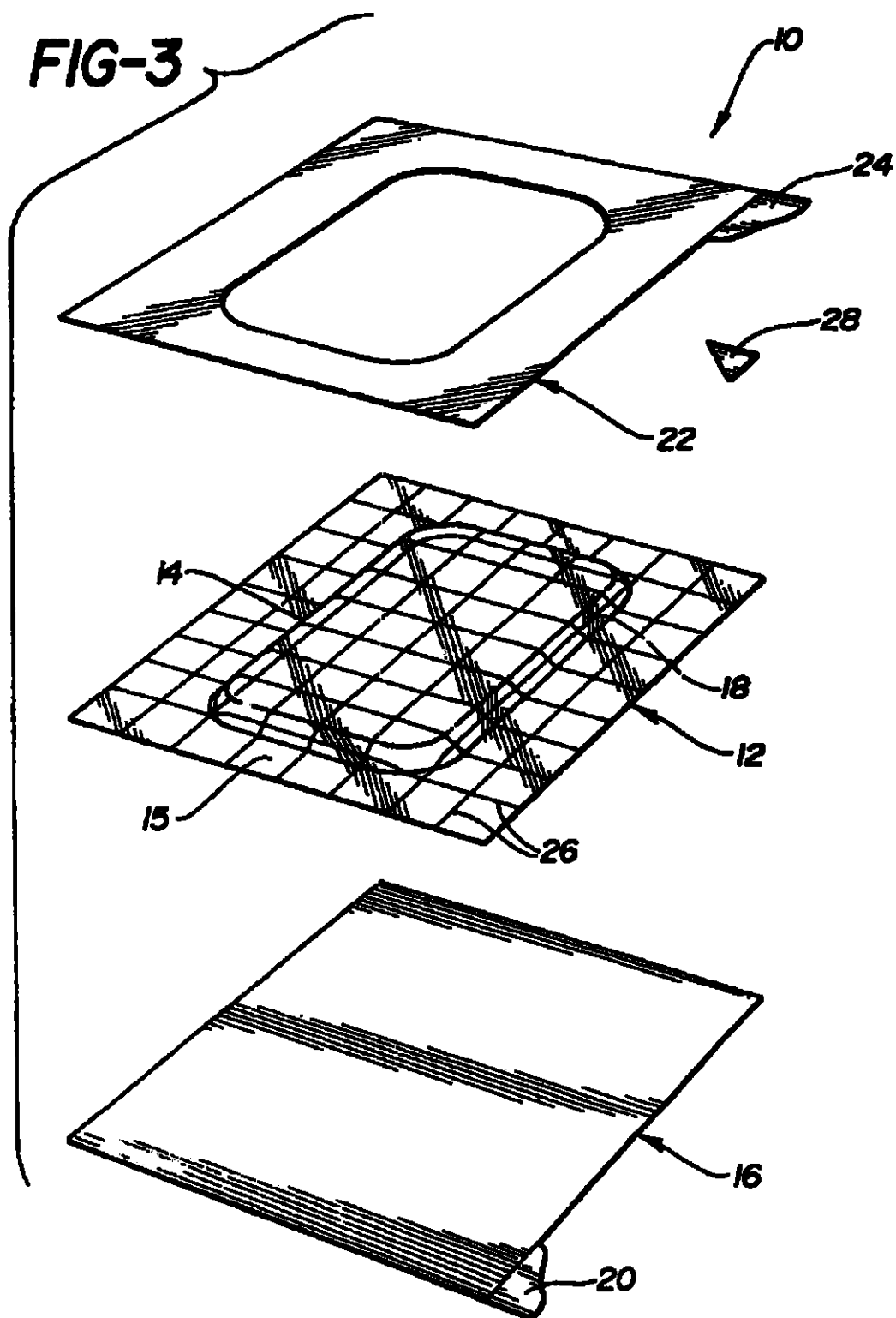


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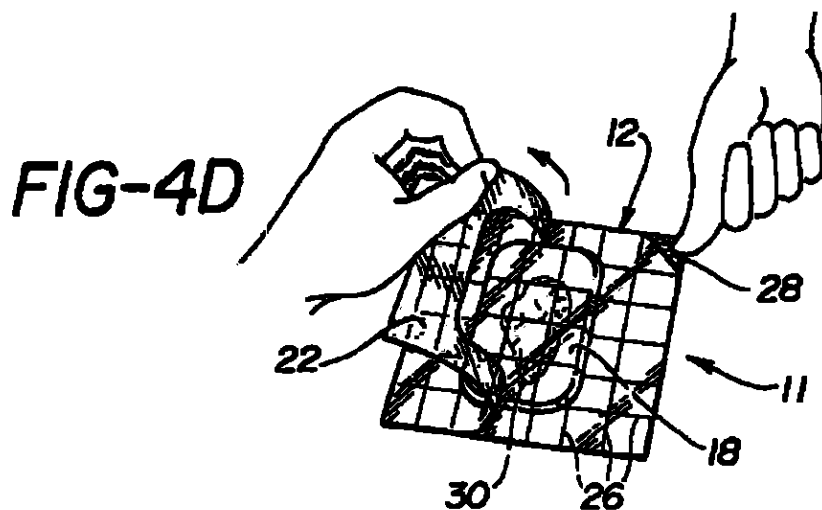
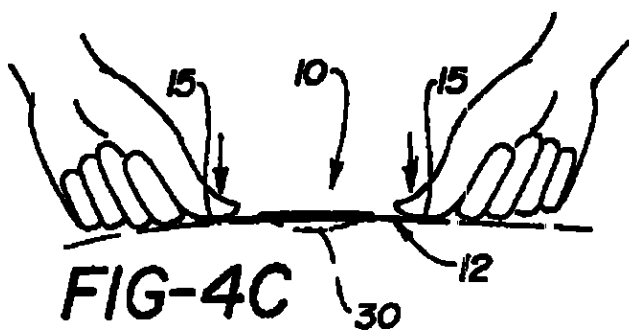
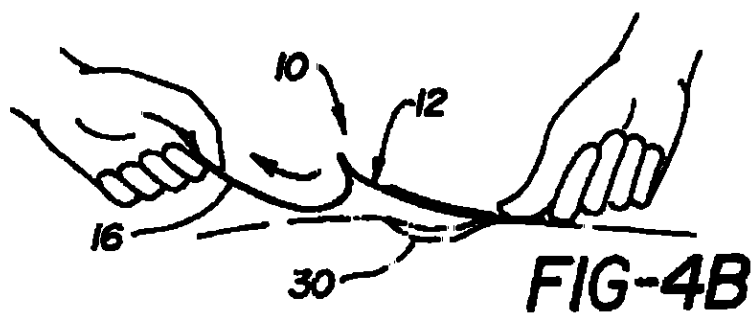
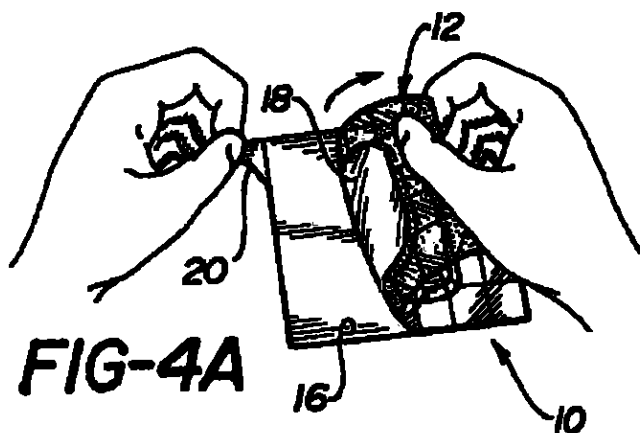


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FIG-3



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United States Patent [19]
Turngren et al.

[11] **Patent Number** **5,891,078**
[45] **Date of Patent** **Apr. 6, 1999**

[54] **STERILE ADHESIVE BANDAGE AND ASSOCIATED METHODS**

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Related U.S. Application Data

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[51] **Int. Cl.** ⁴ ————— A61F 13/00
[52] **U.S. Cl.** ————— 602/58; 602/57 602/900, 604/307 206/441
[58] **Field of Search** ————— 602/41-58, 900, 602/904, 604/307 308 180- 206/440, 441

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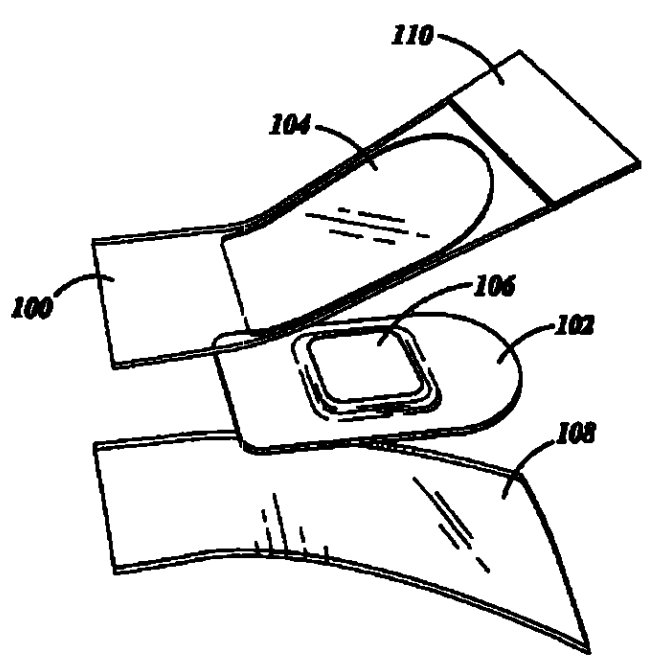
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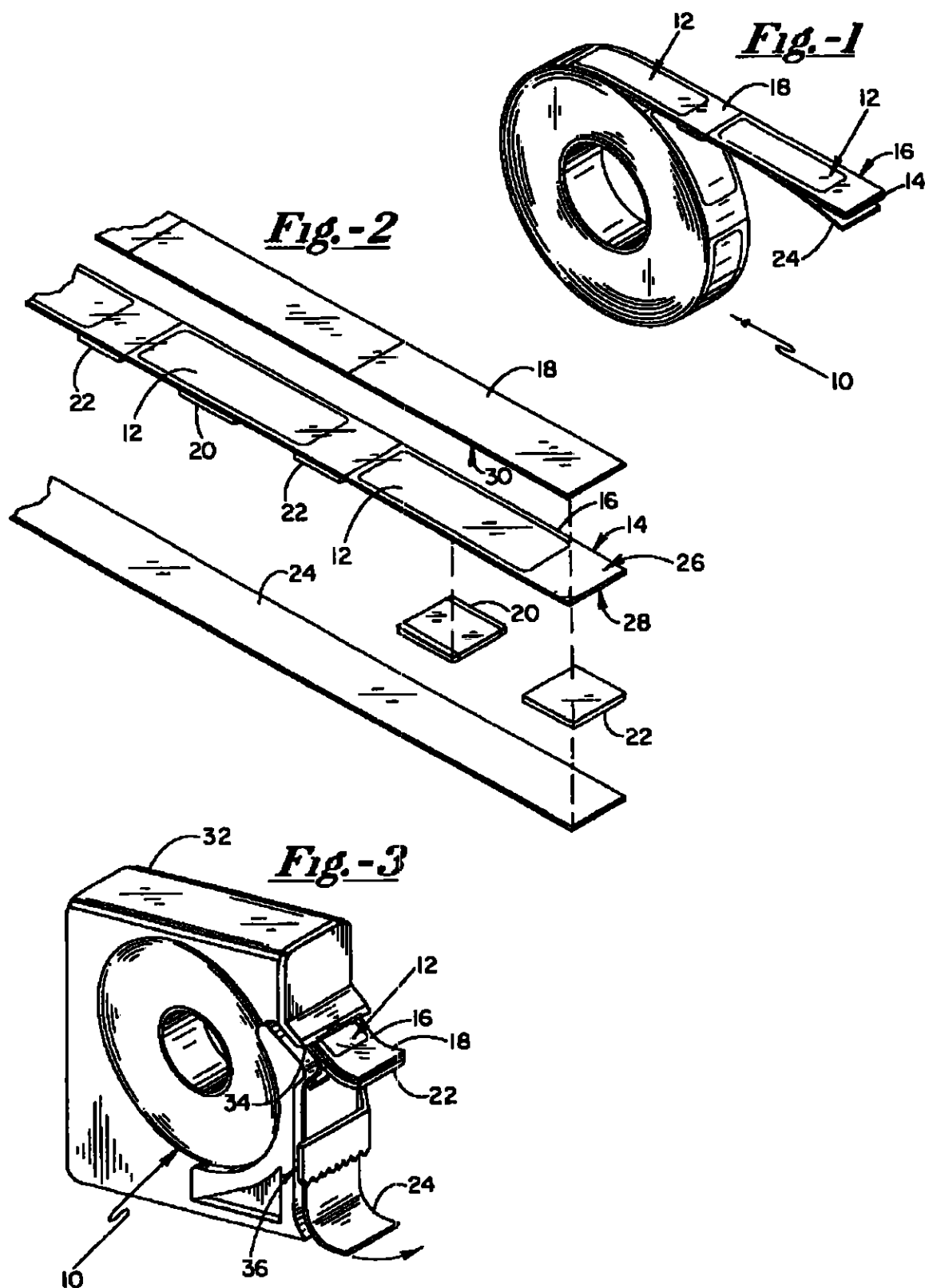
[57] **ABSTRACT**

A sterile delivery system for delivering an adhesive strip or bandage with one hand. The bandage or strip is encapsulated in a protective sterile covering, whereby the bandage or strip may be removed from its sterile covering and applied with one hand without contaminating any portion of the bandage or strip. The delivery system may be manufactured from suitable thin films and may include a blocking member positioned between the strip and the protective sterile covering. The apparatus and method to manufacture the unique bandage or strip is also disclosed.

22 Claims, 11 Drawing Sheets



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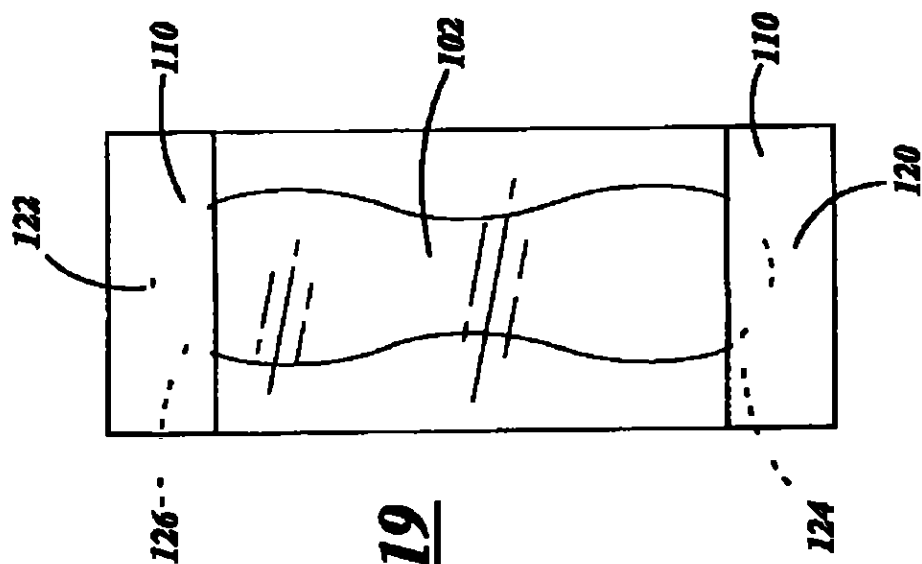


Fig. 19

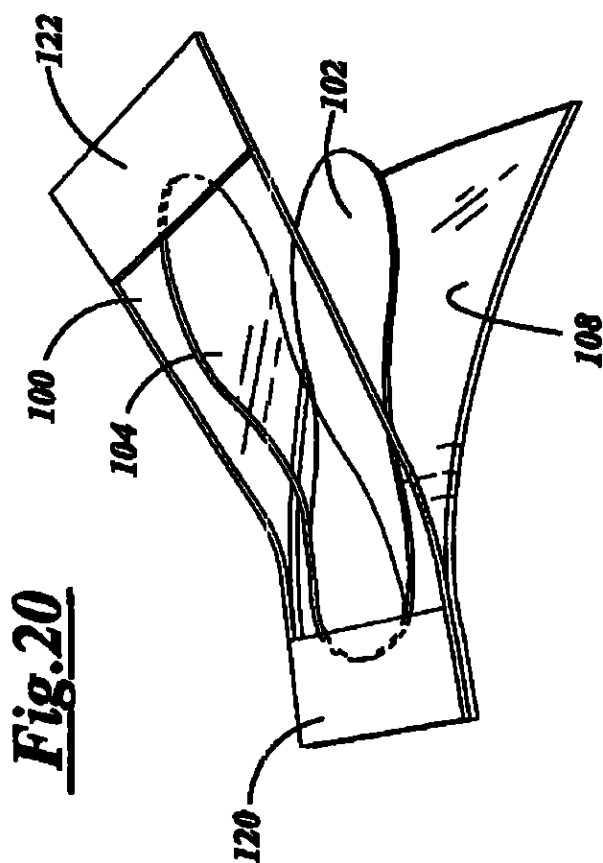


Fig. 20

when the adhesive strip 102 is constructed from a more rigid film such as vinyl, for example

During the manufacture of a continuous roll of delivery devices, wound pads 106 are selectively placed on a continuous roll of thin film suitable for use as the adhesive strip 102. A continuous roll of the blocking film 104 is positioned over an upper surface of the continuous roll of adhesive strips 102. Then a continuous roll of release backing 108 is positioned against the lower surface of the continuous roll of adhesive strips 102. A die cut/kiss cut is then made through the blocking film 104 and adhesive film 102. The die may be formed in any of a variety of desired shapes. The outer frame of the blocking film and adhesive film are stripped away and a continuous roll of carrier film 100 is positioned over the top of the cut out blocking members 104 and adhesive strips 102 (see FIG. 18). The carrier film is die cut at preselected intervals to thereby define the length of the bandage or strip. Of course, the cut may extend through all the layers of film to thereby create a plurality of individual delivery devices. The continuous carrier 100 and release backing 108 may then be rolled onto a spindle to form a continuous roll of sterile delivery devices.

FIGS. 15-17 illustrate the delivery device constructed from thin films having the wound pad removed. Without any limitation intended, the thin films may be transparent to allow the user to center the adhesive strip over the desired location. Applying the adhesive strip to a desired location with a certain degree of precision may prove advantageous in certain applications. For example, the delivery device may be used to securely hold an intravenous (IV) needle and tube against the wrist, whereby centering the needle under the strip may be desirable. The transparent adhesive strip provides a see-through hold down, while isolating the IV needle from potential contaminating contacts with external contaminants.

Referring now to FIGS. 19-20 another alternate embodiment of the sterile delivery device is shown. The adhesive bandage 102 is formed from vinyl, woven fabric, non-woven fabric, polyester or other material suitable for use as an adhesive bandage, wherein the bandage 102 has an adhesive coated on the bottom surface thereof. The bandage 102 is sandwiched between the carrier member 100 and release backing 108, wherein a low tactile adhesive is coated on the lower planar surface of the carrier member 100. First tab 120 is attached to one end of the carrier member 100 and second tab 122 is attached to the opposite end of the carrier member 100. The ends or tips 124 and 126 of the bandage 102 overlap with the respective tabs 120 and 122. Alternatively it may be desirable that only tip 124 overlap with tab 120. An adhesive is applied to tab 120, wherein the overlapping portion of tip 124 adheres to the tab 120. Thus, the carrier member and adhesive portion of the tab overlap the upper surface of the bandage. In use, the user pulls on tab 120 thereby separating the carrier member 100 and bandage 102 from the release backing 108. The difference in tactile between the adhesive on the carrier member 100, tab 120, and strip 102 allows the strip 102 to separate from the release backing 108 while adhering to the carrier member 100 and tab 120. Then the user applies the bandage to a desired surface, pressing against the upper surface of the carrier member 100. Once the bandage is in place, the user then pulls on tab 122 to thereby peel the carrier member 100 and tab 120 from the bandage 102. In this manner, the need for a blocking member is eliminated. Those skilled in the art will appreciate that some form of indicia, for example color coding, may be applied to tabs 120 and 122, wherein the color coding may be utilized by the user to identify the

proper sequence of pulling on the tabs. Of course a dispenser may be utilized such that the user must inherently first pull on tab 120 to separate the bandage and carrier member from the release backing. One such dispenser is disclosed in co-pending application filed by the same inventor concurrently with the present application, the entire disclosure of which is incorporated herein by reference for any purpose.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:

1. A delivery device including a sterile element that may be removed from its sealed enclosure without contaminating any portion of the element, said device comprising:

- (a) a strip being die cut to define a shape of the element,
- (b) a blocking member congruent with said strip and attached to an upper planar surface of said strip,
- (c) a removable carrier member attached to an upper planar surface of said blocking member, wherein said carrier member overlaps the upper planar surface of said blocking member,
- (d) a pull tab associated with a lower planar surface of said carrier member and
- (e) a removable release backing engaged with a lower planar surface of said strip, wherein said release backing overlaps the lower planar surface of said strip, thereby isolating said strip, blocking member and tab between said release backing and said carrier member.

2. The device as recited in claim 1, wherein the carrier member has a light tack adhesive coating deposited on a lower strip engaging surface of said carrier member.

3. The device as recited in claim 1, wherein the strip has an adhesive coating deposited on the lower planar surface of said strip.

4. The device as recited in claim 3 further including a wound pad attached to the lower planar surface of said strip, wherein said wound pad is centered on the lower planar surface of said strip.

5. The device as recited in claim 1, wherein said blocking member includes a light tack adhesive coating deposited on a lower planar surface of said blocking member.

6. The device as recited in claim 1 further including a removal tab attached to the lower planar surface of said carrier member, wherein said pull tab and said removal tab are spaced apart such that a major portion of the strip is positioned therebetween.

7. The device as recited in claim 6 wherein a tip of said strip engages a portion of a lower planar surface of said pull tab, said portion of the lower planar surface of said pull tab having an adhesive deposited thereto.

8. The device as recited in claim 1, wherein said strip is manufactured from a material selected from the group consisting of vinyl, woven fabric, non-woven fabric, and polyester.

9. The device as recited in claim 1, wherein said strip is manufactured from a material selected from the group consisting of a thin film, urethane, and polyurethane.

10. The device as recited in claim 8, further including a removal tab attached to the lower planar surface of said

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