

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 09-024522- -00002-0000

Fecha: 2009-06-01 17:03:41 Dep. 2020 NUECREACION:
Tra 2 PATENTES Eve: 1 REGDEPOSITO
Act. 329 CTOINFORMACION Folios: 40

Señora

Alix Carmenza Céspedes de Vergel

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. S. D.

Referencia: Expediente No. 09.024.522

Solicitud de Patente de Invención titulada: "Vendaje para herida para terapia con vacío para herida con zonas de desempeño variable"

Solicitante: Tyco Healthcare Group LP

MEMORIAL DE COMPLEMENTACIÓN

ÁLVARO CORREA ORDÓÑEZ, mayor de edad y vecino de Bogotá D.C., identificado según aparece al pie de mi firma, en mi condición de apoderado de la sociedad en referencia, manifiesto lo siguiente:

El día 10 de marzo de 2009, bajo el número de radicación 09-024.522, presenté la solicitud de patente de invención de la referencia, para la cual adjunto la copia certificada del documento de prioridad US 12/047,910 del 13 de marzo de 2008 junto con su traducción simple de carátula y reivindicaciones, para cumplir con los requisitos establecidos por la Decisión 486.

Atentamente,

ÁLVARO CORREA ORDÓÑEZ

C.C.No.79.143.366 de Usaquén

T.P.20.281

Anexo: Documento de Prioridad-traducción de carátula y reivindicaciones



LOS ESTADOS UNIDOS DE AMERICA

A TODO AQUEL A QUIEN CONCIERNA LO PRESENTE
DEPARTAMENTO DE COMERCIO DE LOS ESTADOS UNIDOS
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22 de abril de 2009

LA PRESENTE ES PARA CERTIFICAR QUE ADJUNTA A LA MISMA HAY UNA COPIA FIEL DE LOS REGISTROS DE LA OFICINA DE PATENTES Y MARCAS DE LOS ESTADOS UNIDOS DE LOS DOCUMENTOS DE LA SOLICITUD DE PATENTE IDENTIFICADA EN LO QUE SIGUE, QUE CUMPLE LOS REQUISITOS PARA OTORGARLE UNA FECHA DE PRESENTACIÓN BAJO EL 35 USC 111.

NÚMERO DE SOLICITUD: 12/047,910
FECHA DE PRESENTACIÓN: 13 de marzo de 2008

EL CÓDIGO DE PAÍS Y NÚMERO DE SU SOLICITUD DE PRIORIDAD, PARA SER USADA PARA PRESENTACIÓN EN EL EXTRANJERO DE ACUERDO CON LA CONVENCIÓN DE PARIS, ES *ÚS12/047,910*



Por la Autoridad del
De acuerdo con la Secretaría de Comercio para la
Propiedad Intelectual y el Director de la Oficina de
Marcas y Patentes de los Estados Unidos

(Aparece firma ilegible)

M.K. CARTER

Funcionario Certificador

REIVINDICACIONES

1. Una capa de cubierta para un vendaje de herida para uso en una terapia con vacío para herida, la capa de cubierta comprende:

una zona central definida por una porción de una membrana permeable a vapor de humedad desprovista de cualquier recubrimiento que detenga la transmisión de la humedad a través de la membrana;

una zona periférica circunda sustancialmente la zona central, la zona periférica adaptada para suministrar un sello alrededor del perímetro del lecho de la herida;

por lo menos una zona intermedia por o menos parcialmente dispuesto entre la zona central y la zona periférica, a por lo menos una zona intermedia que comprende una sustancia para impartir un efecto terapéutico al lecho de la herida.

2. La capa de cubierta de acuerdo con la reivindicación 1, en donde la zona periférica incluye un adhesivo de alta resistencia al pelado.
3. La capa de cubierta de acuerdo a la reivindicación 1, en donde por lo menos una zona intermedia comprende un primera zona intermedia que incluye un adhesivo resistente al corte.

4. Una capa de cubierta de acuerdo a la reivindicación 3, en donde por lo menos una zona intermedia comprende además una segunda zona intermedia que incluye un recubrimiento de suministro de medicamento.
5. La capa de cubierta de acuerdo con la reivindicación 3, en donde por lo menos una zona intermedia comprende además una segunda zona intermedia que incluye un hidrogel.
6. La capa de cubierta de acuerdo con la reivindicación 3, en donde por lo menos una zona intermedia comprende además una segunda zona intermedia que incluye por lo menos un agente anti infeccioso, un anti microbiano, antibiótico, analgésico, factor de curación, vitaminas, factores de crecimiento, agentes de desbridamiento o nutrientes.
7. La capa de cubierta de acuerdo con la reivindicación 1, en donde la membrana permeable al vapor de la humedad se extiende a la periferia de la capa de cubierta para constituir una capa de respaldo, la zona periférica definida por una capa de adhesivo unida a la capa de respaldo.
8. La capa de cubierta de acuerdo con la reivindicación 1, en donde la zona periférica por lo menos una zona

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intermedia están dispuestas concéntricamente con respecto a la zona central.

9. La capa de cubierta de acuerdo con la reivindicación 1, que comprende además un puerto para permitir el acceso a un reservorio de vacío definido bajo la capa de cubierta para un tubo de vacío.
10. Un aparato para vendaje de herida para uso de un procedimiento de terapia con vacío para herida, que comprende:

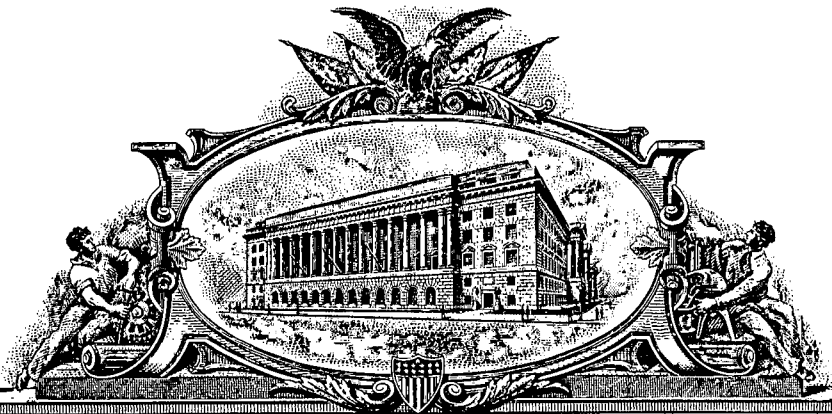
una etapa de contacto adaptada para ubicarse adyacente al lecho de la herida;

un relleno absorbente ubicado adyacente a la capa de contacto dentro del lecho de la herida para recolectar líquidos que exudan desde el lecho de la herida;

una cubierta ubicada sobre el lecho de la herida que define un reservorio de vacío entre estas y que permite el acceso de un tubo de vacío al reservorio de vacío, la capa de cubierta comprende una zona periférica para suministrar un sello alrededor del lecho de la herida, por lo menos una zona intermedia para impartir un efecto terapéutico al lecho de la herida, y una zona central formada de una membrana permeable al vapor de la humedad.

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11. Un aparato de vendaje para herida de acuerdo con la reivindicación 10, en donde la capa de contacto se forma de una película con perforaciones cónicas.
12. Un aparato de vendaje para herida de acuerdo con la reivindicación 10, en donde el material de relleno absorbente comprende filamentos de poliolefina dispuestos en un manojo mulihebra.
13. El aparato de vendaje para herida de acuerdo con la reivindicación 10, que comprende además un sistema de vacío en comunicación fluida con el reservorio de vacío.
14. El aparato de vendaje de herida de acuerdo con la reivindicación 13, en donde el sistema de vacío incluye una fuente de vacío, un frasco de recolección y una válvula de una vía.



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

April 22, 2009

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 12/047,910

FILING DATE: March 13, 2008

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US12/047,910

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**




M. K. CARTER
Certifying Officer

Electronic Acknowledgement Receipt

EFS ID:	2996197
Application Number:	12047910
International Application Number:	
Confirmation Number:	3889
Title of Invention:	VACUUM WOUND THERAPY WOUND DRESSING WITH VARIABLE PERFORMANCE ZONES
First Named Inventor/Applicant Name:	Ronald F. Vitaris
Customer Number:	55825
Filer:	Joseph W. Schmidt/Tricia Tucci
Filer Authorized By:	Joseph W. Schmidt
Attorney Docket Number:	H-KN-00986 (1502-300)
Receipt Date:	13-MAR-2008
Filing Date:	
Time Stamp:	16:59:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 1030
RAM confirmation Number	2291
Deposit Account	190254
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

9

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	DataSheet_HKN00986.pdf	1044747 8123d352d6d126e1ea65od6c43a78d9e b5c45d81	no	4

Warnings:

Information:

2		Application_HKN00986.pdf	581011 9051bb4e19b66b2b1c2369887b47d16 63da80d3f	yes	16
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Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	12
Claims	13	15
Abstract	16	16

Warnings:

Information:

3	Drawings-only black and white line drawings	Figs_HKN00986.pdf	132328 7d35202f920a6bc88d40ea14ca103d85 2b371a30	no	4
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Warnings:

Information:

4	Oath or Declaration filed	Declaration_HKN00986.pdf	209948 5e0ce3ce19d1017fe5a7cdd663f5e302 337080fa	no	6
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Warnings:

Information:

5	Fee Worksheet (PTO-06)	fee-info.pdf	8417 d25aad9e0bbb67986d933381b60c395 53b35c495	no	2
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Warnings:

Information:

Total Files Size (in bytes):			1976451
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VACUUM WOUND THERAPY WOUND DRESSING
WITH VARIABLE PERFORMANCE ZONES

BACKGROUND

1. Technical Field

5 The present disclosure relates generally to a wound dressing for treating an open wound with a vacuum wound therapy treatment. In particular, the disclosure relates to a dressing having a cover layer employing a plurality of zones of variable performance characteristics to promote healing of the wound.

2. Background of Related Art

10 The body's natural wound healing process is a complex series of events beginning at the moment of injury. Initially the body reacts by delivering proteins and other factors to the wound through the blood stream to minimize the damage. Blood clots to prevent blood loss while cells engulf bacteria and debris to carry it away from the wound site. Next, the body begins to repair itself in a stage of healing often referred to as the proliferate phase. This phase is characterized by the deposition granulation tissue in the wound bed. Granulation tissue provides a base structure over which cells may migrate inwardly from the periphery to close the wound. Finally the process ends as collagen gives strength to new tissue over time often forming a scar.

One technique for promoting the natural healing process, particularly, but not exclusively during the proliferate phase, is known as vacuum wound therapy (VWT). Application of a reduced pressure, e.g. sub-atmospheric, to a localized reservoir over a wound has been found to

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assist in closing the wound. The reduced pressure may be effective to promote blood flow to the area to stimulate the formation of granulation tissue and the migration of healthy tissue over the wound in the natural process. Also a reduced pressure may assist in removing fluids exuding from the wound, which may inhibit bacterial growth. This technique has proven effective for
5 chronic or non-healing wounds, but has also been used in for other purposes such as post-operative wound care.

The general VWT protocol provides for the introduction of a filler material into the wound to absorb exudates. The filler material may comprise such materials as non-reticulated foams, non-woven fabrics or gauze. The wound and the filler material may then covered by
10 moisture vapor permeable cover layer that permits oxygen exchange with the environment, which may be essential for wound healing. The cover layer often includes an adhesive periphery that forms a substantially fluid tight seal with the healthy skin surrounding the wound. The cover layer thus defines a vacuum reservoir over the wound where a reduced pressure may be maintained over time by individual or cyclic evacuation procedures.

15 An aspect of concern in a VWT treatment is the management of forces generated in the dressing when a vacuum is applied. Such forces may cause the separation of the dressing from the skin, thereby limiting the effect of the VWT treatment and increasing the probability that microorganisms will infect the wound. Also, such forces may damage newly forming granulation tissue. The application of a vacuum can deform a flexible cover layer such that it
20 compresses the filler and increases its tendency to adhere to the wound bed. Additionally, the deformation of the cover layer creates transverse shear forces along the skin-adhesive interface at the peri-wound area. These shear forces can cause the dressing to shift and/or pull away from the skin where gaps and wrinkles may develop. Such movement, and the mentioned results

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thereof, can inhibit the dressing's ability to provide a seal that is suitable for both the maintenance of a vacuum and for prohibiting the infiltration of contamination.

Adhesives applied to a cover layer to strengthen or reinforce the dressing's attachment to the skin may diminish the moisture vapor permeability of the dressing affecting its ability to permit oxygen exchange with the environment. Diminished moisture vapor permeability could also lead to the accumulation of moisture at the skin-adhesive interface. Permitting such an accumulation undermines the dressing's adhesion to the skin at the peri-wound area, thereby reducing the wear-time of the dressing, the effectiveness of the treatment and the health of the peri-wound area. Accordingly a need exists for a dressing suitable for use in a VWT procedure.

10 **SUMMARY**

The present disclosure describes a dressing for use in a vacuum wound therapy procedure to promote healing of a wound. The dressing includes a cover layer having a plurality of zones of variable performance characteristics. A central zone is defined by a portion of a moisture vapor permeable membrane devoid of any coating that would otherwise inhibit the transmission of moisture through the membrane. A peripheral zone adjacent a periphery of the cover layer is adapted to provide a seal around the perimeter of the wound. At least one intermediate zone is disposed between the central zone and the peripheral zone to impart a therapeutic effect or benefit to the wound.

The peripheral zone may include a high peel-strength adhesive while a first intermediate zone may include a shear-resistant adhesive. A second intermediate zone may include a coating adapted for medicament delivery, a hydrogel for maintaining a moist wound environment, or at

least one of an anti-infective agent, an antimicrobial, antibiotic, analgesic, healing factor, vitamins, growth factors, debridement agents or nutrients.

The moisture variable permeable membrane may extend to a periphery of the cover layer so as to constitute a backing layer for the attachment of an adhesive defining the peripheral zone.

- 5 The peripheral zone and at least one intermediate zone may be arranged concentrically with respect to the central zone. The cover layer may also include a port for permitting access to a vacuum reservoir defined beneath the cover layer for a vacuum tube.

According to another aspect of the disclosure a wound dressing apparatus for use in a vacuum wound therapy procedure includes a contact layer and a filler material positioned in a wound bed and covered by a cover layer. The cover layer defines a vacuum reservoir above the wound bed and permits access of a vacuum tube to the vacuum reservoir. The cover layer includes a peripheral zone to provide a seal around the wound bed, at least one intermediate zone for imparting a therapeutic effect or benefit to the wound bed, and a central zone formed from a moisture vapor permeable membrane.

- 15 The contact layer may be formed from a conical apertured film to promote unidirectional flow of exudates from the wound. The absorbent filler material may include polyolefin filaments arranged in a multi-strand bundle. Also, a vacuum system in fluid communication with the vacuum reservoir may include a vacuum source, a collection canister and a one-way valve.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present disclosure and, together with the detailed description of the embodiments given below, serve to explain the principles of the disclosure.

5 FIG. 1 is an exploded perspective view of a vacuum wound therapy system in accordance with the present disclosure;

FIG. 2A is a perspective view of the vacuum wound therapy system of FIG. 1 assembled for use on a patient;

FIGS. 2B and 2C depict alternate assemblies of the vacuum wound therapy system;

10 FIG. 3A is a reverse angle perspective view of the cover layer of FIG. 1;

FIG. 3B depicts an alternate embodiment of the cover layer;

FIG. 4A is a cross sectional view of the vacuum wound therapy system of FIG. 1 in a first condition exhibiting a vacuum reservoir; and

15 FIG. 4B depicts the vacuum wound therapy system in a second condition wherein the vacuum reservoir is evacuated.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The wound dressing of the present disclosure promotes healing of a wound by providing a reservoir over the wound where a reduced pressure may be maintained. The reservoir subjects the wound to a sub-atmospheric pressure to effectively draw wound fluid, including liquid

exudates, from the wound without the continuous use of a vacuum pump. Hence, vacuum pressure may be applied once, or in varying intervals depending on the nature and severity of the wound. The use of a wound dressing in this manner has been found to promote healing by reducing the probability of infection, stimulating the deposition of granulation tissue and other beneficial processes. The wound dressing of the present disclosure includes a cover layer having multiple performance zones to enhance the effect of a vacuum wound therapy treatment.

The attached figures illustrate exemplary embodiments of the present disclosure and are referenced to describe the embodiments depicted therein. Hereinafter, the disclosure will be described in detail by explaining the figures wherein like reference numerals represent like parts throughout the several views.

Referring initially to FIG. 1, a vacuum wound therapy system according to the present disclosure is depicted generally as 10 for use on a wound "w" surrounded by healthy skin "s." The vacuum wound therapy system 10 includes a vacuum system 12 in fluid communication with a vacuum reservoir 14 (FIG. 4A) defined by or within the wound dressing 16. The vacuum system 12 includes a vacuum source 18 coupled to the dressing 16 through a one-way valve 20 and a vacuum tube 24. A collection canister 28 is provided for wound drainage and debris. The vacuum system 12 is adapted to provide a reduced pressure to the vacuum reservoir 14 appropriate to stimulate healing of the wound. A more detailed description of an appropriate vacuum system 12 is found in commonly assigned U.S. Patent Application Publication 2007/0066946, the entire contents of which are incorporated herein by reference.

Wound dressing 16 generally includes a contact layer 34, filler 38 and a cover layer 40 defining a plurality of performance zones. A backing layer 44 may be coated with various

materials in a juxtaposed relation to define a peripheral zone 48, a first intermediate zone 52, a second intermediate zone 56 and a central zone 58 (FIG. 3A). Alternatively, each zone may comprise an independent layer positioned adjacent the wound bed "w." Each layer is described in greater detail below.

5 Contact layer 34 may be sufficiently conformable to be positioned in direct contact with an irregularly shaped surface of a wound bed "w." A thin film of polyethylene or other suitable non-adherent material may form the contact layer 34 to limit the adherence of filler 38 and other substances to the wound "w." Apertures or perforations in the film permit fluids to pass through the contact layer 34, allowing for the sub-atmospheric pressure to penetrate into the wound "w" and for exudates to flow freely out of the wound "w." By selecting an appropriate film material, the passage of wound exudate through contact layer 34 may be controlled so as to be substantially unidirectional to prevent wound exudate from flowing back into the wound. To promote a unidirectional flow, a conical apertured film, such as those provided by Tredegar Film Products of Richmond, VA, may be selected for forming contact layer 20. This type of film is arranged with apertures positioned at the peaks of cone shaped formations in the film material such that exudate encounters the film as an array of micro-funnels in one direction and an array of collecting basins in the other. Unidirectional flow of exudates may also be promoted by the selection of other materials including a lamination of layers having varying absorptive characteristics. One exemplary material, which may be used as a contact layer is sold under the trademark XEROFLO® by Kendall Corp., a division of Covidien.

Filler 38 may be arranged over contact layer 34 to fill wound "W" to the level of the surrounding healthy skin "s," or alternatively the wound "w" may be overfilled with filler 38. An absorbent material such as non-woven gauze or reticulated foam may be used for filler 38 to

trap any exudate that migrates through contact layer 34. An antimicrobial dressing sold under the trademark KERLIX™ AMD™ by Kendall Corp., a division of Covidien, may be suitable for use as filler 38. To prevent adhesion to the wound “w,” the filler 38 may also comprise a material configured such that its fibers do not tend to protrude through apertures of contact layer 34 where they may become engulfed by newly forming granulation tissue. One particular type of material exhibiting this characteristic is often referred to as “tow.” The manufacturing process for synthetic fibers often includes an extrusion of an indeterminate length of continuous filaments, which are spun together to form fibers. Continuous lengths of un-spun filaments may be arranged in multi-strand bundles which are referred to as tow. A single length of tow formed from a hydrophobic material such as polyolefin may be laid in the wound bed “w” to form filler 38. This arrangement allows for a complete removal of filler 50 when the dressing 16 is changed without re-injuring the wound “w.”

Cover layer 40 may be placed over the wound “W” enclosing the contact layer and filler therein. The periphery of cover layer 40 extends laterally beyond the perimeter of the wound bed “w” so as to contact the healthy skin “s” to form a seal over the wound “w.” As depicted in FIG. 2A, an opening 60 may be provided or formed through the cover layer 40 to provide access for the vacuum tube 44 to communicate with the vacuum reservoir 14, or the vacuum tube 44 may be sealed under the periphery of the cover layer 40 as depicted in FIG 2B. Alternatively, a distinct portal member or port 62 may be provided to facilitate fluid communication between the vacuum system 12 and the vacuum reservoir 14 as depicted in FIG. 2C. Port 62 may be configured as a rigid or semi rigid, low-profile component adapted to receive the vacuum tube 24 in a releasable and fluid-tight manner. The vacuum port 62 may be configured to include a wide and flexible flange 64 about its perimeter. The flange 64 permits an adhesive to be attached to

either an underside of flange 64 for securement to an outer surface of cover layer 40, or to a top side of flange 64 to provide for mounting to the underside of the cover layer 40.

Referring now to FIG. 3A, cover layer 40 includes multiple performance zones 48, 52, 56 and 58 comprising various materials. A backing layer 44 may extend to the periphery of the cover layer 40 to provide a substrate for various coatings or materials defining the various performance zones 48, 52, 56 and 58. As depicted, each of the performance zones 48, 52, 56 and 58 is a continuous band arranged concentrically with respect to the others. The size, shape and position of the zones, however, may be varied according to the needs of the particular wound or treatment. For example, a cover layer 40A as depicted in FIG. 3B may be provided comprising a first intermediate zone 52 formed from a pattern of distinct shapes surrounded by second intermediate zone 56A. The various coatings may be laminated to the backing layer 44 or affixed by other appropriate means. The various materials forming layer 40 are described in greater detail herein below.

Backing layer 44 may be formed from a flexible polymeric membrane to act as a fluid barrier to allow for a sub-atmospheric pressure to be established in vacuum reservoir 14. The material's flexibility accommodates the pressure changes associated with the evacuation cycles in a VWT procedure. Backing layer 44 also serves as a microbial barrier preventing contaminants from entering the wound area. Preferably, the backing layer 44 is formed from a moisture vapor permeable membrane to promote the exchange of oxygen and moisture between the wound site and the atmosphere. A membrane that provides a sufficient moisture vapor transmission rate (MVTR) and is simultaneously impervious to liquid may be selected for use as backing layer 44. Another preferred membrane characteristic is the ability to stretch and conform to the compressed wound filler or wound bed. A membrane's tendency for elongation

when subjected to a vacuum reduces the shear forces transitioned to the peri-wound area. One exemplary material for use in backing layer 44 is a transparent membrane sold under the trade name DURAFLEX® by Deerfield Urethan, a Bayer Material Science Company. Other materials which may be suitable for use in a backing layer include the thin films marketed under the names POLYSKIN®II by Kendall Corp., a division of Covidien, TEGADERM™ by 3M of St. Paul, MN and OPSITE™ by Smith and Nephew PLC of London, UK. A central zone 58 of the cover layer is defined by the area of the backing layer 44 not covered with any material which would tend to lessen the MVTR.

At the periphery of the cover layer 40 is a peripheral zone 48 defined by a continuous layer of high peel-strength, pressure sensitive adhesive. The adhesive forms a seal with the skin "s" around the perimeter of the cover layer to prevent the ingress of atmospheric fluids under the edges of the cover layer 40 when a reduced pressure is established in the reservoir 14. The adhesive defining the peripheral zone 48 is adapted to prevent the loss of adhesion to the skin even when exposed to environmental factors such as exudates from the wound "w" or body movements by the patient. In general, the high peel-strength adhesive is adapted to resist inadvertent lift-off, roll or "flagging," i.e., a failure of the dressing to adhere to itself, at the edges of the cover layer. The adhesive defining the peripheral zone 48 may include, for example, those adhesives included with the dressing sold under the trademark GELVA® Multipolymer Solutions by CYTEC Surface Specialties Inc.

The high peel-strength adhesive defining peripheral zone 48 may be bonded to backing layer 44, or applied directly to the skin "s" surrounding the wound bed "w." The adhesive should preferably be non-irritating and non-sensitizing to the contacted skin, and may be vapor moisture permeable to permit the contacted skin to transmit moisture. Preferably, the peripheral zone 48

and first intermediate zone 52 are positioned so as not to overlap the contact layer 34 as seen in FIGS. 4A and 4B. This arrangement facilitates the changing of certain individual components of the dressing, such as filler 38 without removing the entire dressing 16.

5 Disposed between the peripheral zone 48 and central zone 58 are first and second intermediate zones 52 and 56 respectively. First and second intermediate zones 52, 56 are defined by a layer of a substance for imparting a therapeutic effect or benefit to the wound "w." As indicated above, first and second intermediate zones 52, 56 may be arranged as continuous bands concentric with central zone 58 as seen in FIG. 3A, as a pattern of distinct shapes as seen in FIG 3B, or any other convenient arrangement.

10 First intermediate zone 52 may, for example, be defined by a layer of an adhesive that laterally stabilizes the dressing when a reduced pressure is applied to evacuate the reservoir. As seen in FIG. 4B, when the reservoir is evacuated, the cover layer may tend to flatten against the wound "w." This may result in an outwardly directed force in the dressing 16 which may tend to separate the cover layer 40 from the skin "s." Also, the shear forces in the cover layer 40 may be
15 transmitted to the skin "s," pulling apart newly forming granulation tissue and re-injuring the wound "w." To counteract these tendencies, a shear-resistant adhesive may be selected for use in first intermediate zone 52. Since many high peel-strength adhesives are adapted primarily to resist upwardly directed forces, i.e., those forces tending to lift the cover layer from the skin, a high peel-strength adhesive defining the peripheral zone 48 may be supplemented with an
20 adhesive particularly adapted to resist lateral forces defining the first intermediate zone 52. A shear-resistant adhesive, such as GMS 1753 manufactured by CYTEC Surface Specialties Inc., that is moisture vapor permeable and suitable for use on the skin, may be used to define first intermediate zone 52.

Second intermediate zone 56 may be defined by a layer of a distinct material for providing a therapeutic effect or benefit to the wound. For example, second intermediate zone 56 may be adapted for transdermal medicament delivery. A substance such as an anti-infective agent, an antimicrobial, antibiotic, analgesic, healing factor, vitamins, growth factors, 5 debridement agents or nutrients may be coated on portions of backing layer 108 to define second intermediate zone 56. Alternatively, a hydrogel may be selected for use in second intermediate zone 56 to maintain a moist wound environment. As seen in FIG. 4B, second intermediate zone 56 may be in contact with filler 38 when the reservoir 14 is evacuated to permit transfer beneficial agents thereto. Filler 38 and contact layer 34 may be eliminated if appropriate allowing for second intermediate zone 56 to contact the wound bed directly. It is also contemplated that an additional attachment adhesive may be beneficial for use in second intermediate zone 56.

Although the foregoing disclosure has been described in some detail by way of illustration and example, for purposes of clarity or understanding, it will be obvious that certain 15 changes and modifications may be practiced within the scope of the appended claims.

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What is claimed is:

1. A cover layer for a wound dressing for use in vacuum wound therapy, the cover layer comprising:

- 5 a central zone defined by a portion of a moisture vapor permeable membrane devoid of any coating deterring the transmission of moisture through the membrane;
- a peripheral zone substantially surrounding the central zone, the peripheral zone adapted to provide a seal around a perimeter of a wound bed; and
- 10 at least one intermediate zone at least partially disposed between the central zone and the peripheral zone, the at least one intermediate zone comprising a substance for imparting a therapeutic effect to the wound bed.

2. The cover layer according to claim 1, wherein the peripheral zone includes a high peel-strength adhesive.

3. The cover layer according to claim 1, wherein the at least one intermediate zone comprises a first intermediate zone including a shear-resistant adhesive

15 4. The cover layer according to claim 3, wherein the at least one intermediate zone further comprises a second intermediate zone including a medicament delivery coating.

5. The cover layer according to claim 3, wherein the at least one intermediate zone further comprises a second intermediate zone including a hydrogel.

20 6. The cover layer according to claim 3, wherein the at least one intermediate zone further comprises a second intermediate zone including at least one of an anti-infective agent, an

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antimicrobial, antibiotic, analgesic, healing factor, vitamins, growth factors, debridement agents, or nutrients.

7. The cover layer according to claim 1, wherein the moisture vapor permeable membrane extends to a periphery of the cover layer to constitute a backing layer, the peripheral zone defined by a layer of adhesive bonded to the backing layer.

8. The cover layer according to claim 1, wherein the peripheral zone and the at least one intermediate zone are arranged concentrically with respect to the central zone.

9. The cover layer according to claim 1, further comprising a port for permitting access to a vacuum reservoir defined under the cover layer for a vacuum tube.

10. A wound dressing apparatus for use in a vacuum wound therapy procedure, which comprises:

a contact layer adapted for positioning adjacent a wound bed;

an absorbent filler positioned adjacent the contact layer within the wound bed for collecting liquids exuding from the wound bed;

a cover layer positioned over the wound bed defining a vacuum reservoir there between and permitting access of a vacuum tube to the vacuum reservoir, the cover layer comprising a peripheral zone to provide a seal around the wound bed, at least one intermediate zone for imparting a therapeutic effect to the wound bed, and a central zone formed from a moisture vapor permeable membrane.

11. The wound dressing apparatus according to claim 10, wherein the contact layer is formed from a conical apertured film.

12. The wound dressing apparatus according to claim 10, wherein the absorbent filler material comprises polyolefin filaments arranged in a multi-strand bundle..

13. The wound dressing apparatus according to claim 10, further comprising a vacuum system in fluid communication with the vacuum reservoir.

5 14. The wound dressing apparatus according to claim 13, wherein the vacuum system includes a vacuum source, a collection canister and a one-way valve.

ABSTRACT

A dressing for an open wound includes a cover layer dimensioned for positioning relative to a wound bed. The cover layer permits an evacuation of the space around the wound bed such that a sub-atmospheric pressure may be established to stimulate healing and facilitate the removal of fluid from the wound. Multiple performance zones in the cover layer allow the wound dressing to remain in position through repeated cycles of evacuation without placing undue strain on the wound bed. An outer peripheral zone may include a high peel-strength adhesive while an intermediate zone may include a shear resistant adhesive. A central zone may be devoid of any coating to maximize moisture transmission through cover layer.

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COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL,
DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: *(check one applicable item below)*

- ☒ original
☐ design
☐ supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

- ☐ national stage of PCT

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional
☐ continuation
☐ continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

**VACUUM WOUND THERAPY WOUND DRESSING WITH VARIABLE
PERFORMANCE ZONES**

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SPECIFICATION IDENTIFICATION

the specification of which: *(complete (a), (b) or (c))*

- (a) ☒ is attached hereto.
- (b) ☐ was filed on _____ as ☐ Serial No. _____ or
☐ Express Mail No. _____, as Serial No. not yet known _____
and was amended on _____ *(if applicable)*.

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. 1.67.

- (c) ☐ was described and claimed in PCT International Application No. _____ filed
on _____ and as amended under PCT Article 19 on _____ *(if any)*.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, and

- ☐ in compliance with this duty there is attached an information disclosure statement in accordance with 37 C.F.R. §1.98.

PRIORITY CLAIM (35 U.S.C. §119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- (d) ☒ no such applications have been filed.
- (e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

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**A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §119(a)-(d)**

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(35 U.S.C. §119(e))**

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. §120.

30

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

ALL ATTORNEYS AND REGISTERED PRACTITIONERS ASSOCIATED WITH THE UNITED STATES PATENT AND TRADEMARK OFFICE, CUSTOMER NO. 55825.

SEND CORRESPONDENCE TO:

DIRECT TELEPHONE CALLS TO:

Joseph W. Schmidt, Esq.

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road – Suite 225
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

(631) 501-5700

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

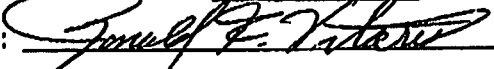
72

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SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full Name of sole or first inventor: Ronald F. Vitaris

Inventor's signature:  Date: 3-13-08

Residence: 9 Doyle Street, Worcester, MA 01606

Country of Citizenship: US

Mailing Address: Same as above

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**CHECK PROPER BOX(ES) FOR ANY OF THE FOLLOWING
ADDED PAGE(S) WHICH FORM A PART OF THIS DECLARATION**

- ☐ Signature for subsequent joint inventors.
Number of pages added ____.
- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or
incapacitated inventor.
Number of pages added ____.
- ☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under
37 C.F.R. §1.47.
Number of pages added ____.

- ☐ Added pages to combined declaration and power of attorney for divisional, continuation,
or continuation-in-part (CIP) application.
Number of pages added ____.

- ☐ Authorization of attorney(s) to accept and follow instructions from representative.

If no further pages form a part of this Declaration then end this Declaration with this page
and check the following item.

- ☒ This declaration ends with this page.

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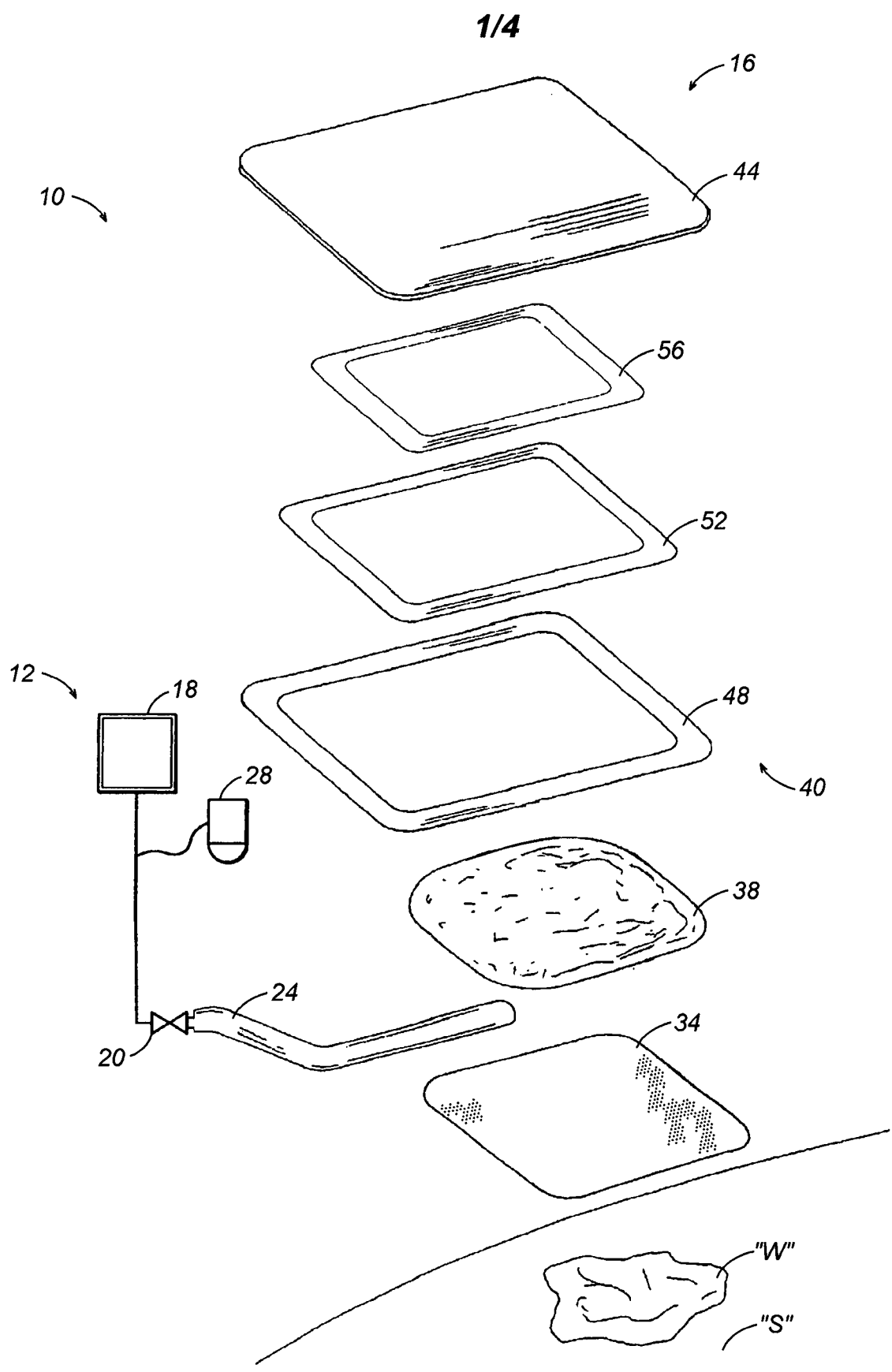


FIG. 1

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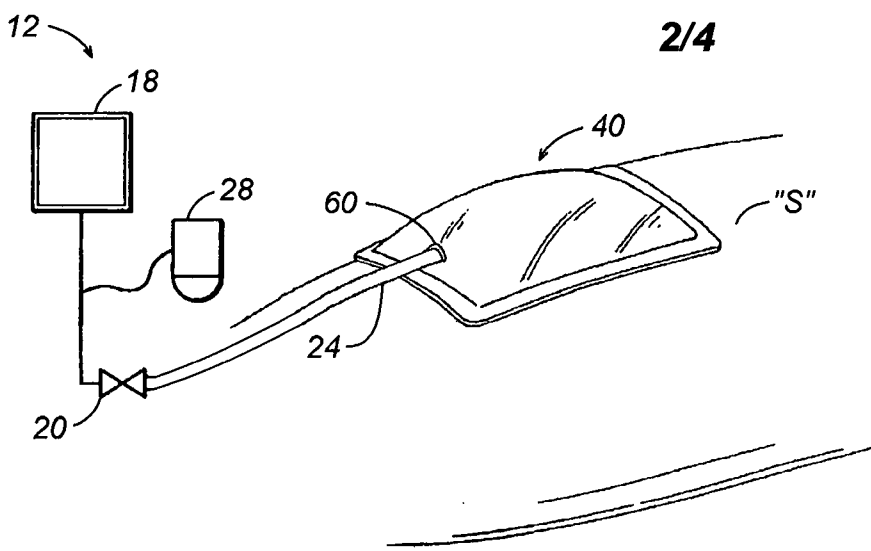


FIG. 2A

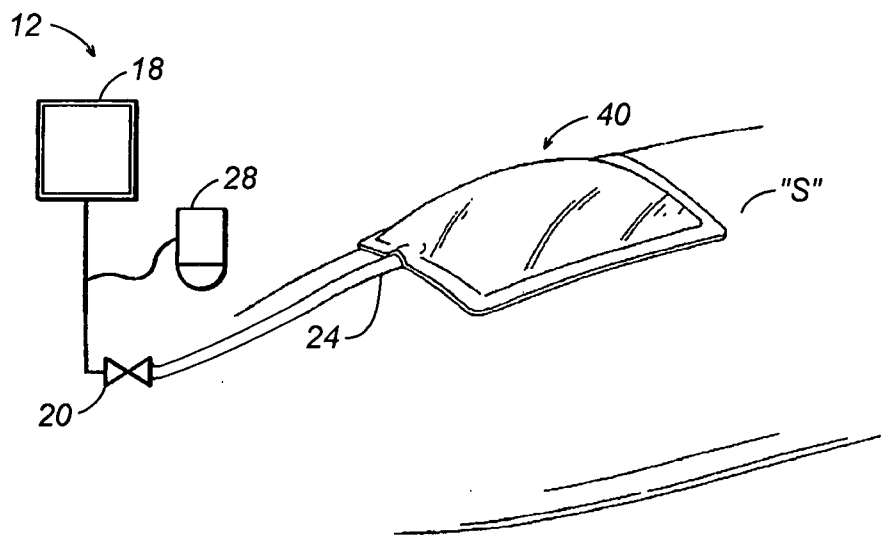


FIG. 2B

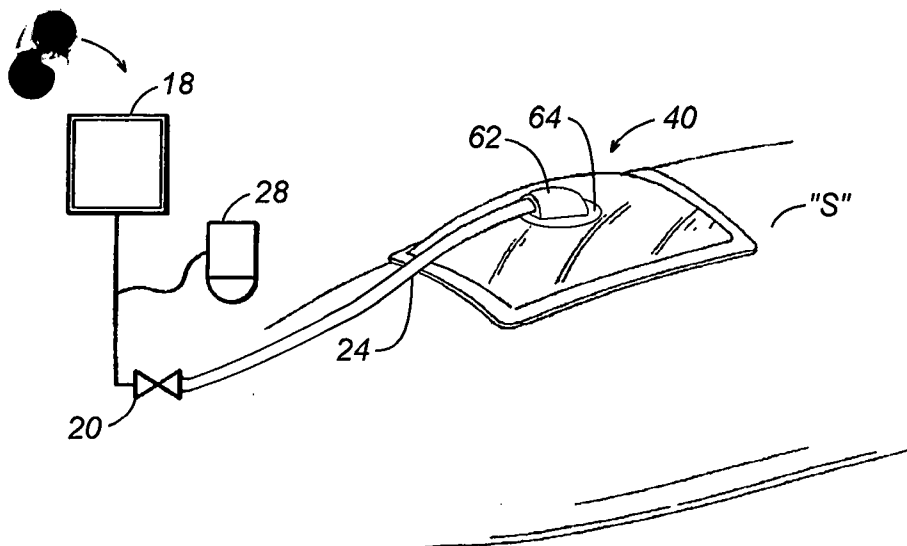


FIG. 2C

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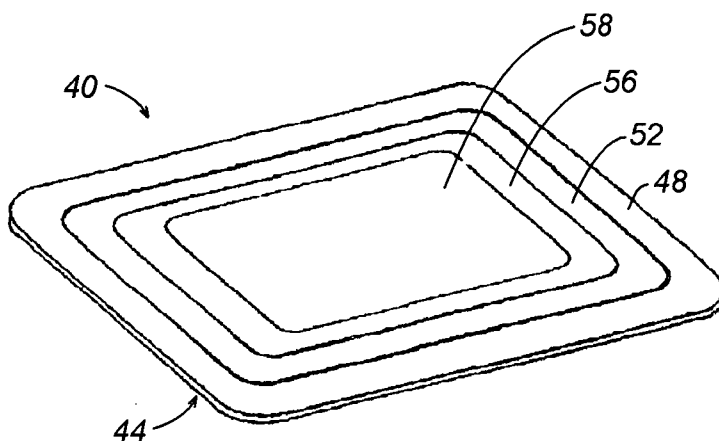


FIG. 3A

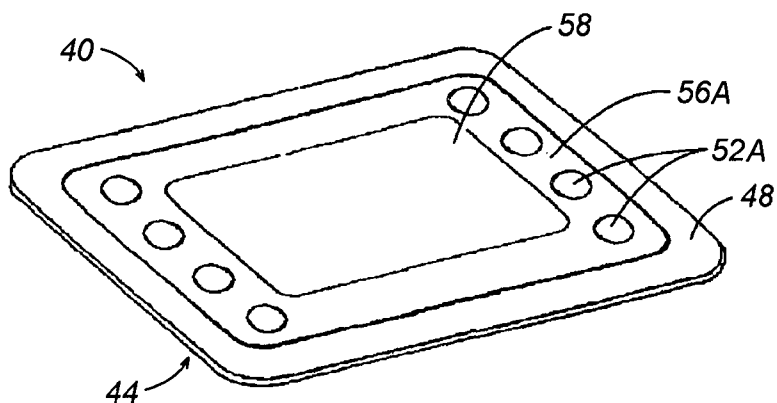


FIG. 3B

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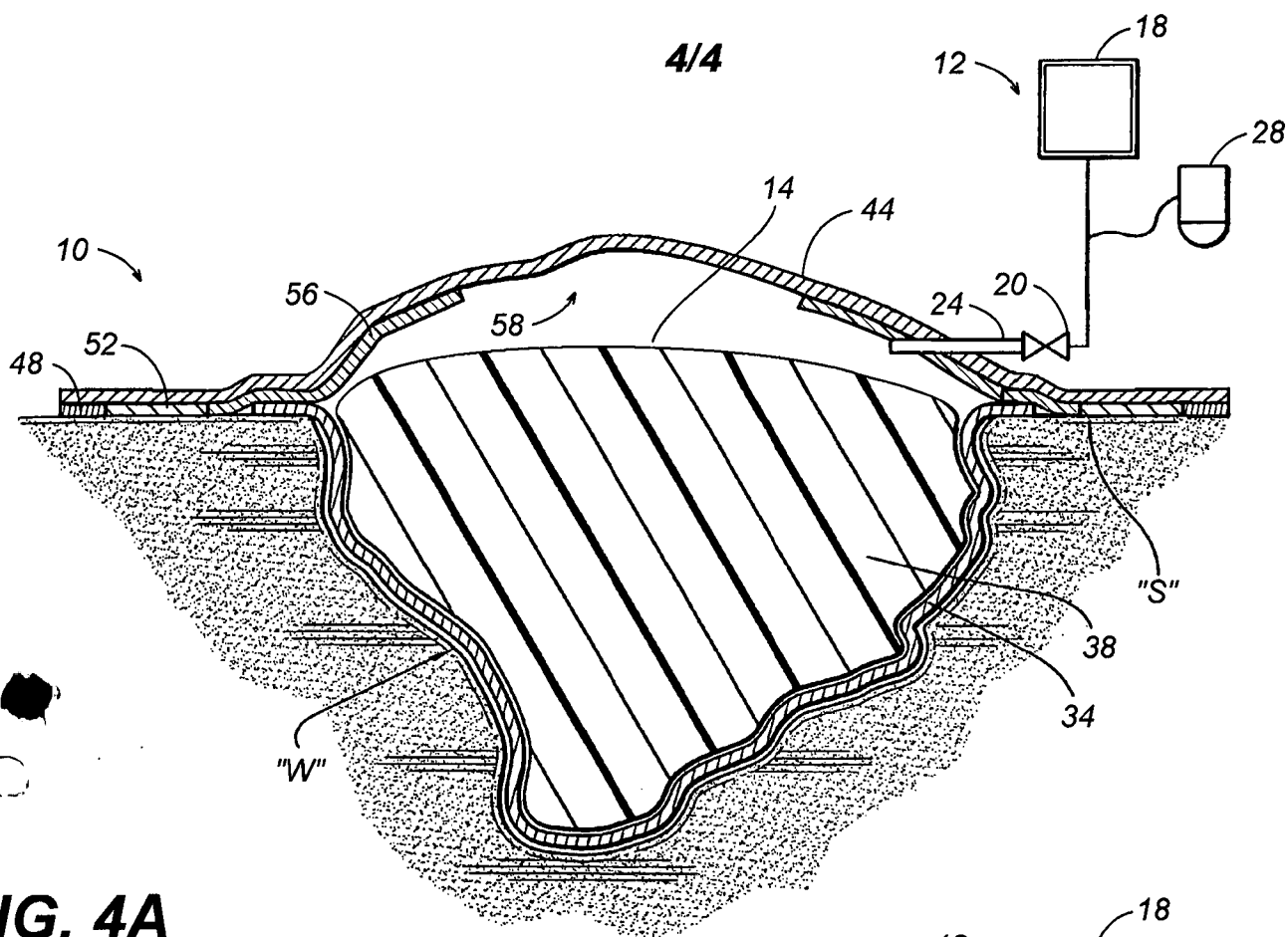


FIG. 4A

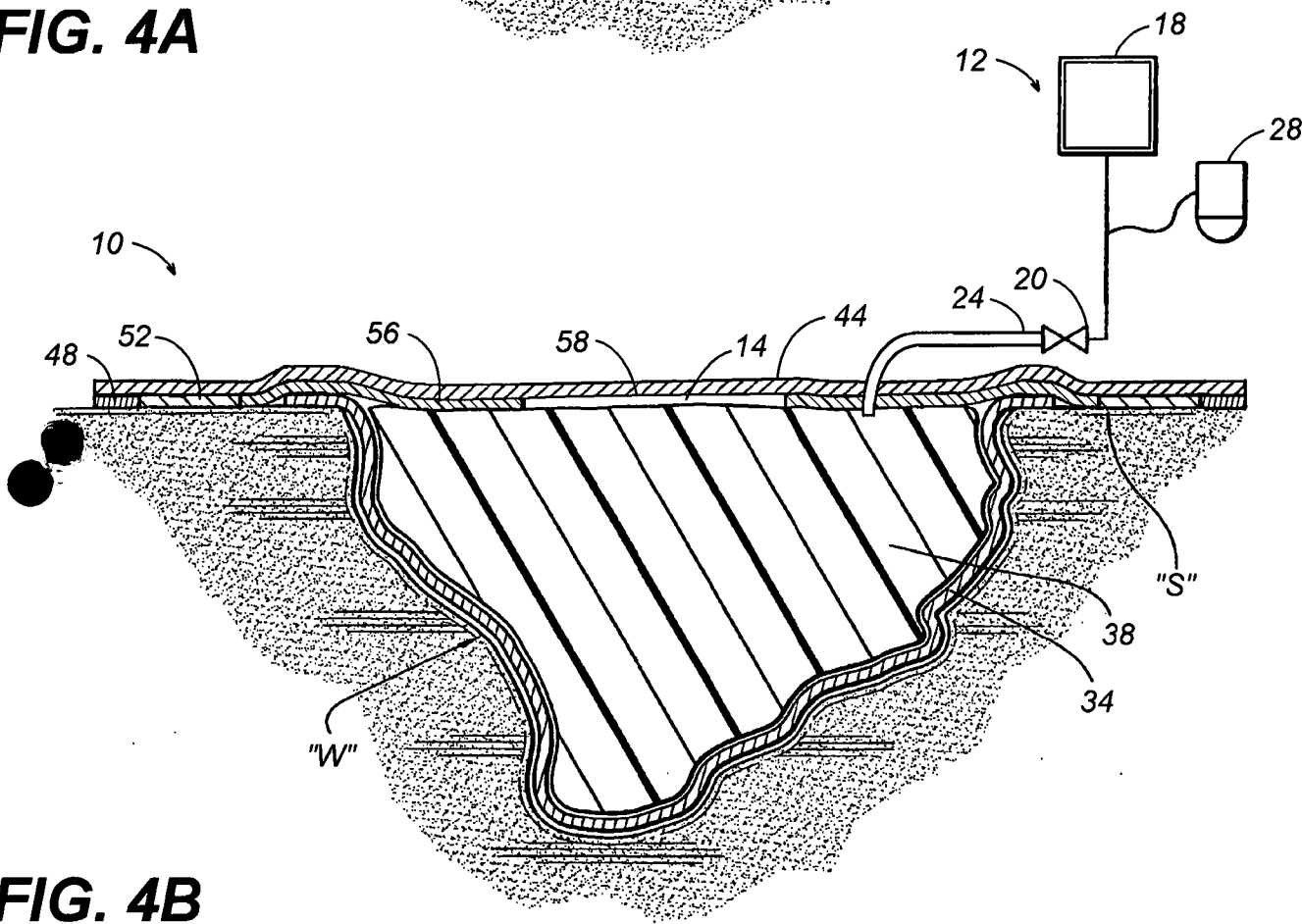


FIG. 4B

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	H-KN-00986 (1502-300)
		Application Number	
Title of Invention	VACUUM WOUND THERAPY WOUND DRESSING WITH VARIABLE PERFORMANCE ZONES		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Applicant Information:

Applicant 1					Remove				
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118			
Prefix	Given Name	Middle Name		Family Name		Suffix			
	Ronald	F.		Vitaris					
Residence Information (Select One)							☒ US Residency	☐ Non US Residency	☐ Active US Military Service
City	Worcester		State/Province	MA	Country of Residence i	US			
Citizenship under 37 CFR 1.41(b) i			US						
Mailing Address of Applicant:									
Address 1		9 Doyle Street							
Address 2									
City	Worcester			State/Province	MA				
Postal Code		01606		Country i	US				
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.									

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).				
☒ An Address is being provided for the correspondence information of this application.				
Customer Number	55825			
Email Address			Add Email	Remove Email

Application Information:

Title of the Invention	VACUUM WOUND THERAPY WOUND DRESSING WITH VARIABLE PERFORMANCE ZONES		
Attorney Docket Number	H-KN-00986 (1502-300)	Small Entity Status Claimed ☐	
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	H-KN-00986 (1502-300)
	Application Number	
Title of Invention	VACUUM WOUND THERAPY WOUND DRESSING WITH VARIABLE PERFORMANCE ZONES	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	Request Not to Publish. I hereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.			
Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	55825		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.			
Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).			
			Remove
Application Number	Country i	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☒ Yes ☐ No
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.	
Assignee 1	Remove

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	H-KN-00986 (1502-300)
		Application Number	
Title of Invention	VACUUM WOUND THERAPY WOUND DRESSING WITH VARIABLE PERFORMANCE ZONES		

If the Assignee is an Organization check here. ☒			
Organization Name	Tyco Healthcare Group LP		
Mailing Address Information:			
Address 1	15 Hampshire Street		
Address 2			
City	Mansfield	State/Province	MA
Country ⁱ	US	Postal Code	02048
Phone Number		Fax Number	
Email Address			
Additional Assignee Data may be generated within this form by selecting the Add Add button.			

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/joseph w. schmidt/			Date (YYYY-MM-DD)	2008-03-13
First Name	Joseph W.	Last Name	Schmidt	Registration Number	36920

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

Information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.