



Industria y Comercio
SUPERINTENDENCIA

Delegatura de Propiedad Industrial

División de Nuevas Creaciones

PCT

SOLICITUD

PATENTE DE INVENCION

21. EXPEDIENTE No.

05-32253

54. TITULO " APOSITO MEDICO QUE CONTIENE UN AGENTE ANTIMICROBIAL "

51. CLASIFICACION INTERNACIONAL A 61 L 15/44 // A 61 L 15/46

A 61 K 31/155 // A 61 P 31/00.

71. SOLICITANTE TYCO HEALTHCARE GROUP LP.

DOMICILIO MASSACHUSETTS, ESTADOS UNIDOS DE AMERICA.

74. APODERADO ALVARO CORREA ORDONEZ
T.P. 20.281

22. BOGOTA, D.C., ABRIL 8 DE 2005

(SS)

PETITORIO

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Industria y Comercio
SUPERINTENDENCIASUPERINDUSTRIA Y COMERCIO
Radicación : 05032253 0020000 Folios: 1145
Fecha (AMD): 2005-04-08 10:55:40
Trámite : 011 PCT-PATENT 379 FASE HACI 411 PRESENTA
Dependencia: 2020 DIVISION DE NUEVAS CREACIONESFORMULARIO ÚNICO DE
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ENTRADA EN FASESUPERINDUSTRIA Y COMERCIO (COPIA)
Radicación : 05032253 0020000 Folios: 114
Fecha (AMD): 2005-04-08 10:55:40
Trámite : 011 PCT-PATENT 379 FASE HACI 411 PRESENTA
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

fase Nacional 02-05-05

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SOLICITUD DE :

☒ X

Patente de Invención

☐

Capítulo I.

☐

Patente de Modelo de Utilidad

☒ X

Capítulo II.

ver folio 117

②

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(71)

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IDENTIFICACION

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NIT

☐

C.E.

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Otro

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Cual

Número

③

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IDENTIFICACION

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Número 79.143.366 de

Usaquén

TP 20.281

④

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⑤

PCT (85)

Solicitud Internacional No. PCT/US2003/032514

Fecha Octubre 14, 2003

Publicación Internacional No. WO 2004/037115 A2

Fecha Mayo 6, 2004

⑥

Título (54)

APÓSITO MÉDICO QUE CONTIENE UN AGENTE ANTIMICROBIAL.

⑦

Clasificación Internacional (51)

A61F

A61K31/155 // A61L15/44 // A61P31/00

⑧

Prioridad

SI ☒ XNO ☐

(33) País de Origen

US

(32) Fecha

Octubre 23, 2002

(31) Número de Solicitud

10/278,072

⑨

Comprobante de pago No. 05-17,701 ; 04-81,410

Fecha MARZO 9 DE 2005; AGOSTO 3
DE 2004

Instrucciones para el diligenciamiento del presente formulario, ver reverso de esta página

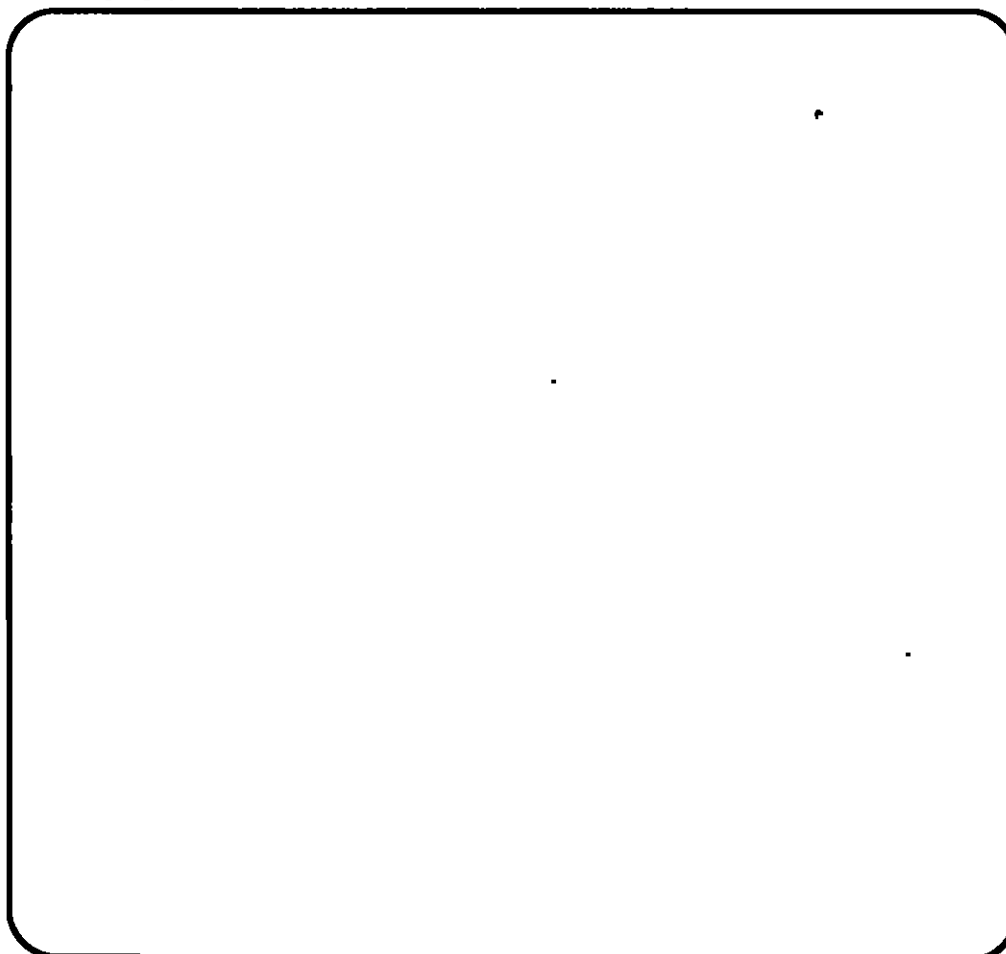
10

ANEXOS

- ☒ Comprobante de pago de la tasa de presentación de la solicitud
- ☐ Documento que acredite la existencia y representación legal cuando el solicitante sea persona jurídica
- ☐ Poderes, si fuere el caso
- ☐ Documento de cesión del inventor al solicitante o a su causante
- ☐ Declaraciones
- ☒ Copia de la solicitud internacional. (Resumen, descripción, reivindicaciones, dibujos)
- ☒ Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos)
- ☐ Copia del examen preliminar internacional efectuado por la Autoridad Internacional de Examen preliminar (IPEA)
- ☐ Traducción del examen preliminar internacional efectuado por la IPEA
- ☐ De ser el caso, copia del contrato de acceso
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- ☐ De ser el caso, certificado de depósito del material biológico
- ☒ Arte final 12 x 12
- ☐ De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud
- ☐ De ser el caso, modificaciones efectuadas a la solicitud internacional.
- ☒ Otros: COPIA DOCUMENTO DE PRIORIDAD Y OTROS DOCUMENTOS DE LA FASE INTERNACIONAL

11

FIGURA CARACTERISTICA



12

Solicito la concesión de la patente.

NOMBRE: ALVARO CORREA ORDÓÑEZ

FIRMA:

C.P. 78.143.366

T.P. 30.281

SUPERINDUSTRIA Y COMERCIO
Radicaion : 05032253 08000000 Folios: 1145
Fecha (AMD): 2005-04-02 10:50:10
Tramite : 011 PCI-PATENT 379 FASE NACI 411 PRESENTA
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

SUPERINDUSTRIA Y COMERCIO(COPIA)
Radicaion : 05032253 08000000 Folios: 1145
Fecha (AMD): 2005-04-02 10:59:40
Tramite : 011 PCI-PATENT 379 FASE NACI 411 PRESENTA
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

NIT : 800176099-2

RECIBO OFICIAL DE CAJA : 5 - 17,701
FECHA : MARZO 9 DE 2005

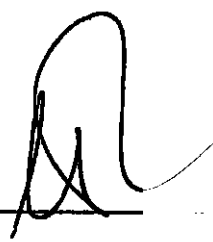
***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	VR. PAGO
ALVARO CORREA ORDOÑEZ	CONSIGNACION	BANCO POPULAR	050-00110-6	37971721	09/03/2005	103,080.000.00

***** C O N C E P T O *****

CANT. RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1 50005-01-06	REGISTRO DE CESION, CAMBIO NOM	
	13 NOMBRES Y ENSENAS COMERCIALES, MAR	224,000.00
	TOTAL :	\$ 224,000.00

SON: DOSCIENTOS VEINTICUATRO MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL ASUNTO No.

219
343

NIT : 800176089-2

SUPER INDUSTRIA Y COMERCIO (COPIA)
Radicación : 0503253 0300000 Folios: 114
Fecha (AND): 2005-04-08 10:59:48
Trámite : 011 PCT-PATENT 379 FASE HACI 411 PRESENTAC
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

RECIBO OFICIAL DE CAJA : 04 - 61,410
FECHA : AGOSTO 3 DE 2004

XXXXX CONSIGNACION XXXXX

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	VALOR PAGO
ALVARO CORREA ORDONEZ	CONSIGNACION	BANCO POPULAR	050-00110-6	14462255	03/08/2004	219,546,000.00

XXXXX CONCEPTO XXXXX

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	91 TASA ANUAL DE MANTENIMIENTO DE PA	219,000.00
TOTAL :			\$ 219,000.00

SOM: DOSCIENTOS DIEZ Y NUEVE MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

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

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
6 May 2004 (06.05.2004)

PCT

(10) International Publication Number
WO 2004/037115 A2

- (51) International Patent Classification⁷: A61F
- (21) International Application Number:
PCT/US2003/032514
- (22) International Filing Date: 14 October 2003 (14.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
10/278,072 23 October 2002 (23.10.2002) US
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22313-1404 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE,
GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,
MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,
RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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

Declarations under Rule 4.17:

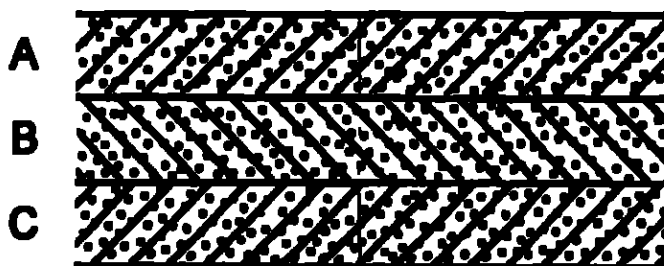
- as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii)) for the following designations AE,
AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH,
CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES,
FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC,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

Published:

- without international search report and to be republished
upon receipt of that report

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

(54) Title: MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT



as polyhexamethylene biguanide (PHMB). The fabric inner layer material may be substantially rayon, and the fabric outer layer material may be substantially polyester, e.g., a combination of textile matrix grade polyester fiber and amorphous binder grade polyester fiber. The fabric is preferably treated with an aqueous solution of surfactant and PHMB to have about 1500-3500 ppm of extractable PHMB.

(57) Abstract: A medical dressing containing an antimicrobial agent is disclosed. The medical dressing comprises a layered fabric comprising an inner layer of substantially hydrophilic material, an outer layer of substantially hydrophobic material on both sides of the inner layer, and an antimicrobial agent. The antimicrobial agent may be releasably impregnated into the fabric, coated on said fabric or a combination thereof. The antimicrobial agent may be a biguanide, such

-1-

MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT**BACKGROUND OF THE INVENTION****Field of the Invention**

The present invention relates to a medical dressing containing an
5 antimicrobial agent, a sponge formed from such a dressing, and methods of
fabricating such a medical dressing and sponge.

Brief Description of Art

Medical dressings have long been used to protect and aid in the healing of
wounds. Various forms and constructions of such medical dressings are known in
10 the art. For instance, U.S. Patent No. 4,211,227, incorporated herein by reference,
discloses a nonwoven surgical sponge material comprising a layered fabric having
an inner core or a substantially hydrophilic material disposed adjacent at least one
outer or surface layer, or between a pair of outer layers, of a substantially
hydrophobic material. The sponge material is bonded by passing the material
15 through rolls engraved in a pattern of lands and grooves such that a repeating pattern
of three degrees of compression are imposed on the material.

U.S. Patent No. 6,369,289, incorporated herein by reference, further
discloses the use of a cellulosic bandage in a method for covering an open wound by
contacting the wound with the bandage having a calculated amount of antimicrobial
20 agent. The cellulosic bandage may be prepared by providing at least one rolled beam
of cellulosic material onto a perforated drum, inserting the beam of material into an
enclosed vessel, adding antimicrobial agent into the vessel, and circulating the
antimicrobial agent for a predetermined period of time.

The use of certain kinds of antimicrobial agents is also known in the art.
25 U.S. Patent No. 4,655,756, for example, relates to a non-woven material treated with
a linear polymeric biguanide having a defined formula, or a mixture of, e.g.,
polyhexamethylene biguanide (hereafter "PHMB") dihydrochlorides with defined

-2-

number average molecular weights. The polymeric biguanide may be present at a concentration of from 500 to 5000 ppm and the non-woven material may be in the form of an article for the collection of human body emissions.

Other types of antimicrobial agents are also known. For example, U.S. Patent No. 5,707,736 discloses a dry, disposable, polymeric product having sustained-release antimicrobial activity formed from a polymeric material having an amine salt antimicrobial agent incorporated therein. The polymeric material may be in the form of fibers, sheets, films, and other stable woven, nonwoven and knitted materials. The antimicrobial agents include, e.g., chlorhexidine gluconate and chlorhexidine hydrochloride.

Additional components, such as adhesives, are also known as components of medical dressings. One such surgical dressing is described in U.S. Patent No. 4,643,180, wherein the dressing comprises a sheet of polymeric film coated on one side with a water based adhesive of defined thickness which includes an antimicrobial agent deposited on the body facing surface of the adhesive.

U.S. Patent No. 4,643,181 also describes a surgical dressing and a process for making a surgical dressing. The dressing comprises a substrate coated on one surface with a solvent-based skin contact adhesive of defined thickness, the adhesive having distributed therein particles of PHMB. The process involves mixing a defined aqueous solution of PHMB hydrochloride with a solvent which is compatible with the adhesive at a mixing speed of no more than 300 rpm, adding the mixture to an adhesive, applying the adhesive to a release surface in an amount of from 40 to 55 grams per square meter, drying the adhesive, and applying a substrate for the dressing to the adhesive.

U.S. Patent No. 4,675,347 relates to an antimicrobial latex composition and a method of manufacturing a shaped article by repeatedly dipping an article into the composition and drying. The composition comprises, e.g., (1) at least one cationic latex component selected from a cationic natural rubber latex and a cationic synthetic polymer latex and (2) a cationic antimicrobial agent incorporated in the cationic latex (1).

-3-

U.S. Patent No. 4,678,704 describes an impregnated fabric material comprising a fabric substrate to which has been bonded an active cationic impregnant along with an anionic indicator dye in combination with a further cationic component, wherein the dye bonds to the further cationic component more readily than to the substrate and the further cationic component competes with the impregnant for bonding to the dye. The cationic impregnant may be a polymeric biguanide, e.g., PHMB.

U.S. Patent No. 4,837,079 relates to a method for making an antimicrobially active, non-woven web comprising the steps of forming an unbounded fibrous web, applying throughout the unbonded fibrous web an uncured binder and PHMB hydrochloride as an antimicrobial agent, the PHMB hydrochloride being substantive to the fibers of the web and to the binder when the web is either wet or dry to prevent the antimicrobial agent from substantially diffusing from the fibers or binder and being present in an amount effective to act as antimicrobial agent, and curing the binder to bind the fibers together to form an antimicrobially active, non-woven web. An antimicrobially active, non-woven web comprising bonded fibers, a binder distributed throughout the fibers in an amount effective to bind the fibers and PHMB hydrochloride which is substantially prevented from diffusing from the fibers or the binder is also disclosed. Further disclosed is a wet wiper that is substantially identical to the claimed web, but which additionally contains a substantially preservative free liquid.

U.S. Patent No. 5,098,417 relates to a wound dressing for systemic administration of a physiologically- or biologically-active agent by controlled release of the agent into such wound. The wound dressing comprises a substrate in the form of a fabric or cloth, at least a portion of which is cellulosic, which has been chemically modified to convert hydroxyl groups in the cellulosic portion to ionic-adsorbing sites, an ionic form of a physiologically- or biologically-active agent (which includes antibacterial agents) adsorbed in the substrate. The ionic bonds hold the agent temporarily to the substrate for controlled release therefrom in proportion to the amount of exudate in contact with the substrate and are formed by

-4-

adsorbing the agent on the substrate at room temperature. The ionic bonds are disassociated upon contact with body exudate from wounds thereby to release the physiologically- or biologically-active agent in an amount in proportion to the amount of exudate in contact with the substrate. Chlorhexidine is mentioned as one
5 of the possible agents.

U.S. Patent No. 5,141,803 relates to a moistened wipe for cleaning and delivering a cationic biocide comprising a flexible absorbent nonwoven substrate impregnated with an aqueous composition comprising defined amounts of potassium sorbate, citric acid, disodium ethylenediaminetetraacetate, a cationic biocide selected
10 from a defined group which includes PHMB hydrochloride and the remainder water. The pH of the composition is from about 3.5 to about 4.5.

U.S. Patent No. 5,156,843 relates to a composition of matter comprising a material provided with interstices having solid particles residing therein. The material is a member selected from the group consisting of joined fibers, woven
15 fabric, non-woven fabric, paper, woven cloth, non-woven cloth, foamed plastic and sponge. The solid particles are from about one to about 100 microns in diameter and contain a substantially continuous network of pores open to the exterior of the particles, with a functional substance retained in the pores. The functional substance may be a biocidal substance that can prevent or retard bacterial, microbial, germ or
20 fungal growth.

U.S. Patent No. 5,498,416 relates to a process for protection of prostheses, implants and/or catheters, of temporary or permanent implantable materials against bacterial colonization and infection. An infection-resistant device capable of progressively releasing in aqueous medium an amount of an antibacterial substance
25 fixed to the device, the amount being effective to prevent bacterial contamination of the device is disclosed. The device comprises a first coating from a solution in aqueous or organic solvent of a biguanide of a defined general formula (which defines monomeric compounds) and a second coating from a solution of the antibacterial substance, the second coating overlying the first coating, and the first
30 coating ensuring adhesion of the antibacterial substance to the device. Illustrative

-5-

devices are described in the paragraph beginning at column 2, line 60 and include urinary catheters, probes, vascular and intraarterial catheters, cardiacal valvular prostheses, arterial prostheses, cardiac simulators, orthopedic prostheses, ocular or dental implants, shunts that are connecting two segments of the circulatory system, and suture thread.

U.S. Patent No. 5,700,742 relates to a method of treating a textile material to inhibit microbial growth which comprises applying to the textile material an oligo- or polymeric biguanide or salt thereof with an inorganic acid or an organic acid having a pK value above 4.5 followed by a strong organic acid having a pK value below 4.5 and free from any aliphatic or oxyalkylene chain containing 12 or more carbon atoms. A textile material treated in accordance with the claimed method is also disclosed.

U.S. Patent No. 5,856,248 relates to cellulose fibers and products comprising cellulose fibers treated to absorb body secretions while substantially decreasing microbial growth, the fibers being chemically modified in a two-stage process comprising a first stage treatment with a water soluble salt of a transition metal and an alkali and a second stage treatment with a solution of a bisbiguanide compound, thereby forming a bond between the cellulose fibers, the transition metal and the bisbiguanide compound. The process may utilize a rinsing step to neutral pH between the two aforementioned stages.

U.S. Patent No. 5,869,073 relates to a liquid composition for applying a non-leachable antimicrobial layer or coating on a surface, comprising a solution, dispersion or suspension of a biguanide polymer, a cross-linker reacted with the biguanide polymer to form an adduct, and an antimicrobial metal, metal salt (e.g. a silver salt) or metal complex, wherein the metal, metal salt or metal complex forms a complex with the adduct, and wherein the antimicrobial layer or coating does not release biocidal levels of leachables into a contacting solution.

U.S. Patent No. 5,817,325 relates to an article of manufacture having disposed on a surface thereof a contact-killing, non-leaching antimicrobial coating which kills microorganisms upon contact. The coating comprises an organic

-6-

polycationic polymer matrix immobilized on the surface having bound or complexed thereto a surface-accessible antimicrobial metallic material such that the antimicrobial material does not release biocidal amounts of elutables into the surrounding environment. The organic matrix may comprise a biguanide polymer, such as PHMB or a polymer containing a biguanide moiety.

U.S. Patent No. 5,849,311 further relates to a contact-killing, non-leaching antimicrobial material, capable of killing microorganisms which come into contact with the material. The material comprises an organic polycationic polymer matrix having non-leachably bound or complexed thereto an antimicrobial metallic material, such that the antimicrobial material does not release biocidal amounts of elutables into the surrounding environment. The polycationic material may be PHMB or a polymer containing a biguanide moiety.

U.S. Patent No. 5,886,048 relates to a method of treating tumor disease in a human or animal with a therapeutically effective amount of PHMB or salt thereof.

U.S. Patent No. 5,985,931 relates to an antimicrobial composition comprising defined amounts of PHMB, a quaternary ammonium compound; and parachlorometaxylenol wherein the combination of the three components is said to exhibit effective antimicrobial activity.

U.S. Patent No. 5,990,174 relates to a method for improving haze formation and storage stability of an antimicrobial composition consisting of water and from 5 to 25% by weight of defined linear polymeric biguanide oligomers. The method comprises adjusting the pH of the aqueous antimicrobial composition to at least 0.1 and less than 5 as determined using an indicator thereby improving the resistance to haze formation and storage stability of the aqueous antimicrobial composition when compared with a corresponding composition at higher pH. Particular concentration and pH limitations are also disclosed.

U.S. Patent No. 5,993,840 relates to a composition comprising a non-woven material containing a mixture of polymeric biguanides subject to desorption when the non-woven material is wetted by urine; and an anionic polymer which is substantially insoluble in urine. The anionic polymer functions to retain the

-7-

biguanides on the material when contacted by urine. A process for forming an absorbent layer and a method of reducing the loss of antimicrobial biguanide, wherein both include the anionic polymer, are disclosed.

5 European Patent Application No. 136900 discloses the application of PHMB to a surgical drape comprising a non-woven fabric and mentions on page 7 that a non-ionic wetting agent in the application formulation is desirable to provide absorbent characteristics to the fabric.

10 U.S. Patent No. 6,017,561 relates to an antibacterial cleaning composition comprising a quaternary ammonium compound, an anionic polymer having an acid number greater than 10 wherein the anionic polymer is partially or completely neutralized by quaternary ammonium compound to form a polymer complex and wherein the polymer complex is greater than about 15% by weight of the solids in the composition, a dispersing agent, which comprises a surfactant that is selected from the group consisting of nonionic surfactant, amphoteric surfactant, and mixtures thereof, and optionally, a solvent. Also disclosed is a sponge device 15 having antibacterial activity that comprises a sponge; and a polymer complex comprising a quaternary ammonium compound and an anionic polymer having an acid number of greater than 10 wherein the anionic polymer is partially or completely neutralized by the quaternary ammonium compound to form the polymer complex which is attached to a surface of the sponge. An adsorbent or absorbent matrix which includes the polymer complex and a method of fabricating an absorbent or adsorbent material which uses at least a quaternary ammonium compound and an anionic polymer are also disclosed. The ammonium compound may be PHMB hydrochloride. Articles such as sponges are also described.

25 U.S. Patent No. 6,160,196 relates to a wound covering comprising a hydrophobic, bacteria-absorbing synthetic or naturally-occurring polymer fiber material, having adhered thereto an antimicrobial active compound which is adapted to not be released into the wound. As described in the specification and included in certain dependent claims, the material can be nonwoven and dependent claim 10 30 recites that the polymer fiber material can be selected from a group which includes

-8-

polyester. The antimicrobial active compounds are described in the passage that begins at column 2, line 29 and include chlorhexidine. In this passage, it is stated the compounds "... are distinguished by the fact that they adhere firmly to the wound covering and are not released, or at least are not released noticeably, into the wound."

U.S. Patent No. 6,180,584 relates to a disinfectant composition comprising a film-forming antimicrobial material (which may be a polymeric biguanide material), an antimicrobial metallic material, and a carrier. The composition, when applied to a surface, forms a non-permanent, adherent, water-insoluble film, wherein the metallic material is non-leachably bound to or associated with the film. The film does not elute antimicrobial materials into contacting water at levels capable of imparting disinfecting action to said water, and is removable by treatment with an alcohol solution. The composition can further include a surfactant.

U.S. Patent No. 6,235,302 relates to a sponge cloth which is based on regenerated cellulose and has been provided with an internal reinforcement consisting of, e.g., viscose fibers or cotton fibers having a staple fiber length of 5 to 50 mm. The sponge cloth is obtained by a process comprising the steps of coagulating and regenerating the cellulose in a bath which has a pH of 13 or higher and which comprises Glauber's salt, NaOH and water, and impregnating the sponge cloth with a biocidally active agent. Representative agents are described and include isothiazolone, benzoisothiazolone and benzimidazole derivatives with biguanides.

OBJECTS AND SUMMARY OF THE INVENTION

It is an object of the present invention to provide a medical dressing comprising an antimicrobial agent as well as a process of making such a medical dressing. It is a further object to provide a sponge formed from the medical dressing as well as a process of making such a sponge.

The medical dressing and sponge formed therefrom are preferably characterized by improved antimicrobial behavior. More particularly, in a preferred embodiment, the medical dressing and sponge formed therefrom provide an

-9-

effective antimicrobial barrier for a wound while also controlling the release of antimicrobial agent contained within an inner portion of the dressing. The antimicrobial agent is preferably concentrated within an inner portion absorbent core of the dressing while an outer barrier layer portion reduces the release of the antimicrobial agent from the dressing.

5 It is a further object of the invention to provide a medical dressing and a sponge formed therefrom wherein the outer hydrophobic layer(s) provide(s) non-adherent surfaces to aid in the healing of wounds and which reduces or eliminates pain experienced by a patient during changes in the dressing or sponge.

10 In accordance with one aspect of the present invention, a medical dressing is provided, comprising:

layered fabric comprising:

an inner layer of substantially hydrophilic material;

an outer layer of substantially hydrophobic material on both sides of

15 the inner

layer, and

an antimicrobial agent, wherein the antimicrobial agent is contained in the inner layer.

20 In accordance with another aspect of the invention, the medical dressing of the invention may be in the form of a sponge comprising plies of the medical dressing material.

BRIEF DESCRIPTION OF THE FIGURES

FIG 1 illustrates a cross-sectional view of one form of the medical dressing containing two outer layers and an inner layer.

25 FIG. 2 illustrates a surface view of one form of the medical dressing containing a cross-shaped incision passing through all plies of the dressing.

-10-

**DETAILED DESCRIPTION OF THE
PREFERRED EMBODIMENTS OF THE INVENTION**

In one embodiment, the inventive medical dressing is based in part upon the dressing disclosed in U.S. Patent No. 4,211,227, the disclosure of which is
5 incorporated herein by reference in its entirety.

In a preferred embodiment, the inventive medical dressing is an antimicrobial drain sponge which is a thermally bonded nonwoven absorbent material, typically in the form of a square that is 2" x 2" or 4" x 4" and having a 6 ply thickness. The material is preferably about 50% polyester and about 50% rayon
10 with each ply formed as a sandwich of a layer of rayon between two layers of polyester. In one embodiment of the invention, as illustrated in FIG. 1, the outer layers (A and C) may be formed from a hydrophobic material, preferably hydrophobic fibers, such as polyester fibers. The inner layer (shown as layer B in FIG. 1) comprises a hydrophilic material, preferably hydrophilic fibers, such as
15 cellulosic fibers. More preferably, the cellulosic fibers are rayon.

In order to impart antimicrobial properties, the material that is to be cut into the individual sponges is impregnated with an aqueous solution of an antimicrobial agent, such as polyhexamethylene biguanide (PHMB). An antimicrobial agent such as PHMB is suitably present in a concentration of about 0.1 to 0.5 % by weight,
20 preferably about 0.15 to 0.35 % by weight, and most preferably about 0.2 to 0.3 % by weight. A surfactant may also be present in the aqueous solution. For example, commercially available non-ionic surfactants, such as TWEEN® 20, which is polyoxyethylene (20) sorbitan monolaurate, may be utilized. PHMB used to prepare the drain sponge may be provided by, e.g., AVECIA Inc. under the designation
25 COSMOCIL® CQ (an aqueous solution of PHMB containing 19-21% w/w active ingredient and a pH of 5.0-5.5). The material may be impregnated with the antimicrobial agent according to any suitable technique, such as, e.g., by dip coating the material in a solution comprising the antimicrobial agent.

The impregnated material may then be pressed at a pressure designed so that
30 the appropriate level of antimicrobial agent, preferably PHMB, remains in the

-11-

material. After drying by passing between heated rollers, the material has a residual antimicrobial agent (e.g. PHMB) content of from 1500 to 3500 ppm. The material is subsequently converted into 4" X 4" and 2" X 2", 6 ply drain sponges. The sponges do not include an adhesive, but have a cross-shaped incision in the center (as
5 illustrated in FIG. 2) that penetrates all 6 plies so that a drain tube can be passed therethrough. The antimicrobial agent (e.g. PHMB) can preferably be released from the medical dressing or sponge in a moist environment to provide antimicrobial activity beyond the edges of the sponge for a limited time. In general, the fabric is treated to have about 1500-3500 ppm of extractable antimicrobial agent, preferably
10 polyhexamethylene biguanide.

The antimicrobial agent is preferably releasably impregnated into the inner layer substantially hydrophilic material of the fabric, coated on said inner layer or a combination thereof. The antimicrobial agent is also preferably controllably releaseable from the fabric in an amount effective as an antimicrobial, more
15 preferably in amount effective as an antimicrobial for a period of up to about 2 days, most preferably up to about 1 day. The antimicrobial amount is defined as the amount of antimicrobial agent applied to the dressing that is needed for providing sufficient antimicrobial characteristics, yet without causing irritation of the skin or open wound.

20 Although the antimicrobial agent may be released from the inner layer material of the fabric, the antimicrobial treatment of the fabric principally allows the dressing to function as a barrier to contamination of the wound from sources outside the wound. In addition, due to the absorbent characteristics of the dressing, microbes absorbed within the inner layer are prevented from escaping through the
25 dressing.

In general, the antimicrobial agent may be any such agent which suitably functions to provide an antimicrobial property to the inventive medical dressing. Such antimicrobial agents are described in some of the above-identified patents, which are herein incorporated by reference for such information. Preferred
30 antimicrobial agents include biguanides, especially polyhexamethylene biguanide

-12-

("PHMB").

The fabric inner layer material is substantially hydrophilic, and is preferably substantially a cellulose fiber, and, more preferably, is substantially rayon. Other inner layer materials may also be utilized, including polysaccharides, alginates, cotton or carboxy methyl cellulose fiber materials. In general, the inner layer material is "substantially hydrophilic" such that wound exudate may be absorbed by the inner layer absorbent core and that the antimicrobial agent may be contained mostly within the absorbent core. In this way, the term "substantially hydrophilic" describes the function of the inner layer material. It also distinguishes the inner layer material over the function of the "substantially hydrophobic" outer layer material, which provides an antimicrobial barrier property and attenuates or reduces the release of antimicrobial agent away from the dressing. The improved retention of antimicrobial agent within the inner layer also lowers the bioburden, i.e., the growth and number of cells, within the dressing during use.

Hydrophobicity and hydrophilicity are commonly reported as the percentage moisture regain for fibers of the material. For the purposes of the present invention, the terms "substantially hydrophilic" and "substantially hydrophobic", as they apply to the inner and outer layers respectively, may be related to the percentage moisture regain for fibers of the respective materials, typically at 70°F and 65% relative humidity. The fibers used in the substantially hydrophobic outer layer should have a moisture regain of less than about 10%, preferably less than about 5%, and most preferably less than about 2% based on the weight of the dry fiber. The fibers used in the substantially hydrophilic inner layer should have a moisture regain of about 5-25, preferably about 10-20, and most preferably about 15-20 times the weight of the dry fiber.

The fabric outer layer material is preferably substantially polyester, and, more preferably, is a combination of textile matrix grade polyester fiber and amorphous binder grade polyester fiber. The binder fibers function to bind, e.g., rayon and textile grade polyester fibers together. Suitable inner layer materials include, e.g., Lenzing 8191 rayon. Suitable outer layer materials include, e.g.

-13-

Wellman Polyester T-203 textile grade polyester and Kosa Polyester 259 amorphous binder grade polyester. The textile to binder fiber weight ratio is preferably about 2:1. Other materials may also be utilized for the outer layer, including, e.g., polyolefins such as polyethylene or polypropylene, nylons, or other thermoplastic fibers.

The hydrophobic layers of the fabric forming the medical dressing may also be imparted with a hydrophilic finish. Such a finish may be applied as a coating of a hydrophilic finishing agent on the outer layers. It may also be applied during the impregnation of the inner layer with the antimicrobial agent by including the hydrophilic finishing agent in the same solution of antimicrobial agent. By contacting the dressing material with the antimicrobial solution containing a hydrophilic finishing agent, the inner layer is impregnated with the antimicrobial solution while the outer layers are imparted with a hydrophilic finish. As used herein, the term "hydrophilic finish" is intended to mean that the hydrophilic characteristics of the outer layer are increased at least to some degree by the use of a hydrophilic finishing agent. In a preferred embodiment, the hydrophilic finish helps to improve the function of the dressing material or sponge by allowing wound exudate to be more easily absorbed by the inner layer absorbent core material. Suitable hydrophilic finishing agents include, e.g., surfactants, such as non-ionic surfactants, which may be typically applied in concentrations of about 0.1 % by weight. As noted above, one such non-ionic surfactant is TWEEN® 20, which is polyoxyethylene (20) sorbitan monolaurate, although other such surfactants may also be utilized.

[0.] A medical sponge formed from plies of the medical dressing material may contain several plies of the dressing material, preferably 2-10 plies, more preferably 4-8 plies, and most preferably 6 plies. A cross-shaped incision may be preferably formed in the center of the sponge that penetrates all plies, thereby allowing an object to pass through the sponge.

In a preferred aspect, the fabric comprises about 50% by weight rayon, about 33% by weight textile matrix grade polyester, and about 17% by weight binder

-14-

grade polyester, based on the weight of the fabric.

The fabric of the medical dressing and sponge of the invention may be processed to impart softness and improved absorbency, according to techniques known in the art, followed by further processing to form the inventive medical dressing and sponge. Suitable techniques include the use of microcreping devices such as are commercially available from Microx, Corp. for the treatment of nonwoven and other materials. It is preferred that such treatments provide an absorbency of from about 6-15, preferably 10-15, times the dry weight of the fabric. As used in the context of the invention, the term "absorbency" refers to the amount of liquid material, such as water or wound exudate, that may be absorbed by the fabric of the medical dressing or sponge.

As compared with other commercial medical dressings and sponges, the present invention provides several advantages and benefits. For example, by containing the antimicrobial agent within the inner layer of the medical dressing and the sponge formed therefrom, the release of the antimicrobial agent is controlled such that sensitive wound or skin areas are not adversely irritated. The presence of the antimicrobial agent within the inner layer also allows for the dressing and sponge to function effectively as a barrier against contamination of the wound. Contamination of areas outside the wound and dressing or sponge due to the retention of the wound exudate within the dressing or sponge is also reduced or prevented. In addition, the use of the outer hydrophobic (nonwoven) layers provides the dressing and sponge with the characteristic of non-adherency to wounds. Further, due in part to the presence of the outer hydrophobic layer(s), the amount of antimicrobial agent within the inner layer necessary to maintain the antimicrobial effectiveness of the dressing or sponge is also reduced compared with other commercial products. As such, the present invention provides a benefit of reduced cost associated with the use of lesser amounts of antimicrobial agent.

The medical dressing of the present invention may also comprise layered fabric consisting essentially of an inner layer of substantially hydrophilic material; an outer layer of substantially hydrophobic material on both sides of the inner layer;

-15-

and an antimicrobial agent, wherein the antimicrobial agent is contained in the inner layer. As used in the context of the invention, the phrase "consisting essentially of" is intended to mean that the certain additional components which would materially affect the basic and novel characteristics of the inventive medical dressing are not included in the layered fabric. As concerns the medical dressing and sponge of the invention, "consisting essentially of" is intended to mean, e.g., that adhesives are not utilized to prepare the layered fabric or that additional agents are not utilized to bind the antimicrobial agent within the inner layer material of the medical dressing.

EXAMPLES

The antimicrobial efficacy of the medical dressing and sponge according to the invention has been investigated. Such tests simulate the use of the dressing or sponge in practice and are based upon the visual observation of microbial activity on growth media placed in contact with the inventive medical dressing or sponge containing a determined amount of microbes. The tests are generally conducted by placing a sample of the antimicrobial agent containing dressing or sponge in contact with growth medium, adding a small volume of microbe containing aqueous solution to the medical dressing or sponge, and incubating the test samples for definite time periods and under controlled temperature and environmental conditions. Following the end of the pre-determined time period, the growth medium is visually observed to determine the extent, if any, of microbial activity or growth on the medium. For the purposes of the present invention, an assessment of the antimicrobial effectiveness of the inventive dressing and sponge against various microbes, including *S. aureus*, *S. epidermidis*, *E. coli*, and *P. aeruginosa*, has been conducted according to this procedure. In all such tests, the medical dressing and sponge according to the invention has been determined to be effective to prevent microbial activity on such growth medium. By comparison, control samples not containing an antimicrobial agent, such as PHMB, were determined using the same procedures and conditions to not prevent microbial activity on such growth medium.

While the invention has been described in detail by reference to specific

WO 2004/037115

PCT/US2003/032514

-16-

embodiments, the skilled artisan will appreciate that various modifications, substitutions, omissions and changes may be made, and equivalents employed, without departing from the spirit of the invention or the scope of the appended claims.

-17-

What is claimed is:

1. A medical dressing comprising:
layered fabric comprising:
an inner layer of substantially hydrophilic material;
5 an outer layer of substantially hydrophobic material on both sides of
the inner layer; and
an antimicrobial agent,
wherein the antimicrobial agent is contained in the inner layer.
2. A medical dressing according to claim 1 wherein the antimicrobial agent
10 is releasably impregnated into the inner layer substantially hydrophilic material of
the fabric, coated on said inner layer, or a combination thereof.
3. A medical dressing according to claim 2 wherein the antimicrobial agent
is releaseable from the fabric in an amount effective as an antimicrobial.
4. A medical dressing according to claim 2 wherein the antimicrobial agent
15 is releaseable from the fabric in an amount effective as an antimicrobial for a period
of up to about 2 days.
5. A medical dressing according to claim 2 wherein the antimicrobial agent
is releaseable from the fabric in an amount effective as an antimicrobial for a period
of up to about 1 day.
- 20 6. A medical dressing according to claim 3 wherein the antimicrobial agent
is a biguanide.
7. A medical dressing according to claim 3 wherein the antimicrobial agent
is polyhexamethylene biguanide.

-18-

8. A medical dressing according to claim 3 wherein the fabric inner layer material is substantially a cellulose fiber.

9. A medical dressing according to claim 3 wherein the fabric inner layer material is substantially rayon.

5 10. A medical dressing according to claim 3 wherein the fabric outer layer material is substantially polyester.

11. A medical dressing according to claim 3 wherein the fabric outer layer material is a combination of textile matrix grade polyester fiber and amorphous binder grade polyester fiber.

10 12. A medical dressing according to claim 11 wherein the textile to binder fiber weight ratio is about 2:1.

13. A medical dressing comprising:
layered fabric comprising:

15 an inner layer substantially of rayon
an outer layer substantially of textile and binder fibers in a 2:1 weight ratio; and

polyhexamethylene biguanide,
wherein the polyhexamethylene biguanide is contained in the inner layer.

20 14. A medical dressing according to claim 13 wherein the fabric is treated with an aqueous solution of surfactant and polyhexamethylene biguanide to have about 1500-3500 ppm of extractable polyhexamethylene biguanide.

-19-

15. A medical dressing according to claim 13 wherein the fabric is formed from:

about 50% by weight rayon,
about 33% by weight textile fibers, and
5 about 17% by weight binder fibers, based on the weight of the fabric.

16. A medical dressing according to claim 15 wherein the fabric is treated with an aqueous solution of surfactant and polyhexamethylene biguanide to have about 1500-3500 ppm of extractable polyhexamethylene biguanide.

17. A sponge formed from plies of the medical dressing material of claim 1.

10 18. A sponge formed from plies of the medical dressing material of claim 13.

15 19. A sponge formed from plies of the medical dressing material of claim 15.

15 20. A sponge formed from plies of the medical dressing material of claim 16.

21. A sponge according to claim 17 having 6 plies.

22. A sponge according to claim 18 having 6 plies.

23. A sponge according to claim 19 having 6 plies.

24. A sponge according to claim 20 having 6 plies.

20 25. A sponge according to claim 17 with a cross-shaped incision in the

-20-

center of the sponge that penetrates all plies to allow an object to pass through the sponge.

5 26. A sponge according to claim 18 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.

27. A sponge according to claim 19 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.

10 28. A sponge according to claim 20 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.

29. A medical dressing according to claim 1 wherein the hydrophobic layers have a hydrophilic finish.

15 30. A medical dressing according to claim 13 wherein the hydrophobic layers have a hydrophilic finish.

31. A sponge according to claim 17 wherein the hydrophobic layers have a hydrophilic finish.

32. A sponge according to claim 18 wherein the hydrophobic layers have a hydrophilic finish.

20 33. A medical dressing according to claim 1, wherein the fabric forming the medical dressing has an absorbency of from 6-15 times the dry weight of the fabric material.

-21-

34. A medical dressing according to claim 13, wherein the fabric forming the medical dressing has an absorbency of from 6-15 times the dry weight of the fabric material.

5 35. A sponge according to claim 17, wherein the fabric forming the medical dressing material of the sponge has an absorbency of from 6-15 times the dry weight of the fabric material.

36. A sponge according to claim 18, wherein the fabric forming the medical dressing material of the sponge has an absorbency of from 6-15 times the dry weight of the fabric material.

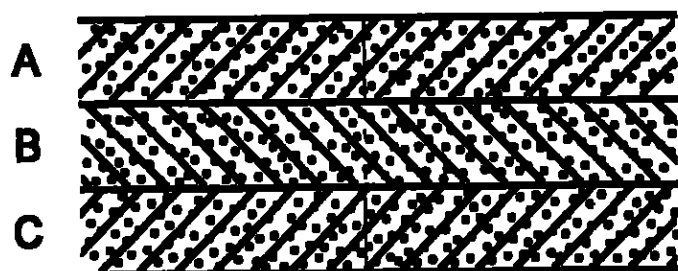


FIG. 1

WO 2004/037115

PCT/US2003/032514

2/2

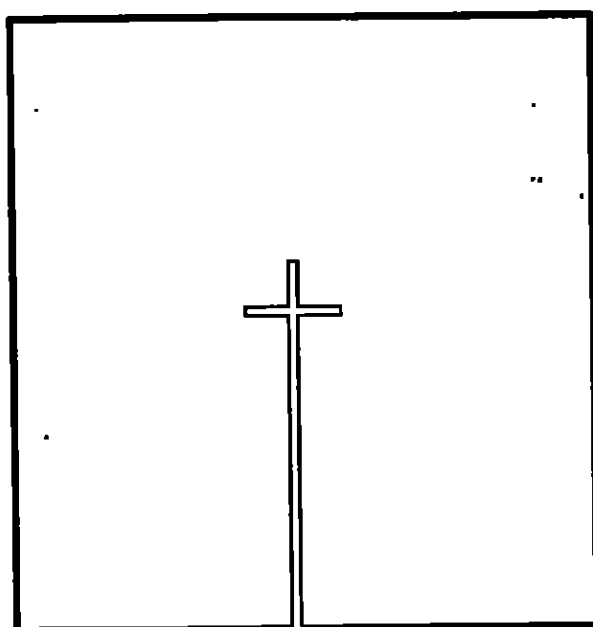


FIG. 2

APÓSITO MÉDICO QUE CONTIENE UN AGENTE ANTIMICROBIAL**ANTECEDENTES DE LA INVENCION****Campo de la Invención**

La presente invención se relaciona con un apósito médico que contiene un agente antimicrobial, una esponja formada de tal apósito, y métodos de fabricar tal apósito médico y esponja.

Breve Descripción de la Técnica

Los apósitos médicos han sido usados largamente para proteger y ayudar en la cicatrización de las heridas. Varias formas y construcciones de tales apósitos médicos son conocidos en la técnica. Por ejemplo, la Patente estadounidense No. 4,211,227, incorporada aquí como referencia, describe un material de esponja quirúrgica no tejido que comprende una tela en capas que tiene un núcleo

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interior o un material sustancialmente hidrofílico dispuesto adyacente en por lo menos una capa exterior o superficie exterior, o entre un par de capas exteriores, de un material sustancialmente hidrófobo. El material de esponja es pegado por medio de pasar el material a través de unos rodillos grabados con un patrón de partes planas y ranuras de modo que un patrón de repetición de tres grados de compresión es impuesto sobre el material.

La Patente estadounidense No. 6,369,289, incorporada aquí como referencia, describe adicionalmente el uso de un vendaje celulósico en un método para cubrir una herida abierta por medio de poner en contacto la herida con el vendaje que tiene una cantidad calculada de un agente antimicrobial. El vendaje celulósico puede ser preparado por medio de suministrar por lo menos un rollo de material celulósico en un tambor perforado, insertar el rollo de material de una vasija encerrada, agregar el agente antimicrobial en la vasija, y hacer circular el agente antimicrobial durante un periodo de tiempo predeterminado.

El uso de ciertas clases de agentes antimicrobiales es también conocido en la técnica. La Patente estadounidense No. 4,655,756, por ejemplo, se relaciona con un material no tejido tratado con una biguadina polimérica lineal que tiene una fórmula definida, o una mezcla de, por ejemplo, biguanida de polihexametileno (de aquí en adelante "PHMB") o dicloruro de ella con pesos moleculares promedio. La biguanida polimérica puede estar presente en una concentración desde 500 a 5.000 ppm y el material no tejido puede estar en la forma de un artículo para la recolección de emisiones del cuerpo humano.

Otros tipos de agentes antimicrobiales son también conocidos. Por ejemplo, la Patente estadounidense No. 5,707,736 describe un producto polimérico seco desechable que tiene una actividad antimicrobial de liberación sostenida formada a partir de un material polimérico que tiene un agente antimicrobial de sal de amina incorporado allí. El material polimérico puede estar en la forma de fibras, láminas, películas, u otros materiales tejidos, no tejidos o tejidos de punto estables. Los agentes

antimicrobiales incluyen, por ejemplo, gluconato de clorexidina y clorhidrato de clorexidina.

Componentes adicionales, tales como adhesivos, también son conocidos como componentes de apósitos médicos. Uno de tales apósitos quirúrgicos se describe en la Patente estadounidense No. 4,643,180, en donde el apósito comprende una lámina de una película polimérica recubierta por un lado por un adhesivo con base en agua de espesor de fluido que incluye un agente antimicrobial depositado en la superficie cara hacia el cuerpo del adhesivo.

La Patente estadounidense No. 4,643,181 también describe un apósito quirúrgico y un proceso para fabricar un apósito quirúrgico. El apósito comprende un sustrato recubierto por una superficie con un adhesivo par contacto con la piel con base en disolvente de espesor definido, el adhesivo tiene distribuido en él partículas de PHMB. El proceso que involucra mezclar una solución acuosa definida de clorhidrato de PHMB con un disolvente que es compatible con el adhesivo en una velocidad de mezclado de no más de 300

rpm, agregando la mezcla a un adhesivo, aplicando el adhesivo a una superficie de liberación en una cantidad entre 40 a 55 gramos por metro cuadrado, secar el adhesivo, y aplicar un sustrato para el apósito al adhesivo.

La Patente estadounidense No.4,675,347 se relaciona con una composición de látex antimicrobial y un método para fabricar un artículo formado por sumergimiento repetitivo de un artículo dentro de una composición y su secado. La composición comprende, por ejemplo, (1) por lo menos un componente de látex catiónico seleccionado a partir de látex de caucho natural catiónico y un látex polimérico sintético catiónico y (2) un agente antimicrobial catiónico incorporado en el látex catiónico (1).

La Patente estadounidense No. 4,678,704 describe un material de tela impregnado que comprende un sustrato de tela al cual se le ha ligado o pegado un impregnante catiónico activo junto con una tinta indicadora aniónica en combinación con un componente catiónico adicional en donde los enlaces de la tinta al componente catiónico adicional

compiten más fácilmente que con los del sustrato o del componente catiónico adicional para enlazar la tinta. El impregnante catiónico puede ser una biguadina polimérica, por ejemplo, PHMB.

La Patente estadounidense No. 4,837,069 se relaciona con un método para hacer una tela no tejida antimicrobialmente activa que comprende las etapas de formar una tela fibrosa no ligada, aplicable a través de la tela fibrosa no ligada un aglomerante no curado y clorhidrato de PHMB como un agente antimicrobial, el clorhidrato de PHMB es sustantivo a las fibras de la tela y al aglomerante cuando la tela está húmeda o seca para impedir que el agente antimicrobial se difunda sustancialmente desde las fibras o del aglomerante y esté presente en una cantidad efectiva para actuar como un agente antimicrobial, y curar el aglomerante para ligar las fibras juntas y formar una tela no tejida antimicrobialmente activa. La tela no tejida antimicrobialmente activa comprende fibras aglomeradas, un aglomerante distribuido a través de las fibras en una cantidad efectiva para aglomerar las fibras y clorhidrato

de PHMB que es sustancialmente impedido de difundirse desde las fibras o del aglomerante como ya se dijo. Adicionalmente se ha descrito un trapo húmedo que es sustancialmente idéntico a la tela reivindicada, pero que adicionalmente contiene un líquido sustancialmente libre de preservativos.

La Patente estadounidense No. 5,098,417 se relaciona con un apósito para herida para administración sistémica de un agente fisiológica o biológicamente activo por medio de liberación controlada del agente hacia la herida. El apósito para heridas comprende un sustrato en la forma de una tela, por lo menos una porción de la cual es celulósica, que ha sido modificada químicamente para convertir los grupos hidroxilo en la porción celulósica a sitios de adsorción iónica, una forma iónica de un agente fisiológica o biológicamente activo (que incluye agentes antibacteriales) adsorbidos en el sustrato. Los enlaces iónicos mantienen el agente temporalmente en el sustrato para una liberación controlada del mismo en proporción a la cantidad de exudado en contacto con el sustrato y son

formados por la adsorción del agente en el sustrato a temperatura ambiente. Los enlaces iónicos son desasociados luego del contacto con el exudado del cuerpo de las heridas liberando así el agente fisiológica o biológicamente activo en una cantidad en proporción con la cantidad de exudado en contacto con el sustrato. La clorexidina es mencionada como uno de los posibles agentes.

La Patente estadounidense 5,141,803 se relaciona con un limpión húmedo para la limpieza y que suministra un biocida catiónico que comprende un sustrato no tejido absorbente flexible impregnado con una composición acuosa que comprende cantidades definidas de sulfato de potasio, ácido cítrico, etilendiamintetracetato de disodio, un biocida catiónico seleccionado de un grupo definido que incluye clorhidrato de HPMB y el resto agua. El pH de la composición está entre 3,5 a 4,5.

La Patente estadounidense No. 5,156,843 se relaciona con una composición de materia que comprende un material provisto con intersticios que tienen partículas sólidas que

residen allí. El material es un miembro seleccionado del grupo que consiste de fibras unidas, tela tejida, tela no tejida, papel, paño tejido, paño no tejido, esponja y plástico espumado. Las partículas sólidas están entre cerca de 100 micrones en diámetro y contienen una red sustancialmente continua de poros abiertos hacia el exterior de las partículas, con una sustancia funcional retenida en los poros. La sustancia funcional puede ser una sustancia biocidal que puede impedir o retardar el crecimiento bacterial, microbial, de gérmenes o de hongos.

La Patente estadounidense No. 5,498,416 se relaciona con un proceso para la protección de prótesis, implantes y/o catéteres, de materiales implantables temporalmente o permanentemente contra la colonización bacterial y la infección. Un dispositivo resistente a la infección capaz de liberar progresivamente en un medio acuoso una cantidad de una sustancia antibacterial fija al dispositivo, la cantidad siendo efectiva para impedir la contaminación bacterial del dispositivo se describe aquí. El dispositivo comprende un primer recubrimiento de una solución en

38

disolvente acuoso u orgánico de una biguanida de una fórmula general definida (la cual define compuestos monoméricos) y un segundo recubrimiento de una solución de la sustancia antibacterial, el segundo recubrimiento se sobrepone al primer recubrimiento, y el primer recubrimiento asegura la adhesión de la sustancia antibacterial al dispositivo. Dispositivos ilustrativos se describen en el párrafo que se inicia en la columna 2, línea 60 e incluye catéteres urinarios, probetas, catéteres vasculares e intraarteriales, prótesis valvular cardíaca, prótesis arterial, simuladores cardíacos, prótesis ortopédicas, implantes oculares o dentales, puentes que conectan dos segmentos del sistema circulatorio, e hilos de sutura.

La Patente estadounidense No. 5,700,742 se relaciona con un método para tratar un material textil para inhibir el crecimiento microbial que comprende aplicar al material textil una oligobiguanida o biguanida polimérica o sal de ellas con un ácido inorgánico o un ácido orgánico que tiene un valor pK por encima de 4,5 seguido por un ácido orgánico

fuerte que tiene un valor pK por debajo de 4,5 y libre de cualquier cadena alifática u oxiaquileno que contiene 12 o más átomos de carbono. Un material textil tratado de acuerdo con el método reivindicado también se ha descrito.

La Patente estadounidense No. 5,856,248 se relaciona con fibras de celulosa y productos que comprenden fibras de celulosa y productos que comprenden fibras de celulosa tratadas para absorber las secreciones corporales mientras que disminuye sustancialmente el crecimiento microbial, las fibras son modificadas químicamente en dos etapas de procesos que comprenden una primera etapa de tratamiento con una sal soluble en agua de un metal de transición y una segunda etapa de tratamiento con una solución de un compuesto de bisbiguanida, formando así un enlace entre las fibras de celulosa, el metal de transición y el compuesto de bisbiguanida. El proceso puede utilizar una etapa de enjuague a pH neutro entre las dos etapas anteriormente mencionadas.

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La Patente estadounidense No. 5,869,073 se relaciona con una composición líquida para ser aplicada a una capa antimicrobial no lixiviada o recubrimiento sobre una superficie, que comprende una solución, dispersión o suspensión de un polímero de biguanida, un reticulador que se hace reaccionar con el polímero de biguanida para formar un aducto, y un metal antimicrobial, sal de metal (por ejemplo sal de plata) o un complejo metálico en donde el metal, la sal de metal o el complejo de metal forman un complejo con el aducto, y en donde la capa antimicrobial o recubrimiento no libera los niveles biocidales de lixiviables dentro de una solución que está en contacto.

La Patente estadounidense No. 5,817,325 se relaciona con un artículo de manufactura que tiene dispuesto sobre una superficie del mismo un recubrimiento antimicrobial no lixiviado que mata al contacto, el cual mata organismos o microorganismos tan pronto entran en contacto. El Recubrimiento comprende una matriz de polímero policatiónico orgánico inmovilizada sobre la superficie que tiene enlaces o ha sido complejoado en ella un material

metálico antimicrobial accesible a la superficie que modo que el material antimicrobial no libera las cantidades biocidas eluibles dentro del ambiente que lo rodea. La matriz orgánica puede comprender un copolímero de biguanida, tal como el PHMB o un polímero que contiene una parte de biguanida.

La Patente estadounidense No. 5,849,311 se relaciona adicionalmente con un material antimicrobial no lixiviado que mata al contacto, capaz de matar microorganismos que entran en contacto con el material. El material comprende una matriz de polímero policatiónico orgánico que tiene enlaces no lixiviables o complejados al mismo un material metálico antimicrobial, de modo que el material antimicrobial no libera las cantidades biocidas de eluibles dentro del ambiente que lo rodea. El material policatiónico puede ser PHMB o un polímero que contiene una parte de biguanida.

La patente estadounidense No. 5,886,048 se relaciona con un método para tratar una enfermedad de tumor en un humano o

animal con una cantidad terapéuticamente efectiva de PHMB o una sal del mismo.

La Patente estadounidense No. 5,985,931 se relaciona con una composición antimicrobial que comprende cantidades definidas de PHMB, un compuesto de amonio cuaternario; y paraclorometaxilenol en donde la combinación de los tres componentes se dice que exhibe actividad antimicrobial efectiva.

La Patente estadounidense No. 5,990,174 se relaciona con un método para mejorar la formación de bruma y la estabilidad de almacenamiento de una composición antimicrobial que consiste de agua y de 5 a 25% en peso de oligómeros de biguanida polimérica lineal definidos. El método comprende ajustar el pH de la composición antimicrobial acuosa a por lo menos 0,1 y menos de 5 según se determinó usando un indicador mejorando así la resistencia a la formación de bruma y la estabilidad del almacenamiento de la composición antimicrobial acuosa cuando se compara con una composición

correspondiente a un pH más alto. La concentración en particular y las limitaciones de pH también se describen.

La Patente estadounidense No. 5,993,840 se relaciona con una composición que comprende un material no tejido que contiene una mezcla de biguanidas poliméricas sujetas a deserción cuando el material no tejido es humectado por la orina; y un polímero aniónico el cual es sustancialmente insoluble en la orina. Las funciones del polímero aniónico para retener las biguanidas en el material cuando entra en contacto por la orina. Un proceso para formar una capa absorbente y un método para reducir la pérdida de biguanida antimicrobial, en donde ambos incluyen el polímero aniónico, se han descrito aquí.

La Solicitud de Patente Europea No. 136900 describe la aplicación de PHMB a un ropaje quirúrgico que comprende una tela no tejida y menciona en la página 7 que un agente humectante no iónico en la aplicación de la formulación es deseable para suministrar características absorbentes a la tela.

La Patente Estadounidense No. 6,017,561 se relaciona con una composición de limpieza antibacterial que comprende un compuesto de amonio cuaternario, un polímero aniónico que tiene un número ácido mayor a 10 en donde el polímero aniónico es parcial o completamente neutralizado por el compuesto de amonio cuaternario para formar un complejo de polímero y en donde el complejo de polímero es mayor a cerca del 15% del peso de los sólidos en la composición, un agente dispersante, que comprende un tensoactivo que es seleccionado del grupo que consiste de tensoactivo no iónico, tensoactivo anfotérico, y mezclas de ellos, y opcionalmente un disolvente. También se describe un dispositivo de esponja que tiene actividad antibacterial que comprende una esponja; y un complejo de polímero que comprende un compuesto de amonio cuaternario y un polímero aniónico que tienen un número ácido mayor a 10 en donde el polímero aniónico es parcial o completamente neutralizado por el compuesto de amonio cuaternario para formar el complejo de polímero el cual está ligado a la superficie de la esponja. Una matriz absorbente o adsorbente que incluye

el complejo de polímero y un método para fabricar un material adsorbente o absorbente que usa por lo menos un compuesto de amonio cuaternario y un polímero aniónico también se describe. El compuesto de amonio puede ser clorhidrato de PHMB. Los artículos tales como esponjas también se describen.

La Patente estadounidense No. 6,160,196 se relaciona con una cubierta para herida que comprende un material de fibra polimérica de ocurrencia natural o sintética que absorbe las bacterias hidrófoba, que tiene adherida a ella un compuesto activo antimicrobial el cual está adaptado a no ser liberado dentro de la herida. Como se describió en la especificación y se incluyó en ciertas reivindicaciones dependientes, el material puede ser no tejido y la reivindicación dependiente 10 dice que el material de fibra polimérico puede ser seleccionado de un grupo que incluye poliéster. Los compuestos antimicrobiales activos son descritos en el pasaje que se inicia en la columna 2, línea 29 e incluye la clorexidina. En este pasaje, se establece que los compuestos "... se distinguen por el hecho de que

ellos se adhieren firmemente a la cubierta para heridas y no son liberados, o por lo menos no son liberados notablemente, dentro de la herida".

La Patente estadounidense No. 6,180,584 se relaciona con una composición desinfectante que comprende un material antimicrobial de formación por película (el cual puede ser un material de biguanida polimérica), un material metálico antimicrobial, y un vehículo. La composición, cuando es aplicada a una superficie, forma una película insoluble en agua, adherente, y no permanente, en donde el material metálico está enlazado de manera no lixiviada a o está asociado con la película. La película no eluye materiales antimicrobiales en contacto con agua a niveles capaces de impartir la acción desinfectante a dicha agua, y es removible por el tratamiento con una solución de alcohol. La composición puede incluir adicionalmente un tensoactivo.

La Patente estadounidense No. 6,235,302 se relaciona con un paño de esponja que está basado en celulosa regenerada y que ha sido provisto con un refuerzo interno que consiste

de, por ejemplo, fibras viscosas o fibras de algodón que tienen una longitud de fibra de 5 a 50 mm. El paño de esponja es obtenido por un proceso que comprende las etapas de coagular y regenerar la celulosa en un baño que tiene un pH de 13 o mayor y que comprende la sal de Glauber, NaOH y agua, e impregnar el paño de esponja con un agente activo biocidamente. Los agentes representativos son descritos e incluyen el isotiazolona, la benzoisotiazolona y derivados de benzimidazol con biguanidas.

OBJETIVOS Y RESUMEN DE LA INVENCION

Un objetivo de la presente invención es suministrar un apósito médico que comprende un agente antimicrobial lo mismo que un proceso para fabricar o hacer tal apósito médico. Un objetivo adicional es suministrar una esponja formada a partir del apósito médico lo mismo que un proceso para hacer tal esponja.

El apósito médico y la esponja formada de él son caracterizados preferiblemente por medio de un

comportamiento antimicrobial mejorado. Más particularmente, en una modalidad preferida, el apósito médico y la esponja formada de él suministran una barrera antimicrobial efectiva para una herida mientras que también controla la liberación del agente antimicrobial contenido dentro de una porción interna del apósito. El agente antimicrobial es concentrado preferiblemente dentro de una porción interior del núcleo absorbente del apósito mientras que una porción de capa de barrera exterior reduce la liberación del agente antimicrobial desde el apósito.

Un objetivo adicional de la invención es suministrar un apósito médico y una esponja formada del mismo en donde la capa exterior hidrófoba o capas exteriores hifófbas suministran superficies no adherentes para ayudar en la cicatrización de heridas el cual reduce o elimina el dolor experimentado por un paciente durante los cambios de apósito o esponja.

De acuerdo con un aspecto de la presente invención, un apósito médico es suministrado, el cual comprende:

Una tela en capas que comprende:

Una capa interior de material sustancialmente hidrofílico;

Una capa exterior de material sustancialmente hidrófobo en ambos lados de la capa interior; y

Un agente antimicrobial, en donde el agente antimicrobial está contenido en la capa interior.

De acuerdo con otro aspecto de la invención, el apósito médico de la invención puede estar en la forma de una esponja que comprende pliegues de material de apósito médico.

BREVE DESCRIPCIÓN DE LAS FIGURAS

La figura 1 ilustra una vista en sección transversal de una forma de apósito médico que contiene dos capas exteriores y una capa interior.

50

La figura 2 ilustra una vista de superficie de una forma del apósito médico que contiene una incisión en forma de cruz que pasa por todos los pliegues del apósito.

DESCRIPCIÓN DETALLADA DE LAS MODALIDADES PREFERIDAS DE LA
INVENCIÓN

En una modalidad, el apósito médico de la invención está basado en parte sobre el apósito descrito en la Patente estadounidense No. 4,211,227, cuya descripción se incorpora aquí como referencia en su totalidad.

En una modalidad preferida, el apósito médico de la invención es una esponja de drenaje antimicrobial la cual es un material absorbente no tejido térmicamente aglomerado, típicamente en la forma de un cuadrado que tiene 2" x 2" o 4" x 4" y tiene un espesor de 6 pliegues. El material es preferiblemente cerca de 50% poliéster y cerca de 50% rayón con cada pliegue formado como un sándwich de una capa de rayón entre dos capas de poliéster.

En una modalidad de la invención, como se ilustró en la figura 1, las capas exteriores (A y C pueden estar formadas de un material hidrófobo, preferiblemente fibras hidrófobas, tal como fibras de poliéster. La capa interior (mostrada como capa B en la figura 1) comprende un material hidrofílico, preferiblemente fibras hidrofílicas, tales como fibras celulósicas. Más preferiblemente, las fibras celulósicas son rayón.

Para poder impartir propiedades antimicrobiales, el material que debe ser cortado en esponjas individuales es impregnado con una solución acuosa de un agente antimicrobial, tal como la biguanida de polihexametileno (PHMB). Un agente antimicrobial tal como el PHMB está presente en forma adecuada en una concentración de cerca de 0,1 a 0,5% en peso, preferiblemente entre 0,15 a 0,35% en peso, y más preferiblemente entre cerca de 0,2 a 0,3% en peso. Un tensoactivo también estar presente en la solución acuosa. Por ejemplo, tensoactivos no iónicos comercialmente disponibles, tales como TWEEN® 20, que es monolaurato de polioxietileno (20) sorbitán, puede ser utilizado. El PHMB

usado para preparar la esponja de drenaje puede estar provisto por, por ejemplo, Avecia Inc. bajo la designación COSMOCIL® CQ (una solución acuosa de PHMB que contiene entre 19 a 21% p/p de ingrediente activo y un pH de entre 5,0 - 5,5). El material puede estar impregnado con el agente antimicrobial de acuerdo con cualquier técnica adecuada, tal como, por ejemplo, por recubrimiento por inmersión del material en una solución que comprende el agente antimicrobial.

El material impregnado puede entonces ser presionado a una presión designada de modo que el nivel apropiado de agente antimicrobial, preferiblemente PHMB, permanezca en el material. Después de secado por medio de hacerlo pasar entre rodillos calientes, el material tiene un agente antimicrobial residual (por ejemplo PHMB) con un contenido entre 1.500 a 3.500 ppm. El material es subsecuentemente convertido en esponja de drenaje de 6 pliegues de dimensiones de 4" x 4" y 2" x 2". Las esponjas no incluyen un adhesivo pero tienen una incisión en forma de cruz en el centro (como se ilustró en la figura 2) que penetra todos

los 6 pliegues de modo que un tubo de drenaje puede pasar por allí. El agente antimicrobial (por ejemplo PHMB) puede ser liberado preferiblemente del apósito médico o de la esponja en un ambiente húmedo para suministrar una actividad antimicrobial más allá de los bordes de la esponja durante un tiempo limitado. En general, la tela es tratada de modo que tenga cerca de 1.500 a 3.500 ppm de agente antimicrobial extraíble, preferiblemente biguanida de polihexametileno.

El agente antimicrobial es impregnado de manera preferible liberablemente dentro de la capa interior de material sustancialmente hidrofílico de la tela, recubierto sobre dicha capa interior o una combinación de éstos. El agente antimicrobial es también liberable de manera preferiblemente controlada de la tela en una cantidad efectiva como un antimicrobial, más preferiblemente en una cantidad efectiva como un antimicrobial durante un periodo de hasta cerca de dos días, más preferiblemente hasta cerca de un día. La cantidad antimicrobial es definida como la cantidad de antimicrobial aplicada al apósito que es

necesaria para suministrar suficientes características antimicrobiales, y todavía sin causar irritación a la piel o a la herida abierta.

Aunque el agente antimicrobial puede ser liberado de la capa interior del material de la tela, el tratamiento antimicrobial de la tela principalmente permite al apósito funcionar como una barrera contra la contaminación de la herida desde fuentes externas a la herida. Adicionalmente, debido a las características absorbentes del apósito, los microbios absorbidos dentro de la capa interior se les impide escaparse del apósito.

En general, el agente antimicrobial puede ser cualquier agente que funcione adecuadamente para suministrar una propiedad antimicrobial al apósito médico de la invención. Tales agentes antimicrobiales son descritos en algunas de las patentes anteriormente identificadas, la cuales se incorporan aquí como referencia para tal información. Los agentes antimicrobiales preferiblemente incluyen las

biguanidas, especialmente la biguanida de polihexametileno ("PHMB").

El material de la capa interior de la tela es sustancialmente hidrofílico, y es preferiblemente sustancialmente una fibra de celulosa, y, más preferiblemente, es sustancialmente rayón. Otros materiales para la capa interna también pueden ser utilizados, incluyendo materiales de polisacáridos, alginatos, algodón o fibras de celulosa carboximetilo. En general, el material de la capa interior es "sustancialmente hidrofílico" de modo que el exudado de la herida puede ser absorbido por el núcleo absorbente de la capa interior y que el agente antimicrobial pueda ser contenido en su mayoría dentro del núcleo absorbente. De esta manera, el término "sustancialmente hidrofílico" describe la función del material de la capa interior. También se distingue el material de la capa interior sobre la función del material de capa exterior "sustancialmente hidrófoba", el cual suministra una propiedad de barrera antimicrobial y atenúa

o reduce la liberación del agente antimicrobial fuera del apósito.

La retención mejorada del agente antimicrobial dentro de la capa interior también disminuye los bioproblemas, es decir, el crecimiento y número de células, dentro del apósito durante el uso.

La hidrofobicidad e hidrofiliicidad son reportadas comúnmente como porcentaje de unidad reganado por las fibras del material. Para los propósitos de la presente invención, los términos "sustancialmente hidrofílicos" y "sustancialmente hidrófobos", según se aplican a las capas interior y exterior respectivamente, pueden ser relacionados con los porcentajes de humedad regados por las fibras de los materiales respectivos, típicamente a 70° F y 65% de humedad relativa. Las fibras usadas en la capa exterior sustancialmente hidrófoba deberían tener una humedad reganada de menos de cerca de 10%, preferiblemente menos del 5%, y más preferiblemente menos del 2% con base en el peso de la fibra seca. Las fibras usadas en la capa

interior sustancialmente hidrofílica deberían tener una humedad reganada de cerca de 5 a 25, preferiblemente cerca de 10 a 20, y más preferiblemente entre 15 y 20 veces el peso de la fibra seca.

El material de capa exterior de la tela es preferiblemente sustancialmente poliéster, y más preferiblemente, es una combinación de una fibra de poliéster grado matriz de textil y una fibra de poliéster grado aglomerante amorfo. Las fibras de aglomerante funcionan para aglomerar, por ejemplo, el rayón y las fibras de poliéster grado textil juntas. Los materiales de capa interior adecuados incluyen, por ejemplo, el rayón Lenzing 8191. Los materiales de capa exterior adecuados incluyen, por ejemplo, el poliéster grado textil Wellman Polyester T-203 y el poliéster grado aglomerante amorfo Kosa Polyester 259. La proporción en peso de textil a fibra aglomerante es preferiblemente cerca de 2:1. Otros materiales también ser utilizados para la capa exterior, incluyendo, por ejemplo, poliolefinas tales como fibras de polietileno o polipropileno, nylon u otras fibras termoplásticas.

Las capas hidrófobas que forman el apósito médico pueden también ser impartidas con un acabado hidrofílico. Tal acabado puede ser aplicado como un recubrimiento de un agente de acabado hidrofílico sobre las capas exteriores. También puede aplicarse durante la impregnación de la capa interior con un agente antimicrobial por medio de incluir el agente de acabado hidrofílico en la misma solución de agente antimicrobial. Al poner en contacto el material del apósito con la solución antimicrobial que contiene un agente de acabado hidrofílico, la capa interior es impregnada con la solución antimicrobial mientras que las capas exteriores se les imparte con un acabado hidrofílico. Como se usa aquí, el término "acabado hidrofílico" tiene el propósito de significar que las características hidrofílicas de la capa exterior son incrementadas en por lo menos algún grado por el uso de un agente de acabado hidrofílico. En una modalidad preferida, el acabado hidrofílico ayuda a mejorar la función del material de apósito o de la esponja permitiendo que el exudado de la herida se más fácilmente absorbido por el material de

núcleo absorbente de la capa interior. Los agentes de acabado hidrofílico adecuados incluyen, por ejemplo, tensoactivos, tales como tensoactivos no iónicos, que pueden ser típicamente aplicados en concentraciones entre 0,1% en peso. Como anotó anteriormente, uno de tales tensoactivo no iónicos es el TWEEN® 20, que es monolaurato de polioxietileno (20) sorbitán, aunque otros de tales tensoactivos pueden también ser utilizados.

Una esponja médica formada de pliegues del material de apósito médico puede contener varios pliegues o capas del material de apósito, preferiblemente de 2 a 10 capas, más preferiblemente entre 4 a 8 capas o pliegues y más preferiblemente 6 capas o pliegues. Una incisión en forma de cruz puede ser formada preferiblemente en el centro de la esponja la cual penetra todos los pliegues, permitiendo así que un objeto pase a través de la esponja.

En un aspecto preferido, la tela comprende cerca de 50% en peso de rayón, cerca de 33% en peso de poliéster grado

60

matriz textil, y cerca de 17% en peso de poliéster grado aglomerante con base en el peso de la tela.

La tela del apósito médico y de la esponja de la invención puede ser procesada para impartirle suavidad y absorbencia mejorada, de acuerdo con las técnicas conocidas en el arte, seguido por un procesamiento adicional para formar un apósito médico y una esponja de la invención. Las técnicas adecuadas incluyen el uso de dispositivos microcrepitantes tales como el disponible comercialmente de Micrex, Corp. para el tratamiento de no tejidos y otros materiales. Es preferido que tales tratamientos suministren una absorbencia de entre cerca de 6 a 15, preferiblemente 10 a 15 veces, el peso seco de la tela. Como se usa en el contexto de la invención, el término "absorbencia" se refiere a la cantidad de material líquido, tal como agua o exudado de herida, que puede ser absorbido por la tela o por el apósito médico o la esponja.

En comparación con otros apósitos y esponjas médicas comerciales, la presente invención suministra varias

ventajas y beneficios. Por ejemplo, por medio de contener el agente antimicrobial dentro de la capa interna del apósito médico y de la esponja formada de éste, la liberación del agente antimicrobial es controlada de modo que las áreas de la piel o heridas sensibles no son irritadas adversamente. La presencia del agente antimicrobial dentro de la capa interior también permite que el apósito y la esponja funcionen efectivamente como una barrera contra la contaminación de la herida. La contaminación de las áreas al exterior de la herida y el apósito o esponja debido a la retención del exudado de la herida dentro del apósito o esponja es también reducido o impedida. En adición, el uso de las capas exteriores hidrófobas (no tejidas) suministra al apósito y a la esponja características de no adherencia a las heridas. Adicionalmente, debido en parte a la presencia de las capas hidrófobas exteriores, la cantidad de agente antimicrobial dentro de la capa interior necesariamente para mantener la efectividad antimicrobial del apósito o esponja también se reduce en comparación con otros productos comerciales. Como tal, la presente invención suministra un beneficio de costo

reducido asociado con el uso de cantidades menores de agente antimicrobial.

El apósito médico de la presente invención también puede comprender tela en capas que consiste esencialmente de una capa interior de material sustancialmente hidrofílico; una capa exterior de materiales sustancialmente hidrófobos por ambos lados de la capa interior; y un agente antimicrobial, en donde el agente antimicrobial es contenido en la capa interior. Como se usa en el contexto de esta invención, la frase "que consiste esencialmente de" tiene el propósito de significar que ciertos componentes adicionales que afectarían materialmente las características básicas y novedosas del apósito médico de la invención no son incluidas en la tela en capas. En cuanto concierne al apósito y a la esponja médicas de la invención, "que consiste esencialmente de" tiene el propósito de significar, por ejemplo, que adhesivos no son utilizados para preparar la tela en capas o que agentes adicionales no son utilizados para aglomerar el agente antimicrobial dentro del material de capa interior del apósito médico.

EJEMPLOS

La eficacia antimicrobial del apósito médico y de la esponja de acuerdo con la invención ha sido investigada. Tales ensayos simulan el uso del apósito o de la esponja en la práctica y se basan en la observación visual de la actividad microbial sobre el medio de crecimiento colocado en contacto con el apósito médico o la esponja de la invención que contienen una cantidad determinada de microbios. Los ensayos son conducidos generalmente por medio de colocar una muestra del apósito o esponja que contienen el agente antimicrobial en contacto con el medio de crecimiento, agregar un pequeño volumen de una solución acuosa que contiene microbios al apósito médico o esponja, e incubar las muestras de ensayo durante periodos de tiempo definidos y bajo condiciones de ambiente y temperatura controladas. Luego al final del periodo de tiempo predeterminado, el medio de crecimiento es observado visualmente para determinar el grado, si hay alguno, de la actividad microbial o del crecimiento en el medio. Para el

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propósito de la presente invención, un acercamiento a la efectividad antimicrobial del apósito o esponja de la invención contra varios microbios, incluyen el *S. aureus*, *S. epidermidis*, *E. coli*, y *P. aeruginosa*, han sido conducidos de acuerdo con este procedimiento. En todos los ensayos hechos, el apósito y la esponja médica de acuerdo con la invención han sido determinado que son efectivos para impedir la actividad microbial en tales medios de crecimiento. Por medio de comparación, las muestras de control que no contienen el agente antimicrobial, tal como PHMB, fueron determinadas usando los mismos procedimientos y condiciones para no impedir la actividad microbial en tales medios de crecimiento.

Aunque la invención ha sido descrita con referencia a modalidades específicas, los artesanos versados en la técnica podrán apreciar que diversas modificaciones, sustituciones, omisiones y cambios pueden ser hechos, y equivalentes pueden ser empleados, sin salirse del espíritu de la invención o del alcance de las reivindicaciones adjuntas.

REIVINDICACIONES

Lo que se reivindica es:

1. Un apósito médico que comprende:

Una tela en capas que comprende:

Una capa interior de material sustancialmente hidrofílico;

Una capa exterior de material sustancialmente hidrófobo en ambos lados de la capa interior; y

Un agente antimicrobial,

En donde el agente antimicrobial es contenido en la capa interior.

2. Un apósito médico de acuerdo con la reivindicación 1 en donde el agente antimicrobial es impregnado de manera liberable dentro del material sustancialmente hidrofílico de la capa interior de

66

la tela, recubierto sobre dicha capa interior, o una combinación de ellos.

3. Un apósito médico de acuerdo con la reivindicación 2 en donde el agente antimicrobial es liberable de la tela en una cantidad efectiva como un antimicrobial.

4. Un apósito médico de acuerdo con la reivindicación 2 en donde el agente antimicrobial es liberable de la tela en una cantidad es efectiva como un antimicrobial durante un periodo de hasta cerca de 2 días.

5. Un apósito médico de acuerdo con la reivindicación 2 en donde el agente antimicrobial es liberable de la tela en una cantidad efectiva como un antimicrobial durante un periodo de hasta cerca de 1 día.

6. Un apósito médico de acuerdo con la reivindicación 3 en donde el agente antimicrobial es una biguanida.
7. Un apósito médico de acuerdo con la reivindicación 3 en donde el agente antimicrobial es biguanida de polihexametileno.
8. Un apósito médico de acuerdo con la reivindicación 3 en donde el material de capa interior de la tela es sustancialmente una fibra de celulosa.
9. Un apósito médico de acuerdo con la reivindicación 3 en donde el material de la capa interior de la tela es sustancialmente rayón.
10. Un apósito médico de acuerdo con la reivindicación 3 en donde material de la capa exterior de la tela es sustancialmente poliéster.

11. Un apósito médico de acuerdo con la reivindicación 3 en donde el material de la capa exterior de la tela es una combinación de fibra de poliéster grado matriz textil y fibra de poliéster grado aglomerante amorfo.

12. Un apósito médico de acuerdo con la reivindicación 11 en donde la proporción de peso del textil a la fibra aglomerante es de 2:1.

13. Un apósito médico comprende:

Una tela en capas que comprende:

Una capa interior sustancialmente de rayón

Una capa exterior sustancialmente de fibras textil y aglomerante en una proporción de peso de 2:1; y

Biguanida de polihexametileno,

En donde la biguanida de polihexametileno está contenida en la capa interior.

14. Un apósito médico de acuerdo con la reivindicación 13 en donde la tela es tratada con una solución acuosa de tensoactivo y biguanida de polihexametileno para tener cerca de 1.500 a 3.500 ppm de biguanida de polihexametileno extraíble.

15. Un apósito médico de acuerdo con la reivindicación 13 en donde la tela está formada a partir de:

Cerca de 50% en peso de rayón,

Cerca de 33% en peso de fibras textiles, y

Cerca de 17% en peso de fibras aglomerantes con base en el peso de la tela.

16. Un apósito médico de acuerdo con la reivindicación 15 en donde la tela es tratada con una solución acuosa de tensoactivo y biguanida de polihexametileno para obtener cerca de 1.500 a 3.500 ppm de biguanida de polihexametileno extraíble.

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17.Una esponja formada de capas de material de apósito médico de la reivindicación 1.

18.Una esponja formada de capas de material de apósito médico de la reivindicación 13.

19.Una esponja formada de capas de material de apósito médico de la reivindicación 15.

20.Una esponja formada de capas de material de apósito médico de la reivindicación 16.

21.Una esponja de acuerdo con la reivindicación 17 que tiene 6 capas.

22.Una esponja de acuerdo con la reivindicación 18 que tiene 6 capas.

23.Una esponja de acuerdo con la reivindicación 19 que tiene 6 capas.

24.Una esponja de acuerdo con la reivindicación 20 que tiene 6 capas.

25.Una esponja de acuerdo con la reivindicación 17 con una incisión en forma de cruz en el centro de la esponja que penetra todas las capas para permitir que un objeto pase a través de la esponja.

26.Una esponja de acuerdo con la reivindicación 18 con una incisión en forma de cruz en el centro de la esponja que penetra todas las capas para permitir que un objeto pase por la esponja.

27.Una esponja de acuerdo con la reivindicación 19 con una incisión en forma de cruz en el centro de la esponja que penetra todas las capas para permitir que un objeto pase por la esponja.

28.Una esponja de acuerdo con la reivindicación 20 con una incisión en forma de cruz en el centro de la

esponja que penetra todas las capas para permitir que un objeto pase por la esponja.

29.Un apósito médico de acuerdo con la reivindicación 1 en donde las capas hidrófobas tienen un acabado hidrofílico.

30.Un apósito médico de acuerdo con la reivindicación 13 en donde las capas hidrófobas tienen un acabado hidrofílico.

31.Una esponja de acuerdo con la reivindicación 17 en donde las capas hidrófobas tienen un acabado hidrofílico.

32.Una esponja de acuerdo con la reivindicación 18 en donde las capas hidrófobas tienen un acabado hidrofílico.

33.Un apósito médico de acuerdo con la reivindicación 1 en donde la tela que forma el apósito médico

tiene una absorbencia de entre 6 a 15 veces el peso seco del material de la tela.

34.Un apósito médico de acuerdo con la reivindicación 13, en donde la tela que forma el apósito médico tiene una absorbencia de entre 6 a 15 veces el peso seco del material de la tela.

35.Una esponja de acuerdo con la reivindicación 17, en donde la tela que forma el material de apósito médico de la esponja tiene una absorbencia entre 6 a 15 veces el peso seco del material de tela.

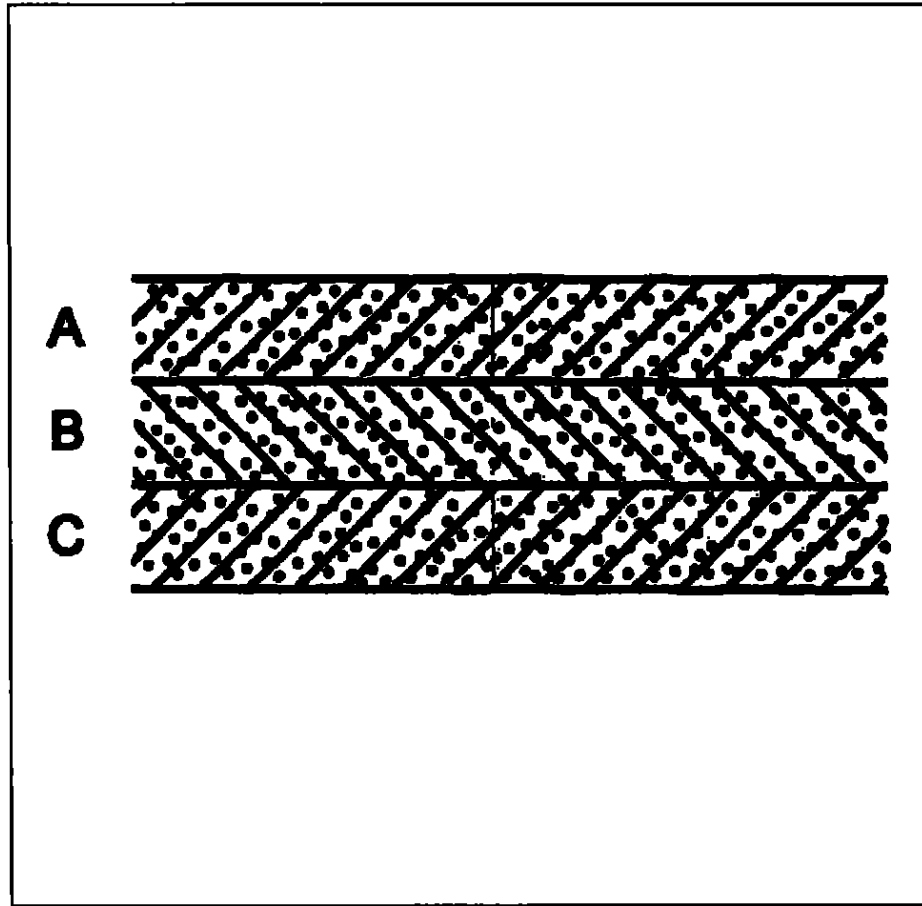
36.Una esponja de acuerdo con la reivindicación 18, en donde la tela que forma el material de apósito médico de la esponja tiene una absorbencia entre 6 a 15 veces el peso seco del material de tela.

APÓSITO MÉDICO QUE CONTIENE UN AGENTE ANTIMICROBIAL**RESUMEN**

Se describe un apósito médico que contiene un agente antimicrobial. El apósito médico comprende una tela en capas que comprende una capa interior de un material sustancialmente hidrofílico, una capa exterior de un material sustancialmente hidrófobo en ambos lados de la capa interior y un agente antimicrobial. El agente antimicrobial puede ser impregnado de manera liberable en la tela, recubierto en dicha tela o una combinación de éstos. El agente antimicrobial puede ser una biguanida, tal como la biguanida de polihexametileno (PHMB). El material de la capa interior de la tela puede ser una fibra de celulosa sustancialmente, preferiblemente rayón sustancialmente, y el material de la capa externa de la tela puede ser sustancialmente poliéster, por ejemplo, una combinación de fibra de poliéster de grado de matriz de textil y una fibra de poliéster de grado aglomerante amorfo. La tela es preferiblemente tratada con una solución acuosa de tensoactivo y PHMB para tener cerca de 1.500 a 3,500 ppm de PHMB extraíble.

SOLICITANTE: TYCO HEALTHCARE GR UP LP

**TITUL : APÓSITO MÉDICO QUE CONTIENE UN AGENTE
ANTIMICROBIAL**

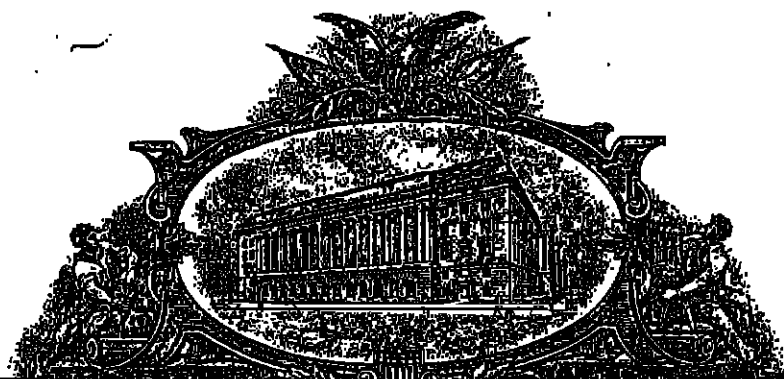


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December 16, 2003

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
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OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.**

APPLICATION NUMBER: 10/278,072

FILING DATE: October 23, 2002

RELATED PCT APPLICATION NUMBER: PCT/US03/32514



**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**

T. Wallace
T. WALLACE
Certifying Officer

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COMPLIANCE WITH
RULE 17.1(a) OR (b)**

Attorney's Docket No. 024637-138

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**UTILITY PATENT
APPLICATION TRANSMITTAL LETTER**

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

21839

SIC

Enclosed for filing is the utility patent application of Harish A. PATEL for

MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT.

- ☐ Applicant(s) hereby request(s) that the above-captioned application **NOT BE PUBLISHED** under 35 U.S.C. § 122(b) and 37 C.F.R. § 1.211. The undersigned hereby certifies that the invention disclosed in this 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.
- ☒ Applicant suggests Figure 1 for inclusion on the front page of the patent application publication and patent.
- Also enclosed are:
- ☒ 2 sheets of drawings;
- ☐ a claim for foreign priority under 35 U.S.C. §§ 119 and/or 365 is ☐ hereby made to __ filed in __ on __;
☐ in the declaration;
- ☐ a certified copy of the priority document;
- ☐ a General Authorization for Petitions for Extensions of Time and Payment of Fees;
- ☒ an Assignment document;
- ☐ an Information Disclosure Statement;
- ☐ a patent application data sheet; and
- ☐ Other: _____.
- ☒ An ☒ executed ☐ unexecuted declaration of the inventor
☒ also is enclosed ☐ will follow.
- ☐ Small entity status is hereby claimed.
- ☐ Please amend the specification by inserting before the first line the sentence:
—This application claims priority under 35 U.S.C. §§ 119 and/or 365 to __
filed in __ on __; the entire content of which is hereby incorporated by
reference.—
- ☐ Please amend the specification by inserting before the first line the sentence:
—This application claims priority under 35 U.S.C. § 119 to U.S. Provisional
Application No. __ entitled __ and filed on __, the entire content of which is hereby
incorporated by reference.—

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Utility Patent Application Transmittal Letter
Attorney's Docket No. 024637-138
Page 2

- ☐ Please amend the specification by inserting before the first line the sentence:
—This application is a continuation of International Application No. ___ filed on ___.
☒ The filing fee has been calculated as follows ☐ and in accordance with the enclosed preliminary amendment:

CLAIMS					
	NO. OF CLAIMS		EXTRA CLAIMS	RATE	FEE
Basic Application Fee					\$740.00 (1001)
Total Claims	36	MINUS 20 =	16	× \$18.00 (1202) =	288.00
Independent Claims	2	MINUS 3 =	0	× \$84.00 (1201) =	
If multiple dependent claims are presented, add \$280.00 (1203)					
Total Application Fee					1,028.00
If small entity status is claimed, subtract 50% of Total Application Fee					
Add Assignment Recording Fee \$40.00 (8021) if Assignment document is enclosed					40.00
TOTAL APPLICATION FEE DUE					\$1,068.00

- ☐ This application is being filed without a filing fee. Issuance of a Notice to File Missing Parts of Application is respectfully requested.
☒ A check in the amount of \$ 1,068.00 is enclosed for the fee due.
☐ Charge \$ _____ to Deposit Account No. 02-4800 for the fee due.
☒ The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Please address all correspondence concerning the present application to:

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Respectfully submitted,

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Date: October 23, 2002

10278072.102302

Attorney Docket No. 024637-138

UNITED STATES PATENT APPLICATION

of

Harish A. Patel

for

MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT

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10278072 . 102302

Attorney Docket No. 024637-138

MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a medical dressing containing an antimicrobial agent, a sponge formed from such a dressing, and methods of fabricating such a medical dressing and sponge.

Brief Description of Art

[0002] Medical dressings have long been used to protect and aid in the healing of wounds. Various forms and constructions of such medical dressings are known in the art. For instance, U.S. Patent No. 4,211,227, incorporated herein by reference, discloses a nonwoven surgical sponge material comprising a layered fabric having an inner core or a substantially hydrophilic material disposed adjacent at least one outer or surface layer, or between a pair of outer layers, of a substantially hydrophobic material. The sponge material is bonded by passing the material through rolls engraved in a pattern of lands and grooves such that a repeating pattern of three degrees of compression are imposed on the material.

[0003] U.S. Patent No. 6,369,289, incorporated herein by reference, further discloses the use of a cellulosic bandage in a method for covering an open wound by contacting the wound with the bandage having a calculated amount of antimicrobial agent. The cellulosic bandage may be prepared by providing at least one rolled beam of cellulosic material onto a perforated drum, inserting the beam of material into an enclosed vessel, adding antimicrobial agent into the vessel, and circulating the antimicrobial agent for a predetermined period of time.

10278072 .102302

Attorney Docket No. 024637-138

[0004] The use of certain kinds of antimicrobial agents is also known in the art. U.S. Patent No. 4,655,756, for example, relates to a non-woven material treated with a linear polymeric biguanide having a defined formula, or a mixture of, e.g., polyhexamethylene biguanide (hereafter "PHMB") dihydrochlorides with defined number average molecular weights. The polymeric biguanide may be present at a concentration of from 500 to 5000 ppm and the non-woven material may be in the form of an article for the collection of human body emissions.

[0005] Other types of antimicrobial agents are also known. For example, U.S. Patent No. 5,707,736 discloses a dry, disposable, polymeric product having sustained-release antimicrobial activity formed from a polymeric material having an amine salt antimicrobial agent incorporated therein. The polymeric material may be in the form of fibers, sheets, films, and other stable woven, nonwoven and knitted materials. The antimicrobial agents include, e.g., chlorhexidine gluconate and chlorhexidine hydrochloride.

[0006] Additional components, such as adhesives, are also known as components of medical dressings. One such surgical dressing is described in U.S. Patent No. 4,643,180, wherein the dressing comprises a sheet of polymeric film coated on one side with a water based adhesive of defined thickness which includes an antimicrobial agent deposited on the body facing surface of the adhesive.

[0007] U.S. Patent No. 4,643,181 also describes a surgical dressing and a process for making a surgical dressing. The dressing comprises a substrate coated on one surface with a solvent-based skin contact adhesive of defined thickness, the adhesive having distributed therein particles of PHMB. The process involves mixing a defined aqueous solution of PHMB hydrochloride with a solvent which is compatible with the adhesive at a mixing speed of no more

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Attorney Docket No. 024637-138

than 300 rpm, adding the mixture to an adhesive, applying the adhesive to a release surface in an amount of from 40 to 55 grams per square meter, drying the adhesive, and applying a substrate for the dressing to the adhesive.

[0008] U.S. Patent No. 4,675,347 relates to an antimicrobial latex composition and a method of manufacturing a shaped article by repeatedly dipping an article into the composition and drying. The composition comprises, e.g., (1) at least one cationic latex component selected from a cationic natural rubber latex and a cationic synthetic polymer latex and (2) a cationic antimicrobial agent incorporated in the cationic latex (1).

[0009] U.S. Patent No. 4,678,704 describes an impregnated fabric material comprising a fabric substrate to which has been bonded an active cationic impregnant along with an anionic indicator dye in combination with a further cationic component, wherein the dye bonds to the further cationic component more readily than to the substrate and the further cationic component competes with the impregnant for bonding to the dye. The cationic impregnant may be a polymeric biguanide, e.g., PHMB.

[0010] U.S. Patent No. 4,837,079 relates to a method for making an antimicrobially active, non-woven web comprising the steps of forming an unbounded fibrous web, applying throughout the unbonded fibrous web an uncured binder and PHMB hydrochloride as an antimicrobial agent, the PHMB hydrochloride being substantive to the fibers of the web and to the binder when the web is either wet or dry to prevent the antimicrobial agent from substantially diffusing from the fibers or binder and being present in an amount effective to act as antimicrobial agent, and curing the binder to bind the fibers together to form an antimicrobially active, non-woven web. An antimicrobially active, non-woven web comprising bonded fibers, a binder distributed throughout

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Attorney Docket No. 024637-138

the fibers in an amount effective to bind the fibers and PHMB hydrochloride which is substantially prevented from diffusing from the fibers or the binder is also disclosed. Further disclosed is a wet wiper that is substantially identical to the claimed web, but which additionally contains a substantially preservative free liquid.

[0011] U.S. Patent No. 5,098,417 relates to a wound dressing for systemic administration of a physiologically- or biologically-active agent by controlled release of the agent into such wound. The wound dressing comprises a substrate in the form of a fabric or cloth, at least a portion of which is cellulosic, which has been chemically modified to convert hydroxyl groups in the cellulosic portion to ionic-adsorbing sites, an ionic form of a physiologically- or biologically-active agent (which includes antibacterial agents) adsorbed in the substrate. The ionic bonds hold the agent temporarily to the substrate for controlled release therefrom in proportion to the amount of exudate in contact with the substrate and are formed by adsorbing the agent on the substrate at room temperature. The ionic bonds are disassociated upon contact with body exudate from wounds thereby to release the physiologically- or biologically-active agent in an amount in proportion to the amount of exudate in contact with the substrate. Chlorhexidine is mentioned as one of the possible agents.

[0012] U.S. Patent No. 5,141,803 relates to a moistened wipe for cleaning and delivering a cationic biocide comprising a flexible absorbent nonwoven substrate impregnated with an aqueous composition comprising defined amounts of potassium sorbate, citric acid, disodium ethylenediaminetetraacetate, a cationic biocide selected from a defined group which includes PHMB hydrochloride and the remainder water. The pH of the composition is from about 3.5 to about 4.5.

10278072 . 102302

Attorney Docket No. 024637-138

[0013] U.S. Patent No. 5,156,843 relates to a composition of matter comprising a material provided with interstices having solid particles residing therein. The material is a member selected from the group consisting of joined fibers, woven fabric, non-woven fabric, paper, woven cloth, non-woven cloth, foamed plastic and sponge. The solid particles are from about one to about 100 microns in diameter and contain a substantially continuous network of pores open to the exterior of the particles, with a functional substance retained in the pores. The functional substance may be a biocidal substance that can prevent or retard bacterial, microbial, germ or fungal growth.

[0014] U.S. Patent No. 5,498,416 relates to a process for protection of prostheses, implants and/or catheters, of temporary or permanent implantable materials against bacterial colonization and infection. An infection-resistant device capable of progressively releasing in aqueous medium an amount of an antibacterial substance fixed to the device, the amount being effective to prevent bacterial contamination of the device is disclosed. The device comprises a first coating from a solution in aqueous or organic solvent of a biguanide of a defined general formula (which defines monomeric compounds) and a second coating from a solution of the antibacterial substance, the second coating overlying the first coating, and the first coating ensuring adhesion of the antibacterial substance to the device. Illustrative devices are described in the paragraph beginning at column 2, line 60 and include urinary catheters, probes, vascular and intraarterial catheters, cardiacal valvular prostheses, arterial prostheses, cardiac simulators, orthopedic prostheses, ocular or dental implants, shunts that are connecting two segments of the circulatory system, and suture thread.

10278072 . 102302

Attorney Docket No. 024637-138

[0015] U.S. Patent No. 5,700,742 relates to a method of treating a textile material to inhibit microbial growth which comprises applying to the textile material an oligo- or polymeric biguanide or salt thereof with an inorganic acid or an organic acid having a pK value above 4.5 followed by a strong organic acid having a pK value below 4.5 and free from any aliphatic or oxyalkylene chain containing 12 or more carbon atoms. A textile material treated in accordance with the claimed method is also disclosed.

[0016] U.S. Patent No. 5,856,248 relates to cellulose fibers and products comprising cellulose fibers treated to absorb body secretions while substantially decreasing microbial growth, the fibers being chemically modified in a two-stage process comprising a first stage treatment with a water soluble salt of a transition metal and an alkali and a second stage treatment with a solution of a bisbiguanide compound, thereby forming a bond between the cellulose fibers, the transition metal and the bisbiguanide compound. The process may utilize a rinsing step to neutral pH between the two aforementioned stages.

[0017] U.S. Patent No. 5,869,073 relates to a liquid composition for applying a non-leachable antimicrobial layer or coating on a surface, comprising a solution, dispersion or suspension of a biguanide polymer, a cross-linker reacted with the biguanide polymer to form an adduct, and an antimicrobial metal, metal salt (e.g. a silver salt) or metal complex, wherein the metal, metal salt or metal complex forms a complex with the adduct, and wherein the antimicrobial layer or coating does not release biocidal levels of leachables into a contacting solution.

[0018] U.S. Patent No. 5,817,325 relates to an article of manufacture having disposed on a surface thereof a contact-killing, non-leaching antimicrobial coating which kills microorganisms upon contact. The coating comprises an organic polycationic polymer matrix immobilized on

10278072.102302

Attorney Docket No. 024637-138

the surface having bound or complexed thereto a surface-accessible antimicrobial metallic material such that the antimicrobial material does not release biocidal amounts of elutables into the surrounding environment. The organic matrix may comprise a biguanide polymer, such as PHMB or a polymer containing a biguanide moiety.

[0019] U.S. Patent No. 5,849,311 further relates to a contact-killing, non-leaching antimicrobial material, capable of killing microorganisms which come into contact with the material. The material comprises an organic polycationic polymer matrix having non-leachably bound or complexed thereto an antimicrobial metallic material, such that the antimicrobial material does not release biocidal amounts of elutables into the surrounding environment. The polycationic material may be PHMB or a polymer containing a biguanide moiety.

[0020] U.S. Patent No. 5,886,048 relates to a method of treating tumor disease in a human or animal with a therapeutically effective amount of PHMB or salt thereof.

[0021] U.S. Patent No. 5,985,931 relates to an antimicrobial composition comprising defined amounts of PHMB, a quaternary ammonium compound; and parachlorometaxylenol wherein the combination of the three components is said to exhibit effective antimicrobial activity.

[0022] U.S. Patent No. 5,990,174 relates to a method for improving haze formation and storage stability of an antimicrobial composition consisting of water and from 5 to 25% by weight of defined linear polymeric biguanide oligomers. The method comprises adjusting the pH of the aqueous antimicrobial composition to at least 0.1 and less than 5 as determined using an indicator thereby improving the resistance to haze formation and storage stability of the

10278072 . 102302

Attorney Docket No. 024637-138

aqueous antimicrobial composition when compared with a corresponding composition at higher pH. Particular concentration and pH limitations are also disclosed.

[0023] U.S. Patent No. 5,993,840 relates to a composition comprising a non-woven material containing a mixture of polymeric biguanides subject to desorption when the non-woven material is wetted by urine; and an anionic polymer which is substantially insoluble in urine. The anionic polymer functions to retain the biguanides on the material when contacted by urine. A process for forming an absorbent layer and a method of reducing the loss of antimicrobial biguanide, wherein both include the anionic polymer, are disclosed.

[0024] European Patent Application No. 136900 discloses the application of PHMB to a surgical drape comprising a non-woven fabric and mentions on page 7 that a non-ionic wetting agent in the application formulation is desirable to provide absorbent characteristics to the fabric.

[0025] U.S. Patent No. 6,017,561 relates to an antibacterial cleaning composition comprising a quaternary ammonium compound, an anionic polymer having an acid number greater than 10 wherein the anionic polymer is partially or completely neutralized by quaternary ammonium compound to form a polymer complex and wherein the polymer complex is greater than about 15% by weight of the solids in the composition, a dispersing agent, which comprises a surfactant that is selected from the group consisting of nonionic surfactant, amphoteric surfactant, and mixtures thereof, and optionally, a solvent. Also disclosed is a sponge device having antibacterial activity that comprises a sponge; and a polymer complex comprising a quaternary ammonium compound and an anionic polymer having an acid number of greater than 10 wherein the anionic polymer is partially or completely neutralized by the quaternary ammonium compound to form the polymer complex which is attached to a surface of the sponge. An

10278072 . 102302

Attorney Docket No. 024637-138

adsorbent or absorbent matrix which includes the polymer complex and a method of fabricating an absorbent or adsorbent material which uses at least a quaternary ammonium compound and an anionic polymer are also disclosed. The ammonium compound may be PHMB hydrochloride. Articles such as sponges are also described.

[0026] U.S. Patent No. 6,160,196 relates to a wound covering comprising a hydrophobic, bacteria-absorbing synthetic or naturally-occurring polymer fiber material, having adhered thereto an antimicrobial active compound which is adapted to not be released into the wound. As described in the specification and included in certain dependent claims, the material can be nonwoven and dependent claim 10 recites that the polymer fiber material can be selected from a group which includes polyester. The antimicrobial active compounds are described in the passage that begins at column 2, line 29 and include chlorhexidine. In this passage, it is stated the compounds "... are distinguished by the fact that they adhere firmly to the wound covering and are not released, or at least are not released noticeably, into the wound."

[0027] U.S. Patent No. 6,180,584 relates to a disinfectant composition comprising a film-forming antimicrobial material (which may be a polymeric biguanide material), an antimicrobial metallic material, and a carrier. The composition, when applied to a surface, forms a non-permanent, adherent, water-insoluble film, wherein the metallic material is non-leachably bound to or associated with the film. The film does not elute antimicrobial materials into contacting water at levels capable of imparting disinfecting action to said water, and is removable by treatment with an alcohol solution. The composition can further include a surfactant.

[0028] U.S. Patent No. 6,235,302 relates to a sponge cloth which is based on regenerated cellulose and has been provided with an internal reinforcement consisting of, e.g., viscose fibers

10278072 . 102302

Attorney Docket No. 024637-138

or cotton fibers having a staple fiber length of 5 to 50 mm. The sponge cloth is obtained by a process comprising the steps of coagulating and regenerating the cellulose in a bath which has a pH of 13 or higher and which comprises Glauber's salt, NaOH and water, and impregnating the sponge cloth with a biocidally active agent. Representative agents are described and include isothiazolone, benzoisothiazolone and benzimidazole derivatives with biguanides.

OBJECTS AND SUMMARY OF THE INVENTION

[0029] It is an object of the present invention to provide a medical dressing comprising an antimicrobial agent as well as a process of making such a medical dressing. It is a further object to provide a sponge formed from the medical dressing as well as a process of making such a sponge.

[0030] The medical dressing and sponge formed therefrom are preferably characterized by improved antimicrobial behavior. More particularly, in a preferred embodiment, the medical dressing and sponge formed therefrom provide an effective antimicrobial barrier for a wound while also controlling the release of antimicrobial agent contained within an inner portion of the dressing. The antimicrobial agent is preferably concentrated within an inner portion absorbent core of the dressing while an outer barrier layer portion reduces the release of the antimicrobial agent from the dressing.

[0031] It is a further object of the invention to provide a medical dressing and a sponge formed therefrom wherein the outer hydrophobic layer(s) provide(s) non-adherent surfaces to aid in the healing of wounds and which reduces or eliminates pain experienced by a patient during changes in the dressing or sponge.

10278072, 102302

Attorney Docket No. 024637-138

[0032] In accordance with one aspect of the present invention, a medical dressing is provided, comprising:

layered fabric comprising:

an inner layer of substantially hydrophilic material;

an outer layer of substantially hydrophobic material on both sides of the inner layer; and

an antimicrobial agent, wherein the antimicrobial agent is contained in the inner layer.

[0033] In accordance with another aspect of the invention, the medical dressing of the invention may be in the form of a sponge comprising plies of the medical dressing material.

BRIEF DESCRIPTION OF THE FIGURES

[0034] FIG 1 illustrates a cross-sectional view of one form of the medical dressing containing two outer layers and an inner layer.

[0035] FIG. 2 illustrates a surface view of one form of the medical dressing containing a cross-shaped incision passing through all plies of the dressing.

DETAILED DESCRIPTION OF THE

PREFERRED EMBODIMENTS OF THE INVENTION

[0036] In one embodiment, the inventive medical dressing is based in part upon the dressing disclosed in U.S. Patent No. 4,211,227, the disclosure of which is incorporated herein by reference in its entirety.

10278072 . 102302

Attorney Docket No. 024637-138

[0037] In a preferred embodiment, the inventive medical dressing is an antimicrobial drain sponge which is a thermally bonded nonwoven absorbent material, typically in the form of a square that is 2" x 2" or 4" x 4" and having a 6 ply thickness. The material is preferably about 50% polyester and about 50% rayon with each ply formed as a sandwich of a layer of rayon between two layers of polyester. In one embodiment of the invention, as illustrated in FIG. 1, the outer layers (A and C) may be formed from a hydrophobic material, preferably hydrophobic fibers, such as polyester fibers. The inner layer (shown as layer B in FIG. 1) comprises a hydrophilic material, preferably hydrophilic fibers, such as cellulosic fibers. More preferably, the cellulosic fibers are rayon.

[0038] In order to impart antimicrobial properties, the material that is to be cut into the individual sponges is impregnated with an aqueous solution of an antimicrobial agent, such as polyhexamethylene biguanide (PHMB). An antimicrobial agent such as PHMB is suitably present in a concentration of about 0.1 to 0.5 % by weight, preferably about 0.15 to 0.35 % by weight, and most preferably about 0.2 to 0.3 % by weight. A surfactant may also be present in the aqueous solution. For example, commercially available non-ionic surfactants, such as TWEEN® 20, which is polyoxyethylene (20) sorbitan monolaurate, may be utilized. PHMB used to prepare the drain sponge may be provided by, e.g., Aveda Inc. under the designation COSMOCIL® CQ (an aqueous solution of PHMB containing 19-21% w/w active ingredient and a pH of 5.0-5.5). The material may be impregnated with the antimicrobial agent according to any suitable technique, such as, e.g., by dip coating the material in a solution comprising the antimicrobial agent.

10278072, 102302

Attorney Docket No. 024637-138

[0039] The impregnated material may then be pressed at a pressure designed so that the appropriate level of antimicrobial agent, preferably PHMB, remains in the material. After drying by passing between heated rollers, the material has a residual antimicrobial agent (e.g. PHMB) content of from 1500 to 3500 ppm. The material is subsequently converted into 4" X 4" and 2" X 2", 6 ply drain sponges. The sponges do not include an adhesive, but have a cross-shaped incision in the center (as illustrated in FIG. 2) that penetrates all 6 plies so that a drain tube can be passed therethrough. The antimicrobial agent (e.g. PHMB) can preferably be released from the medical dressing or sponge in a moist environment to provide antimicrobial activity beyond the edges of the sponge for a limited time. In general, the fabric is treated to have about 1500-3500 ppm of extractable antimicrobial agent, preferably polyhexamethylene biguanide.

[0040] The antimicrobial agent is preferably releasably impregnated into the inner layer substantially hydrophilic material of the fabric, coated on said inner layer or a combination thereof. The antimicrobial agent is also preferably controllably releaseable from the fabric in an amount effective as an antimicrobial, more preferably in amount effective as an antimicrobial for a period of up to about 2 days, most preferably up to about 1 day. The antimicrobial amount is defined as the amount of antimicrobial agent applied to the dressing that is needed for providing sufficient antimicrobial characteristics, yet without causing irritation of the skin or open wound.

[0041] Although the antimicrobial agent may be released from the inner layer material of the fabric, the antimicrobial treatment of the fabric principally allows the dressing to function as a barrier to contamination of the wound from sources outside the wound. In addition, due to the absorbent characteristics of the dressing, microbes absorbed within the inner layer are prevented from escaping through the dressing.

10278072.102302

Attorney Docket No. 024637-138

[0042] In general, the antimicrobial agent may be any such agent which suitably functions to provide an antimicrobial property to the inventive medical dressing. Such antimicrobial agents are described in some of the above-identified patents, which are herein incorporated by reference for such information. Preferred antimicrobial agents include biguanides, especially polyhexamethylene biguanide ("PHMB").

[0043] The fabric inner layer material is substantially hydrophilic, and is preferably substantially a cellulose fiber, and, more preferably, is substantially rayon. Other inner layer materials may also be utilized, including polysaccharides, alginates, cotton or carboxy methyl cellulose fiber materials. In general, the inner layer material is "substantially hydrophilic" such that wound exudate may be absorbed by the inner layer absorbent core and that the antimicrobial agent may be contained mostly within the absorbent core. In this way, the term "substantially hydrophilic" describes the function of the inner layer material. It also distinguishes the inner layer material over the function of the "substantially hydrophobic" outer layer material, which provides an antimicrobial barrier property and attenuates or reduces the release of antimicrobial agent away from the dressing. The improved retention of antimicrobial agent within the inner layer also lowers the bioburden, i.e., the growth and number of cells, within the dressing during use.

[0044] Hydrophobicity and hydrophilicity are commonly reported as the percentage moisture regain for fibers of the material. For the purposes of the present invention, the terms "substantially hydrophilic" and "substantially hydrophobic", as they apply to the inner and outer layers respectively, may be related to the percentage moisture regain for fibers of the respective materials, typically at 70°F and 65% relative humidity. The fibers used in the substantially

10278072.102302

Attorney Docket No. 024637-138

hydrophobic outer layer should have a moisture regain of less than about 10%, preferably less than about 5%, and most preferably less than about 2% based on the weight of the dry fiber. The fibers used in the substantially hydrophilic inner layer should have a moisture regain of about 5-25, preferably about 10-20, and most preferably about 15-20 times the weight of the dry fiber.

[0045] The fabric outer layer material is preferably substantially polyester, and, more preferably, is a combination of textile matrix grade polyester fiber and amorphous binder grade polyester fiber. The binder fibers function to bind, e.g., rayon and textile grade polyester fibers together. Suitable inner layer materials include, e.g., Lenzing 8191 rayon. Suitable outer layer materials include, e.g., Wellman Polyester T-203 textile grade polyester and Kosa Polyester 259 amorphous binder grade polyester. The textile to binder fiber weight ratio is preferably about 2:1. Other materials may also be utilized for the outer layer, including, e.g., polyolefins such as polyethylene or polypropylene, nylons, or other thermoplastic fibers.

[0046] The hydrophobic layers of the fabric forming the medical dressing may also be imparted with a hydrophilic finish. Such a finish may be applied as a coating of a hydrophilic finishing agent on the outer layers. It may also be applied during the impregnation of the inner layer with the antimicrobial agent by including the hydrophilic finishing agent in the same solution of antimicrobial agent. By contacting the dressing material with the antimicrobial solution containing a hydrophilic finishing agent, the inner layer is impregnated with the antimicrobial solution while the outer layers are imparted with a hydrophilic finish. As used herein, the term "hydrophilic finish" is intended to mean that the hydrophilic characteristics of the outer layer are increased at least to some degree by the use of a hydrophilic finishing agent. In a preferred embodiment, the hydrophilic finish helps to improve the function of the dressing

10278072 . 102302

Attorney Docket No. 024637-138

material or sponge by allowing wound exudate to be more easily absorbed by the inner layer absorbent core material. Suitable hydrophilic finishing agents include, e.g., surfactants, such as non-ionic surfactants, which may be typically applied in concentrations of about 0.1 % by weight. As noted above, one such non-ionic surfactant is TWEEN® 20, which is polyoxyethylene (20) sorbitan monolaurate, although other such surfactants may also be utilized.

[0047] A medical sponge formed from plies of the medical dressing material may contain several plies of the dressing material, preferably 2-10 plies, more preferably 4-8 plies, and most preferably 6 plies. A cross-shaped incision may be preferably formed in the center of the sponge that penetrates all plies, thereby allowing an object to pass through the sponge.

[0048] In a preferred aspect, the fabric comprises about 50% by weight rayon, about 33% by weight textile matrix grade polyester, and about 17% by weight binder grade polyester, based on the weight of the fabric.

[0049] The fabric of the medical dressing and sponge of the invention may be processed to impart softness and improved absorbency, according to techniques known in the art, followed by further processing to form the inventive medical dressing and sponges. Suitable techniques include the use of microcreping devices such as are commercially available from Microx, Corp. for the treatment of nonwoven and other materials. It is preferred that such treatments provide an absorbency of from about 6-15, preferably 10-15, times the dry weight of the fabric. As used in the context of the invention, the term "absorbency" refers to the amount of liquid material, such as water or wound exudate, that may be absorbed by the fabric of the medical dressing or sponge.

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Attorney Docket No. 024637-138

[0050] As compared with other commercial medical dressings and sponges, the present invention provides several advantages and benefits. For example, by containing the antimicrobial agent within the inner layer of the medical dressing and the sponge formed therefrom, the release of the antimicrobial agent is controlled such that sensitive wound or skin areas are not adversely irritated. The presence of the antimicrobial agent within the inner layer also allows for the dressing and sponge to function effectively as a barrier against contamination of the wound. Contamination of areas outside the wound and dressing or sponge due to the retention of the wound exudate within the dressing or sponge is also reduced or prevented. In addition, the use of the outer hydrophobic (nonwoven) layers provides the dressing and sponge with the characteristic of non-adherency to wounds. Further, due in part to the presence of the outer hydrophobic layer(s), the amount of antimicrobial agent within the inner layer necessary to maintain the antimicrobial effectiveness of the dressing or sponge is also reduced compared with other commercial products. As such, the present invention provides a benefit of reduced cost associated with the use of lesser amounts of antimicrobial agent.

[0051] The medical dressing of the present invention may also comprise layered fabric consisting essentially of an inner layer of substantially hydrophilic material; an outer layer of substantially hydrophobic material on both sides of the inner layer; and an antimicrobial agent, wherein the antimicrobial agent is contained in the inner layer. As used in the context of the invention, the phrase "consisting essentially of" is intended to mean that the certain additional components which would materially affect the basic and novel characteristics of the inventive medical dressing are not included in the layered fabric. As concerns the medical dressing and sponge of the invention, "consisting essentially of" is intended to mean, e.g., that adhesives are

10278072 102802

Attorney Docket No. 624637-138

not utilized to prepare the layered fabric or that additional agents are not utilized to bind the antimicrobial agent within the inner layer material of the medical dressing.

EXAMPLES

[0052] The antimicrobial efficacy of the medical dressing and sponge according to the invention has been investigated. Such tests simulate the use of the dressing or sponge in practice and are based upon the visual observation of microbial activity on growth media placed in contact with the inventive medical dressing or sponge containing a determined amount of microbes. The tests are generally conducted by placing a sample of the antimicrobial agent containing dressing or sponge in contact with growth medium, adding a small volume of microbe containing aqueous solution to the medical dressing or sponge, and incubating the test samples for definite time periods and under controlled temperature and environmental conditions. Following the end of the pre-determined time period, the growth medium is visually observed to determine the extent, if any, of microbial activity or growth on the medium. For the purposes of the present invention, an assessment of the antimicrobial effectiveness of the inventive dressing and sponge against various microbes, including *S. aureus*, *S. epidermidis*, *E. coli*, and *P. aeruginosa*, has been conducted according to this procedure. In all such tests, the medical dressing and sponge according to the invention has been determined to be effective to prevent microbial activity on such growth medium. By comparison, control samples not containing an antimicrobial agent, such as PHMB, were determined using the same procedures and conditions to not prevent microbial activity on such growth medium.

[0053] While the invention has been described in detail by reference to specific embodiments, the skilled artisan will appreciate that various modifications, substitutions,

10278072 . 102302

Attorney Docket No. 024637-138

omissions and changes may be made, and equivalents employed, without departing from the spirit of the invention or the scope of the appended claims.

10278072 .102302

Attorney Docket No. 024637-138

What is claimed is:

1. A medical dressing comprising:
layered fabric comprising:
an inner layer of substantially hydrophilic material;
an outer layer of substantially hydrophobic material on both sides of the inner
layer; and
an antimicrobial agent,
wherein the antimicrobial agent is contained in the inner layer.
2. A medical dressing according to claim 1 wherein the antimicrobial agent is
releasably impregnated into the inner layer substantially hydrophilic material of the fabric, coated
on said inner layer, or a combination thereof.
3. A medical dressing according to claim 2 wherein the antimicrobial agent is
releasable from the fabric in an amount effective as an antimicrobial.
4. A medical dressing according to claim 2 wherein the antimicrobial agent is
releasable from the fabric in an amount effective as an antimicrobial for a period of up to about
2 days.

10278072 .102302

Attorney Docket No. 024637-138

5. A medical dressing according to claim 2 wherein the antimicrobial agent is releaseable from the fabric in an amount effective as an antimicrobial for a period of up to about 1 day.
6. A medical dressing according to claim 3 wherein the antimicrobial agent is a biguanide.
7. A medical dressing according to claim 3 wherein the antimicrobial agent is polyhexamethylene biguanide.
8. A medical dressing according to claim 3 wherein the fabric inner layer material is substantially a cellulose fiber.
9. A medical dressing according to claim 3 wherein the fabric inner layer material is substantially rayon.
10. A medical dressing according to claim 3 wherein the fabric outer layer material is substantially polyester.
11. A medical dressing according to claim 3 wherein the fabric outer layer material is a combination of textile matrix grade polyester fiber and amorphous binder grade polyester fiber.

10278072, 102302

Attorney Docket No. 024637-138

12. A medical dressing according to claim 11 wherein the textile to binder fiber weight ratio is about 2:1.

13. A medical dressing comprising:

layered fabric comprising:

an inner layer substantially of rayon

an outer layer substantially of textile and binder fibers in a 2:1 weight ratio; and

polyhexamethylene biguanide,

wherein the polyhexamethylene biguanide is contained in the inner layer.

14. A medical dressing according to claim 13 wherein the fabric is treated with an aqueous solution of surfactant and polyhexamethylene biguanide to have about 1500-3500 ppm of extractable polyhexamethylene biguanide.

15. A medical dressing according to claim 13 wherein the fabric is formed from:

about 50% by weight rayon,

about 33% by weight textile fibers, and

about 17% by weight binder fibers, based on the weight of the fabric.

16. A medical dressing according to claim 15 wherein the fabric is treated with an aqueous solution of surfactant and polyhexamethylene biguanide to have about 1500-3500 ppm of extractable polyhexamethylene biguanide.

10278072 .102302

Attorney Docket No. 024637-138

17. A sponge formed from plies of the medical dressing material of claim 1.
18. A sponge formed from plies of the medical dressing material of claim 13.
19. A sponge formed from plies of the medical dressing material of claim 15.
20. A sponge formed from plies of the medical dressing material of claim 16.
21. A sponge according to claim 17 having 6 plies.
22. A sponge according to claim 18 having 6 plies.
23. A sponge according to claim 19 having 6 plies.
24. A sponge according to claim 20 having 6 plies.
25. A sponge according to claim 17 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.
26. A sponge according to claim 18 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.

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Attorney Docket No. 024637-138

27. A sponge according to claim 19 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.

28. A sponge according to claim 20 with a cross-shaped incision in the center of the sponge that penetrates all plies to allow an object to pass through the sponge.

29. A medical dressing according to claim 1 wherein the hydrophobic layers have a hydrophilic finish.

30. A medical dressing according to claim 13 wherein the hydrophobic layers have a hydrophilic finish.

31. A sponge according to claim 17 wherein the hydrophobic layers have a hydrophilic finish.

32. A sponge according to claim 18 wherein the hydrophobic layers have a hydrophilic finish.

33. A medical dressing according to claim 1, wherein the fabric forming the medical dressing has an absorbency of from 6-15 times the dry weight of the fabric material.

34. A medical dressing according to claim 13, wherein the fabric forming the medical dressing has an absorbency of from 6-15 times the dry weight of the fabric material.

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Attorney Docket No. 024637-138

35. A sponge according to claim 17, wherein the fabric forming the medical dressing material of the sponge has an absorbency of from 6-15 times the dry weight of the fabric material.

36. A sponge according to claim 18, wherein the fabric forming the medical dressing material of the sponge has an absorbency of from 6-15 times the dry weight of the fabric material.

10278072, 1027802

Attorney Docket No. 024637-138

ABSTRACT OF THE DISCLOSURE

[0054] A medical dressing containing an antimicrobial agent is disclosed. The medical dressing comprises a layered fabric comprising an inner layer of substantially hydrophilic material, an outer layer of substantially hydrophobic material on both sides of the inner layer, and an antimicrobial agent. The antimicrobial agent may be releasably impregnated into the fabric, coated on said fabric or a combination thereof. The antimicrobial agent may be a biguanide, such as polyhexamethylene biguanide (PHMB). The fabric inner layer material may be substantially a cellulose fiber, preferably substantially rayon, and the fabric outer layer material may be substantially polyester, e.g., a combination of textile matrix grade polyester fiber and amorphous binder grade polyester fiber. The fabric is preferably treated with an aqueous solution of surfactant and PHMB to have about 1500-3500 ppm of extractable PHMB.

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**COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION**

Attorney's Docket No.
024637-138

As a below-named inventor, I hereby declare that:

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 more than one name is listed below) OF THE SUBJECT MATTER WHICH IS CLAIMED AND FOR WHICH A PATENT IS SOUGHT ON THE INVENTION ENTITLED:

MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT

the specification of which

(check one) ☒ is attached hereto;
☐ was filed on _____ as
Application No. _____
and was amended on _____;
(if applicable)

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 TO THE OFFICE ALL INFORMATION KNOWN TO ME TO BE MATERIAL TO PATENTABILITY AS DEFINED IN TITLE 37, CODE OF FEDERAL REGULATIONS, Sec. 1.56 (as amended effective March 16, 1992);

I do not know and do not believe the said invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application; that said invention was not in public use or on sale in the United States of America more than one year prior to said application; that said invention has not been patented or made the subject of an inventor's certificate issued before the date of said application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than twelve months prior to said application;

I hereby claim foreign priority benefits under Title 35, United States Code Sec. 119 and/or Sec. 365 of any foreign application(s) for patent or inventor's certificate as indicated below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application(s) on which priority is claimed:

10278072 .102302

COMBINED DECLARATION AND POWER OF ATTORNEY	Attorney's Docket No. 024637-138
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COUNTRY/INTERNATIONAL	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED
			YES_ NO_
			YES_ NO_

I hereby appoint the following attorneys and agent(s) to prosecute said application and to transact all business in the Patent and Trademark Office connected therewith and to file, prosecute and to transact all business in connection with international applications directed to said invention:

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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.

FULL NAME OF SOLE OR FIRST INVENTOR Harish A. PATEL		SIGNATURE <i>Harish A. Patel</i>	DATE 10/17/02
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FULL NAME OF SECOND JOINT INVENTOR, IF ANY		SIGNATURE	DATE
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POST OFFICE ADDRESS			

APPL. FILING DATE: OCTOBER 23, 2002
TITLE: MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT
INVENTOR: HARISH A. PATEL
APPLICATION SERIAL NO: 10278072, 1027802
SHEET 1 of 2

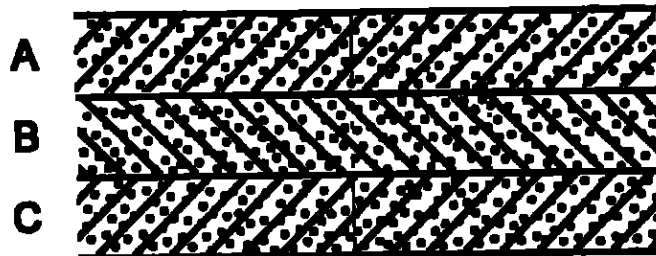


FIG. 1

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APPLN. FILING DATE: OCTOBER 23, 2002
TITLE: MEDICAL DRESSING CONTAINING ANTIMICROBIAL AGENT
INVENTOR: HARISH A. PATEL
APPLICATION SERIAL NO: 10/278072 10/278072
SHEET 2 of 2

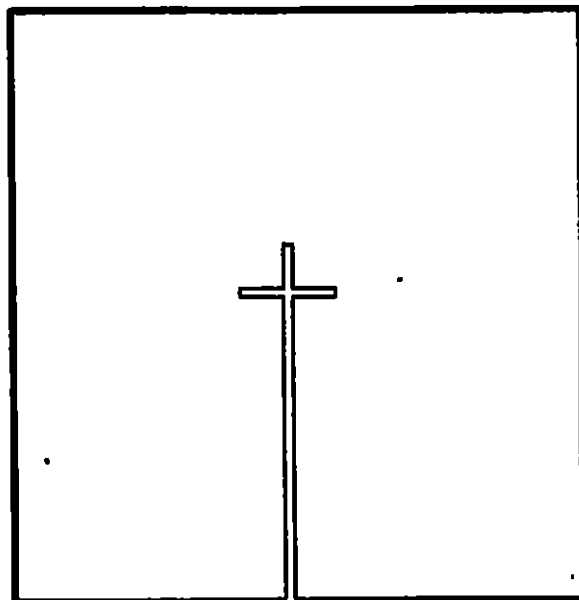


FIG. 2



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Date
11.03.05

Reference	Application No./Patent No. 03777601.0 - 2124 PCT/US0332514
Applicant/Proprietor Tyco Healthcare Group LP	

Entry into the European phase before the European Patent Office

These notes describe the procedural steps required for entry into the European phase before the European Patent Office (EPO). You are advised to read them carefully: failure to take the necessary action in time can lead to your application being deemed withdrawn.

1. The above-mentioned international patent application has been given European application No. 03777601.0.
2. Applicants without a residence or their principal place of business in an EPC contracting state may themselves initiate European processing of their international applications, provided they do so before expiry of the 31st month from the priority date (see also point 8 below).

During the European phase before the EPO as designated or elected Office, however, such applicants must be represented by a professional representative (Arts. 133(2) and 134(1), (7) EPC).

Procedural acts performed after expiry of the 31st month by a professional representative who acted during the international phase but is not authorised to act before the EPO have no legal effect and therefore lead to loss of rights.

Please note that a professional representative authorised to act before the EPO and who acted for the applicant during the international phase does not automatically become the representative for the European phase. Applicants are therefore strongly advised to appoint in good time any representative they wish to initiate the European phase for them; otherwise, the EPO has to send all communications direct to the applicant.

3. Applicants with a residence or their principal place of business in an EPC contracting state are not obliged to appoint, for the European phase before the EPO as designated or elected Office, a professional representative authorised to act before the EPO. However, in view of the complexity of the procedure it is recommended that they do so.
4. Applicants and professional representatives are also strongly advised to initiate the European phase using EPO Form 1200 (available free of charge from the EPO). This however is not compulsory.



Date

Sheet 2

Application No. 03777601.0

- 5. To enter the European phase before the EPO, the following acts must be performed.**
(N.B.: Failure validly to do so will entail loss of rights or other adverse legal consequences.)

5.1 If the EPO is acting as designated or elected Office (Arts. 22(1)(3) and 39(1) PCT respectively), applicants must, within 31 months from the date of filing or (where applicable) the earliest priority date:

- a) Supply a translation of the international application into an EPO official language, if the International Bureau did not publish the application in such a language (Art. 22(1) PCT and Rule 107(1)(a) EPC).
If the translation is not filed in time, the international application is deemed withdrawn before the EPO (Rule 108(1) EPC).
This loss of rights is deemed not to have occurred if the translation is then filed within a two-month grace period as from notification of an EPO communication, provided a surcharge is paid at the same time (Rule 108(3) EPC).
- b) Pay the national basic fee (EUR 160,00) and, where a supplementary European search report has to be drawn up, the search fee (EUR 690,00 ; Rule 107(1)(c) and (e) EPC).
- c) If the time limit under Article 79(2) EPC expires before the 31-month time limit, pay the designation fee (EUR 75,00) for each contracting state designated (Rule 107(1)(d) EPC).
- d) If the time limit under Article 94(2) EPC expires before the 31-month time limit, file the written request for examination and pay the examination fee (EUR 1430,00 ; Rule 107(1)(f) EPC).
- e) Pay the third-year renewal fee (EUR 380,00) if it falls due before expiry of the 31-month time limit (Rule 107(1)(g) EPC).

If the fees under (b) to (d) above are not paid in time, or the written request for examination is not filed in time, the international application is deemed withdrawn before the EPO, or the contracting-state designation(s) in question is (are) deemed withdrawn (Rule 108(1) and (2) EPC). However, the fees may still be validly paid within a two-month grace period as from notification of an EPO communication, provided the necessary surcharges are paid at the same time (Rule 108(3) EPC). For the renewal fee under (e) above, the grace period is six months from the fee's due date (Article 86(2) EPC).

5.2 If the application documents on which the European grant procedure is to be based comprise more than ten claims, a claims fee is payable within the 31-month time limit under Rule 107(1) EPC for the eleventh and each subsequent claim (Rule 110(1) EPC). The fee can however still be paid within a one-month grace period as from notification of an EPO communication pointing out the failure to pay (Rule 110(2) EPC).

- 6. If the applicant had a representative during the application's international phase, the present notes will be sent to the representative, asking him to inform the applicant accordingly.**

All subsequent communications will be sent to the applicant, or - if the EPO is informed of his appointment in time - to the applicant's European representative.

112



Date

Sheet 3

Application No. 03777601.0

7. For more details about time limits and procedural acts before the EPO as designated and elected Office, see the EPO brochure

How to get a European patent
Guide for applicants - Part 2
PCT procedure before the EPO - "Euro-PCT"

This brochure, the list of professional representatives before the EPO, Form 1200 and details of the latest fees are now all available on the Internet under

<http://www.european-patent-office.org>

RECEIVING SECTION





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ETATS-UNIS D'AMERIQUE



Date/Date

19/01/05

Zusammenfassung/Summary

Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n°

03777601.0-2310-PCT/US0332514

Anmelder/Applicant/Demandeur/Patentinhaber/Propriétaire/Titulaire

Tyco Healthcare Group LP

The international search report, or the declaration under Article 17(2)(a) PCT, has been published under Article 21(3) and Rule 48 PCT on 13.01.05. That publication takes the place of the mention of publication of the European search report (Article 157(1) EPC).

The request for examination must be filed within SIX months from the above date (Article 94(2) in conjunction with Article 157(1) EPC). It is not deemed to have been filed until the examination fee has been paid. However, under Article 22 or 39 PCT in conjunction with Article 150(2) and Rule 107(1) EPC, the time limit for filing it does not expire before the end of the 31st month from the filing date (or earliest priority date).

Payment of the designation fees must also be made within the above-mentioned period (Rule 107(1) EPC).

The same applies also for the extension fees.

If the request for examination is not filed in due time, and at least one designation fee is not paid, the European patent application is deemed to be withdrawn (Article 94(3), 79(3) and Rule 108(1) EPC).

For more details see the Guide for applicants Part 2: PCT proceedings before the EPO-"Euro-PCT".

RECEIVING SECTION



Copy for the designated Office (DO/EP)

PCT/US2003/032514

PATENT COOPERATION TREATY

31

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

DENNINGER, Douglas, E.
Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA02048
United States of America

Date of mailing (day/month/year)
15 July 2004 (15.07.2004)

Applicant's or agent's file reference
024637-163

International application No.
PCT/US2003/032514

IMPORTANT NOTIFICATION

International filing date (day/month/year)
14 October 2003 (14.10.2003)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address

MUKAI, Robert, G.
Burns, Doane, Swecker & Mathis,
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State of Nationality

State of Residence

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Facsimile No.
703.836.2021

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address

DENNINGER, Douglas, E. EPO - DG 1
Tyco Healthcare Group LP
15 Hampshire Street
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United States of America 30.07.2004

State of Nationality

State of Residence

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(508) 281-8451

Facsimile No.
(508) 281-6225

Teleprinter No.

(107)

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☒ the designated Offices concerned
☒ the International Searching Authority ☐ the elected Offices concerned
☐ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Céline Faust (Fax 338-8995)

Facsimile No. (41-22) 338.89.95

Telephone No. (41-22) 338 8728

REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

		USUARIO	RADICADOR
PATENTE DE INVENCION (X)	MODELO DE UTILIDAD	()	(/)
- Indicación de que se solicita la concesión de una patente.		(X)	(/)
- Datos de identificación del solicitante o de la persona que se presenta la solicitud.		(X)	(/)
- Descripción de la invención.		(X)	(/)
- Dibujos de ser estos pertinentes. X		(X)	(/)
- Comprobante de Pago de las tasas establecidas. (X)		(X)	(/)
COMPLETA (X)	INCOMPLETA ()		
DISEÑO INDUSTRIAL ()			
- Indicación de que se solicita el registro de Diseño Industrial		()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.		()	()
- Representación gráfica y fotográfica del Diseño Industrial o muestra del Material que incorpora el diseño.		()	()
- Comprobante de pago de las tasas establecidas		()	()
COMPLETA ()	INCOMPLETA ()		
ESQUEMA DE TRAZADO ()			
- Indicación de que solicita el registro de un Esquema de trazado.		()	()
- Datos de identificación del solicitante o de la persona que presenta la solicitud.		()	()
- Representación gráfica del esquema de trazado		()	()
- Comprobante de pago de las tasas establecidas.		()	()
COMPLETA ()	INCOMPLETA ()		

Firma Responsable:

Claudia M. Nava

Fecha: *Bogotá, abril 8 de 2005*

Folio 116

2020
Bogotá, D.C.,

Doctor(a)
ALVARO CORREA ORDOÑEZ

Oficio N°

13'39

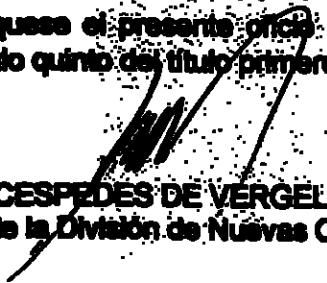
ASUNTO:	Radicación N°	05-32253
	Solicitud Internacional	PCT/US2003/032514
	Fecha límite inicio fase nacional	23/05/2005
	Trámite	011
	Evento	379
	Actuación	430
	Folios	001

Como resultado del examen de forma, realizado con fundamento en el artículo 38 de la Decisión 486 de la Comisión de la Comunidad Andina, artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la Superintendencia de Industria y Comercio, se le comunica que:

- Si fuere el caso, el solicitante debe adjuntar la traducción de los anexos del reporte de examen preliminar internacional (Art. 38.2.b) del tratado PCT.
- La solicitud no contiene la copia del documento en que consta la cesión del derecho a la patente del inventor al solicitante o a su causante. (Art. 28-k) Decisión 486.
- La solicitud no contiene el poder debidamente otorgado, con el lleno de los requisitos exigidos por los artículos 63 y subsiguientes del Código de Procedimiento Civil. Adicionalmente, deberá presentar el documento que acredita la existencia y representación legal de la sociedad solicitante.

En cumplimiento de lo dispuesto por el artículo 39 de la Decisión 486, se le requiere para que dentro del término de dos meses siguientes a la fecha de notificación del presente oficio, complete los requisitos anteriormente enunciados. En caso de no dar cumplimiento al presente requerimiento, la solicitud se considerará abandonada y perderá su prelación.

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 CESPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista de fecha 01 JUL 2005

202027

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