



MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD



agencia española de
medicamentos y
productos sanitarios

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
de acuerdo con el Anexo V de la Directiva 93/42/CEE

EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 18-05-1998

Fecha de prórrogas anteriores: 16-05-2003, 14-05-2008, 17-02-2009

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 16-02-2019	0318

A favor de /In favour of:

Fabricante/Manufacturer:

Nombre/Name: IBERHOSPITEX, S.A.

Dirección/Address: Avda. Catalunya, 4; 08185 – Lliça de Vall (Barcelona) ESPAÑA

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem

Dirección/Address: Idem

Para el producto/For the product:

Categoría/Category: Productos de un solo uso / Single use devices

Grupo genérico/Generic group: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:

IBERHOSPITEX, S.A

Avda. Catalunya, 4; 08185 – Lliça de Vall (Barcelona) ESPAÑA

Este certificado debe ir acompañado por/This certificate must be accompanied by:

- ☐ Certificado de examen CE de tipo (anexo III)/EC Type examination certificate (annex III)
☒ Declaración CE de conformidad (anexo VII)/EC declaration of conformity (annex VII)

Este certificado es consecuencia de la auditoría del sistema de garantía de calidad de la producción y del examen de la documentación técnica contenida en el expediente n° 97 10 0062, y garantiza que los productos descritos cumplen los requisitos de la Directiva.

This certificate is issued on the production quality assurance system audit, and the examination of the technical documentation contained in dossier no. 97 10 0062, and guarantees that the described products fulfils the requirements of the Directive.

Madrid, 17 de febrero de 2014


agencia española de
medicamentos y
productos sanitarios
P.A. art. 14.4 del Estatuto de la AEMPS
(R.D. 1275/2011, de 16 de septiembre)

La Directora agencia española de
medicamentos y
productos sanitarios
ORGANISMO NOTIFICADO
0318

Fco. Javier Muñoz Aizpuru

CORREO ELECTRÓNICO

on0318@aemps.es

ORGANISMO NOTIFICADO 0318



ANEXO N° I/ANNEX NO: I

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
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98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 16-02-2019	0318

A favor de /In favour of:

Fabricante/Manufacturer:

Nombre/Name: IBERHOSPITEX, S.A.

Dirección/Address: Avda. Catalunya, 4; 08185 – Llíça de Vall (Barcelona) ESPAÑA

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem

Dirección/Address: Idem

Productos/Product: 17

Variantes/Variants: 56

Tipo de producto / Device type: Productos para quirófanos o salas de quemados. Apósitos autoadhesivos. Fundas cubreinstrumentos /Operating room devices. Adhesive dressing. Instruments covers

Clasificación/Classification: I estéril / I sterile

1. Productos para quirófanos o salas de quemados/ Operating room devices (GMDN 35091)

1.1 Vestuario y prendas de protección de tela sin tejer/ Operating room devices

1.1.a. Bata de protección estéril/ Sterile protection gown

1.1.b Bata de protección impermeable estéril /Sterile plastified protection gown

1.1.c. Bata quirúrgica reforzada estéril de polipropileno SMMS/ Sterile SMMS polypropylene reinforced surgical gown

Tallas/ Sizes: M, L y XL

1.1.d Bata quirúrgica no reforzada estéril de polipropileno SMMS/ Sterile SMMS non reinforced polypropylene surgical gown

Tallas/ Sizes: M, L y XL

1.2 Fundas cubreinstrumentos de Ø / Instruments covers to Ø: 100 cm y 123 cm (GMDN 45021)



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2. Conjuntos quirúrgicos para diálisis y curas / Dialysis and Healing surgical sets
(GMDN 32142)

2.1 Conjuntos para diálisis/ Dialysis surgical sets:

- 1 Guantes de látex de examen/ Latex examination gloves: 6: 6 ½, 7: 7 ½**
- 1 Talla tisú absorbente / Absorbent surgical drape**
- 4 Tallas absorbentes / Absorbent towels**

2.2 Conjuntos para curas/ Healing surgical sets:

- 1 Guantes de látex de examen/ Latex examination gloves: 6: 6 ½, 7: 7 ½**
- 1 Talla tisú absorbente / Absorbent surgical drape**
- 4 Tallas absorbentes / Absorbent towels**
- 1 Pinzas de disección / Dissection tweezers**
- 1 Pinzas Kocher / Kocher tweezers**

3. Apósitos autoadhesivos /Self-adhesive dressings (GMDN 46854)

3.1 OPER FILM Membrana de poliuretano autoadhesiva/ Polyurethane self adhesive membrane.

Tamaños/Sizes: 60 x 40 cm, 40 x 40 cm, 30 x 40 cm, 30 x 27 cm, 30 x 16 cm, 15 x 10 cm, 10 x 7.5 cm, 60 x 80 cm y 6.5 x 7.5 cm.

3.2- OPER DRES Apósito autoadhesivo con adhesivo acrílico y compresa central de viscosa-poliéster / Acrylic self-adhesive dressing with viscose-polyester central swab

Tamaños/Sizes: 7.2 x 5 cm, 9 x 5 cm, 9 x 10 cm, 9 x 15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.



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3.3- OPER CAT Bolsa apósito autoadhesivo acrílico de viscosa-poliéster/ Acrylic self-adhesive dressing pouch viscose-polyester.

Tamaños/Sizes: 8 x 7.5 cm, 16 x 5 cm.

3.4- OPER DRES FILM. Apósito quirúrgico autoadhesivo de poliuretano con adhesivo acrílico y compresa central de viscosa (90% viscosa y 10% polipropileno) / Polyurethane self-adhesive surgical dressing with acrylic and viscose central swab (90% viscose and 10% polypropylene)

Tamaños/Sizes: 7.2 x 5 cm, 9 x 5 cm, 9 x 10 cm, 9 x 15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.

3.5- OPER EASY Apósito autoadhesivo con adhesivo acrílico de poliuretano/ Polyurethane acrylic self-adhesive dressing.

Tamaños/Sizes: : 7.2 x 5 cm, 9 x 12 cm y 9 x 15 cm.

3.6- OPER STRIP Tira adhesiva de suturas cutáneas/ Skin sutures adhesive strip.

Tamaños/Sizes: 3 x 75 mm, 6 x 38 mm, 6 x 75 mm, 6 x 100 mm, 12 x 100 mm y 25 x 125 mm.

3.7- OPER EASY I.V Apósito transparente con adhesivo acrílico de poliuretano para fijación de cánulas/ Polyurethane acrylic self-adhesive transparent dressing for cannula fixation.

Tamaños/Sizes:: 7.2 x 5 cm.

3.8- OPER EASY I.V STRIP Apósito transparente con adhesivo acrílico de poliuretano para fijación de cánulas con tiras de refuerzo / Polyurethane acrylic self-adhesive transparent dressing for cannula fixation with securing strips.

Tamaños/Sizes: : 9 x 7 cm.

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3.9- OPER FILM SURGICAL Apósito autoadhesivo con adhesivo acrílico de poliuretano transparente/ *Polyurethane acrylic self-adhesive transparent dressing*
Tamaños/Sizes: 24 x 16 cm, 24 x 27 cm, 24 x 40 m, 34 x 40 cm, 34 x 60 cm y 53 x 80 cm.

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad.

This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 17 de febrero de 2014

La Directora

 **agencia española de
medicamentos y
productos sanitarios**
P.A. art. 14.4 del Estatuto de la AEMPS
(R.D. 1275/2011, de 16 de septiembre)

 **agencia española de
medicamentos y
productos sanitarios**
ORGANISMO NOTIFICADO
0318

Fco. Javier Muñoz Aizpuru

ORGANISMO NOTIFICADO 0318

Traducere din limba engleză

CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE

Data emiterii inițiale: 18-05-1998

Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009

Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

Emis pentru:

Producător:

Nume: IBERHOSPITEX, S.A.

Adresa: Avda. Catalunya, 4; 08185 - Llica de Vail (Barcelona) SPANIA

Reprezentant UE autorizat:

Nume: Idem

Adresa: Idem

Pentru produsul:

Categorie: Dispozitive de unică folosință

Grup generic: Specificat în anexele la prezentul Certificat.

Tip: Specificat în anexele la prezentul Certificat.

În centrele de producție:

IBERHOSPITEX, S.A

Avda. Catalunya, 4; 08185 - Llica de Vail (Barcelona) SPANIA

Prezentul Certificat trebuie să fie însoțit de:

- Certificat de examinare tip CE (anexa III)
- Declarație de conformitate CE (anexa VII)

Prezentul Certificat este emis în urma auditului sistemului de asigurare a calității producției și pe baza examinării documentației tehnice din dosarul nr. 97 10 0062, și garantează faptul că produsele descrise îndeplinesc cerințele Directivei.

Madrid, 17 februarie 2014,

Director

Fco. Javier Munoz Aizpuru

Semnătură indescifrabilă

Ștampila Ministerului sănătății din Spania

Ștampila Agenției spaniole pentru medicamente și produse sanitare

CORREO ELECTRONICO
on0318@aemps.es

ORGANISM NOTIFICAT 0318

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CI CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
28022 MADRID
TEL: 902101322
FAX: 91 822 52 89



ANEXA NR. I
CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE
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Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009



Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

Emis pentru:

Producător:

Nume: IBERHOSPITEX, S.A.

Adresa: Avda. Catalunya, 4; 08185 - Llica de Vail (Barcelona) SPANIA

Reprezentant UE autorizati:

Nume: Idem

Adresa: Idem

Produs: 17

Variante: 56

Tip dispozitiv: Dispozitive pentru sala de operație. Pansamente adezive. Huse pentru instrumente

Clasificare: I steril

1. Dispozitive pentru sala de operații (GMDN 35091)

1.1 Dispozitive pentru sala de operații

1.1.a. Halat de protecție steril

1.1.b Halat de protecție plastifiat steril

1.1.c. Halat chirurgical îngroșat polipropilenă SMMS steril. Dimensiuni: M, L și XL

1.1.d Halat chirurgical neîngroșat polipropilenă SMMS steril. Dimensiuni: M, L și XL

1.2 Huse instrumente Ø: 100 cm și 123 cm (GMDN 45021)

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2. Seturi chirurgicale de tratament și dializă (GMDN 32142)

2.1 Seturi chirurgicale de dializă:

1 Mănuși de examinare din latex: 6, 6 1/2, 7, 7 1/2

1 Câmp operator absorbant

4 Prosoape absorbante

2.2 Seturi chirurgicale de tratament:

1 Mănuși de examinare din latex: 6, 6 1/2, 7, 7 1/2

1 Câmp operator absorbant

4 Prosoape absorbante

1 Pensete de disecție

1 Pensete Kocher

3. Pansamente autoadezive (GMDN 46854)

3.1 OPER FILM Membrană autoadezivă din poliuretan.

Dimensiuni: 60 x 40 cm, 40 x 40 cm, 30 x 40 cm, 30 x 27 cm, 30 x 16 cm, 15 x 10 cm, 10 x 7.5 cm, 60 x 80 cm și 6.5 x 7.5 cm.

3.2- OPER DRES Pansament auto-adeziv din acrilic cu tampon central din poliester - vâscoză

Dimensiuni: 1.2 x 5 cm, 9x5 cm, 9x10 cm, 9 x 15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.

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în conformitate cu anexa V a Directivei 93/42 CEE

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98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

3.3- OPER CAT Pansament auto-adeziv acrilic pungă vâscoză - poliester.

Dimensiuni: 8 x 7.5 cm, 16 x 5 cm.

3.4- OPER DRES FILM Pansament chirurgical auto-adeziv poliuretan cu tampon central din viscoză și acrilic (90% viscoză și 10% polipropilenă)

Dimensiuni: 7.2 x 5 cm, 9x5 cm, 9 x 10 cm, 9x15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.

3.5- OPER EASY Pansament auto-adeziv acrilic poliuretan.

Dimensiuni : 7.2 x 5 cm, 9 x 12 cm și 9 x 15 cm.

3.6- OPER STRIP Bandă adezivă pentru suturi cutanate.

Dimensiuni: 3 x 75 mm, 6 x 38 mm, 6 x 75 mm, 6 x 100 mm, 12 x 100 mm și 25 x 125 mm.

3.7- OPER EASY I.V. Pansament transparent auto-adeziv din acrilic poliuretan pentru fixarea canulei

Dimensiuni: 7.2 x 5 cm.

3.8- OPER EASY I.V. STRIP Pansament transparent auto-adeziv din acrilic poliuretan pentru fixarea canulei cu benzi de fixare. *Dimensiuni: : 9 x 7 cm.*

Organism notificat 0318

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MINISTERIO DE SANIDAD,
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Agencia Espanola de Medicamentos
y Productos Sanitarios





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Certificat nr.	Data valabilității	NR
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3.9- OPER FILM SURGICAL Pansament transparent auto-adeziv din acrilic poliuretan
Dimensiuni: 24 x 16 cm, 24 x 27 cm, 24 x 40 m, 34 x 40 cm, 34 x 60 cm și 53 x 80 cm.

Prezentul certificat acoperă toate mărci comerciale produselor incluse de producător în declarația de conformitate.

Madrid, 17 februarie 2014,

Director
Fco. Javier Munoz Aizpuru

Semnătură indescifrabilă

Stampila Ministerului sănătății din Spania

Stampila Agenției spaniole pentru medicamente și produse sanitare

Organism notificat 0318

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MINISTERIO DE SANIDAD,
SERVICIO SOCIALES
E IGUALDAD
Agencia Espanola de Medicamentos
y Productos Sanitarios



Ministerul Sănătății din Spania și Agenția spaniolă pentru medicamente și produse sanitare și a fost prezentat mie în întregime.

Traducerea înscrisului prezentat are un număr de 5 pagini și a fost efectuată potrivit cererii scrise înregistrate cu nr. 57 / 04.08.2014, păstrate în arhiva subsemnatei.

S-a încasat onorariul de 80 lei, cu Factura nr. 410 / 04.08.2014.

INTERPRET ȘI TRADUCĂTOR AUTORIZAT

Olaru Ruxandra, www.trada.ro, office@trada.ro, telefon: 0729.22.6789





UNE-EN ISO 13485:2013 CERTIFICADO DE PRÓRROGA
UNE-EN ISO 13485:2013 EXTENSION CERTIFICATE

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios.
Medical devices – Quality management systems - Requirements for regulatory purposes.

PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 16-05-2003

Fechas de prórroga anteriores/Previous extension: 9-06-2004, 17-02-2009, 17-02-2014

Fecha de validez/This Certificate is valid until: 17.02.2019

Certificado nº/Certificate no: 2014 02 0041 EN

Empresa/ Company

IBERHOSPITEX, S.A

Nombre y dirección/name and address:

Avda. Catalunya, 4; 08185 – Llíça de Vall (Barcelona) ESPAÑA

Objeto de la Certificación/Applicable to:

Diseño y desarrollo, y producción de productos sanitarios/ Design and manufacture of medical devices

Ámbito tecnológico/Technological scope:

Especificado en Anexo a este Certificado/Specified in Annex to this Certificate.

La Agencia Española de Medicamentos y Productos Sanitarios, certifica que la empresa reseñada más arriba tiene establecido y aplica un sistema de gestión de de calidad de conformidad con la norma UNE-EN ISO 13485:2013 (EN ISO 13485:2012 e ISO 13485:2003).

The Agencia Española de Medicamentos y Productos Sanitarios, certifies herewith that the company named above has established and applies a quality management system according to the standard UNE-EN ISO 13485:2013 (EN ISO 13485:2012 and ISO 13485:2003).

Madrid, 17 de febrero de 2017

**LA DIRECTORA DE LA AGENCIA ESPAÑOLA DE
MEDICAMENTOS Y PRODUCTOS SANITARIOS**



Belén Crespo Sánchez-Eznarriaga

CORREO ELECTRÓNICO

on0318@aemps.es

CERTIFICACIÓN 13485

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**C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 902101322
FAX: 91 822 52 89**

Anexo al certificado nº 2014 02 0041 EN /annex to certificate no: 2014 02 0041 EN
Fecha /date: 17 de febrero de 2017

Ámbito tecnológico/technological scope:

PRODUCTOS SANITARIOS NO ACTIVOS/ NON-ACTIVE MEDICAL DEVICES :

PRODUCTOS SANITARIOS NO ACTIVOS, NO IMPLANTABLES, EN GENERAL/ GENERAL NON ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES:

- Productos no activos para anestesia y respiración, emergencia y cuidado intensivo/ *Non-active devices for anaesthesia, respiration, emergency and intensive care*
- Dispositivos de acceso percutáneo, para tratamiento de enfermedades vasculares/ *Percutaneous access device for treatment of vascular disease*

IMPLANTES NO ACTIVOS/ NON-ACTIVE IMPLANTS :

- Implantes cardiovasculares no activos / *Non-active cardiovascular implants*

PRODUCTOS PARA CUIDADO DE HERIDAS/ DEVICES FOR WOUND CARE:

- Vendajes y apósitos para heridas/ *Bandages and wound dressings*

OTROS PRODUCTOS SANITARIOS NO ACTIVOS DIFERENTES DE LOS ESPECIFICADOS ARRIBA

- Equipamiento y vestimenta destinados a la preservación de la contaminación del paciente en entornos médico-quirúrgicos/ *Equipment and clothing for the preservation of patient contamination in medical-surgery settings*

PRODUCTOS SANITARIOS ACTIVOS NO IMPLANTABLES/ ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES :

PRODUCTOS SANITARIOS ACTIVOS, EN GENERAL/ GENERAL ACTIVE MEDICAL DEVICES :

OTROS PRODUCTOS SANITARIOS ACTIVOS NO IMPLANTABLES:

- Productos para drenaje y succión/ *Drain and suction devices*

PRODUCTOS SANITARIOS QUE INCORPORAN DETERMINADAS TECNOLOGÍAS/MEDICAL DEVIDES INCORPORATING ESPECIFIC SUBSTANCES

-PRODUCTOS SANITARIOS QUE INCORPORAN SUSTANCIAS MEDICINALES/ MEDICAL DEVICES INCORPORATING MEDICINAL SUBSTANCES

MINISTERUL SANATATII, SERVICIILOR SOCIALE SI EGALITATII
AGENTIA SPANIOLA PENTRU MEDICAMENTE SI PRODUSE SANITARE

CERTIFICAT DE PRELUNGIRE UNE-EN ISO 13485 :2013
Dispozitive medicale – sisteme de gestionare a calitatii – cerinte de reglementare

PRELUNGIRE – Data initiala : 16-05-2003
Prelungiri precedente : 9-06-2004, 17-02-2009, 17-02-2014
Prezentul certificat expira la data de : 17.02.2019
Certificat nr. : 2014 02 0041 EN

Compania: IBEROHOSPITEX, S.A.
Denumirea si adresa: Avda. Catalunya, 4; 08185 Llica de Vall (Barcelona) SPANIA
Obiectul certificatului: Proiectarea si fabricatia dispozitivelor medicale
Scopul tehnologic: Specificat in Anexa prezentului Certificat.

Agentia spaniola pentru medicamente si produse sanitare certifica, prin prezentul, faptul ca societatea comerciala mentionata mai sus a stabilit si aplicat un sistem de gestionare a calitatii conform standardului UNE-EN ISO 13485:2013 (EN ISO 13485:2012 si ISO 13485:2003).

Madrid, 17 Februarie 2017
DIRECTOAREA AGENTIEI SPANIOLE PENTRU MEDICAMENTE SI PRODUSE SANITARE
Belen Crespo Sanchez-Eznarriaga
(Semnatura indescifrabila si stampila Agentiei)

REDACTAT ELECTRONIC CERTIFICAT 13485 C/CAMPEZO, 1 – CLADIREA 8
on0318@aemps.es Pagina 1 din 2 28022 MADRID
Tel.: 902101322
Fax: 91 822 52 89



Data: 17 Februarie 2017

Scop tehnologic:

DISPOZITIVE MEDICALE INACTIVE:

DISPOZITIVE MEDICALE GENERALE, INACTIVE, NEIMPLANTABILE:

- Dispozitive inactive pentru anestezie, respiratie, asistenta de urgenta si terapie intensiva
- Dispozitive de acces percutanat pentru tratamentul afectiunilor vasculare

IMPLANTURI INACTIVE:

- Implanturi cardiovasculare inactive

PRODUSE DE ÎNGRIJIRE A LEZIUNILOR:

- Bandaje si pansamente pentru leziuni

DISPOZITIVE MEDICALE INACTIVE, ALTELE DECAT CELE ENUMERATE ANTERIOR:

- Echipamente si imbracaminte pentru prevenirea contaminarii pacientilor din unitatile medico-chirurgicale

DISPOZITIVE MEDICALE ACTIVE, NEIMPLANTABILE:

DISPOZITIVE MEDICALE ACTIVE, DE UZ GENERAL:

ALTE DISPOZITIVE MEDICALE NEIMPLANTABILE:

- Dispozitive pentru drenaj si aspiratie

DISPOZITIVE MEDICALE CARE INCORPOREAZA SUBSTANTE SPECIFICE:

- DISPOZITIVE MEDICALE CARE INCORPOREAZA SUBSTANTE MEDICINALE

CERTIFICAT 13485

Pagina 2 din 2

MINISTERUL SANATATII,
SERVICIILOR SOCIALE
SI EGALITATII
AGENTIA SPANIOLA
PENTRU MEDICAMENTE
SI PRODUSE SANITARE

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



Oper dres

Surgical dressing



Hospital Care

Maximum protection
without sticking to the wound

Optimal fixation. High absorption capacity. High perspiration. Sterile.





Hospital Care

Oper dres

Surgical dressing

Offers a perfect combination

Oper dres is a non woven material dressing which is adaptable, sterile, hypoallergenic, autoadhesive and extensible. It is specially designed to protect surgical wounds.

An extensible non woven material with high porosity

Thanks to an advanced manufacturing process, the **Oper dres** adhesive is applied on polyester material, respecting its porosity. The dressing's permeable nature avoids skin softening and accelerates the healing of the wound.



A fine permeable and non stick film

The pad's fine film of **Oper dres** allows the dressing to be removed at any time, without any sticking to the wound.

Protective layers designed for sterile positioning

The protective layer is precut and folded in such a way that the dressing can be quickly applied without having to touch the part which will be in contact with the wound.



High adhesion power without chemical solvents

Oper dres's high adhesive power and elasticity allow for perfect fixation on the most difficult parts of the body.

A pad with high absorption power

The viscose and polyester fibers guarantee a maximum level of absorption of exudations and their uniform retention within the pad.

Oper dres

Surgical dressing

Sterile autoadhesive dressing

Autoadhesive material (Non woven 100% polyester, acrylic copolymer adhesive, silicon paper)

Presentation					
Reference	Dressing dimensions	Pad dimensions	Units per box	Boxes per carton	Sales unit
0037107	7,2x5 cm	4,5x2,8 cm	50	36	1800
0037117	9x5 cm	4,5x2,8 cm	50	36	1800
0037127	9x10 cm	4,5x5,8 cm	40	26	1040
0037137	9x15 cm	4,5x9,6 cm	40	20	800
0037147	9x20 cm	4,5x14,5 cm	40	16	640
0037157	9x25 cm	4,5x18,9 cm	40	15	600
0037167	9x30 cm	4,5x23,1 cm	40	12	480
0037177	9x35 cm	4,5x30 cm	50	9	450

00951091 - rev. 2011/10/03



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CE
0318

Oper easy IV

Dressing for securing the catheter, providing protection and allowing observation of the puncture site

Oper easy IV strip

Dressing for extra-firmly securing the catheter, providing protection and allowing observation of the puncture site



IV transparent polyurethane film with and without strips

Indicated for securing the catheter and for protection and observation of the puncture site

Oper easy IV and Oper easy IV strip are highly breathable, hypoallergenic, elastic and adaptable transparent polyurethane film surgical dressings.

Dressings with split, designed to protect peripheral intravenous catheter sites and secure tubes or medical devices, which allow visual inspection of the puncture site without changing the dressing.

Permeable to O₂ and impermeable to liquids and microorganisms

The polyurethane film is permeable to gases and so allows the skin and the wound to breath, while acting as a barrier to liquids and microorganisms, reducing the risk of infection.

Impermeability to water makes it safer and provides greater protection for the patient.

Oper easy IV strip to ensure the catheter is firmly secured

The IV strip presentation adds two non-woven fabric reinforcement strips to increase safety for cannulae. The catheter is more firmly secured at the puncture site, preventing the risk of accidental removal.



Permeable to oxygen and impermeable to liquids

Oper easy IV

Dressing for securing the catheter, providing protection and allowing observation of the puncture site

Oper easy IV strip

Dressing for extra-firmly securing the catheter, providing protection and allowing observation of the puncture site

Transpirable and impermeable to liquids, acting as a barrier against microorganisms

Oper easy IV presentations

Reference	Dressing dimensions	Units per pack	Packs per case	Selling units
0037457	7.2 x 5 cm	100	36	3,600

Oper easy IV strip presentations

Reference	Dressing dimensions	Units per pack	Packs per case	Selling units
0037467	9 x 7 cm	100	32	3,200

Composition: PE film, PU film, acrylic adhesive, silicone paper.

Technical characteristics

Support	Polyurethane	Permeability (MVTR)	720 ($\pm 10\%$) g · m ⁻² · 24 h ⁻¹ at 37° C
Support thickness	25 \pm 5 microns	Adhesive	Acrylic
Colour	Transparent	Adhesion to steel	250 - 850 g / 25 mm
Weight	40 \pm 7 g / m ²		

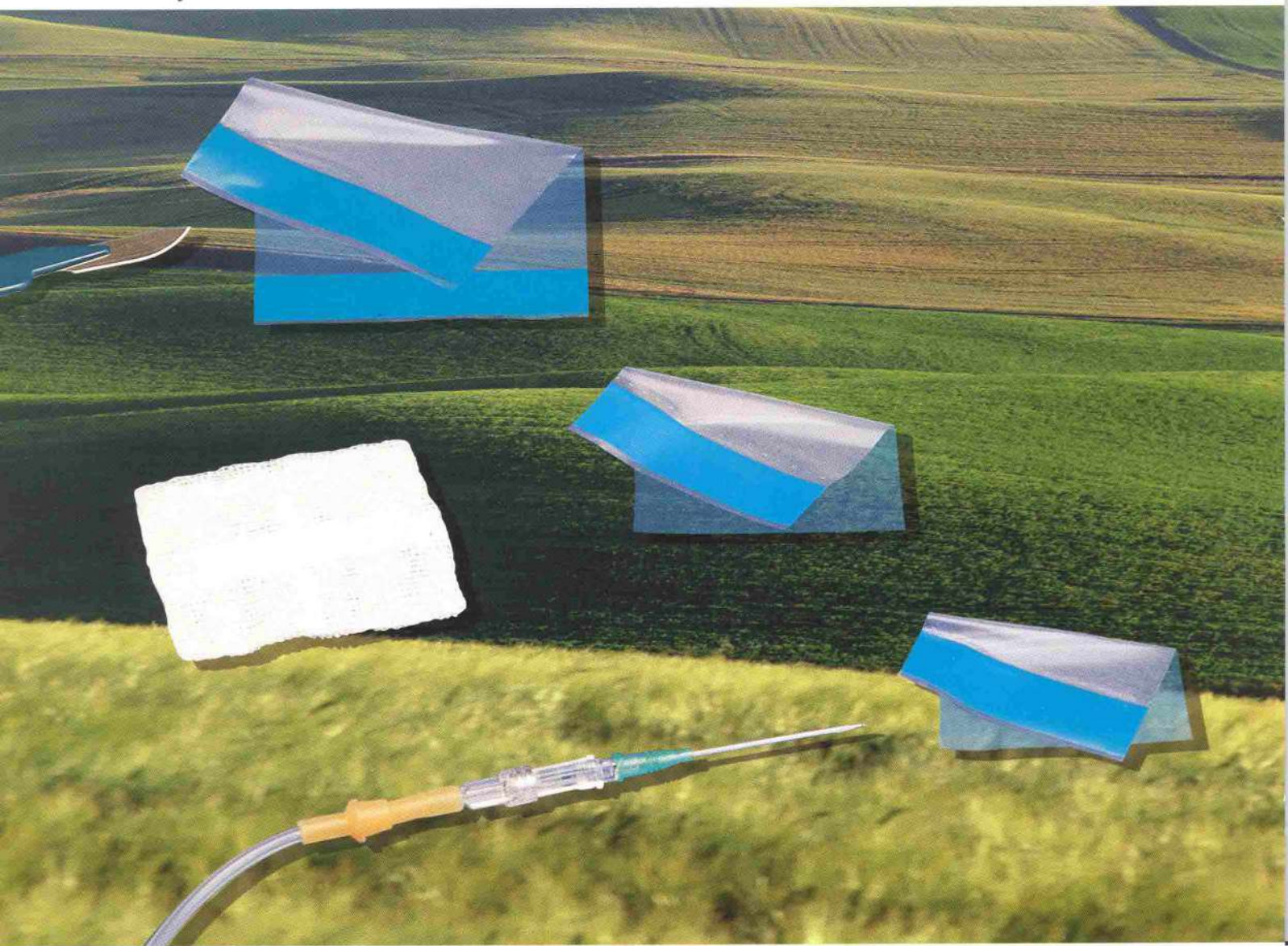
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Rev: 2013-07-04



Manufactured and marketed by _____

Oper film®

Transparent protection



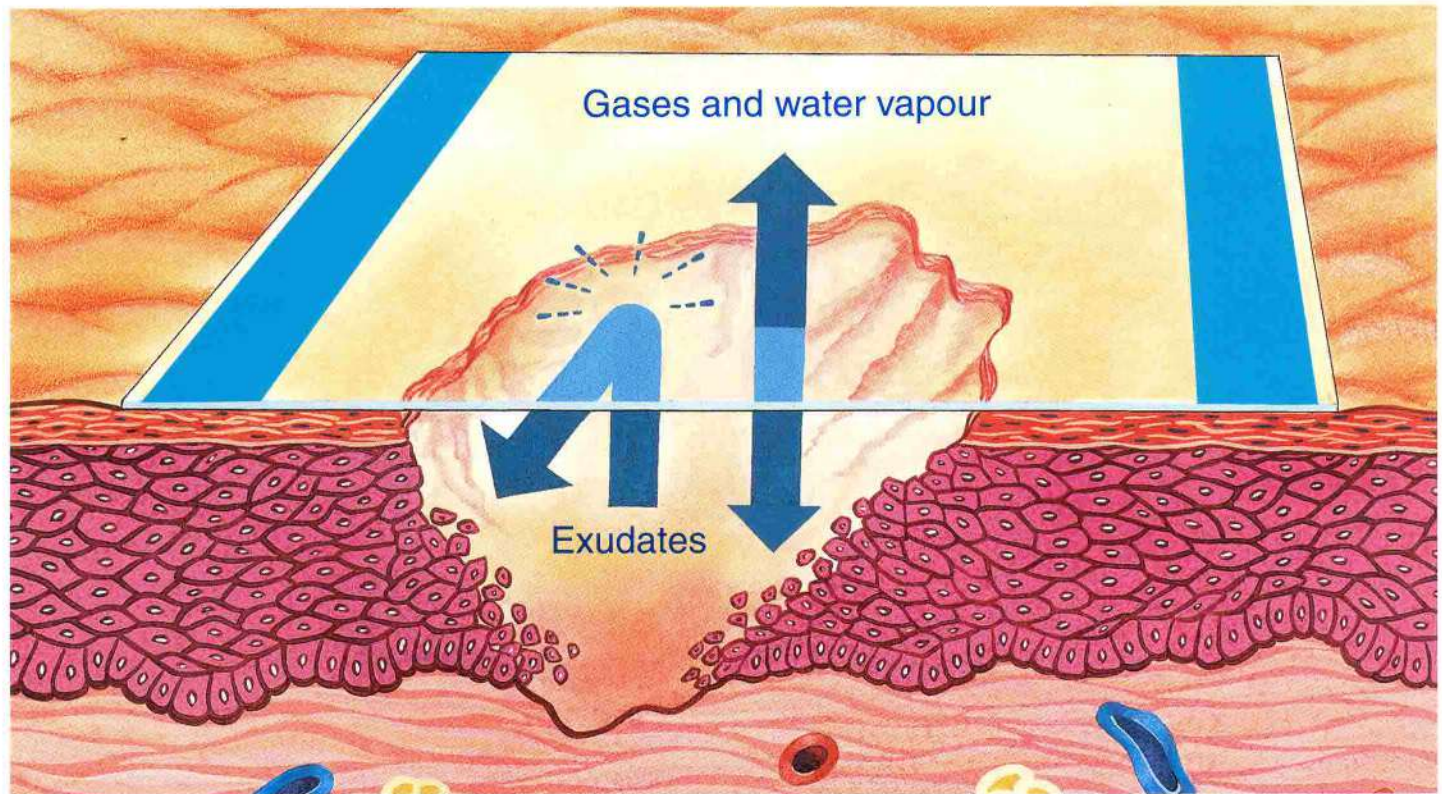
- ***Catheter fixation***
- ***Incision field***
- ***Dressing for burns, ulcers, skin grafts***



IBERHOSPITEX S.A.

Oper film[®] offers numerous advantages

OPER FILM is a transparent polyurethane membrane which is elastic and adhesive. Due to its intrinsic characteristics, it has various medical and therapeutic applications.



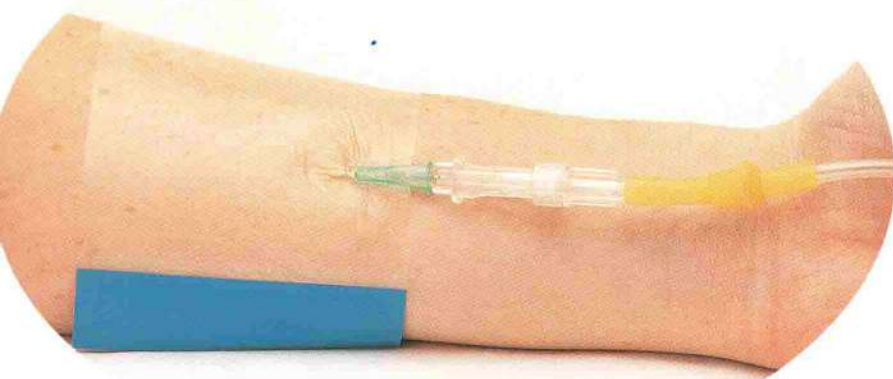
OPER FILM'S ADVANTAGES

- | | |
|---|---|
| ● Effective protection | ➡ Less risk of infections |
| ● Impermeable to liquids | ➡ Retains wound exudations |
| ● Permeable to gases and water vapour | ➡ Permits oxygen at both wound and skin |
| ● Adheres well on dry skin without damaging the wound | ➡ Optimal and lasting fixation |
| ● Transparent | ➡ Constant visual control of wound |
| ● Elasticity without deformation | ➡ Perfect adaptation to all body parts |
| ● Sterile and hypoallergenic | ➡ Maximum safety during use |

Advantages in a diversity of applications

OPER FILM AS A PROTECTIVE DRESSING

Accelerates the curing process of lesions and creates a better environment for the healing of wounds such as ulcers, first and second degree burns, skin grafts.

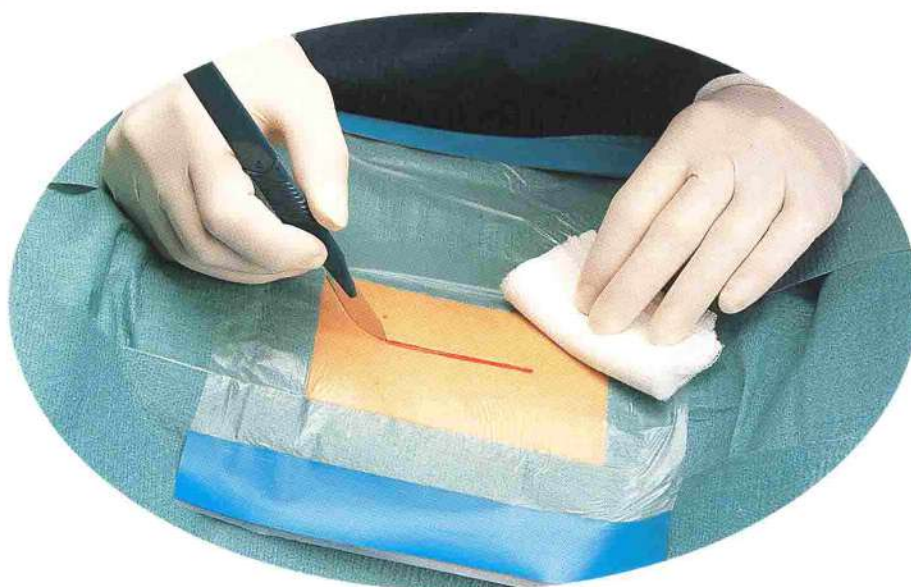


OPER FILM FOR THE FIXATION OF CATHETERS

Simultaneously provides excellent fixation and an effective protection against infections, thus making it easier to control visually the area surrounding the puncture.

OPER FILM DURING SURGERY

Deters the migration of bacteria from the skin to the surgical wound, and remains in optimal conditions even during prolonged interventions.



Oper film®

Adhesive and transparent polyurethane membrane

Technical chart

PROPERTIES	UNIT	QUANTITY	TOLERANCE	STANDARD
Permeability	g/m. ²	140	± 20	DIN 53352
Adhesiveness	N/cm.	2,7	± 0,8	AFERA 4001 (Steel)
Adhesive weight	g/m. ²	44	± 4	DIN 53455
Elasticity Longitudinal Transversal	%	> 450 > 450		

Presentation

REFERENCE	DIMENSIONS	UNITS PER BOX	BOXES PER CARTON	SALES UNIT
0031027	40 x 60 cm.	10	8	80
0031037	40 x 40 cm.	15	8	120
0031047	30 x 40 cm.	20	8	160
0031057	27 x 30 cm.	20	8	160
0031067	16 x 30 cm.	20	8	160
0031077	10 x 15 cm.	60	8	480
0031087	7,5 x 10 cm.	100	8	800
0031097	60 x 80 cm.	10	4	40
0031117	6,5 x 7,5 cm.	125	8	1000

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CE
0318



Adhesive skin sutures

■ Composition

Polyester and polyamide non-woven fabric, acrylic adhesive, silicone-coated paper.

Oper strip presentations

Reference	Dressing dimensions	Units per pack	Packs per case	Selling units
0037800	3 x 75 mm	50 x 5	4	1,000
0037801	6 x 75 mm	50 x 3	4	600
0037802	6 x 38 mm	50 x 6	5	1,500
0037803	6 x 100 mm	50 x 10	6	3,000
0037804	12 x 100 mm	50 x 6	6	1,800
0037805	25 x 125 mm	50 x 4	5	1,000

Technical characteristics

Support	Polyester and polyamide non-woven fabric	Permeability (MVTR)	$\geq 850 \text{ g} \cdot \text{m}^{-2} \cdot 24 \text{ h}^{-1}$ at 37 °C
Support thickness	0.30 ± 0.05 µm	Adhesive	Acrylic
Colour	Beige	Adhesion to steel	250 - 700 g / 25 mm
Weight	39 - 49 g / m ²	Weight of adhesive	45 ± 5 g / m ²

Ref: 00951141
Rev: 2013-06-19

■ Precautions

Oper strip is a sterile product; do not use if the packet is open or damaged. Single-use product. Do not re-sterilize.

■ Contraindications

Oper strip should not be used in the following cases:

- When the wound is infected.
- If there is excessive tension on the skin.
- On secondary healing wounds.
- If proper adhesion cannot be achieved (excess exudate, presence of fat or hair, etc).
- On deep wounds, unless to keep the skin edges together while transferring the patient to a medical centre.



Manufactured and Marketed by



Innovative Health Technologies

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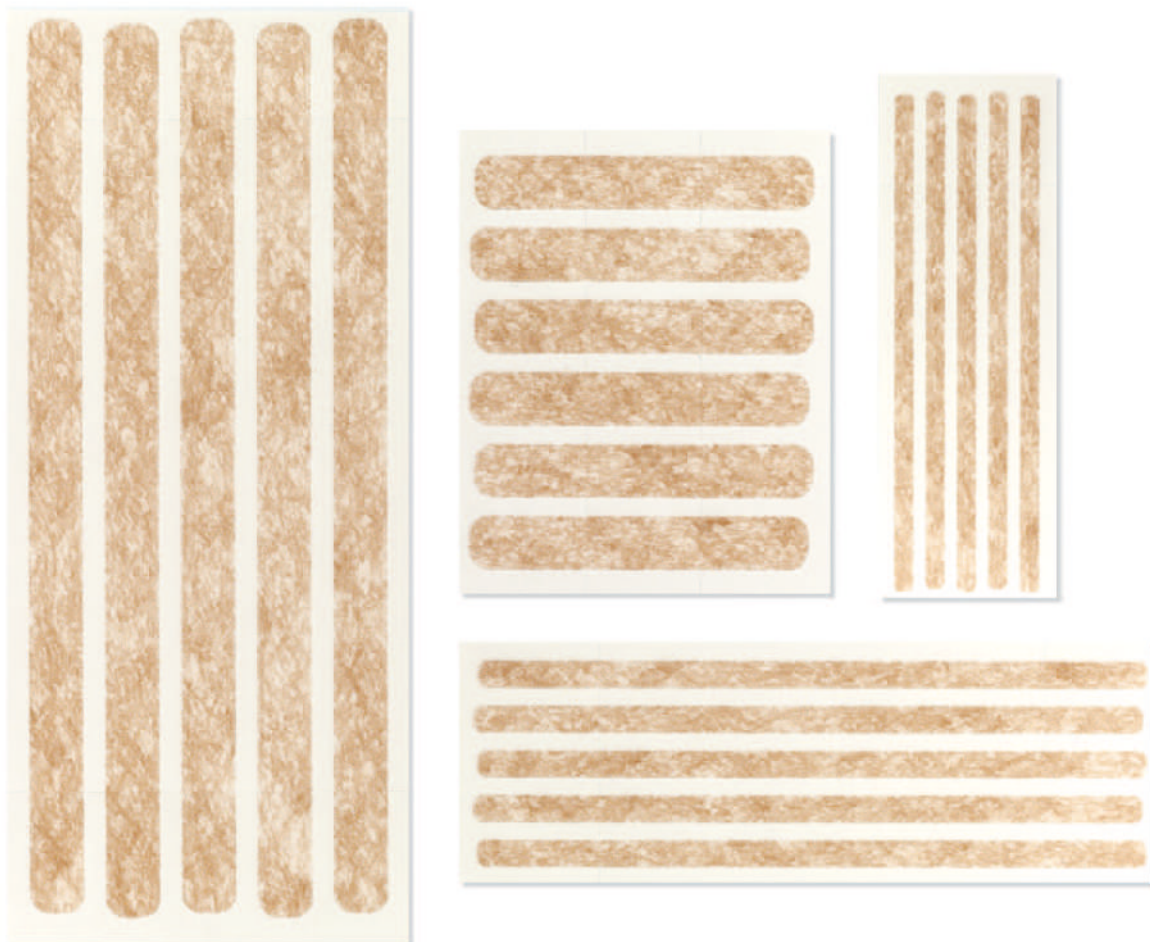
Oper strip

Adhesive skin sutures



Fast and easy to apply skin sutures

Aids wound healing, keeping scarring to a minimum



Fast and easy to apply skin suture strips
with hypoallergenic adhesive

Oper strip

Adhesive skin sutures

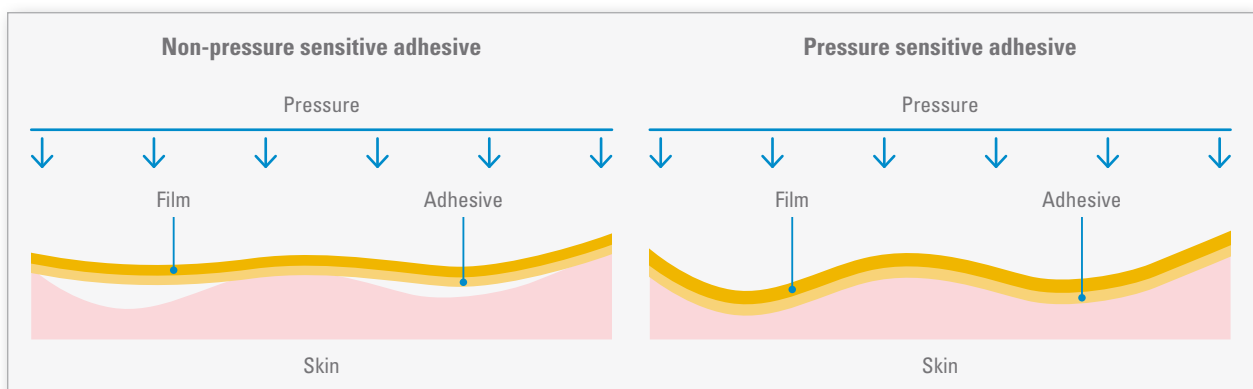
Oper strip provides support that gives stability to the wound, aiding healing and keeping scarring to a minimum for:

- Superficial or moderately-deep skin cuts.
- Lacerations and surgical incisions.
- Traditional sutures.
- Substitute after removal of sutures.

■ Provides support, aiding healing

Oper strip is an adhesive skin suture strip, made of breathable, non-woven polyamide/polyester fabric and coated with latex-free hypoallergenic acrylic adhesive.

It provides excellent adherence, secure approximation of the wound edges and high resistance to traction. It does not peel off in contact with water or with movement. Removal is easy and painless with no residue. Oper strip can remain in place for up to 7 days.



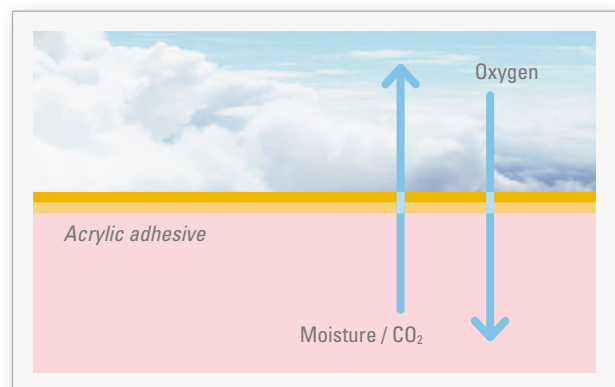
■ Acrylic adhesive

- Pressure-sensitive.
- Temperature resistant (0-55 °C).
- Waterproof.
- Permeable to moisture.
- Smooth and stable adherence to the skin.
- Easy to remove.

■ Highly breathable

Advanced production process.

The adhesive on our suture strips is applied onto non-woven polyamide/polyester fabric, providing excellent permeability to O₂ and moisture.



■ Excellent adherence on areas subject to movement

The non-woven polyamide/polyester fabric provides high resistance to traction on parts of the body subject to movement: joints, highly contoured areas and places where oedema is expected.

■ Flesh colour

Better results aesthetically.

■ Latex-free

Oper strip is latex-free. Latex is a component used in many adhesives which can cause allergic reactions in predisposed patients (ranging from skin rash to anaphylactic shock).

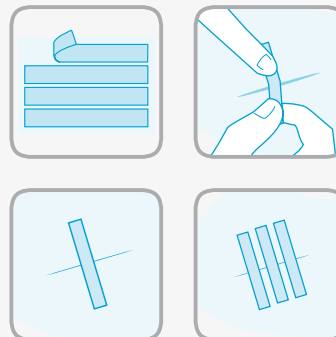
■ Hypoallergenic

Allergic reactions occur due to sensitivity to an adhesive in particular or to the adhesive backing; the greater the exposure to the component, the more severe the reaction. Oper strip contains no known allergens or irritant substances. Standardised protocol tested.



Instructions for use

1. Thoroughly clean and disinfect the wound and surrounding area.
2. Dry the wound and surrounding area.
3. Ensure that there are no foreign bodies remaining in the wound.
4. Remove the protective packaging and take out a suture strip, handling it with clean hands.
5. When using the suture strip alone, approximate and accurately align the wound edges and place a strip perpendicular to the cut.
6. The first strip should be placed at the centre of the wound.
7. To place the strip, stick one end at one side of the wound, without stretching it. Next, approximate the wound edges and stick the other end of the strip down at the other side.
8. The remaining strips required should be placed parallel to the first until the entire length of the wound is covered.
9. Leave a space of 2 to 5 mm, depending on the length and depth of the wound, between each strip. The most usual space to leave is 2 or 3 mm.
10. To reduce the tension on the wound, a strip can be placed on each side perpendicular to the wound over the ends of the adhesive strips covering the wound.
11. No specific follow-up is necessary after removal of the strips once the wound has healed, although visual inspection of the healing process is recommended.



Oper tape

Surgical tape



Hospital Care

A safe and comfortable barrier

Optimal fixation. High perspiration. Elasticity and comfort. Hypoallergenic adhesive.



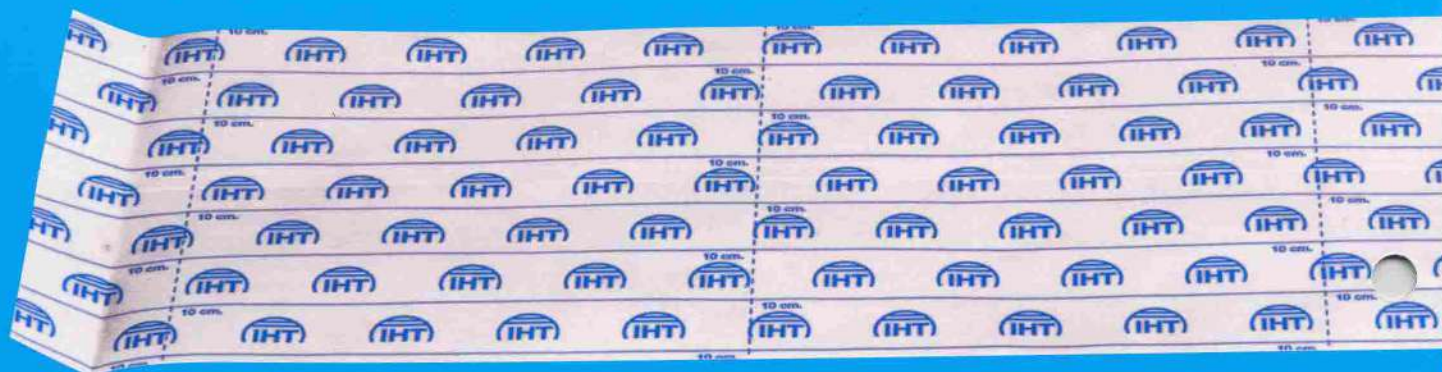
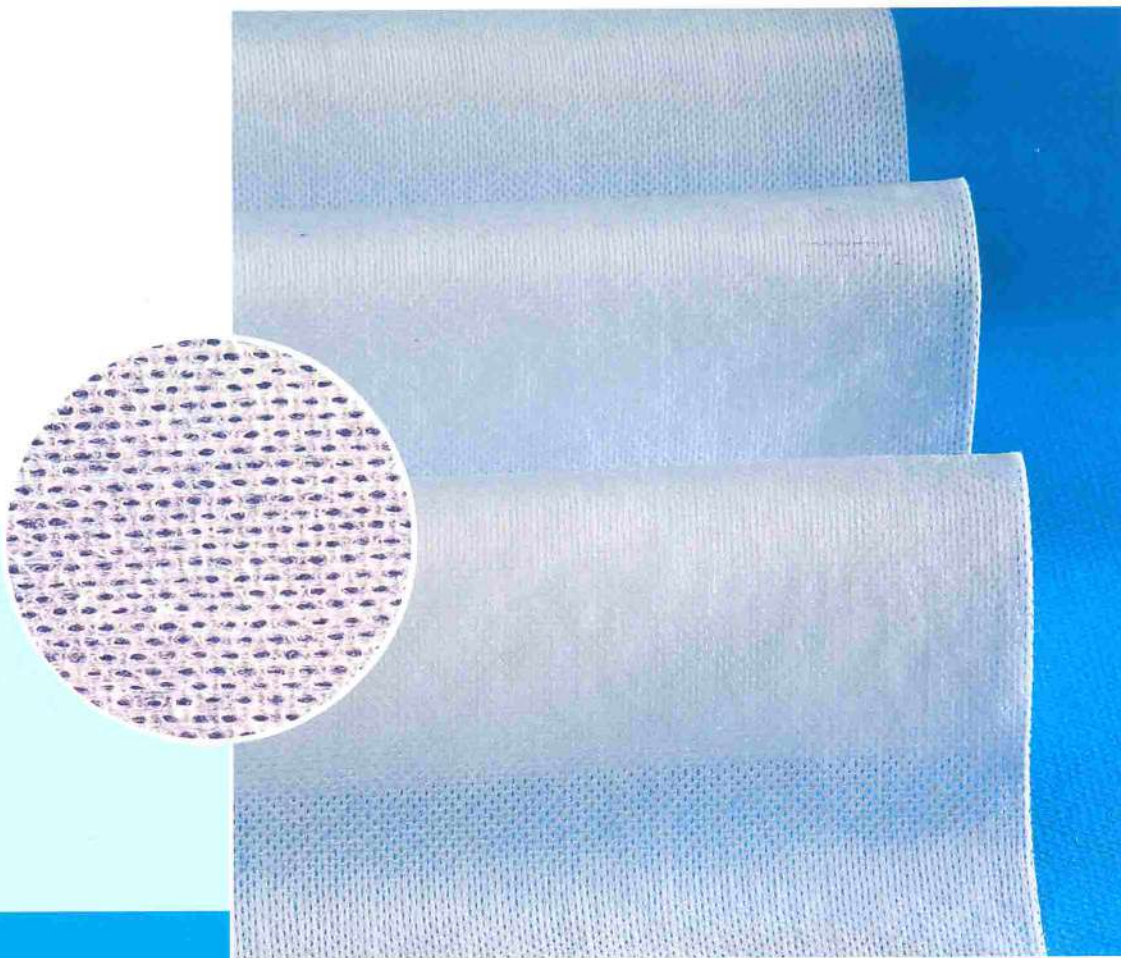


Oper tape

Surgical tape

Extensible and really perspirant

Oper tape system for fixing compresses is an adaptable, extensible, highly porous, non woven material covered by a hypoallergenic adhesive. The adhesive area is protected by precut silicon paper which allows quick and easy application.





Transversal extensibility of the non woven material

Being a transversally extensible strip **Oper tape** can be used on articulations without risk of loosening.

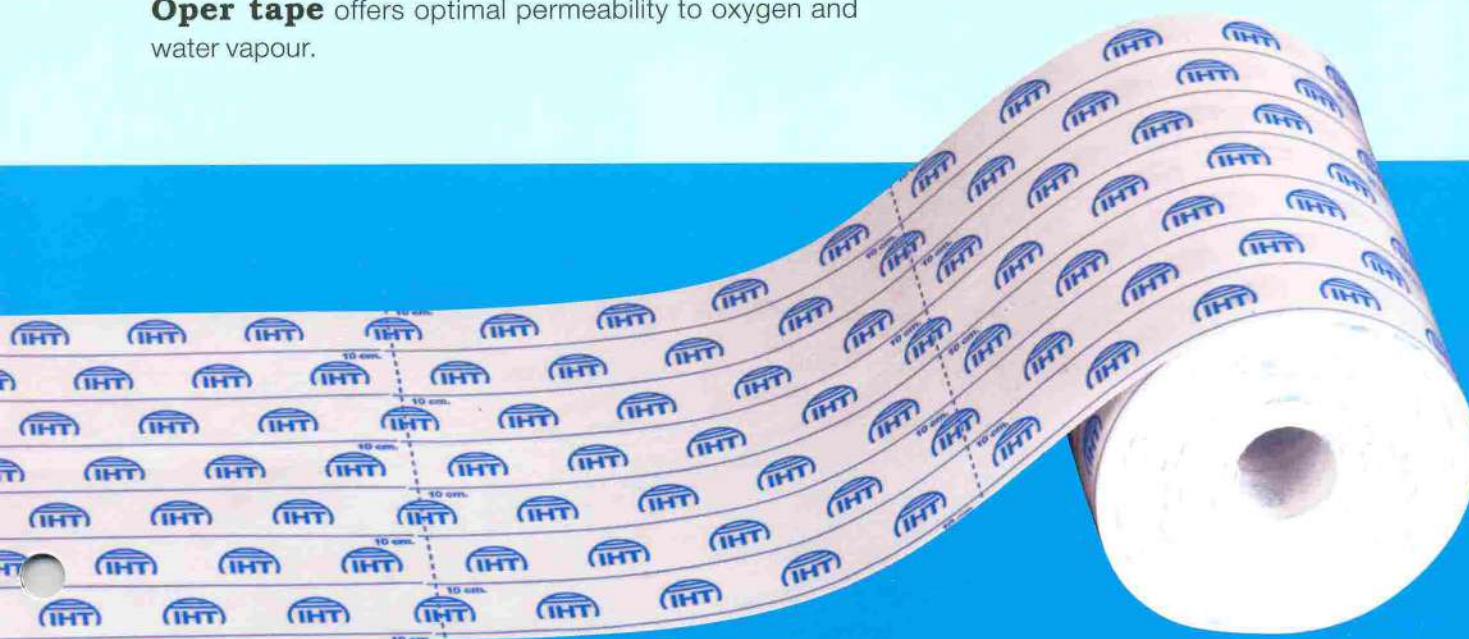


Different size presentations

The extensive range of sizes of **Oper tape** allows for the covering of any size of pad in one application, thus facilitating the work of hospital staff.

Permeable to oxygen and water vapour

Thanks to the high porosity of the non woven material together with the ultimate production process of adhesive fixing, **Oper tape** offers optimal permeability to oxygen and water vapour.



Oper tape

Surgical tape

Maximum adaptability and comfort

Autoadhesive material (Non woven 100% polyester, acrylic copolymer adhesive, silicon paper)

Presentation				
Reference	Dimensions	Units per box	Boxes per carton	Sales unit
0032210	2,5 cm x 10m	2	180	360
0032220	5 cm x 10m	1	180	180
0032230	10 cm x 10m	1	90	90
0032240	15 cm x 10m	1	60	60
0032250	20 cm x 10m	1	47	47
0032260	30 cm x 10m	1	30	30

00951101 - rev. 2011/09/20



Oper tape paper

Surgical tape for sensitive skin



Surgical tape for sensitive skin

Surgical tape made of non-woven cellulose fabric

Highly-porous white adhesive tape with hypoallergenic acrylic adhesive, indicated for:

- Securing dressings and first aid material.
- Securing cannulas, probes and catheters.
- Protecting ostomy devices.
- Securing facial dressings.
- For patients with sensitive skin.
- For prolonged use.



Adhesive tape for application on sensitive skin

The non-woven fabric and the hypoallergenic adhesive used enable application on sensitive skin (neonatology, geriatrics, paediatrics, dialysis, etc.) or repeat applications to the skin.

A highly-porous non-woven fabric

Its high porosity helps to maintain the integrity of the skin.

Thanks to an advanced production process, Oper tape paper adhesive is applied to non-woven cellulose fabric, providing high permeability to oxygen and steam.

Oper tape paper is resistant to extreme temperatures and moisture.

Easy to use

For the patient

The hypoallergenic acrylic adhesive can be removed easily without trauma and without leaving residue. It does not contain latex.

For healthcare personnel

The acrylic adhesive is sensitive to pressure and can be gently adhered; adhesiveness increases over time.

Oper tape paper's wide range of sizes enables any compress size to be covered in a single application, thereby facilitating hospital personnel's work.



Surgical tape made of non-woven cellulose fabric

Oper tape paper

Surgical tape for sensitive skin

Soft surgical tape



Presentations

Reference	Tape measurements	Rolls per pack	Packs per case	Selling units
0038100	1,25 cm x 5 m	24	40	960
0038101	2,5 cm x 5 m	12	40	480
0038102	5 cm x 5 m	6	40	240
0038106	1,25 cm x 9,1 m	24	30	720
0038107	2,5 cm x 9,1 m	12	30	360
0038108	5 cm x 9,1 m	6	30	180
0038109	7,5 cm x 9,1 m	4	30	120

Composition: acrylic adhesive and non-woven cellulose fabric.

Technical characteristics

Support	Non-woven cellulose/polyester	Adhesiveness	250 - 700 g / 25 mm
Weight	35 ± 3,5 g / m ²	Adhesive on the back	100 - 300 g / 25 mm
Adhesive weight	35 ± 5 g / m ²	Permeability (MVTR)	2600 ± 250 g · m ² · 24 h ⁻¹ at 37 °C



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 **Innovative Health Technologies**

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Ref: 995111
Rev: 2013-07-01



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PRODUCT SPECIFICATION

Oper tape silk



DIFFERENT PRESENTATIONS

- **0038131:** Oper tape silk 1.25 cm x 9.1 m
- **0038132:** Oper tape silk 2.5 cm x 9.1 m
- **0038133:** Oper tape silk 5 cm x 9.1 m
- **0038134:** Oper tape silk 7.5 cm x 9.1 m
- **0038125:** Oper tape silk 1,25 cm x 5 m
- **0038126:** Oper tape 2.5 cm x 5 m
- **0038127:** Oper tape silk 5 cm x 5 m

THERAPEUTIC PURPOSE

Oper tape silk is a white artificial silk tape with hypoallergenic acrylic adhesive, especially designed for sensitive skins and indicated for:

- Securing all kinds of dressings, bandages and pads.
- Securing catheters, probes and cannulas.
- Securing feeding tubes, drainage tubes and measuring devices.

DESCRIPTION

Oper tape silk is a white artificial silk tape with hypoallergenic acrylic adhesive. Very well tolerated by the skin. Its artificial silk fabric support enables correct transpiration and protects against water and dirt.

Oper tape silk is easy-to-tear, waterproof tape.

Oper tape silk is suitable for applying to sensitive skins without causing irritation. It fits perfectly, even on the most contoured parts of the body.

It has good shear strength and presents zigzag edges to prevent it from unweaving and facilitate tearing.

MATERIALS

Support:

White artificial silk fabric.

Adhesive:

Hypoallergenic acrylic adhesive.

“Latex-free product”

PROPERTIES

Tape for application to sensitive skins

The artificial silk fabric support of **Oper tape silk** is the part that is secured to healthy skin. It is laminated with a hypoallergenic adhesive mass. **Oper tape silk** enables the skin to breathe, thus preventing it from macerating.

Waterproof

The artificial silk fabric and acrylic adhesive are waterproof, so the patient can wash without risk of the tape becoming loose.

High-adherence power with no chemical solvents

The high adhesive power of **Oper tape silk** enables perfect fixation, even on the most contoured parts of the body, and it leaves no trace when removed.

Tape easily torn in both directions

The artificial silk fabric is easily torn in both directions, so it can be easily and securely applied and its surface can be written on.

Available in several sizes

The range of **Oper tape silk** sizes enables any pad size to be covered in a single application, thus making the jobs of healthcare personnel easier.

APPLICATION

- Use suitable tape for the indicated application.
- Always apply the tape to clean and dry skin.
- Choose adhesive strength according to clinical requirements and skin condition.
- Increase the tape's adherence by slightly pressing with the yolks of the fingers.
- Do not apply the tape with tension, unless clinically required.

TECHNICAL SPECIFICATIONS

Support (white artificial silk fabric)

PROPERTIES	UNIT	VALUE	STANDARD
Grammage	g/m ²	69 ± 3	CC-ME-067
Mesh construction	Threads/cm	43 ± 1	UNE 40600-5
Warp construction	Threads/cm	23 ± 1	UNE 40600-5

Adhesive support (artificial silk fabric with acrylic adhesive)

PROPERTIES	UNIT	VALUE	STANDARD
Grammage	g/m ²	65 ± 5	CC-ME-012
Adhesiveness	g/25 mm	300-900	UNE-EN ISO 1939
Rear	g/25 mm	40-230	UNE-EN ISO 1939
MVTR	g/m ² .24h A 37° C	850 ± 20%	UNE-EN ISO 19726-2

DIMENSIONS

REFERENCE	DRESSING DIMENSIONS
0038131	1,25 cm x 9,1 m
0038132	2,5 cm x 9,1 m
0038133	5 cm x 9,1 m
0038134	7,5 cm x 9,1 m
0038125	1,25 cm x 5 m
0038126	2,5 cm x 5 m
0038127	5 cm x 5 m

PACKAGING

REFERENCE	DRESSING DIMENSIONS	UNITS PER CARTON	CARTONS PER BOX	UNITS PER BOX (SELLING UNIT)
0038131	1,25 cm x 9,1 m	24	30	720
0038132	2,5 cm x 9,1 m	12	30	360
0038133	5 cm x 9,1 m	6	30	180
0038134	7,5 cm x 9,1 m	4	30	120
0038125	1,25 cm x 5 m	24	40	960
0038126	2,5 cm x 5 m	12	40	480
0038127	5 cm x 5 m	6	40	240

The product is presented in 9.1 and 5 m rolls packed in cartons adapted to its shape and grouping.

The cartons are grouped together in IBERHOSPITEX, S.A. cardboard boxes for transport, with a label indicating:

- Company name
- Product code and description
- EC marking without ON
- Lot
- Units
- Production date
- Expiry date
- EAN 128 bar code
- Harmonised symbols

STORAGE

Store the product in regular medical material storage conditions: in a cold and dry place, protected from light.

COMMENTS AND PRECAUTIONS

The product can be used by both specialised medical personnel, in a surgical or ambulatory setting or at home.

- Do not apply to open or infected wounds.
- Do not apply under tension or to wet skin.
- Do not apply to burns.