

AVVERTENZE-ISTRUZIONI PER L'UTILIZZO

ITALIANO

Nomi commerciali: DERMADINE PLUS telo da incisione con antisettico iodato. Dermadine Plus è in classe II secondo la Direttiva 93/42/CEE

Composizione: DERMADINE PLUS: Polietileneharpaks, akrýlkæbæstef med iod, kaliumiodid.

⚠️ⓘ Prima di utilizzare il DM, leggere attentamente le istruzioni e le avvertenze.

Indicazioni d'uso: I telì da incisione della linea Dermadine Plus sono indicati per l'ultima-azione del campo operatorio a protezione della cute come barriera meccanica al passaggio di microorganismi prima dell'incisione chirurgica in tutti gli interventi operatori. Nel DM Dermadine Plus l'azione anticellulare antisettica dello iodio supporta l'attività di disinfezione e barriera esercitata dal telo durante l'intervento.

Avvertenze speciali: Il DM è un materiale plastico non conduttivo, in casi di defibrillazione o manovre dove è richiesto dispositivo elettrico, rimuovere il film dal skin. **Avvertenze su tenuta adesiva:** Per avere la massima tenuta del DM sulla cute del paziente, assicurarsi che la cute sia perfettamente asciutta. Nell'applicazione evitare la formazione di pieghe o bolle di aria. **Avvertenze su adesivo:** Nel caso si riscontrino piccoli punti o addensamenti di colore marrone scuro o ambrati sull'adesivo del DM questi non rappresentano né una barriera esercitata dal telo durante l'intervento. **Controindicazioni:** Non usare su pazienti con sensibilità nota ai materiali con cui è realizzato il DM. **Effetti indesiderati dello iodio:** non usare Dermadine Plus in soggetti con sensibilità nota allo iodio o complessi iodurati. L'interazione dello iodio con l'acetone può portare alla formazione di composti irritanti. Il Dermadine Plus è biocompatibile ma si potrebbero manifestare a livello della cute effetti quali bruciore, iododerma, eruzioni anemiformi, diminuzione della velocità di cicatrizzazione dei tessuti, irritazione delle mucose. In caso di reazione allergica togliere il telo, contattare il medico e avviare la terapia ospedaliera.

Istruzioni per l'uso: Fig.1 Togliere il telo da incisione dal SBS sterile. Rimuovere la successiva protezione in carta. Fig.2 Disiniettare il sito chirurgico secondo le metodiche definite dalla S. Operatoria. Assicurare tamponando l'area disinfeziata prima di applicare il film Dermadine Plus. Assicurarsi che la cute del paziente sia perfettamente asciutta. Fig.3 Effettuare la disinfestazione del telo Dermadine Plus da entrambi i lati. Svolgerlo mantenendo il telo in tensione. Rimuovere la protezione inferiore tirando centralmente, lentamente e mantenendo un angolo di 90° con il film. Evitare distacchi forcati e trasversali. Fig.4 Con il telo disteso e posto a pochi cm dalla cute asciutta del paziente applicarlo nell'area chirurgica conformando alle necessità del chirurgo. Fig.5 Su una gara sterile, fare pressione sulla linea di incisione e senza tenderlo eccessivamente muoversi verso l'esterno. Fare attenzione ad evitare formazione di pieghe o bolle di aria.

Fig.6 Per rimuovere il telo, staccarlo delicatamente formando un angolo di 180° con la cute ripiegandolo su se stesso. Durante la rimozione il telo deve essere il più vicino possibile alla cute. Evitare tensioni eccessive. Usare la massima cautela in caso di cute particolarmente fragile e/o con scarsa elasticità, al fine di evitare possibili ferite o danni al paziente, soprattutto nella zona di incisione.

Precauzioni e Avvertenze: Monouso. La sterilità del DM è garantita a confezione intatta. Operare con cautela durante la sterilità. Scartare ogni busta danneggiata o non perfettamente sigillata. Il DM deve essere usato solo da personale qualificato. L'utilizzatore è responsabile del corretto impiego. Il DM è esclusivamente per uso esterno. Il DM è inteso per essere utilizzato una sola volta e su un singolo paziente. Non sono ammessi sterilizzazioni o riutilizzo. Non utilizzare il DM dopo la data di scadenza indicata sulla confezione.

Preservation methods: Store the product at room temperature, protected from light and humidity, in ventilated environments, raised off the floor, in its own protective packaging. Keep away from excessive temperatures or humidity. **Storage:** Irradiation. **Disposal:** Dispose of the DM after use in accordance with the national laws in force for potentially contaminated DM.

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TIASET, DERMADINE PLUS è un marchio registrato di TIASET di Carresi Lorenzo.

BRUGSVEJLEDNING

DANISH

Mærkenavn: DERMADINE PLUS incisionsfilm med antisæptisk iod Dermadine Plus tilhører klasse III i henhold til direktiv 93/42/EØF

Sammensætning: DERMADINE PLUS: Polyurethanharpaks, akrýlkæbæstef med iod, kaliumiodid.

⚠️ⓘ Læs disse vejledninger og advarsler grundigt inden brug af Medical De-vice (MD).

Brugsvejledning: Dermadine Plus er beregnet til at beskytte huden under kirurgiske indgreb, hvor det fungerer som en mekanisk barriere der forhindrer overføring af mikroorganismer inden incision. I DM Dermadine Plus hjælper iodets antisæptiske virkning til med den desinfektion og barriere, som afdækningen underligger endregret.

Særlige advarsler: MD er et ikke-ledende plastmateriale, så ved defibrillering eller procedur, som forudsætter brug af elektriske apparater, fjernes filmen fra huden.

Advarsler om klæbeevnen: Huden skal være fuldstændig tør inden påføring for at garantere maksimal adhesion. Under påføring af filmen må ingen folder eller luftbobler dannes. Advarsler om klæbeevnen: Huden skal være fuldstændig tør inden påføring for at garantere maksimal adhesion. Under påføring af filmen må ingen folder eller luftbobler dannes.

Advarsler om festemiddelet: Hvis det dannes mørkebrune eller orange flekker eller markeringer i festemiddelet på DM Dermadine Plus, betyder dette at det er nøgalt med produktet. Kontraindikationer: Använd inte Dermadine Plus på patienter med bekräftad överkänslighet mot iod eller jodforbinder. Interaktionen mellan iod och acetone kan resultera i uppkomst av föreningar som verkar irriterande på huden. Dermadine Plus är biokompatibel, men effekter som röt, hudinfektioner, akneliknande bultar, minskad ärrbildningsförmåga i vävnad och irriterade dermatit, kan förekomma på huden. I händelse av allergiska reaktioner: ta bort incisionsfilmen, kontakta läkare och meddela sjukhuspostet.

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Brugsvejledning: Fig. 1 Fjern incisionsfilmen fra den sterile SBS (indpakning). Fjern det ekstra papirbeskyttelse.

Fig. 2 Desinficer operationsområdet i henhold til operationsussens procedur, og sørg for, at det desinficerede område er fuldstændig tørt, inden Dermadine Plus påføres.

For at opnå det bedste resultat skal patientens hud være tør inden påføring.

Fig. 3 Hold i begge sider af de ikke-klæbende kantene på Dermadine Plus-folien. Pakk til foliens midte og hold den stramt. Fjern underlaget ved å d det forsigtigt fra midten, i en 90-graders vinkel på 90 grader i forhold til filmen. Hvis eller fjern ikke beskyttelsen på værs.

Fig. 4 Med filmen holdt några centimeter fra patientens hud (som ska vara helt torr) og applicer-na den sedan över ingreppsområdet efter behov.

Fig. 5 Använd steril gasväv för att trycka längs snittlinjen och jämna ut luft, utan att sträcka filmen för mycket. Sørg for, at der ikke er nogen folder eller luftbobler, som kan kompromit-tere filmens klæbeevne under det kirurgiske indgreb.

Fig. 6 Fjern filmen bider fra huden ved en vinkel på 180 grader, fra sår det imod hud selv.

Fig. 7 To hold filmen gennem alt det der er for påføring. For at sikre optimal tryk, skal du holde filmen på begge sider af de ikke-klæbende kanter på Dermadine Plus-folien. Pakk til foliens midte og hold den stramt. Fjern underlaget når du tar filmen fra kånigul hud eller hud med lidt elastisitet så at patientens hud ikke skades.

Förhållsregler og advarsler: Engangsbrug. Steriliteten af MD er garanteret, når indpakningen er forseglet. Bruges kun til sterile procedurer. Bortskaf alle beskadigede eller uløse-rogte emballager. MD kan kun bruges af kvalificerede operatører. Brugeren er ansvarlig for korrekt brug af produktet. MD er kun til udvortes brug. MD er beregnet til engangsbrug på en enkelt patient. Gensterilisering eller genanvendelse er forbudt. Brug ikke MD efter udløbsdatoens angivet på emballagen.

Opskrævningsmetoder: Opbevar produktet ved rumtemperatur, beskyttet mod lys og fugtighed, i omgivelser med god udluftning, hver op fra gulvet og i det gens beskyt-teselskabning. Holdes væk fra højde, temperatur eller fugtighed. **Steriliseringsmiddelet:** Bestråling. **Bortskaffelse:** MD bortskaffes efter brug i henhold til de gældende nationale love for potentielt kontamineret MD.

TIASET, DERMADINE PLUS er registrerede varemærke tilhørende TIASET di Carresi Lorenzo.

ISTRUCTIONS FOR USE

ENGLISH

Brand Name: DERMADINE PLUS incision film with iodine antiseptic Dermadine Plus is in class III according to the directive 93/42/CEE

Composition: DERMADINE PLUS: Polyurethaneplastic resin, acrylic adhesive iodine potassium iodide

⚠️ⓘ Read these instructions and warnings carefully before using Medical Device (MD).

Indications of use: Dermadine Plus are intended to protect the skin in surgical procedures, acting as a mechanical barrier which prevents the transfer of microorganisms before incision. Avec Dermadine Plus l'antiseptique auxiliaire action de iodine supports the disinfection and barrier activity exerted by the drape during the intervention.

Special warnings: MD is a non-conductive plastic material, so for defibrillation or procedures requiring the use of electrical devices, remove the film from the skin.

Warnings on adhesive capacity: To guarantee maximum adhesion ensure that the skin is perfectly dry before application. Make sure no creases or air bubbles form when applying the film. **Warnings on the adhesive:** The appearance of dark brown or amber colored dots or marks on the MD Dermadine Plus adhesive is not an imperfection or alteration of the product. **Contraindications:** Do not use on patients with acknowledged sensitivity to materials used to make Dermadine Plus. **Iodine side effects:** do not use Dermadine Plus in people with known sensitivity to iodine or iodophor compounds. The interaction of iodine with acetone can lead to the formation of irritating compounds. **Dermadine Plus** is biocompatible but effects such as burning, iododerma, acne-like eruptions, decrease in the rate of scarring of the tissues, irritation of the mucous membranes may occur at the level of the skin. In the case of allergic reaction, remove the towel, contact the doctor and notify the hospital pharmacy. **Conseils d'utilisation:** Fig. 1 Retirer la face li inciser de l'emballage stérile. Enlever la protection additionnelle en papier.

Fig. 2 Désinfecter la zone opératoire conformément aux méthodes définies par le bloc opératoire et assurer tamponnant l'aire désinfectée avant d'appliquer le film Dermadine Plus.

Fig. 3 Effortuer la désinfection du film Dermadine Plus des deux côtés avant d'appliquer.

Fig. 3 Tenez les deux bouts non adhésifs du Dermadine Plus Déballer le film le en maintenant sous tension.

Fig. 4 With the film held taut apply a few centimeters from the patient's perfectly dry skin, apply it to the surgical area according to requirements.

Fig. 5 Use a sterile gauge, to apply pressure along the incision line and smooth outwards without stretching the film excessively. Make sure there are no creases or air bubbles, which could compromise the film's adhesion properties, during surgery.

Fig. 6 To remove the film, peel it off the skin gently at an angle of 180 degrees and hold it only with the fingers. Avoid excessive pulling. Take extreme care when removing the film from the skin with little elasticity so as not to injure or damage the patient's skin.

Precautions and Warnings: Disposable. The sterility of MD is guaranteed when the pack-aging is sealed. Use for sterile procedures only. Discard all damaged or unsealed packages. MD must be used by qualified operators only. The user is responsible for using the product correctly. MD is for external use only. MD is designed for single use on a single patient. Re-sterilization or reutilization is prohibited. Do not use the MD after the expiry date indicated on the package.

Preservation methods: Store the product at room temperature, protected from light and humidity, in ventilated environments, raised off the floor, in its own protective packaging. Keep away from excessive temperatures or humidity. **Sterilising agent:** Irradiation. **Disposal:** Dispose of the DM after use in accordance with the national laws in force for potentially contaminated MD.

TIASET, DERMADINE PLUS is TIASET of Carresi Lorenzo registered trademarks.

MODE D'EMPLOI

Non commercial: DERMADINE PLUS film à inciser avec antiséptique iodé Dermadine Plus est certifié classe III selon la directive 93/42/CEE

Composition: DERMADINE PLUS: Résine plastique en Polyuréthane, Iode adhésif acrylique, Iodure de potassium

⚠️ⓘ Avant d'utiliser le dispositif médical veuillez lire attentivement les conseils d'utilisation et les avertissements.

Mode d'emploi: Dermadine Plus a pour but de protéger la peau pendant les interventions chirurgicales. En agissant comme une barrière mécanique il empêche le transfert de micro-organismes avant l'incision. Avec Dermadine Plus l'action auxiliaire antiséptique de l'ode désinfecte et crée une barrière défectieuse par le champ pendant l'intervention.

Avvertissements speciali: Ce DM est fabriqué à partir d'un film plastique non conducteur donc en cas de défibrillation ou de procédures nécessitant l'utilisation de dispositifs électriques, retirez le film de la peau.

Avvertissements commerciali: Adhèsivo: Afin d'obtenir une meilleure adhérence assurez-vous que la peau soit parfaitement sèche. Évitez la formation de plis ou de bulles d'air lors de l'application. **Avvertissements commerciali:** Adhèsivo: L'apparition de points ou de zones bruns foncés ou ambrés sur l'adhésif de DM Dermadine Plus ne constitue ni une imperfection ni une altération du produit. **Contre-indications:** N'utilisez pas sur les patients souffrant d'une sensibilité aux matériaux présents dans Dermadine Plus. **Effets indésirables liés à l'ode:** N'utilisez pas Dermadine Plus sur les patients souffrant d'une sensibilité à l'ode ou aux composés iodurés. Interaction de l'ode avec l'acétone peut mener à la formation de composés irritants. **Dermadine Plus** est biocompatible mais il pourrait avoir des effets sur la peau tels que brûlure, iododermie, éruptions de type acnéique, réduction du taux de cicatrisation des tissus, irritation des muqueuses. En cas de réaction allergique retirez le dispositif, contactez le médecin et avisiez la pharmacie hospitalière. **Conseils d'utilisation:** Fig. 1 Retirer la face li inciser de l'emballage stérile. Enlever la protection additionnelle en papier.

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GERBACHSANLEITUNG

GERMAN

Handelsbezeichnung: DERMADINE PLUS - INZISIONSFOLIE MIT JOBBESCHÜTUNG Dermadine Plus entspricht der Klasse III gemäß Medizinprodukte-Richtlinie 93/42/EG

Inhalt: DERMADINE PLUS: Polyurethan-Folie, Acrylklebstoff, Iod imprägniert

⚠️ⓘ Vor der Verwendung des Medizinproduktes lesen Sie die Anweisungen und Warnhinweise.

Wirkungsbereich: Dermadine Plus schützt die Haut und wirkt als mechanische Barriere, die die Übertragung von Mikroorganismen vor der Incision verhindert. In DM Dermadine Plus unterstützt die antiseptische Zusatzwirkung von Iod die Desinfektions- und Barriereaktivität, die das Tuch ausübt.

Anwendungsinformation: Das Medizinprodukt besteht aus nicht leitendem PE-Material. Entfernen Sie daher bei Defibrillation oder Verfahren, bei denen elektrische Geräte erforderlich sind, die Folie von der Haut.

Hinweise zum Halftern: Für eine bestmögliche Haftung muss die Haut absolut trocken sein. Beim Aufbringen sollen Falten oder Luftblasen vermieden werden. **Hinweise zum Klebstoff:** Dunkelbraune oder bräunliche Verfärbungen. Kleine Punkte oder Verdichtungen auf dem Klebstoff des Medizinproduktes stellen keine Mängel oder Veränderungen des Produktes dar.

Kontraindikationen: Nicht bei Patienten mit bekanntem Allergien gegen die Inhaltsstoffe von Dermadine Plus verwenden. Verwenden Sie Dermadine Plus nicht bei Personen mit bekannter Empfindlichkeit gegenüber Iod- oder Jodphor-Komplexen. Die Wechselwirkung von Iod mit Aceton kann Reizungen bewirken. Dermadine Plus ist biokompatibel, aber Effekte wie Brennen, Joddermie, aknelähnlicher Ausschlag, Verringerung der Narbenbildung im Gewebe und Reizung der Schleimhäute können dennoch auftreten. Bei allergischen Reaktionen die Folie entfernen, den Arzt kontaktieren und die hasierten Abfälle einsenden.

Anwendungsinformation: Abb. 1 Die Folie aus der sterilen Verpackung nehmen. Zusätzliche Schutzfolie entfernen.

Fig. 2 Desinfizieren die Operationsfläche gemäß den Hygienrichtlinien desinfizieren. Bitte stellen Sie sicher, dass die Haut des Patienten vor dem Applizieren der Folie trocken ist.

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Fig. 6 To remove the film, peel it off the skin gently at an angle of 180 degrees and hold it only with the fingers. Avoid excessive pulling. Take extreme care when removing the film from the skin with little elasticity so as not to injure or damage the patient's skin.

Precautions and Warnings: Disposable. The sterility of MD is guaranteed when the pack-aging is sealed. Use for sterile procedures only. Discard all damaged or unsealed packages. MD must be used by qualified operators only. The user is responsible for using the product correctly. MD is for external use only. MD is designed for single use on a single patient. Re-sterilization or reutilization is prohibited. Do not use the MD after the expiry date indicated on the package.

Preservation methods: Store the product at room temperature, protected from light and humidity, in ventilated environments, raised off the floor, in its own protective packaging. Keep away from excessive temperatures or humidity. **Sterilising agent:** Irradiation. **Disposal:** Dispose of the DM after use in accordance with the national laws in force for potentially contaminated MD.

Fig. 1 Retirer la face li inciser de l'emballage stérile. Enlever la protection additionnelle en papier.

Fig. 2 Désinfecter la zone opératoire conformément aux méthodes définies par le bloc opératoire et assurer tamponnant l'aire désinfectée avant d'appliquer le film Dermadine Plus.

Fig. 3 Effortuer la désinfection du film Dermadine Plus des deux côtés avant d'appliquer.

Fig. 3 Tenez les deux bouts non adhésifs du Dermadine Plus Déballer le film le en maintenant sous tension.

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