

UTILIZZO PREVISTO/INDICAZIONI PER L'USO

Denver Splint® è destinato a offrire supporto esterno a seguito di rinoplastica o fratture nasali.

Denver Splint è indicato per l'uso postoperatorio su pazienti sottoposti a rinoplastica e fratture nasali al fine di applicare una pressione delicata con la leggera imbottitura, per la riduzione dell'edema e la stabilizzazione esterna dei frammenti ossei.

LITENTE PREVISTO

Denver Splint è stato progettato per essere utilizzato da operatori sanitari, ad esempio medici specializzati in chirurgia estetica o plastica, chirurghi di traumatologia facciale e otorinolaringoiatri.

CONTROINDICAZIONI

SKIN-PREP® va utilizzato esclusivamente sulla cute intatta

AVVERTENZE E PRECAUZIONI

1. Non applicare il tutore direttamente sulla cute: in soggetti sensibili potrebbe causare una lieve sensibilizzazione. Tra la cute e il tutore frappare il cerotto.
2. Evitare l'uso prolungato. Non applicare il tutore su cute già irritata o con altre patologie causate infezioni e contagi oppure il tutore potrebbe non svolgere la sua funzione e recare danno al paziente.
3. Non inter-sferrilizzare.
4. Non utilizzare il prodotto in caso di imballaggio danneggiato o che appare aperto non intenzionalmente prima dell'uso oppure se l'imbutitura dorsale appare compressa.
5. Non usare in casi noti di lesioni gravi del tessuto molle che compromettono il flusso sanguigno alla pelle.
6. Rimuovere il tutore prima di eseguire radiografie, TC o risonanze magnetiche. I tutori possono alterare la qualità dell'immagine.
7. SKIN-PREP - Attenzione: causa grave irritazione agli occhi. Evitare il contatto con gli occhi - In caso di contatto: accendere, risciacquare accuratamente gli occhi con acqua pulita. In caso di comparsa di rossore o altri segni di irritazione, interrompere l'uso. Attenzione: potrebbe causare sonnolenza e vertigini.
8. Pericolo: liquido e vapore altamente infiammabili. Conservazione: mantenere asciutto e al riparo dalla luce, limite superiore di temperatura 25°C/77°F.
9. Prodotto Tape - Per una buona adesione la cute deve essere pulita, asciutta e non unta.

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PREPARAZIONE
*Per pannelli/fogli termoplastici e serie 4000: preriscaldare l'unità oppure riscaldare l'acqua a 71-82°C (160-180°F)

For use with the Denver Split is intended to provide external support after rhinoplasty or nasal fractures. The Denver Split is indicated to be used postoperatively on rhinoplasty and nasal fracture patients to provide cushioned pressure to reduce edema and to provide external stabilization of bony fragments.

INTENDED USER: The Denver Split is intended to be used by healthcare professionals, such as, plastic and cosmetic surgeons, facial trauma surgeons, and otolaryngologists.

CONTRAINDICATIONS: SKIN-PRÉP® for use on intact skin only.

- WARNINGS AND PRECAUTIONS**
- Do not apply splint directly to skin—may cause mild sensitization in certain sensitive individuals.
 - Apply paper tape first.
 - For Single Use Only. Do not reuse. Reuse of device could result in infection, contamination or device failure which could lead to patient harm.
 - Do not resterilize.
 - Do not use if package is damaged or unintentionally opened prior to use, or if dorsal pad is compressed.
 - Do not use in known cases of severe soft tissue injuries that compromise blood supply to the skin.
 - Remove splint prior to X-ray, CT or MRI imaging. Splints may interfere with image quality.
 - SKIN-PRÉP - Warning: causes serious eye irritation. Avoid contact with eyes. In the case of accidental contact, flush eyes well with water. Should redness or other signs of irritation appear, discontinue use. Warning: may cause drowsiness and dizziness. Store: Keep dry and away from sunlight, upper temperature limit of 25°C/77°F.
 - Protecto Tape - Skin should be clean, dry, and free of oils to assure good adhesion.

APPLICATION INSTRUCTIONS

PREPARATION
*For series 4000 and Thermoplastic Sheets/Flats: Preheat unit or heat water to 160-180°F (71-82°C)

- Cleanse and dry skin of nose.
- Use alcohol sponge to wipe nose. Dry skin of nose after wiping.
- Express edema manually from skin.
- Apply a uniform coating of SKIN-PRÉP® to nasal skin and allow to dry (approximately 30 seconds).
- If an area intended to be covered is missed, wait until SKIN-PRÉP has dried then reapply.
- Apply edema again.
- Apply overlapping paper tape to nose.

APPLICATION

Series 1500 Kit & Non-Kit

- Trim dorsal pad length to fit splint size. Apply center dorsal pad vertically to tape on the dorsum of the nose. **DO NOT TOUCH SKIN WITH DORSAL PAD.**
- Remove paper backing from Velcro® (i.e. adhesive segment) of splint and apply to paper tape on nose. **DO NOT TOUCH SKIN WITH SPLINT.** Narrow end of splint should point toward nasofrontal angle.
- Shape metal segment of splint and attach to Velcro.

DO NOT TOUCH SKIN WITH SPLINT.

- Mold by bending wings of splint toward face to make Velcro contact. **DO NOT PINCH.**

Series 2000 Kit & Non-Kit

- Trim dorsal pad length to fit splint size. Apply center dorsal pad vertically to tape on the dorsum of the nose. **DO NOT TOUCH SKIN WITH DORSAL PAD.**
- Remove paper backing from adhesive side of splint.
- Shape metal. Apply adhesive side of splint to tape on the nose. **DO NOT PINCH.**

DO NOT TOUCH SKIN WITH SPLINT.

- Apply softened splint and mold over the nose.
- If further molding is required, remove splint, re-soften in hot water and reapply.
- When in place, the splint should touch only the underlying tape and should not touch the skin.

Series 4000 Kit & Non-Kit

- Trim dorsal pad length to fit splint size. Apply center dorsal pad vertically to tape on the dorsum of the nose. **DO NOT TOUCH SKIN WITH DORSAL PAD.**
- Soften splint in 160-180°F (71-82°C) water for 30 to 60 seconds.
- Remove splint from water using forceps or a tongue depressor to avoid burning fingers.
- Mold briefly on towel. The splint will cool but remain workable for approximately one minute.
- Apply softened splint and mold over the nose.
- If further molding is required, remove splint, re-soften in hot water and reapply.
- When in place, the splint should touch only the underlying tape and should not touch the skin.

Series 5000 Kit & Non-Kit

- Remove paper backing from adhesive segment of Velcro® Loop Splint Segment and apply to paper tape on nose. Narrow end of Velcro Loop Splint Segment should point toward nasofrontal angle.
- Shape metal segment of splint and attach hook Velcro to loop splint segment.
- Attached dorsal pad will be vertical on dorsum of the nose. Mold by bending wings of splint toward the face to make Velcro contact. **DO NOT PINCH. DO NOT TOUCH SKIN WITH SPLINT.**

Thermoplastic

- Design desired shape using gauze or paper towel. Check fit to patient.
- Place shape over Thermoplastic Sheet/Flat and cut splint shape with bandage scissors.
- Soften splint in 160-180°F (71-82°C) water for 30 to 60 seconds.
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Utilisation PRÉVUE/RECOMMANDATIONS D'UTILISATION
L'attelle nasale Denver Split® est un dispositif conçu pour fournir un soutien externe à une rhinoplastie ou une fracture nasale.
L'attelle nasale Denver Split est indiquée pour une utilisation post-opératoire après une rhinoplastie ou une fracture nasale. Elle procure une pression et une protection afin de réduire les oedèmes et de stabiliser les fragments osseux de façon externe.

UTILISATEUR PRÉVU
L'attelle nasale Denver Split doit être utilisée par des professionnels de la santé, par exemple des chirurgiens plastiques et esthétiques, des chirurgiens spécialisés en traumatologie faciale ou des otorhinolaryngologistes.

CONTRA-INDICATIONS
SKIN-PRÉP® doit être utilisé sur de la peau saine uniquement.

AVERTISSEMENTS ET PRÉCAUTIONS

- Ne pas appliquer l'attelle directement sur la peau : cela pourrait entraîner une sensibilisation chez certains patients. Appliquer d'abord une bande de papier.
- Usage unique exclusivement. Ne pas réutiliser. Toute réutilisation de ce dispositif est susceptible d'entraîner une infection, une contamination ou une défaillance du dispositif, qui pourrait provoquer des blessures chez le patient.
- Ne pas resteriliser.
- Ne pas utiliser si l'emballage est endommagé ou ouvert par inadvertance avant utilisation, ou si le cossinnet dorsal est aplati.
- Ne pas utiliser dans les cas avérés de détérioration sévère des tissus mous compromettant l'apport sanguin vers la peau.
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- Ne pas utiliser dans les cas avérés de détérioration sévère des tissus mous compromettant l'apport sanguin vers la peau.
- Retirer l'attelle avant tout examen radiologique, scanographique ou IRM. Les attelles peuvent nuire à la qualité de l'image.
- SKIN-PRÉP® - Avertissement : peut provoquer une sévère irritation des yeux.
- SKIN-PRÉP® - Attention : causes sérieux de contact accidentel, rincer abondamment les yeux avec de l'eau Si une ougueur ou tout autre signe d'irritation apparaît, cesser d'utiliser le produit. Avertissement : Peut provoquer une somnolence et des étourdissements. Danger : Liquide et vapeur hautement inflammables.
- Stockage : Conserver au sec, à l'abri du soleil. La température ne doit pas dépasser 25°C/77°F.
- Protecto Tape - Pour assurer une bonne adhérence, la peau doit être propre, sèche et exempte de graisse.

INSTRUCTIONS D'UTILISATION

PRÉPARATION
*Série 4000 et feuilles thermoplastiques : Préchauffer le dispositif ou faire chauffer de l'eau à 71-82 °C (160-180 °F).

Application

- Nettoyer et sécher la peau du nez.
- Passer un tampon imbibé d'alcool sur le nez, puis l'essuyer. Sécher la peau du nez après nettoyage.
- Évacuer le liquide de l'œdème en exerçant une pression à la main.
- Appliquer une couche uniforme de SKIN-PRÉP® sur la peau du nez et laisser sécher (environ 30 secondes). Si une zone cible n'a pas été couverte, attendre que le SKIN-PRÉP ait séché, puis procéder à une nouvelle application.
- Retirer la pression sur l'œdème.
- Appliquer la bande de papier à cheval sur le nez.

DO NOT TOUCH SKIN WITH SPLINT.

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Series 1500 Kit & Non-Kit

- Trim dorsal pad length to fit splint size. Apply center dorsal pad vertically to tape on the dorsum of the nose. **DO NOT TOUCH SKIN WITH DORSAL PAD.**
- Remove paper backing from Velcro® (i.e. adhesive segment) of splint and apply to paper tape on nose. **DO NOT TOUCH SKIN WITH SPLINT.** Narrow end of splint should point toward nasofrontal angle.
- Shape metal segment of splint and attach to Velcro.

DO NOT TOUCH SKIN WITH SPLINT.

- Mold by bending wings of splint toward face to make Velcro contact. **DO NOT PINCH.**

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- Soften splint in 160-180°F (71-82°C) water for 30 to 60 seconds.
- Remove splint from water using forceps or a tongue depressor to avoid burning fingers.
- Mold briefly on towel. The splint will cool but remain workable for approximately one minute.
- Apply softened splint and mold over the nose.
- If further molding is required, remove splint, re-soften in hot water and reapply.
- When in place, the splint should touch only the underlying tape and should not touch the skin.

DO NOT PINCH. DO NOT TOUCH SKIN WITH SPLINT.

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