Mepitel® One Soft Silicone Wound Contact Layer
Instructions for use

Product Description

Mepitel One is a transparent and soft wound contact dressing, with one side composed of the porous polyamide film applied with adherent silicone (Safetac).

Safetac® technology

Safetac® is a soft silicone adhesive technology that reduces pain and trauma to the wound surface. Safetac® technology is less painful because it:

1. Can be gently adhered to dry surfaces such as skin, but not to wet surfaces such as open wounds;
2. Covers skin pores and more skin surface to prevent peeling from the skin;
3. Sealing the wound area to ensure that exudate does not spread to the surrounding skin and reduce the risk of maceration.

Mode of Action

- Mepitel One is not absorbent. The open perforated structure allows exudate to pass vertically into a secondary absorbent dressing pad, which must be changed as required by the conditions of the wound and the amount of exudate in order to prevent maceration.
- The integrity of the Mepitel One dressing reduce the necessity for frequent primary dressing changes and allows secondary dressing changes with minimised pain as required. Due to the non-sticky top surface and adequate adhesion to skin it is also possible to use Mepitel One as a stand alone product for protection of damaged skin.
- Mepitel One can be used under compression bandages.
- Mepitel One can be cut to different sizes to suit the shape and location of the wound.

Intended use

Mepitel One is a wound contact layer dressing designed for the treatment of exudative wounds on the body surface such as surgical incisions, partial thickness burns, diabetic foot and surgical trauma (abrasions, lacerations).

Instructions for use

Mepitel One with this symbol can help you apply and remove the dressing on skin tears. For these wounds, there is a risk of re-opening the flap when removing the dressing. Apply the dressing with the arrow pointing in the

same direction as the flap. Start application from the base of the flap. When removing the dressing, begin removal following the printed symbol, in the direction the arrow is pointing.

1. Cleanse the wound in accordance with clinical practice and dry the surrounding skin thoroughly.
2. Choose a size of Mepitel One that covers the wound and the surrounding skin by at least 2 cm. For larger wounds, more overlap is required. If more than one piece of Mepitel One is used, overlap the dressings. Make sure that the holes are not blocked.
3. Remove the protective plastic layers and apply Mepitel One with the sticky side to the wound.
4. The dressing is applied in a correct way when you can read the text printed on the dressing. Smooth the dressing in place onto the surrounding skin to get a good seal.
5. Apply an outer absorbent dressing, on top of Mepitel One and fixate.

Dressing change

Mepitel One may be left in place for up to 7 days depending on the condition of the wound and surrounding skin, or as indicated by clinical practice. To prevent maceration, exudate should pass freely through the dressing and the holes should not be blocked.

If the absorption of the secondary dressing pad reaches saturation, it should be replaced, while the Mepitel One does not need to be replaced.

The Mepitel One can be used independently.

Warning

Mepitel One should be used correctly to avoid leaving marks when used for mesh skin grafting after burns or facial plastic surgery.

Precautions

- If you see signs of infection e.g. fever or the wound or surrounding skin becoming red, warm or swollen, consult a health care professional for appropriate treatment.
- If Mepitel One is used on Epidermolysis Bullosa patients, employ extra surveillance at dressing changes. When used on partial thickness burns with high risk of rapid granulation, avoid placing pressure on the dressing.
- When used on after facial resurfacing, pressure should be avoided when removing the dressing, lift and reposition the dressing at least every second day.
- When used on bleeding wounds or wounds with high viscosity exudate, Mepitel

One should be covered with a moist absorbent dressing pad.

- When using Mepitel One for the fixation of skin grafts and protection of blisters, the dressing should not be changed before the fifth day post application.
- Determine the replacement frequency based on physician's clinical procedures.

Storage

Mepitel One should be stored in a dry environment at room temperature.

Sterilization

Mepitel One is sterilized by ethylene oxide. Do not use if inner package is damaged or opened prior to use.

Do not re-sterilize.

Product model/ specification

Product model	Specification
289000	5×7cm
289100	5×7.5cm
289170	6×7cm
289200	8×10cm
289270	9×10cm
289300	7.5×10cm
289400	12×15cm
289470	13×15cm
289500	10×18cm
289700	17×25cm
289670	24×27.5cm

Period of validity: 3 years.

Manufacturer

Manufacturer：Mölnlycke Health Care AB
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Revision No.：20161486 REV.7WF

Mölnlycke®

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Website: www.molnlycke.cn

Registration number: 国械注进20162141486

Technical Requirement No.: 国械注进20162141486

Production date/expiration date: see label.

Revision date: 3th Jun 2025

Revision No.: 20161486 REV.7WF

Logo description：

LOT	Batch code		Do not re-use
	Expiry date	STERILE EO	Sterilize Sterilization method: ethylene oxide sterilization
REF	Catalogue number		Single sterile barrier system
	Manufacturer		Do not use if package is damaged
MD	Medical device		Caution. See instructions for use
CE 2797	CE-mark with Notified Body identification number Compliant with European Medical Device Regulation (MDR)		

版本号：20161486 REV.7WF

Mepitel® One Soft Silicone Wound Contact Layer
自粘性软聚硅酮伤口敷料
使用说明书

产品说明
自粘性软聚硅酮伤口敷料是一种透明、柔软的伤口接触层敷料，一面由涂有软聚硅酮粘胶（司肤泰克）的多孔的聚酰胺薄膜组成。

司肤泰克®技术
司肤泰克®是一种软聚硅酮粘胶技术，可以减少病人的痛苦和对创面的创伤。司肤泰克®技术较少疼痛的原因是它：

1. 可轻柔地粘贴在干燥的表面，如皮肤，但不粘附于湿润的表面，如开放性创面；
2. 覆盖皮肤毛孔和较多的皮肤表面，防止从皮肤上剥离；
3. 创面区域的密封，保证渗液不波及周围皮肤以及减少浸渍风险。

作用机理
自粘性软聚硅酮伤口敷料不具有吸水性，创面渗出液是通过开放的网状孔进入到二级吸收性敷料垫，二级敷料要根据创面和渗出液量状况进行更换以避免浸渍发生。

自粘性软聚硅酮伤口敷料和软聚硅酮粘胶技术的结合减少了频繁更换初级敷料的必要性；也减轻了更换二级敷料时的疼痛。由于自粘性软聚硅酮伤口敷料跟皮肤有足够的附着力，并且不粘连皮肤表面，因此可以单独使用自粘性软聚硅酮伤口敷料来保护受损皮肤。

自粘性软聚硅酮伤口敷料可与包扎绷带结合使用。

自粘性软聚硅酮伤口敷料可以剪切成不同的尺寸以适合创面形状和位置。

适用范围
自粘性软聚硅酮伤口敷料是一种伤口接触层敷料，用于体表渗出性伤口的治疗，包括手术切口、二度烧伤、糖尿病足及外科创伤（擦伤、裂伤）。

使用说明


带有此符号的自粘性软聚硅酮伤口敷料可以帮助您正确贴敷和去除用于皮肤撕裂伤保护的敷料。对于这些伤口，在移除敷料时存在重新打开皮瓣的风险。贴敷敷料时箭头，指向与皮瓣相同的方向。从皮瓣底部开始贴敷。取下敷料时，按照箭头指示的方向，按照打印的符号开始取下

1. 根据临床需要清洁创面并擦干周围皮肤。
2. 选择适合尺寸的自粘性软聚硅酮伤口敷料，覆盖住创面床和周围皮肤边缘至少 2 厘米。较大尺寸的创面需要更多的重叠。如果不只需要一片自粘性软聚硅酮伤口敷料，可以将自粘性软聚硅酮伤口敷料重叠使用，但要确保网孔没

有被阻塞。
3. 揭开自粘性软聚硅酮伤口敷料保护膜，并将自粘性软聚硅酮伤口敷料粘性的一边放在创面床上。
4. 揭开保护膜并将自粘性软聚硅酮伤口敷料平坦地敷于创面周围皮肤上，以确保很好的封闭周围皮肤。
5. 在自粘性软聚硅酮伤口敷料上可以使用二级吸收性敷料。

更换频率

根据创面或皮肤条件情况（渗出液应能自由通过敷料，网孔不被阻塞）自粘性软聚硅酮伤口敷料可在一般创面上最长保留 7 天，但应根据临床操作规程和伤口的具体情况由医生进行判断。

如果二级敷料垫的吸收量达到饱和，则应更换，而自粘性软聚硅酮伤口敷料可以不用更换。

自粘性软聚硅酮伤口敷料是可以独立使用的敷料。

警示

自粘性软聚硅酮伤口敷料用于烧伤后的网状植皮或面部整形时，应当正确使用以免留下印痕。

注意事项

- 根据临床实践，若发现创面有感染的迹象，应请医疗专家（专业人士）给予适当的医学治疗。
- 自粘性软聚硅酮伤口敷料用于大疱表皮松懈症患者时，更换敷料时要特别注意。自粘性软聚硅酮伤口敷料用于烧伤中的网状植皮时，应避免在敷料上施以不必要的压力。
- 自粘性软聚硅酮伤口敷料用于面部整形时，揭起敷料时应避免加压，至少每隔一天要将自粘性软聚硅酮伤口敷料重新放置。
- 当用于出血创面或有较多粘性渗出液的创面时，自粘性软聚硅酮伤口敷料上应覆以吸收性敷料垫。
- 自粘性软聚硅酮伤口敷料用于皮肤移植片固定时，应在使用 5 天后更换。
- 根据医生的临床操作规程确定更换频率。

储存

自粘性软聚硅酮伤口敷料应常温储存于干燥环境中。

灭菌

本产品经环氧乙烷灭菌，无菌包装。如使用前包装破损或打开，请勿使用。不可再次消毒使用。

有效期：3 年

版本号：20161486 REV.7WF

规格型号

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注册人/生产企业

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代理人及售后服务单位联系方式

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医疗器械注册证号：国械注进 20162141486

产品技术要求编号：国械注进 20162141486

生产日期/失效日期：见标签

中文说明书版本日期：2025 年 6 月 3 日

版本号：20161486 REV.7WF

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Mölnlycke®

标识说明：

LOT	批号		一次性使用
	使用期限	STERILE EO	无菌 灭菌方式：环氧乙烷灭菌
REF	产品代码		单层无菌屏障系统
	制造商		如包装破损 请勿使用
MD	医疗器械		注意.参阅说明书
CE 2797	带有公告机构识别号的 CE 标志 符合欧洲医疗器械法规（MDR）		