Mölnlycke®

Mepilex® Lite
Instruction for Use

Product description

Mepilex Lite is an absorbent self-adhesive soft silicone foam dressing, its composition is as follows:
A layer of soft silicone wound contact layer, a layer of polyurethane foam absorption layer, a layer of breathable and waterproof outer membrane.

Safetac ® technology

Safetac® it is a technology of soft silicone, which can reduce the patient's pain and trauma to the wound. The reason why Safetac ® technology is less painful is because it:
1. Gently stick on a dry surface, such as skin, but will not stick on a wet surface, such as an open wound;
2. Covers skin pores and more skin surface, thereby preventing it from being peeled off on the skin;
3. Sealing the wound area, to reduce risk of maceration.

Mode of action

Mepilex Lite is a highly conformable dressing that absorbs exudates, maintains a moist wound environment.
The Safetac layer will seal the edges of the wound, preventing exudates from leaking into the surrounding normal skin, reducing the risk of maceration.
Mepilex Lite can be cut according to the shape and position of the wound.
Mepilex Lite can be combined with the use of bandages.

Intended use

Mepilex Lite can be used for the management of non to low exuding wounds such as leg and foot ulcers, pressure ulcers, partial thickness burns, radiation skin reactions and Epidermolysis Bullosa. Mepilex Lite can also be used as a protection of compromised and/or fragile skin.

Instruction for use

1. Cleanse the wound in accordance with clinical practice.
2. Thoroughly dry the skin around the wound.
3. Select an appropriate dressing size. The dressing should cover the dry surrounding skin by at least 1–2 cm for small sizes (sizes up to 12,5×12,5 cm) and 3–5 cm for large sizes. If required, the dressing may be cut to suit various wound shapes and locations.
4. Remove the first release film and apply the adherent side to the wound.
5. Remove the remaining release film and smooth down the dressing on the skin. Do not stretch the dressing.

6. When necessary, fixate the dressing with a bandage or other fixation.

Replacement frequency

Mepilex Lite can be kept on the wound for several days according to the wound condition and surrounding skin condition, or as indicated by clinical practice.
A change in dressing regimen may result in an initial increased level of exudate that temporarily may require an increased frequency of dressing changes.
Disposal should be handled according to local environmental procedures.

Precautions

- Do not use on patients with known hypersensitivity to the dressing or its materials.
- Do not use together with oxidising agents such as hypochlorite solutions or hydrogen peroxide.
- If you see signs of clinical infection e.g. fever or if the wound or surrounding skin becomes red, warm or swollen, consult a health care professional for appropriate treatment.
- Mepilex Lite is ethylene oxide sterilization of aseptic packaging, such as packaging is damaged or opened prior to use, do not use. This product cannot be sterilized again for use.
- Do not reuse, if reused performance of the product may deteriorate and cross contamination may occur.

Storage

Mepilex Lite should be stored in a dry environment below 35°C (95°F) and protected from light.

Sterilization

Sterile packaging, sterilized with ethylene oxide. Do not use if sterile barrier is damaged or opened prior to use.

Do not re-sterilise.

Do not use expired products.

Shelf-life: Three years.

Other information

If any serious incident has occurred in relation to the use of Mepilex Lite, it should be reported to Mölnlycke Health Care and to your local competent authority.
Mepilex® and Safetac® are registered trademarks of Mölnlycke Health Care AB.

Specifications

Model	Specification（cm × cm）
284000	6 × 8.5
284100	10 × 10

Mölnlycke®

284123	12.5×12.5
284300	15 × 15
284500	20 × 50

Registrant/Manufacturer

Name: Molnlycke Health Care AB 瑞典墨尼克医疗用品有限公司
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Registration License Number: 国械注进 20173141524
Product Technical Requirements No.: 国械注进 20173141524
Chinese IFU version date: 11th Jun, 2025
Chinese IFU version: 20171524 REV.6WF
See the Chinese label for other content

Symptom indication:

	Do not re-use	REF	Catalogue number
	Keep dry	UDI	Unique Device Identifier
	Expiry date	STERILE EO	Sterilize Sterilization method: ethylene oxide sterilization
LOT	Batch code		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：20171524 REV.6WF

Mepilex® Lite
自粘性软聚硅酮泡沫敷料
使用说明书

产品说明：

自粘性软聚硅酮泡沫敷料是一种具有吸水性的软聚硅酮泡沫敷料。它的构成如下：

一层软聚硅酮伤口接触层，一层聚氨酯泡沫吸收层，一层透气并防水的外敷薄膜。

司肤泰克®技术

司肤泰克®是一种软聚硅酮技术，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. 轻轻地粘贴在干燥的表面，如皮肤，而不会粘贴在湿润的表面，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，减少浸渍风险。

作用机理

自粘性软聚硅酮泡沫敷料是一种十分舒适的敷料，它可以吸收渗液保持一个平衡湿润的伤口愈合环境。

司肤泰克层封闭创口的边缘，防止渗出物渗漏到周围正常皮肤，减少创口的浸渍。

自粘性软聚硅酮泡沫敷料可根据伤口的形状和位置作相应的裁剪。

自粘性软聚硅酮泡沫敷料可以结合绷带一起使用。

适用范围

自粘性软聚硅酮泡沫敷料可以用于无渗液或少渗液的创口，例如腿部和足的溃疡、褥疮、中度皮肤烧伤、皮肤放射性灼伤以及大疱性表皮松懈症。自粘性软聚硅酮泡沫敷料也可用来保护易受损伤的脆弱皮肤。

使用说明

1. 按照临床惯例清洁伤口。
2. 彻底拭干伤口周围皮肤。
3. 选择合适的敷料尺寸。小尺寸的敷料应覆盖干燥的周围皮肤至少 1-2 厘米（尺寸可达 12.5×12.5cm），大尺寸的敷料应覆盖 3-5 厘米。如果需要，敷料可以被裁剪以适应不同的伤口形状和位置。
4. 取下第一个护页，将具有粘性的一面敷于伤口。
5. 去除剩余的护页，将敷料平铺于伤口。避免伸拉。
6. 有必要时，可以用绷带或其他固定物固定自粘性软聚硅酮泡沫敷料。

更换频率

自粘性软聚硅酮泡沫敷料根据伤口条件和周围皮肤的情况可以在伤口上保留达数天，或根据临床的具体情况使用。

敷料使用方式的改变可能会导致渗出液的初始水平增加，从而暂时需要增加敷料更换的频率。

应按照当地环境程序进行处置。

注意事项

已知对敷料或其材料过敏的患者请勿使用。

请勿将自粘性软聚硅酮泡沫敷料与次氯酸盐溶液或过氧化氢等氧化剂同时使用。

若出现临床感染的征象，例如发烧，伤口或周围皮肤变红、发热或肿胀，请咨询医务人员，以得到适当的抗感染治疗。

自粘性软聚硅酮泡沫敷料为环氧乙烷灭菌的无菌包装，如使用前包装破损或打开，请勿使用。本产品不能再次灭菌使用。

禁止重复使用。如果重复使用，产品的性能则可能恶化，并可能发生交叉感染。

储存

自粘性软聚硅酮泡沫敷料应避光储存在 35℃（95°F）以下的干燥环境中。

灭菌

无菌包装，经环氧乙烷灭菌，如果内包装在使用前破损或打开，请勿使用。

请勿再次灭菌使用。

请勿使用过期产品。

其他信息

如果发生任何与使用自粘性软聚硅酮泡沫敷料相关的严重事件，应向 Mölnlycke Health Care 和您当地的主管部门报告。

Mepilex®和司肤泰克®是瑞典墨尼克医疗用品有限公司的注册商标。

有效期：三年

规格型号

型号	规格（cm×cm）
284000	6×8.5
284100	10×10
284123	12.5×12.5
284300	15×15
284500	20×50

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注册人/生产企业

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医疗器械注册证编号：国械注进 20173141524

产品技术要求编号：国械注进 20173141524

生产日期/失效日期：见标签

中文说明书修订日期：2025 年 6 月 11 日

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标识说明：

	一次性使用		产品代码
	保持干燥		医疗器械唯一标识
	使用期限		无菌 灭菌方式：环氧乙烷灭菌
	批号		单层无菌屏障系统
	制造商		如包装破损 请勿使用
	医疗器械		注意.参阅说明书
	带有公告机构识别号的 CE 标志 符合欧洲医疗器械法规（MDR）		