Version No.: 20163315 REV.5WF



Mepitel® Silicone Wound Contact Layer IFU

Product description

The Mepitel[®] Silicone Wound Contact Layer is composed of a silicone-coated polyamide mesh, protected on both sides by polyethylene films which must be removed prior to use. The dressing is made from medical-grade polyethylene, polydimethylsiloxane, and polyamide 6.

Safetac® technology

Safetac® is a soft silicone adhesive technology designed to minimize pain to patient and trauma to wounds and the surrounding skin at dressing removal.

Mechanism of action

The microporous, open mesh structure of the Mepitel® Silicone Wound Contact Layer allows vertical flow of exudate into the secondary absorbent dressing, preventing exudation from the side. This dressing also reduces the need for frequent changes of the primary dressing.

Indications for use

The Mepitel® Silicone Wound Contact Layer consists of a silicone-coated polyamide mesh and is intended for the management of the following wound types: skin tears, skin abrasions, surgical incisions, traumatic wounds, second-degree burns, epidermolysis bullosa, partial and full thickness grafts, diabetic ulcers, and venous or arterial ulcers.

Instructions for use

- 1. Cleanse the wound thoroughly and dry the surrounding skin.
- 2. Choose an appropriate size of Mepitel that covers the wound and the surrounding healthy skin by at least 1 cm. Mepitel can be cut to size as needed before removing the protective film. If more than one piece of Mepitel is required, overlap the dressings, making sure that the pores are not blocked.
- 3. While holding the larger protective film, remove the smaller one. Moisten gloves to avoid adherence to Mepitel.
- 4. Smooth Mepitel in place onto the surrounding skin, ensuring a good seal.
- 5. Apply a secondary absorbent dressing pad on top of Mepitel. In contoured or jointed areas (e.g. under arm, under breast, inner elbow, groin, deep wounds), ensure sufficient padding is applied to keep the Mepitel held flat against the surface of the wound.
- 6. Fix in place with a suitable fixation device, such as a bandage.

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Frequency of change

- Depending on the condition of the wound (the exudate could pass freely through the dressing and the holes are not blocked), Mepitel may remain in place for several days.
- When the secondary absorbent dressing is saturated it should be changed with Mepitel left in place.
- Mepitel is a dressing that can be used alone. If signs of unanticipated wound deterioration occur, please consult a clinician promptly.
- The cumulative duration of use for this product should not exceed 30 days.
- When used for mesh grafting following burns or facial resurfacing, please ensure correct application to avoid leaving marks.

Precaution(s)

- During the clinical practice, if you see signs of infection, consult a health care professional for appropriate drug therapy.
- When Mepitel is used for mesh grafting in burn patients, avoid unnecessary pressure on the dressing.
- When Mepitel is used for facial resurfacing, avoid placing pressure upon the dressing, lift and reposition the dressing at least every second day.
- When used on bleeding wounds or wounds with high viscosity exudate, Mepitel should be covered with a moist absorbent dressing pad.
- When Mepitel is used for the fixation of skin grafts and protection of blisters, the dressing should not be changed before the fifth day post application.

Storage

Store the product at room temperature in a dry environment.

Sterilization

The product is sterilized using ethylene oxide and is supplied sterile. Do not use if the package is damaged or opened prior to use.

For single use only. Do not re-sterilise.

Shelf life: 3 years.

Product models/specifications

Model	Dressing specification
290510	5×7.5cm
290710	7.5×10cm
291010	10×18cm
292005	20×30cm

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Registrant/manufacturer

Name: Mölnlycke Health Care AB

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Medical Device Registration Certificate No.: NMPA (I) 20162143315

Product Technical Requirements No.: NMPA (I) 20162143315

Date of Manufacture/Expiry Date: See the labels.

Chinese IFU Version Date: July 30, 2025

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Legend

LOT	Lot number	2	Single-use
REF	Product code	STERILE EO	Sterile Sterilization mode: EO
	Use-by date		Single-layer sterile barrier system
	Manufacturer		Do not use if the package is damaged
MD	Medical device	\triangle	Caution. Consult the IFU

CE marked with notified body identification number
Complies with the European Medical Device Regulation