

Product Specifications

Brand : Klinion®

Product : Kliniderm® Silicone Wound Contact Layer

Product description

Kliniderm® Silicone Wound Contact Layer is a sterile, transparent and flexible wound dressing. The soft silicone layer does not stick to the wound surface and reduces trauma to delicate new tissue upon removal.

The dressing consists of three layers:

- PET film
- Polyurethane net that is one-side coated with a soft silicone adhesive
- Release film

The middle layer is the functional component and the coated surface should contact the wound. The porous structure of the wound contact layer allows exudate to pass into a secondary absorbent dressing. The wound contact layer prevents the secondary dressing from sticking to the wound and ensures atraumatic dressing changes. The wound contact layer seals around the wound edges, preventing the exudate from leaking onto the surrounding skin, thus minimizing the risk of maceration. High transparency allows wound inspection during application and wear.

Intended use

Kliniderm® Silicone Wound Contact Layer is indicated for use in combination with a secondary absorbent dressing on a wide range of exuding wounds, such as diabetic foot ulcers, pressure ulcers, leg (venous and arterial) ulcers, first and second-degree burns, surgical wounds and traumatic wounds. The dressing can also be used as a wound protective layer on non-exuding wounds and on areas with fragile skin.

Classification

Class IIb under the Medical Devices Regulations (SI 2002 No. 618, as amended) and
Class IIb under Regulation (EU) 2017/745 Medical Device Regulation (MDR).

Product Specifications

Product & Packaging Reference

Product Reference	Description	Size (*)	Pieces per Peel Pouch	Inner Carton (pcs)	Outer Carton (pcs)
40514880	KLINIDERM® SILICONE WOUND CONTACT LAYER 5 X 7,5 CM	5 X 7,5 CM	1	10	700 (10 x 70)
40514881	KLINIDERM® SILICONE WOUND CONTACT LAYER 7,5 X 10 CM	7,5 X 10 CM	1	10	400 (10 x 40)
40514882	KLINIDERM® SILICONE WOUND CONTACT LAYER 10 X 18 CM	10 X 18 CM	1	10	700 (10 x 70)
40514883	KLINIDERM® SILICONE WOUND CONTACT LAYER 20 X 30 CM	20 X 30 CM	1	5	150 (5 x 30)
40514884	KLINIDERM® SILICONE WOUND CONTACT LAYER 17 X 25 CM	17 X 25 CM	1	5	200 (5 x 40)
40514885	KLINIDERM® SILICONE WOUND CONTACT LAYER 12 X 15 CM	12 X 15 CM	1	10	700 (10 x 70)
40514886	KLINIDERM® SILICONE WOUND CONTACT LAYER 24 X 27.5 CM	24 X 27.5 CM	1	5	150 (5 x 30)

*Sizes are approximate

Product Reference	Description	Size (*)	EAN Inner Carton	EAN Outer Carton
40514880	KLINIDERM® SILICONE WOUND CONTACT LAYER 5 X 7,5 CM	5 X 7,5 CM	8715343022078	8715343022085
40514881	KLINIDERM® SILICONE WOUND CONTACT LAYER 7,5 X 10 CM	7,5 X 10 CM	8715343022092	8715343022108
40514882	KLINIDERM® SILICONE WOUND CONTACT LAYER 10 X 18 CM	10 X 18 CM	8715343022115	8715343022122
40514883	KLINIDERM® SILICONE WOUND CONTACT LAYER 20 X 30 CM	20 X 30 CM	8715343022146	8715343022153
40514884	KLINIDERM® SILICONE WOUND CONTACT LAYER 17 X 25 CM	17 X 25 CM	8715343022160	8715343022177
40514885	KLINIDERM® SILICONE WOUND CONTACT LAYER 12 X 15 CM	12 X 15 CM	8715343749296	8715343749289
40514886	KLINIDERM® SILICONE WOUND CONTACT LAYER 24 X 27.5 CM	24 X 27.5 CM	8715343749265	8715343749258

*Sizes are approximate

Product Specifications

Features

- Sterile
- Transparent
- Flexible
- Does not stick to the wound surface and reduces trauma to delicate new tissue upon removal
- Allows exudate to pass into an outer absorbent dressing, ensures atraumatic secondary dressing changes and minimizes the risk of maceration
- Can remain in place up to/be used during 14 days

Precautions

- In case of signs of infection, consult a healthcare professional for adequate infection treatment.
- Do not use on patients with a known sensitivity to silicone, PET film or polyurethane.
- Sterile if pouch and seal are intact. Do not use if damaged.
- Do not re-use. Re-use can cause serious infections.
- Do not re-sterilize.
- For external use only.
- For use by healthcare professional.
- Single use.
- The longest cumulative use should be less than 30 days.
- Do not use on third-degree burns.

Specifications

Component	Material
Carrier/backing layer	Polyethylene terephthalate (PET) film
Wound contact layer	Polyurethane (PU) net, one-side coated with a soft silicone adhesive
Release liner	Coated PET

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Presence of specific components

Component	Present
Latex	No
Phthalates	No
Substances of animal origin	No
Substances of human origin	No
Blood or blood derivates	No
Medicinal substances	No

Sterilization

EO sterilized.

Storage conditions

The products should be stored in the original packaging, in a cool, well-ventilated and dry place, protected from direct sunlight.

Shelf life

Kliniplast® Kids has a shelf-life of 3 years from production date, when stored under specified conditions.

Picture



Product REF: 40514882

Product Specifications

Approval	Name	Date	Signature
Global Product Manager Wound Care	Myrthe Engelen		
RA specialist	Alexandra Duarte		