

TECHNICAL DATA SHEET (TDS)

Product Name: Med-Cover® Barrier Film

Category: Medical Device

Class: Class 1- other
(Non-sterile and without measurement function)



1. General Product Description

Med-Cover Barrier Film is 100% silicone based. It forms a long-lasting transparent barrier layer which can dry in a maximum of 35-45 seconds. This transparent barrier layer is long lasting, breathable, durable and provides full protection against potential damage. The plaster, ostomy adapter, which will be used after the product is applied, does not prevent wound care products from adhering. It is neither toxic nor irritating.

2. Instruction for Use

- Visually inspect the bottle of Med-Cover Barrier Film for damage prior to opening. Do not use damaged products.
- Skin should be clean and dry prior to application of Barrier Film.
- Hold the spray nozzle 10-15 cm (4-6 inches) away from the skin and apply smoothly. While moving the spray in a wide motion, ensure that the entire application point is covered with film. If there is an area that is overlooked, have the product reapplied to that area.
- Reapplication of the barrier film is required with each dressing and/or bonding. In cases where it is not possible to apply to the skin, the medical adhesive can be applied on and easily removed.
- When used as a protectant against body fluids, feces, or urine etc. and no adhesive products are applied to skin it is recommended to reapply the barrier film every 24-72 hours depending on situation.
- More frequent application may be necessary in applications that require frequent cleaning (e.g., defecation with constant diarrhea).
- Close the cover of the product when not in use.

3. Presentations:

Med Cover Barrier Film product is presented in a tube of 30 ml and 50ml.
A detailed product list is given in the table below.

Barcode	Reference no	Product name	Quantity	Classification
8683148050032	MCS0010	Barrier Film	30 ml	Class I - other
8683148050049	MCS0020	Barrier Film	50 ml	Class I -other

4. Ingredients

INCI Name	CAS No	EC No	Function
Polydimethylsiloxane	63148-62-9	613-156-5	Solvent
Cyclopentasiloxane	541-02-6	208-764-9	Solvent
Trimethylsiloxysilicate	-	-	Barrier Film
Phenyl Trimethicone	2116-84-9	218-320-6	Wash-off Resistance, Shine

5. General Appearance: Liquid, Transparent

6. Shelf life: 3 years

7. Primary packaging: High Density Polyethylene

Barrier Film 30ml	Packing Details	Pack/Box/Pallet Amount	Weight	Dimensions
	Pack	30ml/Bottle	0,042 KGS	3,5cm x 3,5cm x 9,3 cm
	Box	152 Bottle/Box	7,4 KGS	29,5cm x 29,5cm x 23 cm
	Pallet	48 Boxes/Pallet	370 KGS	80cm x 120cm x 195cm

Barrier Film 50ml	Packing Details	Pack/Box/Pallet Amount	Weight	Dimensions
	Pack	50ml/Bottle	0,069 KGS	3,5cm x 3,5cm x 12 cm
	Box	98 Bottle/Box	7,8 KGS	29,5cm x 29,5cm x 23 cm
	Pallet	48 Boxes/Pallet	390 KGS	80cm x 120cm x 195cm