Technical Data

Askina® Barrier Film spray

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1. Administrative information about B. Braun

1.1 Name: B. BRAUN MEDICAL SAS

1.2 Status:
Legal Manufacturer:
Avery Dennison Medical Ltd.,
IDA Business Park,
Ballinalee Road, Longford,
Ireland.
N39 DX73

1.3 Quality system certification:
B. Braun Medical SAS Quality system complies with: EN ISO 13485:2016
Avery Dennison Medical Ltd., Quality system complies with: EN ISO 13485:2016

2. Information on the medical device

2.1 Trademark: Askina®

2.2 Indication

The product is indicated for protecting intact, damaged skin from body fluids in the areas of:

- Incontinence skin care
- Peri-stomal protection
- Peri-wound protection

Barrier Film helps to protect (48-72h) intact or damaged skin from irritation that may arise from urinary and/or fecal incontinence, digestive juices, fluid draining from wounds.

2.3 Intended patient population

The product may be used on adults, children. And infants over 12 weeks old.

2.4 Product description

Barrier Film is a sterile polymeric solution that forms an even film when applied to the skin.

2.5 Precaution of use

- Replace cap over spray nozzle when not in use.
- Barrier Film is not to be used as the only covering in situations that require dressing protection from bacterial contamination / penetration e.g. intravenous therapy catheter sites and full or partial thickness wounds. Barrier - Film is not to be used on infected skin.
- Flammable and should be used in a well ventilated area. Avoid using around flames and sources of ignition.

3. Features/ patient benefits

- Non-stinging solvent
- Dries rapidly to form a film (under 30")
- Colourless/ transparent (no pigment)
- The product does not leave a tacky residue on the skin when dry.
- The product has no odour 30 seconds after application.
- Good permeability for oxygen and water vapour
- +/- 140 pumps

4. Product characteristics

4.1 Material composition

Non-cytotoxic acrylate co- polymer solution containing disiloxane. (Disiloxane 93 ± 2% by weight, and Acrylate Copolymer 7 ± 2% by weight.)

4.2 Medical device classification

Class I non-sterile (sterile until first use) under Annex IX Rule 4
EU Directive: 93/42/EEC

4.3 Sterility

Class I non-sterile (sterile until first use)

4.4 Shelf life

3 years

4.5 Storage conditions

Should be stored in the original container in a dry place at ambient temperature and humidity, and away from direct heat or sunlight. Product should be discarded 28 days after opening.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
Keep out of reach of children

5. Instructions for use

1. PRODUCT DESCRIPTION
Barrier Film is a polymeric solution which forms a uniform film when applied to the skin. The product is dispersed in a non-stinging solvent, which dries rapidly. The film is colourless, transparent, and possesses good oxygen and moisture vapour permeability. Barrier Film helpsto protect intact or damaged skin from irritation caused by urine and/or fecal incontinence, digestive juices and wound drainage. Barrier Film is a multiple use device that is intended for single patient use.

2. INTENDED PURPOSE
Barrier Film is a liquid intended for use as a film-forming product that upon application to intact or damaged skin forms a long lasting waterproof barrier, which acts as a protective interface between the skin and bodily wastes and fluids. It is intended as a primary barrier against irritation from bodily fluids and can be used on adults and children.

2.1 INTENDED POPULATION
The product may be used on adults, children and infants over 12 weeks old.

2.2 INTENDED USERS
Intended for use by health professionals and may be used in a hospital, community and home setting.

3. INDICATIONS
The products are indicated for protecting intact or damaged skin from body fluids in the areas of:
- Incontinence skin care
- Peri-stomal skin protection
- Peri-wound skin protection

4. CONTRAINDICATIONS
Barrier Film is not to be used as the only covering in situations that require dressing
protection from bacterial contamination / penetration, e.g. intravenous therapy catheter sites and full or partial thickness wounds. Barrier film is not to be used on infected skin.

5. WARNINGS
Barrier Film, in liquid form, is flammable; use in a well-ventilated area. Avoid using
around flames and sources of ignition. Keep out of reach of children.
Do not use if pack is damaged or open

6. INFORMATION FOR USE
-Visually inspect spray bottle for damage prior to opening.
- Skin should be clean and dry prior to application of Barrier Film.
- Hold spray nozzle 100 to 150 mm (4–6 inches) from skin and apply a smooth, uniform coating of film over entire area of concern, while moving spray in a sweeping motion.
- If an area is missed, reapply to that area only after first application of Barrier Film has dried (approximately 30 seconds).
- If Barrier Film is applied to an area with skin folds or other skin-to-skin contact, make sure that skin-contact areas are separated to allow the film to thoroughly dry before returning to normal position.
- When used under adhesive tapes, dressings, or devices:
- Allow Barrier Film to thoroughly dry before covering with dressing or adhesive
products.
- Reapplication of Barrier Film is necessary each time dressing and/or adhesive
- Products are changed: the barrier film is removed by the adhesive.
- When used as a protectant against body fluids, feces, or urine etc., and no adhesive
products are applied to skin:
- Reapplication of Barrier Film is recommended every 24-72 hours, depending on frequency of cleaning.
- In extreme cases (e.g. constant diarrheal stooling) with very frequent cleansing, more frequent applications may be necessary (i.e. every 12-24 hours).
- If desired, the film can be removed by using most medical adhesive removers as
directed. Clean and dry the involved area and reapply Barrier Film.
- Replace cap over spray nozzle when not in use.

Ingredients
Disiloxane, Acrylate Copolymer

7. CLINICAL BENEFITS /SPECIAL NOTES
Barrier films offer protection to the skin against subsequent moisture contact. The Barrier film forms a thin layer, repelling moisture and potential irritants, thus protecting the skin.

Caution
1. Should redness or any other signs of irritation appear, or if redness or signs of irritation persist, cease the use of Barrier Film and consult a physician.
2. Use of other barrier products, ointments, creams or lotions may significantly reduce the effectiveness of Barrier Film.
3. Contents of the spray bottle are sterile until first use.

8. STORAGE
Barrier film should be stored in the original container in a dry place at ambient temperature and humidity, and away from direct heat or sunlight. Product should be discarded 28 days after opening.

9. DISPOSAL
Product - This must be disposed of in compliance with anti-pollution and other laws of the country concerned. Contact your local service providers for further information.

Packaging - Disposal must be made in accordance with local waste management regulations. Outer packaging may be recycled . Contact your local service providers for further information.

10. PRESENTATION
- 28 ml Spray Bottle 1pk

11. COMPLAINTS
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
For complaints, questions or comments, contact Avery Dennison Medical Customer Support at phone +353 43 3349586.

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Longford, N39 DX73. Ireland
phone +353 43 3349586
fax +353 43 3349566

12. DISTRIBUTOR
B. Braun Hospicare Ltd.
Collooney, Co. Sligo,
F91 C892, Ireland
Phone: +353 71 911 5000
Fax: +353 71 911 5064
www.bbraun.com/living-with-a-stoma

Made in Ireland

6. References

References	Capacity	Packaging
5036	28 mL	1 per box

Commercialized and manufactured by:
B. BRAUN MEDICAL SAS | 26 Rue Armengaud | 92210 Saint-Cloud - France
Tel. 01 41 10 53 00 | Fax 01 41 10 75 68 | www.bbraun.com