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1.0 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 helps to 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.

Barrier Film Spray is a multiple use device that is intended for single patient use.

2.0 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.

3.0 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

4.0 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.

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5.0 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.

6.0 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

7.0 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.

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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.

8.0 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.

9.0 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.

10.0 SYMBOLS ON LABELLING

WARNINGS	
	Flammable
	Do not use if the pouch is damaged or opened.
	Medical Device
	Single Patient Multiple Use
STORAGE	
	

11.0 PRESENTATION


Cat. No.	Size	No. / Box
BF2801	28 ml Spray Bottle	1
BF2812	28 ml Spray Bottle	12

12.0 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.

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For complaints, questions or comments, contact Avery Dennison Medical Customer Support at phone +353 43 3349586.



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Made in Ireland

Date of Issue: Oct 2024

13.0 REVISION HISTORY

Revision	Change History	Date	Originator
A	MDR Release	20/07/2021	P Slattery
B	Add UKCA symbol Add date of issue	22/10/24	P Slattery

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