	Title	Instructions for Use Barrier Film Swab and Wipe	
	Revision	04	
	Technical documentation Number	TF006	

1.0 PRODUCT DESCRIPTION

Barrier Film is a polymeric solution which forms a uniform film when applied to the skin using a swab (foam applicator) or wipe. 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.

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 body 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 caregivers 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.


5.0 WARNING



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.

	Title	Instructions for Use Barrier Film Swab and Wipe	
	Revision	04	
	Technical documentation Number	TF006	

6.0 INFORMATION FOR USE

- Visually inspect Sachet for damage prior to opening
- Follow local protocols on the handling of sterile product.
- Skin should be clean and dry prior to application of Barrier Film.
- Remove foam applicator from sachet and apply a uniform coating of film over entire area of concern.
- 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 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.

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.
2. Use of other barrier products, ointments, creams or lotions may significantly reduce the effectiveness of Barrier Film.

8.0 STORAGE

Barrier Film should be stored in a dry place at ambient temperature and humidity, and away from direct heat or sunlight.







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.

	Title	Instructions for Use Barrier Film Swab and Wipe	
	Revision	04	
	Technical documentation Number	TF006	


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
	Sterile Barrier System/ Sterile Packing
STORAGE	
	
STERILE	
	

11.0 PRESENTATION

Cat. No.	Size	No./Box
BF0105	1ml Foam Applicator (Swab)	5
BF0125	1ml Foam Applicator (Swab)	25
BF0305	3ml Foam Applicator (Swab)	5
BF0325	3ml Foam Applicator (Swab)	25
BW0125	1ml Wipe	25

	Title	Instructions for Use Barrier Film Swab and Wipe	
	Revision	04	
	Technical documentation Number	TF006	

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.

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





Avery Dennison Medical Ltd.
IDA Business Park, Ballinalee Road
Longford, N39 DX73. Ireland
phone +353 43 3349586
fax +353 43 3349566

Made in Ireland

13.0 REVISION HISTORY

Revision	Change History	Date
04	MDR Release	30/09/2020

14. APPROVAL

Review and Approval	
<u>Name and Title</u>	<u>Signature and Date</u>
Elaine Minagh Regulatory Affairs Manager	 30/09/2020
Emmett McArdle R&D Manager	 30/09/2020