1. PRODUCT DESCRIPTION

Foam is a sterile, hydrophilic foam wound dressing that includes a polyurethane foam wound contact surface with high absorption capacity and a vapour permeable, water and bacteria resistant polyurethane film outer layer.

In the presence of exudate, Foam helps maintain a moist wound environment conducive to natural healing conditions.

2. INTENDED PURPOSE

Long term, non-invasive wound dressings intended principally for the management of moderately to heavily exuding, partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent.

2.1 INTENDED POPULATION

Individuals of all ages who are at risk of developing

- pressure ulcers
- venous and arterial leg ulcers
- diabetic foot ulcers
- first and second degree burns
- tracheostomy wounds

2.2 INTENDED USER

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

3. INDICATIONS

Foam is indicated for the management of moderately to heavily exuding, partial to full thickness wounds, such as

- pressure ulcers
- venous and arterial leg ulcers
- diabetic foot ulcers
- first and second degree burns
- tracheostomy wounds

Foam may also be used as an aid for the prevention of skin breakdown.

4. CONTRAINDICATIONS/SAFETY INFORMATION

Foam is contraindicated for

- ulcers resulting from infections, such as tuberculosis, syphilis, deep fungal infections
- bites or third degree burns
- dry wound conditions

In case of infection with inflammatory signs (temperature, oedema, redness, pain), contact proper medical authority. Resume use of Foam when normal healing conditions are present again.

5. WARNINGS

 Do not use if pouch is damaged or opened

 Do not re-use. Re-use of single-use devices creates a potential risk to the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

6. INFORMATION FOR USE

Foam is very simple to apply, requiring no special skills or equipment. The interval between dressing changes will depend entirely upon the state of the wound. On heavily exuding wounds, daily changes may be required at the beginning of treatment but this may be reduced to every 2 to 3 days for low exuding or epithelialising wounds.

6.1 Preparation

a) Visually inspect pouch for damage prior to opening.
b) Cleanse the wound with sterile saline or Ringer solution and sterile swabs.
C) Dry the skin surrounding the wound.

6.2 Dressing Application

a) Follow local protocols on the handling of sterile product.
b) Select the appropriate Foam size that will completely cover the wound surface, ensuring a 2 to 3 cm margin beyond the edges of the wound. If necessary, several dressings can be overlapped to cover very large wound areas.
c) Apply Foam with the foam side directly to the wound surface (shining polyurethane film outside) and fix it with an appropriate secondary dressing, e.g. a fixation or compression bandage.
d) In case of venous leg ulcers, compression therapy may be used in conjunction with Foam treatment, when so directed by a physician.

6.3 Dressing Change

You should replace dressing if it becomes soiled, saturated or if exudate/ drainage is observed or adhesion is compromised. Otherwise, replace dressing per established facility protocol

Where leakage occurs the dressing should be changed immediately.

a) Gently remove Foam
b) Follow procedure 6.1 a) to 6.2 c) to apply a new dressing.

7. CLINICAL BENEFIT

The wound may initially appear to increase in size in the early stages of treatment with Foam dressings. This is normal and occurs as any wound debris is removed from the edges of the wound. This clears the way for healing.

In the management of moderately to heavily exuding wounds, Foam can only make the overlying environment more conducive to healing. There are cases where healing is impaired

as a result of underlying conditions; in these instances, Foam alone may make little or no progress, and suitable treatment of the underlying conditions will be necessary as well. Therefore, if after 4-6 weeks of Foam treatment, there has been no improvement then, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed with a healthcare professional.

Foam should be left in place as long as possible in order to prevent trauma to the fragile newly formed tissue and to reduce cross contamination through frequent dressing changes.

Thick necroses should be removed before applying Foam.

8. STORAGE

Store dressings away from direct sunlight at ambient temperature and humidity.

9. DISPOSAL

The foam dressings should be disposed of based on the hospital or healthcare professional advice.

10. SYMBOLS ON LABELLING

WARNINGS	
	Do not use if the pouch is damaged or opened.
	Medical Device
	Sterile Barrier System/ Sterile Packing
STERILISATION	
	
STORAGE	
	

11. PRESENTATION

Foam is available in the following sizes:

Size
5 x 7 cm
10 x 10 cm
10 x 15 cm
10 x 20 cm
15 x 20 cm
15 x 15 cm
20 x 20 cm

12. 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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13. REVISION HISTORY

Revision	Change History	Date
04	MDR Release	23/09/2020

14. APPROVAL

Review and Approval	
Name and Title	**Signature and Date**
Elaine Minagh Regulatory Affair Manager	23/09/2020
Emmett McArdle R&D Manager	30/09/2020