1. PRODUCT DESCRIPTION

Foam Border and Foam Sacrum are sterile, hydrophilic foam dressings that include a polyurethane foam wound contact surface with high absorption capacity and a vapour permeable, water and bacteria resistant polyurethane film outer layer, which extends beyond the perimeter of the foam to form an adhesive border.

In the presence of exudate, Foam Border and Foam Sacrum help 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
- Surgical wounds

2.2 INTENDED USER

Intended for use by a health professional, and may be used in a community or hospital setting.

3. INDICATIONS

Foam Border and Foam Sacrum are 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
- Surgical wounds

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

4. CONTRAINDICATIONS/SAFETY INFORMATION

Foam Border and Foam Sacrum are 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 a proper medical authority. Resume use of Foam Border or Foam Sacrum 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 Border and Foam Sacrum are 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 the product pouch for damage prior to use
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. Select the appropriate Foam Border or Elta Foam® Sacrum size that will completely cover the wound surface, ensuring that the foam island completely covers the wound surface with a 2 to 3 cm margin beyond the edges of the wound
b) Grasp the tabs with both hands. Position the dressing over the wound site with the tab sides facing downward. Slowly peel away the tab from one side of the dressing.
c) Apply with a rolling motion to the wound site.
d) Remove the second tab. To secure, gently apply pressure to the dressing as it attaches the wound.
e) When dressing a sacral ulcer, slightly flex dressing and place into the gluteal fold. Smooth outward to ensure adhesion. Examine the dressing on a daily basis for leakage or other problems. If no problems arise, the dressing may be left in place for up to 7 days before another dressing is required.

6.3 Dressing Changes

Foam Border and Foam Sacrum should be changed when the dressing is saturated with exudate (2 to 3 days on average).The dressing may be left in place up to 7 days when there is little exudates or changed every 24h when the amount of exudates is significant. Where leakage occurs the dressing should be changed immediately.

a) Gently pressing down on the skin, carefully free the dressing edges one at a time and remove.
b) Follow procedure 6.1 a) to 6.2 e) to apply a new dressing.

7. CLINICAL BENEFIT / SPECIAL CONDITIONS

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 necrosis should be removed before applying foam.

8. STORAGE

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

9. SYMBOLS ON LABELLING

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

10. PRESENTATION

Foam Border is available in square/ rectangular shape in the following sizes:

Dressing Size	Foam Size
11x13cm	5x7cm
16x16cm	10x10cm
16x26cm	10x20cm
26x26cm	20x20cm

Foam Sacrum is available in triangular shape in the following size:

Dressing Size	Foam Size
18x20cm	14x16cm

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.

CE 1639

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

Made in Ireland

12. REVISION HISTORY

Revision	Change History	Date
04	MDR Release	

13. APPROVAL

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