1. PRODUCT DESCRIPTION

SilFoam is a sterile, absorbent, self-adherent soft silicone wound dressing. It comprises of a soft silicone skin and wound contact layer, a polyurethane foam layer with low to moderate absorption capacity and a vapour permeable, water and bacteria resistant polyurethane film outer layer. It is available in a border and non-border version. In the presence of exudate, SilFoam helps maintain a moist wound environment conducive to natural healing conditions.

Product Composition:

Polyurethane, copolyamide, polyacrylate, silicone, polyethylene

2. INTENDED PURPOSE

Long term, non-invasive wound dressings intended principally for the management of low to moderately 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

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

2.2 INTENDED USER

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

3. INDICATIONS

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

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

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

4. CONTRAINDICATIONS/ SAFETY INFORMATION

SilFoam is contraindicated for

- bites or third degree burns

- In case of infection with inflammatory signs discontinue use and resume when normal healing conditions are present again.

- Skin reactions may occur in very rare cases
- The product may not be used in case of a known intolerance or an allergy to one or several of its components.
- The dressing is indicated for low to moderately exudating wounds so should not be used on highly exudative wounds

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.

Skin reactions may occur in rare cases. The product may not be used in case of a known intolerance or an allergy to one or several of its components

Because of its good adhesive properties Remove with caution if skin is fragile (e.g. parchment skin).

Do not use the product simultaneously with oxidizing solutions, e.g. hydrogen peroxide or hypochlorite solution'.

If skin condition worsens or does not improve within 2-3 to weeks of use then the diagnosis and therapy should be reassessed

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

The frequency with which the dressing is changed should be adapted to reflect the wound's healing progress, depending on the amount of exudate.

Particularly in cases of an advanced degree of epithelialization over the wound and drying exudate, it may prove prudent to change to other wound treatment products.

SilFoam 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 SilFoam.

In the management of light to moderately exuding wounds, SilFoam 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, SilFoam alone may make little or no progress, and suitable treatment of the underlying conditions will be necessary as well. Therefore, if after 2-3 weeks of SilFoam treatment, there has been no improvement then, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed.

Continue the causal treatment such as compression therapy for venous & arterial leg ulcers or pressure relief for decubital ulcers

6. INFORMATION FOR USE

The Silicone dressing 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 moderately 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 up to maximum of 7 days wear time.

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 SilFoam 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) 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.
d) Apply with a rolling motion to the wound site.
e) Remove the second tab. To secure, gently apply pressure to the dressing as it attaches to the wound.
f) 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.

g) In case of venous & arterial leg ulcers, compression therapy may be used in conjunction with Silfoam treatment, when so directed by a physician.

6.3 Dressing Changes

SilFoam should be changed when the dressing is saturated with exudate (2 to 3 days on average). Dressing may be left in place up to 7 days when there is little exudate or changed every 24 hours when the amount of exudate is significant. Where leakage occurs the dressing should be changed immediately.

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

7. CLINICAL BENEFIT

The benefits and features of the Silfoam Range are:

- Minimises trauma at dressing change
- Easy application and removal
- Secure adhesion
- Exudate passes through the silicone adhesive quickly into the foam, due to excellent wicking properties
- Significant absorption capacity resulting in reduced risk of maceration at the wound edges
- Can be left in place for up to one week allowing for longer undisturbed wound healing
- Conforms to the natural contour of the body making it comfortable to wear

8. STORAGE

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

9. DISPOSAL

The silicone 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

SilFoam is available in a bordered and non-bordered version in a range of sizes.

Description	Size	Units/box	Article Number
SilFoam	5 x 7 cm	3	93050703
SilFoam	5 x 7 cm	10	93050710
SilFoam	6.4 x 6.4 cm	10	93060610
SilFoam	10 x 10 cm	3	93101003
SilFoam	10 x 10 cm	5	93101005
SilFoam	10 x 10 cm	10	93101010
SilFoam	10 x 20 cm	3	93102003
SilFoam	10 x 20 cm	5	93102005
SilFoam	10 x 20 cm	10	93102010
SilFoam	10.2 x 12.7 cm	10	93101310
SilFoam	15 x 15 cm	3	93151503
SilFoam	15 x 15 cm	5	93151505
SilFoam	16.5 x 20.3 cm	10	93172010
SilFoam	20 x 20 cm	5	93202005
SilFoam Heel	20.3 x 12.7 cm	10	93201310
SilFoam Border	4 x 5 cm	3	94040503
SilFoam Border	4 x 5 cm	10	94040510
SilFoam Border	5 x 7cm	3	94050703
SilFoam Border	5 x 7cm	10	94050710
SilFoam Border	9 x 9cm	10	94090910
SilFoam Border	10 x 10cm	3	94101003
SilFoam Border	10 x 10cm	10	94101010
SilFoam Border	12.7 x 15.7cm	10	94131610
SilFoam Border	15 x 15cm	3	94151503
SilFoam Border	15 x 15cm	10	94151510
SilFoam Border	10 x 20cm	3	94102003
SilFoam Border	10 x 20cm	10	94102010
SilFoam Border	18 x 18cm	10	94181810
SilFoam Border	20 x 20cm	5	94202005
SilFoam Border Sacrum	18 x 20cm	5	94182005
SilFoam Border Sacrum	18.6 x 18.8cm	10	94191910
SilFoam Border Sacrum	23 x 23cm	5	94232305

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.

CE 1639

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13. REVISION HISTORY

Rev	Change History	Originator	Date
A	Initial upload to MC. Section 2, 3 correct indication – remove word 'heavily Section 4 updated contraindications to include allergy, update sentence of infection (following CER update) Section 5: Add warnings Section 6: Add up to max 7 days wear time Section 7: update clinical benefits	P. Slattery	16 Jan 2023
b	Section 1: Correct high absorption to low to medium absorption Section 2 remove caregivers	P. Slattery	18 July 2023
C	Update to add arterial leg ulcers from Section 3 and throughout document. Add issue date	A Boateng P Slattery	11 Dec 2023

14. APPROVAL

Review and Approval	
Name and Title	**Signature and Date**
Angel Boateng, RA Associate	Will be captured electronically via Mastercontrol
Elaine Minagh RA Manager	Will be captured electronically via Mastercontrol