	<b>Title</b>	<b>Instructions for Use SilFoam Heel</b>	
	<b>Revision</b>	A	
	<b>Technical documentation Number</b>	LFD-PKG-001020	

## 1. PRODUCT DESCRIPTION

Silfoam Heel 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.

## 2. INTENDED PURPOSE

Long term, non-invasive wound dressings intended principally for the management of light 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

- diabetic foot ulcers
- first and second degree burns

### 2.2 INTENDED USER

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

## 3. INDICATIONS

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


- 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 Heel is contraindicated for


- bites or third degree burns
- In case of infection with inflammatory signs discontinue use and resume use of SilFoam 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

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## 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 very rare cases.
-  Because of its good adhesive properties the product should be removed with caution if the skin is fragile (e.g. parchment skin).
-  Do not use the product simultaneously with oxidizing solutions, e.g. hydrogen peroxide or hypochlorite solution.
-  The wound may initially appear to increase in size in the early stages of Heel dressing 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
-  In the management of light to moderately exuding wounds, the Silicone Heel dressing 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, Heel dressing 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 Silicone Heel dressing treatment, there has been no improvement then, in line with accepted wound management practice, the original diagnosis and overall therapy should be reassessed.
-  The Heel dressing 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.

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-  Thick necroses should be removed / debrided before applying the Silicone Heel dressing.

## 6. INFORMATION FOR USE

The Silicone Heel 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 in accordance with normal procedures.
- b) Gently dry the skin surrounding the wound.

### 6.2 Dressing Application

- a) Follow local protocols on the handling of sterile product.
- b) Remove protective liner and apply the adherent side of the dressing to the prepared wound, ensuring the dressing will comfortably wrap around the contour of the foot. If necessary, place the dressing inside out and carefully roll the adhesive contact layer onto the foot, ensuring that the wound bed is covered. To secure, gently apply pressure to the dressing as it attaches to the wound.
- c) Avoid stretching the dressing.

### 6.3 Dressing Change


The Silicone Heel dressing should be changed after 24 hours to 7 days, depending on the amount of exudate from the wound. Where leakage occurs the dressing should be changed immediately.

- a) Gently remove the Silicone Heel as affected area could be painful. Clean the wound as necessary prior to application of a fresh dressing.
- b) Follow procedure above to apply a new dressing.

## 7. CLINICAL BENEFIT / PRECAUTIONARY MEASURES

**The benefits and features of the Silfoam Range are:**

- Minimises trauma at dressing change
- Easy application and removal
- Secure adhesion

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- 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

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

#### 11. PRESENTATION

The Silicone Heel dressing is only available in one size. This size had been chosen to allow the majority of heel wounds to be managed appropriately.

Description	Size	Units/box	Article Number
SilFoam Heel	20.3 x 12.7 cm	10	93201310
SilFoam W Heel	21.5 x 15.4cm	10	98211510
SilFoam W Heel	21.5 x 15.4 cm	5	98211505

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## 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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**Made in Ireland**


## 13. REVISION HISTORY

Revision	Change History	Originator	Date
A	Initial upload to MC. Section 1,6 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 Section 11 – added Silfoam W Section 13, 14 added.	P. Slattery	16 Jan 2023

## 14. APPROVAL

Review and Approval	
<u>Name and Title</u>	<u>Signature and Date</u>
Patricia Slattery, Senior RA Specialist	Will be captured electronically via Mastercontrol
Elaine Minagh RA Manager	Will be captured electronically via Mastercontrol



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Emmett McArdle, R&D Manager	Will be captured electronically via Mastercontrol
Paul Saunders, Global Marketing Segment Manager	Will be captured electronically via Mastercontrol
Aoife Fleming, QA Engineer	Will be captured electronically via Mastercontrol

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