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## 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 the following wounds;

- Pressure ulcers
- Venous and arterial leg ulcers
- Diabetic foot ulcers
- First and second-degree burns

### 2.2 INTENDED USER

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

## 3. INDICATIONS

Silfoam is indicated for the management of low to moderately exuding, partial to full thickness wounds; specifically, the following wounds;

- 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.

## 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

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- 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.
- The dressing should not be used on dry 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.
- 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<sup>7</sup>.
- 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
- The product may not be used in case of a known intolerance or an allergy to one or several of its components

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- Dressings should only be used as part of a comprehensive pressure ulcer prevention programme

## 6. INFORMATION FOR USE

The Silfoam 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.

### 6.1 Preparation

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

### 6.2 Dressing Application


- Follow local protocols on the handling of sterile product.
- 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.
- 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.
- Apply with a rolling motion to the wound site.
- Remove the second tab. To secure, gently apply pressure to the dressing as it attaches to the wound.
- 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.
- 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.

- Gently remove Silfoam.
- Follow procedure 6.1 to 6.2 to apply a new dressing.

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**7. CLINICAL BENEFIT**

- 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
- Absorption Capacity /Excellent Absorption / light to moderate fluid handling capacity
- Self-adherent / Edge-to-edge adhesive
- Maintains moist wound environment
- Optimal moisture vapor transmission rate
- 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**





To minimize the risk of potential infection hazards or environmental pollution, Silfoam should be disposed of following disposal procedures according to applicable local laws, regulations and infection prevention standards.

**10. SYMBOLS ON LABELLING**

<b>WARNINGS</b>	
	Do not use if the pouch is damaged or opened.
	Medical Device
	Sterile Barrier System/ Sterile Packing
	Unique device identifier
	Distributor
	Country of Manufacture
<b>STERILISATION</b>	

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<b>STORAGE</b>


## 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 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

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Description	Size	Units/box	Article Number
Silfoam Border Sacrum	25.5 x 22cm	10	94262210
<b>Silfoam W</b>			
Silfoam W	5x5	10	95050510
Silfoam W	5x5	5	95050505
Silfoam W	7.5x7.5	10	95070710
Silfoam W	7.5x7.5	5	95070705
Silfoam W	10x10	10	95101010
Silfoam W	10x10	5	95101005
Silfoam W	15x15	5	95151505
Silfoam W	15x20	5	95152005
Silfoam W Border	7.5x7.5	10	96070710
Silfoam W Border	7.5x7.5	5	96070705
Silfoam W Border	10x10	10	96101010
Silfoam W Border	10x10	5	96101005
Silfoam W Border	15x15	5	96151505
Silfoam W Border	15x20	5	96152005
<b>Silfoam V</b>			
Silfoam V	5x5	10	95050510
Silfoam V	5x5	5	95050505
Silfoam V	7.5x7.5	10	95070710
Silfoam V	7.5x7.5	5	95070705
Silfoam V	10x10	10	95101010
Silfoam V	10x10	5	95101005
Silfoam V	15x15	5	95151505
Silfoam V	15x20	5	95152005
Silfoam V Border	7.5x7.5	10	96070710
Silfoam V Border	7.5x7.5	5	96070705
Silfoam V Border	10x10	10	96101010
Silfoam V Border	10x10	5	96101005
Silfoam V Border	15x15	5	96151505
Silfoam V Border	15x20	5	96152005
Silfoam Lite	5 x 5 cm	10	MED L300610
Silfoam Lite	5 x 7 cm	10	MED L300710
Silfoam Lite	6 x 6 cm	10	MED L300810
Silfoam Lite	6.4 x 6.4 cm	10	MED L300910
Silfoam Lite	7.5 x 7.5 cm	10	MED L300010
Silfoam Lite	10 x 10 cm	10	MED L300110
Silfoam Lite	10 x 20 cm	5	MED L300205
Silfoam lite	10.2 x 12.7 cm	5	MED L301005
Silfoam lite	15 x 15 cm	5	MED L300305
Silfoam lite	15 x 20 cm	5	MED L300405
Silfoam Lite	16.5 x 20.3 cm	5	MED L301105
Silfoam Lite	20 x 20 cm	5	MED L300505
Silfoam Lite Border	4 x 5 cm	10	MED L310610
Silfoam Lite Border	5 x 7cm	10	MED L310710
Silfoam Lite Border	6 x 6 cm	10	MED L311810
Silfoam Lite Border	7.5 x 7.5 cm	10	MED L310010
Silfoam Lite Border	9 x 9cm	10	MED L310910
Silfoam Lite Border	10 x 10cm	10	MED L310110
Silfoam Lite Border	12.7 x 15.7cm	5	MED L310805
Silfoam Lite Border	15 x 15cm	5	MED L310305

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Description	Size	Units/box	Article Number
Silfoam Lite Border	15 x 20cm	5	MED L310405
Silfoam Lite Border	10 x 20cm	5	MED L310205
Silfoam Lite Border	18 x 18cm	5	MED L311005
Silfoam Lite Border	20 x 20cm	5	MED L310505
Silfoam Lite Border Sacrum	16 x 17.5cm	5	MED L311905
Silfoam Lite Border Sacrum	18 x 18cm	5	MED L311105
Silfoam Lite Border Sacrum	18 x 20cm	5	MED L311205
Silfoam Lite Border Sacrum	18.6 x 18.8cm	5	MED L311305
Silfoam Lite Border Sacrum	21 x 22cm	5	MED L312005
Silfoam Lite Border Sacrum	23 x 23cm	5	MED L311505
Silfoam Lite Border Sacrum	25.5 x 22cm	5	MED L311605
Askina DresSil	5 x 7cm	10	ADM5295710
Askina DresSil	10 x 10cm	3	ADM5291003
Askina DresSil	10 x 10cm	10	ADM5291010
Askina DresSil	10 x 20cm	10	ADM5291210
Askina DresSil	15 x 15cm	5	ADM5291505
Askina DresSil	20 x 20cm	5	ADM5292005
Askina DresSil Border	6 x 6cm	10	ADM5396610
Askina DresSil Border	7.5 x 7.5cm	10	ADM5397510
Askina DresSil Border	10 x 10cm	10	ADM5391010
Askina DresSil Border	10 x 20cm	10	ADM5391210
Askina DresSil Border	15 x 15cm	3	ADM5391503
Askina DresSil Border	15 x 15cm	10	ADM5391510
Askina DresSil Border	15 x 20cm	10	ADM5395210
Askina DresSil Border	20 x 20cm	5	ADM5392005
Askina DresSil Sacrum	16 x 17.5cm	5	ADM5491605
Askina DresSil Sacrum	21 x 22cm	5	ADM5492105

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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**

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**13.0 REVISION HISTORY**

<b>Revision</b>	<b>Change History</b>	<b>Date</b>	<b>Originator</b>
A	Initial upload into Master Control	18/05/21	D. Casey
B	Addition of Silfoam Lite codes	12/07/23	P Slattery
C	Section 3 Indications: remove words 'such as' Section 11: Removed Heel products from table. Remove approvals section.	17 Oct 23	P Slattery
D	Add UKCA symbol	22 Oct 2024	P Slattery

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