

#### 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

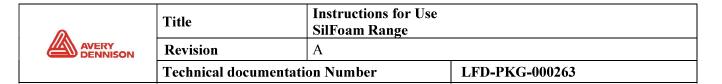
- pressure ulcers
- venous and arterial leg ulcers
- diabetic foot ulcers
- first and second degree burns

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

### 4. CONTRAINDICATIONS/ SAFETY INFORMATION

SilFoam is contraindicated for

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



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

• Skin reactions may occur in very rare cases

### 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

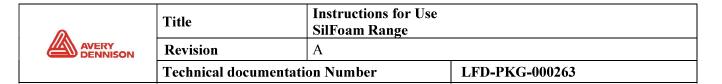
The Silicone dressing is very simple to apply, requiring no special skills or equipment. The interval between dressing changes will depend entirely upon the state of the wound. On moderately exuding wounds, daily changes may be required at the beginning of treatment but this may be reduced to every 2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

### 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 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

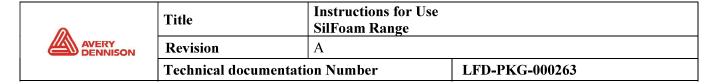
- Minimises trauma at dressing change
- Easy application and removal
- · Secure adhesion
- Exudate passes through the silicone adhesive quickly into the foam, due to excellent wicking properties
- Significant absorption capacity resulting in reduced risk of maceration at the wound edges
- Can be left 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
- Reduced pain on removal

#### 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.



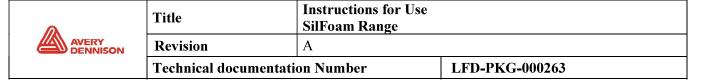
## 10. SYMBOLS ON LABELLING

WARNIN	WARNINGS				
	Do not use if the pouch is damaged or opened.				
MD	Medical Device				
	Sterile Barrier System/ Sterile Packing				
STERILISATION					
STERILE					
STORAGE					
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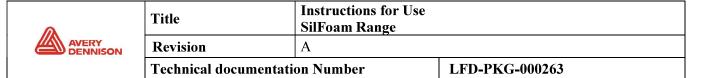
## 11. PRESENTATION

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

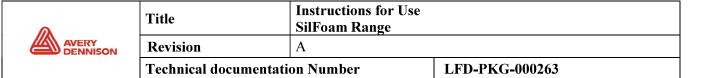
Description	Size	Units/box	Article Number	
SilFoam	5 x 7 cm	3	93050703	
SilFoam	5 x 7 cm	10	93050710	
SilFoam	6.4 x 6.4 cm	10	93060610	
SilFoam	10 x 10 cm	3	93101003	
SilFoam	10 x 10 cm	5	93101005	
SilFoam	10 x 10 cm	10	93101010	
SilFoam	10 x 20 cm	3	93102003	
SilFoam	10 x 20 cm	5	93102005	
SilFoam	10 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	



Description	Size	Units/box	Article Number	
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	
SilFoam Border Sacrum	25.5 x 22cm	10	94262210	
Silfoam W				
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	
Silfoam V				
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	



Description	Size	Units/box	Article Number
SilFoam Lite	16.5 x 20.3 cm	5	MED L301105
SilFoam Lite	20 x 20 cm	5	MED L300505
SilFoam Heel	20.3 x 12.7 cm	5	MED L301205
SilFoam Lite Heel	21.5 x 15.4 cm	5	MED L301305
SilFoam Lite Heel	21 x 13.5 cm	5	MED L301405
(cup)	00.04.0		1455 1 00 1505
SilFoam Lite Heel (cup)	22 x 21.6 cm	5	MED L301505
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
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



Description	Size	Units/box	Article Number
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
Askina DresSil Heel	22 x 21.6cm	5	ADM5592205

### 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

### 13.0 REVISION HISTORY

Revision	Change History	Date	Originator
A	Initial upload into MasterControl	18/05/21	D. Casey
В	Addition of Silfoam Lite Codes	12/07/23	P Slattery

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<b>A</b>	Ti	itle	Instructions for Use SilFoam Range			
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Technical documentation Number		on Number	LFD	-PKG-000263		
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# 14.0 Approvals

<u>Section 14</u> Review and approval				
Name and title	Signature and Date			
Originator: Patricia Slattery Senior Regulatory Affairs Specialist				
Marketing:				
Paul Saunders Senior Global Marketing Manager				
Quality:				
Shan Perkin Quality Manager				
Regulatory: Elaine Minagh RA Manager				
Research and Development: Emmett McArdle R&D Manager				