	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	

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

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	

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

- 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.

RELEASE

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	

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.

RELEASE

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	


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 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

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	


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

RELEASE

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	

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 (cup)	21 x 13.5 cm	5	MED L301405
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

RELEASE

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	

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
B	Addition of Silfoam Lite Codes	12/07/23	P Slattery

	Title	Instructions for Use SilFoam Range	
	Revision	A	
	Technical documentation Number	LFD-PKG-000263	

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14.0 Approvals

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

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