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| 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

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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.



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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.



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10. SYMBOLS ON LABELLING

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| 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 |



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| 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 |


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| 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 |

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| 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 |



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14.0 Approvals

| Section 14 Review and approval | |
|---|---------------------------|
| <u>Name and title</u> | <u>Signature and Date</u> |
| 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 | |

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