

INSTRUCTIONS FOR USE

ahc-SilFoam

1. PRODUCT DESCRIPTION

ahc-SilFoam is a sterile, absorbent, self-adherent wound dressing. It consists of a soft silicone skin and wound contact layer, a polyurethane foam layer with high absorption capacity, and a vapor-permeable, water- and bacteria-resistant polyurethane film outer layer. ahc-SilFoam is available in a border and a non-border versions. In the presence of exudate, ahc-SilFoam helps maintain a moist wound environment conducive to natural healing conditions.

The product is composed of:

Polyurethane, copolyamide, polyacrylate, silicone, polyethylene

2. PURPOSE OF USE

The ahc-SilFoam is a non-invasive wound dressing which can be used in long-term therapy for patients with damaged dermis and/or secondary wound healing. Wounds range from moderately to heavily exuding.

2.1 TARGET GROUP

Addressed are affected persons of all ages with:

- Pressure sores
- venous and arterial leg sores
- diabetic foot sores
- First and second degree burn

ahc-SilFoam can also be used as an aid to prevent skin damage.

2.2 TARGET USER GROUP

ahc-SilFoam is intended for use by healthcare professionals and caregivers, and can be used in a hospital, medical practice, and homecare setting.

3. INDICATIONS

ahc-SilFoam is indicated for the treatment of light to moderate, up to heavily exuding, partial to extensive wounds, such as.

- Pressure sores
- venous and arterial leg sores
- diabetic foot sores
- First and second degree burns

ahc-SilFoam can also be used as an aid to prevent skin damage.

4. CONTRAINDICATIONS/SAFETY INSTRUCTIONS

ahc-SilFoam is contraindicated in:

- Sores due to infections such as. Tuberculosis, syphilis, deep fungal infections
- Third degree bites or third grade burns

In case of infection with inflammatory signs (fever, edema, redness, pain), contact your responsible attending physician. Resume therapy with ahc-SilFoam when the wound condition permits again and healing conditions are restored.

- In very rare cases, skin reactions may occur.

5. WARNINGS



Do not use if the bag is opened or damaged. A damaged or opened package is to be considered non-sterile.



Do not reuse. ahc-SilFoam is a single-use sterile product. Reuse of single-use devices poses a potential risk to the patient or user. This can lead to contamination and / or impairment of functionality. Contamination and / or limited functionality of the dressing may result in patient injury, illness or death.

6. USE INFORMATION

ahc-SilFoam is very easy to apply and requires no special skills or tools.

The dressing change interval depends entirely on the condition of the wound. Moderately exuding wounds may require daily changes at the beginning of treatment, but this may be reduced to every 2 to 3 days for low exudate or epithelializing wounds.

6.1 PREPARATION

- a) Thoroughly check the packaging for integrity before opening.
- b) Before use and at dressing changes, wound cleansing according to medical standards and/or wound debridement is recommended to remove exudate, fibrinoid deposits and other contaminants.
- c) Gently dry the wound area.

6.2 APPLICATION OF THE DRESSING

- a) Follow the local regulations for handling sterile products.
- b) Select the appropriate ahc-SilFoam size that completely covers the wound and extends 2 - 3 cm beyond the wound edge. If necessary, several dressings can be placed together to cover very large wounds.
- c) Grasp the tabs with both hands. Position the dressing over the wound site with the flap sides down. Slowly pull the tab off one side of the dressing.
- d) Cover the wound with rolling movements.
- e) Remove the second tab. Apply gentle pressure to the dressing to secure, gently adhering to the wound.
- f) When dressing a sacrum sore, bend the dressing slightly and place it in the fold of the buttock.

Smooth outward to ensure adhesion. Inspect the dressing daily for leaks or other problems. If no abnormalities occur, the dressing can be left on the wound for up to 7 days before a dressing change is required.

g) In the case of venous leg sores, compression therapy can be applied together with ahc-SilFoam if ordered by a physician.

6.3 DRESSING CHANGE

ahc-SilFoam should be changed when the dressing is saturated/full of exudate (on average after 2 to 3 days). If there is little exudate, the dressing can be left in place for up to 7 days or changed every 24 hours if there is a lot of exudate. If it is no longer airtight/a leak occurs, the dressing should be changed immediately.

- a) Carefully loosen and remove ahc-SilFoam from the wound.

OBSOLETE

b) Follow procedures 6.1 a) to 6.2 c) to apply a new dressing.

7. CLINICAL ADVANTAGE/SPECIAL CONDITIONS

- Continuation of causal treatment such as compression therapy for venous leg sores or pressure relief for pressure sores.
- The product must not be used in case of known intolerance or allergy to one or more of its components .
- Due to the good adhesive properties, the product applied on sensitive skin (e. g. parchment skin) should be removed with care.
- Do not use the product simultaneously with oxidizing solutions, e.g. Hydrogen peroxide or hypochlorite solution.
- In the initial stages of treatment with ahc-SilFoam, the wound may initially appear larger. This is normal and occurs when wound debris is removed from the wound edges. This accelerates the healing process.
- The frequency of dressing changes should be adjusted to the healing progress of the wound, depending on the amount of exudate.
- Especially in cases of advanced epithelialization over the wound and drying exudate, it may be useful to switch to other modern wound treatment products.
- When treating lightly to moderately exuding wounds, ahc-SilFoam can have a healing-promoting effect on the wound environment. There are cases where healing is impaired due to underlying conditions; in these cases, ahc-SilFoam alone may make little or no progress, and appropriate treatment of the underlying conditions is mandatory. Therefore, if improvement has not occurred after 4-6 weeks of treatment with ahc-SilFoam, the original diagnosis and overall therapy should be reevaluated in accordance with accepted wound care practice.
- ahc-SilFoam should be left in place as long as possible to prevent injury to the delicate newly formed tissue (ensure wound debridement) and reduce cross-contamination through frequent dressing changes. Thick necroses should be removed before applying ahc-SilFoam.

8. STORAGE




Protect the dressings from direct sunlight and moisture/humidity, and store at room temperature.







ATTENTION: Do not use if the packaging or peel pouch is damaged. Use the products only until the expiration dates indicated on the packaging.

9. DISPOSAL

Silicone foam dressings should be disposed of according to hospital or healthcare professional instructions.

10. SYMBOLS FOR LABELING

WARNINGS	
	Do not use if the package is damaged.
	Medical product
	Caution

	Sterile barrier system/ sterile packaging
STERILISATION	
	 
STORAGE	
	

11. PACK SIZES AND UNITS

ahc-SilFoam is available in a bordered and a non-bordered version in different sizes.

Description	Size	Piece/Carton	Item number	Pharma Central Number (PZN)
ahc-SilFoam Border	7,5 cm x 7,5 cm	10	ahc-SF757510B	18250016
ahc-SilFoam Border	7,5 cm x 7,5 cm	50	ahc-SF757550B	18250045
ahc-SilFoam Border	10 cm x 10 cm	10	ahc-SF101010B	18250051
ahc-SilFoam Border	10 cm x 10 cm	50	ahc-SF101050B	18250068
ahc-SilFoam Border	15 cm x 15 cm	10	ahc-SF151510B	18250074
ahc-SilFoam Border	15 cm x 15 cm	50	ahc-SF151550B	18250080
ahc-SilFoam	1 cm x 10 cm	10	ahc-SF101010	18249929
ahc-SilFoam	1 cm x 10 cm	50	ahc-SF101050	18249993

12. COMPLAINTS

Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

Contact Avery Dennison Medical Customer Service at +353 43 3349586 with any complaints, questions or comments.



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ahc-SilFoam

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