Silicone foam dressing with border (Type I)

Instructions for Use

- **Products description**

Silicone foam dressing with border (Type I) improves absorption and retention by the combination of a foam and superabsorbent layer. It absorbs exudate through silicone perforations from the wound and provides a moist wound healing environment to promote wound healing. The silicone wound contact layer reduces pain and trauma during dressing changes, and enhances patient's comfort. The waterproof outer layer protects the wound from dirt and bacteria.

- **Function principle**

Silicone foam dressing absorbs exudate and provides a moist wound healing environment to promote wound healing. The perforated silicone contact layer provides gentle adhesion and secure fixation and does not stick to the moist wound resulting in less pain for patients. The polyurethane foam layer absorbs exudates and transfers it to a superabsorbent layer using a non-woven spreading layer. Super absorbent fibres absorb and retain exudate by forming a gel, minimizing the risk for maceration. The waterproof outer layer protects the wound from dirt and bacteria.

- **Intended purpose & Indications**

➢ Intended purpose

Silicone foam dressing with border is a wound dressing that absorbs wound exudate and provides a moist wound healing environment to promote wound healing. It can also prevent pressure ulcer.

➢ Indications

Silicone foam dressing with border is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears) and surgical wounds. Silicone foam dressing with border can also be used on dry/necrotic wounds in combination with gels. Silicone foam dressing with border reduces postoperative blistering, and may also be used as part of a prophylactic therapy to help prevent skin damage, e.g. pressure ulcers.

- **Intended user**

The product shall be used by or under the supervision of a healthcare professional.

- **Intended patient population**

Patient who has the indications: pressure ulcers, leg and foot ulcers, traumatic wounds (e.g. skin tears), surgical wounds and dry/necrotic wounds.

- **Clinical benefit**

1. As an adjunct to pressure ulcer prevention: reduce the incidence of pressure ulcers when combined with usual pressure injury prevention practices.
2. For wound management: reduce patient pain at dressing change/removal.
3. For wound management: promote wound healing.

- **Contraindications**

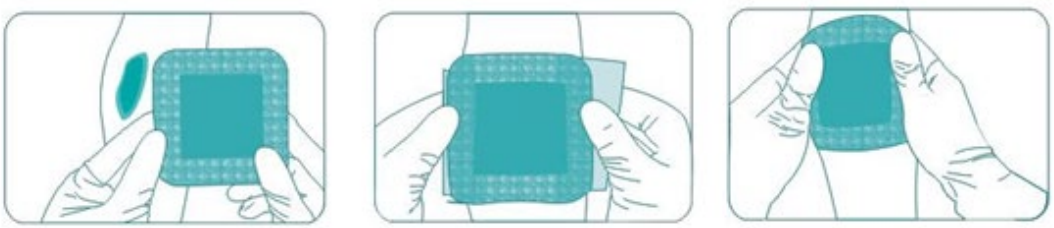
1. Check the wound for signs of infection before use, if infection occurs, see a health care professional.
2. Do not use on the patients with a known hypersensitivity to the product itself or to its components.
3. Do not use on third degree burns.

- **Complications or side-effects**

Very occasionally, there will be some potential risks associated with the use of Silicone Foam Dressing with the following:

- Adverse reactions (eczema, erythema, pruritus, blister formation, skin rash, allergy etc.)
- Wound infections
- Risk of maceration (fluid leakage)
- Risk of skin stripping

- **Instructions for use**



➢ First step:

Clean the wound area in accordance with normal procedures. Ensure the peri-wound skin is dry.

➢ Second step:

Select a dressing size of silicone foam dressing with border large enough to overlap the wound edges by at least 1-2 cm for smaller sizes (sizes up to 12.5×12.5cm), and 3-4cm for larger sizes in order to protect the surrounding skin from maceration and fix the dressing securely.

➢ Third step:

Remove the release film and apply the adherent side to the wound. Smooth the dressing from the center to the edge without leaving any gap, press the dressing edge to ensure good adhesion.

➢ Fourth step:

To remove the dressing: gently lift the corner of the dressing and slowly peel.

Note:

1. The dressing change interval may be several days. Change the dressing before it is fully saturated, at signs of leakage, or as indicated by clinical practice. The dressing may be left in place up to 7 days.
2. When necessary, fixate the dressing with a bandage or other fixation.

- **Warnings**

1. Do not reuse. Reuse will cause cross-contamination.

2. Do not use if package is damaged or open.

3. Do not use together with oxidizing agents such as hypochlorite solutions or hydrogen peroxide.

4. Due to the gentle adhesive used, do not use this dressing to secure other medical devices to the patient.

5. If reddening or sensitization occurs discontinue use and see a healthcare professional.

- **Storage and transport conditions**

The product should be stored in dry conditions.

Keep the product away from direct sunlight and keep dry.

- **Disposal**

Disposal should be handled according to local environment procedures.

- **Other information**

1. The foam may change colour to more yellow when exposed to light, air and/or heat. This has no influence on product properties.

2. The intended user does not need training for this product.

3. If have any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority.



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- **The meaning of the symbols used**

Symbol					
Title	Manufacturer	Authorized representative in the European Union	Date of manufacture	Use-by date	Batch code
Symbol					
Title	Catalogue number	Importer	Distributor	Country of manufacture	Sterilized using ethylene oxide
Symbol					
Title	Single sterile	Do not use if	Do not re-use	Keep away	Keep dry

	barrier system	package is damaged		from sunlight	
Symbol					
Title	This way up	Consult instructions for use	CE marking	Medical device	Unique device identifier

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