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born to **care**.

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Medical Device



Conformité
Européenne



Caution



Instructions for Use



EO sterilization



Single use only



Do not resterilize



Keep Dry



Keep away
from sunlight



Do not use
if package is damaged



Unique device
identifier



Batch Code



Distributor



Manufacturer



Authorized representative
in the European
Community/European Union



Use by date



Date of
manufacture

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Flexy  **FOAM SILICONE DRESSING**[®]

SILICONE FOAM DRESSING

Fluid Handling



Instructions for Use

EN Flexy® Silicone Foam Dressing

Fluid Handling Iconography:

Absorbent Category	Total fluid Handling Capacity (g/cm²)	
Low	0.01 - 4.99	●○○○
Moderate	5.00 - 14.99	●●○○
High	15.00 - 24.99	●●●○
Ultra-High	25.00 or greater	●●●●+

BS EN 13726-1 2023 - Annex E total fluid handling

This leaflet contains important information. It is recommended to read the instructions carefully before use.

Intended use

The Flexy Silicone Foam Dressing is suitable for many types of exuding wounds including leg and pressure ulcers superficial and partial thickness burns, donor sites, postoperative wounds and skin abrasions. The dressing absorbs exudates and maintains a moist wound-healing environment whilst minimizing the risk of maceration.

Contraindications

- Do not use this product on patients with known allergies or sensitivities to silicone.

Warning and Precautions

- The Flexy Silicone Foam Dressing is disposable. Do not use if the inner package is damaged.
- The products have a shelf-life of 3 years. Do not use beyond the expiration date.
- This product is sterilized. Use immediately after opening the packaging. The usage time of a product should not exceed 7 days, and no more than 30 days for cumulative use.
- The products should be stored in an environment with suitable temperature, protection from light, and ventilation.
- Immediate medical consultation is required under the following conditions:
Uncertainty in diagnosis – Inability to identify the wound type or underlying medical conditions;
Laypersons must not attempt self-application without clinical guidance.

- The products are not suitable for arterial bleeds.
- Do not overlay or overlap foam dressings.
- Do not stretch the skin or dressings during application.
- Silicone is hydrophobic and will not adhere to wet skin.

Side-effects

There are no known side effects associated with the use of this product.

Directions for Use

1. Application instruction

Silicone Foam Dressing and instruction for use are contained. Please keep in mind each stage of under-mentioned instructions is in strict chronological (consecutive) order, even when mentioned in the same sentence.

- Cleanse the wound in accordance with local clinical protocols.
- Select an appropriate sized dressing.
- Ensure the foam pad covers the entire wound area with a minimum overlap of 2cm around the edges of the wound.
- Prepare and clean the skin surrounding the wound area and remove excess moisture.
- Remove the pre-printed release liners and apply pad-side down to the wound.
- Smooth the dressing border down to ensure good adherence with the peri-wound skin.
- Always ensure the Silicone Foam dressings are not applied too tightly.

2. Removal

Careful and correct dressing removal is vital to minimize the risk of damaging the wound bed and new granulating tissue;

- Remove the retention dressing or bandage and carefully lift the dressing away from the wound.
- The dressing should be removed slowly and carefully following the direction of hair growth.
- As the dressing is removed, the newly exposed skin should be supported.
- Dispose of used dressings in accordance with local clinical waste disposal regulations.

Frequency of Change

- The use of foam dressings should always be re-evaluated if wound exudate levels change.
- During the early stages of wound management, observe the wound daily for signs of infection or other complications (or as recommended by local clinical protocols).
- Infected wounds should be inspected and treated as per local clinical protocol.
- The frequency of dressing change is determined by the condition of the wound and local clinical protocols.
- Dressings can be left in place, undisturbed, for up to 7 days, or until exudate is visible and approaches 2 cm from the edge of the dressing, whichever is sooner.

Storage and Shelf Life

- Should be stored horizontally.
- Keep Dry.
- Keep away from sunlight and heat.
- The products have a shelf-life of 3 years.
- Do not use after the expiry date printed on the packaging.

If any serious incident has occurred while using this device, please report to national authority and to the manufacturer.