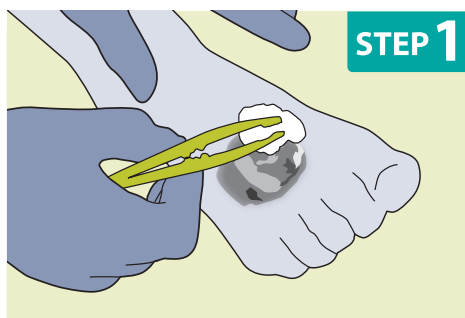


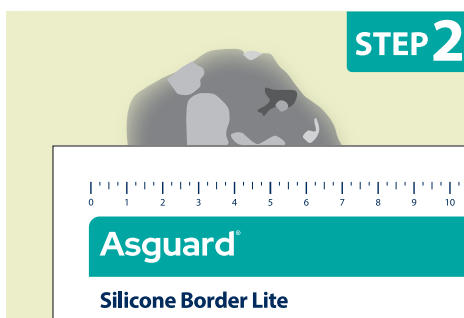
Silicone Border Lite (Instructions For Use)

Asguard Silicone Border Lite Foam is a thin dressing consisting of a polyurethane backing layer, an absorbent foam layer, a perforated silicone wound contact layer, and a release layer. The dressing is self-adhesive and absorbent to absorb exudate, maintain a moist wound environment and minimize the risk of maceration. The silicone wound contact layer reduces pain and trauma during dressing changes and improves patient comfort. The waterproof outer layer protects the wound from dirt and bacteria.



STEP 1

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

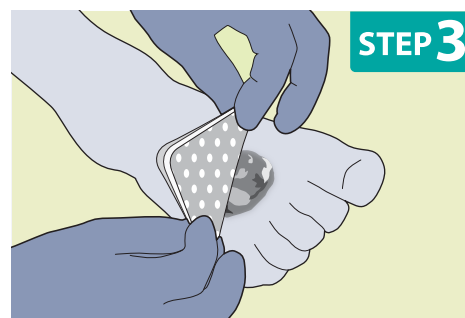


STEP 2

Asguard®

Silicone Border Lite

Select a dressing size of Asguard Silicone Border Lite dressing 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.



STEP 3

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.



STEP 4

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

Note:

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. When the dressing is applied to the sacral area, it may be left in place for up to 5 days. Continuous use cannot be more than 30 days.

Observation when used for pressure ulcer prevention: frequently inspect the skin for pressure injuries by lifting back one corner, inspecting and then repositioning the dressing.

When necessary, fixate the dressing with a bandage or other fixation.

DRESSING CHANGE

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CONTRAINDICATIONS

Check the wound for signs of infection before use, if infection occurs, see a health care professional.

Do not use on the patients with a known hypersensitivity to the product itself or to its components.

Do not use on third degree burns.

INDICATIONS

Used by or under the supervision of the healthcare professional:

Silicone foam lite dressing with border (Type II) is indicated for wound management on shallow, granulating wounds, acute and chronic exudative wounds, full and partial thickness wounds (such as pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, first and second degree burns, donor sites, skin tears). It can also be used for the prevention of medical device related pressure injuries on intact skin, as part of a pressure injury prevention protocol.

Available for household consumer:

Silicone foam lite dressing with border (Type II) is indicated for wound management of superficial exudative wounds (such as minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds, minor burns, etc.) or for the prevention of pressure injuries to intact skin.

Silicone Border Lite (*Instructions For Use*)

PRODUCTS DESCRIPTION

Silicone foam lite dressing with border (Type II) is a thin dressing consisting of a polyurethane backing layer, an absorbent foam layer, a perforated silicone wound contact layer, and a release layer. The dressing is self-adhesive and absorbent to absorb exudate, maintain a moist wound environment and minimize the risk of maceration. The silicone wound contact layer reduces pain and trauma during dressing changes and improves patient comfort. The waterproof outer layer protects the wound from dirt and bacteria.

FUNCTION PRINCIPLE

Silicone foam lite dressing with border is a self-adherent, absorbent dressing that maintains a moist wound environment. The waterproof outer layer protects the wound from dirt and bacteria.

INTENDED PURPOSE

Silicone foam lite dressing with border is a self-adherent, absorbent dressing that maintains a moist wound environment to promote wound healing.

INTENDED USER

The product may be used by household consumer (only available for superficial exudative wounds) or used by or under the supervision of a healthcare professional.

INTENDED PATIENT POPULATION

Used by or under the supervision of the healthcare professional:
Patient who has the indications: shallow, granulating wounds, acute and chronic exudative wounds, full and partial thickness wounds (such as pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, first and second degree burns, donor sites, skin tears), or for the prevention of pressure injuries to intact skin.

Available for household consumer: Patient who has the indications: superficial exudative wounds (such as minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds, minor burns, etc.) or for the prevention of pressure injuries to intact skin.

CLINICAL BENEFIT

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

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

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

Household consumer should read this brochure carefully before use. If there is any unclear content, please consult a healthcare professional or stop using this product. When required, healthcare professionals should provide appropriate advice to patients on how to apply, monitor the dressing, remove, and dispose of the dressing and when to contact a healthcare professional as detailed in this IFU.

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

SIDE-EFFECTS

Very occasionally, there will be some potential risks associated with the use of Asguard Silicone Border Lite dressing such as:

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

WARNINGS

- Do not reuse. Reuse will cause cross-contamination.
- Do not use if package is damaged or open.
- Do not use together with oxidizing agents such as hypochlorite solutions or hydrogen peroxide.
- Due to the gentle adhesive used, do not use this dressing to secure other medical devices to the patient.
- If reddening or sensitisation occurs discontinue use and see a healthcare professional.