

Biatain® Silicone Lite

en Silicone foam dressing



Instructions for use

Please read the following instructions carefully.

23328521 Version 1

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Intended purpose

The product is intended for moist wound healing and exudate management.

The product is intended to be used by health care professionals and patients under the supervision of health care professionals.

Indications

Biatain Silicone Lite

- is indicated for a wide range of non- to low exuding wounds. This includes acute wounds such as donor sites, post-operative wounds and traumatic wounds; and chronic wounds such as leg ulcers, pressure ulcers and non-infected diabetic foot ulcers.

Warnings

Do not re-use the single use product as cross contamination may occur, potentially leading to infection.

Reprocessing, washing, disinfection and/or resterilisation may compromise product characteristics, causing additional risk of physical harm or infection to the user.

Cautions

A health care professional should frequently inspect and manage infected wounds, diabetic wounds and wounds which are solely or partially caused by arterial insufficiency, in accordance with local guidelines.

Do not use the product with oxidising solutions e.g. hypochlorite and hydrogen peroxide solutions, as this may cause product degeneration which may lead to deterioration of the wound. Ensure that any other evaporating solution is completely dried off before applying the product.

Do not use if package is damaged, as sterility of the product may have been compromised, potentially leading to infection.

Keep away from sunlight as it may impact product performance which may lead to maceration.

The product is not made with natural rubber latex, however rare contamination with trace amounts of natural rubber latex during manufacturing or packaging may occur, potentially leading to allergic reactions in patients with known or suspected allergies to natural rubber latex.

Possible side-effects related to the use of wound dressings may include: skin irritation/inflammation, allergic skin reaction, maceration, pain, hyper granulation, and blistering.

Information

The product is a thin, sterile, single use polyurethane foam dressing with a silicone adhesive.

Biatain Silicone Lite

- may be left in place for up to 7 days depending on the amount of exudate, dressing conditions and type of wound
- may be left in place during showering
- may be used together with Purilon Gel for autolytic debridement of necrotic tissue
- may be used on patients who are in treatment for a local or systemic infection at the discretion of a health care professional
- is suitable for use in combination with compression therapy

The product consists of:

- a vapour permeable top film which is bacteria- and waterproof
- an absorbent polyurethane foam
- a perforated silicone adhesive
- turquoise release liners

If you experience a suspected allergic reaction or any other side effects, please contact your health care professional.

Sterilised using ethylene oxide (EO).

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

Special storage conditions

Keep away from sunlight.

How to use

Preparation

Cleanse the wound and periwound skin in accordance with local guidelines, e.g. lukewarm water or physiological saline solution.

Gently dry the periwound skin.

If any film, cream, ointment or similar product is used, allow the periwound skin to dry before applying the product.

Application

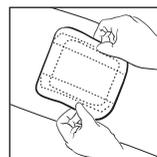
Select a product where the foam overlaps the wound edge by approximately 1-2 centimetres.

Open the pouch and pick up the product from the packaging.

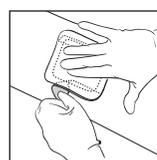


Use the release liners to avoid touching the adhesive side and to ensure aseptic application.

Remove the center release liner.



Apply the adhesive side towards the wound.



Remove the remaining release liners, one at a time.

Gently run your fingers around the edge of the product to ensure an even and smooth fit to the skin.

Removal

The product should be changed when clinically indicated, when visible signs of exudate approach the edge of the foam or after 7 days.

Loosen the adhesive border before gently lifting the product away from the wound and removing the product. If the product is difficult to remove, it should be moistened with water or physiological saline solution until it removes easily.

Disposal

The product is intended for single use only and should be disposed of in accordance with local guidelines, e.g. with normal household waste.

Do not flush the product down the toilet.

Reporting of incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

Explanation of symbols



Medical device



Indicates that the product is in compliance with European legislation for medical devices



Catalogue number



Use-by date (YYYY-MM-DD)



Batch code



Date of manufacture (YYYY-MM-DD)



Manufacturer



Consult instructions for use



Do not re-use



Sterilised using ethylene oxide



Single sterile barrier system



Not made with natural rubber latex



Do not use if package is damaged and consult instructions for use



Indicates a carrier that contains Unique Device Identifier information



Global Trade Item Number



Keep away from sunlight



Recyclable packaging



Absorption capability