Biatain® *Silicone Lite*

en Silicone foam dressing

Coloplast

CE 2460

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Instructions for use
Please read the following instructions carefully.

23328519 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 shower
- 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 protective films

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.

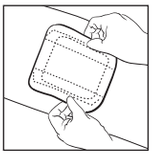
If any film, cream, ointment or similar product is used, allow the periwound skin to dry before applying the product.

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 protective films to avoid touching the adhesive side and to ensure aseptic application.

Remove the center protective film.



Apply the adhesive side towards the wound.

Remove the remaining protective films, 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

MD	Medical device
CE 2460	Indicates that the product is in compliance with European legislation for medical devices
REF	Catalogue number
	Use-by date (YYYY-MM-DD)
LOT	Batch code
	Date of manufacture (YYYY-MM-DD)
	Manufacturer
	Consult instructions for use
	Do not re-use
STERILE EO	Sterilised using ethylene oxide
STERILE EO	Single sterile barrier system
LATEX	Not made with natural rubber latex
	Do not use if package is damaged and consult instructions for use
UDI	Indicates a carrier that contains Unique Device Identifier information
GTIN	Global Trade Item Number
	Keep away from sunlight
	Recyclable packaging
	Absorption capability