Biatain® Silicone Ag

Coloplast

en Silicone foam dressing with silver
Heel

CE 2460

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Instructions for use
Please read the following instructions carefully.

23340170 Version 1

Intended purpose
The product is intended for moist wound healing and exudate management of wounds with delayed healing due to bacteria or wounds at risk of infection.

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

Indications
Biatain Silicone Ag
- is indicated for a wide range of low- to highly exuding wounds with delayed healing due to bacteria or wounds at risk of infection. This includes acute wounds such as second degree burns, donor sites, post-operative wounds and traumatic wounds; and chronic wounds such as leg ulcers, pressure ulcers and diabetic foot ulcers.

Contra-indications
The use of the product by children, pregnant or nursing women and patients with severe hepatic or renal impairment has not been investigated. Use of the product by this population is not justified due to lack of data. Consult a health care professional for further advice.

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.

The product should not be used on patients with a known sensitivity to silver. If you experience a suspected allergic reaction or any other side effects, please contact your health care professional.

Concomitant use with other silver-containing products has not been investigated. Extensive treatment periods in very large wounds (e.g. large burn wounds with total body surface area above 20%) should be done under careful medical supervision. As with any wound management therapies involving silver-containing compounds, potential risks resulting from local accumulation of silver should be considered.

In the event of a systemic infection, topical silver does not replace the need for systemic therapy or other adequate infection treatment.

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.

The use of cleansing agents other than physiological saline solution or tap water in combination with the product has not been investigated.

Remove the product prior to radiation treatment or examinations that include x-rays, ultrasonic treatment, diathermy or microwaves as it may interfere with the results.

The use of the product during MR scan above 3 Tesla has not been investigated.

Application of the product with enzymatic debriding agents has not been investigated.

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 sterile, single use, antimicrobial polyurethane foam dressing with a silicone adhesive.

Biatain Silicone Ag
- contains an antimicrobial silver complex homogeneously dispersed throughout the foam. Silver is released to the wound bed when in contact with wound exudate
- is effective against bacterial species known to delay wound healing such as *Pseudomonas aeruginosa* and *Staphylococcus aureus*. These bacterial species are known to form biofilms
- demonstrates *in-vitro* antimicrobial activity for up to 7 days
- may reduce odour caused by micro-organisms in the wound
- 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 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.
- can be left in place during MR scan. It is compatible up to 3 Tesla

The product consists of:
- a vapour permeable top film which is bacteria- and waterproof
- an absorbent polyurethane foam with silver
- a perforated silicone adhesive
- turquoise protective films

Dark spots may appear on the product due to the silver content. This will not affect product performance and you can still use the product.

Sterilised using ethylene oxide (EO).

Summary of safety and clinical performance will be made available on completion of the European database on medical devices (Eudamed) https://ec.europa.eu/tools/eudamed. It is found in Eudamed by searching for the following Basic UDI-DI: 57089322852968C

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

Medicinal substance
This product incorporates silver at an average of 0.95 mg per cm² foam.

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.

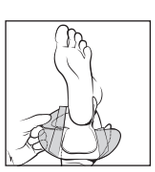
If the wound is low-exuding, the product may be moistened with sterile physiological saline solution before application.

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

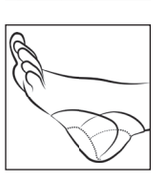
Open the pouch and pick up the product from the packaging.

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.

The product may cause a transient discolouration of the wound bed, which can be removed by gentle washing.

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
	Contains a medicinal substance
	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