



DEVICE DESCRIPTION

SYLKE® Skin Closure is a single-use, sterile, woven silk fibroin mesh strip coated on one side with a pressure-sensitive adhesive. The adhesive surface is covered by a removable release liner with a pre-slit tab.

HOW SUPPLIED

Each SYLKE® Skin Closure strip is provided sterile in an individually sealed pouch. The device is available in multiple lengths and widths. Refer to product label and regional catalog for specific dimensions and available packaging configurations.

INTENDED USE

SYLKE® Skin Closure is a sterile, single-use, silk fibroin mesh strip with a pressure-sensitive adhesive intended for topical skin closure and wound support. The device is used to hold together well-approximated skin edges of a wound, and to cover and protect the wound. The device is designed for wear of up to 14 days. SYLKE® Skin Closure may be applied by healthcare professionals or, where permitted by applicable laws and regulations, by lay users following the included instructions.

INDICATIONS

SYLKE® Skin Closure is indicated for topical closure and coverage of thoroughly cleansed simple lacerations and minor cuts, where it may be used as the primary skin closure. SYLKE® Skin Closure is also indicated for topical closure and coverage of post-surgical skin incisions in which deeper layers have been closed, where it is used as an adjunct to sutures or staples. Wound edges must be easily approximated without tension.

CONTRAINDICATIONS

- SYLKE® Skin Closure is contraindicated for use on infected or contaminated wounds. Signs of infection may include: pus, pain, warmth, redness, swelling, and/or fever. If any signs of infection are present, seek medical attention.
- SYLKE® Skin Closure is contraindicated for use on wounds containing dirt, debris, or other contaminants. Wounds must be thoroughly cleansed prior to application. Trapping contaminants beneath the device may lead to infection.
- SYLKE® Skin Closure is contraindicated for use in high-tension wounds without the support of additional skin closure devices e.g., sutures.
- SYLKE® Skin Closure is contraindicated for use on wounds that are actively bleeding.
- SYLKE® Skin Closure is contraindicated for use below the skin surface.
- SYLKE® Skin Closure is contraindicated for use on mucosal surfaces or surrounding areas including lips, inside the mouth, eyes, eyelids, or the genital and perianal region.

WARNINGS

- SYLKE® Skin Closure is intended to be worn for up to 14 days. Early removal of SYLKE® Skin Closure may result in skin stripping, pain, and/or redness. To aid in early removal, SYLKE® Skin Closure may be soaked in warm water to soften the adhesive. If signs of infection are present around the wound covered by SYLKE® Skin Closure, contact a medical professional.
- Do not use SYLKE® Skin Closure if the sterile package is damaged or compromised.
- Individuals with a history of sensitivity to silk or adhesive materials may be at increased risk for skin irritation or allergic reaction. Monitor for signs of hypersensitivity, including redness, swelling, or rash at the application site. If any of these develop, remove the device and contact a healthcare provider.

PRECAUTIONS

- Apply SYLKE® Skin Closure only to areas where adhesion can be obtained. Causes of inadequate adhesion include exudate, skin oils, moisture, or areas containing dense hair such as the scalp.
- Performance of SYLKE® Skin Closure under a secondary dressing has not been evaluated. Healthcare providers should use clinical judgment when considering the use of a secondary dressing over SYLKE® Skin Closure. Lay users should not apply a secondary dressing over SYLKE® Skin Closure without first consulting a healthcare provider.
- Submersion in water may impact the device's performance and duration of use.

ADDITIONAL INFORMATION

SYLKE® Skin Closure is not made with natural rubber latex.

SYLKE® Skin Closure has not been evaluated for use in hyperbaric oxygen therapy (HBOT) environments. Safety and performance under hyperbaric conditions have not been established. Healthcare providers should use clinical judgment when considering the use of SYLKE® Skin Closure on patients undergoing HBOT.

STORAGE

For best results, store in a cool, dry place away from direct sunlight. Do not use after the expiration date printed on the label.

STERILITY

SYLKE® Skin Closure is sterilized by ethylene oxide gas. Do not re-sterilize. Do not use if package is opened or damaged. Do not use SYLKE® Skin Closure if strip is damaged or discolored. Discard any unused material.

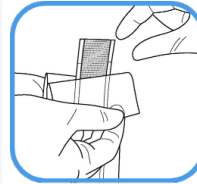
APPLICATION

SYLKE® Skin Closure should only be used on clean, dry wounds when the skin edges of the wound are easily approximated without tension. Examine environment where SYLKE® Skin Closure will be handled and applied and ensure the absence of visible dirt or contaminants.



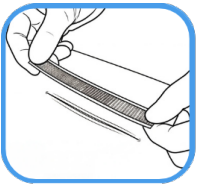
1 FIGURE A

Thoroughly cleanse and dry wound to prepare skin for proper adhesion of SYLKE® Skin Closure to the wound edges.



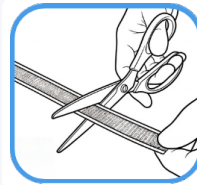
2 FIGURE B

Open sterile pouch. Remove SYLKE® Skin Closure strip from pouch.



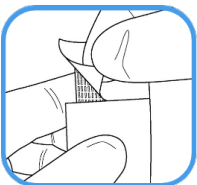
3 FIGURE C

With the release liner still in place, hold the strip alongside the wound to measure the required length. The strip should extend at least 1 cm beyond each end of the wound.



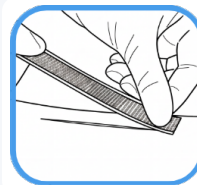
4 FIGURE D

Using clean scissors, trim the strip to the appropriate length.



5 FIGURE E

Hold the strip and peel back the pre-slit tab to expose the adhesive.



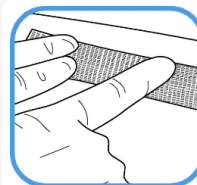
6 FIGURE F

Place the exposed adhesive section on the skin at least 1 cm beyond one end of the wound. Press firmly to anchor the strip to the skin.



7 FIGURE G

While holding the anchored end in place, slowly peel away the release liner and press the adhesive strip along the length of the wound. The strip should extend at least 1 cm beyond the opposite end of the wound. If the wound length exceeds the length of a single strip, repeat previous steps with additional devices.



8 FIGURE H

Press firmly along the entire length of the strip to secure. Check that all edges are flat against the skin and no sections are lifted. Proper adhesion is achieved by applying pressure evenly across the strip.

INSTRUCTIONS FOR WEAR

- When showering, do not scrub the device with a loofah, exfoliant, or other abrasive. Gently pat dry.
- Do not swim or fully submerge the wound while wearing SYLKE® Skin Closure.
- Keep wound clean and free of dirt and debris. Dirt trapped in the SYLKE® Skin Closure may cause irritation or infection.
- Contact a healthcare provider if the device detaches partially or completely before 14 days or if signs of infection or irritation are present.
- Remove SYLKE® Skin Closure after 14 days.
- SYLKE® Skin Closure is a single-use device and must not be reapplied after removal

REMOVAL INSTRUCTIONS

- 1 Gently lift the edge of SYLKE® Skin Closure at one end of the wound.
- 2 Slowly peel SYLKE® Skin Closure away from the skin along the line of the wound. Use other hand to stabilize the surrounding skin to decrease tension as the SYLKE® Skin Closure strip is peeled off.
- 3 If SYLKE® Skin Closure does not easily remove from skin, soak strip in warm water to soften adhesive.
- 4 Once fully removed, discard the skin closure strip in a standard disposal bin. Do not re-use or re-sterilize the device.
- 5 Any residual adhesive and/or dried wound exudate can be gently cleaned from the skin with warm soapy water. If residue remains, a medical adhesive remover may be used to loosen adhesive remnants.

INFORM THE MANUFACTURER

If you have any questions or comments, please contact SYLKE®, Inc. at info@sylke.com.

Please report a serious incident occurring in relation to the device to SYLKE®, Inc. at quality@sylke.com and the local regulatory authority.

The Instructions for Use are provided in electronic format. If a paper copy is required, it can be requested free of charge, including shipping, via compliance@sylke.com.