# SYLKE Adhesive Wound Closure Dressing

*May 2024*

## Overview

Wound closure products are used to approximate wound edges, and offload tension to promote wound healing. SYLKE is made of a hypoallergenic stretch silk fibroin dressing that provides elasticity and movement while keeping wound edges together. The dressing allows for control of mild to moderate exudate while providing protection from contaminants. SYLKE adhesive wound closure dressing can be worn up to 2 weeks with regular bathing. Removal is facilitated with "warm salt water or dabbed with a rubbing alcohol-soaked cotton ball to soften the adhesive". [1,2] SYLKE is contraindicated for wounds that are infected, signs of infection, dirty wounds, high tension wounds, and those actively bleeding. The product is not intended to be used on mucosal areas, near or on the eye, or intimate areas as it can cause damage to those areas. [2]

## Actions for Consideration

### PARTNER

**ENGAGE SUBJECT MATTER EXPERTS**
Assess plans for product use and implementation. Include surgeons, wound care physicians and nurses, and value analysis leaders.

**CONSIDER IMPACT OF USE**
Understand indications for use, cost impact, and surgeon perceived benefit.

**UNDERSTAND CONCERNS**
Continue conversations and identify concerns related to utilization vs. cost and benefit with wound care, infection prevention, and surgeons.

### CONNECT

**SEEK CLINICAL IMPACT**
Identify opportunities, through product use, to support improved quality of care. Evaluate patient outcomes.

**CONDUCT ANALYSIS**
Compare current product and proposed product pricing, and consider trial period to determine benefit.

**DETERMINE POPULATION**
Work with key stakeholders to determine appropriate patient population for use.

### COMMUNICATE

**EDUCATE AND TRAIN**
Engage supplier to determine need for training and consider an algorithm to identify appropriate patient population for use.

**PLAN AHEAD**
Create education plan regarding product usage & expected outcomes.

**FOLLOW-UP FOR FEEDBACK**
Monitor use to ensure correct patient population is targeted as well as outcomes to ensure product is meeting expectations.

## Professional Society Statements & Clinical Practice Guidelines

### US Food and Drug Adminstration

There are no formal guidelines or statements related directly to the use of the SYLKE product. However, in the *Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin - Class II Special Controls Guidance for Industry and FDA Staff*, it provides current thoughts in relation to topical approximation of skin: materials used, risk to health, shelf life, sterility and clinical studies. [3] Found here.

### Centers for Medicare & Medicaid Services

While the Centers for Medicare & Medicaid Services does not make recommendation on guidelines for use, in their *Surgical Dressings - Policy Article,* they address qualifying dressing requirements. More information can be found here. [4]

*See Reference section for complete listing of research sources.*

## Clinical Evidence

Evidence within this category is related to the safety and effectiveness of silk based dressings, and does not address SYLKE specifically. A sample of the available evidence is provided.

A comprehensive literature search (2018) included 29 studies on the effectiveness of silk fibroin and silk sericin dressings in wound healing. The study showed that silk-based dressings were effective in wound healing "by promoting cell attachment, migration, and collagen deposition". Limitations of studies were noted as only one human random control trial was completed, with all other studies conducted being either in vitro or in vivo animal models of wound healing. [5]

A 2023 randomized, single-blinded study comparing the use of silk bioprotein wound dressing with Dermabond Prineo looked at safety and efficacy related to medical adhesive-related skin injuries. The study included 25 patients who were dressed with Dermabond Prineo on one side of their body and on the contralateral side with the silk bioprotein dressing after undergoing abdominoplasty or reduction mammaplasty procedures. The use of silk dressings showed considerably less discomfort (1 in 25), rash (0 in 25) , and the need for steroid or antibiotic treatment (0 in 25) compared to the control side of Dermabond Prineo. [6]

## Clinical Insights: HealthTrust Huddle Feedback

Members of the HealthTrust Huddle network provided insights & experiences using these products. [7]

### HealthTrust Huddle Insights

**Advantages:**

- **Potential for enhanced wound healing**
- **Potential for faster wound healing**
- **Ability to approximate wound edges**
- **Less frequent dressing changes needed**
- **Remains in place , even while bathing for up to 2 weeks**
- **Dressing flexibility, allows for body movement**
- **Hypoallergenic material**

**Locations for use:**

- **Hospital**
- **Out-patient clinic**
- **Physician offices**

*See Reference section for complete listing of research sources.*

## FDA Approval

SYLKE has been registered as an FDA Class 1 medical device since October 2023. It is indicated for "use as a topical wound closure device in the treatment and coverage of simple lacerations, cuts, puncture wounds, and post-surgical wounds. Sylke® Adhesive Wound Closure may be used in conjunction with skin sutures to assist in the closure of skin edges." [2]

*Information on FDA product classification levels can be found **here**.*

## Summary

1. Advantages of these silk dressings include: long wear times, allows the ability to bathe, offloads tension, and has flexibility.
2. As this may be a physician preference item, engaging a physician champion will be beneficial for peer to peer discussions.
3. Studies have found that silk dressings are safe and effective forms of surgical wound treatment.

## HealthTrust Clinical Resources

**Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials. [8,9]**

ASK A QUESTION | PROVIDE YOUR FEEDBACK | SHARE YOUR VOICE | NETWORK WITH PEERS

**PERSONALIZED REQUEST SERVICE & RESOURCE LIBRARY**

www.hpginsights.com

**PEER NETWORKING**

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

## References

1. SYLKE. SYLKE Adhesive Wound Closure. SYLKE. Accessed May 13, 2024. https://www.sylke.com/pages/product-page
2. SYLKE. Instruction of Use. SYLKE. Accessed May 13, 2024. https://www.sylke.com/pages/instructions-for-use
3. U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Plastic and Reconstructive Surgery Devices Branch Division of Surgical, Orthopedic and Restorative Devices Office of Device Evaluation. Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin - Class II Special Controls Guidance for Industry and FDA Staff. FDA. Published online 2023. Accessed May 13, 2024. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/tissue-adhesive-adjunct-wound-closure-device-intended-topical-approximation-skin-class-ii-special
4. Centers for Medicare & Medicaid Services. Article - Surgical Dressings - Policy Article (A54563). www.cms.gov. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=54563
5. Kamalathevan P, Ooi PS, Loo YL. Silk-Based Biomaterials in Cutaneous Wound Healing: A Systematic Review. Advances in Skin & Wound Care. 2018;31(12):565-573. doi:10.1097/01.ASW.0000546233.35130.a9
6. Rouhani DS, Singh NK, Chao JJ, Almutairi A, Badowski-Platz R, Seradj MH, Mofid MM. Silk Bioprotein as a Novel Surgical-Site Wound Dressing: A Prospective, Randomized, Single-Blinded, Superiority Clinical Trial. Aesthet Surg J Open Forum. 2023 Oct 20;5:ojad071. doi: 10.1093/asjof/ojad071. PMID: 37899912; PMCID: PMC10603584.
7. 2024 Huddle Network. SYLKE. Collected April 2024.
8. HealthTrust Performance Group. Clinical Knowledge Insights. http://www.hpginsights.com/. Published 2023. Accessed May 7, 2024.
9. HealthTrust Performance Group. HealthTrust Huddle. https://huddle.healthtrustpg.com/forum/. Published 2023. Accessed May 7, 2024.