

LABORATOIRES URGO HEALTHCARE

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FICHE TECHNIQUE

LUHUS0007

URGOSTRIPS, sutures chirurgicales adhésives stériles**URGOSTRIPS, sterile adhesive surgical suture**

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URGOSTRIPS, sterile adhesive surgical suture

□ DESCRIPTION:

Urgostrips is a medical device presented as pre-cut strips, laid flat on a silicone-coated layer with double grip tabs, and protected with a sterile peel sachet. Each Urgostrips strip consists of a non-woven backing coated with an adhesive mass.

Sterile (sterilized with ethylene oxide).

□ PRESENTATIONS :

DIMENSIONS
73 x 3 mm
73 x 6 mm
100 x 6 mm
100 x 12,5 mm

□ PROPERTIES:

The sterile adhesive Urgostrips sutures promote aesthetic healing process thanks to their high resistance to rupture, their high adherence and their high cutaneous tolerance.

□ INTENDED USE:

Rapid and sterile closures of superficial wounds and surgical incisions.

In particular:

- Suture for small emergency surgery, dermatological surgery, plastic surgery and limited post-operative incisions (< 2.5 cm)
- Primary sutures on superficial wounds or without tensile overstress
- Use as secondary reinforcement between stitches or staples or as a replacement after the 3rd day to limit the risk of disfigurement
- Sutures under plasters or resins

A wound (or a cut) is considered as superficial if it only reaches the skin or the immediate underlying fats. If an accidental superficial wound overpasses 3 cm, a doctor should be consulted within the 6 hours following the accident to determine if the wound should be sutured or cared (glued with a special surgical adhesive, ...)

□ INSTRUCTIONS FOR USE:

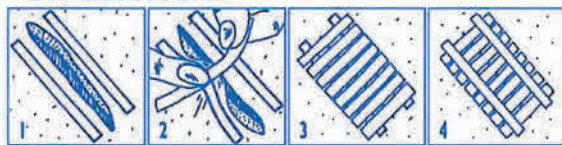
For people under 16 years, it must be applied by an adult

1. Clean and disinfect the wound and its surrounding area with an antiseptic solution. Monitor haemostasis if necessary (stop the bleeding).
Dry with a sterile compress to enhance the adhesion of the strips.
2. Open the sachet aseptically. If the strips should be cut, the scissors should be sterile or disinfected with alcohol.

3. After a thorough hand washing with water and soap, apply 2 parallel strips along and on both sides of the wound, (see illustration)
4. Make sure that fingers are not placed on the part of the strip which shall come in contact with the wound. Apply a third strip perpendicularly on one edge of the wound and, while slightly stretching it, apply it on the opposite edge to draw the wound edges near, without overlaying.
5. Apply the next strips in the same way until the wound closure is completed. Finish the assembly by applying 2 strips across to reinforce the whole.

Leave the strips in place (3 to 4 days) until they come off or until they lose function. Replace the strips according to the instructions for use until complete healing. The wound must stay dry. The primary healing of a superficial wound lasts about ten days.

See illustrations.



□ PRECAUTIONS FOR USE:

- The presence of hair or greasy products on skin may impact the adherence.
- Single-use sterile strips. Do not re-use or re-position a strip already applied, do not keep a strip in an open sachet (otherwise risk of infection).
- Do not re-sterilise. Check the integrity of the sterile protector before use. Do not use if the package is damaged.
- To limit the risk of secondary wound infection, it is recommended to cover the whole with an antiseptic dressing. Do not remove and change the strips at each dressing renewal.
- Wound healing is facilitated if the positioning of the strip avoids space or overlaying between the edges of the wound.
- Inspect the wound and the surrounding area regularly in order to detect any signs of infection such as pain, redness, oedema, odour or pus formation.
In case of any doubt or infection, contact your physician or health care professional.
- Keep the sachets in their original box.
- Do not use after the expiry date (indicated on the box and the sachet)

□ CONTRA-INDICATIONS:

- Do not use on infected, exudative or bleeding wounds.
- Do not apply on eyes or eyes lids
- Do not use on joint areas (high risk of tensile overstress or strips tearing)
- Do not use URGOSTRIPS more than 30 consecutive days.
- Contraindicated for premature babies and infants weighing less than 3.5 kg.

□ **TECHNICAL DATA:**

CHARACTERS	TECHNICAL CHARACTERISTICS
Adhesive power	4.0 to 6.4 N/cm
Rupture strength	≥ 30 N/cm
Sterility	Sterile

□ **REGULATORY STATUS:**

In the European Union: "URGOSTRIPS, sterile adhesive surgical suture" is a CE 0459 marked class II a medical device.

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