



Clozex Wound Closure Device

INSTRUCTIONS FOR USE

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IMPORTANT: Please visit our website at www.clozex.com to review our training videos and instructions.

The Clozex® Wound Closure Device is a single-use non-invasive sterile skin closure used to close minor cuts and lacerations. A single device matching the approximate wound length can be used, or multiple devices may be aligned side by side to close longer length wounds. The device is applied to clean, dry skin prior to skin closure, remains on the skin during wound healing (7-10 days), and may be removed by lifting the edges and peeling the device from the skin. The device is made of polymeric films (flexible medical grade plastics) coated with non-latex, pressure sensitive skin adhesive. Clozex Wound Closure Device is intended for children and adults.

Indications for Use

Clozex® wound closure device is indicated for patient therapies requiring non-invasive approximation of skin lacerations. The closure devices can also be used as an adjunct to suture closures or as reinforcement for wounds or incisions after early suture or staple removal.

Contraindications

- Do not use if wound is not clean or dry. The presence of excessive blood, wound fluids, skin oils, moisture, or hair will impact adhesion to the skin.
- Do not use on any dirty or infected wounds.
- When allergy to skin adhesives is known or suspected.
- Do not use on deep wounds where fatty tissue is visible, non-healing wounds, burns, or in high tension wounds that are not easily closed.

Warnings

- Skin should be clean, dry and free of wound fluids, skin oils, excess prep residue, or hair.
- Wound swelling may cause skin shearing, skin blistering, or loss of tape adhesion to occur.
- Application of any surgical tape or adhesive based device may cause skin stripping upon removal.
- A small percentage of individuals may experience allergic reaction and/or hypopigmentation or hyperpigmentation (temporary skin discoloration) of the skin following removal.
- Do not use if the device is damaged during the procedure. Risk of device failure may occur if damaged.
- Do not use if package is opened or damaged.
- Single use device. Do not reuse. Risk of device failure or infection may occur if reused.
- Do not use if the sterile pouch is compromised prior to use.
- If the wound shows signs of redness, infection, or does not heal, consult a physician.

Precautions

- Consult healthcare professional if wound shows signs of redness, infection, or does not heal.
- Properly clean wound and control bleeding prior to applying. The skin should be clean, dry, and free of skin oils for good adhesion prior to applying.
- Do not apply skin closures under excessive tension. Skin shearing, skin blistering or loss of adhesion may result if excessive tension is applied.
- You may take brief showers with your Clozex device in place, but avoid letting the direct, constant force from the stream of water contact the device. Do not scrub the area. Do not swim, use a hot tub, or soak the device in a bath, as this may weaken the adhesives. If your wound gets wet, gently pat the area dry with a towel.
- Wound closure length of the device is indicated on the Clozex sterile pouch for each part number.
- If multiple devices are used, devices can be aligned side by side to allow closure of a longer length wound.
(Applicable to part numbers offering multiple closures.)
- The Clozex device will gradually start to release over time as your wound heals. To remove the Clozex closure, gently grasp both edges and slowly lift the device off the skin, peeling only in the direction along the length of the wound. **DO NOT PEEL ACROSS THE WOUND.**
- Instruction for safe disposal: Place in plastic bag and throw in trash.

DISCLAIMER

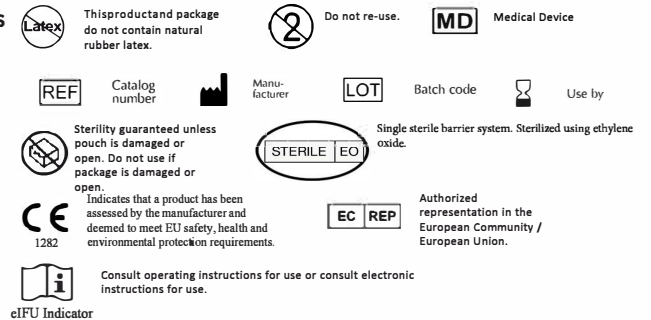
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If you have any specific questions about any medical matter, you should consult your doctor or other professional healthcare provider. If you are suffering from a medical condition, you must seek immediate medical attention. Do not disregard medical advice or discontinue medical treatment because of information in these instructions or on our website.

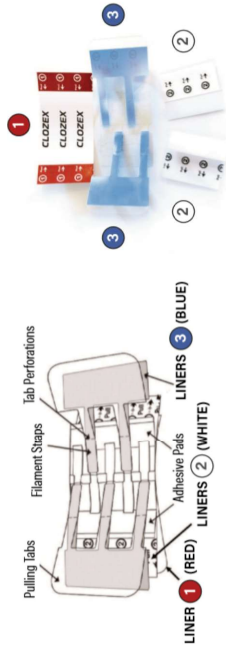
Nothing in this medical disclaimer will limit or exclude our liabilities that may not be excluded under applicable law.

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Explanation of symbols



The liners of Clozex closures are numbered 1, 2, 3 and color-coded RED, WHITE, BLUE to indicate the sequence of liner removal.



1 CLEAN

PROPERLY CLEAN WOUND AND CONTROL BLEEDING PRIOR TO APPLYING. Clean and dry the skin at least 2 inches (50 mm) around the wound, taking care to remove wound fluids and excessive skin oils. Clozex closures should only be applied to dry skin. (Sterile gauze and alcohol pad included in Emergency Laceration Kits only.)



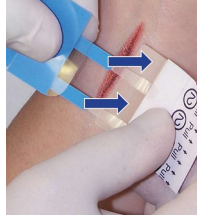
2 UNCOVER

Peel open the pouch and remove the skin closure device. Grasp the LINER 2 (WHITE) and LINER 3 (BLUE) along with the clear pulling tab in one hand and peel off LINER 1 (RED) with the other hand to expose the adhesive on both clear pads of the device.



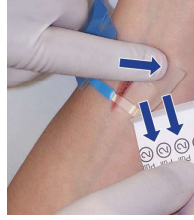
3 POSITION

Turn the device over with adhesive pads facing the skin. Grasping the two white liners, widen the gap between the adhesive pads to prepare for each adhesive pad to be applied independently to the skin edge.



4 APPLY TO WOUND EDGE

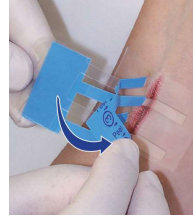
APPLY BOTH PADS TO DRY SKIN ONLY. Holding the LINERS 2 (white), apply each clear adhesive pad to the skin approximately 1/16 inch (1-2mm) back from each side of the wound edge. Gently press to secure each half one at a time.



5 COMPLETE PAD APPLICATION

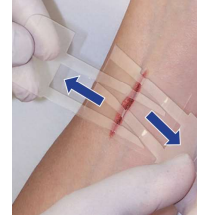
Gently remove LINER 2 (white) while holding the adhered pad to the skin and gently press the pad to secure it firmly to the skin. Repeat step 5 to apply the second pad to the second wound edge.

DRY TOPS OF ADHESIVE PADS IF NEEDED BEFORE PROCEEDING.



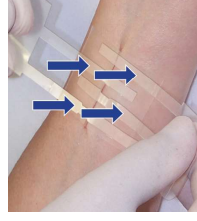
6 PREPARE FOR CLOSURE

Holding both of the clear pulling tabs and LINERS 3 (BLUE) upright and perpendicular to the wound, peel down LINER 3 (BLUE) on each side exposing the adhesive of the filament straps. **IMPORTANT** – do not allow premature adhesion of the filament straps to the adhesive pads before ready.



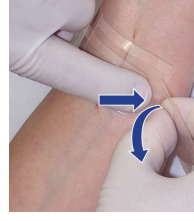
7 ALIGN

Holding the clear pulling tabs in each hand, pull the wound edges closed uniformly all along the wound edge until optimum skin edge alignment is achieved.



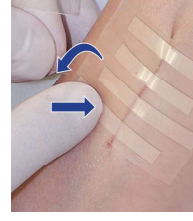
8 SECURE

When the skin edges are properly aligned, lower the filament straps down onto the dry secured adhesive pads. Press on the filament straps to secure them onto the adhesive pads to maximize overall adhesion.



9 REMOVE PULLING TABS

To remove the ends of the pulling tabs, press each adhered filament strap next to the perforation and gently twist off the end.



10 REMOVE PULLING TABS

Repeat step 9 to remove ends of pulling tabs on the other side.



11 COVER

Cover the wound area with a bandage at your discretion to keep the area dry and clean. Do not adhere the adhesive portion of the cover bandage or tape directly onto the clozex device as this could result in accidental removal or damage of the device. (Cover bandage included in Emergency Laceration Kits only).