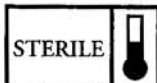


BIOBRANE®

temporary wound dressing

CE 0197



GLOVE INSTRUCTIONS

BIOBRANE is a biocomposite dressing made from an ultrathin, semipermeable silicone membrane mechanically bonded to a flexible knitted trifilament nylon fabric. A nontoxic mixture of highly purified peptides derived from porcine dermal collagen has been bonded to the nylon/silicone membrane to provide a highly flexible and conformable composite dressing with adherence properties and a hydrophilic, biocompatible surface.

The semipermeable silicone membrane controls water vapor loss at rates comparable to normal skin and provides a flexible adherent covering for the wound surface. It conforms to the entire hand allowing joint movement and minimizes the proliferation of bacteria on the wound surface by minimizing dead space.

BIOBRANE is applied with **FABRIC (DULL) SIDE DOWN**, wrinkle-free against a wound surface from which all loose or necrotic skin has been debrided or excised. Initial adherence results from the fibrin on the clean wound surface preferentially bonding to the collagen surface of the dressing. Stronger secondary adherence results from physical entrapment of fibrin and tissue ingrowth into the nylon fabric.

Wound Selection

The BIOBRANE glove is intended for covering clean partial thickness burn wounds of the hand. The glove promotes early movement of the burned hand.

Caution: The BIOBRANE glove is not recommended for meshed autografts on fingers or hands because of the potential for shearing the grafted tissue.

Warning: In rare instances, allergic reactions to BIOBRANE have been reported. If a patient shows evidence of an allergic reaction, BIOBRANE should be removed and its use discontinued.

Application

- Application should be to freshly debrided or excised wounds containing less than 10⁶ bacteria/g tissue.
Caution: The debridement or excision must be done thoroughly to remove all coagulum or eschar. BIOBRANE will not adhere to dead tissue and any remaining necrotic tissue may cause infection.
- Establish hemostasis prior to application of the BIOBRANE glove.
- Immerse the appropriate size glove in sterile water, then slip over the hand to obtain a uniform wrinkle-free fit.
- Do not turn any part of the glove inside out. Fitting the glove, as received, over the hand/fingers automatically places the **FABRIC (DULL) SIDE DOWN** against the wound surface.
- Under slight tension immobilize the glove using staples, tape, sutures, or skin closure strips.
- Wrap the hand and each finger with a dry gauze dressing or other stenting device to hold the glove firmly in contact with the entire wound surface. Minimize hand movement until adherence occurs (24 to 36 hours postapplication).

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Nursing Patient Instructions

24 Hours Postapplication

- Do not remove the outer dressing. Do not get the dressing wet.
- Do not move the gloved hand more than necessary.

24 to 36 Hours Postapplication

- Remove the outer dressing down to the BIOBRANE glove and observe for the following:
 - If the glove is adherent and no fluid accumulation is present, rewrap with gauze for protection.
 - If areas of the glove are loose, but the underlying tissue is still viable, aspirate or roll out any nonpurulent fluid collection, rewrap with a gauze dressing and observe in 24 hours for adherence.
 - If the glove is loose and there is purulent drainage underneath, remove the purulent non-adherent areas and use conventional topical antimicrobial therapy to reduce bacterial contamination to safe levels.

48 to 72 Hours Postapplication

- Remove the outer dressing down to the BIOBRANE glove and check the adherence. If the glove is adherent, the outer dressing need not be reapplied. If nonadherent, treat as referenced above.
- Observe the BIOBRANE glove daily for bubbles and purulence and treat as referenced above. BIOBRANE should be removed from areas of the wound with signs of infection.
- Remove staples, tape, sutures, or skin closure strips 3 to 4 days postapplication or when adherence is achieved.
- Once the glove is adherent, patients can be bathed according to standard burn unit protocols.
- Once the glove is adherent, movement of the burned area can be initiated.

Removal

- Begin removing the glove when the underlying tissue is healed, typically 7 to 14 days. The dressing should be dry and loose in spots, and the patient may report itching.
- If areas are loose, they can be trimmed away until the entire wound has healed.
- BIOBRANE will peel off healed tissue relatively easily. The application of a petroleum based ointment or soaking prior to removal facilitates the removal process.

Caution: If bleeding occurs during removal or if patient complains of excessive pain, stop and wait 1 to 2 additional days. Forced removal may result in wound reinjury. Also, if BIOBRANE becomes adherent to a partial thickness wound which has progressed to a full thickness wound, it should be removed in the operating room.

HOW SUPPLIED

Sterile, BIOBRANE gloves are available in four sizes and are interchangeable between the left and the right hand.

Size	No./Box	REF
Large	2	8459-099-68
Medium	2	8459-099-67
Small	2	8459-099-66
Pediatric	2	8459-099-65

STORAGE

There are no special storage requirements. Results from shelf life studies performed on product that was stored for three years at room temperature indicated that the product remained sterile and pyrogen-free. Moreover, degradation of collagen peptides did not occur.

MANUFACTURER:

UDL Laboratories, Inc.
Sugar Land, Texas USA 77478
Tel. +1-877-446-3679



DISTRIBUTOR:

UDL Laboratories, Inc.
Rockford, IL USA 61103

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EU Responsible Person:
MDSS GmbH
Schiffgraben 41
D-30175 Hannover
Germany
Tel. +49-511-6262-8630

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