BIOBRANE®
BIOBRANE®-L

temporary wound dressing

CE 0197

STERILE

INSTRUCTIONS

BIOBRANE is a biocomposite dressing made from an ultrathin, semipermeable silicone membrane mechanically bonded to a flexible knitted trifilament nylon fabric; BIOBRANE-L utilizes a monofilament nylon. 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 surface irregularities allowing joint movement and early ambulation and minimizes the proliferation of bacteria on the wound surface by minimizing dead space.

BIOBRANE/BIOBRANE-L 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.

The lower weight monofilament thread utlitized in BIOBRANE-L results in less secondary adherence.

Wound Selection

The differences in adherence between BIOBRANE and BIOBRANE-L should be considered relative to the wound. Suggested uses are as follows:

BIOBRANE	Clean partial thickness burn wounds Donor sites
BIOBRANE-L	Meshed autografts

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

Application

- Application should be to freshly debrided or excised wounds, or meshed autografts containing less than 10^5 bacteria/g tissue.
  Caution: The debridement or excision must be done thoroughly to remove all coagulum or eschar. BIOBRANE/BIOBRANE-L will not adhere to dead tissue and any remaining necrotic tissue may cause infection.
- Establish hemostasis prior to application of BIOBRANE/BIOBRANE-L.
- Apply **FABRIC (DULL) SIDE DOWN**, wrinkle-free against the wound surface with slight tension.
- Note: If less secondary adherence is desired (e.g. deeper donor sites or meshed autografts), BIOBRANE-L is recommended.
- Under slight tension immobilize BIOBRANE/BIOBRANE-L using staples, tape, sutures, or skin closure strips and wrap area with a dry gauze dressing or other stenting device to hold the dressing firmly in contact with the wound surface for 24 to 36 hours.

Nursing/Patient Instructions

24 Hours Postapplication

Do not remove the outer dressing. Do not get the dressing wet.
Do not move the covered area more than necessary.

24 to 36 Hours Postapplication

Remove the outer dressing down to the BIOBRANE/BIOBRANE-L and observe for the following:

- If the BIOBRANE/BIOBRANE-L is adherent and no fluid accumulation is present, rewrap with gauze for protection.
- If the BIOBRANE/BIOBRANE-L is 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 BIOBRANE/BIOBRANE-L is loose and there is purulent drainage underneath, remove the purulent nonadherent 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/BIOBRANE-L and check for adherence. If adherent, the outer dressing need not be reapplied. If nonadherent, treat as referenced above.
- Observe the covered wound daily for bubbles and purulence and treat as referenced above. BIOBRANE/BIOBRANE-L 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 BIOBRANE/BIOBRANE-L is adherent, patients can be bathed according to standard burn unit protocols, and motion of the burned area can be initiated.

Removal

- Remove the BIOBRANE/BIOBRANE-L when the tissue underneath is healed, typically 7 to 14 days. The dressing should be dry and loose in spots, and the patient may report itching.
- If edges are loose, they can be trimmed away until the entire wound has healed.
- Remove by starting at one corner and pull gently. BIOBRANE/BIOBRANE-L 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, 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/BIOBRANE-L 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, individually packaged pieces are available in the following sizes:

Size	Biobrane No. Box/REF	Biobrane-L No. Box/REF
5" x 5" (13 cm x 13 cm)	5/8459-0095-25	5/8459-0096-25
5" x 15" (13 cm x 38 cm)	5/8459-0095-76	5/8459-0096-76
10" x 15" (25 cm x 38 cm)	5/8459-0095-77	5/8459-0096-77
15" x 20" (38 cm x 50 cm)	1/8459-0095-79	Not available

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.

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English
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