PERMEADERM

Biosynthetic Wound Matrix

Rx Only

Care and Handling Instructions

Stedical Scientific Inc. is the legal manufacturer for PermeaDerm B, C and Glove:

Stedical Scientific, Inc.
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Phone: 1-858-753-9530

PermeaDerm is available in three configurations:

PermeaDerm B, PermeaDerm C and PermeaDerm Glove

Device Description and Intended use: PermeaDerm B, C and Glove are intended for use as a Biosynthetic Wound Matrix to provide a moist wound healing environment on cleanly debrided non-infected wounds after hemostasis has been established.

Indications for use:

PermeaDerm is indicated for partial-thickness burn wounds and other partial-thickness wounds, pressure ulcers (sores), venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Mohs, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds, donor sites and coverage of meshed autograft.

PermeaDerm Glove is indicated for debrided partial thickness hand burns.

Single Use: PermeaDerm Biosynthetic Wound Matrix are sterile, single use products sold by prescription only. Do not reuse. Do not resterilize.

Instructions for use:

1. Open sealed pouch to extract sterile PermeaDerm from white Tyvek card and place on sterile tray. Refer to "This Side Up" label.
2. The 2D smooth surface faces the white Tyvek card.
3. The 3D bio-coated nylon surface of PermeaDerm faces away from the Tyvek card.

CRITICAL: Place the 3D bio-coated nylon surface against the debrided wound to ensure early adherence. Note: When the 3D bio-coated surface is pressed against itself the surfaces do not stick together, however when the smooth 2D silicone surface is pressed against itself the surfaces will stick together.

4. Once the PermeaDerm Glove is placed on the hand, locate "Peel Here" label to remove and discard the mylar backing.

- PermeaDerm should only be used on cleanly debrided, non-infected wounds with the nylon side in contact with the wound surface. All debris and non-viable tissue must be removed prior to the application of PermeaDerm.
- PermeaDerm should be minimally stretched to remove wrinkles while maintaining the bioengineered, three dimensional structure of the wound matrix and can be stretched to a greater degree should the clinician wish to increase porosity of the wound matrix.
- PermeaDerm can be used as a matrix subsequent to use with other medical device(s), therapies or device biologics. Refer to antimicrobial agents, surgical or enzymatic debridement.

CAUTION: Do not elongate more than 10%, minimize elongation when using on the face.

- Staples, sterile tape, glue or other anchoring methods can be used to secure PermeaDerm in place.
- A sterile outer wrap (gauze) is placed over PermeaDerm to absorb exudate and blood that will pass through the slits.
- The outer wrap is held in place for 24 – 36 hours with light pressure to achieve the desired adherence. Once blood or fluid exudation through PermeaDerm has ceased and adherence has been achieved, PermeaDerm does not require outer dressings.
- PermeaDerm should be left in place until healing occurs. For the superficial burn and donor sites, this is typically 7 – 14 days. For meshed autografts, it depends on the degree of meshing. Larger meshed autografts take longer to heal the interstices. Chronic wounds heal more slowly and may require new product application if PermeaDerm becomes non-adherent.

Warnings:

- The use of PermeaDerm on any patient with a known allergy to porcine or Aloe vera materials is contraindicated.
- If a patient has a rare allergic reaction to PermeaDerm it must be immediately removed and its use discontinued.

Warnings:

- If suppuration occurs beneath PermeaDerm, PermeaDerm should be removed, the wound cleansed, and wound care altered to include topical application of an antimicrobial agent.

Nursing/Patient Instructions

Within 24 Hours Post Application

- Do not remove the sterile outer wrap (gauze) or allow PermeaDerm to get wet.
- Keep contact and movement of the covered area to an absolute minimum.

24 – 36 Hours Post Application

- Remove the sterile outer wrap (gauze) to reveal the PermeaDerm layer and observe for the following:
- If PermeaDerm is adherent and no fluid accumulation is present, rewrap with sterile gauze for protection.
- If PermeaDerm is loose but the underlying tissue is viable, aspirate or roll out any non-purulent fluid accumulation, rewrap with sterile gauze dressing and observe in 24 hours for adherence.
- If PermeaDerm is loose and there is purulent accumulation underneath, remove the associated non-adherent areas of PermeaDerm and use conventional topical antimicrobial therapy to reduce bacterial contamination to safe levels.

48 – 72 Hours Post Application

- Remove the sterile outer wrap (gauze) to reveal the PermeaDerm layer and check for adherence. If adherent, the outer dressing need not be reapplied. If non-adherent, treat as referenced above.

- Observe the PermeaDerm covered wound daily for bubbles and purulence and treat as referenced above. PermeaDerm should be removed from areas of the wound with signs of infection.

- Remove staples, sterile tape, sutures, or other anchoring methods 3 – 4 days post application or when adherence is achieved.

- Once PermeaDerm is adhered, patients can be bathed in accordance with standard burn unit protocols and motion of the burned areas can be initiated.

Removal

- Remove PermeaDerm when the tissue underneath is healed, typically between 7 – 14 days. PermeaDerm should be dry and loose in spots and the patient may report some itching.
- If the edges are loose, they can be trimmed away until the entire wound has healed.
- Remove by starting at one corner and pulling gently. PermeaDerm 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 – 2 additional days. Forced removal may result in wound injury. If PermeaDerm becomes adherent to a partial thickness wound that has progressed to a full thickness wound, it should be removed in the operating room.

Storage and Transportation

- PermeaDerm shall be able to be used under the following operating environment conditions:
  Temperature: from 50°F (10°C) to 80°F (27°C).

  Humidity: zero to 80% non-condensing
  Atmospheric Pressure: 15 to 11 psi (-500 to 8,000 ft. elevation)

- PermeaDerm shall be able to be stored under the following storage environment conditions:
  Temperature: from 40°F (4°C) to 85°F (29°C).

  Humidity: zero to 80% non-condensing
  Atmospheric Pressure: 15 to 10.25 psi (-500 to 10,000 ft. elevation).

- PermeaDerm shall be able to be transported under the following transport environment conditions:
  Temperature: from 40°F (4°C) to 90°F (32°C).

  Humidity: zero to 80% non-condensing
  Atmospheric Pressure: 15 to 10.25 psi (-500 to 10,000 ft. elevation).

Sterile individually packaged PermeaDerm Biosynthetic Wound Matrix is available in a variety of sizes.

Package Security: If PermeaDerm product has been opened or damaged, please return to Stedical Scientific Inc.

Expiration Date: The expiration date is printed on the immediate package label. Do not use after the expiration date.

PermeaDerm can be used as a matrix subsequent to use with other medical device(s), therapies or device biologics. Refer to antimicrobial agents, surgical or enzymatic debridement.

For any complaint, please send to the following:

complaints@stedical.com