Dermal Template

PELNAC™

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PELNACTM has been designed for use as a temporary dermal matrix for all skin loss wounds that are partial thickness to deep dermis. PELNACTM is gradually replaced by host tissues as the atelocollagen structure is re-vascularised with fibroblasts and capillary infiltrates. This usually occurs between 21-28 days, although this will depend on other patient factors. The silicone layer can be easily separated from the atelocollagen matrix at this time, and the vascularised wound bed can be covered with a thin split thickness skin graft at this time, or left to heal by secondary intention.

PELNACTM consists of two layers; a porcine tendon derived atelocollagen sponge layer, approximately 3mm in thickness and a thin reinforced silicone film layer. PELNACTM is prepared by freeze-drying and does not require pre-washing before use, and can be stored at room temperature. PELNACTM is easy to prepare for use (see usage instructions) and is available in a wide range of sizes from 3 x 4cm to 200 x 240cm - this will aid in helping to reduce product wastage and therefore help cost effectiveness.

Clinical Advantage
- PELNACTM has been shown to have high “take” rates, with 95-100% vascular in-growth and with no infection.
- A thin split thickness skin graft can be used to cover the re-vascularised PELNACTM, thus reducing donor site injuries or the need for large and complex flap surgery.
- Minimal skin contracture as site recovers and pigmentation is restored.

Product Characteristic
- Made from atelocollagen derived porcine tendon and a reinforced silicone layer.
- The 3mm deep, soft collagen sponge structure ensures excellent contact with the irregular wound surface and helps reduce the appearance of surface irregularities.
- A wide variation of sizes and styles of PELNACTM appropriate for many wound conditions.
- Ease of use, transportation and storage due to freeze-dried preparation of product.

Mechanism of Action
- Fibroblasts and capillary infiltration into the atelocollagen structure from the recipients surrounding tissue will help form a good dermis-like tissue in approx. 21-28 days.
- Fenestrated PELNACTM will aid the re-vascularisation process and assist in wound drainage.

Post Placement Care
- PELNACTM should be cut to the size of the wound area and not overlap the wound onto healthy tissue. PELNACTM can be secured in place with the help of sutures or staples.
- PELNACTM silicone layer should be covered with a gauze, water resistant dressing (such as Jelonet™) or silver impregnated dressing, with enough pressure so that no dead spaces exist between the silicone and the outer dressing. Silicone dressings should NOT be applied on top of the PELNACTM silicone layer.
- The outer dressing can be changed after 2-3 days, however PELNACTM should not be changed or the silicone outer layer disturbed for at least 7-10 days.
- The Silicone layer will lift away from the PELNACTM atelocollagen when vascularisation has occurred and is ready for application of the Split Thickness Skin Graft (STSG).
- Dress the STSG with the standard hospital dressing procedure.

Intended Use
- Burn injuries, deep / partial thickness wounds
- Scar release / resurfacing of contacted burn scars
- Trauma injuries, such as de-gloving of soft tissue
- Wounds created by removal of melanoma or BCC
- Removal of Giant Cell Nevus
- Any large area of skin loss
- Chronic wounds
**Silicone film**

**Split-thickness skin graft**

**Collagen**

**sponge**

**Variation**

**Usage**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Immerse PELNACTM thoroughly in sterile physiological saline.</td>
</tr>
<tr>
<td>2</td>
<td>Perform hemostasis and thoroughly wash the wound.</td>
</tr>
<tr>
<td>3</td>
<td>Trim PELNACTM to fit the shape of the wound.</td>
</tr>
<tr>
<td>4</td>
<td>Apply the collagen sponge surface to the wound surface.</td>
</tr>
<tr>
<td>5</td>
<td>Secure PELNACTM along healthy skin with sutures or surgical staplers with no wrinkles or bubbles.</td>
</tr>
<tr>
<td>6</td>
<td>Cover the upper surface with gauze and secure it with light pressure.</td>
</tr>
<tr>
<td>7</td>
<td>The silicone film will naturally peel off when a light redish coloured dermis-like tissue has formed.</td>
</tr>
<tr>
<td>8</td>
<td>Perform a split-thickness skin graft.</td>
</tr>
</tbody>
</table>

**Healing Process**

1. **PELNACTM** is applied to full-thickness skin defects.
2. Fibroblasts and capillaries invade and infiltrate into the spaces in collagen sponge.
3. Collagen sponge is gradually replaced by newly synthesized collagen into dermis-like tissue.
4. After 2-3 weeks, the silicone film is peeled off, leading to wound closure with split-thickness skin graft.

**Variation**

**Fenestrated Type**

- **Characteristics:** Allows drainage of wound exudates, and provides a flexibility and good adherence to cover the wound surface. Good application for the wounds which exudates are excreted in large amounts.
- **Structure:** Two-layered material consists of collagen sponge and a silicone film reinforced with mesh, on which slits are placed.

**Fortified Type**

- **Characteristics:** Easy to suturing. The fortified type is 4.5 times stronger than the standard type with respect to suturing (tensile strength).
- **Structure:** Two-layered material consists of collagen sponge and a silicone film reinforced with mesh.

**Single Layer Type**

- **Characteristics:** Good application for the wounds and surgical techniques which require no silicone film.
- **Structure:** Single-layered material consists of collagen sponge.

**COMPOSITION**

- Collagen sponge layer
- Silicone film layer
- Mesh
- Atelocollagen derived from porcine tendon
- Silicone resin
- Non-adhesive silicone gauze

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Case Report

Donor Site of Skin Flap Extraction
In dorsum pedis: 32 years old, male

1. After skin flap harvest
   The tendon was exposed

2. Soon after application of PELNAC™

3. 17 days after application of PELNAC™
   (Just before skin graft)
   A good wound bed formation was observed

4. Soon after transplant a 8/1,000 inches skin graft

5. 6 months after skin graft

6. 13 months after skin graft
   Functional disorders of the tendinis musculi extensoris hallucis longi did not occur

Traumatic Skin Defect
In leg: 53 years old, male

1. Male patient with stable Necrotizing Fasciitis injury

2. Application of large sheets of Fenestrated PELNAC™ at surgery

3. PELNAC™ covered with water resistance dressing and gauze

4. Post op 6 months, good graft take, skin quality and pigmentation and complete flexation of knee joint.

In fingertips of left hand: 32 years old, male

1. After debridement of wound

2. Soon after application of PELNAC™

3. 1 year after application of PELNAC™

2 weeks after application of PELNAC™, the silicone film was removed and an ointment treatment was continued without skin grafting until epithelialization is achieved. Epithelialization was achieved in 35 days post operatively.

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**Third Degree Burn**

In lower leg: 67 years old, female

1. Before the operation
2. After debridement
   - Full-thickness skin defects were caused
3. Soon after application of PELNACTM
4. 3 weeks after operation.
   - Before removal of silicone film
   - Dermis-like tissue was generated and silicone film was about to fall out
5. After removal of silicone film
   - A wound bed formation having good blood flow was observed

**Skin Defect after Tumor Removal**

On nasal dorsum: 39 years old, male

1. Basal cell carcinoma
2. The tumor and surrounding skin including 3mm safety margin was removed
   - The nasal bone was exposed
3. Soon after application of PELNACTM
4. 19 days after application of PELNACTM
   - After pathological examination, silicone film was peeled off and full thickness skin graft placed on the regenerated tissue
5. 2 years after skin graft
   - Grafted site had a good appearance

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**Advantages for usage of PELNACTM for skin defect after tumor removal**

During pathological examination for removed tumor, skin defect is temporarily covered by PELNACTM until diagnostic outcome is ascertained

1. In case that additional resection is not necessary
   - Progress as regular usage of PELNACTM, wait granulation formation, remove a silicone film and proceed skin graft

2. In case that additional resection is necessary
   - Remove the skin tumor with PELNACTM itself

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**Adverse Events**

No adverse event occurred in the 60 cases of the clinical study conducted before Japanese approval and 807 cases included in PMCF (Post Market Clinical Follow-up) in Japan.

**Reduce superfluous skin graft**
**Non-clinical Study**

**Formation of Dermis-like Tissue (Guinea Pigs)**

A full-thickness skin defect 1.5 × 1.5 cm was prepared in the backs of guinea pigs, PELNAC™ trimmed to 1.5 × 1.5 cm and saturated with sterilised physiologic saline was applied to the skin defect site, and the margin was sutured. One, two and three weeks after implantation of PELNAC™, the recipient sites (sample application sites) and surrounding tissues were removed. The tissues were fixed with 10% formalin, stained with HE, and examined histologically.

As a result, collagen sponge was filled with fibroblasts and capillaries, and was completely digested and turned into newly regenerated tissues. Also in a case of smaller defect areas, growth of the epidermis was noted along the upper surface of the regenerated tissue.

**Literature**

Contraindications

PELNACTM may exacerbate conditions in patients showing sensitivity to porcine-derived products (such as insulin), or silicone materials. PELNACTM may increase infection in patients showing a sudden rise in body temperature and who appear to be showing signs of infection during the use of PELNACTM. Do not use in patients with a history of hypersensitivity to proteins of animal origin. Do not use in infected wound sites.

Precautions

Caution should be exercised in patients susceptible to such allergic symptoms as bronchial asthma or urticaria. PELNACTM has no antibacterial activity and care must be taken regarding bacterial infection. In particular, if infected wounds are present at or near the application site, adequate disinfection should be performed at the time of operation. If infection does occur it should be treated in accordance with local clinical practice. If PELNACTM is used on a moving area such as a joint, affix in the same manner as an ordinary skin graft. Discard device if mishandling has caused possible damage or contamination.

Use PELNACTM carefully to prevent the tear of the silicone film when suturing it. Use the fortified type or the fenestrated type when the tear of the silicone film is expected. Use the single layer type for the usage in which the suturing is not needed, because it has not a silicone film. PELNACTM should not be applied until excessive exudates, bleeding, acute swelling and infection are controlled. Use the fenestrated type when a lot of exudates and the drainage is necessary, and when the relapse of the infection in the wound in which infection was removed is expected. [Because there is a possibility that the exudates separate PELNACTM from the wound surface and that the infection relapses.] Use it with careful attention to prevent the bacterial intrusion, dryness and accumulation of water. Detach the silicone layer before the granulation reaches the silicone layer, observing the granulation situation from about one week after the operation. Remove the silicone layer completely surgically when the silicone layer is involved by the granulation particularly in using the fenestrated type. Thorough debridement or excision must be performed to remove any remaining necrotic tissue that may cause infection. If any of the following conditions occur, PELNACTM should be removed: infection, wound colonisation, sepsis, chronic inflammation (initial application of PELNACTM may be associated with transient, mild, localised inflammation), allergic reaction, excessive redness, pain or swelling.

Product Variation and Code

<table>
<thead>
<tr>
<th>Size</th>
<th>Dimensions (mmxmm)</th>
<th>Package (1 box)</th>
<th>Type (Thickness of Collagen Layer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3S</td>
<td>40 × 30</td>
<td>1</td>
<td>Fenestrated 3mm</td>
</tr>
<tr>
<td>SS</td>
<td>40 × 60</td>
<td></td>
<td>Fortified 3mm</td>
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<tr>
<td>S</td>
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<td>Single Layer 3mm</td>
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<tr>
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<tr>
<td>L</td>
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<td></td>
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<tr>
<td>LL</td>
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<td></td>
</tr>
<tr>
<td>3L</td>
<td>200 × 240</td>
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<td></td>
</tr>
</tbody>
</table>

Ethylene oxide sterilised. Do not use if package is open or damaged. Single use only. Use immediately after opening. Any portions unused after opening the package should be discarded. Do not re-sterilise. Store in a dry place (≤ 30°C / 86°F). Avoid exposure to high temperatures. Expiry date is indicated on the outer packaging.