Ethylene oxide sterilized. 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-sterilize. Store in a dry place (ʽ30° C / 86° F). Avoid exposure to high temperatures. Expiry date is indicated on the outer packaging.

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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.

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If any of the following conditions occur, PELNACTM should be removed: infection, wound colonization, sepsis, chronic inflammation (initial application of PELNAC TM may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.

Contraindications

- PELNACTM may exacerbate conditions in patients showing sensitivity to porcine-derived products (such as insulin), or silicone materials.
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http://www.gunze.co.jp/e/medical/
**INTENDED USE**

Granulation formation in full-thickness skin defects caused by the following disorders or injuries.

1. Third-degree burn (Deep burn)
2. Traumatic skin defect wound
3. Skin defect after tumor or nevus removal
4. Site of skin flap extraction etc.

**PRODUCT OUTLINE**

Full-thickness skin defects were traditionally treated by skin flap and allograft etc., but those treatments are likely to cause the problem such as donor site repair, the supply of those materials.

Artificial dermis — PELNAC™ — consists of two layers basically: a porcine tendon-derived atelocollagen sponge layer and silicone film. It is suitable for use in full-thickness skin defects and wounds and used as alternative materials for traditional treatment for the formation of new dermis-like tissue by invasion of fibroblasts into the atelocollagen sponge matrix.

### Clinical Advantage

- Provides a high survival rate of secondary skin grafts and satisfactory aesthetic results.
- Thin split-thickness skin graft is achievable and it reduces the damage of donor site, minimizing skin sacrifice.
- Minimal contraction or pigmentation after treatment

### Product Characteristic

- Made of atelocollagen derived from porcine tendon and silicone.
- The soft collagen sponge structure ensures excellent contact with the irregular wound surface.
- Various types appropriate for wound condition are available.
- Easy transportation and storage by re-freeze dried condition

### Mechanism of Action

- Fibroblasts and capillaries infiltrate into atelocollagen from the recipient matrix and surrounding tissues and form good dermis-like tissue.
- Regeneration of dermis-like tissue is clearly different in features including collagen arrangement from scar tissue.

### HEALING PROCESS

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

### VARIATION

<table>
<thead>
<tr>
<th>Type</th>
<th>Characteristics</th>
<th>Structure</th>
<th>COMPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenestrated type</td>
<td>Easy to suturing</td>
<td>Two-layered material consists of collagen sponge and a silicone film reinforced with mesh, on which silt is placed.</td>
<td>Collagen sponge layer — Atelocollagen derived from porcine tendon</td>
</tr>
<tr>
<td>Fortified type</td>
<td>4.5 times stronger than the standard type with respect to suturing tensile strength (4.5 times stronger than the standard type with respect to suturing tension strength).</td>
<td>Two-layered material consists of collagen sponge and a silicone film.</td>
<td>Collagen sponge layer — Atelocollagen derived from porcine tendon</td>
</tr>
<tr>
<td>Standard type</td>
<td>Good transparency enables observation of the wounds.</td>
<td>Two-layered material consists of collagen sponge and a silicone film.</td>
<td>Collagen sponge layer — Atelocollagen derived from porcine tendon</td>
</tr>
<tr>
<td>Single layer type</td>
<td>Good application for the surgical techniques which require no silicone film.</td>
<td>Single-layered material consists of collagen sponge.</td>
<td>Collagen sponge layer — Atelocollagen derived from porcine tendon</td>
</tr>
</tbody>
</table>

**USAGE**

1. Immerse PELNAC™ thoroughly in sterile physiological saline.
2. Perform hemostasis and thoroughly wash the wound.
3. Trim PELNAC™ to fit the shape of the wound.
4. Apply the collagen sponge to the wound surface.
5. Secure PELNAC™ along healthy skin with sutures or surgical staples with no wrinkles or bubbles.
6. Cover the upper surface with gauze and secure it with light pressure.
7. The silicone film will naturally peel off when a light reddish colored dermis-like tissue has formed.
8. Perform a split-thickness skin graft.
CASE REPORT

### Donor Site of Skin Flap Extraction

**In Dorsum Pedis : 32 years old, Male**

1. After skin flap harvest, the extensor tendon was exposed.
2. Soon after application of PELNAC™
3. 30 days after application of PELNAC™ (just below skin graft) A good woundbed formation was observed.
4. Soon after transparent 8/1,000 inches skin graft
5. 6 months after skin graft
6. 10 months after skin graft

**In Back of Left Hand : 53 years old, Female**

1. After detachment of wound The extensor tendon was exposed.
2. Soon after application of PELNAC™
3. 17 days after application of PELNAC™ (just below skin graft)
4. After removal of silicone film Good granulation was observed.
5. Soon after split-thickness skin graft (10/1,000 inches)
6. 14 months after skin graft: Shrinkage of grafted skin did not occur, and the appearance was very good.

### Traumatic Skin Defect

**In Back of Left Hand : 53 years old, Female**

1. After detachment of wound
2. Soon after application of PELNAC™
3. 17 days after application of PELNAC™ (just below skin graft)
4. After removal of silicone film Good granulation was observed.
5. Soon after split-thickness skin graft (10/1,000 inches)
6. 14 months after skin graft: Shrinkage of grafted skin did not occur, and the appearance was very good.

**In Fingertips of Left Hand : 32 years old, Male**

1. After detachment of wound
2. Soon after application of PELNAC™
3. 1 year after application of PELNAC™

### Third Degree Burn

**In Lower Thigh : 67 years old, Female**

1. Before the operation
2. After debriement: Full-thickness skin defects were caused.
3. Soon after application of PELNAC™
4. 3 weeks after operation: Before removal of silicone film Dehiscence 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 obtained.

#### Donor Site (Back of Lower Thigh)

1. Soon after skin graft (B: 1/500 inches)
2. 1 year after skin graft Less contracture and satisfactory aesthetic outcome.
3. Donor site just after operation
4. Skin after operation: Less hypertrophic scar due to a thin Split-thickness skin graft.

#### Skin Defect after Tumor Removal

**On Nasal Dorsum : 39 years old, Male**

1. Basal cell carcinoma
2. The tumor and surrounding skin including 3 mm safety margin was removed. The nasal bone was exposed.
3. Soon after application of PELNAC™
4. 19 days after application of PELNAC™ After pathological examination, silicone film was peeled off and full-thickness skin graft placed on the regenerated tissue.
5. 1 year after operation
6. 2 years after skin graft Grafted site had a good appearance.

#### Advantages for usage of PELNAC™

- **For skin defect after tumor removal**
  - During pathological examination for removed tumor, skin defect is temporarily covered by PELNAC™ until diagnostic outcome is ascertained.
  - In case that additional resection is not necessary
    - Progress as regular usage of PELNAC™, wait granulation formation, remove a silicone film and proceed skin graft.
  - In case that additional resection is necessary
    - Remove the skin tumor with PELNAC™ itself.
    - Reduce superfluous skin graft.

### 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.
Formation of Dermis-like Tissue (Guinea Pigs)

A full-thickness skin defect 1.5 x 1.5 cm was prepared in the backs of guinea pigs, PELNACTm trimmed to 1.5 x 1.5 cm and saturated with sterilized physiologic saline was applied to the skin defect site, and the margin was sutured. One, two and three weeks after implantation of PELNACTm, 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 area, growth of the epidermis was noted along the upper surface of the regenerated tissue.

One week after application

Cells consisting primarily of monocytes were distributed over the entire recipient site, but fibroblasts and capillaries had infiltrated into the deep layers and the spaces were filled by fibroblasts and capillaries. In the shallow layers, however, the sponge structure remained.

Two weeks after application

Fibroblasts that infiltrated from the wound surface and wound margins were distributed to the shallow layers, and the sponge structure had disappeared except in some parts. The epithelium extended along the upper surface of the tissue regenerated from peripheral tissues. No abnormality was noted in the tissues around the PELNACTm application site.

Three weeks after application

Growth of fibroblasts and capillaries was observed to the shallow layers, and the application site was covered by the epithelium extending from peripheries. A structure differing from scar tissue and resembling the normal dermis was observed although the collagen fibers were slightly thinner than those in surrounding tissues. No abnormality was noted in tissues around the PELNACTm application site.

Contraction Inhibition of Wound

Full-thickness skin defects were made on the backs of guinea-pigs and PELNACTm were placed on the disinfected skin defects. Three weeks after application, the areas where PELNACTm was placed were measured by calipers. The percentage of three weeks post-operative area to the original one reveals the ability of the materials to prevent the wound from contracting. As a result, the contraction can be prevented by contraction of a dermis-like tissue by PELNACTm.

LITERATURE


NON-CLINICAL STUDY

Mean±SD

Controls : only silicone film

Ability of preventing wound from contraction(%) = Post-operative area/original area×100(%)
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