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 defect 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.

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

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Clinical Advantage

VARIATION

HEALING PROCESS

PELNACTM 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

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 fortified with mesh.

Standard type

Characteristics:
Good transparency enables a easy observation of the wounds.
Structure:
Two-layered material consists of collagen sponge and a silicone film.

Single layer type

Characteristics:
Good application for the wounds and surgical techniques
Structure:
Single-layered material consists of collagen sponge.

COMPOSITION

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

USAGE

1. Immerse PELNACTM thoroughly in sterile physiological saline.
2. Perform hemostasis and thoroughly wash the wound.
3. Trim PELNACTM to fit the shape of the wound.
4. Apply the collagen sponge surface to the wound surface.
5. Secure PELNACTM along healthy skin with sutures or surgical staplers 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.
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 PELNACTM

3) 20 days after application of PELNACTM
    (just before skin graft)
    A good wound bed formation was observed.

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

5) 16 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 Back of Left Hand : 53 years old, Female

1) After debridement of wound
   The extensor tendon was exposed.

2) Soon after application of PELNACTM

3) 17 days after application of PELNACTM
    (just before skin graft)

4) After removal of silicone film
   Good granulation was observed.

5) Soon after a split-thickness skin graft
   (10/1,000 inches)

6) Soon after skin graft

7) 4 months after skin graft
   Shrinkage of grafted skin did not occur
   and it showed good appearance and colour.

In Fingertips of Left Hand : 32 years old, Male

1) After debridement of wound

2) Soon after application of PELNACTM
   2 weeks after application of PELNACTM, the silicon film
   was removed and an ointment treatment was continued
   without skin grafting until epithelialization is achieved.
   Epithelialization was achieved in 35 days postoperatively.

3) 1 year after application of PELNACTM
Third Degree Burn
In Lower Thigh : 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.

Donor Site (Back of Lower Thigh)

6) Soon after skin graft (8/1,000 inches)
7) 1 year after skin graft
Less contracture and satisfactory aesthetic outcome.
8) Donor site just after operation
9) 1 year after operation
Less hyperplastic 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 surround skin including 3 mm 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.

Advantages for usage of PELNAC™ 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 PELNAC™, wait granulation formation, remove a silicone film and proceed skin graft.
2) 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 × 1.5 cm was prepared in the backs of guinea pigs, PELNAC™ trimmed to 1.5 × 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 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 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 deep layers. The product adhered tightly to the surrounding tissues. In the deep layers, the sponge structure had disappeared, 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 product 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 that extended 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 PELNAC™ application site.

**Contraction Inhibition of Wound**

Full-thickness skin defects were made on the backs of guinea-pigs and PELNAC™ were placed on the disinfected skin defects. Three weeks after application, the areas where PELNAC™ 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 PELNAC™.

**LITERATURE**

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Mean±SD

Ability of preventing wound from contraction (%)

Post-operative area/original area×100 (%)

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1. 2. 3. 4. from the scalp. Ann Plast Surg. 1997; 39: 489-94.
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 (≤30°C / 86°F). Avoid exposure to high temperatures. Expiry date is indicated on the outer packaging.

**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.

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 the infection was removed is expected. [Because there is a possibility that the exudates separate PELNACTM from the wound surface and that the infection relapses.]

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.

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

**PRODUCT VARIATION and CODE**

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*Custom made

Concerted surgical solutions

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