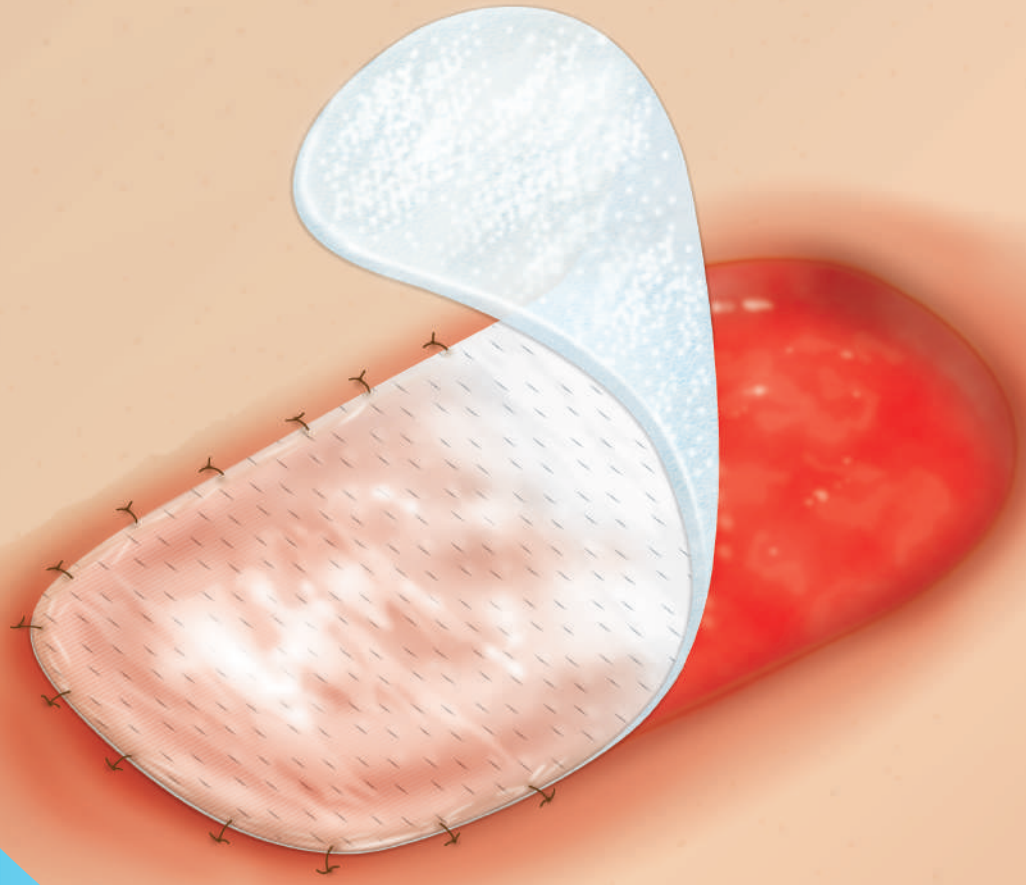
GUNZE



ARTIFICIAL DERMIS

PELNAC™

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 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, minimizes 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.

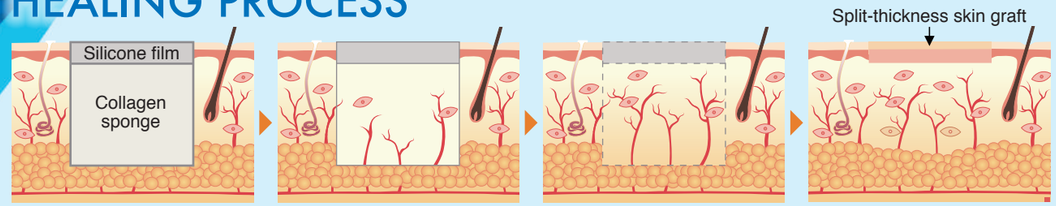
INTENDED USE

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.

HEALING PROCESS



PELNAC™ is applied to full-thickness skin defects.

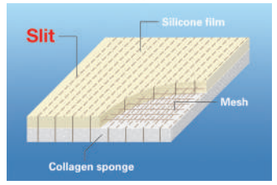
Fibroblasts and capillaries invade and infiltrate into the spaces in collagen sponge.

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

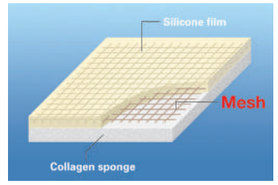
Fenestrated type



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.

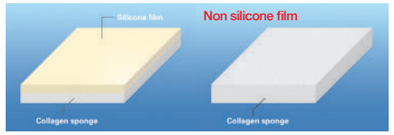
Fortified type



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 / Single layer type



Characteristics：
Good transparency enables a easy observation of the wounds.

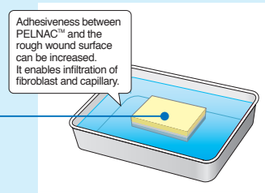
Structure：
Two-layered material consists of collagen sponge and a silicone film.

Characteristics：
Good application for the wounds and surgical techniques which require no silicone film.

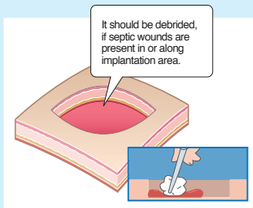
Structure：
Single-layered material consists of collagen sponge.

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

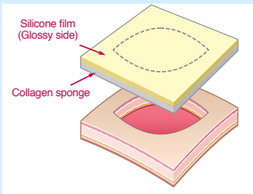
USAGE



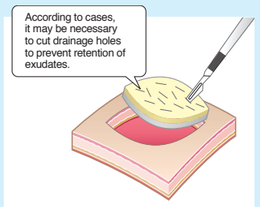
1 Immerse PELNAC™ thoroughly in sterile physiological saline.



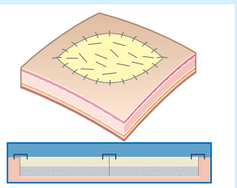
2 Perform hemostasis and thoroughly wash the wound.



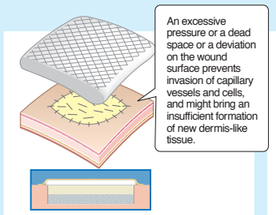
3 Trim PELNAC™ to fit the shape of the wound.



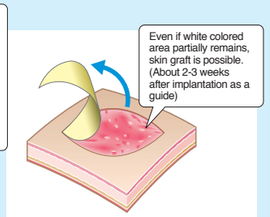
4 Apply the collagen sponge surface to the wound surface.



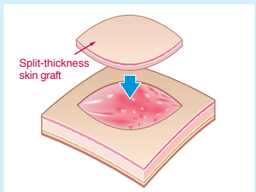
5 Secure PELNAC™ along healthy skin with sutures or surgical staplers with no wrinkles or bubbles.



6 Cover the upper surface with gauze and secure it with light pressure.



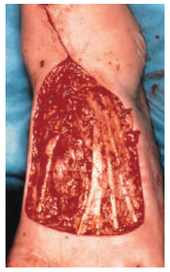
7 The silicone film will naturally peel off when a light redish colored dermis-like tissue has formed.



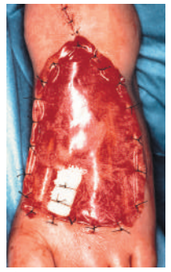
8 Perform a split-thickness skin graft.

CASE REPORT

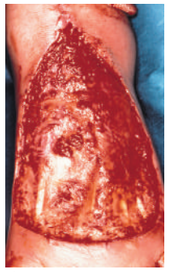
Donor Site of Skin Flap Extraction
In Dorsum Pedis : 32 years old, Male



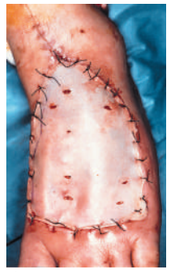
1) After skin flap harvest
The tendon was exposed.



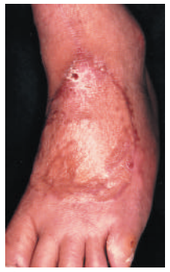
2) Soon after application of PELNAC™



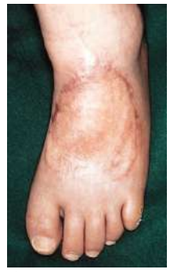
3) 20 days after application of PELNAC™ (Just before skin graft)
A good wound bed formation was observed.



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

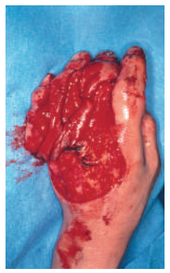


5) 6 months after skin graft

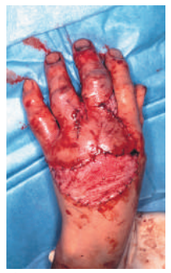


6) 13 months after skin graft
Functional disorders of the tendinis musculi extensoris hallucis longi did not occur.

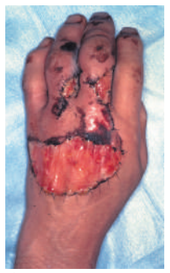
Traumatic Skin Defect
In Back of Left Hand : 53years old, Female



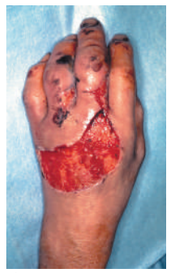
1) After debridement of wound
The extensor tendon was exposed.



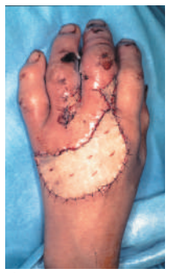
2) Soon after application of PELNAC™



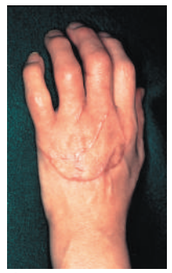
3) 17 days after application of PELNAC™ (Just before skin graft)



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

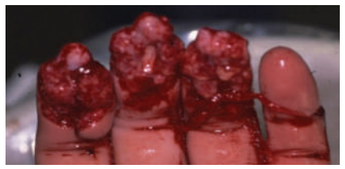


6) Soon after a split-thickness skin graft (10/1,000 inches)

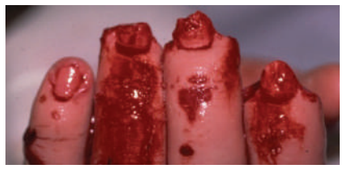


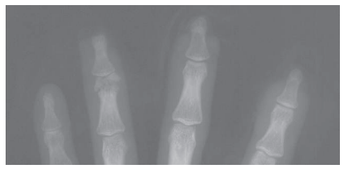
7) 4 months after skin graft
Shrinkage of grafted skin did not occur and it showed good appearance and colour.

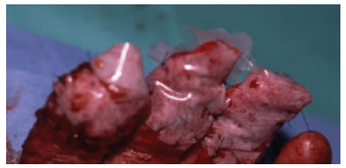
In Fingertips of Left Hand : 32 years old, Male



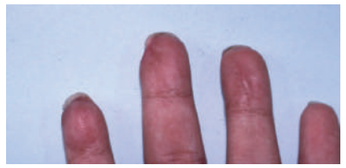
1) After debridement of wound

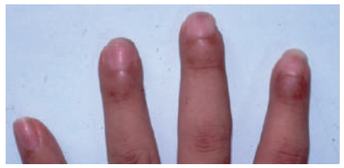






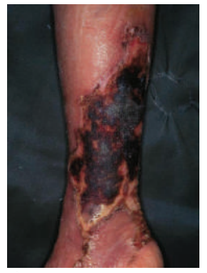
2) Soon after application of PELNAC™
2 weeks after application of PELNAC™, the silicon film was removed and an ointment treatment was continued without skin grafting until epithelialization is achieved. Epithelialization was achieved in 35 days postoperatively.



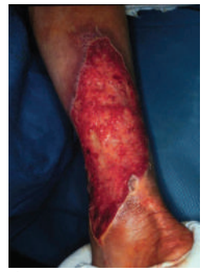


3) 1 year after application of PELNAC™

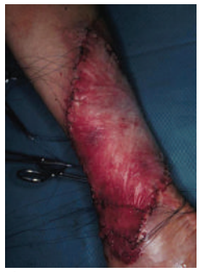
Third Degree Burn
In Lower Thigh : 67 years old, Female



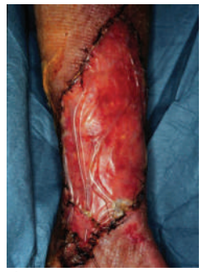
1) Before the operation



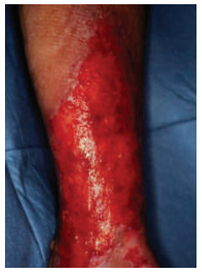
2) After debridement
Full-thickness skin defects were caused.



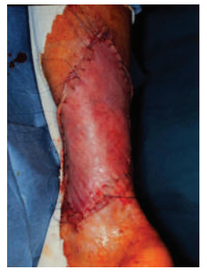
3) Soon after application of PELNAC™



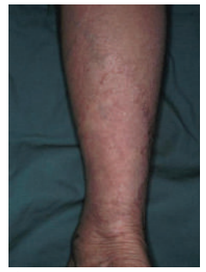
4) 3 weeks after operation. Before removal of silicone film
Dermis-like tissue was generated and silicone film was about to fall out.



5) After removal of silicone film
A wound bed formation having good blood flow was observed.

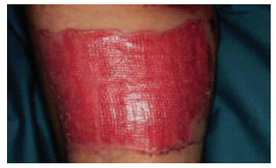


6) Soon after skin graft (8/1,000 inches)

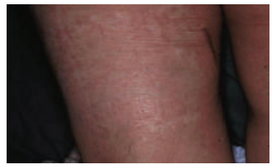


7) 1 year after skin graft
Less contracture and satisfactory aesthetic outcome.

Donor Site (Back of Lower Thigh)

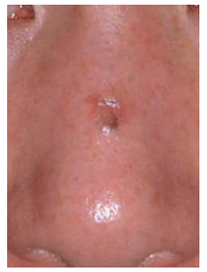


8) Donor site just after operation

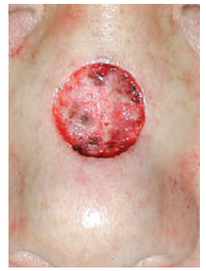


9) 1 year after operation
Less hyperplastic scar due to a thin Split-thichness skin graft.

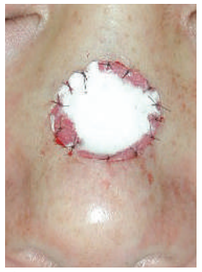
Skin Defect after Tumor Removal
On Nasal Dorsum : 39 years old, Male



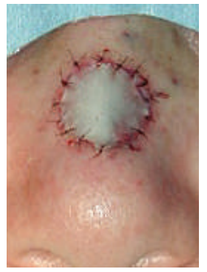
1) Basal cell carcinoma



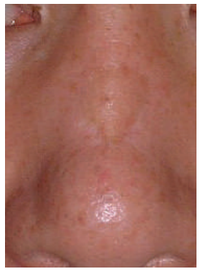
2) The tumor and surround skin including 3 mm safety margin was removed
The nasal bone was exposed.



3) Soon after application of 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) 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.

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.

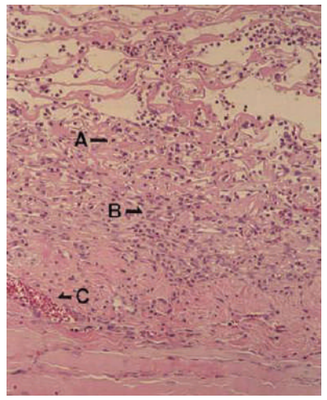
NON-CLINICAL STUDY

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 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.

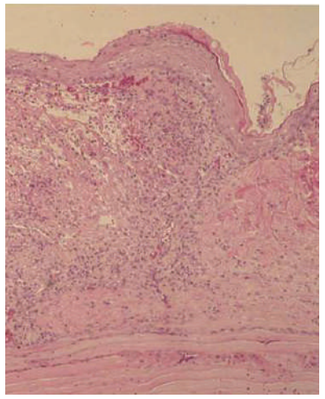
One week after application

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.



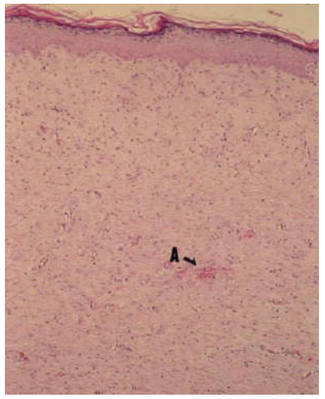
Two weeks after application

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 place 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™.

	Ability of preventing wound from contraction(%)
PELNAC™	48.6±11.3(n=17)
Controls	19.6±9.8(n=9)

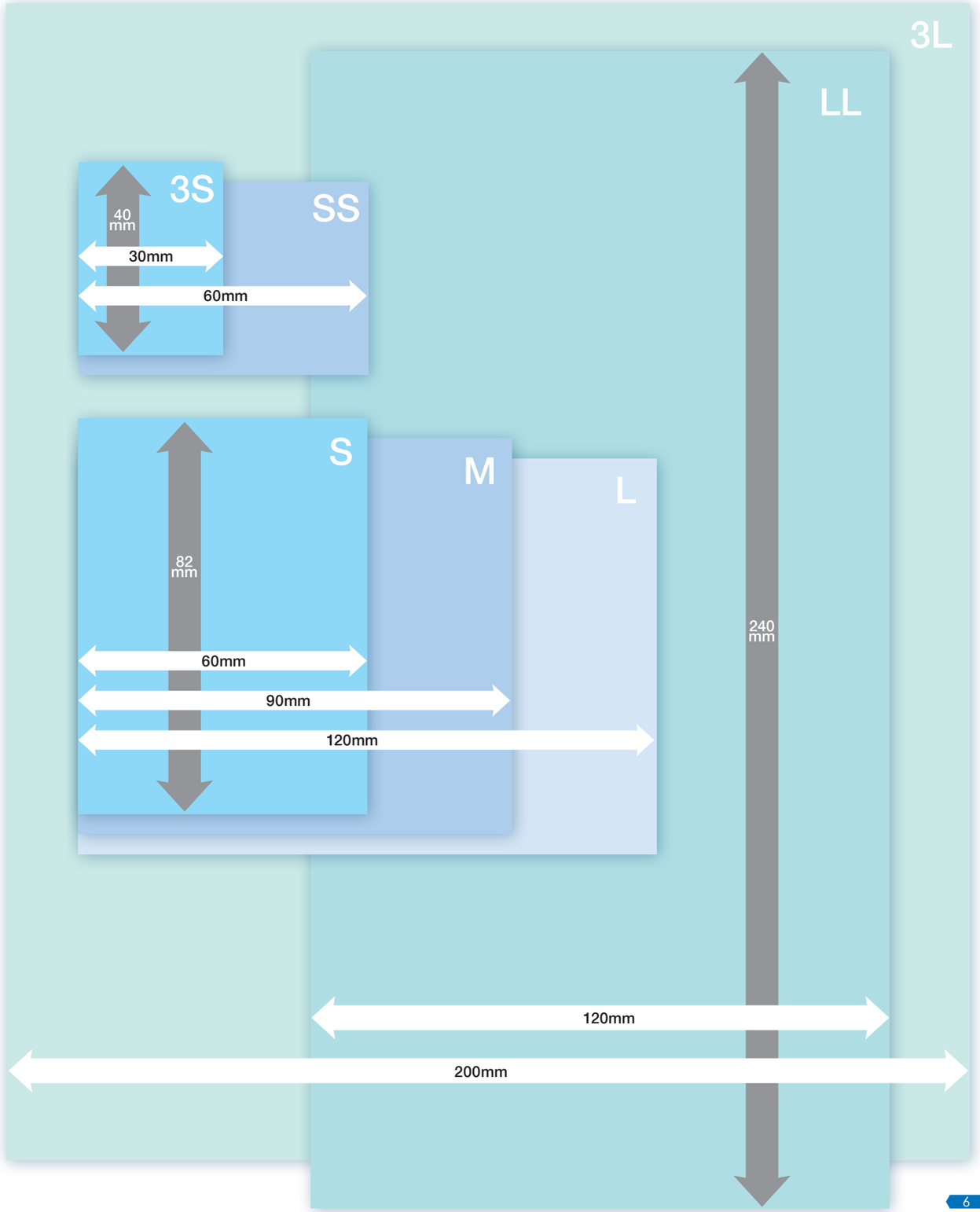
Mean±SD

Controls : only silicone film
Ability of preventing wound from contraction(%)
= Post-operative area/original area×100(%)

LITERATURE

1. Suzuki S, et al. : Further applications of "bilayer artificial skin". Br J Plast Surg. 1995; 48: 222-9.
2. Soejima K, et al. : Treatment of giant pigmented nevus using artificial dermis and a secondary skin graft from the scalp. Ann Plast Surg. 1997; 39: 489-94.
3. Suzuki S, et al. : Long-term follow-up study of artificial dermis composed of outer silicone layer and inner collagen sponge. Br J Plast Surg. 2000; 53: 659-66.
4. Muneuchi G, et al. : Combined treatment using artificial dermis and basic fibroblast growth factor (bFGF) for intractable fingertip ulcers caused by atypical burn injuries. Burns. 2005 ; 31: 514-7.

SIZE VARIATION (FULL SCALE)



PRODUCT VARIATION and CODE

Size	Dimensions (mm×mm)	Package (1 box)	Type (Thickness of collagen layer)				
			Fenestrated	Fortified	Standard	Single Layer	
			3mm				1.5mm
3S	40 × 30	1	PN-D40030*	PN-F40030	PN-R40030	PN-S40030	PN-S40030T*
SS	40 × 60		PN-D40060*	PN-F40060	PN-R40060	PN-S40060*	PN-S40060T*
S	82 × 60		PN-D82060	PN-F82060	PN-R82060	PN-S82060	PN-S82060T*
M	82 × 90		PN-D82090	PN-F82090	PN-R82090	PN-S82090*	PN-S82090T*
L	82 × 120		PN-D82120	PN-F82120	PN-R82120	PN-S82120*	PN-S82120T*
LL	120 × 240		PN-D120240	PN-F120240	PN-R120240	PN-S120240*	PN-S120240T*
3L	200 × 240		PN-D200240	PN-F200240	PN-R200240	PN-S200240*	PN-S200240T*

*Custom made

Carton

Pouch


Tray


Product

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】

- PELNAC™ may exacerbate conditions in patients showing sensitivity to porcine-derived products (such as insulin), or silicone materials.
- PELNAC™ 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 PELNAC™.
- 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.
- PELNAC™ 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 PELNAC™ 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 PELNAC™ 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.
- PELNAC™ 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 PELNAC™ 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, PELNAC™ should be removed: infection, wound colonization, sepsis, chronic inflammation (initial application of PELNAC™ may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.

GUNZE LIMITED
MEDICAL DIVISION
http://www.gunze.co.jp/e/medical/

Japan
TOKYO OFFICE
Nihonbashi2-10-4, Chuo-ku, TOKYO 103-0027 Japan
Tel: +81-3-3276-8718 Fax: +81-3-3276-8696
AYABE FACTORY
46 Natsumegaichi, Aono-cho, Ayabe, KYOTO 623-8513 Japan

Europe
DUESSELDORF OFFICE
Louise-Dumont-Strasse31, 40211, DUESSELDORF Germany
Tel: +49-211-36-03-66 Fax: +49-211-36-13-164

Asia Pacific
GUNZE MEDICAL DEVICES (SHENZHEN) LIMITED
Room 2516, Kerry Centre, 2008 Renminnan Rd., SHENZHEN 518001 P.R. China
Tel: +86-755-8230-0553 Fax: +86-755-8230-0469

U.S.A.
GUNZE INTERNATIONAL USA, INCORPORATED
5 West 37th Street, Suite 800 New York, NY, 10018, U.S.A.
Tel: +1-212-354-9060 Fax : +1-212-354-6171