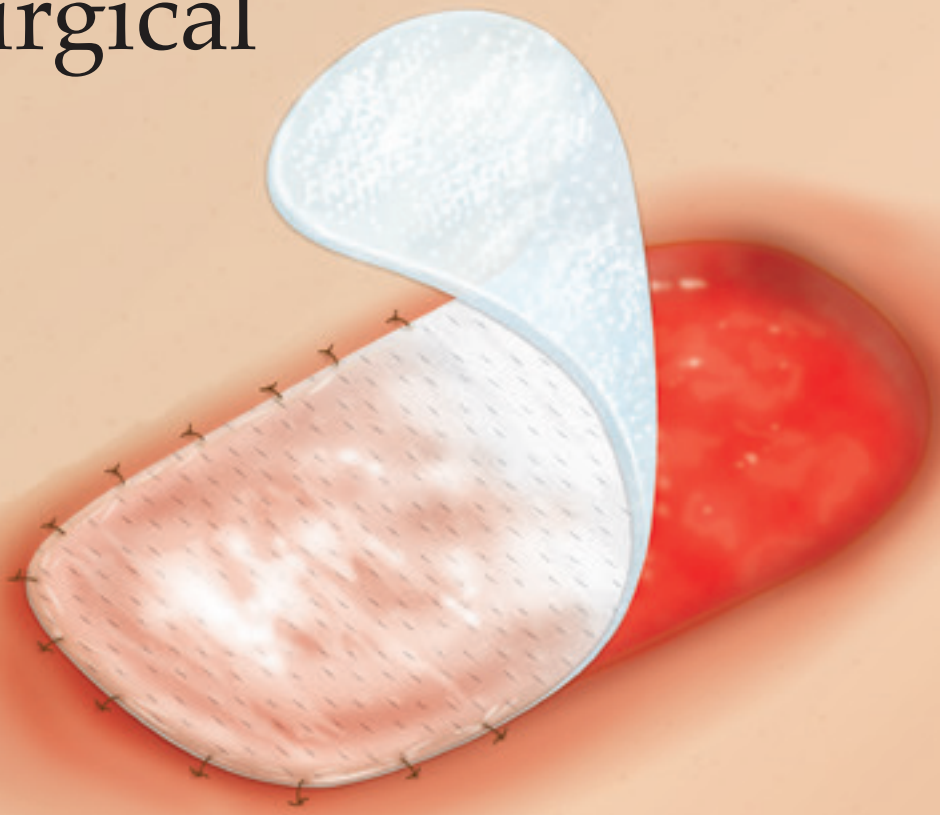
Eurosurgical



Dermal Template

PELNAC™

www.eurosurgical.co.uk

Product Outline

PELNAC™ has been designed for use as a temporary dermal matrix for all skin loss wounds that are partial thickness to deep dermis. PELNAC™ 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.

PELNAC™ consists of two layers; a porcine tendon derived atelocollagen sponge layer, approximately 3mm in thickness and a thin reinforced silicone film layer. PELNAC™ is prepared by freeze-drying and does not require pre-washing before use, and can be stored at room temperature. PELNAC™ 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

- PELNAC™ 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 PELNAC™, 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 PELNAC™ 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 PELNAC™ will aid the re-vascularisation process and assist in wound drainage.

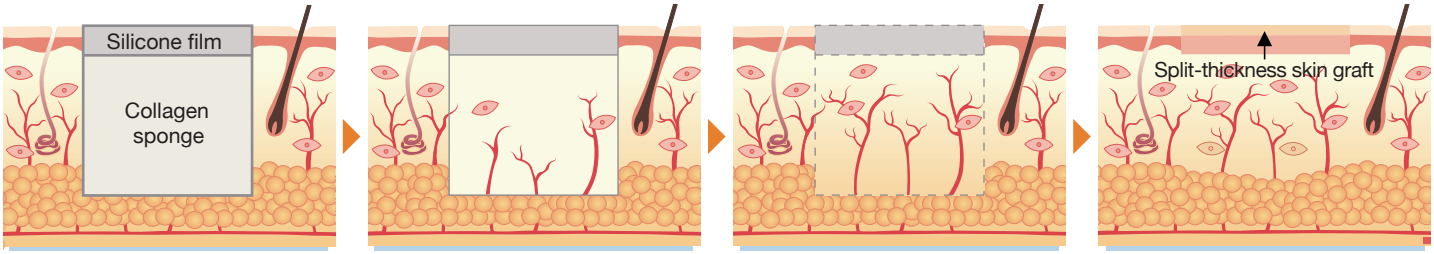
Post Placement Care

- PELNAC™ should be cut to the size of the wound area and not overlap the wound onto healthy tissue. PELNAC™ can be secured in place with the help of sutures or staples.
- PELNAC™ 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 PELNAC™ silicone layer.
- The outer dressing can be changed after 2-3 days, however PELNAC™ should not be changed or the silicone outer layer disturbed for at least 7-10 days.
- The Silicone layer will lift away from the PELNAC™ 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

Healing Process



PELNAC™ is applied to full-thickness skin defects

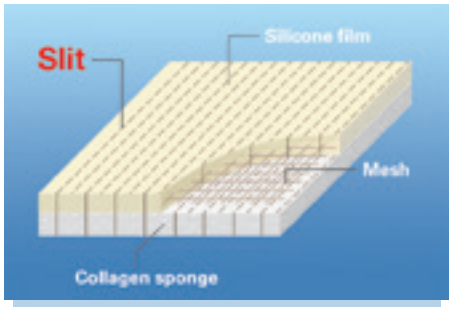
Fibroblasts and capillaries invade and infiltrate into the spaces in collagen sponge

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

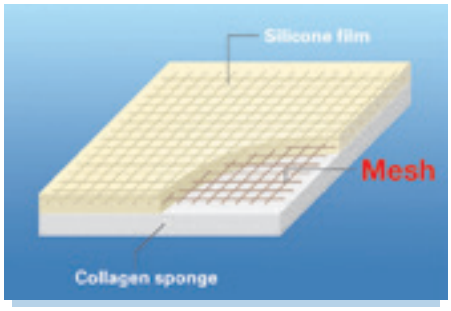
Fenestrated Type



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.

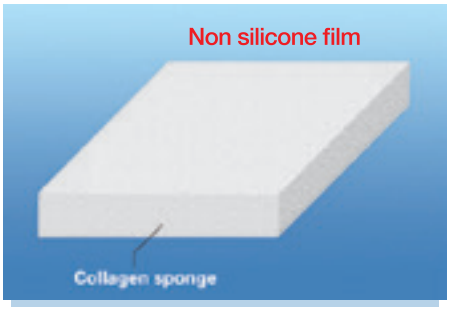
Fortified Type



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 reinforced with mesh.

Single Layer Type



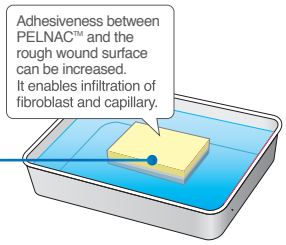
Characteristics
Good application for the wounds and surgical techniques which require no silicone film.

Structure
Single-layered material consists of collagen sponge.

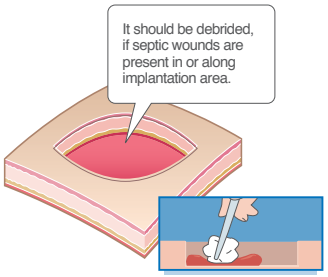
COMPOSITION

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

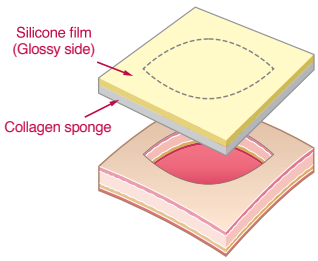
Usage



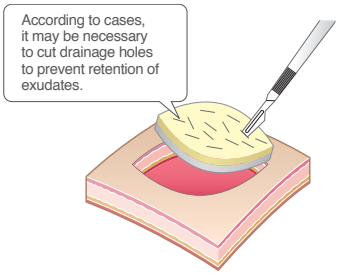
1 Immerse PELNAC™ thoroughly in sterile physiological saline.



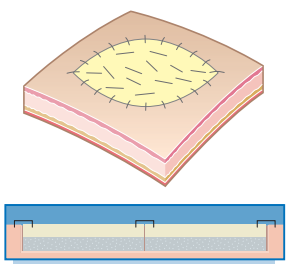
2 Perform hemostasis and thoroughly wash the wound.



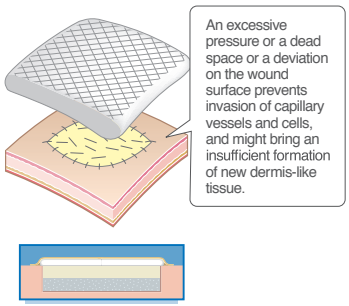
3 Trim PELNAC™ to fit the shape of the wound.



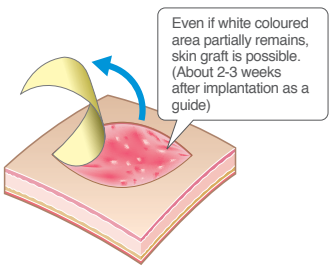
4 Apply the collagen sponge surface to the wound surface.



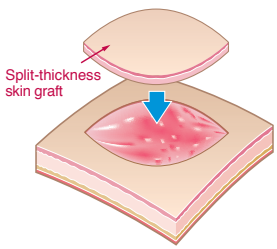
5 Secure PELNAC™ along healthy skin with sutures or surgical staplers with no wrinkles or bubbles.



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 coloured dermis-like tissue has formed.

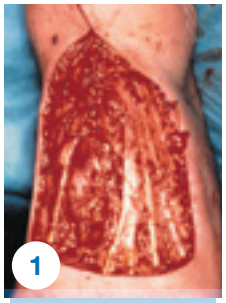


8 Perform a split-thickness skin graft.

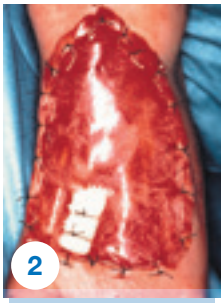
Case Report

Donor Site of Skin Flap Extraction

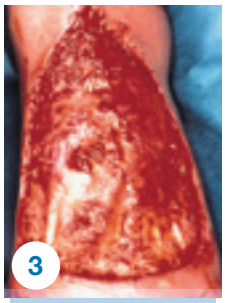
In dorsum pedis : 32 years old, male



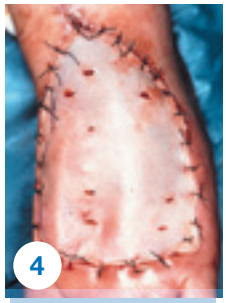
After skin flap harvest
The tendon was exposed



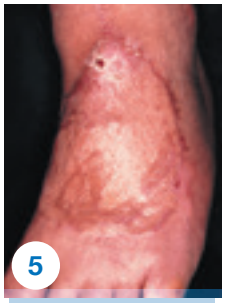
Soon after application of PELNAC™



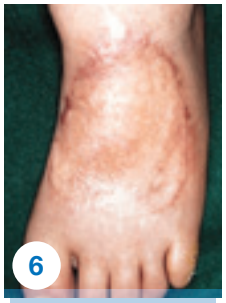
17 days after application of PELNAC™
(Just before skin graft)
A good wound bed formation was observed



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



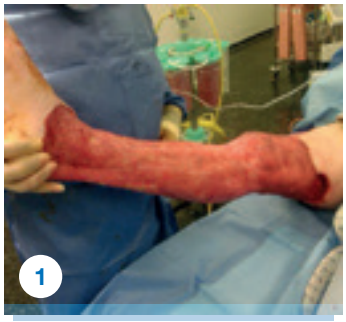
6 months after skin graft



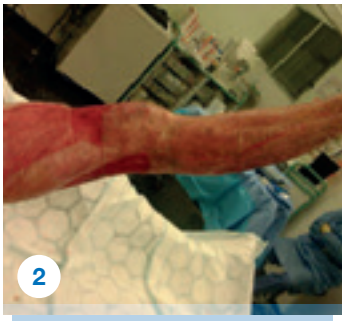
13 months after skin graft
Functional disorders of the tendinis musculi extensoris hallucis longi did not occur

Traumatic Skin Defect

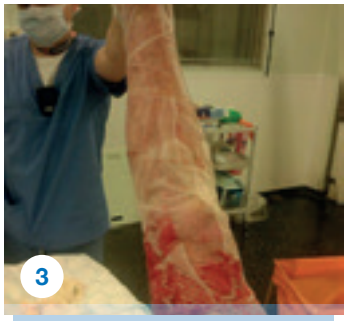
In leg : 53 years old, male



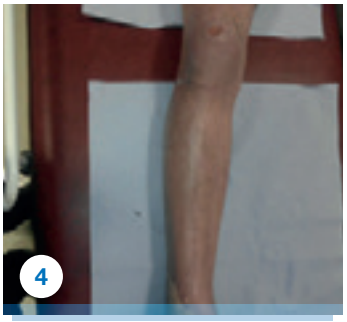
Male patient with stable Necrotizing Fasciitis injury



Application of large sheets of Fenestrated PELNAC™ at surgery

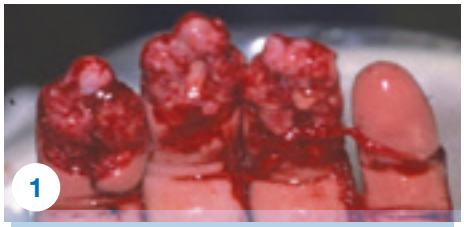


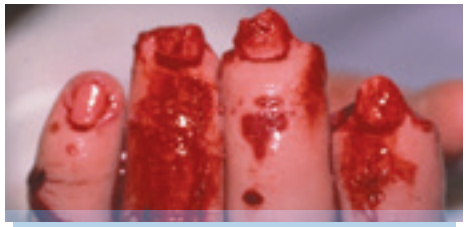
PELNAC™ covered with water resistance dressing and gauze

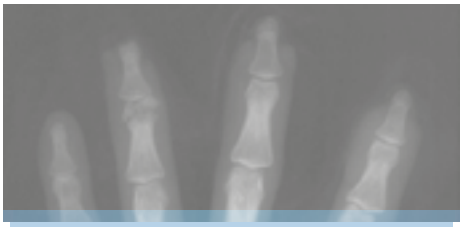


Post op 6 months, good graft take, skin quality and pigmentation and complete flexation of knee joint.

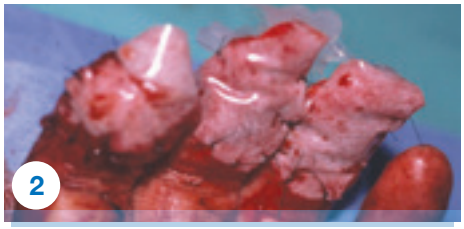
In fingertips of left hand : 32 years old, male

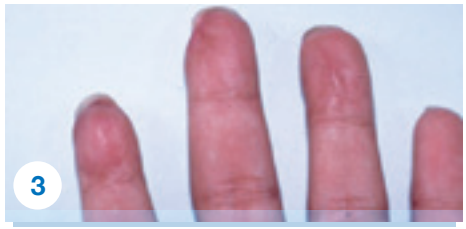


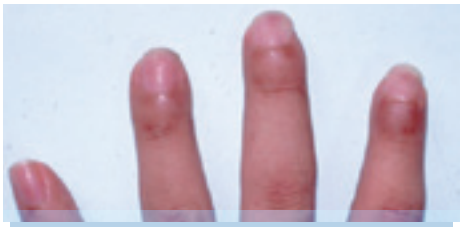




After debridement of wound







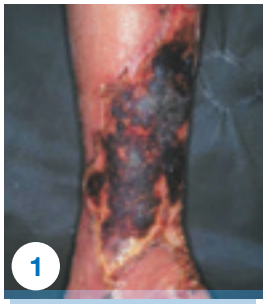
Soon after application of PELNAC™

1 year after application of PELNAC™

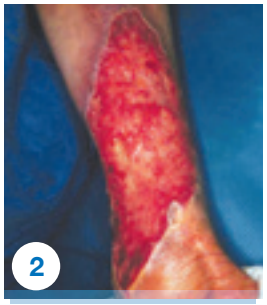
2 weeks after application of PELNAC™, the silicone film was removed and an ointment treatment was continued without skin grafting until epithelialization is achieved. Epithelialization was achieved in 35 days post operatively.

Third Degree Burn

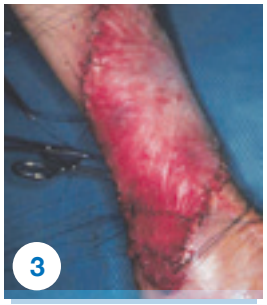
In lower leg : 67 years old, female



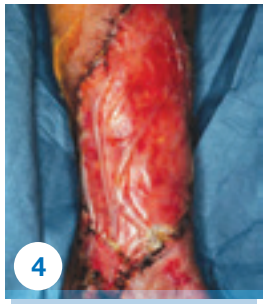
Before the operation



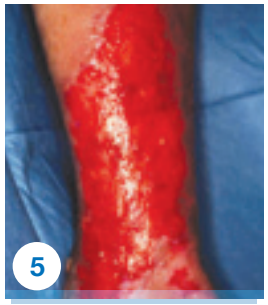
After debridement
Full-thickness skin defects were caused



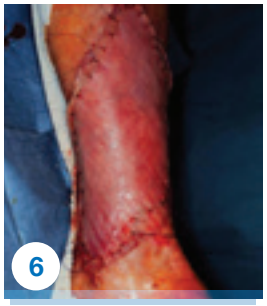
Soon after application of PELNAC™



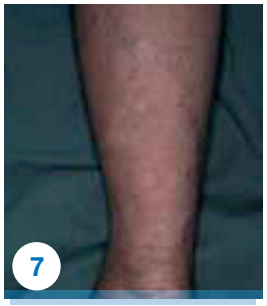
3 weeks after operation. Before removal of silicone film
Dermis-like tissue was generated and silicone film was about to fall out



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

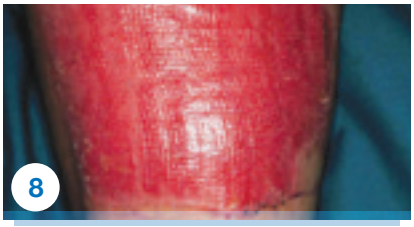


Soon after skin graft (8/1,000inches)

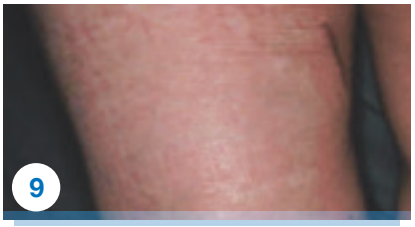


1 year after skin graft
Less contracture and satisfactory aesthetic outcome

Donor Site (Back of Lower Thigh)



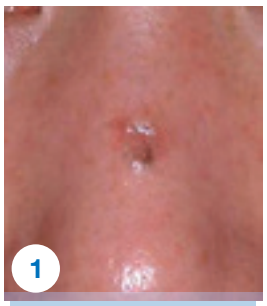
Donor site just after operation



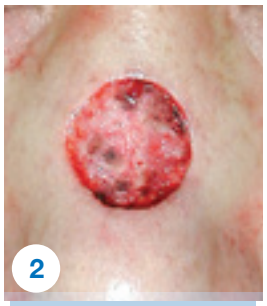
1 year after operation
Less hyperplastic scar due to a thin Split-thickness skin graft

Skin Defect after Tumor Removal

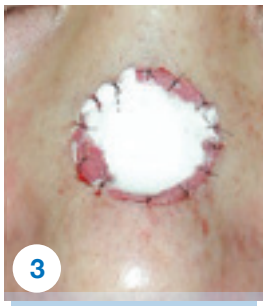
On nasal dorsum : 39 years old, male



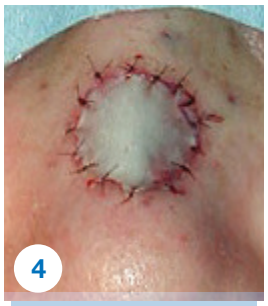
Basal cell carcinoma



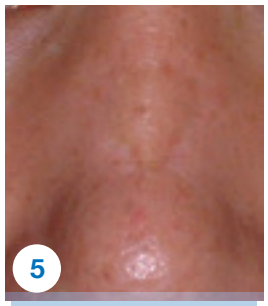
The tumor and surrounding skin including 3mm safety margin was removed
The nasal bone was exposed



Soon after application of PELNAC™



19 days after application of PELNAC™
After pathological examination, silicone film was peeled off and full thickness skin graft placed on the regenerated tissue



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

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.

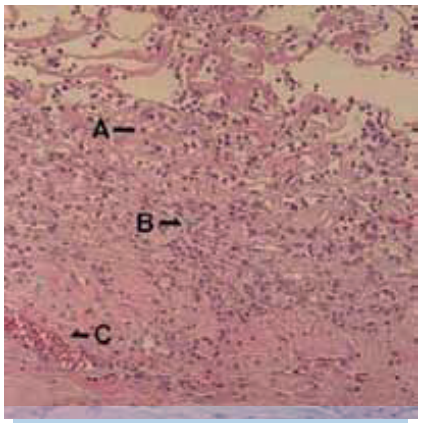
Reduce superfluous skin graft

Non-clinical Study

Formation of Dermis-like Tissue (Guinea Pigs)

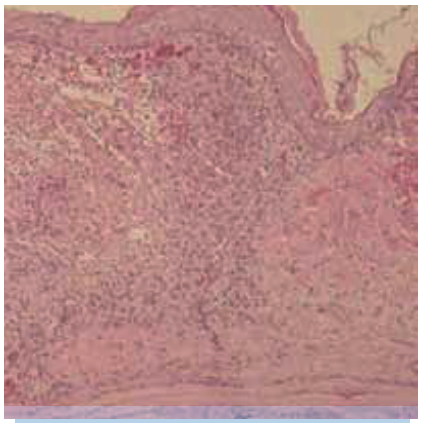
A full-thickness skin defect 1.5 × 1.5cm was prepared in the backs of guinea pigs, PELNAC™ trimmed to 1.5 × 1.5 cm and saturated with sterilised physiologic saline was applied to the skin defect site, and the margin was sutured. One, two and three weeks after implantation of PELNAC™, the recipient sites (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.



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 fibres were slightly thinner than those in surrounding tissues. No abnormality was noted in tissues around the PELNAC™ application site.

Formation of Dermis-like Tissue (Guinea Pigs)

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

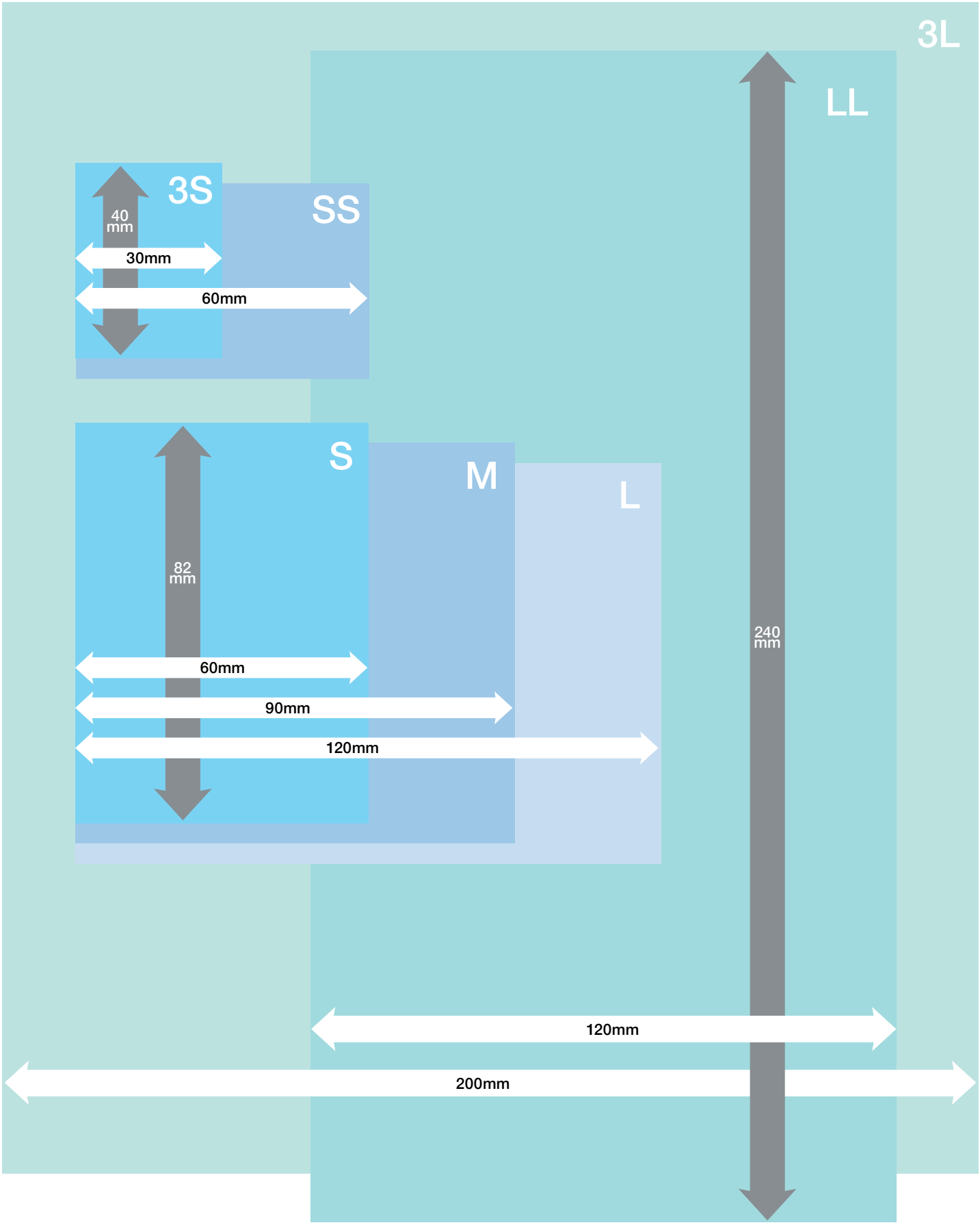
Controls : only silicone film

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

Literature

1. SuzukiS, et al. : Further applications of “bilayer artificial skin”. Br J Plast Surg. 1995; 48: 22-9.
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	Single Layer
			3mm		
3S	40 × 30	1	PN-D40030	PN-F40030	PN-S40030
SS	40 × 60		PN-D40060	PN-F40060	PN-S40060
S	82 × 60		PN-D82060	PN-F82060	PN-S82060
M	82 × 90		PN-D82090	PN-F82090	PN-S82090
L	82 × 120		PN-D82120	PN-F82120	PN-S82120
LL	120 × 240		PN-D120240	PN-F120240	PN-S120240
3L	200 × 240		PN-D200240	PN-F200240	PN-S200240

Carton

Pouch


Tray


Product

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.

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 colonisation, sepsis, chronic inflammation (initial application of PELNAC™ may be associated with transient, mild, localised inflammation), allergic reaction, excessive redness, pain or swelling.

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