GUNZE

ARTIFICIAL DERMIS

PELNAC™

GUNZE MEDICAL DIVISION

PRODUCT OUTLINE

What's PELNAC™?

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

Artificial Dermis "PELNAC™" consists typically of two layers: A porcine tendon-derived atelocollagen sponge layer and a silicone film. PELNAC™ is used to replace and regenerate damaged or defective dermal layers. Once applied to the wound, PELNAC™ helps to form a new dermis-like tissue as the fibroblasts infiltrate into the atelocollagen sponge matrix.

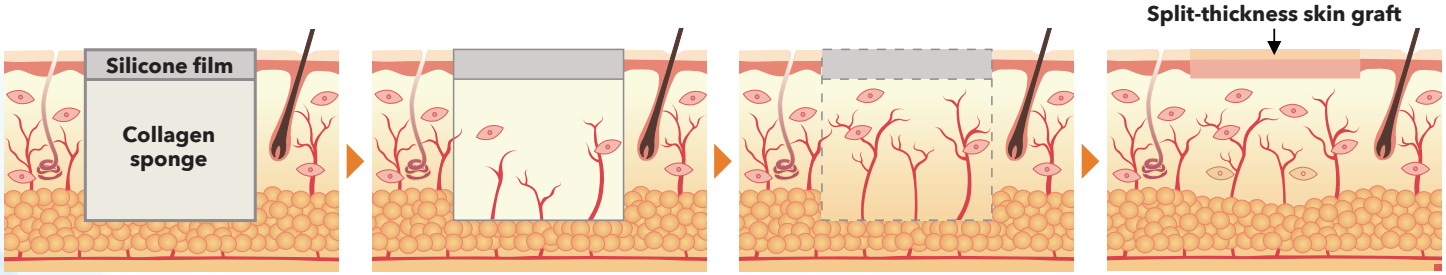
Clinical Advantages

- Ensures high take rates of skin grafts and a good aesthetic outcome.
- Enables thin split-thickness skin grafts, which reduces the damage done to the donor site, thereby minimizing skin sacrifice.
- Minimal contraction and pigmentation after treatment.

Product Characteristics

- Consists of an atelocollagen sponge layer made from porcine tendon and a silicone film.
- The soft collagen sponge structure ensures excellent contact with the irregular wound surface.
- PELNAC™'s wide range of product variations offer an ideal adjustment to the wound condition.
- PELNAC™ is delivered in a freeze dried condition. This ensures an easy storage and transportation.

HEALING PROCESS



PELNAC™ is applied to full-thickness skin defects

Fibroblasts and capillaries infiltrate into the collagen sponge.

The collagen sponge is gradually replaced by newly synthesised collagen to form the new dermis-like tissue.

After 2-3 weeks, the silicone film is peeled off, leading to wound closure with split-thickness skin graft.

INDICATIONS

1. Full-thickness burns

2. Traumatic skin defect wounds

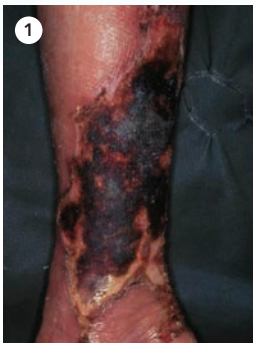
3. Skin defects after tumor or nevus removal

4. Sites of skin flap extraction

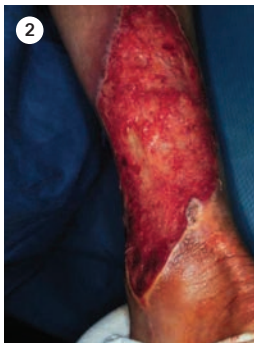
CASE REPORT

Third Degree Burn

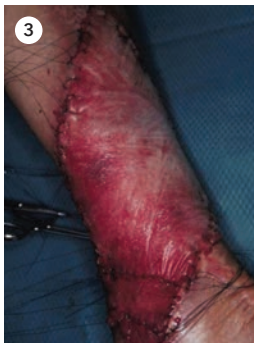
Lower Thigh : 67 years old, Female



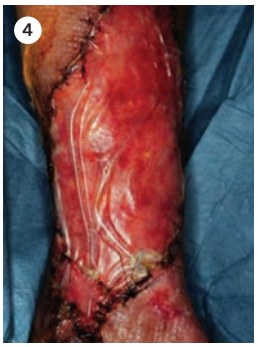
Before the operation



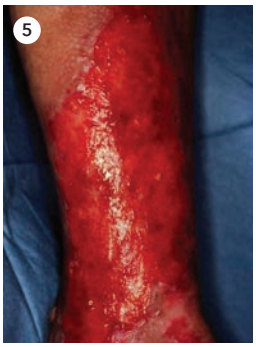
After debridement



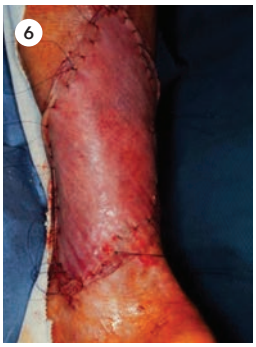
Soon after application of PELNAC™



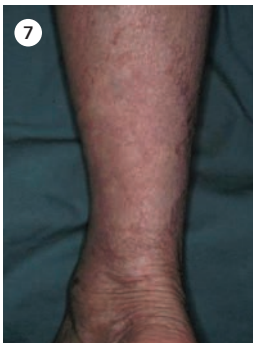
3 weeks after operation. Before removal of silicone film.



After removal of the silicone film.

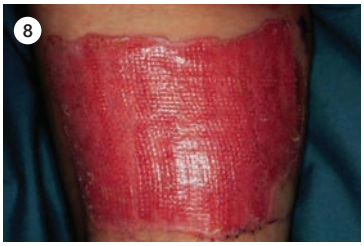


Soon after skin graft (8/1000 inches)

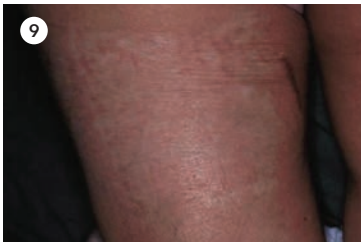


1 year after skin graft

Donor Site (Back of Lower Thigh)



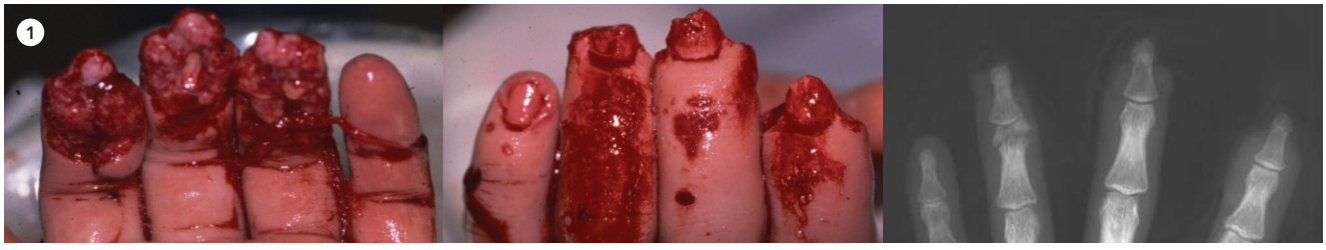
Donor site just after operation



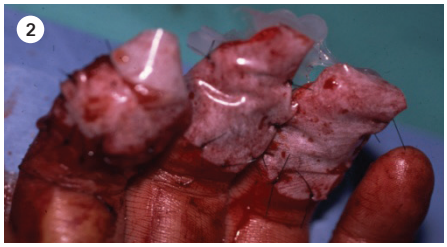
1 year after operation

Traumatic Skin Defect

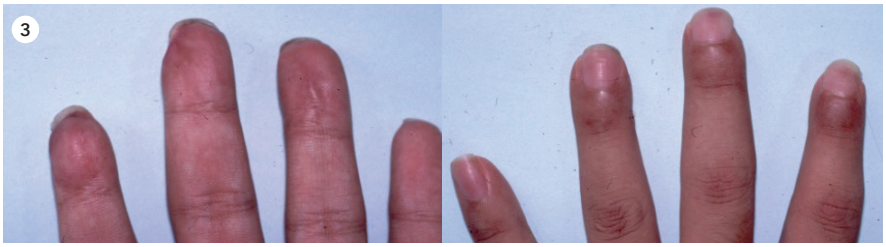
Fingertips of Left Hand : 32 years old, Male



After debridement of the wound

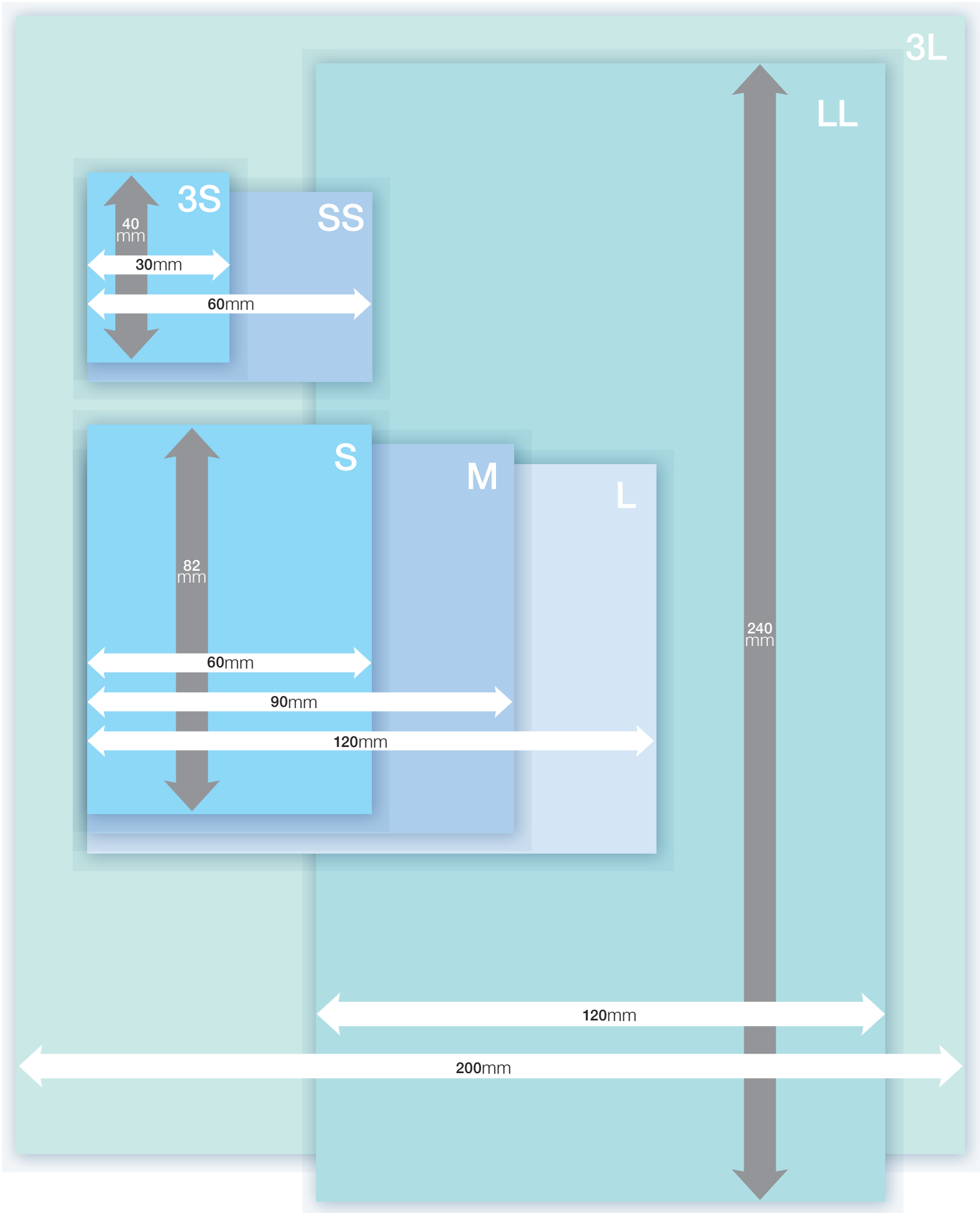


Soon after application of PELNAC™



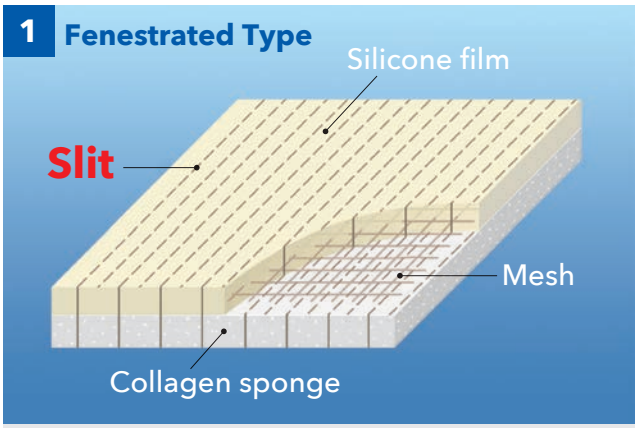
1 year after application of PELNAC™

SIZE VARIATION (Full scale)



VARIATION

1 Fenestrated Type



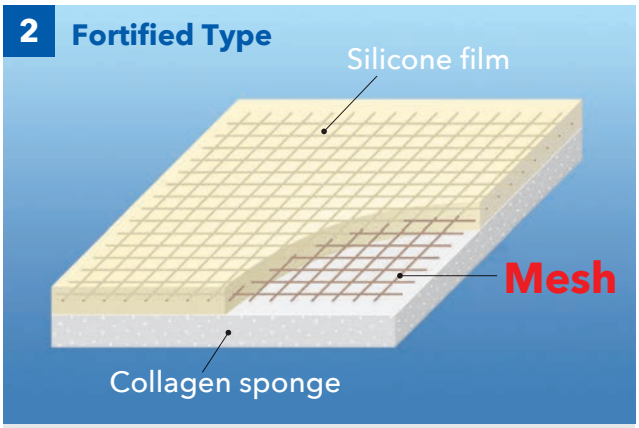
Characteristics

- Allows drainage of wound exudates
- Recommended when exudates are excreted in large amounts
- Flexible structure of the collagen sponge allows for good adherence to the wound surface

Structure

Two-layered material, consisting of a collagen sponge and a silicone film reinforced with a mesh and in which slits are cut.

2 Fortified Type



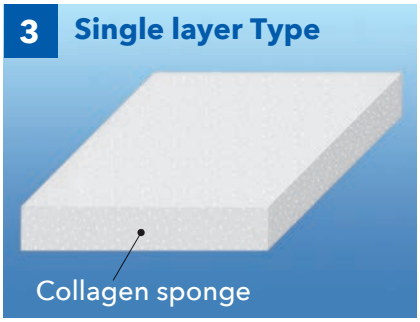
Characteristics

- Easy to suture
- Since the collagen sponge is reinforced with mesh to increase strength, making it easy to suture.

Structure

Two-layered material, consisting of a collagen sponge and a silicone film fortified with a mesh.

3 Single layer Type



Characteristics

Recommended for wounds and surgical techniques which require no silicone film.

Structure

Single-layered material, which made of collagen sponge only.

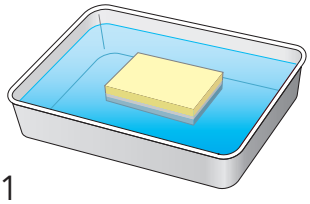
COMPOSITION

Collagen sponge layer
Atelocollagen derived from porcine tendon

Silicone film layer
Silicone resin

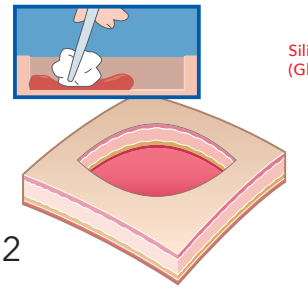
Mesh
Non-adhesive gauze

USAGE



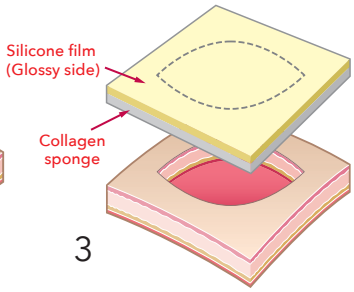
1

Immerse PELNAC™ thoroughly in sterile physiological saline.



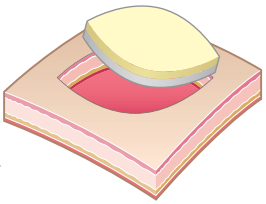
2

Perform hemostasis and thoroughly wash the wound.



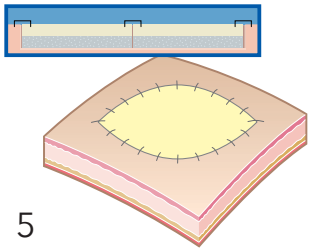
3

Trim PELNAC™ to fit the shape of the wound.



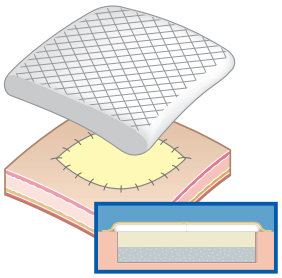
4

Apply the collagen sponge surface to the wound surface.



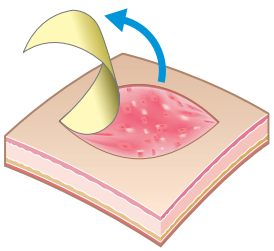
5

Secure PELNAC™ along the healthy skin with sutures or surgical staplers avoiding wrinkles or bubbles.



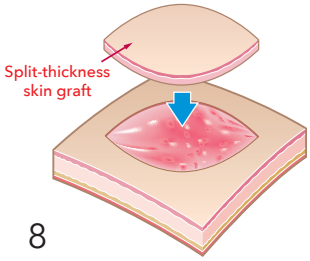
6

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



7

The silicone film will naturaly peel off when a light red colored dermis-like tissue has formed.



8

Perform a split-thickness skin graft.

PRODUCT VARIATION and CODE

Size	Dimension*	Sheet/Box	Fenestrated	Fortified	Single Layer
3S	40 x 30(mm)	1	PN-D40030	PN-F40030	PN-S40030
SS	40 x 60(mm)	1	PN-D40060	PN-F40060	PN-S40060
S	82 x 60(mm)	1	PN-D82060	PN-F82060	PN-S82060
M	82 x 90(mm)	1	PN-D82090	PN-F82090	PN-S82090
L	82 x 120(mm)	1	PN-D82120	PN-F82120	PN-S82120
LL	120 x 240(mm)	1	PN-D120240	PN-F120240	PN-S120240
3L	200 x 240(mm)	1	PN-D200240	PN-F200240	PN-S200240

Carton

Pouch

Tray

*1mm = 0.03937in

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. Avoid exposure to high temperatures and protect from freezing (1°C / 34°F - 30°C / 86°F). Expiry date is indicated on the outer packaging.

CONTRADICATIONS

- 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 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.
- In particular, when PELNAC™ is used on a moving area such as a joint, mechanical dislodgment of PELNAC™ should be avoided.
- Discard device if mishandling has caused possible damage or contamination.
- Use PELNAC™ carefully to prevent the tear when suturing it, especially for the single layer type. Use the fortified type or the fenestrated type when the tear is expected.
- PELNAC™ should not be applied until excessive exudates, bleeding, acute swelling and infection are controlled.
- Use the fenestrated type when a lot of exudates are emitted and therefore drainage is necessary, and when a relapse of the infection in the wound in which the infection was removed is expected. [Because there is a possibility that excessive 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 dermis-like tissue reaches the silicone layer, observing the dermis-like tissue situation from about one week after the operation. Remove the silicone layer completely surgically in case the silicone layer is involved by the dermis-like tissue, in particular when using the fenestrated type.
- Before application, 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. In case of incident intra-operational or post-operational, the device should be removed and disposed based on the protocol and/or the clinical judgment of the practitioner.

GUNZE
a touch of comfort

GUNZE LIMITED Medical Division
http://www.gunze.co.jp/e/medical/

KYOTO MEDICAL DIVISION
(Head office & Factory)
46, Natsumegaichi, Aono-cho, Ayabe,
KYOTO 623-8513, Japan
Tel: +81-3-3276-8718
Fax: +81-3-3276-8696

Japan/Asia Pacific
TOKYO OFFICE
TOKYO SHIODOME BUILDING,
1-9-1 Higashi-Shimbashi, Minato-ku,
Tokyo 105-7315, Japan
TEL +81-3-4485-0007
FAX +81-3-4485-0040

Europe
GUNZE INTERNATIONAL EUROPE GmbH
Oststraße 80, 40210 Düsseldorf, Germany
Tel: +49-211-3613-971
Fax: +49-211-3613-164

China
GUNZE MEDICAL DEVICES (SHENZHEN) LIMITED
Room 802, 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
390 Fifth Avenue, Suite 903, New York,
NY 10018, U.S.A.
Tel: +1-212-354-9060
Fax: +1-212-354-6171

PNG-202201-K