LifeNet Health® Biologics

# DermACELL AWM™ Decellularized Dermis

## INSTRUCTIONS FOR USE

LifeNet Health
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Read this entire package insert carefully prior to use.

## CONTENTS IN THE PACK

Decellularized Dermis (Dermacell AWM) preserved in a glycerol based solution.

Dermacell AWM is restricted to sale by or on the order of a licensed healthcare provider.

## DESCRIPTION

Dermacell AWM was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The dermis was processed using a proprietary technology, which safely renders the dermal matrix acellular without compromising the biomechanical properties for its intended surgical applications.

Dermacell AWM achieves a sterility assurance level (SAL) of $1 \times 10^{-6}$ via gamma irradiation and is preserved using Preservon® processing technology.

## USE OF DERMACELL AWM

Dermacell AWM is indicated for homologous use for the replacement of damaged skin due to diabetic foot ulcers, venous leg ulcers, dehisced surgical wounds, and traumatic burns.

## CONTRAINDICATIONS

Dermacell AWM is contraindicated for use in any patient who has a known or suspected allergy to any of the antibiotics and/or processing reagents listed in this package insert. Dermacell AWM is contraindicated in the presence of infection, necrosis, and underlying osteomyelitis unless debridement or excision have been performed and measures are being taken to address infection.

## WARNINGS AND PRECAUTIONS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any allograft bio-implant, the potential for transmission of infectious agents exists.

This bio-implant may contain residuals of antibiotics (Gentamicin, Lincomycin, Polymyxin B Sulfate, and/or Vancomycin), N-Lauroyl Sarcosinate (detergent), Benzonase (endonuclease), and/or glycerol. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents.

## POTENTIAL ADVERSE EVENTS

Potential adverse events or outcomes include, but are not limited to, infection, allograft tissue rejection, allergic reaction to residual processing reagents, loss of bio-implant structural integrity, reoperation and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to Dermacell AWM (See **COMPLAINTS AND RETURNS** section).

## STORAGE REQUIREMENTS

The distributor, intermediary and/or end-user clinician or facility is responsible for storing Dermacell AWM under appropriate conditions prior to further distribution or implantation.

Dermis must be stored as listed in the table below:

| Storage Temperature | Storage Cautions |
|---|---|
| 15° – 30°C | **Do not freeze or refrigerate** |
| | Store in its original cardboard sleeve |
| | Minimize excessive exposure to light and protect from excessive heat |

**The packaging may contain a temperature sensitive dot that will turn from white to pink or red if the upper temperature limit has been exceeded. Do not use the decellularized dermis if the temperature dot appears to be a color other than white.**

## INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties and/or performance.

## GENERAL INSTRUCTIONS:

- Use on a single occasion for a single patient only.
- Once the packaging is opened, the dermis must be used for the current procedure or discarded.
- Any unused dermis must be discarded in an appropriate biohazard waste container.
- Inspect the dermis, inner and outer packaging, and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the dermis is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
- When the temperature dot is present, do not use the dermis if the dot appears to be a color other than white.
- Use aseptic technique at all times.
- Do not re-sterilize.
- Keep the dermis stored according to recommended storage instructions until preparing it for implantation.

## PREPARATIONS FOR USE

**ORIENTATION: Dermacell AWM has two physically distinct sides; a reticular side and a papillary side. In general, when applied, the papillary side will face up while the reticular side is placed against the surgical wound or the most vascularized tissue. The dermis is packaged with the papillary side visible through the clear side of the packaging.**

1. **Non-Sterile Team Member:** Open the cardboard sleeve and retrieve the pouch from within
2. Aseptically open the outer peel pack and present inner pouch to the Sterile Team Member.
3. **Sterile Team Member:** To maintain orientation of the dermis, the papillary side should be marked with a sterile marker immediately after opening the inner pouch. **The dermis is packaged with the papillary side visible through the clear side of the packaging.** Dermis: Open the inner peel pouch and remove the dermis along with its slip sheet. Remove the slip sheet prior to application.
4. **NOTE: Rinsing is not required prior to application, however it may improve handling.** If a rinse is preferred by the physician, continue to the rinse instructions below.

**If not used immediately, keep dermis moist until implantation.**

## RINSE INSTRUCTIONS (OPTIONAL)

5. **Non-Sterile Team Member:** Prepare a sterile rinse basin with enough sterile isotonic solution (e.g., sterile saline) to completely cover the dermis.
   **CAUTION: Ensure the rinse solution does not exceed 42°C as this may damage the dermis.**
6. **Sterile Team Member:** After opening the packaging per the instructions above, remove the dermis from the slip sheet and immerse the dermis in sterile isotonic solution for a minimum of 1 minute. Ensure the dermis is completely submerged in solution during the rinse.
7. Keep the dermis completely submerged in sterile isotonic solution until needed. **The maximum sterile isotonic solution exposure time for Dermacell AWM is four hours.**

## TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation.

## COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or PharmaLeaf India Private Limited, Bangalore, India Phone: +91 80 43588999 or LifeNet Health (available 24 hours a day) +1-757-464-4761 ext. 2000 and have the bio-implant's identification number available (see label).

## SHELF LIFE

Dermacell AWM is labeled with a shelf life between 3 and 5 years. Please refer to the expiration date on the product label.

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For patent information, please visit www.lifenethealth.org/patents



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