

FREQUENTLY ASKED QUESTIONS

Decellularized Dermis – Storage and Shipping Considerations

Room Temperature Decellularized Dermis

- **Receiving:** LifeNet Health's bio-implant integrity is maintained if the external and internal packaging has not been compromised, and the defined standard shipping procedures have been met. It is not necessary to monitor the temperatures within the package upon receipt. The receiving personnel at the receiving facility must check the integrity of the external shipping container for damage, and check the integrity of the internal bio-implant package to ensure, for example, that all seals are intact and the packaging has no cracks or punctures. The receipt information must be documented.
- **Storage Requirements:** Decellularized dermal tissues must be stored at room temperatures (between 15°C to 30°C or 59°F to 86°F). DO NOT refrigerate or freeze the product.
- **Packaging:** LifeNet Health's decellularized dermal tissue is packaged in laminated pouches that have been validated to maintain integrity during storage and standard shipping procedures.
- **Transportation by LifeNet Health:** LifeNet Health's decellularized dermal tissue is transported in insulated shipping containers that have been validated to maintain acceptable temperatures for 72 hours from the time of shipping. Attention is paid when ordering to expected date and time of receipt by the customer, to assure that no delay occurs in transporting these materials.
- **Transportation by Tissue Intermediaries:** We recommend the following shipping materials (or equivalent) be used to transport decellularized dermis materials to end users (hospital, clinician's offices) within the 72-hour shipping time limit:

Box: Available through VWR – Fisher Scientific (www.vwr.com)
TL 12109 Cardboard shipper with 1 ½ inch (wall thickness) Styrofoam insert
Outer dimensions – 15 ¾ L x 13 ¾ W x 12 ¼ Tall (in inches)

Koolit Blocks: Available through Cold Chain Technologies (www.coldchaintech.com)
Koolit Foam Brick, item 323F (4 needed per shipment)
Koolit bricks should be stored at room temperature – no need to refrigerate or freeze

Instructions for preparing shipment with Koolit Blocks:

- 1) Up to 30 units of decellularized dermis can be shipped per box.
- 2) Place 2 room temperature (22°C ± 3°C) Koolits blocks in bottom of Styrofoam shipper within corrugated box.
- 3) Place decellularized dermis units on top of previously placed Koolit blocks.
- 4) Place an additional 2 room temperature Koolit blocks on top of decellularized dermis.
- 5) Fill remaining space with appropriate documents and choice of filler materials.

As an alternative to the recommended shipping system, decellularized dermis can be shipped at wet ice temperatures. However, appropriate measures must be implemented to ensure that sufficient wet ice is present to maintain a consistent temperature for the duration of the shipment. LifeNet Health has demonstrated acceptable shipping with 10 pounds of wet ice in the TL-12109 insulated shipper described above. Wet ice transports is not recommended for shipments lasting longer than 24 hours. Grafts must be placed in a waterproof barrier to protect them from making contact with any moisture. The receiving party must verify, through visual inspection, that wet ice is present when products are received. Once the inspection is complete, the decellularized dermis must be stored as described above.