

FREQUENTLY ASKED QUESTIONS

Decellularized Dermis – Storage, Shipping and Returns

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, check the integrity of the product’s packaging to ensure, for example, that all seals are intact and the packaging has no cracks or punctures, and check that the thermal dot indicator on the graft package is white. 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 or mailer pouches 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 customer, to assure that no delay occurs during transportation of these materials.

- **Why is the Dermis shipper validated for receiving?**
 - LifeNet Health validates that the graft’s shipping container has been temperature controlled for the designated amount of time as noted on the Dermis shipper or mailer to ensure the graft has not been exposed to temperatures exceeding its upper limit.
- **If my Dermis mailer has expired, how do I know my dermis graft is still viable?**
 - LifeNet Health stamps each Dermis shipper or mailer with an expiration at the time of packaging to guarantee controlled and proper temperature ranges during shipping. While the Dermis shipper or mailer may “expire” for decellularized dermis products (ArthroFLEX®, DermACELL®, and OrACELL®), the graft is still viable as long as the Dermis shipper or mailer and graft have been stored within the proper temperature range and the temperature dot indicator on the graft’s outer packaging has not changed and remains white.

Returns: LifeNet Health may allow the return of our bio-implants if specific conditions are met. LifeNet Health reserves the right to refuse credit if the conditions and specifications are not met or the returned dermal tissue is received damaged or the thermal dot indicator has changed. Please refer to the return and credit policy for full details. To initiate a return, call Client Services at 888-847-7831 to obtain a Return Material Authorization (RMA) number and request a return shipper, if needed. There may be a fee associated with obtaining a return shipper. Ensure to write the RMA number on the outside of the shipper.

- **Can I still reuse the Dermis shipper or mailer for return shipping?**
 - Possibly. If the graft was received in an inflated pouch, the Dermis mailer is not reusable. If the dermal allograft was received in a cardboard box with Styrofoam insert, the shipper could be reused as long as neither the shipping container nor Koolit blocks have been damaged and are intact. To obtain a new mailer and return label, reference return instructions above.
- **How should the Dermis shipper or mailer be packed for dermis returns?**
 - See Table I for pack out configurations.

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Table I: Dermis Mailer Pack-Out Configuration

Product Brand	Shipper type	Number of Grafts to Return	Number and type of Bricks Required	How to Pack
All ArthroFlex All Oracell All Dermacell – Except those order codes listed below	Medium Pouch/Polybag 14x18"	1-2	2 Nordic Ice Bricks –	Place individual graft sleeve into own zipper bag and then into mailer. Nordic bricks will be sandwiched between grafts when returning 2 grafts. Cardboard pads will be outermost within mailer. Seal & Inflate Pouch (see below).
Dermacell Codes: DCELL206, DCELL207 DCELL208, DCELL209 DCELL216 DCELL256, DCELL257 DCELL258, DCELL259 DCELL214M-233M	Extra-Large Pouch/Polybag 19x24"	1-2	3 Nordic Ice Bricks –	Place individual graft sleeve into own zipper bag and then into mailer. Nordic bricks will be in a dermis refrigerant insert and sandwiched between grafts when returning 2 grafts. Cardboard pads will be outermost within mailer. Seal & Inflate Pouch (see below).
All ArthroFlex Dermacell Oracell	Box with Styrofoam Insert 15.75x13.75x12.25"	1-30	4 Koolit Blocks	Place two Koolit blocks in bottom of Styrofoam insert. Place graft in zipper bag (if available) and then place on top of Koolit blocks. Place two additional Koolit blocks on top of the graft. Fill remaining area with packing pellets. Seal shipping container.

- **How do I seal and inflate the Dermis mailer?**
 - To Seal: Expose the envelop adhesive by removing the tape near the envelop opening, and seal the envelop shut.
 - To Inflate: Puncture the four holes at the four “Puncture Here” locations on the pouch and allow for full expansion of the polyurethane insulator. Use care to ensure puncture does not penetrate through the mailer and damages the product or refrigerant brick.
- **Key reminders:**
 - Do NOT combine frozen and ambient temperature grafts in the same shipping container.
 - Must ship via courier that accepts human tissue and offers tracking services at customer’s expense, with delivery within three business days.
 - Return item(s) to the location the original was shipped from.
 - Do NOT freeze the Nordic ice brick or Koolit blocks prior to return shipping. Store at room temperature, or between 15-30° C.

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Transportation by Tissue Intermediaries: LifeNet Health recommends the following shipping materials (or equivalent) be used to transport decellularized dermis allografts to end users (hospital, clinician's offices) within the 72-hour shipping time limit. Refer to the product websites for more specific information regarding the recommended shipping materials.

Derma Pouch Mailer

Pouch: Available through Thermal Shipping Solutions - (www.thermalshipping.com)

Item number: KM-21214-2 (small), KM-21418-2 (medium) or KM-21924-0 (extra-large)

Nordic Ice bricks available through Nordic Ice (www.nordicice.com)

Item number: NB18

Corrugated pads available through Uline – (www.uline.com)

Item #: S-3961 (small), S-18195 (medium), S-18996 (extra-large)

There is also a small pouch available that is not shown in Table I, but is listed in the supplies above. The small pouch is packed the same as the medium. Grafts that can be shipped in the small pouch are all Oracell grafts; all ArthroFlex grafts except for AFLEX150; and Dermacell codes that fall within the range of DCELL100 to DCELL154.

Box Shipper

Insulated Shipper available through VWR or Fisher Scientific (www.vwr.com or www.fishersci.com)

Item number: TL-12109 Cardboard shipper with 1.5 inch (wall thickness) Styrofoam insert

Koolit Blocks available through Cold Chain Technologies (www.coldchaintech.com)

Item number: 323F (four needed per shipment)

****NOTE:** Nordic Ice Bricks and Koolit blocks are not interchangeable.