

TISSUE HAS BEEN DECLARED SAFE FOR HUMAN TRANSPLANTATION

Description

LAB™AMNIO is a sterile, minimally manipulated, dehydrated, non-viable cellular human amnion membrane allograft. The allograft is derived from human placental tissue collected from consenting donors. The dehydrated allograft is processed aseptically and is sterilized by irradiation to achieve a sterility assurance level (SAL) of 1×10^{-6} according to the standards established by the International Organization for Standardization (ISO).

LAB™AMNIO is prepared in accordance with Health Canada CTO Regulations. **LAB™AMNIO** passes USP <71> sterility test. All procedures for donor screening, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks (AATB), international laws and regulations as required.

Donor screening and testing

LAB™AMNIO is manufactured from donated human tissue that meets specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease.

The donor's blood samples are tested for the following infectious diseases: HIV-1/2 antibody, Hepatitis B surface antigen, Hepatitis B core antibody (Total), Hepatitis C antibody, HIV (NAT), HBV (NAT), HCV (NAT), HTLV I/II antibody, Malaria, Syphilis, WNV (NAT).

Traceability

Recipient records must be maintained for the purpose of tracing tissue post-application in accordance with Sections 43-54 of the CTO Regulations. The Tissue Utilization Record is included in the package. We encourage physicians to fill out and return the record to: **Labtician Ophthalmics Inc.** at 2140 Winston Park Drive, Unit 6, Oakville, ON L6H 5V5.

The LOT number, Product Code, Donor ID, Tissue size, Manufacturing and Expiry date must be recorded on the Tissue Utilization Record.

Storage and Expiry

LAB™AMNIO must be stored and maintained in its original package in a clean, dry environment at room temperature until it is ready to be used by the clinician. The product has been validated for storage between 15°C and 30°C.

Shelf-life

3 years from the date of manufacturing, when stored as recommended.

Ophthalmic usage

LAB™AMNIO is intended as a permanent inlay-graft, temporary onlay-graft or wound covering and, filling-in graft. **LAB™AMNIO** is an allograft tissue, for homologous use at the recommendation of an eye care professional, for the purpose of supporting the healing processes in various conjunctival and corneal conditions and, to provide a physical barrier in protecting an ocular wound. Depending on the application technique, the tissue can be applied on the ocular surface followed by the placement of a bandage contact lens, or with fibrin glue and/or sutures if necessary.

LAB™AMNIO is for single use only, in one patient, applied by an eye care professional.

Packaging and handling

LAB™AMNIO is aseptically packaged in a sterilized hermetically sealed

aluminum-PVC foil pouch. The aluminum-PVC foil pouch containing the allograft is additionally packed in a second aluminum-aluminum foil pouch. The foil pouch is sealed, labeled and then packed in a single carton box.

Available sizes

LAB™AMNIO is available in different size variants including 9 mm disc, 9mm double layer disc, 12mm disc, 12mm disc with pinhole, 12mm double layer disc, 3 cm x 3 cm, 3 cm x 3 cm double layer, 2 cm x 2 cm triple layer to suit multiple wound types and sizes

Recommended instructions for use

These recommendations are designed only to serve as a general guideline. They are not intended to supersede or replace current institutional protocols or professional clinical judgment and guidelines concerning patient care and management. The use of **LAB™AMNIO** should be made according to the clinical decision of the physician.

The inner pouch is considered sterile. Use caution when opening. Please take great care when removing the graft from the internal pouch. The allograft is thin and extremely light-weight.

Preparation and application instructions

1. Open the box containing the **LAB™AMNIO**.
2. Tear open the outer pouch.
3. Remove the inner pouch using aseptic technique. Both the inner foil pouch and its content may be placed directly onto the sterile field.
4. Tear the inner pouch open only when ready to apply the allograft onto the eye.
5. Dry the ocular surface. The drier the ocular surface the easier the application.
6. Remove the allograft carefully from the package using a smooth-tip forcep.
7. Place the allograft at the desired ocular area.
8. Gently smooth out any wrinkles and folds on the tissue using an eye spear.
9. A bandage contact lens is commonly placed over the graft. Fibrin glue or sutures may be applied if necessary.

Remember to fill out the Tissue Utilization Record and return to Labtician Ophthalmics, Inc.

Note

Allografts are human tissue products and appearance may vary between donors. Variations in color (tan to light brown), opacity, and thickness are normal due to the nature of human tissue.

Contraindications

LAB™AMNIO should not be used on patients with known hypersensitivity to ofloxacin, vancomycin and amphotericin B.

It should not be used on:

- 1) areas with active or latent infection and/or
- 2) into a patient with a disorder that would create an unacceptable

risk of post-operative complications.

As with any allograft, complications at the graft site may occur postoperatively. Although donor tissue is evaluated and processed following strict CTO requirements, communicable diseases including those of unknown etiology, transmission of infectious agents such as viruses, bacteria, and fungi, as well as immune rejection of, or allergic reaction to the tissue are possible.

Warnings

1. Do not resterilize, keep away from sunlight, do not use if package is damaged and consult instructions for use, keep dry, keep out of reach of children. Do not re-use. Contains biological material of human origin.
2. Caution should be used when treating patients with a known sensitivity to ofloxacin, vancomycin, and amphotericin antibiotics. Expert opinion is required before use on babies and pregnant women.
3. The graft is intended for single-patient use only, on a single occasion.
4. Strict donor screening and laboratory testing, along with dedicated processing and sterilization methods are employed to reduce the risk of any disease transmission. However, as with all biological implants, an absolute guarantee of tissue safety is not possible. As with any allograft, complications at the graft site may occur post operatively that are not readily apparent. These include, but are not limited to:
 - Transmission of communicable diseases, including those of unknown etiology
 - Transmission of infectious agents such as viruses, bacteria and fungi
 - Immune rejection of, or allergic reaction to, implanted HCT/PS
5. Discard all damaged, mishandled or potentially contaminated tissue.
6. This product has not been tested in combination with other products.
7. Allograft shall not be offered, distributed or dispensed for veterinary use.
8. Use is limited to eye care professionals only.
9. Do not rinse tissue prior to use.
10. Consult instructions for use.
11. Do not use once passed its expiration date. All expired products must be discarded.

The disposal of unused and expired product as well as its packaging must be performed in accordance with accepted medical practice and applicable provincial and federal laws and regulations.

Errors, accidents or adverse events.

Errors, accidents or adverse reactions or outcomes must be reported immediately to the **Labtician Ophthalmics, Quality Assurance and Regulatory Department**. Email: qar@labtician.com / Phone: 905-829-0055 ext. 6221

					
Lot Number	Consult Instructions For Use	Use-by Date	Keep Away From Sunlight	Double Sterile Barrier System	Keep Dry
					
Product Code	Do Not Reuse	Do not Resterilize	Do not use if packaging is damaged and consult instructions for use	Sterilized using irradiation	Caution
					
Prescription Use Only	Contains Biological Material of Human Origin	Keep Out of Reach Of Children			

Imported/distributed by: **Labtician Ophthalmics, Inc.**

2140 Winston Park Drive, Unit 6, Oakville, ON L6H 5V5 Canada

E-mail: qar@labtician.com / Phone: 905-829-0055 ext. 6221

Health Canada Establishment Licence No.: 100040



Source establishment: **LifeCell International Pvt. Ltd.**

No. 26, Keelakottaiyur, Vandalur-Kelambakkam Main Road, Chennai 600127


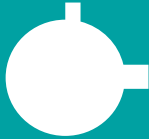
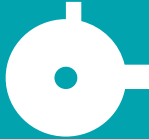




E-mail: info@lifecell.in / Phone: 1-800-266-5533

USFDA Facility Registration No. FEI: 3007953176

AATB Accredited Member #00323

Health Canada Establishment Licence No.: 100282



Products	LABTICIAN LABAMNIO 9	LABTICIAN LABAMNIO 9D	LABTICIAN LABAMNIO 12	LABTICIAN LABAMNIO 12V	LABTICIAN LABAMNIO 12D	LABTICIAN LABAMNIO 3x3	LABTICIAN LABAMNIO 3x3D	LABTICIAN LABAMNIO G
Indications	CONJUNCTIVAL SURFACE: Pterygium surgery, chemical burns, conjunctival chalasis, leaking bleb CORNEAL SURFACE RECONSTRUCTION: Non-healing PED neurotrophic ulcers, keratitis sicca, overlay post PRK							Glaucoma Shunt Tube Covering
Dimensions	9 mm in diameter Single thickness	9 mm in diameter Double thickness	12 mm in diameter Single thickness	12 mm in diameter with 2 mm pin-hole Single thickness	12 mm in diameter Double thickness	3 x 3 cm ² Single thickness	3 x 3 cm ² Double thickness	2 x 2 cm ² Triple thickness
								
Orientation	If the larger projection is distanced clockwise from the smaller one, the epithelial side is facing the cornea.	Double-layered graft. It can be placed in any orientation, as both sides are epithelial surfaces.	If the larger projection is distanced clockwise from the smaller one, the epithelial side is facing the cornea.	If the larger projection is distanced clockwise from the smaller one, the epithelial side is facing the cornea.	Double-layered graft. It can be placed in any orientation, as both sides are epithelial surfaces.	If the membrane's cut edge is facing right and away from the surgeon, the stromal side is facing down and the epithelial side is facing up.	Double-layered graft. It can be placed in any orientation, as both sides are stromal surfaces.	Triple-layered graft. Both sides are stromal surfaces.
Principles Of Surgery	INLAY OR GRAFT technique OVERLAY OR PATCH technique FILLING-IN OR LAYERED technique							LAB™AMNIO-G is prepared to cover GDD (glaucoma drainage device) tubes.

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