# Surgeon **Packet**



# Committed to tissue quality, safety & outcomes!

# **Medical Advisory Committee:**

Woodford S. Van Meter, M.D. Hossein Asghari, M.D. Richard A. Eiferman, M.D. Lawrence R. Tenkman, M.D. John C. Meyer, M.D.

301 E. Muhammad Ali Blvd. Louisville, KY 40202 (502) 852-5457-Main (502) 852-5471-Fax



1510 Newtown Pike Suite 220 Lexington, KY 40511



#### **Donor Clearance**

We strive on excellence by providing superior quality tissue and superior quality work. Every cornea intended for transplantation undergoes specular microscopy evaluation and slit-lamp bio-microscopy evaluation by our highly trained Eye Bank Technicians. Tissue provided by the Kentucky Lions Eye Bank meets EBAA, FDA & KLEB donor and tissue suitability criteria.

Our team works with you to ensure that your individual tissue preferences and needs are met. You can rest assured that every tissue recovered undergoes a rigorous medical review by qualified staff. Tissue is not released prior to receiving hard copy, required serologic test results from a CLIA certified and FDA registered laboratories. Required serologic tests:

- HIV 1 & 2, plus O
- HBsAG
- HBV NAT
- Anti-HBc
- HCV ab
- HCV NAT
- HIV-1 NAT
- Syphilis (RPR)
- ABO/RH testing available upon request

Tissue offers are typically sent out 24-48 hours in advance of surgery. You will receive comprehensive donor and tissue information, serologic test results (if results are back) and imaging of the tissue that is being offered.

The Kentucky Lions Eye Bank provides a wide range of services to meet your needs. Tissue is recovered 24 hours a day, 7 days a week. We are responsible for coordinating the procurement, evaluation, distribution and placement of eye tissue for transplant and research needs. Below is a list of services offered:

- SeraTears™ Autologous Serum Eye Drops (ASED)- Dilution 20% or 50% with Saline or Refresh Tears
- Emergency tissue
- Specialized tissue preparation-DSAEK & DMEK
- Cornea storage solution-Optisol GS

KLEB recommends warming the cornea to room temperature for (1) hour prior to transplantation to maximize the effect of the antibiotic contained within the solution.

• Sclera-whole, half & quarter size stored in 100% ETOH, 2-year shelf life

KLEB recommends re-hydrating the sclera in BSS or NS (60-100 cc). Sclera should then be transferred into a second sterile basin and soaked for an additional 5-20 minutes.

- Aftercare program to connect recipient & donor families
- Research/Training tissue-upon request

#### Importing

On occasion we may need to import tissue to meet our scheduled surgery demands. We only import tissue from EBAA accredited and FDA registered eye banks. Prior to the offer, a KLEB Quality Control form is completed to ensure tissue meets all suitability standards. This includes a review of the serologic test results & that an acceptable cause of death has been determined that meets EBAA and FDA standards.

If the tissue is received by KLEB prior to the scheduled surgery, it under goes another check prior to packaging and shipment to verify that is has the following:

- Proper packaging to ensure corneal tissue was maintained at a temperature of 2°-8°C
- An intact tamper evident seal on the tissue container
- Acceptable storage solution color
- Verification that the tissue identification number on the tissue container label, the tissue information form and the tissue package insert matches the tissue accepted

### Requesting Tissue, Tissue Packaging & Delivery, Tracking & Cancellations:

#### Request of Tissue

Tissue is requested via our Surgeon Portal by the surgeons' office.

#### Packaging & Delivery

Delivery of tissue is guaranteed within an hour prior to the scheduled surgery. In some cases, the tissue may arrive the day before surgery. Corneal tissue is packaged to ensure the temperature is maintained between 2°-8°C. In emergency cases, tissue will arrive as soon as possible depending on location of surgery.

We utilize couriers, staff and volunteers to ship surgical tissue. We work closely with all delivery personnel to educate them on the proper handling of packaged tissue.

#### Tissue Tracking

The FDA requires the tracking of the tissue to the consignee

The Joint Commission requires tissue tracking to the recipient

The Eye Bank is required to track the tissue from the donor to the consignee or final disposition

\*\*A Recipient Information Form is included with each tissue and must be returned to the eye bank following surgery.

#### Cancellation(s)

All cancellations must be communicated to KLEB distribution immediately. Call (502) 852-5457, option #1, to report surgery cancellations and for pick-up instructions and information.

#### **Post-Operative Outcomes Solicitation & Follow-Up**

Post-operative outcomes information is required by the EBAA between 3-6 months post-operatively. The post-operative follow-up forms will be sent to your office for completion. Please return at your earliest convenience!

#### **Adverse Reaction**

In the event of an adverse reaction, the consignee agrees to report it immediately and help investigate its cause. The Adverse Reaction Report Form is included with the paperwork that accompanies the donor tissue. This form must be completed and returned via email to our Quality Assurance & Regulatory Affairs Manager, Nicole Wilson, at <a href="mailto:nwilson@kylionseyebank.org">nwilson@kylionseyebank.org</a>.

# **Our History**

Welcome to the Kentucky Lions Eye Bank. Where corneal transplants come deeply rooted from our history.

#### **Committed to tissue quality, safety & outcomes!**

The nation's first eye bank was established in New York City in 1944, under the direction of Dr. R. Townley Paton. Margaret Sanders Adams (daughter of the famed Col. Harland Sanders), developed a keen interest in helping the blind. Margaret traveled to New York in 1945, along with Dr. Paton to learn about eye banking and corneal transplants. Upon her return to Louisville, she approached the Louisville Lions Club for help. The Lions Club appropriated funds and sent one of its members and Margaret back to New York to further study the eye banking program there. When they returned it was recommended that the club pursue eye banking.

The Sight Restoration Society was formed in 1945, with the Louisville Lions Club President. The University of Louisville joined forces with this project. In 1947, Dr. Townes performed the first corneal transplant in Kentucky.

Not much has changed since then. Our mission continues to be restoring sight through corneal transplant, ocular research and medical education. We have two locations, one in Louisville and one in Lexington, Kentucky. We work closely with KODA to promote eye, organ and tissue donation while respecting and honoring the donors and their families who so selflessly give the gift of sight. KLEB currently serves 115 counties in Kentucky, 4 in Indiana and 2 in West Virginia. We are a federally designated 501 (c)(3) not-for-profit organization. KLEB is EBAA accredited and is registered with the FDA. KLEB also holds a current State of California Tissue Bank License & a Health Canada CTO Registration Certificate.

#### **Surgeon Testimonials**

"The Kentucky Lions Eye Bank was formed in 2017 by the merger of the University of Kentucky Eye Bank and the University of Louisville Lions Eye Bank. The Kentucky Lions Eye Bank is an EBAA accredited eye bank serving the entire state of Kentucky. Recently inspected by the FDA, there were no deficiencies. KLEB provides cornea tissue for full thickness and lamellar keratoplasty procedures, cornea and sclera tissue for glaucoma shunt and plastics procedures and Autologous Serum Eye Drop (ASED) for patients with dry eyes. With offices in Lexington & Louisville, transportation networking across the state and a close working relationship with KODA, this not-for-profit eye bank is a jewel serving the people of Kentucky"

- Woodford S. VanMeter, M.D.

"The eye bank has and continues to be very helpful in assisting with caring for our patients. They are prompt and reliable. Very grateful for their continued assistance"
-Peter Timoney, M.D.

"Serum tear therapy is one of the most effective ways to treat eye pathology. From dry eyes to non-healing corneal ulcers & defects. Thanks to the eye bank, we now have access to this modality in our community" -Bruce Koffler, M.D.

## **Surgeon/Scheduler Info & Tissue Preferences:**

Tissue provided by the Kentucky Lions Eye Bank meets EBAA, FDA & KLEB donor and tissue suitability criteria.

Surgeon:	Phone:
Birthday:	Email:
Preferred method of contact:	Tissue Offers go to:
Office contact:	Phone:
Birthday:	Fax:
Death-to procurement interval: 16 hours or less	Death-to surgery interval: 7 days or less
Preference:	Preference:
Surgery Locations:	
Age range of donors: 2-75	
Preference:	-
PK/EK Standards: Endothelial cell count PK procedures: 2,000 or greater EK procedures: 2,400 or greater	DSAEK preparation standards: Standard: 90-130 post-cut thickness Ultrathin: 50-90 post-cut thickness
Preference:	Markings: Epithelium centration dot 4 gutter marks @ 3,6,9 & 12 "S" stamp upon request Other markings upon request
	Preference:
<u>DMEK preparation standards:</u> 9.5 mm graft size Peripheral hinge (Central hinge upon request) "S" stamp Additional graft sizes upon request	DMEK Pre-loaded standards: 8.0 mm graft size "S" stamp Additional graft sizes upon request
Preference:	Preference:
*Willing to reschedule surgery due to lack of tissue	
Any international contacts:	