Mobile Vision Care

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INFORMED CONSENT FOR AMNIOTIC MEMBRANE ALLOGRAFT

Please read the following consent form and sign at the bottom where indicated. Do not sign this form unless you have read and understood this document.

Patient Name: _____ **Facility:** _____

INTRODUCTION-This information is being provided to you so that you can make an informed decision about the use of donated Amniotic Membrane tissue.

BACKGROUND-The Amniotic membrane is part of the human placental tissue that is closest to the baby during embryonic development in the womb. It protects the baby from any harm and it has natural therapeutic actions which help the baby develop.

The amniotic membrane tissue has been found to help damaged or inflamed eye surfaces heal faster. Eyes treated with Amniotic membranes may have quicker healing, less pain, less scarring, and less inflammation.

Amniotic Membranes have been used by physicians all over the world to treat eye diseases such as recurrent corneal erosion, infectious/inflammatory keratitis, Herpes, superficial epithelial defects, severe dry eye syndrome, and other corneal diseases.

They are a safe, effective treatment provided by a tissue bank regulated by the FDA. The tissue has passed many quality control tests before it is provided to your doctor.

STERILIZATION-Amniotic Membranes are procured and processed according to Good Tissue Practices (GTP) and Good Manufacturing Practices (GMP) regulations established by the United States Food & Drug Administration (FDA). Placental tissues are retrieved from donor mothers after elective cesarean section under full informed consent. The donor mothers are screened at delivery for infectious, malignant, neurological and autoimmune diseases and other exposures or social habits and also undergo a physical exam to determine the suitability for human transplantation. Donors are tested by a CLIA certified independent laboratory using FDA licensed test kits around the time of delivery and found to be serologically negative for, at minimum, the following tests:

*HIV 1 & HIV 2, Antibody	*HIV 1 Virus (NAT)
*Hepatitis B surface antigen (HBsAg)	*Hepatitis B core antibody (HBcAb)
*Hepatitis C Antibody (HCVAb)	*Hepatitis C Virus (NAT)
*HTLV 1 & 2 antibodies	*Syphilis (RPR)
*West Nile Virus, WNV, (NAT)	*Chagas (T. Cruzi)

PATIENT CONSENT-Although all screening and microbial testing results were found to be satisfactory for my Amniotic Membrane tissue, I understand as with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated.
In signing this form, I give consent to use Amniotic Membrane tissue on my eye(s) and that I have read this consent form; and although it contains medical terms, which I may not completely understand, I have had the opportunity to ask questions and have had them answered to my satisfaction. I also give my permission for medical data concerning my procedure and related photo / video recordings to be released to physicians and others demonstrating a "need to know" for clinical study.

_____ _____

Signature of Patient Date Signature of Witness Date

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Signature of Doctor Date