Ensuring Superior Surgical Outcomes Through Technological Innovation

As a dedicated physician, providing innovative treatment to your patients with the highest quality of outcomes is a foremost priority. With this in mind, **Bio-Tissue** brings you a new generation of ocular surface tissue therapies designed to accelerate the regeneration of damaged tissue while reducing recipient discomfort associated with ocular surface reconstruction.

Created using our patented cryopreservation method, AmnioGraft®, AmnioGuard™, and ProKera® deliver the natural healing properties of amniotic membrane to restore the wound space with minimal scarring and inflammation. Bio-Tissue's amniotic membrane allografts facilitate the short-term success of surgical procedures as well as the long-term stability of the wound space when used as indicated.

By eliminating the need to harvest your patient's own tissue, amniotic membrane reduces pain and discomfort, limits complications, reduces surgical time and optimizes surgical outcomes.

Bio-Tissue has contributed over ten years of research and innovation to the ophthalmic community and remains committed to creating ophthalmic products that will advance the treatment of ocular surface diseases.

Tissue Safety and Quality Assurance

AmnioGraft® and ProKera® 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 auto-immune 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)

Amniotic membrane is processed using a validated, proprietary method to produce AmnioGraft®. The final product is released after microbiological testing yields no growth of microorganisms (aerobic, anaerobic, or fungal). AmnioGraft® and ProKera® are preserved in a validated and patented storage medium.

Contact Bio-Tissue today and learn how our ocular surface tissue therapies can optimize your surgical results.

Customer Service

Toll Free: 1-888-296-8858

For Medical Consultation

Scheffer C.G. Tseng, M.D., Ph.D.
Phone: 305-274-1299
E-mail: stseng@ocularsurface.com
Website: www.osref.org

Surgical instruction available through the Ocular Surface Research & Education Foundation:
Website: www.osref.org
E-mail: osref_info@osref.org

For More Information

BIO-TISSUE

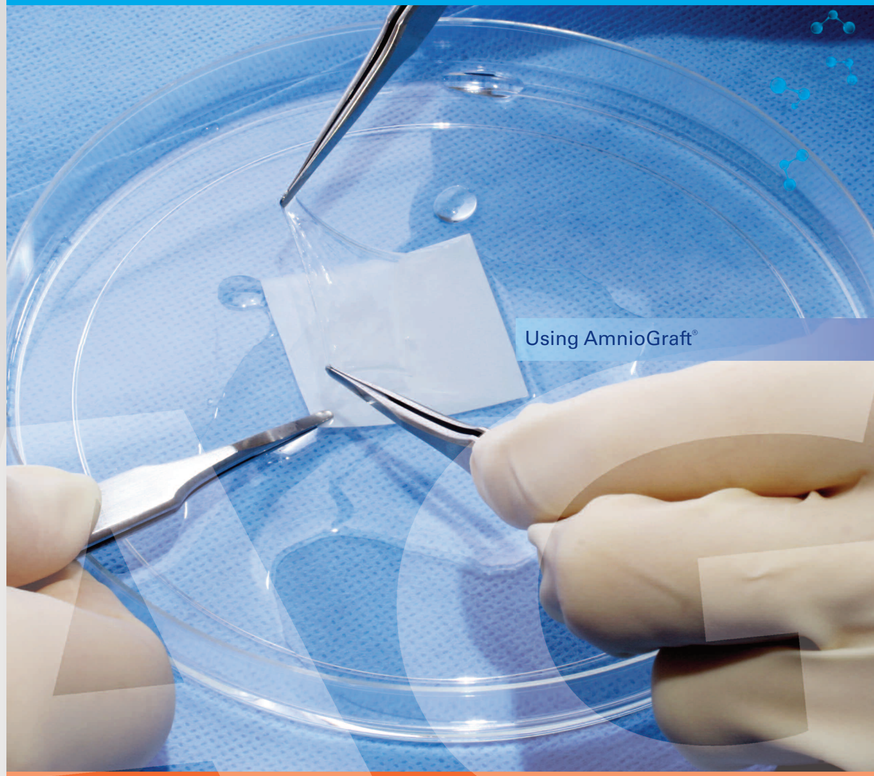
7000 SW 97th Avenue, Suite 211
Miami, FL 33173
Phone: 305-412-4430
Fax: 305-412-4429
E-mail: info@biotissue.com
Website: www.biotissue.com

AmnioGraft®: US Patent # 6,152,142 and 6,326,019

www.biotissue.com

REV A 05/10

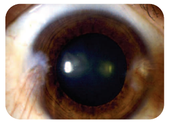
Ensuring Superior Surgical Outcomes Through Technological Innovation



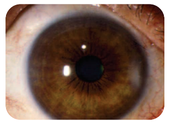
The ***Only*** Amniotic Membrane Graft for Ocular Surface Wound **Repair** & **Healing**

AMNIOGRAFT® *brought to you by* BIO-TISSUE

AMNIOGRAFT®



Pterygium ***before*** AMNIOGRAFT® treatment.



Pterygium ***after*** AMNIOGRAFT® treatment.

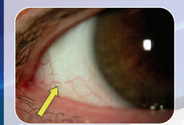
Enhanced Ocular Wound Therapy

AMNIOGRAFT® is a cryopreserved amniotic membrane that acts as a tissue replacement and therapeutic treatment for a wide range of ophthalmic indications. Because the membrane is minimally manipulated, AMNIOGRAFT® retains natural cytokines and growth factors in its matrix which suppress inflammation, reduce pain and promote ocular surface healing. AMNIOGRAFT® is used in a surgical setting and is attached to the ocular surface with sutures or glue.

AMNIOGRAFT® as a superior alternative

Bio-Tissue offers the only commercially available amniotic membrane that preserves the native integrity, activity, and function exhibited by the tissue in utero for ocular surface wound repair and wound healing. Our proprietary processing and preservation method retains vital cytokines and growth factors which facilitate healing mechanisms.

CCh ***before*** AMNIOGRAFT® treatment.



CCh ***after*** AMNIOGRAFT® treatment.

www.biotissue.com

Natural Healing Properties:

Bio-Tissue's proprietary processing and preservation method retains vital cytokines and growth factors for:

Biologic Actions

- Anti-Scarring
- Anti-Inflammation
- Anti-Angiogenesis
- Pain Reduction
- Promotion of Epithelial Healing

- DURABLE
- EASY TO HANDLE
- EASY TO SUTURE

Bio-Tissue's products work synergistically with the patient's own system to enhance and speed tissue repair, resulting in a calm, white eye with minimal discomfort. Since 1997, ophthalmologists worldwide have used Bio-Tissue's products to treat a wide array of ocular surface diseases, endorsing their capabilities in ocular surface wound healing and repair.

Easy to determine AMNIOGRAFT® orientation: Stromal side is "sticky," Epithelial side is not.

"Sticky," Stromal side (manufactured adhered to the nitrocellulose paper)

"Non-Sticky" Epithelial side

AMNIOGRAFT® sizes:

Catalog #	Size
AG-1510	1.5 x 1.0 cm
AG-2015	2.0 x 1.5 cm
AG-2520	2.5 x 2.0 cm
AG-3535	3.5 x 3.5 cm

Surgical Indications for AMNIOGRAFT®

Corneal Indications:

- Persistent Epithelial Defects and Ulcers
- Corneal Erosion and Descemetocele
- Acute Stevens-Johnson Syndrome
- Chemical and Thermal Burns
- Bullous/Band Keratopathy
- Infectious Keratitis and Scleritis

Conjunctival Indications:

- Pterygium & Pinguecula
- Conjunctivochalasis
- Symblepharon
- Fornix Reconstruction

Storage Instructions:

EASY TO STORE!

Storage Time	Storage Device	Ideal Temperature Range
Until expiration date on packaging	-80°C Freezer	-85°C to -50°C (-121°F to -58°F)
1 year after receipt or until expiration date on outer product package, whichever comes first	Standard home freezer *(freezer compartment)*	-49°C to 0°C (-56°F to 32°F)
3 months after receipt or until expiration date on outer product package, whichever comes first	Standard home refrigerator *(refrigerator compartment)*	1°C to 10°C (33.8°F to 50°F)
Until expiration date written on outer shipping container	Unopened insulated container	2°C to 20°C (35.6°F to 38°F)

References:

Bhat, P, Foster, CS. Amniotic Membrane Grafting. Contemporary Ophthalmology. January 15, 2008;7(1):1-8.

Sangwan, VS, Burman, S, Tejwani, S, Mahesh, S, Murthy, Ramesh. Amniotic membrane transplantation: A review of current indications in the management of ophthalmic disorders. Indian J Ophthalmology. 2007;55:251-60.

Kenyon, K. Amniotic Membrane Mother's Own Remedy for Ocular Surface Disease. Cornea. August 2005;24(6):639-642.

Bouchard C, John T. Amniotic membrane transplantation in the treatment of ocular surfaces diseases, The Ocular Surface. 2004; 2:201-211.

Tseng S, Espana E, Kawakita T, Di Pascuale M, Li W, He H, Liu T-S, Cho T-H, Gao Y-Y, Yeh L-K, Liu C-Y. How Does Amniotic Membrane Work? The Ocular Surface 2004; 2(3):177-187.

Solomon A, Meller D, Prabhasawat P, John T, Espana EM, Steuhl K-P, Tseng SCG. Amniotic membrane grafts for non-traumatic corneal perforations, descemetoceles and deep ulcers. Ophthalmology. 2002;109:694-703.

Solomon A, Pires RTF, Tseng SCG. Amniotic membrane transplantation after extensive removal of primary and recurrent pterygia. Ophthalmology. 2001;108:449-460.