

Generation²



IOP

Ambio dry²™

Processed Human Amniotic Membrane Allografts

 IOP Inc.

Processed Human Amniotic Membrane Historical Background and Surgical Use

Historical Background

The successful surgical use of dehydrated, substrate-free human amniotic membrane – for the surgical treatment of the ocular surface – was first reported by both Lavery and Sorsby in 1946.

In 1980s, Dr. Juan F. Batlle re-pioneered the surgical use of preserved amniotic membrane for the treatment of pterygium and other ocular conditions. Dr. Batlle's research noted the importance of utilizing preserved amniotic membrane containing devitalized, intact cellular components.

In 2002, the AmbioDry™ Amniotic Membrane technology was introduced to the ophthalmic surgical community. This "generation 1" AmbioDry technology featured a dehydrated, decellularized configuration for the surgical management of ocular wounds.

Today, with continued direction and input from industry leaders like Dr. Juan Batlle, a second generation AmbioDry technology is available: AmbioDry².

Surgical Application

AmbioDry² may be used for the surgical management of:

- Pterygium
- Persistent Epithelial Defects
- Dermoids
- Fornix Reconstruction/Symblepharon
- Corneal Ulcerations/Perforations
- Bullous Keratopathy



"The surgical use of preserved amniotic membrane transplantation (AMT) has been reported for decades as a viable and advantageous substitute for conjunctival autografts. Significantly less surgical time is required and host conjunctiva is preserved."



Juan F. Batlle, M.D.
Pioneer, AMT
President & Founder,
Centro Microcirugia Ocular
Laser (Santo Domingo, DR)

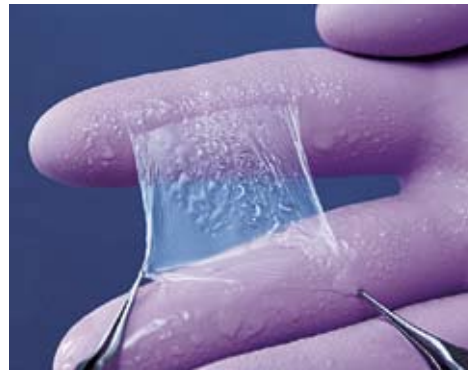
AmbioDry²

Advancements, Advantages and Benefits Continued Innovation for Optimal Surgical Utility

Optimized Storage & Surgical Utility

AmbioDry²™ is a processed, dehydrated, substrate-free amniotic membrane tissue graft. Each unit is sterilized and packaged with proprietary, device-like methods, designed to optimize storage and utility. AmbioDry² can be stored on the shelf. No freezing or refrigeration is required.

This unique membrane can be trimmed in its dry state, applied to the surgical site, activated within minutes and then fixated into place.



Improved Visual Orientation Identification

AmbioDry² features a unique, proprietary “watermark” impression on the graft surface—for the simple, error-free identification of the basement membrane and stromal surfaces. The basement membrane can be easily identified by noting the proper vertical orientation of the “IOP” watermark.



IOP “watermark” identifies the basement membrane.

More Biostructurally Intact

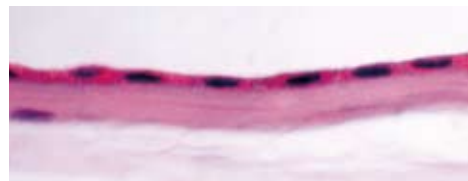
AmbioDry² tissue technology combines minimally-manipulative tissue processing methods with validated sterilization processes to produce a unique, high-quality amniotic membrane technology.

The generation 1 AmbioDry tissue process produced a decellularized collagen membrane, void of epithelial cells and fibroblasts.



Generation 1 AmbioDry: Photomicrograph notes (1) the absence of epithelial cells on the surface of the membrane with (2) an intact basement membrane.

The new generation AmbioDry² provides a more intact, native amniotic membrane graft. While the unique tissue process destroys potential bioburden and virulence, the membrane’s devitalized cellular components – along with its dense connective matrix - are preserved.



Generation 2 AmbioDry²: Photomicrograph shows (1) an intact epithelial cell structure on the membrane’s surface; (2) an intact dense basement membrane and (3) the presence of a loose collagen layer with fibroblasts. Nominal thickness: 35 microns.



Human Amniotic Membrane Allografts

Procured, processed and configured with our focus on the surgeon and the patient.

Tissue Safety *Donor Selection, Screening & Testing*

All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. AmbioDry2 allografts are procured and processed according to standards established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). All tissues are recovered under full informed consent of the donors (represented by the mothers of the newborn children). The donors have consented to transfer of the allografts to third parties. A thorough medical and social history of the donor is also obtained, including detailed family history. The donor is screened for:

Blood Type & Rh Factor	HTLV-1 Antibody	Hepatitis Core Antibody
HIV-1 Antibody	HTLV-2 Antibody	Hepatitis Surface Antigen
HIV-2 Antibody	Syphilis Screening	Hepatitis C Antibody
HIV-NAT	CMV	

All tests results are reviewed prior to the release of the tissue. Only tissue from donors that have a normal CBC, test negative for serology and test negative or non-reactive for infectious diseases and contamination are released.



Reimbursement Information

HCPCS Code: V2790

Amniotic Membrane For Surgical Reconstruction, per procedure.

CPT Code 65780

Amniotic Membrane Transplantation, Ocular Surface Reconstruction

Ordering Information

AmbioDry2 Configurations

Item #	AD- 5120	AD-5230	AD-5440	AD-5150
Size	1 x 2 cm	2 x 3 cm	4 x 4 cm	15 mm disk
Storage	Room Temp: 5° to 32° C (41° to 90° F)			
Nominal Thickness	35 microns			



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