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AmnioFix™ EpiFix™

April 2011

Overview

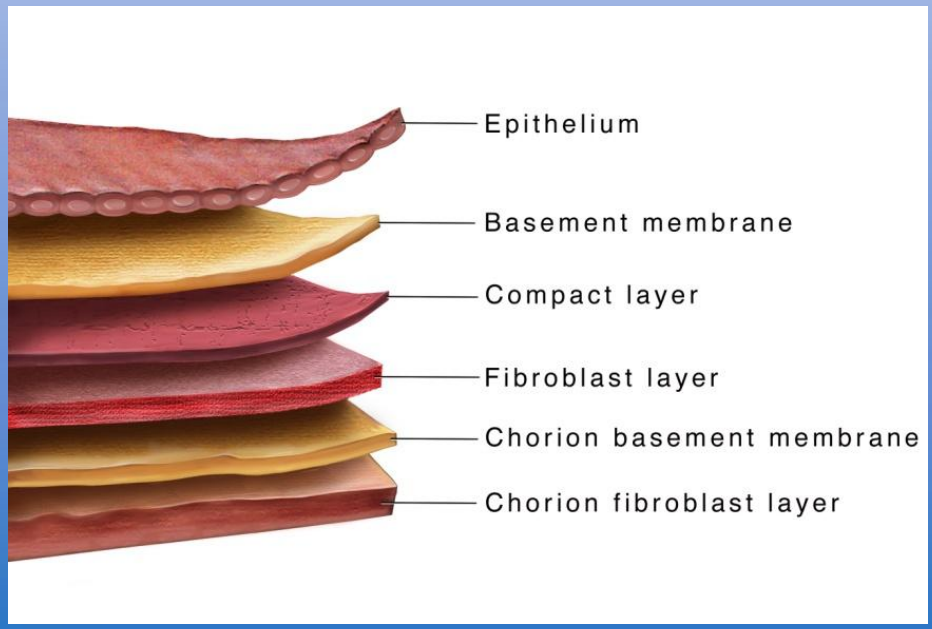
- Amniotic Membrane Allografts are composed of human amniotic membrane which comprises the innermost layer of the placenta and lines the amniotic cavity
- Amniotic Membrane Allografts serve as a biologically active implant or graft for tissue regeneration application

The Tissue Donation Process

- Prospective donors are referred from OB/GYN physicians.
- Only scheduled cesarean section births are used for transplant.
- Surgical Biologics attends each donation.

Anatomy and Physiology

- The amniotic membrane is a non-vascular tissue comprising the innermost layer of the placenta, and consists of a single layer which is attached to a basement membrane.
- Histological evaluation shows the membrane layers consist of epithelium cells, thin reticular fibers (basement membrane), a thick compact layer and fibroblast layer.
- The fibrous layer of amnion contains cell anchoring collagen types: IV, V and VII.



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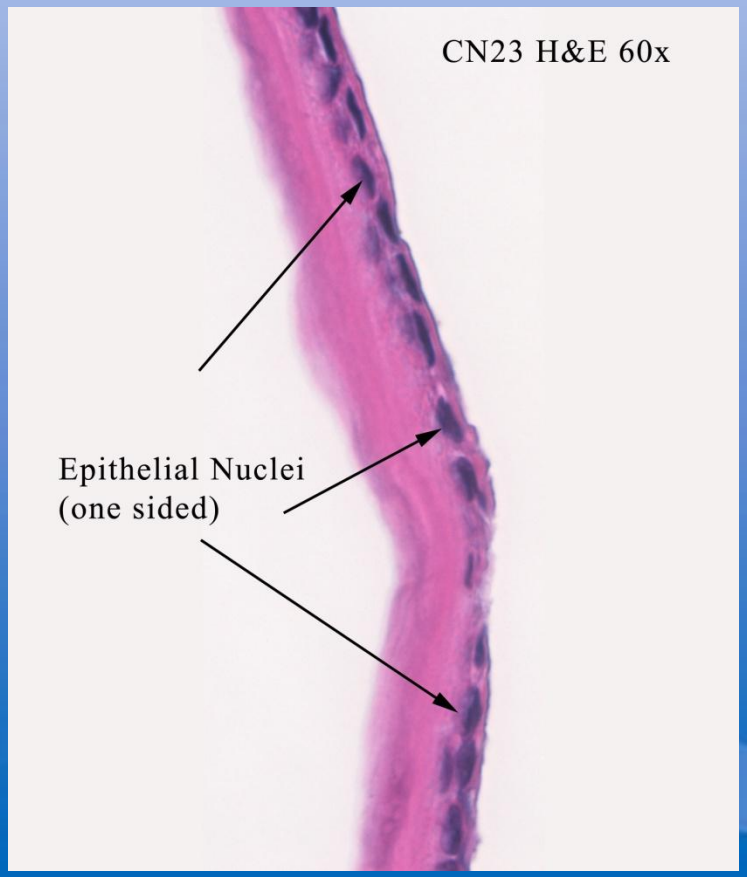
Innovations in Biomaterials

AmnioFix EpiFix

H&E Stain of Amnion (Post Process)



Why the Purion® Process?

The Purion Process

- provides increased surgical confidence.
- yields a reliable graft which ensures patient safety.
- has been validated for effective bioburden reduction.

The Purion Process

- has been specifically developed for the unique characteristics of amniotic membrane.
- minimal graft manipulation maintains structural integrity.

Purion Processed Products Are Easy…

- to store
- to ship
- for the clinician to handle
- to orient prior to placement at the surgical site

Clinical Application

- Human amniotic membrane allograft has been used for various types of reconstructive surgical procedures since the early 1900's.
- Widespread usage in ophthalmic procedures in the U.S. with over 30,000 implants.
- The membrane serves as a substrate material, more commonly referred to as a biological implant or patch graft and is biologically active.
- Unique grafting characteristics:
  - Provides a matrix for cellular migration/proliferation
  - Natural biological barrier
  - Non-immunogenic
  - Promotes increased healing
  - Stores at room temperature

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EpiFix Wound Care Application

On-going clinical Evaluation

- 70 year old female non-insulin dependent with ulceration of left heel. Ulcer present for 7-8 months secondary to callus formation.
- Grade II full thickness ulceration
- Pre-treatment ulcer size- 1.9 X 1.8 X 0.3 (cm)
- Post-treatment ulcer size- 1.0 X 0.08 X 0.1 (cm)
- Fifty percent wound closure at 4 weeks.
- Only one graft was applied for treatment duration

Pre-operative

4 Week Post-operative

EpiFix Wound Types

- EpiFix is for the management of all types of acute and chronic wounds that are free of necrotic tissue and visible signs of infection.
- Partial- and full-thickness wounds
- Venous, diabetic, pressure, and chronic vascular ulcers
- Trauma wounds (including burns)
- Surgical wounds

Application of EpiFix

- Dressing may be secured using steristrips
- May be used with AG (silver) dressings
- Non-adhering dressing (ie. Mepitel)
- May be used with wound vac.
  - Pressure setting should not exceed 125mmHg
  - Used on intermittent setting

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Application of EpiFix

Size graft using sterile instruments and dry gloves

Trim graft to cover entire wound to wound margins

Graft will self adhere to wound site, reposition if necessary

Apply non-adhering dressing

May use steri-strips if necessary

Apply sterile 4x4s

Bandage and off-load wound site