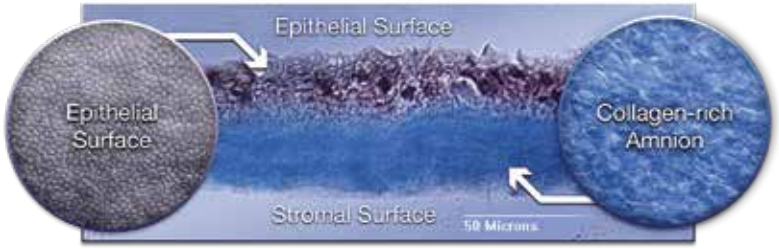
celera™ Patch | Protein Preserved Allograft

More Than Just a Membrane, Amnion May Enhance Healing by Reducing Inflammation & Risk of Infection [2, 4, 5, 6, 11]

DURABLE SOFT TISSUE COVERING

Celera™ Patch is made up of a layer of cuboidal epithelial cells attached to the collagen matrix that makes up the basement membrane and stromal fibroblast layer.

Celera™ Patch– 20x Light Microscopy + Trichrome*



*Data on file

NATURAL BIOLOGICAL SCAFFOLD

Celera Patch is an Extracellular Matrix (ECM) isolated from placental origin, an elegant model for cellular signaling and tissue formation.

VERSATILE SURGICAL APPLICATIONS

Celera Patch is a versatile product with a variety of potential clinical applications when a biological covering or cell scaffold is needed. The use of membrane has demonstrated potential applications in the following areas:

- Adhesion Barrier [9]
- Chronic Wound Allograft [7]
- Reduce Scar Tissue Formation [12]
- Nerve Bundle and Peripherial Wrap [8, 9]
- Periodontal Guided Tissue Regeneration [3]
- Dermal Burns [11]

PRESERVATION AND STERILIZATION

Celera Patch is preserved using a patent-pending technology that utilizes a gentle, non-oxidative dehydration process. This process coupled with our sterilization validation is designed to minimize protein denaturing and to preserve the structural integrity of the extracellular matrix.

COMPREHENSIVE SAFETY & QUALITY ASSURANCE PROGRAM

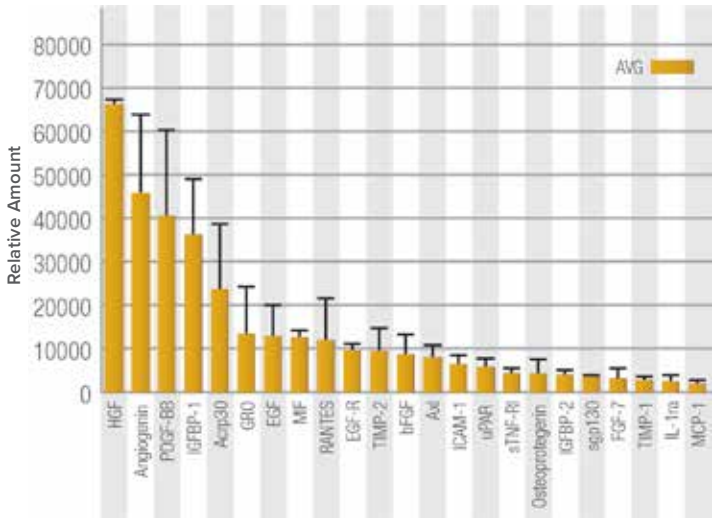
Celera Patch is terminally sterilized using low dose E-beam radiation. Donor tissue is obtained through a full-term birth consent program in partnership with FDA regulated and accredited recovery organizations. Maternal screening includes:

- Hepatitis B core antigen (HBcAg)
- Hepatitis C antibodies (HCV Ab)
- Human Immunodeficiency Virus 1/O/2 antibodies (HIV-1/O/2 Ab)
- Human T-lymphotrophic virus I/II (HTLV-I/II)
  Anti-Hepatitis B core total antibodies (HBc Total)

REGULATORY

- Celera Patch is processed in ISO Certification Class 100 environments.
- All products are tracked in a GxP compliant software using serialized inventory controls.
- Celera Patch is regulated by the FDA under 21 CFR 1271.
- Amniolife is registered with the FDA as a Human Cells Tissues and Cellular and Tissue-based Products establishment.

CELERA™ PATCH CYTOKINE CONTENT*



*ELISA panel data on file at AmnioLife Corporation

PRODUCT SIZES

SINGLE LAYER

- 14mm - AM - 13014
- 16mm - AM - 13016
- 18mm - AM - 13018
- 20mm - AM - 13020
- 2cm x 3cm - AM -13023
- 2cm x 4cm - AM -13024
- 2cm x 6cm - AM -13026
- 3cm x 8cm - AM -13038
- 4cm x 4cm - AM -13044
- 4cm x 6cm - AM -13046
- 7cm x 7cm - AM -13077

DUAL LAYER

- 2cm x 3cm - AM -13223
- 2cm x 4cm - AM -13224
- 2cm x 6cm - AM -13226
- 3cm x 8cm - AM -13238
- 4cm x 4cm - AM -13244
- 4cm x 6cm - AM -13246
- 7cm x 7cm - AM -13277

REFERENCES: [1]Amer et. al. Human Amnion as a Temporary Biologic Barrier after Hysteroscopic Lysis of Severe Intrauterine Adhesions: Pilot Study. J Minim Invasive Gynecol. (2010) 17(5):605-11. [2]Buhimschi I et. al The novel antimicrobial peptide β3- defensin is produced by the amnion: a possible role of the fetal membranes in innate immunity of the amniotic cavity. Am J Obstet Gynecol (2004) 191:1678– 1687. [3]Gurinsky, B. A novel dehydrated amnion allograft for use in the treatment of gingival recession: An observational case series. J Implant Advan Clin Dentistry. (2009) Vol 1, No. 1. [4]Hao Y et. al. Identification of antiangiogenic and antiinflammatory proteins in human AM. Cornea (2000) 19:348–352. [5]Kim J et. al. Amniotic membrane patching promotes healing and inhibits proteinase activity on wound healing following acute corneal alkali burn. Exp Eye Res (2000) 70:329–337 [6]Li H et. al. Immunosuppressive factors secreted by human amniotic epithelial cells. Invest Ophthalmol Vis Sci (2005) 46:900–907. [7]Mermet I et. al. Use of amniotic membrane transplantation in the treatment of venous leg ulcers. Wound Repair Regen. (2007) 15:459–464. [8]Mligiliche N et. al Extra-cellular matrix of human amnion manufactured into tubes as conduits for peripheral nerve regeneration. J Biomed Mater Res (2002) 63:591–600. [9]Mohammad J et. al. Modulation of peripheral nerve regeneration: a tissue-engineering approach. The role of amnion tube nerve conduit across a 1-centimeter nerve gap. Plast Reconstr Surg. (2000)105:660–666. [10]Sawhney C.P. Amniotic membrane as a biological dressing in the management of burns. Burns. (1989) 15, (5), 339-342. [11]Stock et. al. Natural antimicrobial production by the amnion. Am J Obstet Gynecol (2007);196:255.e1-255.e6. [12]Subach BR and Copay AG. The use of dehydrated amnion/chorion membrane allograft in patients who subsequently undergo reexploration after posterior lumbar instrumentation. Adv Orthop. (2015) 2015:501202.