celera™ Fluid

Protein Preserved Allograft

Introducing an Alternative in Injury and Wound Management

INJECTABLE LIQUID ALLOGRAFT

Celera™ Fluid is a non-structural decellularized fluid allograft intended for homologous use such as providing a cushion around a tissue. A 100 year[3] historical use of these products in clinical applications has proven their safety and efficacy[1,8,9]. Celera Fluid contains high levels of growth factors and anti-inflammatory cytokines (see reverse Celera Fluid Growth Factor and Binding Protein Analysis, data on file).

POTENTIAL CLINICAL APPLICATIONS

Celera Fluid is a unique alternative to invasive surgical procedures with a variety of potential applications that may include:

- Tendonitis[6]
- Reduction of scarring[7]
- Chronic wound covering[2]
- Soft tissue or bone trauma[4,5]
- Localized inflammation[4]

PRODUCT SIZES

- 0.5 ml - AF -13205
- 1.0 ml - AF -13210
- 2.0 ml - AF -13220

MAR-CRF-002

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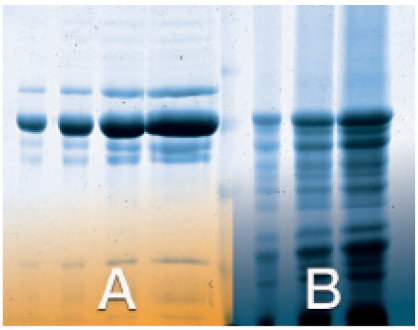
PROTEIN PRESERVATION & CHARACTERIZATION

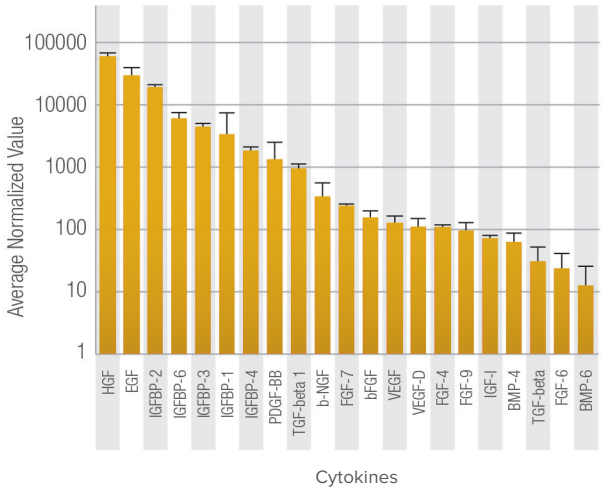
Celera Fluid is processed using an extensively tested proprietary amniotic fluid purification technology which allows for rapid retrieval of fluid without compromising protein integrity (Figure 1). Cells and extracellular debris are removed, yet an array of soluble cytokines and growth factors are still present in Celera Fluid (Figure 2).

Figure 1. Celera™ Fluid – SDS-PAGE*
*Data on file



The distinct banding pattern is indicative of intact native proteins (A) compared to degraded control (B).

Figure 2. Celera™ Fluid Growth Factor and Binding Protein Analysis



COMPREHENSIVE SAFETY & QUALITY ASSURANCE PROGRAM

Donor tissue is obtained through a full-term birth consent program at IRB-approved hospital collection sites. Sterility testing is performed on every lot with the standards specified in USP <71>. In addition, Endotoxin testing consistent with USP <85> is utilized as a part of the release criteria for each lot. Maternal screening for infectious disease testing includes:

- Hepatitis B core antigen (HBcAg)
- Hepatitis C antibodies (HCVAb)
- Human Immunodeficiency Virus 1/O/2 antibodies (HIV-1/O/2 Ab)
- Human T-lymphotrophic virus I/II (HTLVI/II)
- Anti-Hepatitis B core total antibodies (HBcTotal)

REGULATORY

- Celera Fluid is processed in ISO Certified, Class 100 manufacturing environments.
- All products are tracked in a GxP compliant tracking software using serialized inventory controls.
- Celera Fluid is processed and promoted under the guidance of 21 CFR 1271. Registered with the US FDA as a HCT/P establishment.

REFERENCES: [1]Amer M, Abd-El-Maeboud K (2006) Amnion graft following hysteroscopic lysis of intrauterine adhesions. J Obstet Gynaecol Res 32:559-66. [2]Bazrafshan A, Owji M, Yazdani M, Varedi M (2014) Activation of mitosis and angiogenesis in diabetes-impaired wound healing by processed human amniotic fluid. J Surg Res 188(2)545-52. [3]Davis J (1910) Skin transplantation with a review of 550 cases at the Johns Hopkins Hospital. Johns Hopkins Med J 15:307. [4]Hizli D1, Yilmaz S, Kosus N, Kosus A, Haltas H, Hizli F, Kafali H (2013) Antiadhesive role of human amniotic fluid on peritoneal adhesion formation in a rat model. Experimental study. J Reprod Med 58(3-4):161-6. [5]Kerimoglu S, Livaoglu M, Sonmez B, Yulug E, Aynaci O, Topbas M, Yarar S (2009) Effects of human amniotic fluid on fracture healing in rat tibia. J Surg Res 152(2):281-7. [5]Ozgenel GY, Filiz G (2001) Effects of human amniotic fluid on peritendinous adhesion formation and tendon healing after flexor tendon surgery in rabbits. J Hand Surg Am 26:332. [7]Ozgenel GY, Filiz G (2003) Effects of human amniotic fluid on peripheral nerve scarring and regeneration in rats. J Neuro Surg 98:371. [8]Sabella N (1913) Use of the fetal membranes in skin grafting. Med Rec 83:478-480. [9]Stern M (1913) The grafting of preserved amniotic membranes to burned and ulcerated surfaces, substituting skin grafts. JAMA 60:973.

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