INJECTABLE LIQUID ALLOGRAFT

Celera™ Fluid is a non-structural decellularized fluid allograft intended for homologous use such as providing a cushion around a tissue. 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:

- Tendonitis¹
- Chronic wound covering²
- Reduction of scarring³
- Soft tissue or bone trauma⁴,⁵
- Localized inflammation⁴

PRODUCT SIZES

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

REFERENCES:

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 (HTLV-I/II)
- Anti-Hepatitis B core total antibodies (HBCTotal)

REGULATORY

- Celera Fluid is processed in ISO Certified, Class100 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.

ORDERING INFORMATION:

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