



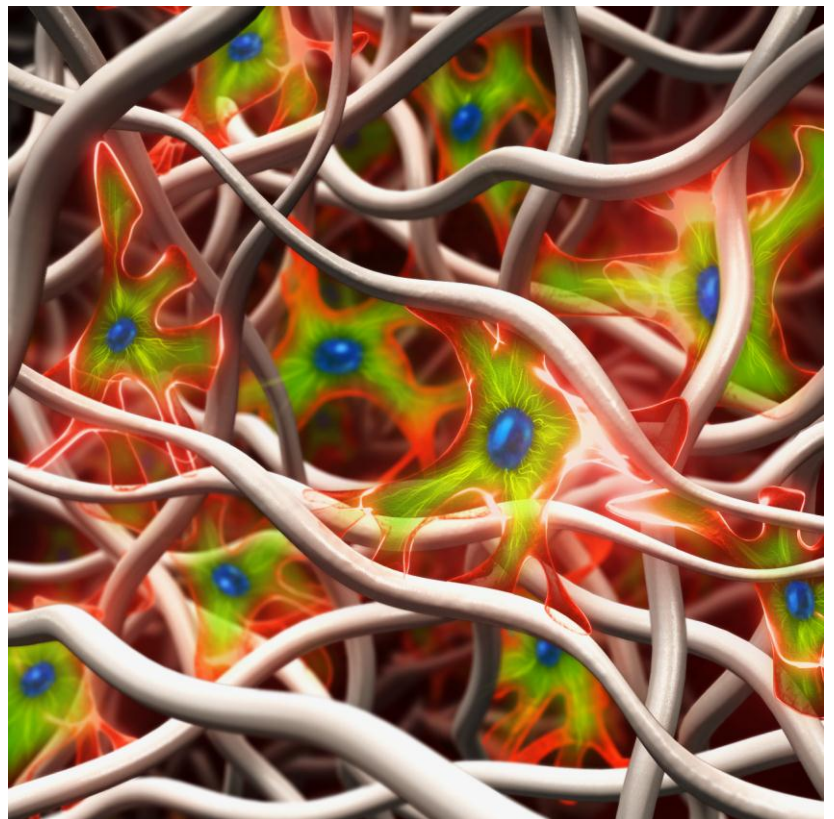
NuCel[®]

BIOACTIVE AMNIOTIC SUSPENSION (HCT/P)

NuCel is an allograft derived from human amnion and amniotic fluid.

These human amniotic tissues provide an enhanced environment for tissue growth, repair and healing. Due to their natural benefits, these tissues have been used in specialized surgical applications for many years. NuCel provides a new and more flexible formulation designed to bring these benefits to bear for surgical patients generally. NuCel's formulation is based on a proprietary process designed to protect the natural biologic characteristics of these tissues.

There are many applications in which the unique properties of human amniotic tissues may be beneficial to patients.



Properties of Amniotic Tissues and Fluids

The properties and surgical benefits of amniotic tissues and fluids have been well-studied. These tissues are known to contain:

- Collagen types III, IV, V and proteoglycans
- Hyaluronic acid
- Trophic proteins including BMP's
- Growth factors
- Multipotential stem cells.

The tissues have been shown to stimulate tissue repair and healing as well as offering anti-scarring and anti-inflammatory properties. Unlike cadaveric tissues, these tissues are obtained from younger living donors, so donor age and tissue viability are not a factor.

Time of Harvest



DONOR TESTING

- Antibodies to the human immunodeficiency virus type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- HIV-1/ Hepatitis C by Transcription Mediated Amplification
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B total core antibody
- Antibodies to the hepatitis C virus (anti-HCV)
- Antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II)
- Syphilis using FDA-licensed tests. If the blood sample to be used for Syphilis screening is determined and documented to be unacceptable for the screening assay (e.g. hemolysis, sample testing time restriction), then an FDA-licensed treponemal-specific confirmatory assay may be performed instead (e.g. FTA-Abs).

DONOR SCREENING

- Physical Exam
- Medical record evaluation
- Licensed physician review of donor record
- Medical director review and release of every donor
- Medical and social history evaluation with live donor



Processing

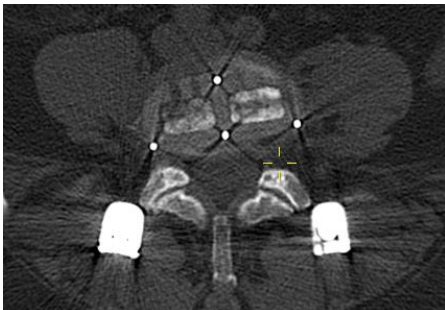
SAFETY PROFILE

- Aseptic tissue processing
- Multiple cultures performed at harvest and after final processing
- Recovery and Processing carried out by AATB accredited facilities using rigorous quality standards
- CGTP and ISO compliant



TISSUE PREPARATION

- Careful processing is used to protect the properties of amniotic tissues.
- Tissues are cryopreserved to maintain bioactivity.



6 Months Post-Operative CT Scan