



Product Definition:

NuCel is human amniotic tissue. Amniotic tissues are immune privileged which means it can be used in any body, because it does not express MHC Class II antigens. Surgeons use amniotic materials to reduce inflammation and prevent scarring.

NuCel is morselized amnion and cells derived from amniotic fluid. It is composed of five types of collagen and fibronectin. The five types of collagen are;

- Epithelium layer
- Basement membrane – Collagen types III, IV, V, Laminin, Fibronectin, Nidogen
- Compact layer – Collagen types I, III, V, VI, Fibronectin
- Fibroblast layer – Collagen types I, III, IV, Nidogen, Laminin, Fibronectin
- Intermediate (Spongy) layer – Collagen types I, III, IV, Proteoglycans

It lacks Class II Antigens. Extensive donor testing is performed to ensure quality product.

NuCel comes frozen in a vial with a locked cap. It is intended for use as an in vivo wound covering. If the vial is open – DO NOT USE.

NuCel is intended for single patient, one time use only. Once opened, allograft must be used immediately or discarded.

Clinical History of Amniotic Tissues/Fluid:

Amniotic tissues have a long informal therapeutic history. Please see the following references for more information.

Burgos H. Angiogenic and growth actors in human amnio-chorion and placenta. Eur J Clin invest 1983 Aug;13 (4):289-96

Underwood MA, Gilbert WM, Sherman MP. Amniotic fluid: Not just fetal urine anymore Perinatol 2005 May;25(5):341-8

Delo DM, De Coppi P, Bartsch G, Jr, Atala A. Amniotic fluid and placental stem cells. Methods Enzymol 2006;419:426-38

Faulk WP, Matthews R, Stevens PJ, Bennett JP, Burgos H, His BL. Human amnion as an adjunct in wound healing. Lancet 1980 May 31;1 (8179): 1156-8

Shimberg M. The use of amniotic fluid concentrate in orthopaedic conditions. J Bone Joint Surg Am 1938;20:167-177

Karacal N. Kosucu P, Cobanglu U, Kutlu N. Effect of human amniotic fluid on bone healing. J Surg Res 2005 Dec;129 (2);283-7

Kermoglu S, Livaoglu M, Sonmez B, Yulug E, Aynaci O, Topbas M, Yazar S. Effects of human amniotic fluid on fracture healing in rat tibia. J Surg Res 2008 Mar. 18

Reference: AFcell Monograph – The Science of Amniotic Tissue for Wound Covering



PREPARATION INSTRUCTIONS

1. Maintain the product at -80°C or colder until immediately prior to use. Add the appropriate amount of normal saline to product that is maintained between 34° and 37°C.
2. Remove product from cold storage and open the carton.
Remove the outer package from the carton. Peel open the pouch and remove the vial from the mounting card.
3. Place the vial in the warm sterile water / saline solution. Do not completely thaw the contents in the vial. Only thaw the vial for 20-30 seconds so that contents in the vial come out as a frozen plug.
4. Using aseptic technique, carefully empty the vial into a sterile basin and add an appropriate amount of saline.
5. Allow the frozen plug to finish the thawing process in the saline until all the material is in a liquid state.
6. The HCT/P is ready to use.

Safety and Testing:

The Medical Director of the registered recovery agency has determined that the donor of the tissue contained in this product is eligible to donate tissue for transplantation based on meeting the following criteria: (1) the results of donor screening indicated that the donor was free from risk factors based on clinical evidence of infection caused by relevant communicable disease agents and diseases and (2) the results of donor testing for the following relevant communicable disease agents are negative or nonreactive:

- 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)

At the time of procurement, cultures of the tissue are taken and grown out for evaluation.

Donor tissue with cultures testing positive for the following microorganisms are excluded:

- Clostridium
- Streptococcus pyogenes (group A)
- Enterococcus
- Fungi (mold or yeast phase)

Additionally, a donor's medical history and behavior risk assessment are obtained prior to donation incorporating U.S. Public Health Service guidelines. Discussions with physicians and/or the donor mother are conducted to identify circumstances that may lead to the exclusion of the donor or donated tissue.

PROCUREMENT

Tissue procurement is performed by BioRecovery LLC, 8570 Cordes Circle #8, Germantown, TN 38139 on the behalf of BioDlogics LLC. BioRecovery is an FDA-registered tissue bank using aseptic techniques. At the time of procurement, medical records are collected and reviewed as part of the donor eligibility determination made by BioRecovery.

PROCESSING

NuCel is processed on the behalf of BioDlogics LLC, Germantown, TN by Wuxi Apptec, Philadelphia, PA. Wuxi Apptec is an FDA registered tissue bank and is accredited by the American Association of Tissue Banks. The HCT/Ps are processed in a controlled environment using methods designed to prevent contamination and cross-contamination of the products. Technical quality assurance standards are rigorously maintained by BioDlogics contract processors.

Contact Information:

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