PREDICTIVE BIOTECH

Revolutionary·Regenerative·Therapeutic

AmnioCyte Plus™

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Amniotic Matrix Allograft

AmnioCyte Plus™ is a minimally manipulated human tissue allograft derived from the extracellular matrix of the amniotic membrane. AmnioCyte Plus™ is processed to preserve cytokines, growth factors and scaffolding proteins in amniotic membrane for homologous use.

Innovative Development

Predictive Biotech's innovative human cell and tissue products are processed in our FDA registered lab. Our minimally manipulated tissue products are prepared utilizing proprietary extraction methods that reduce the loss of important structural proteins, cytokines and growth factors.

Quality Assurance

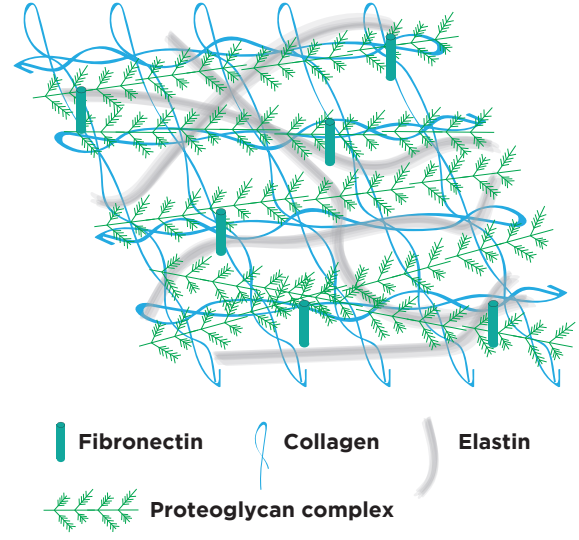
AmnioCyte Plus™ is processed from donated human tissue from full-term deliveries. Comprehensive medical and social histories of the donors are obtained and tissues are procured, processed, and tested in accordance with standards established by FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a certified laboratory in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493.

FDA regulatory compliance

AmnioCyte Plus™ is regulated as a human cell and tissue product (HCT/P) under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. AmnioCyte Plus™ is intended for homologous use.

Key Characteristics of Amniotic Extracellular Matrix

The extracellular matrix of the amniotic membrane contains a high concentration of cellular scaffolding, cytokines, growth factors and proteins.



Composition

The extracellular matrix (ECM) is a collection of extracellular molecules that provide the structural support needed for surrounding cells. The amniotic ECM is comprised of collagens, multi-adhesive glycoproteins, elastin, glycosaminaglycans, growth factors and cytokines.

Key Cytokines Present in Amniotic Extracellular Matrix

General Cytokines	pg/ml
Fetuin-A	68,931
Interleukin 37	1,824
Macrophage Colony	2,771
Serpin A4	5,533
Syndecan - 4	626
Growth Factor Cytokines	
Bone Morphogenic Protein - 7	178
Complement Component 5a	695
Fibroblast Growth Factor	814
Platelet Derived Growth Factor	39
Thrombospondin - 2	1,739
Scaffolding Cytokines	
Adhesion G Protein	7,205
Collagen 1,2,3	34.7 ug/ml
Elastin	359.2 ug/ml
Fibronectin	500 ng/ml
Hyaluronic Acid	5 mg/ml
Homeostatic Cytokines	
Cystatin - B	1,724
Galectin - 9	1,633
Granulysin	2,669
Lipocalin - 2	637
Syndecan - 4	626

AMNIOTIC MATRIX ALLOGRAFT INFORMATION & PREPARATION INSTRUCTIONS

DESCRIPTION
AmnioCyte Plus™ is a minimally manipulated human tissue allograft derived from the extracellular matrix of the amniotic membrane. AmnioCyte Plus™ is processed to preserve cytokines, growth factors and scaffolding proteins in amniotic membrane for homologous use.

REGULATORY STATUS
AmnioCyte Plus™ is regulated by the FDA as a human tissue-based product under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. This product is distributed ONLY to licensed health care practitioners.

QUALITY ASSURANCE
AmnioCyte Plus™ is processed from the amniotic membranes that were collected from donors with normal, full-term pregnancies. Each donor is carefully screened. Comprehensive medical and social histories of the donors are obtained and tissues are procured, processed, and tested in accordance with FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a certified laboratory in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493. Current testing cannot provide absolute assurance that the tissue will not transmit infectious disease to the recipient. Each donor is tested for HBsAg (Hepatitis B Surface Antigen), HBcAb (hepatitis B core antibody), HCV (hepatitis C antibody), HIV I/II-Ab (Antibody to Human Immunodeficiency Virus Types 1 and Syphilis detection test, HIV NAT (HIV Nucleic Acid Test), and HCV NAT (HCV Nucleic Acid Test). AmnioCyte Plus™ is tested post-processing to demonstrate the absence of bacterial and fungal pathogens. AmnioCyte Plus™ is non-pyrogenic. All testing results are reviewed by the Medical Director of Predictive Biotech (2735 E. Parleys Way, Suite 205, Salt Lake City, UT 84109).

GUIDANCE
This human cell and tissue product is not recommended for people who have a known sensitivity to AmnioCyte Plus™ and is not recommended for intravenous use.

WARNINGS
AmnioCyte Plus™ may contain a small fraction of red blood cells. Most patients who receive an infusion or injection with red blood cells experience no complications. However, if the patient should experience symptoms that include nausea, fever, chills, dark urine, chest and lower back pain consult their physician. No adverse clinical reactions to this tissue product have been reported. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to Predictive Biotech. If a disease transmission complication from AmnioCyte Plus™ use is confirmed to be fatal, report immediately to the state health department and Predictive Biotech. If a patient has an adverse reaction related to the use of AmnioCyte Plus™, immediately discontinue its use.

PRECAUTIONS
- Do not use if package seal is broken. Discard material if mishandling has caused possible damage or contamination. Do not resterilize.
- Do no place product onto sterile field, only the interior of the vial is sterile.
- AmnioCyte Plus™ must be used prior to the expiration date on the product label.

HOW SUPPLIED
This package contains a human tissue allograft. In addition to this product insert, the following items should be included in the product package:

- Vial(s) of Allograft Material
- Tissue Utilization Record
- Thaw Instruction Card
- Packing List
- Product Label(s)
- Instruction for use

STORAGE
AmnioCyte Plus™ is supplied/shipped frozen (-80°C, on dry ice) until package is opened. AmnioCyte Plus™ must be stored frozen at -80°C or colder, until used or expiration date is reached. AmnioCyte Plus™ may be stored up to expiration date as long as the package has not been breached, and temperature maintained. If you find package has been breached in any way or that temperature has not been maintained at -80°C dispose of appropriately DO NOT USE. The tissue product is for a single patient, one time use only. Once opened, the tissue must be used immediately or disposed of appropriately. Please refer to product ID label for expiration information. Proper storage is the responsibility of the end user.

Instructions continued on back page

AMNIOTIC MATRIX ALLOGRAFT INFORMATION & PREPARATION INSTRUCTIONS

HCT/P PROCESSING
AmnioCyte Plus™ is processed in a controlled, aseptic environment using methods designed to prevent contamination of the tissues. Final products are sized and packaged according to approved specifications and procedures.

RECIPIENT TRACKING
The FDA requires a system of record keeping that enables the tracking of human tissue-based products from donor to consignee and vice versa. It is the responsibility of the practitioner to maintain sufficient records to permit prompt identification of the recipient. Product use must be documented by filling out and returning the enclosed Tissue Utilization Record for each product used. Affix the pre-printed label to the Tissue Utilization Record and fill out all applicable sections and return to Predictive Biotech, 2735 E. Parleys Way, Suite 205, Salt Lake City, UT 84109 . If AmnioCyte Plus™ is not used (for any reason) after opening, complete the Tissue Utilization Record and indicate the method of disposal.

RECOMMENDED USAGE
These recommendations are designed to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

INSTRUCTIONS FOR USE

1. Open product package & remove the product tube from packaging.

2. Allow product to thaw (room temperature for 5-10 minutes or hold in hand for 2-5 minutes, until ice completely melts) and invert tube several times to mix completely. After the contents have been thawed, place the vial in an upright position and gently tap it on a hard surface to transfer all the contents of the vial to the bottom.

3. To inject allograft, remove cap by unscrewing the lid counter-clockwise. Secure a 21-23G needle to syringe. Aspirate allograft into syringe

For product information or to report an adverse event, telephone 1-888-407-9761.
The Health Care Practitioner receiving this human tissue shall have sole discretion and responsibility to determine in accordance with applicable law and professional standards if the allograft is usable and suitable for any and all uses to which the Health Care Practitioner shall apply the allograft, and upon delivery of the human tissue by Predictive Biotech to the Health Care Practitioner and thereafter the Health Care Practitioner accepts and shall have full responsibility and liability with respect to such allograft. ALL HUMAN TISSUE FURNISHED BY PREDICTIVE BIOTECH, INC. TO THE HEALTH CARE PRACTITIONER IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OF THIRD PARTY PROPRIETARY RIGHTS UNLESS DISCLAIMING SUCH WARRANTIES IS PROHIBITED BY LAW.

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