



PolyCyte™

Structural Wharton's Jelly Allograft

PolyCyte™ is a minimally manipulated human tissue allograft derived from the Wharton's Jelly of the umbilical cord. PolyCyte™ is processed to preserve cytokines, growth factors, proteins and structural integrity of Wharton's jelly 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

PolyCyte™ 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

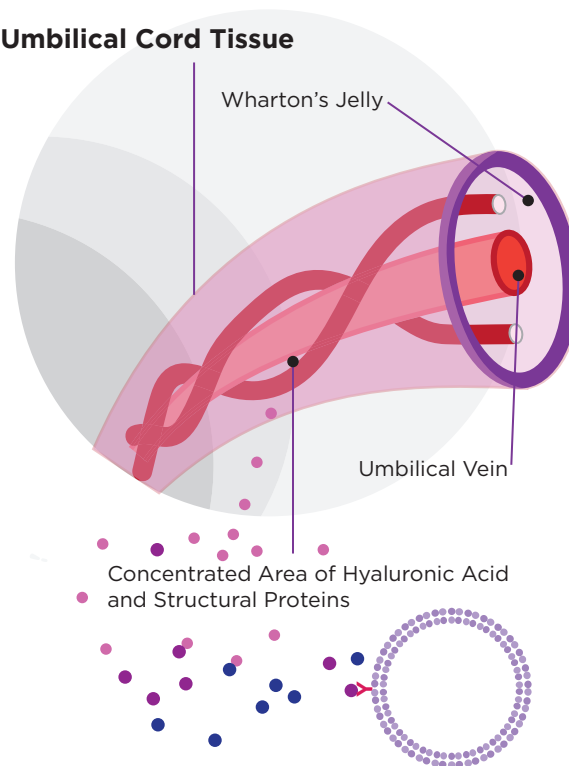
PolyCyte™ is regulated as a human cell and tissue product (HCT/P) under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. PolyCyte™ is intended for homologous use.

Key Characteristics of Structural Wharton's Jelly

The cushioning and structural support elements from the Wharton's Jelly consist of a network of structural proteins, cytokines, chemokines and growth factors.

Hyaluronic acid is the most abundant component of the glycosamnioglycans found in the umbilical cord matrix. Hyaluronic acid is also a key factor in the viscoelastic properties in synovial fluid of joints.

Umbilical Cord Tissue



Key Cytokines Present in Structural Wharton's Jelly

General Cytokines	pg/ml
Fetuin-A	53,052
Interleukin 37	1,361
Macrophage Colony	10,078
Serpin A4	13,310
Syndecan - 4	27

Growth Factor Cytokines

Bone Morphogenic Protein - 7	335
Complement Component 5a	6,091
Fibroblast Growth Factor	455
Platelet Derived Growth Factor	36
Thrombospondin - 2	16,477

Scaffolding Cytokines

Adhesion G Protein	58,961
Collagen 1,2,3	
Elastin	
Fibronectin	
Hyaluronic Acid	42 mg/ml ³

Homeostatic Cytokines

Cystatin - B	5,830
Galectin - 9	8,398
Granulysin	1,385
Lipocalin - 2	1,757
Syndecan - 4	27

STRUCTURAL WHARTON'S JELLY ALLOGRAFT INFORMATION & PREPARATION INSTRUCTIONS**DESCRIPTION**

PolyCyte™ is a minimally manipulated human tissue allograft derived from the Wharton's Jelly of the umbilical cord. PolyCyte™ is processed to preserve cytokines, growth factors, proteins and structural integrity of Wharton's jelly for homologous use.

REGULATORY STATUS

PolyCyte™ 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

PolyCyte™ is processed from umbilical cords 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). PolyCyte™ is tested post-processing to demonstrate the absence of bacterial and fungal pathogens and 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 PolyCyte™ and is not recommended for intravenous use.

WARNINGS

No adverse clinical reactions to this tissue product have been reported. PolyCyte™ may contain a small fraction of red blood cells. Most patients who receive an infusion 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. PolyCyte™ lots are tested to meet or exceed the FDA requirements of 21 CFR 1271 regulations on the homologous use of an HCT/P product. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to Predictive Biotech (1-888-407-9761). If a disease transmission complication from PolyCyte™ 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 PolyCyte™, 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 not place product onto sterile field, only the interior of the vial is sterile.
- PolyCyte™ 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

PolyCyte™ is supplied/shipped frozen (-80°C, on dry ice) until package is opened. PolyCyte™ must be stored frozen at -80°C or colder, until used or expiration date is reached. PolyCyte™ 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.

STRUCTURAL WHARTON'S JELLY ALLOGRAFT INFORMATION & PREPARATION INSTRUCTIONS**HCT/P PROCESSING**

PolyCyte™ 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 PolyCyte™ 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 NON INFRINGEMENT OF THIRD PARTY PROPRIETARY RIGHTS UNLESS DISCLAIMING SUCH WARRANTIES IS PROHIBITED BY LAW.

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