



PolyCyte™ 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, and proteins 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 production methods that reduce the loss of important 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

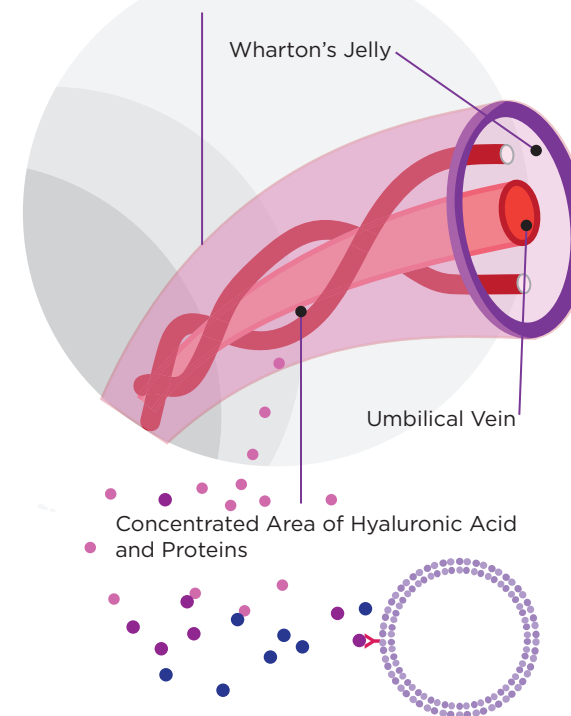
PolyCyte™ is an allograft derived from Wharton's jelly. PolyCyte™ is mechanically processed whereby the Wharton's jelly material is broken up into component parts to isolate the tissue elements (collagen fibers, elastin, hyaluronan, growth factors and cytokines) and does not contain live cells. This product, extracted from Wharton's jelly, is not considered by the FDA as a human cell and tissue product (HCT/P) and is exempt from regulation under 21 CFR 1271 and Section 361 of the PHS Act. PolyCyte™ is manufactured under cGMP regulations per CFR 210 and 211.

Key Characteristics of Wharton's Jelly

The cushioning and support elements from the Wharton's jelly consist of a network of 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 Wharton's Jelly

General Cytokines	pg/ml
Fetuin-A	✓
Interleukin 37	✓✓
Macrophage Colony Stimulating Factor	✓✓✓
Serpin A4	✓✓✓
Syndecan - 4	✓
Growth Factor Cytokines	
Bone Morphogenic Protein - 7	✓✓✓
Complement Component 5a	✓✓✓
Fibroblast Growth Factor	✓
Platelet Derived Growth Factor - AA	✓✓
Thrombospondin - 2	✓✓✓
Scaffolding Cytokines	
Adhesion G Protein	✓✓✓
Collagen 1, 2, 3	
Elastin	
Fibronectin	
Hyaluronic Acid	✓✓✓
Homeostatic Cytokines	
Cystatin - B	✓✓✓
Galectin - 9	✓✓✓
Granulysin	✓✓
Lipocalin - 2	✓✓✓
Intracellular Adhesion Molecule 1	✓