

## **Regenerative medicine**

Today, a cutting-edge technology called regenerative medicine, allows your body to regenerate and rejuvenate from within. It is a simple non-surgical procedure that takes place directly in the office, taking only minutes from start to finish, with little to no downtime. This advancement comes in the form of umbilical cord-derived mesenchymal cells or human biologics. These cells can differentiate into cartilage, bone, muscle, ligament, and organ, as well as a host of growth factors, cytokines, and proteins that eliminate inflammation and provide the tissue with the ideal conditions for regeneration.

If you suffer from joint, arthritis, cartilage degeneration, bone fractures, ligament tears, chronic wounds, chronic inflammation, pain, and other disorders, then human biologics can reduce or eliminate your pain and restore full mobility to your life.

Human biologics have the potential to reduce or eliminate symptoms and drastically improve your quality of life.

## **HOW CAN REGENERATIVE MEDICINE HELP ME?**

In our office, we work with two companies for our human biologics, including Biogenix and Regenerative labs. Here are some of the available products.

ProText™, Biogen10, and Biogen30 are Wharton's jelly structural connective tissue allograft that provides cushioning and structural support to the site of a defect. A defect is defined as missing or damaged tissue in the body. Missing or damaged tissue often compromises the stability and structural integrity of its surrounding area, providing for a wide array of symptoms.

Wharton's jelly is processed to preserve the structural integrity and original characteristics of the connective tissue relating to its utility to supplement missing or damaged tissue in the recipient.

## **REGENERATIVE LABS' AND BIOGENIX'S HIGH-QUALITY PROCESSING**

Regenerative Labs birth tissue allografts are derived from healthy, consenting mothers after full-term, live, planned, Cesarean section (C-section) deliveries. Donors are healthy women thoroughly screened for risk factors and clinical evidence of relevant communicable diseases. A careful medical and social history is collected to ensure the donor meets all eligibility requirements.

Before processing, these non-embryonic tissues undergo extensive medical, social, and blood testing. Only tissue cleared after this stringent screening regimen is processed and re-tested under standards established by the American Association of Tissue Banks (AATB) and FDA requirements. Every precaution is taken to eliminate the potential risk of infectious diseases through comprehensive testing following the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493 and the FDA. Regenerative Labs verifies each step of the

manufacturing process to ensure the most stringent safety standards are met and maintained from start to finish.

### **PROTEXT™/Cryotext/Biogenix10/Biogenix 30**

ProText™, Cryotext, Biogenix 10, and Biogenix30 are Regenerative Labs and Biogenix's labs most concentrated Wharton's jelly connective tissue supplement. Regenerative Labs and Biogenix's Wharton's jelly allografts are regulated under section 361 of the Public Health Service Act (PHS) and 21 CFR Part 1271. ProText, Cryotext, Biogenix10, and Biogenix30 are processed to preserve the structural integrity, and original relevant characteristics of Wharton's Jelly as observed in the donor and are intended for homologous use only. Regenerative Labs' and Biogenix products are ethically derived and do not contain any material obtained from an embryo or fetus. Regenerative Labs and Biogenix labs birth tissue allografts are derived from healthy, consenting mothers after full-term, live, planned, Cesarean section (C-section) deliveries.

### **ADVANTAGES OF WHARTON'S JELLY**

This connective tissue contains high amounts of extracellular matrix components, including collagen types I, III, and V, elastin, and fibronectin that provide a natural scaffold to facilitate cellular adhesion<sup>1, 2</sup>. Wharton's jelly primarily provides cushioning and structural support to the umbilical cord but also contains a natural source of long-chain hyaluronic acid as well as numerous cytokines and growth factors. Studies have described placental tissues as "immune privileged" as they rarely evoke an immune response in the body, reducing the risk of adverse reaction<sup>4</sup>.

### **WHAT IS A STRUCTURAL DEFECT?**

A defect is defined as missing or damaged tissue in the body. Missing or damaged tissue often compromises the stability and structural integrity of its surrounding area, providing for a wide array of symptoms.

### **SUPPLEMENTING A DEFECT**

ProText, Cryotext, Biogenix10 and Biogenix30 is a Wharton's jelly structural connective tissue allograft that provides cushioning and structural support to the site of a defect. Wharton's jelly is processed to preserve the structural integrity and original characteristics of the connective tissue relating to its utility to supplement missing or damaged tissue in the recipient. If you may be dealing with a structural defect, ask your physician if you could benefit from connective tissue supplementation.

### **FAQS**

|  |                                                                              |
|--|------------------------------------------------------------------------------|
|  | <b>WHAT IS PROTEXT? What is Cryotext? What are Biogenix10 and Biogenix30</b> |
|--|------------------------------------------------------------------------------|

ProText and Cryotext are Regenerative Lab's most concentrated Wharton's jelly connective tissue supplements. As is Biogenix10 and Biogenix30 is also Wharton's Jelly connective tissue supplement. These Wharton's jelly allografts are regulated under section 361 of the Public Health Service Act (PHS) and 21 CFR Part 1271. ProText™ and Cryotext are processed to preserve the structural integrity, and original relevant characteristics of Wharton's jelly as observed in the donor and are intended for homologous use only.

ProText, Cryotext, Biogenix10, and Biogenix30 provide cushioning and structural support to the site of a defect. Wharton's jelly is processed to preserve the structural integrity and original characteristics of the connective tissue relating to its utility to supplement missing or damaged tissue in the recipient.

This connective tissue contains high amounts of extracellular matrix components, including collagen types I, III, and V, elastin, and fibronectin that provide a natural scaffold to facilitate cellular adhesion<sup>1, 2</sup>. Wharton's jelly primarily provides cushioning and structural support to the umbilical cord but also contains a natural source of long-chain hyaluronic acid as well as numerous cytokines and growth factors. Studies have described placental tissues as "immune privileged" as they rarely evoke an immune response in the body, reducing the risk of adverse reactions.

|  |                                    |
|--|------------------------------------|
|  | <b>WHAT IS IN WHARTON'S JELLY?</b> |
|--|------------------------------------|

Wharton jelly is the mucoid connective tissue that surrounds the two arteries and one vein of the umbilical cord. Within Wharton jelly, fibroblast-like and mesenchymal-like cells can collectively be called human umbilical cord perivascular cells (HUCPV).(2)

Wharton's jelly, a gelatinous connective tissue contained in the umbilical cord, is abundant in mesenchymal stem cells (MSCs) that express CD105, CD73, CD90, Oct-4, Sox-2, and Nanog, among others, and have the ability to differentiate into osteogenic, adipogenic, chondrogenic, and other lineages. Moreover, Wharton's jelly-derived MSCs (WJ-MSCs) do not express MHC-II and exhibit immunomodulatory properties, which makes them a good alternative for allogeneic and xenogeneic transplantations in cellular therapies. Therefore, the umbilical cord, especially Wharton's jelly, is a promising source of mesenchymal stem cells. (1)

|  |                                                   |
|--|---------------------------------------------------|
|  | <b>WHO IS REGENERATIVE LABS? WHO IS BIOGENIX?</b> |
|--|---------------------------------------------------|

Regenerative Labs and Biogenix labs are first-class, state-of-the-art professional labs. They spared no expense when it came to the technology necessary to produce the quality regenerative

products they expect for their customers. They determine all the protocols, policies, and decisions regarding the lab, and the result is the best and safest human tissue products available.

|  |                                                  |
|--|--------------------------------------------------|
|  | <b>WHERE DOES THE WHARTON'S JELLY COME FROM?</b> |
|--|--------------------------------------------------|

Regenerative Labs and Biogenix Birth Tissue Allografts are derived from living, healthy donors after a full-term pregnancy and a scheduled Caesarean section (C-section). Donors are healthy women who are thoroughly screened for communicable diseases. A careful medical and social history is collected in advance to ensure the mother meets all eligibility requirements.

Allograft products preserve the placenta and fluid, which are typically discarded. Tissues are then tested to ensure viability and safety. Once tested, these tissues are processed using the standards established by the American Association of Tissue Banks (AATB). Their Allografts are sent to a fully accredited, CLIA-certified independent lab for sterility testing prior to release.

Studies have described the placental tissues as “immune privileged” because they rarely evoke an immune response in the human body. This reduces the risk of an adverse immune reaction. Amniotic tissue also has reported anti-inflammatory, antibacterial, and anti-fibrotic properties.

|  |                                                                                                |
|--|------------------------------------------------------------------------------------------------|
|  | <b>WHAT QUALITY CONTROLS ARE IN PLACE FOR REGENERATIVE LABS<br/>TISSUES AND BIOGENIX LABS?</b> |
|--|------------------------------------------------------------------------------------------------|

Donors are thoroughly screened for risk factors and clinical evidence of relevant communicable diseases. A careful medical and social history is collected in advance to ensure the donor meets all eligibility requirements. These tissues undergo extensive and comprehensive medical, social, and blood testing before processing. Only tissue cleared after this stringent screening regimen is processed and retested under standards established by the American Association of Tissue Banks (AATB) and FDA requirements. Every precaution is taken to eliminate the potential risk of infectious diseases through comprehensive testing following the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493 and the FDA. These labs verify each step of the manufacturing process to ensure the most stringent safety standards are met and maintained from start to finish.

|  |                                                                         |
|--|-------------------------------------------------------------------------|
|  | <b>HOW DO I KNOW IF I AM A CANDIDATE FOR<br/>REGENERATIVE MEDICINE?</b> |
|--|-------------------------------------------------------------------------|

If you have pain in a joint and the area is degenerated, you may be a candidate for regenerative medicine. If you have pain in your knee, hip, back, shoulder, or other joints, you may qualify for

regenerative medicine. Other symptoms may include numbness, tingling, pain, and burning in their hands or feet.

|  |                                |
|--|--------------------------------|
|  | <b>WHAT WILL I HAVE TO DO?</b> |
|--|--------------------------------|

The best thing to do is schedule a free consultation and evaluation with our office. Once at the office, you will receive a thorough history, followed by an evaluation performed by our medical team. Further testing, X-rays, or MRIs will be requested if needed. Followed by a follow-up appointment, including recommendations and the best course of action to help with your health concern.

|  |                                                            |
|--|------------------------------------------------------------|
|  | <b>IS THERE ANY DOWNTIME REQUIRED AFTER THE INJECTION?</b> |
|--|------------------------------------------------------------|

These applications are minimally invasive. You do not need to take time off work after getting the injection. There will be no sedation or anesthetic administered during the application. We use a cold spray called ethyl chloride at the point of the injection. You can drive yourself to and from the clinic. The medical staff will provide you with specific post-injection instructions depending on what application you received. We typically tell you to take it easy for a few days after receiving the injection. This does not mean that you should lay in bed the entire time. You can be mobile and active, but as a general rule, if it hurts, don't do it.

|  |                                                  |
|--|--------------------------------------------------|
|  | <b>HOW MUCH DOES REGENERATIVE MEDICINE COST?</b> |
|--|--------------------------------------------------|

Currently, regenerative medicine is not covered by insurance. Prices vary depending on the severity, problem, and dosage amount. Cost varies from patient to patient, depending on the severity, problem, and dosage amount. Cost can range from \$3,000 and up.

The doctor can discuss treatment options and cost in your consultation

## **RESOURCES**

1. Journal of Clinical Medicine, 2020 Apr; 9(4): 1102. Published online 2020 Apr 12. doi: 10.3390/jcm9041102
2. Science Direct, Biologics in Orthopaedic Surgery, Anthony F. De Giacomo MD, ... Neal S. ElAttrache MD, in Biologics in Orthopaedic Surgery, 2019
3. Sobolewski K, Bańkowski E, Chyczewski L, Jaworski S. Collagen and glycosaminoglycans of Wharton's jelly. Biol Neonate. 1997;71(1):11-21. doi: 10.1159/000244392. PMID: 8996653.
4. Velarde F, Castañeda V, Morales E, Ortega M, Ocaña E, Álvarez Barreto J, Grunauer M, Eguiguren L, Caicedo A. Use of Human Umbilical Cord and Its Byproducts in Tissue

Regeneration. Front Bioeng Biotechnol. 2020 Mar 10;8:117. doi: 10.3389/fbioe.2020.00117. PMID: 32211387; PMCID: PMC7075856.

5. Gupta A, El-Amin SF 3rd, Levy HJ, Sze-Tu R, Ibim SE, Maffulli N. Umbilical cord-derived Wharton's jelly for regenerative medicine applications. J Orthop Surg Res. 2020 Feb 13;15(1):49. doi: 10.1186/s13018-020-1553-7. PMID: 32054483; PMCID: PMC7017504.
6. Deus IA, Mano JF, Custódio CA. Perinatal tissues and cells in tissue engineering and regenerative medicine. Acta Biomater. 2020 Jul 1;110:1-14. doi: 10.1016/j.actbio.2020.04.035. Epub 2020 May 14. PMID: 32418650.