MARKET & COMPLIANCE

- **OUR PRODUCTS ARE DERIVED ONLY FROM HEALTHY, PRE-SCREENED LIVE C-SECTION BIRTHS.**
- **TO ENSURE PATIENT SAFETY, OUR DONOR SELECTION, TISSUE RECOVERY AND PROCESSING PROCEDURES MEET OR EXCEED ALL APPLICABLE INDUSTRY STANDARDS.**
- **ALL PRODUCTS UNDERGO INDEPENDENT STERILITY TESTING AND ARE MANUFACTURED IN A QUALIFIED FACILITY.**
- **SIGNATURE BIOLOGICS TISSUE PRODUCTS ARE COMPLIANT UNDER SECTION 361 OF THE PUBLIC HEALTH SERVICE ACT ACCORDING TO 21 CFR PART 1271.10. THEY ARE REGULATED AS A HUMAN CELL AND TISSUE PRODUCT – FOR HOMOLOGOUS USE ONLY.**
- **PRESCRIPTION USE ONLY FOR SALE TO LICENSED HEALTHCARE PROFESSIONALS.**

Distributed by:

MISSION & VISION

Signature Biologics uses its innovative techniques to manufacture human placental derived products to support and improve the natural healing processes of the body. We strive to produce best-in-class products that better the quality of life of patients.

Our vision is to maintain the premier status as the trusted source of innovative placental derived therapeutic solutions in the nation, characterized by the highest quality products and improved functional patient outcomes.

VALUES

QUALITY: To meet or exceed the highest regulatory standards to ensure products consistently meet established specifications.

INTEGRITY: To conduct all business operations with the utmost commitment to transparency, trustworthiness, and golden rule ethics.

INNOVATION: To utilize a constant focus on research to develop novel and unique processes and best-in-class products.

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PR-BSC-002 rv.00 20MAR2020

Beyond Stem Cells

Placental Allograft Product Education

www.signaturebiologics.com

Patient Educational Information

BEYOND STEM CELLS

Minimally invasive surgical and medical techniques typically result in improved outcomes, reduction in complications, and less discomfort to the patient. Finding these minimally invasive alternatives is the goal of both patients and clinicians.

'Stem cells' are advertised as one of those alternatives. Stem cell products generally refer to the use of stem cell isolations, which are regulated as drugs or bio-pharmaceuticals in the USA. There are currently no FDA approved stem cell therapies available in the USA.

Tissue products are an alternative that goes beyond stem cells by utilizing the structural characteristics of the natural tissue. These are regulated as a biologic and are considered transplant tissues.

REGENERATIVE MEDICINE

The process of replacing or 'regenerating' human cells, tissues, or organs to restore or establish normal function. This process can use tissue from either an autologous or allogeneic origin.

Autologous *– From You to You*

- Invasive, potentially painful, and not as rich and potent as placental tissue
- Must be used the same day – which does not allow for third party testing

Allogeneic *– From Donor to You*

- Non-invasive and no pain involved
- Provided by FDA regulated tissue banks
- Manufactured with industry safety guidelines

ONE TISSUE – MANY COMPONENTS

STRUCTURAL TISSUE

- Tissue can be seen with the unaided eye
- Tissues derived from the umbilical cord and the amniotic membrane provide structural benefits
- Umbilical cord tissue can be used to supplement cushioning in the same way that it cushions critical blood flow between mother and child
- Amniotic membrane can be used as a barrier in the same way that it serves as a barrier between mother and child
- Placental tissue is a rich source of natural regenerative cells. Those cells use molecules to help the immune system, stimulate regeneration, and reduce inflammation

	Sources			
Characteristics	**Umbilical Cord**	**Amnion**	**Bone Marrow Aspirate**	**PRP** (Platelet Rich Plasma)
Structural	✓	✓		
MSCs	✓	✓	✓	
Exosomes & Microvesicles	✓	✓	✓	
Cytokines	✓	✓	✓	✓
Growth Factors	✓	✓	✓	✓

PATIENT SAFETY

ETHICS

Embryonic Cells:
These cells are harvested from human embryos. There is not a widely accepted, ethical and safe medical purpose for these cells today.

Placental Tissue:
No embryonic tissue or embryonic stem cells are utilized in placental derived products.

Placental tissue comes from informed, consenting healthy women.

- Obtained from a scheduled c-section, in a clean environment from a full term, live birth
- Donor's medical and social history are reviewed by a Medical Director and kept on file

REGULATED

Human tissue products are regulated by the FDA under 21 CFR 1271 within a department called the Center for Biologics Evaluation and Research (CBER).

Signature Biologics, as a registered tissue manufacturer, abides by industry leading standards, including:

- American Association of Tissue Banks (AATB), Current Good Manufacturing Practice (cGMP), Current Good Tissue Practice (cGTP), and International Organization for Standardization (ISO 9001)