REVITASTEM
UMBILICAL CORD STEM CELLS & PEPTIDES

Frequently Asked Questions

What makes RevitaStem products different from other stem cell products?

1. Autologous stem cells derived from one's bone marrow or fat tissue have served as the mainstay of rejuvenative stem cell therapy for the last decade. Such treatment has shown to have considerable benefits for many patients, but there are significant downsides, including the difficulty in obtaining mesenchymal stem cells (MSCs) from bone marrow or fat and the emergence of superior replacement tissue. Autologous stem cells often suffer from significantly reduced efficacy due to limited regenerative capacity from age, chronic illness, and inflammation or cumulative negative effects of environmental toxins, unhealthy lifestyle and medications, which is not the case with umbilical cord tissue derived mesenchymal stem cells (UCTMSCs). Additionally, autologus stem cells often lack the cell numbers, viability and the amount of signaling molecules that are essential for optimal results.

2. The effects of umbilical tissue derived MSC treatment include direct replacement of the injured tissue with growth of the MSCs, paracrine action on injured cells and supporting tissue, activation of stem cells in and around the injured tissue, indirect effects on tissue support cells, stimulation of revascularization, protection of tissue from stress-induced apoptosis, protection of tissue and cells from neurotoxins, anti-inflammatory actions and immune modulatory effects.

3. When compared to autologous stem cells from bone marrow or fat, the young cells derived from umbilical cord tissue (9 months since conception) are more primitive, metabolically more active, have a faster rate of self-renewal, secrete more growth factors, senesce (gets old) slower, lack the accumulation of lifelong cellular damage from toxins, inflammation and aging, and have more anti-inflammatory and neuroprotective effects.

4. The RevitaStem mesenchymal stem cell products are minimally manipulated human tissue allograft suspensions, derived from multiple components to maximize mesenchymal stem cell number, cell activity and cell viability for optimal healing and regenerative effect. Most autologous stem cell providers' products contain 1-3% MSCs. RevitaStem utilizes proprietary processing that results in products having much higher levels of MSCs (up to 20% MSCs, based on third-party testing and verification).

5. We use a proprietary method of isolation of MSCs, supporting cells, peptides, growth factors and cytokines. RevitaStem products contain a precise combination of stem cells and supporting components from multiple tissues, including umbilical cord (Wharton's Jelly), cord blood, perivascular tissue and amniotic membrane. This combination of tissues along with proprietary processing techniques results in higher levels (often many-fold higher) of not only stem cells, but also growth factors, peptides, signaling molecules and cytokines, which are all vital components for optimal repair and rejuvenation.

How do umbilical cord tissue stem cells differ from embryonic stem cells?

UCTMSCs have many features of embryonic stem cells with a wide spectrum of differentiation, including the expression of a multitude of pluripotency genes, but unlike embryonic stem cells, they are not tumorigenic. In fact, to the contrary, UCTMSCs are shown to suppress and attenuate tumor formation and growth by secretion of cytokines and other paracrine effects.

Is there a risk of infection?

RevitaStem products are tested for relevant communicable diseases that exceed the required FDA standards for tissue donation, including HIV I/II , Hepatitis C, Hepatitis B, Syphilis and HTLV. In addition to testing negative on all tests, donors must not have any risk factors for increased risk of acquiring communicable disease agents. As an added precaution, the product is further tested on multiple levels for sterility via bacterial and fungal cultures.

The risk of infection of UCTMSCs is extremely low and shown to be lower than autologous sourced stem cells. This is due to a variety of factors over and above the extensive testing, including the fact that the umbilical tissue derived stem cells are less likely to be infected than other maternal or fetal tissues, even if both mother and baby carry an infection. One reason is that the stem cells lack many of the surface antigens that viruses and bacteria need to infect a cell.

From an evolutionary standpoint, the reduced risk of chronic infection by the cells makes sense, as most every infection has preferred tissues that it infects, but if the preferred tissue were anything in the umbilical cord, they would be discarded at birth and not transmitted to offspring or a new host. Thus, any infection that utilizes umbilical tissue would not survive a single generation. We know of no reports of transmission of a chronic infection, and a number of studies show that the risk of severe and mild side effects, including infection, are lower than those undergoing an autologous transplant.

Do UCTMSCs need cross matching?

UCTMSCs do not express HLA-DR or other MHC-II antigens. Thus, they are immunoprivileged - they are not seen as foreign and do not elicit the body's immune reaction against the cells. Additionally, the UCTMSCs secrete numerous immunomodulatory substances that are shown to modulate the body's immune system, reducing inflammation and autoimmunity. Umbilical cord stem cells are shown to be a treatment of graph versus host disease that can be caused by standard stem cell transplant.

How does UCTMSCs compare to amniotic products?

When compared to amniotic products on the market, the superiority of RevitaStem products is obvious. While amniotic products do contain important cytokines and growth factors, they contain very low numbers of live stem cells. The FDA prohibits them describing their products as "stem cell products." Amniotic products lack the many benefits stem cells are able to provide, including the ability to hone into areas of injury and inflammation and secrete appropriate cytokines and growth factors that are often required for healing.

How does RevitaStem compare to the few umbilical cord stem cell products on the market?

When compared to other umbilical cord derived stem cell products on the market, RevitaStem products offer significant advantages. RevitaStem products provide a much greater concentration of MSC s as well as a complete spectrum of growth factors, peptides, cytokines and immune modulating signaling molecules that provide superior rejuvenation and healing effects than comparable products.

Most companies that market umbilical cord stem cells obtain cells from umbilical cord blood only, as it is the easiest component to work with. The most challenging component is the cord tissue, which has a MSC rich area called Wharton's jelly--a protective gelatinous material surrounding the three blood vessels coursing through the cord. Vast numbers of studies have demonstrated that Wharton's jelly is particularly rich in MSC's, and these MSC's have remarkable clinical benefits.

Additionally, the serum of umbilical cord blood contains valuable proteins and growth factors, such as TIMP-2 protein, which has been shown to promote memory and learning. Most (if not all) companies either throw away the serum or put it into cosmetic products, which sell at a premium. Our exclusive laboratory carefully preserves the serum and puts it back into the final product, thus infusing the product with many of the remarkable proteins and growth factors that are originally contained in the cord blood.

What is the difference between RevitaStem and RevitaFlex?

RevitaStem: 30 million/cc, with components from umbilical cord blood, cord tissue, (both Wharton's jelly and perivascular region), cord blood (serum)

and amniotic membrane. This is the only product is the US market that includes all four components. The proprietary processing preserves most of the therapeutic elements (some are yet to be discovered). Because of the purity, the product can be safely given in large quantities, as large as 12cc at one time (done for many patients already). Over 20,000 doses were given last quarter without a significant reported side-effect.
Offered in 1cc & 2cc vials.

RevitaFlex: 14 million/cc, with a significant amount of extracellular matrix, including elements such as growth factors, collagen scaffold, lipids, proteins, carbohydrate and other nutrients. These elements help the stem cells to adhere, protect, cushion, lubricate and reduce inflammation.
Offered at 0.5cc, 1cc & 2cc vials for local injections.

Are these products FDA approved?

UTCMSCs are regulated by the FDA but are not approved by the FDA because they are not considered a medication. They are "minimally manipulated" cellular-based products, which, again, are regulated by the FDA but are not approved as a drug. Cellular-based products are not classified as medications, so they cannot be approved as a medication. RevitaStem products are processed from donated human tissue in accordance with FDA guidelines as a cellular or tissue-based product (HCT/P) for homologous use (cells doing what they naturally do) under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. The facility is FDA registered and inspected, cGMP compliant, and follows the American Association of Tissue Banks (AATB) guidelines.

Are the RevitaStem products from expanded cell lines?

None of our products have gone through any "expansion" process. Although many companies use expanded cells, it is against FDA guidelines to do so.

Are the cells in a vial from one donor or multiple donors?
All cells in our product (derived from cord blood, cord tissue & amniotic membrane) are from a single donor within each vial and each lot. Each vial has lot # and donor ID that can be traced to the origin if the recipient ever desires to do so in the future.

Are there future changes anticipated to the product?

RevitaStem and its suppliers are also committed to constant and continual refinement, improvement and product development so you can be assured that you are getting the most superior product available.

What markers are checked to determine if stem cells are in the product?

We check an array of markers and have proprietary methods with pending patent submissions so not all are revealed to competitors, but the basic markers include CD90, CD73, HLA-DR, HLA-ABC, CD34, Cd45, glycoproteins A. Also, growth factors such as VEGF, FGF-2, IL 1-ra, SCF are tested.

What conditions are umbilical cord stem cells used for?

Doctors in many specialties are using stem cell therapies for a wide-range of conditions.

- Chronic Lyme disease
- Chronic fatigue syndrome and fibromyalgia
- Autism
- Types I and II diabetes
- Rheumatoid arthritis, Crohn's disease, lupus and other autoimmune disorders
- Parkinson's, ALS, Alzheimer's and other neurological diseases
- Heart diseases
- Respiratory disorders
- Athletic injuries
- Chronic pain
- Spinal cord injuries and other orthopedic conditions

- Cosmetic and aesthetic issues treated by cosmetic dermatologists

Where will the cells be shipped from?

The cells will be shipped on dry ice from one of our fulfillment centers located in Los Angeles, New York and Florida.

What is the cost of the shipping?

There is a $125 flat shipping fee within the continental United States. Deliveries are made Monday through Friday. Saturday or priority FedEx (morning delivery) is available for an additional $75 fee.

How many days of advance notice is required to place the order?

Orders generally need to be placed by 1 pm two days prior to the desired delivery date, but if next day delivery is required, we ask that you contact the office directly. We will be happy to expedite the order if possible.

How are they shipped?

Cells are shipped on dry ice in an extended-duration shipper, specifically designed for cryopreserved products with an outer box, styrofoam inner box with a thermo-shield. A three layer patented Thermal Shield barrier was added, resulting in increased temperature stability and protects contents if the outer package is seriously mishandled.