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## Amniotic Derived Stem Cell Therapy

Stem cell treatments are not new in medicine, having been used for decades in wound care and other specialties. Now, modern medicine is finally breaking through with regenerative therapy, with their role becoming more prominent as their potential becomes apparent for musculoskeletal condition repair. In orthopedics, amniotic tissue and its components are demonstrating the potential for a broad spectrum of applications.

### What are amniotic derived stem cells?

Stem cells are the most basic cells living in the human body. Beginning in the embryonic stage, they have the ability to become many types of cells, from skin cells to muscle, from bone to cartilage. Amniotic cells and components are derived from amniotic fluid, placenta and umbilical cord obtained during scheduled caesarean sections from consenting donors. There is no harm to the fetus and no blood from the fetus is used, only the amniotic tissue that would be discarded anyway.

Researchers have discovered that the amniotic tissue has an extremely high concentration of stem cells, even more than bone marrow in adults. When processed at an FDA regulated lab, the biologic material contains a multitude of regenerative properties, such as growth factors, hyaluronic acid and stem cell activators. Also, amniotic tissue is immuno-privileged, meaning that a rejection reaction is extremely rare when given to a patient.

### Properties of Amniotic tissue and stem cells

1. They have important *anti-inflammatory properties* including cytokines that help relieve pain. There is no steroid component to amniotic derived injections.
2. The product contains *growth factors* which can help promote new tissue growth and help to call in the body's own reparative cells.
3. The product contains *hyaluronic acid*. This is a prominent component of joint fluid, and is important for lubricating cartilage, decreasing inflammation and pain, and promoting growth of new cartilage.
4. Amniotic tissue is an excellent source of concentrated *stem cell activators* which promote the tissue healing response.

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### **What growth and repair factors are found in amniotic tissue?**

Highly concentrated in amniotic tissue is an abundant source of over 250 identified growth and tissue repair factors. Some of these include:

EGF (Epidermal Growth Factor), bFGF (Fibroblastic Growth Factor), KGF (Keratinocyte Growth Factor), IL-6 (Interleukin 6), IL-8 (Interleukin 8), HGF (Hepatocyte Growth Factor), PDGF (Platelet Derived Growth Factor), TGFb1 (Transforming Growth Factor beta 1), Fibronectin, Laminin, Proteoglycans, Hyaluronic acid, and Cytokines

### **Why are These Injections Good for Pain Relief?**

Amniotic stem cells have anti-inflammatory properties, which means that the therapy involving them is great for pain relief. Unlike cortisone, whose role is only to decrease the pain, the stem cell injections are also treating the source of the pain. Since joint pains are caused by damaged tissue and cartilage, amniotic derived stem cell injections may potentially repair or replace the damaged cells and help the body create new tissue to grow healthy and strong.

### **How is Amniotic Tissue Classified by the FDA?**

The US Food and Drug Administration (FDA) classifies amniotic tissue as a HCT/P (Human Cells, Tissues, and Cellular and Tissue-Based Products). An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR part 1271 if it meets all the following criteria (21 CFR 1271.10(a)): the tissue is minimally manipulated, intended for homologous use and is not combined with other cells or tissues. There can be no systemic effect or dependence on the metabolic activity of living cells to achieve its primary function and the tissue has to have a localized effect *in vivo*.

If an HCT/P does not meet all of the criteria in 21 CFR 1271.10(a) it will be regulated as a drug, device, and/or biological product and a pre-market review would be required.