



**A CONSUMER GUIDE TO
AMNIOTIC STEM CELLS**

SEPARATING FACT FROM FICTION

Amniotic Tissues: Fact and Fiction

The idea that we might be able to harvest viable stem cells for orthopedic medicine from routinely discarded birth tissues is a promising one. However, other than bone marrow transplantations, there are currently no FDA-approved uses for allogeneic stem cell products. Unfortunately, the vials of amniotic “stem cells” that sales reps are currently hawking to many physician providers contain no living stem cells. We are currently in an era we like to call the Stem Cell Wild West, and it appears that almost every provider on the corner is pushing stem cell therapy. Patients need to arm themselves against unknowledgeable providers or flat-out fraudulent claims. To help you do this, we’ve created an amniotic consumer guide, containing important things you need to know about amniotic “stem cells.”

1. What Are Amniotic Tissue-Based Products?

While in the mother’s womb, babies are encased in a fluid-filled sac. The material that forms the walls of the sac is the amniotic membrane. When a woman’s water breaks as she goes into labor, this sac is ruptured, and the water that leaks out is the amniotic fluid. After childbirth, the amniotic membrane and fluid can be collected, sterilized, and processed into a variety of tissue-based products. Regrettably, these amniotic membrane and fluid-based products are currently being pitched and distributed to doctors as amniotic “stem cell” products.

2. Are There Stem Cells in Amniotic Tissues?

[Yes, there are limited stem cells in fresh amniotic membrane and fluid.](#) However, once the tissues are processed into an FDA-compliant human tissue-based product, the included cells are purposefully killed or “terminally sterilized.” This is done because federal regulations state that these tissue-based products cannot be dependent on the activity of living cells. In fact, if any of these stem cells did survive, the product would have to be classified as a drug by the FDA, and it would not be marketable until clinical trials for each indication could be completed. In the past, companies selling amniotic products containing living cells have received FDA enforcement letters stating their product is a drug and, therefore, must be regulated as such. Currently, all amniotic tissue-based products are classified by the FDA as a human tissue without living cells, meaning they do not need to undergo clinical-trials validation before being sold.

3. What Do Amniotic Tissues Contain?

Interestingly, [amniotic fluid, on average, is about 75% baby urine](#), so in an environment that is already filled with urea and uric acid, logic dictates it may be difficult for stem cells to thrive. Processed amniotic fluid does retain some growth factors and cytokines that can be injected to help with healing. Additionally, amniotic fluid contains collagen and other extracellular matrix proteins. However, platelet rich plasma (PRP) also contains your own healing growth factors, it's not nearly as expensive, and it's much easier to obtain. So when considering regenerative potential, we cannot justify spending a thousand dollars or more on a vial of amniotic fluid when we can accomplish the same thing with a few hundred dollars worth of PRP.

4. Why Are Sales Reps Pushing Amniotic “Stem Cells”?

From the horses mouth, “It’s a slimy industry.” [Expensive vials of amniotic tissue-based products represent a scalable, one-size-fits-all product that molds with the traditional mass-marketing business plan of the pharmaceutical industry.](#) PRP, on the other hand, requires a doctor’s office to take blood from the patient and process it into a growth-factor-rich therapeutic. Importantly, the PRP comes from the patient’s own blood, eliminating any possibility of rejection, and if processed correctly can be customized specifically for the patient’s needs. Unfortunately, for many providers, the process of drawing patients’ blood is inconvenient, the equipment required to make PRP can be cost prohibitive, and the process can be too time consuming. For these providers, it’s more convenient to buy the ready-to-inject vials of amniotic “stem cells” the reps are pushing.

5. Why Are Providers Advertising Their Use of Amniotic “Stem Cells”?

The simple answer is, most probably just don’t know any better. [They believe they are using amniotic “stem cells” because they believe what the sales reps are pitching.](#) The reps should know the difference, but perhaps even some of them don’t know what it is—or what it isn’t—they’re selling. Unless a physician provider has access to state-of-the-art labs to fully investigate a new product, they must rely upon sales pitches, passing misinformation and fraudulent treatments on to their patients.

6. How Do We Know Vials of Amniotic Fluid Contain No Stem Cells?

If amniotic tissue-based products contained living stem cells, Regenexx would become one of the biggest customers. However, [we did the lab research on these amniotic products to determine the validity of these claims](#) and uncovered [the great amniotic stem cell deception](#). We began the project in our clinic lab, but handed it over to the Interventional Orthopedics Foundation (IOF) because the market became overloaded with amniotic products, and this outpaced our ability to keep up. [The IOF research scientist looked at many things during the amniotic stem cell study](#), including the following:

- Did the products have any living cells?
- Did the products help older stem cells?
- Did the products have any growth factors?

Using sophisticated equipment (seen in this video: <https://www.youtube.com/watch?v=WOd0RVIfNh4>), the IOF did not find living cells in these products. Additionally, the products did not help performance in older stem cells, and they did not have more growth factors than a PRP shot.

7. Is There Any Research on Amniotic Stem Cells?

Multiple searches in the US National Library of Medicine returned one study that looked at amniotic membrane that had been chopped up and then injected into patients suffering from plantar fasciitis; [however, this amniotic product contained no stem cells](#). This is another amniotic tissue-based product in which the [amniotic membrane is cleaned, tested, processed \(usually freeze-dried\), and cut into sheets or finely chopped \(micronized\) for injection](#). To contrast, [there's a good deal of research showing that bone marrow stem cells are likely helpful in treating orthopedic conditions](#), so you'd think if providers are going to use amniotic stem cell products, there would be research to support their use, but it's just not there.

The upshot? You now have this amniotic consumer guide to keep you informed and well armed each time you enter the Stem Cell Wild West. Make sure you do your research and know what you're getting. So many claims are being thrown around by physicians using these materials that aren't accurate, and the use of amniotic "stem cells" is, by far, the most concerning as they simply don't exist as a current orthopedic treatment option. While we might be able to justify a purpose for using them for their growth factors, at this point the patient's own platelet rich plasma (PRP) provides a better treatment and financial benefit. When stem cells are needed for orthopedic issues, there is still no better alternative out there than bone marrow stem cells. We'll continue to use our advanced lab facilities and research capabilities to stay on top of what's best for Regenexx patients.

The Deception of Amniotic Stem Cells





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