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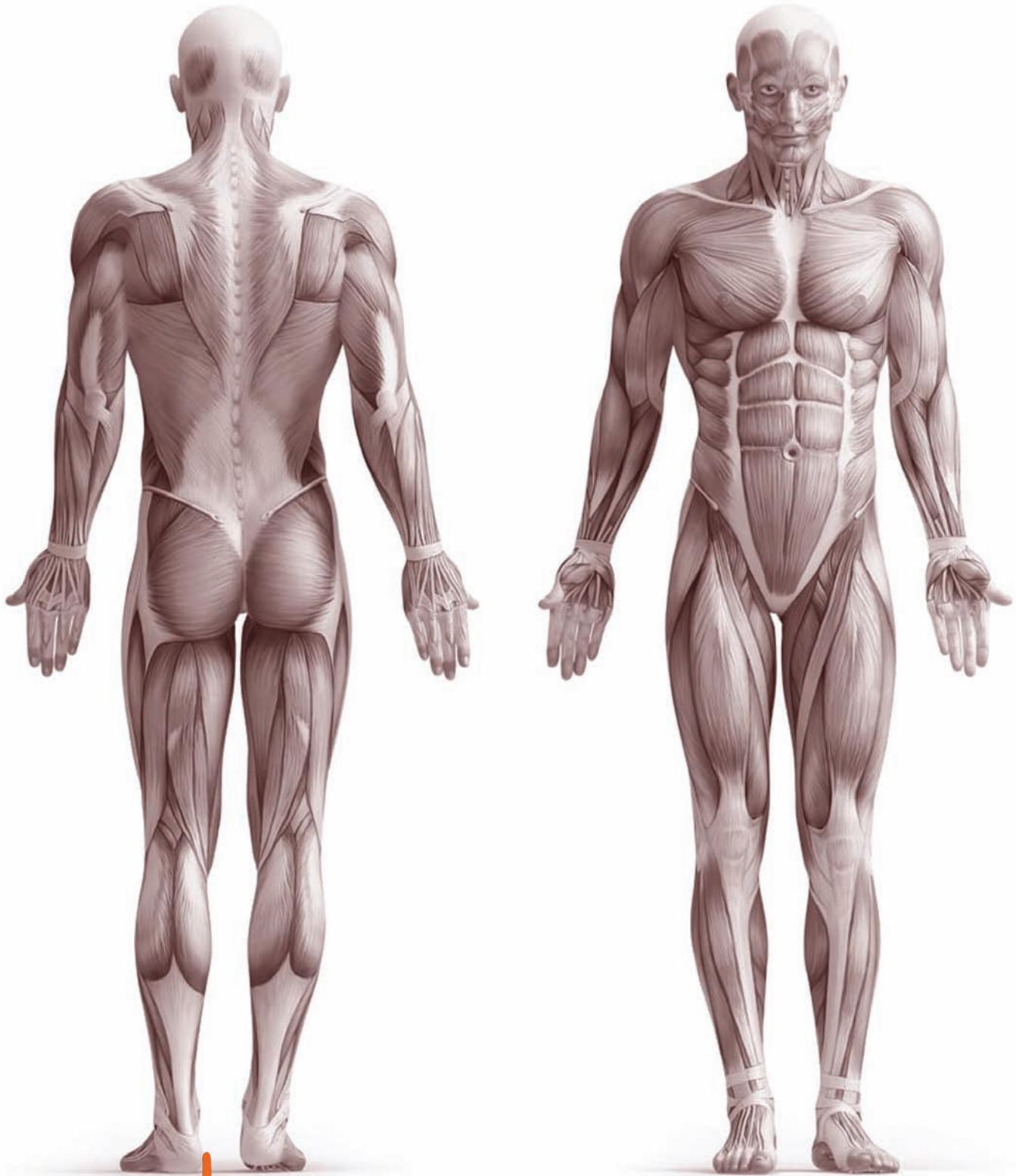
*News*

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## STEM CELL THERAPY

The Future of Medicine is Offered Today





*New ReGeneration*  
**ORTHOPEDICS**



# The Stem Cell Alternative to Orthopedic Surgery

## —What You Need to Know

by New Regeneration Orthopedics

Stem Cell treatments using the patient's own living stem cells are providing surgery-free pain relief for tens of thousands of patients that would otherwise have to endure major orthopedic surgeries. However, physicians specialized in this field of Interventional Regenerative Orthopedics are growing more and more concerned about the confusion and misinformation associated with stem cell procedures. If you've ever wondered if stem cell or platelet therapy might be a good alternative for you or someone you love, this article will help you learn more.

Dr. James Leiber, founder and medical director of Tampa Bay's New ReGeneration Orthopedics of Florida and former Air Force physician and medical consultant to the president and vice president at the White House, says his patients are benefiting tremendously from stem cell and platelet therapies. For example, greater than 90% of patients with knee arthritis (of all severities) report improvement after a Regenexx stem cell procedure when surveyed at one year and beyond with an average improvement in pain and function at New Regeneration Orthopedics of 60-70%. However, it's important for the patient and the physician to do their due diligence.

First, the physician has to match the patient with the correct treatment. The best candidates for successful regenerative therapies are active people with shoulder, elbow, hand/wrist, hip, knee, foot/ ankle, and spine problems. Dr. Leiber and his team, which includes Interventional Pain Specialist Dr. Michael Amoroso MD and Sports Medicine specialist Ron Torrance DO, use a careful intake process to determine which patients are most likely to have successful outcomes from stem cell or platelet treatments. Those who are not candidates may be advised to utilize a different treatment strategy, including surgery. Dr. Leiber advises patients to be wary of doctors who say stem cell treatments are for everyone and for every condition. He and his colleagues do a thorough evaluation and provide an honest assessment of each patient's chances for success, as well as any risks.

New ReGeneration Orthopedics is part of a national network known as Regenexx, which developed the patented technology and scientific literature that guides procedures performed by the group. The first orthopedic stem cell injection procedures in the U.S. were performed by Regenexx in 2005. Since then, physicians affiliated with Regenexx have performed more than 57,160 Regenexx procedures and have created half of the world's published orthopedic

stem cell research literature. Patients are tracked by a team of professional researchers as part of national database registry collecting data on safety and clinical outcomes. Because this is the only database of its kind, Regenexx has also been able to confirm large cost savings of their procedures when compared to traditional orthopedic surgeries for the same conditions. Regenexx is working with large self-funded insurance companies across the country to get insurance coverage for Regenexx procedures for their employees. See [regenexxcorporate.com](http://regenexxcorporate.com) Regenexx outcome data and research publications are transparently posted on their website – [regenexx.com](http://regenexx.com)

Dr. Leiber was the first to bring Regenexx to Florida in 2012, and New ReGeneration remains the exclusive practice on Florida's west coast offering this technology.

In addition to its focus on using the patient's own living cells rather than donor cells, Regenexx is built around 8 core principles:

#### **Advanced Imaging and Placement**

– Very few physicians, including orthopedic surgeons, are trained in the use of advanced ultrasound and fluoroscopy (live X-ray) imaging techniques for diagnosing tissue damage and for guiding placement of the cells into these tissues precisely and safely. By using a "tissue preservation" model rather than surgical, cortisone injection, or narcotic pain prescription models, new sophisticated techniques had to be invented.

Regenexx affiliates are among the most highly trained injection specialists in the world.

#### **Bone Marrow Harvesting Technique**

- Regenexx uses the highest quality stem cells from the patient's bone marrow.

Techniques for harvesting the bone marrow and isolating the cells in the laboratory are unique to Regenexx and reliably provide 5–20 times higher stem cell counts than what could be obtained via automated bedside centrifuges.

Also, contrary to popular belief, bone marrow procedures performed properly under guidance are very tolerable with minimal discomfort during or after the procedure.

**Dosage** – Regenexx physicians use advanced technology to count the stem cells and deliver a precise dose. Total stem cell counts and percentage of living cells are counted for each bone marrow procedure. Platelets and growth factors obtained from the blood or the bone marrow are also isolated to be used with stem cells as part of the treatment protocol.

Different tissue types respond better to different concentrations of platelets (often referred to as Platelet Rich Plasma or PRP). But unlike other doctors dabbling in this field, Regenexx's laboratory techniques allow for individualized treatment plans with platelet counts ranging from 1 to 40 times concentrated as compared to the blood and the ability to keep or remove white blood cells or red blood cells. In a given procedure, there may be many different versions of the PRP used depending on the tissue type and ultimate goal.

### **Five Warning Signs About Amniotic and Cord Stem Cell Therapy**

*Dr. Leiber and all of the Regenexx providers use only your own living bone marrow cells, never amniotic or cord cells.*

**Stating or implying that their amniotic or cord products contain "Live Stem Cells."** The patented Regenexx procedure uses your own living stem cells taken from your bone marrow. Amniotic or cord cell products have been found to

contain no living stem cells.

**Providing bait-and-switch research to support their use of amniotic and cord stem cells rather than bone marrow cells.** Because products containing live cells from donors are not approved by the FDA, research data from other countries using live amniotic and cord stem cells do not apply to what is being used in the U.S.

**Citing outcome statistics for their therapies, but providing no supporting**



**Anesthesia** – Because some local anesthesia can kill stem cells, Regenxx providers use carefully selected drugs during the procedure and utilize various techniques for maintaining patient comfort during a procedure.

**Research Lab** – Regenxx maintains a sophisticated, university-quality lab to constantly study and improve its procedures. There is no other sophisticated lab in the U.S. that is solely focused on this goal.

**Safety** – Regenxx has published the largest and longest research pertaining to the safety of orthopedic stem cell procedures.

**Lifestyle modifications** - good outcomes are dependent on the health of the

patient's cells and the environment they are placed into. Individualized advice pertaining to food, medications, supplements, exercise, and other factors is an important part of the protocol in advance of and after the actual procedure.

**Stem Cell Protocol** – For many conditions, especially arthritis related, the Regenxx protocol includes a pre-injection procedure that “tills the soil” in preparation for the actual re-injection of stem cells or “planting the seeds” a few days later and ends with “fertilizer” treatment a few days later. This is a patented protocol. Some people may benefit from platelet procedures periodically to maintain a healthy environment in the joint.

**data.** Regenxx provides extensive research, including joint-specific data, at <https://www.regenxx.com/outcomes>

**Claiming that their amniotic or cord therapy can grow new cartilage.** Dead amniotic and cord stem cells cannot grow a new joint or brand-new cartilage. In fact, no stem cells from any source can grow a new joint. When a patient has lost all the cartilage and has nothing left but bone-on-bone, stem cells cannot typically grow new cartilage. Occasionally new

cartilage growth is seen but not consistently. Ligaments and tendons and bone can regenerate with stem cell injections. But, please keep in mind that cartilage itself has no nerve endings and is not usually a source of pain. Patients with severe knee pain and no cartilage can return to high level athletics (even the Ironman) after a Regenxx procedure.

**Claiming injections of the younger stem cells in the amniotic and cord product will help older stem cells act younger.**

Additionally, *Culture-Expanded Stem Cells* offer another treatment option for patients. At this time, growing stem cells into much higher quantities for purposes other than laboratory research, such as injecting into human tissue, is not allowed by the FDA in the U.S. However, Regenexx also maintains a world-class laboratory in the Cayman Islands where patients can go and have their stem cells grown and even stored for future use. This process allows for stem cell counts that are 100-1000 times higher than what can be obtained in the U.S., allowing for more potent procedures, higher counts and opening the possibility of treating multiple body regions at the same time. New ReGeneration Orthopedic doctors are licensed in Grand Cayman and can provide these procedures for you.

Dr. Leiber points out that one of the major sources of patient confusion is due to the various kinds of practices offering widely varied treatments that often lack precision, scientific support, living cells, or all three.

“Many practices are using stem cells from fat,” Dr. Leiber said, “The process of obtaining stem cells from fat tissue requires processing steps that violate FDA regulations for use of body tissue for procedures. This is considered to be an unapproved use of a drug, and is illegal for orthopedic use. FDA has drawn a clear line in the sand and medical clinics using this approach are being cited and warned. Also, many practices are offering amniotic or placental type “stem cells.” Please be aware that none of these products actually contained living stem cells when Regenexx tested them. Additionally, if they did contain live stem cells, they would require FDA

approval as a drug, which has never occurred. Doctors are either offering this without knowledge of this or purposely misleading patients. These products do contain growth factors, which can be helpful. However, not as much as a simple Platelet Rich Plasma (PRP) injection which costs about \$1,000. Some doctors are charging up to \$10,000 - \$20,000 for this and injecting it randomly (even without image guidance) into a joint in 5 minutes. It makes me very upset to know that patients are getting taken advantage of and not receiving high-quality, evidenced-based care. It makes us all look bad as well because we get clumped into the same category as everyone else.”

He advises patients that are evaluating healthcare providers to do their research. Ask the doctor what the stem cell source is. A valid source for orthopedic use would be your own bone marrow stem cells. Other products made from amniotic or placental tissues and umbilical cord blood from donors do not have living cells. Currently it is not legal to possess or use live amniotic or cord stem cells for clinical use. So, if a doctor tells you they are using products containing live stem cells from donors, you should be very wary. These products might provide some clinical benefit due to their concentration of growth factors, but there really is an absence of research to support using them for orthopedic procedures at this time and certainly not worth the price that these doctors are asking for it. The Regenexx procedure harvests your own stem cells and injects them during the same day, which is permitted by the FDA. Additionally, be wary of providers who are offering stem cell treatments for anything and everything that ails you. This is not a magic panacea for

### **Five Warning Signs - cont'd**

Published studies on many orthopedic applications have found no link between the age of the patient's own bone marrow stem cells and the outcome of their bone marrow stem cell procedure. Regenexx has tested the impact that these amniotic products have on an older person's stem cells and have found that they actually inhibit their growth.

**Regenexx doctors are world experts in the field of Interventional Regenerative Orthopedics with a dedication and focus on thorough clinical and skilled ultrasound evaluations, advanced harvesting and laboratory techniques to obtain more and better functioning stem cells, and advanced skills in the placement of the cells into damaged orthopedic tissue.**

all diseases. Research is evolving but be careful about treating internal medicine and brain related conditions, with stem cells. Regenexx doctors don't dabble in treatment of these conditions, the focus and expertise is on orthopedic and some neurologic related conditions.

Finally, the procedure should be performed by a licensed MD or DO certified in interventional orthopedics by the Interventional Orthopedic Foundation (IOF), not a physician assistant (PA) or nurse practitioner (NP) or a Chiropractor (DC). They should be using a musculoskeletal ultrasound and advanced live-image fluoroscopy to pinpoint the precise location of the injections. A full surgical setup is needed, including equipment to measure vital signs, as well as oxygen, crash cart and automated defibrillator.

If you or someone you love is considering surgery for knee, elbow, foot, ankle, hand, wrist, hip, shoulder or spine pain, visit [www.newregenortho.com](http://www.newregenortho.com) or call 941-357-1773. The Regenexx procedure is permitted by the FDA, but it is not yet covered by Medicare and many commercial insurance companies. Many self-insured employers are approving the Regenexx procedure as a covered benefit for their employees because they are realizing the tremendous advantages in efficacy, recovery and cost. The New ReGeneration Orthopedics staff is standing by to help you determine if Regenexx is right for you. Dr. Leiber, Dr. Amoroso, and Dr. Torrance are routinely providing seminars around the Tampa Bay area to help patients learn more about these procedures, and those seminars are listed on the New ReGeneration Orthopedics website.

For patients who want to stay ahead of their orthopedic problems, New ReGeneration Orthopedic offers a ProActive program that assesses the whole body and plans out a strategy for the year and offers various discounts and benefits. "Our patients tend to be active people of all ages who want to maintain an active lifestyle," Dr. Leiber adds. "Whether they are playing golf or tennis, running, cycling or playing with children and grandchildren, they count on us to help keep them stay in the game." PN

The infographic is titled "The Regenexx® Difference" and "VERSUS OTHER STEM CELL SOLUTIONS". It features several key points: "#1 THE FIRST ORTHOPEDIC STEM CELL PROCEDURE IN THE U.S. NOW WITH MORE THAN A DECADE OF EXPERIENCE"; "THE MOST RESEARCHED STEM CELL PROCEDURE FOR ORTHOPEDIC CONDITIONS" with a microscope icon; "100% FOCUSED ON TREATING ORTHOPEDIC CONDITIONS" with a doctor icon; "PUBLISHED PATIENT OUTCOMES & SAFETY DATA" with a clipboard icon; "10 to 20 TIMES MORE STEM CELLS THAN SIMILAR PROCEDURES (PER UNIT VOLUME)" with a molecular structure icon; "ALL INJECTIONS AND STEM CELL HARVESTING UTILIZE ADVANCED IMAGING GUIDANCE FOR PRECISION"; "ALL DOCTORS ARE MUSCULOSKELETAL EXPERTS WITH EXTENSIVE TRAINING IN ORTHOPEDIC INJECTIONS" with a doctor icon; "PROPRIETARY MULTI-INJECTION STEM CELL PROTOCOL FOR THE BEST POSSIBLE OUTCOMES" with molecular structure icons; "DEDICATED LAB RESEARCH TEAM FOR CONTINUOUS PROCEDURE IMPROVEMENTS" with flask and test tube icons; "THE ABILITY TO COUNT CELLS AND DOSE APPROPRIATELY BY CONDITION" with a bar chart icon; and "TENS OF THOUSANDS OF PROCEDURES PERFORMED SINCE 2005 • REGENEXX.COM" at the bottom.

