

YOUR COMPLETE GUIDE TO NON-SURGICAL REGENERATIVE ORTHOPEDICS

FLORIDA'S PREMIER REGENEXX PROVIDER

Next Generation Stem Cell & Platelet Based Procedures

RegenTampaBay.com





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Change is Necessary

We need a change in the traditional approach to orthopedics and pain management. There is an epidemic of chronic pain in this country as <u>126 million people suffer</u> from some sort of pain in the last 3 months. Of that 126 million, 40 million people have pain everyday and 20 million have pain that is severe enough to limit their activities and/or ability to work.

Until recently, standard treatments for musculoskeletal injuries to joints, tendons, ligaments, muscle, and bone have been focused on opioid narcotics, anti-inflammatory drugs (NSAIDS), cortisone injections, ablation (burning) of nerves, and surgeries. Regrettably, these mainstay strategies are fraught with potentially serious adverse effects, generally have mediocre results, and in many cases, can even worsen the problem.

For example:

- Narcotics are addictive and drug overdose deaths have been increasing at an alarming rate
- Both cortisone and NSAIDS can accelerate <u>cartilage loss</u> in a joint
- NSAIDS also increase the risk of gastrointestinal bleeding, kidney failure, heart attack, and stroke
- Cortisone elevates sugar levels, increases risk of infection, and is quite potent at further degenerating already weakened tissue
- Common surgeries for knee meniscus tears increase degeneration and the likelihood of a joint replacement in the future
- Surgeries to repair torn knee ACL's result in more severe arthritis in the future
- Joint replacements carry serious risks such as heart attack, stroke, clotting, and infection
- Lumbar fusions for low back pain are generally ineffective according to the most recent research and create new problems above and below the fused segments

There is a desperate need for new, better, and safer strategies. This is where interventional non-surgical regenerative orthopedics comes into play.

What is Interventional Non-surgical Regenerative Orthopedics?

Interventional non-surgical regenerative orthopedics is an innovative, natural, and highly successful alternative to common medical approaches to conditions that would otherwise require surgery. This exciting field opens up opportunities to treat orthopedic or musculoskeletal injuries, arthritis, and other degenerative conditions by using a tissue preservation strategy that uses the body's own healing cells to help restore more normal function to the human body. Regenerative orthopedic procedures encourage your body to actually heal and strengthen the damaged tissue. Advanced treatment protocols concentrate your own platelets, growth factors, and stem cells and deliver them precisely (under image guidance) into the site of your injury to support and promote natural healing.

Who is Regenexx?

<u>Regenexx</u> offers the world's most advanced protocols and training in these non-surgical treatments of common orthopedic injuries and degenerative conditions. In 2005, Regenexx physicians were the first in the United States to inject stem cells into orthopedic tissue. Regenexx procedures have remained the gold standard in non-surgical regenerative treatments. Regenexx provides custom solutions backed by extensive published research. All patients are tracked by a team of researchers for safety and outcomes.

More than 90,250 procedures have been performed as of 2019 and this number continues to increase daily. Today, Regenexx is the world's largest, cohesive physician group dedicated to practicing advanced stem cell and



platelet orthobiologics. Fortune 500 companies and many other self-insured companies have seen the value of Regenexx, offering these procedures as a covered benefit and a preferred treatment strategy for their employees with musculoskeletal conditions. These companies are seeing cost-savings of 75% over traditional medical approaches and patient/employee satisfaction of greater than 95%.

Regenexx Tampa Bay physicians are amongst the world leaders in this field and are long standing partners with Regenexx.

Interventional (Non-surgical) Regenerative Orthopedics can be complex to explain. Let's break down each aspect of our protocols so that you can better understand our methods.

Orthobiologics

"Orthobiologics" is the term used for the liquid solutions that are injected directly into damaged musculoskeletal tissue. These materials are typically made from substances that are naturally found in your body and are used to help injuries such as broken bones, injured muscles, tendons, and ligaments strengthen and heal.

Our bodies are designed to repair damage. Unfortunately, various external and internal factors can get in the way of our bodies completely healing an injury. Regenexx orthobiologic treatments use your body's natural healing agents to repair or mitigate damage by concentrating and focusing them at the precise site of your injury or pain. This approach allows for natural, efficacious healing without the need for surgery. In short, these procedures help overcome whatever barrier or threshold is needed to complete the repair process.

• Bone-marrow Stem Cells - Our stem cells are incredibly powerful and play many roles. For example, these cells can turn into other types of cells and release substances that orchestrate a repair response. Stem cells

work as our body's primary means of repairing damage. While there are different types of stem cells, we use only the one with demonstrated efficacy - mesenchymal stem cells (MSC). The most effective MSCs (based on current research literature) are derived from bone marrow. Despite what some people advertise, MSCs are currently the only source of tissue from which stem cells can be derived that are in compliance with FDA regulations. These stem cells are drawn from the back of the pelvis and have the capacity to turn into bone, muscles, tendons, ligaments, and in a limited way, cartilage. After the cells are drawn, they are processed, isolated, and concentrated in our lab to derive 5-20 times more stem cells per unit volume when compared to a bedside centrifuge machine that the majority of physicians outside of Regenexx use. These stem cells are then injected using precise image guidance (both live ultrasound and Xray) into injured or weak tissue to rebuild, repair, or mitigate the effects of the injury. When used in a skilled way, the joint will become more stable, less inflamed, and more functional. Our extensive research protocols using MSCs derived from bone marrow have shown excellent outcomes in treating most orthopedic injuries. We believe that at least 70% of all orthopedic surgeries can be replaced with this less invasive, safer strategy.



"My surgery for a lumbar spine fusion was scheduled and I was dragging my right leg due to an accident...then I found Regenexx. I had PRP on my lower back in February of 2017. By July I was playing pickleball and riding my mountain bike. After that, I also had the same-day stem cell procedure on my wrist due to an old injury that had turned into arthritis and limited me significantly. Twelve months later I am back throwing the football with my grandson" — B.J.

- Culture Expanded Stem Cells We practice the <u>culture expansion (growth) of stem cells</u> into larger quantities at our licensed site in Grand Cayman. This technology is used in select patients who have more severe orthopedic conditions, patients who want to treat multiple joints, and/or for patients who want to store and save cells for future treatments (stored at their current age). This procedure is not US FDA-approved, but is the subject of an FDA-approved phase 2 clinical trial and is permitted in Grand Cayman as the practice of medicine. A small number of Regenexx physicians (including at Regenexx Tampa Bay) are licensed to practice in the Cayman Islands and perform this advanced treatment.
- Adipose-Derived Stem Cells In some cases, adipose or fat-derived stem cells can be used effectively as a part of a larger treatment plan for orthopedic injuries to create a fat graft that supports and holds in place other structures allowing them to heal appropriately. In the U.S, adipose derived stem cells (which requires advanced laboratory techniques) are FDA regulated as a drug and therefore require clinical trials for approval. This has not been done to date. However, adipose tissue that has been "minimally manipulated" can be used as an adjunct or a stand-alone injectable material, but to be clear, this is NOT really a "stem cell" procedure.

 Platelet-Rich Plasma - Platelet-rich plasma (PRP) is created by concentrating the platelets in your blood to enhance healing. These platelets have growth factors that can jump-start your normal healing process and encourage your body to heal itself. Our proprietary lab processing allows us to create customized and individualized products based on your unique issues to maximize the repair process. We refer to Regenexx PRP as SCP (super concentrated platelets). The difference between Regenexx's PRP and most other PRP is visible. Standard fare PRP is reddish in color because it still contains a significant number of red blood cells. Regenexx's PRP is amber in color due removal of the harmful red blood cells and also due to its higher concentration of growth factors that can be customized from 2-20 times above what a basic centrifuge machine can produce. Our outcomes have demonstrated that this super-concentrated PRP produces better tissue healing in tendon injuries and better stimulation of the local stem cells to promote healing.



"I want to offer your team of professional staff and most particularly, to esteemed Dr. Leiber, my profound and most sincere gratitude. It is from your services and caring that I am now finding my pathway to a new lease on wellness. Dr. Leiber's outstanding and impeccable knowledge and gifts of stimulating self-healing have been the spark to ignite my body's much hoped for self-repair and renewal abilities. I am indebted to your services and look forward to upcoming and all future treatments!" — J.O.

- Platelet Lysate Platelet lysate is a highly specialized derivative of PRP. Normal PRP isolates platelets from the blood while slowly releasing growth factors into the site of the injury over the course of approximately one week. Our research shows that in some cases, a faster, more intense release of healing factors creates an improved healing response. By stripping all of the growth factors from platelets and making them available for immediate use, platelet lysate accomplishes this goal. As we have learned better ways to encourage the fast release of growth factors over the years, Regenexx's proprietary platelet-lysate processing technology is now on its fifth generation. There are times we combine Platelet Lysate with SCP to get both a fast and slow release of growth factors at the same time.
- **Cytokines** While there is not nearly as much long-term research regarding cytokines, the initial results are promising. Regenexx uses Alpha 2 Macroglobulin (A2M), a cytokine that reduces inflammation and removes from tissues certain chemicals that have been shown to be destructive to cartilage. A2M is derived from a different part of your blood than PRP and shows tremendous promise as a means of treating or preventing osteoarthritis. Regenexx continues to lead the way in researching new ways to better use the body's natural healing agents to treat orthopedic injuries.

• Extra-cellular Matrix (ECM) - An extra-cellular matrix is best described as a scaffold on which cells can grow. We use an ECM that is derived from amniotic membrane that contains proteins and growth factors. We believe that this matrix can help platelets or stem cells in certain clinical scenarios such as tendon repair. It should be noted that the amniotic ECM product is NOT a stem cell procedure. This is commonly <u>fraudulently</u> <u>advertised</u> as a stem cell product by providers outside of the Regenexx network. No living stem cells are found in these products and if they did contain any, they would be required to obtain FDA approval – which has yet to occur.

Why Non-surgical Regenerative Orthopedics is The Best Alternative to Surgery

The Benefits of Regenexx Stem Cell and PRP Therapy

 Expertise - Regenexx selects physicians through a competitive and selective process. Only highly trained musculoskeletal specialist physicians are considered for entry into the Regenexx network.
After approval, the physician must receive further training on imageguided precision techniques through the Interventional Orthopedic Foundation's intense multi-level curriculum before being certified to perform Regenexx procedures for any given body area.



• **Quality** - Not all regenerative products are created equally. Every Regenexx location has an on-site orthobiologics lab to generate superior substances. Our proprietary lab-processing techniques allow us

to achieve much higher concentrations of cells than can be achieved with a typical bedside centrifuge. On-site lab processing allows us to create custom individualized orthobiologic solutions from your cells to treat your specific injury in order to achieve the best results.

- **Precision** Precise image guidance allows us to target the exact location of an injury. The importance of this can not be overstated. This meticulousness allows for far more consistent and sophisticated treatments that are safer with better clinical outcomes than would be available without image guidance.
- **Minimal Risk** These needle-based techniques are the foundation of a tissue preservation strategy that strengthens tissue and avoids the side effects of surgical procedures which involve cutting, scraping, burning, and removing tissue. It's high finesse, lower risk, and eliminates the risk of developing scar tissue.
- **Minimal downtime** Recovery from an Interventional Orthopedic procedure is much quicker than a surgery and allows you to get back on your feet, back to work, and back to the activities you love faster.

Reference» Proven Results and Patient Outcome Data

Overview Of Our Stem Cell And PRP Procedures

Regenexx procedures are the world's most advanced stem cell and blood platelet procedures for treating orthopedic injuries, arthritis and other degenerative conditions. Before, during, and after your procedure, our exceptional staff works to provide a comfortable, personalized experience to each of our patients to determine the best course of action and help facilitate the entire healing process.

The first step in this process is to schedule and attend a New Patient Evaluation. This is an hour-long personalized consultation with one of our physicians. During this evaluation, our goal is to ensure that we fully understand what you are experiencing and so that you can make an informed decision regarding your treatment.

Related Article» 9 Ways to Enhance Your Stem Cells Before Treatment

Stem Cell

The Regenexx stem-cell protocol is called a same-day procedure because the stem cells are harvested and reinjected on the same day. For most patients, however, the recommended protocol is a series of injections of different orthobiologics that happens over the course of about a week depending on each unique situation. These injections include a prolotherapy pre-injection, the same-day stem-cell extraction and re-injection procedure, and a blood draw and post-injection of multiple Regenexx's proprietary platelet-rich plasma concentrations. This process applies to procedures for the knee, hip, shoulder, hand, wrist, foot, ankle, elbow, and spine though there are times where we will recommend only the same-day bone marrow extraction and reinjection procedure without the pre or post-injections.



"When I came to see Regenexx Tampa Bay, I was so upset that none of my previous doctors could come up with any solution that might help me to become more mobile again and decrease my pain level. When I came for my first appointment, I was met with respect, concern, and possibilities. Between the stem cell procedure and several platelet procedures in both legs, I am fully functional and, for the first time in 2.5 years, I was able to travel once again to Honduras (in 95-degree heat, on my feet 8 hours a day and loving over 200 children a day.)" — J.H.

- First Appointment (Pre-injection) Your first visit involves an injection of a special hypertonic dextrose solution that creates a mild inflammatory environment that is conducive to healing. The purpose of this part of the procedure is to cause the same kind of acute inflammation that might occur during an injury. The pre-injection initiates your body's own healing process and prepares your joints for the reinjection of your stem cells. To use a farming metaphor, this step is like tiling the soil. Your first visit will take between 30 and 60 minutes.
- Second Appointment (Bone Marrow Aspiration (BMA) This appointment will last approximately 40 minutes. During this procedure, you will lie on your stomach on the procedure table where a local anesthetic will be applied. The physician will then draw bone marrow from the back of your iliac crest using precise image guidance. The doctor will usually draw the marrow from the back of the pelvis on both sides. Some patients will be given an oral sedative and pain medication to help to ease anxiety, relax the muscles, and dampen the pain prior to the bone marrow draw. The bone marrow aspiration process is often described by patients as being only mildly uncomfortable and is typically well tolerated. It is essential to fast (no food or caffeine; water only) for 3 hours prior to this procedure.
- Third Appointment (Re-injection) This is the second injection in a series of three and typically takes 1 2 hours. Your re-injection appointment will take place approximately 2 5 days after your pre-injection and takes place between three and eight hours after the bone marrow aspiration. Local anesthesia is used to numb the area being treated. If we are treating an extremity (shoulder, elbow, knee, ankle, foot), you may be offered a nerve block. Your stem cells will be injected using real-time imaging guidance (ultrasound or fluoroscopy) to ensure your cells are injected precisely where needed.
- Fourth Appointment (Blood Draw) The blood draw is scheduled for the morning of your post-injection and takes approximately 15-20 minutes. The blood is used to prepare your post-injection.
- Fifth Appointment (Post-injection) This your final injection in a series of three and will take about 15-30 minutes. The post-injection appointment takes place 2 5 days after the stem cell re-injection. The post injection is a combination of super-concentrated platelets (SCP) and platelet lysate (PLM), which are derived from your own blood. It is created in our on-site orthobiologics lab by a skilled technician who can include more of the blood components that encourage and support healing while removing other components that



"I am a retired 59-year-old male. In the early years of this decade, I started having pain associated with my right shoulder. At first, I selfmedicated with a combination of Advil and Extra Strength Excedrin. Recently my PC Physician referred me to Regenexx Tampa Bay. After performing the appropriate tests, Dr. Leiber recommended PRP Injections. Four months have now passed since the injections and appropriate therapy. My shoulder is now pain-free and I am no longer taking any pain relief medication." — K.S. cause unnecessary inflammation and discomfort. These growth factors aid and stimulate the re-injected stem cells to enhance the healing process. Local anesthesia is used to numb the area being treated.

• **Post-Procedure** - The stem-cell injection produces a micro-injury in the joint. As a result, expect the joint to be sore for two to three days. Your physician may prescribe pain medicines that will not hinder the healing caused by the procedure. Patients can additionally take Tylenol but are asked to avoid NSAIDs. The goal is to allow the stem cells to attach and then to protect them while they differentiate into various tissues. For this reason, you will be asked to keep the joint as still as possible for 30-60 minutes after the procedure. Do not take a bath for three days, but a shower 12 hours after the procedure is fine. For the first few days after, you should limit activity on the joint. Wear all recommended braces or boots. Most patients report a modest improvement in the 6-8 weeks. You will notice that as time goes on your pain that occurred before is less severe and frequent. Most patients are able to resume light activities after 5 to 7 days. Usually, at 6 to 8 weeks patients begin to resume a more vigorous exercise schedule. Most of our very active patients are able to return to their regular routine in 6 weeks and push their performance to higher levels in 8 to 12 weeks. Improvements will continue throughout this time period. Most patients notice continued healing over many months. Our outcome data suggests peaking at 1-2 years out. Results vary by patient and depend on the condition of the area treated age, and general health.

PRP

For most patients, the recommended SCP or PL protocol involves a blood draw and an injection on the same day. This process applies to procedures for the spine, knee, hip, shoulder, hand, wrist, foot, ankle, and elbow. Also, Platelet Lysate is often recommended for back and spine treatments that include injections around nerves in the epidural space.



- **Procedure Day** On your procedure day, blood is drawn from a vein in your arm typically in the morning. This blood is then processed and prepared in our lab for re-injection within 24 hours. We use this blood to prepare an injection of highly concentrated platelet-rich plasma containing the growth factors isolated from your blood. This blood draw takes 15-20 minutes. During your second appointment of the day, this platelet-rich plasma is injected under precise image guidance into the treatment site. Local anesthesia is used to numb the area being treated. If we are treating an extremity (shoulder, elbow, knee, ankle, foot), you may be offered a nerve block. This procedure takes approximately 1 hour.
- **Post-Procedure** We suggest moving the joint around gently multiple times within hours after the injections to disperse the platelet derived injection or prolotherapy throughout the tissues. This seems to decrease the amount and duration of pain from the injections. Also, avoid excessive activity in the hours after injection. Anticipate moderate to significantly increased pain and stiffness for the first 2-3 days following your procedure as the Regenexx SCP and PL injections also produce a micro-injury in the joint. Your physician may

prescribe pain medicines that will not hinder the healing caused by the procedure. Patients can additionally take Tylenol, but are asked to avoid NSAIDs. You may have swelling in the treated joint(s). After this short period of time, we anticipate a gradual decrease in soreness and return to baseline over a period of 1-2 weeks. We suggest waiting 6-8 weeks before returning to full strength activities unless instructed otherwise by your physician.

In general, we always try to look at more than one injured part. As a result, it's very likely we will recommend other types of conservative care to restore normal biomechanics. This might include physical therapy, different types of myofascial release, or specific home exercises. Our physicians work with professional therapists who have years of experience in understanding the needs of a regenerative medicine patient.

Note» Results typically become apparent over 1-3 months but sometimes can take as long as 6-9 months.

We understand that you want to get back to normal as soon as possible. All of our procedures are designed to promote as much early activity as possible, here is a general guide to when you can return to normal activity:

- Bone healing procedure (for fracture nonunion or avascular necrosis) You must be off the area on crutches until the pain from the procedure subsides. You can then move toward slowing increasing activities over the next few weeks. Total time off the area for most patients is 1-3 weeks with returning to normal activities at about 6 weeks. The only exception is when there is an existing rod or plate stabilizing the fracture site, in these cases you will be allowed more activity more quickly.
- Joint procedure For joints with cartilage loss, low impact activities would be encouraged within one week after the procedure. Full high impact activities would be expected to return at 6-8 weeks.
- Partial tendon/ligament/muscle tear Low impact activities would be encouraged immediately after the procedure. Full high impact activities would be expected at approximately 6-12 weeks.

Note» Some of our patients will require a second or even third procedure. Our usual protocol involves 1-3 injection cycles, but the majority of our patients get a single procedure.

Areas That Can Be Treated

Regenexx procedures can strengthen and heal damage to bone, muscle, cartilage, tendons, ligaments, and some nerves anywhere in your body. Our customized treatment protocols use your body's own healing agents to repair orthopedic injuries without surgery.

Shoulder

- Rotator cuff tears
- Shoulder arthritis
- Labrum tears
- Loose or torn ligaments

Elbow

- Tennis elbow
- Golfer's elbow
- Elbow arthritis
- Biceps tendon tears

Spine

- Low back pain
- Neck pain
- Sacroiliac joint pain or instability
- Bulging/herniated/torn disc
- Continued pain after lower back or neck surgery
- Arthritis
- Atrophied muscles
- Instability
- Pinched nerve/sciatica
- Spinal stenosis
- Spondylolysis

Hip

- Osteoarthritis
- Labral tears
- Tendon tears or sprains

Other Conditions

- Non-union fractures
- Osteonecrosis/Avascular necrosis
- TMJ syndrome

Hand & Wrist

- Carpal tunnel syndrome
- TFCC tear
- Thumb or finger arthritis
- Trigger finger
- Tendon or ligament tears, sprains, or strains

Knee

- ACL, PCL, MCL, LCL tears or sprains
- Osteoarthritis
- Meniscus injuries
- Patellafemoral syndrome

Foot & Ankle

- Ankle arthritis
- Plantar Fasciitis
- Toe arthritis
- Ankle tendon or ligament
- tears, sprains, or strains

Potential Complications

Our complications to date have been in the mild to moderate category and rare (using the HHS OHRP guidelines for complications reporting). This categorization means that either the complication (i.e. transient swelling) required no medical treatment (mild), or if it did require medical treatment, the treatment was simple. Regenexx has published the world's largest safety and complications tracking study to date of adult stem cell use in patients. This study did not show any serious stem cell related complications and did not show that any patient developed stem cell-related cancer. In our opinion, infection is the most dangerous complication, but Regenexx has the longest safety profile in the market and we always take proper precautions to prevent this during our procedures.

Is Interventional Non-surgical Regenerative Orthopedics Right For You?

It almost always makes sense to start with a less invasive and safer approach to a chronic, non-life threatening orthopedic pain-related condition. Anyone, at any age can be a candidate for a Regenexx procedure as long as they have an orthopedic condition that is keeping them from doing the activities they want to do.

The likelihood of success will vary to some extent based on age, the severity of the condition, general health, other medical conditions, medications, nutrition, environmental chemical exposure, sleep, stress, etc.

Even in situations where certain factors may decrease your likelihood of a positive outcome (such as chronic use of certain medications that interfere with healing such as prednisone), there may be options and advice that the doctor can provide to improve your chances to the point that it would be worth a try.

This is why it is so important to have a thorough consultation with a Regenexx Tampa Bay doctor to look at your specific situation and provide you with an individualized and collaborative recommended plan of care.



"I have been a ballerina and an acrobat for most of my life. Forty years later I was hurting when I tried to do basic things such as putting my socks and shoes on, walking, and teaching tap-dance classes (which I loved). I had been diagnosed with advanced hip arthritis and was told that a hip replacement was my only choice. I was scheduled for surgery but resisted. I knew people whose lives were ruined after such surgery. After doing my research, I found Regenexx Tampa Bay and had the stem cell procedure more than a year ago. Now, I can pretty much do whatever I want. I am so thankful to feel I've recovered without surgery thanks to Regenexx!" — R.L.

Regenexx Tampa Bay

Regenexx Tampa Bay is Florida's premier and most experienced non-surgical regenerative medicine center. We are proud to offer the nation's most advanced orthopedic stem cell treatments for injuries and arthritis. Our procedures increase function, decrease pain, and offer the patient viable alternatives to invasive surgery typically followed by lengthy periods of downtime and painful rehabilitation. Interventional regenerative orthopedics is our primary focus.



James Leiber, DO <u>Physician Bio</u>



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<u>Is Regenexx Right For You?</u> Find out if you are a candidate.

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