

Regenexx Glossary

This glossary provides detailed definitions for terms frequently used in regenerative orthopedic medicine. Use this glossary as a guide to better understand common and specialized words and phrases including: “stem cell”, “orthobiologics”, “minimal manipulation”, “bone marrow concentrate”, “platelet-rich plasma”, and more.

Adult Stem Cells

Stem cells found in the adult human body, as opposed to those removed from embryos. When applicable, Regenexx procedures exclusively involve adult stem cells, and none involve embryonic stem cells.

Allogeneic

From one human into another. Off-the-shelf “stem cell” products are allogeneic, as they are typically derived from donated birth tissue prior to being packaged, shipped to the doctors who use them, and then injected into patients. All allogeneic “stem cell” products are required to be approved by the FDA before being administered to patients in the United States.

Amniotic Fluid

The fluid which surrounds the fetus while in utero. Amniotic fluid is often processed, packaged, and sold as an injectable product in the United States, with claims that contains stem cells. However, in the absence of FDA approval, the FDA treats amniotic fluid products as adulterated and misbranded, and therefore unlawful. Regenexx does not use amniotic fluid in any of its procedures. Additionally, numerous studies have shown that amniotic fluid products contain no stem cells.

Autologous

The implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered. See Code of Federal Regulations: 21 C.F.R. § 1271.3(a). The Regenexx procedures exclusively involve the use of autologous (“your own”) cells and tissue, which reduces patient safety risks and supports regulatory compliance.

Blind Injection

An injection into the body without image guidance. When patients have mild orthopedic conditions, like carpal tunnel syndrome, a doctor may “blindly” inject the patient with cortisone (or similar injectables) within the standard of care. However, for more complex conditions, or when more complex areas of the body are involved, doctors should use image guidance tools like ultrasound and fluoroscopy. All the Regenexx procedures involve image guidance for the most accurate administration of orthobiologics possible.

Bone Marrow Concentrate

Bone marrow concentrate (or “Concentrated Bone Marrow” or “Bone Marrow Aspirate Concentrate” or “BMAC”), is a concentrated form of autologous bone marrow. Bone marrow concentrate is the result of centrifuging bone marrow to obtain a smaller volume which is more highly concentrated with cells and growth factors and therefore more useful as an injectate.

Clinical Trial

A clinical trial, also known as a clinical investigation, is a research study in which people (“subjects”) volunteer to help find answers to specific health questions. Most often, the term “clinical trial” is associated with the development of new drugs and biological products in the United States, as the FDA typically requires product sponsors to test their products through multiple phases of clinical trials in order to establish safety and effectiveness. Clinical trials are a critical part of the drug development process, but by nature carry risks all potential “subjects” should understand. First, the new drugs and biological products being researched in clinical trials have not yet been proven safe and effective, as that “proof” will only be established once the clinical trial is complete. Second, in many clinical trials, product sponsors are required to establish that their new drug or biological product is superior to a placebo, so subjects might receive the placebo instead of the product being studied and not be told which they received. Third, product sellers often use the term “clinical trial” as sales jargon to induce patients to purchase their unapproved product, so it is important for potential subjects to participate only after they have a full understanding of the entire process and the risks that may be involved.

Concentrate

(verb) To increase the density of a substance, or (noun) the product which results from concentration. Regenexx physicians “concentrate” blood and bone marrow to obtain smaller volumes that are denser with cells and growth factors, thereby making them (for instance, bone marrow concentrate) more useful as orthobiologic injections.

Cord Blood Stem Cells

Cord blood stem cells are collected from the umbilical cord and placenta after a baby is born, as cord and placental blood contain large numbers of blood-forming stem cells. In the United States, cord blood stem cells are often employed in the treatment of complex conditions, such as leukemia and lymphoma, within the standard of care. Those cord blood stem cell products are either approved by the FDA or being studied in an authorized clinical trial and manufactured and used in highly regulated environments. However, unscrupulous sellers also sell unapproved cord blood stem cell products as orthobiologic injectates, which has led to well-documented public health crises and FDA warnings and consumer alerts.

Culture Expanded

Culture expansion is the process of multiplying cells over the course of days or weeks by exposing them to natural growth factors in a laboratory. Culture expansion allows the treating physician to obtain a greater quantity of cells for injection into the patient, which can be useful when treating larger areas of the body, such as the hip, or more complex conditions, such as avascular necrosis.

Embryonic Stem Cells

Embryonic stem cells are stem cells from discarded embryos. Historically, embryonic stem cells have been associated with a wide range of safety and ethical concerns and are not available to patients in the United States. Regenexx procedures do not use embryonic stem cells.

Exosomes

Exosomes are nanoparticles secreted by cells that contain nucleic acids, proteins and lipids. Products marketed as “exosomes” typically result from the chemical treatment of cells and are therefore treated as “more-than-minimally-manipulated” by the FDA and subject to FDA’s approval requirements. Regenexx does not use exosome products due to their unknown health risks and non-compliant regulatory status.

FDA

The United States Food & Drug Administration. For more information on how FDA's regulations apply to Regenexx's suite of orthobiologics procedures, please visit our [FAQ page](#).

FDA-approved

Medical products which have been explicitly "approved" by FDA.

Fluoroscopy

Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie. During a fluoroscopy procedure, an X-ray beam is passed through the body. The image is transmitted to a monitor so the movement of a body part or of an instrument or contrast agent ("X-ray dye") through the body can be seen in detail. Fluoroscopy is one of the two types of image guidance used by Regenexx physicians to precisely administer autologous bone marrow and blood to patient injuries.

Growth Factors

Natural proteins which allow cells to multiply.

HCT/P

Human cells, tissues, or cellular or tissue-based products. See Code of Federal Regulations: 21 C.F.R. § 1271.3(d). HCT/Ps include human cells and tissues that are used as medical products in human patients, whether autologous or allogeneic, but do not include autologous blood and bone marrow when used in the Regenexx procedures.

Homologous Use

The repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. See Code of Federal Regulations: 21 CFR § 1271.3(c). In 2018, Regenexx's founder, Dr. Christopher Centeno, and more than thirty other nationally recognized physicians collaborated on a published [study](#) concluding that bone marrow concentrate is "homologous" when used in orthopedics, as it behaves similarly to in vivo bone marrow which the body naturally releases when bones, joints or tendons are injured.

Image Guided

All Regenexx procedures involve “image guided” injections of concentrated blood and/or bone marrow. Image guidance leads to more precise injections, which are critical for the proper administration of orthobiologics. Fluoroscopy and Ultrasound are defined elsewhere in this glossary.

Interventional Orthobiologics

Interventional orthopedics is a growing medical specialty involving the image-guided injection of orthobiologics (defined below) as an alternative to orthopedic surgery. Regenexx’s Interventional Orthobiologic procedures exclusively involve concentrated blood and bone marrow because they are well understood and comply with state and federal law.

Interventional Orthopedics

Interventional orthopedics involves the injection of drugs, lubricants, and other injectates into injured areas of the body as an alternative to surgery. Commonly used injectates in interventional orthopedics include hyaluronic acid, epidurals, and steroids. More recently, the concept of interventional orthopedics has expanded to include interventional orthobiologics, which involves the injection of orthobiologics (defined below) to address musculoskeletal injuries.

Mesenchymal Stem Cells

Mesenchymal stem cells (or “MSCs”) are multipotent stem cells found in bone marrow that are important for making and repairing skeletal tissues, such as cartilage and bone. Mesenchymal stem cells can differentiate into a variety of cell types, including osteoblasts (bone cells), chondrocytes (cartilage cells), myocytes (muscle cells), and adipocytes (fat cells which give rise to marrow adipose tissue).

Minimal Manipulation

FDA regulations provide two meanings for “minimal manipulation” depending on the tissue involved. For structural tissue, such as bone or fat, minimal manipulation means “processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement.” For non-structural tissue and cells, minimal manipulation means “processing that does not alter the relevant biological characteristics of cells or tissues.” See Code of Federal Regulations: 21 CFR § 1271.3(d)(4). If an HCT/P is “more than minimally manipulated,” FDA requires that it be FDA approved.

Orthobiologics

Orthobiologics is a broad category of medical products and procedures involving the use of biological materials for the treatment of orthopedic conditions.

Platelets

Cell fragments that circulate in the blood and also contain exosomes and growth factors.

Platelet Lysate

Platelet lysate (PL) is a specialized derivative of platelet-rich plasma (PRP), which is subject to additional concentration that allows blood platelets to open and immediately release their natural growth factors at the area of injection. Normally, PRP isolates platelets from the blood which slowly release growth factors into the site of the injury over the course of roughly one week. In some cases, however, our research shows that a faster, more intense release of the blood's factors creates a better healing response, making Platelet Lysate the preferred orthobiologic. Platelet Lysate is often recommended for back and spine treatments due to its fast release and reduced inflammation but is also available for treatments involving the knee, hip, shoulder, hand, wrist, foot, ankle, and elbow.

Platelet Rich Plasma ("PRP")

PRP is autologous blood which centrifuged to obtain a sample that is highly concentrated with the blood's natural cell and growth factor populations. The smaller, denser portion of concentrated blood is better suited for orthobiologics' procedures than blood in its original state, half of which is water. PRP injections can have a stimulating effect on the repair cells within the targeted area, making those cells work harder to perform their natural job of healing the body.

Prolotherapy

Prolotherapy involves the injection of saline or sucrose into the injured area of the patient's body to promote natural healing. Generally, prolotherapy signals to the body that a particular tissue needs attention, which promotes the migration of immune cells and healing agents.

Regenexx SCP

A non-surgical procedure developed and used by Regenexx which involves autologous “super concentrated platelets,” otherwise called “highly concentrated PRP.” Regenexx’s proprietary lab processing removes nearly all white and red blood cells from the autologous blood sample, resulting in a greater opportunity for your body to improve in pain and function, with less inflammation and swelling. The difference between Regenexx SCP and other varieties of PRP is visible. While PRP is reddish in color because of its higher red blood cell count, Regenexx’s SCP is thicker and more amber in color due to its higher percentage of cells and growth factors.

Regenexx SD

A non-surgical procedure developed and used by Regenexx involving the “same day” concentration and administration of highly concentrated bone marrow (see, Bone Marrow Concentrate, above). Regenexx SD treatments may also involve separate injections over the course of weeks or months, depending on the specific needs of the patient.

Regeneration

Repairing or growing new tissue.

Regenerative Medicine

The use of orthobiologics to trigger the body’s natural regeneration capabilities.

SANS

Stability, Articulation, Neurologic, Symmetry. This system was developed by Regenexx’s founder, Christopher Centeno, M.D., and first introduced as a concept in the book “Orthopedics 2.0”. SANS is a method of treatment involving orthobiologics for musculoskeletal injuries.

Stem Cell

Click [here](#) for Regenexx’s interpretation of the term “stem cells,” including how that term is used colloquially, how it has changed over time, and how actual stem cells are involved in the Regenexx procedures.

Ultrasound

Diagnostic ultrasound, also called sonography or diagnostic medical sonography, is an imaging method that uses sound waves to produce images of structures within your body. Ultrasound is one of two types of image guidance used by Regenexx physicians to precisely administer blood and bone marrow to patient injuries.