

# INFORMED CONSENT FOR VENIPUNCTURE FOR L-PRF/PRGF Growth Factor Preparation using the patient own blood

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You have the right to be given information about your proposed soft tissue graft so that you are able to make the decision as to whether to proceed with surgery. What you are being asked to sign is confirmation that you have been given information on the nature of your proposed treatment, the known risks associated with it and the possible alternatives.

## PLEASE ASK IF YOU HAVE ANY QUESTIONS BEFORE SIGNING THIS DOCUMENT

#### **EXPECTED BENEFITS**

Bloods contains cells such as white and red blood cells and platelets, all of which have important functions. Platelets are the key cells in wound healing due to their role in clot formation and the release of signaling molecules called cytokines, while white blood cells, called leukocytes, have an important role in infection control and inflammation. Medi-fuge, a dedicated medical centrifuge, is designed to prepare Leukocyte and Platelet Rich Fibrin (L-PRF) or Plasma-Rich Growth Factor, a high-density fibrin network with a high concentration of leukocytes and platelets, and with autologous concentrated growth factors, using a patient's own blood with the purpose of reinforcing the natural process of healing in a surgical or wounded site.

Between 10 and 50 mL (up to 3.3 tablespoons) of blood will be used During blood collection, you will experience the discomfort of a needle prick. Localized bruising may occur where the blood was taken (venipuncture site). Some individuals feel temporary lightheaded at the sight of blood; this passes quickly. There is a small risk of infection and nerve damage at the venipuncture site.

venipuncture site.	
DATE:	
PATIENT NAME:	
SIGNATURE	

# PLATELET RICH PLASMA/FIBRIN/PLASMA-RICH GROWTH FACTOR For DENTAL PROCEDURE

We hope to provide our patients with established technology that accelerates the healing process in the most natural way possible. We aim to improve our surgical technique and provide you with the very best results possible. We deploy the latest techniques of the rapidly advancing biotechnical world.

The latest advancement involves understanding how our own body's natural growth factors help to accelerate the healing process and is currently being applied in our oral reconstruction procedures. The technique involves the use of very specific healing factors found in our bloodstream and more specifically in our blood cells or platelets.

Platelet Rich Plasma (PRP) is a volume of autogenous (your own) plasma that has a platelet concentrate above the body's normal baseline. Normal platelet values in the blood range from 150,000 to 400,000/ml. Today, scientific proof has unequivocally demonstrated dramatically enhanced bone and soft tissue healing using Platelet Rich Plasma with concentrations of 1,000,000. Until now, the use of PRP has been confined to the hospital setting. This was due mainly to the cost of separating the platelets from the blood and a large amount of blood needed to produce a suitable quantity of platelets. Our office now possesses the technology to harvest, process, concentrate and deliver these growth factors directly to our operative sites. This technique represents the latest in bio-tissue engineering and cellular therapy and has been perfected over the past ten years. Now, our office can harvest and produce a high-quality concentrate of platelets from blood drawn directly from our patients while they are undergoing outpatient surgery.

What is Platelet Rich Plasma/Growth Factors (aka PRP or more specifically Autogenous Platelet Concentrate, and we emphasize autogenous which refers to your own)?

PRP permits the body to take advantage of the normal healing pathways at a greatly accelerated rate. During the healing process, the body rushes many cells and cell-types to the surgical site in order to initiate the healing process. One of those cell types is platelets. Platelets are carriers of proteins specifically involved in the regeneration of injured tissues; these proteins are termed Growth Factors. Platelets perform many functions, including the formation of a blood clot and ultimately the release of growth factors (GF) into the wound. The GF (platelet-derived growth factors PDGF, transforming growth factor beta TGF, vascular endothelial growth factor, epithelial growth factor and insulin-like growth factor ILGF) function to assist the body in repairing itself by stimulating stem cells to regenerate new tissue. The more growth factors sequestered and released into the wound; the more stem cells stimulated to produce new host tissue. Thus, it has been demonstrated that PRP permits the body to heal more rapidly and more efficiently.

One of the above growth factors (TGF), contains a sub-family of growth factors that is valuable in our bone grafting procedures. This factor is bone morphogenic protein (BMP), and it has been shown to induce the formation of new bone when concentrated around living bone cells (osteoblasts). This is

of great significance when it is used in conjunction with the placement of dental implants. By adding PRP, and thus BMP, to the implant site with autogenous (your own) bone cells, we can grow bone more predictably and faster than ever before. This enables us to place implants in areas of the mouth that may not have been previously possible

[Platelet Rich Plasma/Plasma Rich Growth Factor] has many clinical applications:

- Bone grafting for dental implants. This includes onlay and inlay grafts, sinus lift procedures, ridge augmentation procedures, and closure of cleft lip and palate defects.
- Repair of bone defects created by removal of teeth or small cysts
- Repair of fistulas between the sinus cavity and mouth

[Platelet Rich Plasma/Plasma-Rich Growth Factor] has many advantages:

- Safety: PRP is a by-product of our patient's blood; therefore, disease transmission is not an issue.
- Convenience: PRP is processed in our office, under strict sterile conditions, simultaneously while the patient is undergoing an outpatient surgical procedure, such as the placement of dental implants. The patient's own blood is removed at the time of preparation of the IV site for general anesthesia.
- Faster healing: The super saturation of the wound with PRP, and the described growth factors, produces an increase of tissue synthesis and thus faster tissue regeneration.
- Cost-effectiveness: Since PRP harvesting is performed with only a small portion of blood in the doctor's office, the patient need not incur the expense of the harvesting procedure in the hospital or at the blood bank.

## Frequently asked questions about PRGF/PRF:

**Is PRP/PRGF safe?** Yes. During the outpatient surgical procedure, a small amount of blood is drawn out via the IV. This blood is then placed in a specially designed centrifuge machine (Harvest Technologies Corporation) and processed under the strictest guidelines. In less than fifteen minutes, the Platelet Rich Plasma is formed and ready to use.

How long has PRP been in use? As an adjunctive hospital procedure, application of PRP has been in use for about a decade by Oral Surgeons, Plastic Surgeons, Orthopedic Surgeons and Cardiovascular Surgeons.

Why hasn't it been used in an office sooner? Until recently the technology to accurately produce the concentrate was not available in private practice. The process was complex, time-consuming,

expensive, and required large volumes of the patient's blood. It involved outside personnel and the transfusion of blood products. Furthermore, through research we have discovered that it is not enough to merely concentrate platelets but equally as important, we must concentrate them and produce a quality concentrate. Normal centrifugation will concentrate platelets, but it destroys the integrity of the platelets rendering them useless.

How then is the PRP/PRGF produced in your office? At the same time, we begin our general anesthesia IV line we withdraw a small portion of your blood. This blood is then processed in a specialized centrifuge (designed by Harvest Technologies Corporation) that spins and automatically separates the red blood cells from the plasma. Then, using a double centrifuge technique, the plasma is further processed, and an autologous platelet concentrate and its active growth factors are produced. The entire process takes only 15 minutes and is completed simultaneously while we are treating you surgically!

**Can PRP be used alone to stimulate bone formation?** No. PRP must be mixed with your own bone or allograft for the most beneficial effects

**Are there any contraindications to PRP?** Very few; patients with bleeding disorders or blood diseases do not qualify for this in-office procedure.