

PLATELET RICH PLASMA PRP CONSENT FORM

Tele:

PLATELET RICH PLASMA

Information Sheet and Informed Consent

It is important that you read this information carefully and completely

THE TREATMENT:

Platelet Rich Plasma, or also known as “PRP” is an injection treatment whereby a person's own blood is used. A fraction of blood (10cc-55cc) is drawn up from the individual patient into a syringe. This is a relatively small amount compared to blood donation which removes 500cc. The blood is spun down in a special centrifuge (*according to standard Harvest Techniques*) to separate its components (Red Blood Cells, Platelet Rich Plasma, and Plasma.) The platelet rich plasma is first separated then activated with a small amount of calcium to allow the release of growth factors from the platelets which in turn amplifies the healing process. PRP is then injected into the area to be treated. Platelets are very small cells in your blood that are involved in the clotting process. When PRP is injected into the damaged area it causes a mild inflammation that triggers the healing cascade. As the platelets organize in the clot they release a number of enzymes to promote healing and tissue responses including attracting stem cells to repair the damaged area. As a result new collagen begins to develop. As the collagen matures it begins to shrink causing the tightening and strengthening of the damaged area. When treating injured or sun and time damaged tissue they can induce a remodeling of the tissue to a healthier and younger state. The full procedure takes approximately 45 minutes - 1 hr. Generally 2-3 treatments are advised, however, more may be indicated for some individuals. Touch up treatment may be done once a year after the initial group of treatments to boost and maintain the results. Smokers have less response to this treatment because the toxins in smoke block the response of the stem cells.

PRP has not been FDA approved for this use.

ALTERNATIVE TREATMENTS: Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments: laser treatments, chemical skin-peels, dermabrasion, or other skin procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are also associated with alternative forms of medical or surgical treatment.

CONTRAINDICATIONS: PRP used for aesthetic procedures is safe for most individuals between the ages of 25-80. There are very few contraindications, however, patients with the following conditions are not candidates: 1) Acute and Chronic Infections 2) Skin diseases (i.e. SLE, porphyria, allergies) 3) Cancer 3) Chemotherapy 4) Severe metabolic and systemic disorders 5) Abnormal platelet function (*blood disorders, i.e. Haemodynamic Instability, Hypofibrinogenaemia, Critical Thrombocytopenia*) 6) *Chronic Liver Pathology* 7) Anti-coagulation therapy, 8) Underlying Sepsis, 9) Systemic use of corticosteroids within two weeks of the procedure, and 10) pregnant or breastfeeding.

RISKS & COMPLICATIONS: Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences of facial filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The long term effect of facial fillers beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of facial filler as a soft tissue filler may be discovered.

Bleeding and Bruising: It is possible to have bleeding during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba and other “herbs / homeopathic remedies” may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before or after PRP injections.

Swelling and Redness: Swelling (edema) is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary. **Pain:** Discomfort associated with injections is normal and usually of short duration. Visible needle marks from the injections occur normally and resolve in a few days.

Infection: Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.

Drug and Local Anesthetic Reactions: There is the possibility that a systemic reaction could occur from the local anesthetic when PRP is performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment of these conditions may be necessary.

Unsatisfactory Result: PRP injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from filler injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended in addition to additional treatments.

Pregnancy and Nursing Mothers: Animal reproduction studies have not been performed to determine if PRP injections could produce fetal harm. It is not recommended that pregnant women or nursing mothers receive PRP injections.

DISCLAIMER Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your medical provider may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

INFORMED CONSENT - PLATELET RICH PLASMA

- I _____ have read the 2 page information sheet and hereby authorize my medical provider and/or such assistants as may be selected by my provider to perform the **PLATELET RICH PLASMA TREATMENT**.
- I understand what my medical provider can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- I understand that I may start to see improvements immediately or improvement may be gradual. I understand that multiple treatments may be necessary to achieve desired results. Touch up treatments may be necessary to maintain desired results. No guarantee, warranty, or assurance has been made to me as to the results that may be obtained. Clinical results will vary per patient. I agree to adhere to all safety precautions and regulations during the treatment.
- I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and /or court cost and reasonable legal fees, should this be required. No refunds will be given for treatments received.
- I have read and understand the Pre and Post-Treatment Instructions. I agree to follow these instructions carefully. I understand that compliance with recommended pre and post procedure guidelines are crucial for healing, prevention of side effects and complications as listed above.
- I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
- I realize that not having the procedure is an option.
- I acknowledge that I have been informed that some of the treatment may be "Off-label". I understand that it is not experimental and accept its use.
- I understand that I can withdraw my consent at any time.

Patient Signature

Date: _____

Witness Signature

Date: _____