PLATELET-RICH FIBRIN GEL CONSENT FORM

INSTRUCTIONS: This is an informed consent document that has been prepared to help inform you about the Platelet Rich Fibrin **Gel** technique. It is important that you read this information carefully and completely. Please initial each section, indicating that you have read the page and sign the consent for the procedure proposed by your practitioner. *

INTRODUCTION: The Platelet-Rich Fibrin **Gel** technique uses the latest generation of Smart Blood Concentrates to generate a complex Fibrin Matrix rich in Platelets, Leukocytes and Mesenchymal stem cells. For 10-12 days this results in the constant release of Growth factors and interleukins which accelerate tissue healing and regenerating processes.

PRF **Gel** is effective in most cases; no guarantees can be made that a specific patient will benefit from this procedure. Additionally, the nature of cosmetic procedure may require a patient to return for numerous visits in order to achieve the desired results or to determine whether PRF **Gel** may not be completely effective at treating the particular condition. The healing process takes time and the final result won't be readily visible for many months.*

INDICATIONS OF USE: ON or OFF LABEL USE only concerns marketing & promotional material for a product. Physicians are free to use any medical device for any purpose, even a use that the FDA has not approved. PRF technique is used to accelerate tissue healing and skin regeneration processes through Blood Concentrate. This proposed use is "Off-label" that is, not specifically approved by the FDA. It is important to understand that the proposed use is not experimental and if suggested by your provider, it is because it is safe and effective. *

POSSIBLE RISKS AND SIDE EFFECTS ASSOCIATED WITH PRF

- **1. DISCOMFORT:** Discomfort may be experienced during blood draw where there is a slight pinch to insert the needle for the blood collection as well as during the procedure if PRF is injected into the site. Repeat injections may be necessary. *

- **2. BRUISING, SWELLING, INFECTION:** With any minimally invasive procedure, bruising of the treated area may occur. Additionally, there may be swelling noted. Finally, skin infection is rare, but always a possibility with any injection or incision into the skin. *

- **3. SCARRING:** Scar at entry point is extremely rare but must always be considered a possibility when entering the skin. Delayed wound healing and/or scarring may occur. *

- **4. CONTRAINDICATIONS:** Smokers may have less response to this treatment as toxins in smoke block the response of the Stem Cells. Cell death or Fibrosis may occur. *

Patient initials: _____

- There may be some variation I achieving the results requested as everyone's body type is different and may have a different response. No guarantees or warrantees with respect to final outcome or its longevity can be offered.

- **TREATMENT**
    - ✓ You may take pain medication such as Tylenol.
    - ✓ A numbing cream is applied to the area of treatment.
    - ✓ Approximately 10 cc of whole blood is drawn from your arm.
    - ✓ The tubes of blood are centrifuged to separate the component cells. Platelets, Leukocytes and Mesenchymal stem cells are separated and used for this procedure.
    - ✓ The liquid is then transferred into a syringe and injected using a tiny needle.

- **ADDITIONAL PROCEDURES MAY BE NECESSARY.** In some situations, it may not be possible to achieve optimal results with a single procedure and other procedures may be necessary. The practice of medicine is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

- **PHOTOGRAPHS.** Photographs are taken for clinical documentation and for scientific purposed in publications and presentations. Identity will always be protected.

- **FINANCIAL RESPONSIBILTIES.** The cost of procedure may involve several charges for the services provided. The total may include fees charged by your doctor/practitioner, the cost of supplies, or laboratory tests if needed. Additional costs may occur should complications develop from the procedure.

- **DISCLAIMER:** Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks. The informed-consent process to define principles of risk disclosure should generally meet the needs of patients in most circumstances. However, Informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your practitioner may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge. Informed-consent document 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 subject to change as science knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent that follows. *

- I understand that no warranty or guarantee has been made to me as to result or cure. I realize that, as in all medical treatment, complications or delay in recovery may occur which could lead to the need for additional treatment, and could also result in economic loss to me because of my inability to return to activity as soon as anticipated. *

Patient initials: _____

- I understand that my practitioner may discover other or different conditions, which require additional or different procedures than those planned. I authorize the practitioner and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment. *

- I understand that the results may relax over time and additional procedures may be required. *

CONSENT: Your consent and authorization for this procedure is strictly voluntary. By signing this informed consent form, you hereby grant authority to your physician/practitioner to use PRF for regeneration purposes and/or to administer any related treatment as may be deemed necessary or advisable in the diagnosis and treatment of your condition.

The nature & purpose of this procedure and the potential complications & side effects have been fully explained to me I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them. I understand that No refunds will be given for treatments received. No guarantee has been given by anyone as to the results that may be obtained by this treatment. I acknowledge that I have been informed about the Off-Label FDA status of dermal fillers and I understand it is not experimental and accepts its use.

I have read this informed consent and certify that I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I have had enough time to consider the information given me by my physician/practitioner and feel that I am sufficiently advised to consent to this procedure. I accept the risks and complications of the procedure. I certify if any changes occur in my medical history I will notify the office.

I hereby give my voluntary consent to this procedure and release my practitioner, the facility, medical staff, and specific technicians from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age and am not under the influence of alcohol or drugs. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Should I have any questions or concerns regarding my treatment / results, I will notify this office at _____ immediately so that timely follow-up and intervention can be provided.

_____ _____ _____

Patient Name (please print name) Patient Signature Date

_____ _____ _____

Witness Name (please print name) Witness Signature Date

Patient initials: _____