



## **Consent for Vaginal Submucosal/Suburethral, Labial, and Clitoral Injection of PRP and Administration of Anesthesia**

### **A. Purpose**

Though Platelet-Rich Plasma (PRP) comes from your own body and has demonstrated a low complication rate in other areas of the body, injecting PRP into vaginal structures and near the clitoris (the Orgasm Shot™, abbreviated as the O-Shot™) is a new procedure and so could cause some unexpected side effects or complications. The purpose of the O-Shot™ is to enhance sexual sensitivity in patients who experience decreased sexual desire. In patients who experience stress incontinence, the O-Shot™ can improve collagen formation in the area above the vagina and below the urethra allowing for reduction in urinary leakage.

Nothing contained in this consent form or in any other information provided to potential patients is intended to represent a promise, guarantee or warranty that any patient who undergoes the O-Shot™ will achieve a particular result. Individual results may vary, and no responsibility is assumed for failure to achieve a desired result. The use of PRP in this procedure is an 'off label' use, and no promise or representation, guarantee or warranty regarding its use, benefit or other quality is made. No representations that the use of this product and this procedure is approved by the FDA or any other agency of the federal or state government is made.

### **B. Benefits**

This treatment is natural in that your own cells are used, treated with a substance that is not foreign to the body, and injected into the specified areas. Since a distillate of growth factors from your own blood (PRFM) is used, there should be no side effects from the material injected. The body reacts to the treated cells as it does to a wound and immediately starts repairing the tissue. This builds the underlying tissue with tightening, smoothing, and increased blood flow. You should see improvements immediately, although there is usually a return to prior treatment status in 3-5 days as the water is absorbed and prior to the complete action of the cellular regenerative process. Within 2-4 weeks you will see improvement with continued changes for 12 weeks.

There is actual growth of new tissue by stimulation of uni-potent stem cells, so the change is not from something foreign being in the body but from the body actually rejuvenating and growing. The PRFM stimulates new blood flow with new blood vessels (neovascularization).

The results of this treatment should and can last, but results may vary and research documenting the longevity or results are ongoing.



### **C. Treatment**

You may take a pain medication, such as Tylenol™ or a prescription medication may or a prescription medication may be requested. You may ask for an anti-anxiety medication to use prior to the treatment.

A numbing cream (lidocaine, bupivacaine, or tetracaine) is applied to the vagina treatment areas.

Approximately 10cc (less than 2 tablespoons) of blood are drawn in the same way blood samples are taken for routine lab tests.

The tubes of blood are centrifuged to separate the component cells. Platelets are separated and used for this procedure.

The platelets are treated with calcium chloride which acts as an activator for the plasma cells. The platelets release growth factors into the liquid of the tube.

The liquid is transferred into a syringe and injected into the vagina using a 30G 1" needle and a process is used to distribute the growth factors and increase their effectiveness.

### **D. Foreseeable Risks and Discomforts**

The primary risks and discomforts are related to the blood draw where there is a slight pinch to insert the needle for collection and there is a potential for bruising at the site. The injections at the treatment locations cause pain similar to an intramuscular injection (since a small needle and numbing cream are used).

There is a potential for bruising at the injection sites. Pain from bruising could occur.

Smokers have less positive response to this treatment than non-smokers, since the toxins in tobacco smoke block the response of the stem cells.

There may be some variation in achieving the results requested as everyone's body type is different and may have a different response.

Potential risks may include:

- Bleeding
- No effect at all
- Constant awareness of the G-Spot
- A sensation of always being sexually aroused
- Constant vaginal wetness
- Mental preoccupation of the G-Spot
- Alteration of the function of the G-Spot
- Sexual function alteration
- Hematoma or bruising



- Hematuria (blood in urine)
- Alteration of vaginal sensations (usually with more intense pleasure)
- Hypersexuality (overactive sex drive)
- Alteration of the female sexual response cycle
- Varied results
- Sex life alteration

#### **E. Post-Treatment**

The post treatment therapy has been explained at the time of injection and I acknowledge that written instructions were given and are understood.

#### **F. Consent for Anesthesia**

When local anesthesia and/or sedation is used by the practitioner: I consent to the administration of such local anesthetics as may be considered necessary by the physician in charge of my care. I understand that the risks of local anesthesia include: local discomfort, swelling, bruising, allergic reactions to medications, and seizures from lidocaine.

#### **G. Follow-Up**

Shelly LaFrance, FNP or a qualified staff member of Moonstone Medical Aesthetics will follow up with you to check on your progress and answer any questions. You may call the office to report on your progress or ask questions. Shelly LaFrance, FNP or a member of Moonstone Medical Aesthetics can be reached at 360.326.3171.

#### **H. Privacy**

Your privacy is protected as described in our office Privacy Act Document.

#### **I. Payment**

I understand that this procedure is cosmetic in nature and that payment is my responsibility. Payment in full is required at the time of service and is non-refundable. I also understand that the cost of additional treatments, including enhancements, in order to help me achieve my desired goals, will be my financial responsibility.

I have read the above document and understand it.

If this procedure involves the use of other materials, a separate and additional consent form may be used.

The practitioner and staff have answered all my questions satisfactorily. I accept the risks and complications of this procedure.



Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Patient Name: \_\_\_\_\_ *(Please Print)*

Practitioner Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Practitioner Name: Shelly LaFrance, FNP