

# Consent for Vaginal Submucosal/Suburethral and Clitoral Injection of Platelet Rich Plasma (PRP) [OShot®] and Administration of Anesthesia

### PROCEDURE DESCRIPTION

The OShot is an innovative new procedure that utilizes the power of your very own growth factors to stimulate stem cells. This application of regenerative medicine stimulates new cell growth and differentiation in the clitoral and anterior vaginal tissue. It has been shown to be an effective treatment for urinary incontinence, as well as improving sexual sensitivity and sexual relations in many patients. In the procedure, first a powerful anesthetic agent (a combination of bupivacaine, tetracaine, and lidocaine) is applied topically to the clitoral area, and less than one inch into the anterior vaginal wall. As the anesthetic takes effect, a small amount of your blood (usually less than 10 cc) is drawn, and then spun down in a special centrifuge. This spinning process separates the red blood cells from the platelet rich plasma (PRP). The PRP will then be injected into the clitoris and less than one inch into the anterior vaginal wall.

## CONSENT FOR PROCEDURE [O-Shot®]

I have received information about my condition, the proposed treatment, alternatives, and related risks. This form contains a brief summary of this information. I have received an explanation of any unfamiliar terms and have been offered the opportunity to ask questions. I understand I may refuse consent and I GIVE MY INFORMED AND VOLUNTARY CONSENT to the proposed procedures and the other matters shown below. I also consent to the performance of any additional procedures determined in the course of a procedure to be in my best interests and where delay might impair my health.

- 1. I authorize Dr. Rebecca Greco and the appropriately trained staff of Physician's Ageless Solutions to treat my condition, including performing further diagnosis and the procedures described below, and taking any needed photographs.
- 2. I understand the proposed procedure(s) to be: vaginal submucosal/suburethral and clitoral PRP (platelet rich plasma) Injections, also known as The Orgasm Shot<sup>®</sup>/The O Shot<sup>®</sup>
- 3. I understand the risks associated with the proposed procedure(s) to be:

Bleeding

Infections

Urinary retention

No effect at all

Allergic reactions

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

Urethral injury (tube you urinate through)

Urinary retention

Hematuria (blood in urine)

UTI (Urinary Tract Infection)

Urinary Urgency (feel like you always have to urinate)

**Urinary Frequency** 

Increased/worsening nocturia (waking up several times at night to urinate)

Change in urinary stream

Urethral vaginal fistula (hole between urethra and vagina)

Vesico-vaginal fistula (hole between bladder and vagina)

Dyspareunia (Painful intercourse)

Need for subsequent surgery

Alteration of vaginal sensations

Scar formation (vaginal)

Urethral stricture (abnormal narrowing of the urethra)

Local tissue infarction and necrosis

Yeast infections

Vaginal Discharges

Spotting between periods

Bladder Pains

Overactive Bladder (OAB)

Bladder Fullness

**Exposed Material** 

Pelvic Pains

Pelvic Heaviness

**Erosions** 

**Fatigue** 

Damage to nearby organs including bladder, urethra and ureters

Alteration of bladder dynamics

Post-operative pain

Prolonged pain

Intractable pain

Alteration of the female sexual response cycle

Failed procedure

Varied results

Psychological alterations

Relationship problems

Sex life alteration

Decreased sexual function

Possible hospitalization for treatment of complications

Lidocaine toxicity

Anesthesia reaction

**Embolism** 

Depression

Reactions to medications including anaphylaxis

Nerve damage

Permanent numbness

Slow healing

Swelling

Sexual dysfunction

Allergy

Nodule formation

- 4. I also understand that there may be other RISKS OR COMPLICATIONS, OR SERIOUS INJURY from both known and unknown causes. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the risks of the procedure.
- 5. I understand that 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. I understand the alternatives to the proposed procedures and the related risks to be: do nothing.

### **CONSENT FOR ANESTHESIA**

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.

## **PATIENT CERTIFICATION:**

By signing below I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents of this form. I understand the information on this form and give my consent to what is described above and to what has been explained to me.

SIGNATURE OF PATIENT and DATE
DDINTED NAME OF DATIFALT
PRINTED NAME OF PATIENT
PHYSICIAN ATTESTATION I have explained the procedure(s), alternative(s) and risks to the person or persons whose signature is affixed above. The patient has verbally communicated to me that they understand the contents of this form.
/
SIGNATURE OF PHYSICIAN OR DESIGNEE OBTAINING CONSENT and DATE
PRINTED NAME OF PHYSICIAN