

Patient Consent to Receive the Orgasm Shot™

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. At present, it is only being offered as part of a clinical trial designed to assess its effectiveness and safety.

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 Orgasm Shot™/O-Shot™ will achieve a particular result. Individual results do 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.

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

A. CONSENT FOR PROCEDURE

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. _____ 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, clitoral, and labial, PRP (platelet rich plasma) injection (The Orgasm Shot™/The O Shot™).

4. I understand the risks associated with the proposed procedure(s) to be:

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

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 the alternatives to the proposed procedures and the related risks to be: do nothing.

B. CONSENT FOR ANESTHESIA

1. When local anesthesia and/or sedation is used by the physician:

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.

C. 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

D. 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

E. INTERPRETER ATTESTATION (when applicable)

I have provided translation to the person(s) whose signature(s) is affixed above.

_____/_____
SIGNATURE OF INTERPRETER and DATE