

Consent for Orgasm Shot® / O Shot® Procedure Vaginal Submucosal/Suburethral, Clitoral, and/or Labial Injection of Platelet Rich Plasma And Administration of Anesthesia

CONSENT FOR ORGASM SHOT®/O SHOT® 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 have not received any promise, guarantee or warranty that my undergoing the Orgasm Shot®/O Shot® procedure will achieve a particular result. I fully understand that individual results do vary, and that Dr. Steven Fein/Chrislyn Chaloupka assumes no responsibility for failure to achieve a desired result. 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. Steven Fein/Chrislyn Chaloupka to treat my condition, including performing further diagnosis and the procedures described below, and taking any needed photographs.
2. I understand the proposed Orgasm Shot®/O Shot® procedure(s) to be: a procedure for vaginal, labial, and clitoral rejuvenation, using blood-derived growth factors (platelet-rich fibrin matrix (PRFM), platelet-rich plasma (PRP) injections.
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

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.

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 / DATE

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 / NURSE PRACTITIONER / DATE

INTERPRETER ATTESTATION (when applicable)

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

_____/_____
SIGNATURE OF INTERPRETER / DATE

WITNESS ATTESTATION

I have witnessed the above physician or designee explain the procedure(s), alternative(s) and risks to the person or persons whose signature is affixed above. I have witnessed the above patient verbally communicate to the above physician or designee that they understand the information and contents of this form.

_____/_____
SIGNATURE OF WITNESS / DATE