NOOR
ESTHETIQUE AND WELLNESS CENTER

O SHOT CONSENT FORM

Tele:

INFORMATION SHEET AND INFORMED CONSENT FOR VAGINAL SUBMUCOSAL/SUBURETHRAL, CLITORAL and/or LABIAL INJECTION OF PLATELET RICH PLASMA (O-SHOT) AND ADMINISTRATION OF ANESTHESIA

It is important that you read this information carefully and completely.

The Orgasm Shot™/ O Shot involves isolation of PRP (platelet rich plasma) followed by a very specific method of amplifying or augmenting the vaginal tissues with injection of that PRP. The method of isolating the PRP is an FDA approved process. **Though the method of preparing the PRP has been approved by the FDA for orthopedic and surgical use, PRP use in the vagina has not been evaluated by the FDA.**

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 representation 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.

RISKS OF TREATMENT

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences.

Problems associated with the use of the O-Shot can relate to normal occurrences following PRP injections or potential complications following PRP injections. I understand the risks associated with the proposed procedure(s) to be:

A sensation of always being aroused
Allergic reactions
Allergy
Alteration of bladder dynamics
Alteration of the female sexual response cycle
Alteration of the function of the G-Spot
Alteration of vaginal sensations
Bladder fullness and pain
Constant awareness of the G-spot
Damage to nearby organs, including bladder, urethra and ureters
Decreased sexual function
Depression
Exposed material
Failed procedure
Hematoma
Increased/worsening nocturia (waking up several times at night to urinate)
Infections
Lidocaine toxicity
Local tissue infarction and necrosis
Nerve damage
Nodule formation
Overactive bladder (OAB)
Pelvic heaviness
Pelvic pains
Permanent numbness
Change in urinary stream
Bleeding
Constant vaginal wetness
Painful intercourse
Embolism
Erosion
Fatigue
Hematuria (blood in urine)
Mental preoccupation of the G-Spot

Unsatisfactory Result: PRP alone may not produce an outcome that meets your expectations. There is the possibility of a poor or inadequate response from filler injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to additional treatments.

Unknown Risks: The long term effect of PRP injections is unknown. The possibility of additional risk factors or complications may be discovered.

Pregnancy and Nursing Mothers: It is not recommended that pregnant women or nursing mothers receive the O-Shot.

CONSENT FOR ANESTHESIA:

I understand that local anesthesia and/or sedation may be 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.

ADDITIONAL TREATMENT NECESSARY

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of PRP injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with the O-Shot injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

HEALTH INSURANCE

Most health insurance companies exclude coverage for the O-Shot procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for the O-Shot used to treat medical conditions. Please carefully review your health insurance subscriber information pamphlet.

FINANCIAL RESPONSIBILITIES

The cost of the O-Shot may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that this procedure is covered by your health insurance. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the injections and will also be your responsibility. **In signing the consent for this procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

I understand and unconditionally and irrevocably accept this.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your medical provider may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current state of medical knowledge.

Informed-consent documents 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 are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

INFORMED CONSENT FOR VAGINAL SUBMUCOSAL/SUBURETHRAL, CLITORAL and/or LABIAL INJECTION OF PLATELET RICH PLASMA (O-SHOT) AND ADMINISTRATION OF ANESTHESIA

- I ______________________________________ hereby authorize my medical provider and/or such assistants as may be selected by my medical provider to perform the VAGINAL SUBMUCOSAL/SUBURETHRAL, CLITORAL and/or LABIAL INJECTION OF PLATELET RICH PLASMA (O-SHOT) AND ADMINISTRATION OF ANESTHESIA

- I understand what my medical provider can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

- I understand that multiple treatments may be necessary to achieve desired results. No guarantee, warranty, or assurance has been made to me as to the results that may be obtained. Clinical results will vary per patient. I agree to adhere to all safety precautions and regulations during the treatment.

- I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and /or court cost and reasonable legal fees, should this be required. No refunds will be given for treatments received.

- I have read and understand the Pre and Post-Treatment Instructions. I agree to follow these instructions carefully. I understand that compliance with recommended pre and post procedure guidelines are crucial for healing, prevention of side effects and complications as listed above.

- I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

- For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

- I realize that not having the procedure is an option.

- It has been explained to me in a way that I understand
  - The above treatment or procedure to be undertaken
  - There may be alternative procedures or methods of treatment
  - There are risks to the procedure or treatment proposed
  - There are risks t receiving anesthesia or sedation

- I understand that I can withdraw my consent at any time.

____
Patient Signature

______________________________________ Date: ______________________________
Witness Signature