Las Vegas Urogynecology

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Physician's Surgical Procedure Disclosure and Patient's Consent

TO THE PATIENT: You have the right to be informed about your condition and the recommended surgical, medical or diagnostic procedure so that you may make the decision whether or not to undergo the procedure after knowing the risks involved and any treatment alternatives available to you. This information is not meant to alarm you; it is an effort to make you better informed so that you may give or withhold your consent to the procedure. If you do not understand any of the information provided, ask your physician to explain it to you.

1. **DIAGNOSIS:** I (we) voluntarily request my physician, Victor E. Grigoriev, and such associates, technical assistants, and other health care providers as they may deem necessary, to treat my CONDITION:

   Incontinence (loss of urinary control).

2. **PROCEDURE(S):** I (we) understand that the following surgical procedure(s) are planned for me on or about (month) _____(day) _____ (year) _____. I voluntarily consent to and authorize this (these) PROCEDURE(S) for the following purpose(s):

This procedure involves placing a sling under the bladder neck (where the urethra meets the bladder) to support the urethra. This sling is comprised of the patient's own fascia (connective tissue) transplanted from another area of the patient's body, or fascia processed from animals or cadavers, or comprised of synthetic material.

For this procedure, the patient lies face up with legs raised and held in stirrups. Some form of anesthesia (loss of feeling caused by drugs) is administered. An incision (surgical cut) is made in the vagina. This incision is carried down to the tissue around the urethra, taking care not to enter the urethra or bladder.

The doctor places the sling underneath the bladder neck. The upward compression occurs by the sling having enough friction to stay in place by itself. Or, in other cases, the sling is sewn or stapled to the abdominal muscles. Alternatively, screws are used to attach the sling to the pelvic bones.

The incision is closed with sutures. A catheter is left in the bladder to drain urine during the recovery period. The doctor may also perform a cystoscopy (insertion of a thin, tubular, lighted instrument into the urethra and bladder to view these structures).

(URETHRA - URETHRAL SLING - FEMALE)

Proposed Benefit(s):

Benefits include control or reduction of incontinence (loss of urinary control).

Procedure Anatomical Location:

_____

3. MATERIAL RISKS: Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks related to the performance of the surgical, medical and/or diagnostic procedure(s) planned for me, including:

- No guarantee of control of incontinence.
- Recurrence of incontinence requiring further procedures.
- Irritation, urgency to urinate, and/or frequency of urination.
- Retention of urine requiring prolonged catheterization (tube inserted to remove urine)

  including use of self-catheterization or including placement of tube through the abdomen into the bladder.
- Inflammation, infection, or allergic reaction to sling material, requiring removal of sling.
- Discomfort of vagina, urethra, or lower abdomen from sutures supporting the urethra.
- Need for cystocele repair (surgery to prevent protrusion of bladder into vagina).
- Infection of incision, bone, muscle or sling, requiring further treatment including removal of sling.
- Erosion (breaking down) of sling, injuring urethra and requiring removal and further treatment.
- If sexually active, discomfort with sexual intercourse.
- Injury or perforation (tear) of bowel, bladder and/or urethra, recognized or unrecognized during the procedure, requiring repair of injury, removal of sling, and/or inability to complete procedure.
- Injury to blood vessels (blood loss) or nerves (loss of sensation or motor function) to pelvis or legs.

Additional material risks of surgical, medical and/or diagnostic procedure(s) include: death, cardiac arrest, brain damage, disfiguring scar, paralysis or partial paralysis, loss or loss of function of a limb or organ, blood clots in veins or lungs, severe loss of blood, allergic reaction and infection.

4. **ALTERNATIVES TO PROCEDURE:** The following practical alternatives to this procedure have been discussed with me:

Alternatives include observation, pessary (a device placed in the vagina to support the pelvic organs), other types of open surgical repair, or insertion of catheter (tube inserted to remove urine).

5. **LIKELY OUTCOME IF NO TREATMENT:** I have been informed of the likely outcome if no treatment is provided, as follows:

If the procedure is refused, the patient will experience continued incontinence (loss of urinary control).

6. ANESTHESIA: I (we) understand that anesthesia involves additional risks but I (we) request the use of an anesthetic for the relief and protection from pain during the planned and additional procedure(s), if any. I (we) realize the anesthesia may have to be changed without explanation to me (us).

I (we) understand that certain complications may result from the administration of anesthesia. Common side affects include, but are not limited to: nausea, vomiting, pain where injection is given, injury to blood vessels. Although rare, unexpected severe complications with anesthesia can occur and include the possibility of infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death. Other risks and hazards which may result from the use of general anesthetics range from minor discomfort or injury to the vocal cords, mouth, teeth or eyes to pneumonia. I (we) understand other risks and hazards resulting from spinal or epidural anesthetics include headaches, backaches, persistent weakness, numbness and chronic pain. I (we) understand other risks and hazards resulting from a major/minor nerve block include weakness, persistent numbness and residual pain. I (we) understand other risks and hazards resulting from moderate sedation/analgesia, also called conscious sedation, include retrograde amnesia (inability to remember the procedure), depressed blood pressure and depressed breathing rate.

Additional anesthesia information supplied to the patient:

_____
_____
_____

[ ] Anesthesia is to be administered by or under the direction of an Anesthesiologist

OR

[ ] Anesthesia is to be administered by _____

7. TREATMENT LIMITATIONS: I impose no specific limitations or prohibitions regarding treatment other than those that follow:

[If none, so state.]

_____
_____
_____

8. DISPOSAL OF TISSUE: I (we) authorize the disposal of any surgically removed tissue or parts resulting from the procedure according to accustomed practice.

9. BLOOD PRODUCTS: I (we) understand that if blood products are required, their use may improve my overall condition or save my life. I (we) understand that certain complications may result from the use of blood products. The more common risks include (but are not limited to) infection/irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, shock, or death. I also know there is a very small risk of infection, including the risk of hepatitis (<1 in 200,000) and/or HIV/AIDS (<1 in 2 million).

[ ] I (we), consent to the use/administration/transfusion of blood products as deemed necessary.

[ ] I (we), do not consent to the use/administration/transfusion of blood products as deemed necessary.

10. CONSENT TO TREATMENT OF UNFORESEEN CONDITIONS: I (we) understand that my physician may encounter or discover other or different conditions which require additional or different procedures than those planned. I (we) authorize my physician, and associated technical assistants, and other health care providers to perform such other procedures which are advisable in their professional judgment.

11. OUTCOME: I (we) understand that the practice of medicine is not an exact science, and that no warranty or guarantee has been made to me as to result or cure.

12. CONSENT TO TRAINING PARTICIPATION: This facility may have an educational role in the training of paramedical personnel.

Admittance of students and/or technical representatives

[ ] I (we) consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

[ ] I (we) do not consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

Participation of students and/or technical representatives

[ ] I (we) consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

[ ] I (we) do not consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

13. PHOTOGRAPHY: I (we) agree that still or video photography, audio recordings, or medical data may be taken during these treatments/procedures. These may be placed in my permanent medical record. I agree that these images, recordings, or data may be used for education, training, or performance improvement programs as long as no information that could identify me is used.

14. MEDICAL DEVICES: I (we) accept that during the treatments/procedures, the doctor or dentist may need to place a medical device in my body. If a medical device is implanted in my body, personal information (such as my name, social security number, and medical information) will be given to the maker of the device for quality control purposes.

CONSENT:

I (we) have been given sufficient opportunity to ask questions about my condition, alternative treatments, risks of treatment, the procedures to be used, and the risks and hazards involved. All of my questions have been answered to my satisfaction, and I (we) have sufficient information to give this informed consent. I hereby consent to the above-described procedure.

I (we) certify that this form has been fully explained to me (us), and that I have read it, or have had it read to me (us), that the blank spaces have been filled in and that I (we) understand its contents.

_____ Date:_____

Signature of Patient or Legally Responsible Person (A.M./P.M.) Time:_____

_____

Printed Name of Patient or Legally Responsible Person

_____

Signature of Witness (Include Position / Title)

_____

Printed Name of Witness

_____

To Be Completed By Physician After Patient Consent Completed:

I certify that the procedure(s) described above, including the risks, possible complications, anticipated results, alternative treatment options, including non-treatment, have been explained by me to the patient or his or her legal representative before the patient or his/her legal representative consented.

_____

Treating Physician

Date:_____

Time: _____ (A.M./P.M.)