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Patient Medical Record (write in or apply sticker)

Name: _____

Medical Record No. _____

DOB: _____

Admitting MD: _____

Physician's Surgical Procedure Disclosure and Patient Consent: Penis – Self-Injection Therapy

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 decide 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. You may have additional consent discussions regarding: anesthesia, the administration of blood or blood products, certain medications, or additional persons involved in the procedure you are consenting to.

REASON FOR PROCEDURE: I (we) voluntarily request my physician, _____, and such associates, technical assistants, and other health care providers as they may deem necessary, to treat my condition: Erectile dysfunction. This is difficulty obtaining and/or maintaining an adequate erection for intercourse or other sexual activity.

PROCEDURE(S): I (we) understand that the following surgical procedure(s) is planned for me on or about (month) _____ (day) _____ (year) _____. I voluntarily consent to and authorize this (these) procedure(s): Penis- Self-Injection Therapy

Procedure Description: This procedure involves injecting a medicine into the penis. This will help you to have an erection. An erection occurs when the penis fills with blood and then traps the blood in the penile shaft. This may be an injection of one or more medicines at the same time. The medicine(s) relax(es) the muscle cells surrounding the arteries of the penis. This allows more blood to enter the penis. It also prevents outflow of blood, thus causing an erection.

You or your partner will use a small needle to inject the medicine into the base of the penis. The injection may be done with a needle and syringe. It may also be done with an auto injection device. These may be prefilled with the medicine or you may have to draw it up from a container. You will need to alternate the injection site each time. The injection may be done approximately 10-20 minutes prior to sexual activity. The effects may last from 30 to 120 minutes. If your erection lasts more than 4 hours, seek medical attention.

Proposed Benefit(s): This procedure may allow you to have an erection. It may make intercourse possible.

Site or location of the operation/procedure: See description of treatment/procedure.

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:

- Fear of needles.
- Pain or redness at the treatment site.
- The results of the procedure may not look or feel the way you or others want it to.
- Allergic reaction. May include itching, hives, swelling, difficulty breathing, drop in blood pressure, possible loss of consciousness.
- Blood clot(s) under the skin of the penis.
- Injections may not work, or continue to work in the future.
- Scar tissue may prevent placement of a penile prosthesis in the future.
- Damage to the corpora cavernosa (chambers in the penis that fill with blood), bladder or urethra, bowel, or nearby structures. This may be discovered during the procedure, or later.
- Infection, inflammation, or abscess at the injection site. This may occur close to the time of your procedure or later.
- Priapism. An erection that will not go away and lasts more than four hours. This requires immediate medical attention.
- Problems with penile erection, including bending or scar tissue.
- Scar tissue causing later blockage or other problems.

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 a limb or organ, blood clots in veins or lungs, severe loss of blood, allergic reaction, and infection.

ALTERNATIVES TO PROCEDURE: The following practical alternatives to this procedure, including the risks and benefits of those alternatives, have been discussed with me:

- Watching and waiting with the doctor.
- Psychotherapy or sex therapy.
- Medicines to treat symptoms. This may be in the form of a pill or medicine directly inserted into the opening at the tip of the penis (urethra).
- Hormonal therapy.
- Vacuum therapy. This is a device to help obtain an erection.
- Pressure rings. These help maintain an erection by preventing blood flow out of the shaft.
- Prosthesis implantation. This is the placement of tubes within the penis to create an erection.
- Vascular surgery. This consists of creating a bypass to improve blood flow.
- You may choose not to have this procedure.

LIKELY OUTCOME IF NO TREATMENT: I have been informed of the likely outcome if no treatment is provided, as follows: If you choose not to have this procedure, you will continue to have problems having an erection. This may prevent you from having intercourse.

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

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

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.

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.

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.

CONSENT TO TRAINING PARTICIPATION: My physician or 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.

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 (we) 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.

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 procedure described above.

I (we) certify that this form has been fully explained to me (us), and that I (we) 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.

Signature of patient or person authorized
to give consent

(Relationship to patient)

Date

Printed name of patient or person authorized to give consent

Signature of Witness (Include Position I Title)

Date

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.

Signature of Treating Physician

Date