

TESTOSTERONE/TESTOSTERONE-ANASTROZOLE
PELLET INSERTION CONSENT FORM

Testosterone pellet implantation has been used for androgen replacement since 1940. Implants may be manufactured or compounded. A physician or physician's assistant implants the pellets under the skin of the abdominal wall or upper gluteal area through a small incision using local anesthesia. Complications may occur and may include, but are not limited to, extrusion of the pellet, bleeding, bruising, swelling, skin discoloration, scarring, acne and infection. There may be discomfort following the procedure. An ice pack may be applied.

Pellets dissolve and are not removed. Pellets avoid the liver. There is not an increase in clotting factors or elevation of liver enzymes. Alternatives to testosterone implants include topical creams and gels, patches, lozenges or injections. Testosterone does not cause prostate cancer, but may stimulate an undiagnosed prostate cancer. If your PSA is elevated, you will need written approval from your urologist or primary care physician prior to testosterone therapy. Testosterone may also increase the production of red blood cells. If the red blood count elevates above normal, you may donate blood or lower your dose of testosterone. Testosterone, delivered by pellet implantation decreases sperm production and testicular size, and may worsen sleep apnea. A few recent studies have suggested an increased risk of cardio-vascular events in men receiving testosterone therapy, particularly in men with a history of heart disease. In June 2014, the FDA issued a warning about increased blood clots in veins.

CONSENT FOR TREATMENT: I HAVE BEEN INFORMED THAT I MAY EXPERIENCE ANY OF THE COMPLICATIONS TO THIS PROCEDURE AS DESCRIBED BELOW.

Bleeding, bruising, swelling, infection and pain, lack of effect (typically from lack of absorption), thinning hair, male pattern baldness, increased growth of prostate and prostate tumors, extrusion of pellets, and hyper sexuality (overactive libido). There can be 10-15% shrinkage in testicle size. There can also be a significant reduction in sperm production. Testosterone is the major substrate or "building block" for estrogen. Symptoms of excess estrogen include fluid retention, bloating, breast tenderness, irritability and weight gain. You may be treated with an estrogen blocker, anastrozole, which can be combined with testosterone in the compounded pellet implant. Testosterone and estrogen levels may be checked to assess the absorption of testosterone and the conversion to estrogen.

- If there is a concern about prostate cancer, you may elect a 3-4 month trial of treatment with a shorter acting testosterone preparation (gel, patch, shot). If the PSA is elevated, pellets may be implanted after a negative prostate biopsy and clearance by your urologist. Pellets are not removed.
- Notify the doctor if you are diabetic and have had a joint replacement.
- You must notify the physician of any allergies or bleeding problems prior to the procedure including anti-coagulant (Coumadin, Plavix) or aspirin therapy.
- You should notify your primary health care provider that you have the testosterone implants and need follow-up care, including and annual CBC (blood count).
- If PSA increases on testosterone therapy, you must see your doctor or a urologist.
- You should avoid vigorous physical activity for 5 days following the insertion of the pellets.

I have been encouraged and have had the opportunity to ask any questions regarding pellet therapy. All of my questions have been answered to my satisfaction. I further acknowledge that there may be risks of testosterone therapy that we do not yet know, at this time, and the risks and benefits of this treatment have been explained to me and I have been informed that I may experience complications, including one or more of those listed above. I accept these risks and benefits and I consent to the insertion of hormone pellets under my skin. This consent is ongoing for this and all future pellet insertions.

I have read and understand the above information. I understand the procedure, benefits, risks, and alternatives to the "Implantation of Testosterone/Testosterone-anastrozole Pellets" and testosterone therapy.

I agree to allow _____, M.D. or _____, P.A. to implant the testosterone and testosterone-anastrozole pellets. I understand that Dr. _____ will not be assuming my healthcare.

I agree to hold Dr. _____ harmless for any complications that may occur. I have discussed any questions or concerns with Dr. _____ or _____, P.A.

I agree to follow up with my primary care physician for my routine medical care, annual physical exam and prostate exam.

Print Name

Signature

Date

