



Informed Consent Testosterone or Testosterone with Anastrozole Implants: MALE

Testosterone (T) pellets have been used for hormone therapy since 1940. T and other “pellets” for insertion are ‘compounded’. They are placed under the skin of the lower abdomen or “love handle” area as an outpatient office procedure under local anesthesia. Complications may occur and can include extrusion of the pellet, bleeding, bruising, scarring or infection. Pellets completely dissolve and are not removable. Side effects of T therapy may include an increase in facial and body hair, or acne. Beneficial effects T are dose dependent, but appear to plateau between 1000 and 1400 ng/dl.

Pellets deliver T for four months on average in males. T stimulates the bone marrow to produce red blood cells, which may in occasional cases elevate the red blood cell count and require a blood donation. Serum T levels on implant therapy may be higher than “normal” levels for some laboratory’s reference ranges. Symptoms often return when serum levels approach the high or mid-normal range. Your testosterone level will vary significantly throughout the day with pellets as they did when you were younger with optimally functioning testicles. T pellet therapy reverses the muscle (and possibly bone loss) associated with aging.

Despite recent news articles to the contrary, the majority of well-done and reproducible scientific studies report a beneficial effect of T on heart disease. Please notify Sarah Roberson MSN, FNP-C prior to the procedure if you have a history of prostate cancer. It is recommended that you have an annual exam by your primary care provider.

T is the major substrate or ‘building block’ for estrogen. Symptoms of excess estrogen include fluid retention, bloating, anxiety, irritability, breast pain or weight gain. An estrogen blocker, anastrozole, may be combined with T in the compounded implant if you convert too much T into estrogen. The inclusion of anastrozole in T pellets is an ‘off label’ use of anastrozole.

- It is recommended that you have a negative prostate exam and normal PSA prior to therapy. If Sarah is not your primary care provider, it is your responsibility to notify her about any changes in this prior to pellet insertion.
- No vigorous physical activity for 5 days following the procedure. Weight lifting and walking are allowed 48 hours after insertion. No water immersion for 5 days
- You may remove the dry dressing and shower the day after insertion. Leave the skin tapes in place.
- You must notify the physician of any allergies or bleeding problems prior to the procedure including anti-coagulant (i.e. Coumadin, Plavix) or aspirin therapy. Your risk of bleeding increases with these.
- If applicable, you must notify your oncologist prior to having the T or T + anastrozole pellets placed.

I have read and understand the above information. I understand the procedure, benefits, risks, side effects and alternatives to the ‘Implantation of Hormone Pellets’. I understand that Testosterone-Anastrozole combination pellets are not FDA approved. I agree to allow Sarah Roberson, MSN, FNP-C to implant the pellets. I understand that Sarah will not be assuming the role of my primary health care provider unless she and I have mutually agreed for her to do so. I agree to hold Complete Integrative Care and its providers harmless for any complications that may occur. I am aware that the actual pellet and insertion of the pellet is not a covered service by my insurance and that I will be responsible to pay the full fee at the time of check-in for my pellet insertion.

Witness

Patient Name

Patient Signature

Date

DOB

*Off label use: of, relating to, or being an approved drug legally prescribed by a physician for a purpose for which it has not been specifically approved.

abbreviation: T (testosterone)