



## Informed Consent Testosterone or Testosterone with Anastrozole Implants: Female

Testosterone (T) pellets have been used for hormone therapy in women since 1940. There is no FDA approved T therapy for women. T and other pellets are ‘compounded’ and are used ‘off label’ in women. They are placed under the skin of the lower abdomen, flanks, or upper buttock 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. Possible side effects of T therapy may include an increase in facial and body hair, acne, or swelling/enlargement of the clitoris. The beneficial effects and side effects of testosterone are dose dependent, meaning that the higher the dose the more benefits but the higher the chance of side effects.

Pellets deliver T for three months on average in females. T stimulates the bone marrow to produce red blood cells, which may elevate the red blood cell count. Serum T level while on implant therapy is higher than normal levels in females. Menopausal symptoms often return when serum levels approach the upper normal range for a young female. T levels vary significantly throughout the day with pellets as they did when you were much younger with optimally functioning ovaries.

In very rare cases, estrogen may be given along with testosterone as a vaginal cream, topical patch, or implant. Estrogen can stimulate the breast, uterine lining, and cause uterine bleeding and increase the risk for breast cancer. If you are to receive estrogen this will be discussed in detail with you. Progesterone may be prescribed as an oral capsule if abnormal uterine bleeding occurs

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 for symptoms of excess estrogen production. This is an ‘off label’ use.

- No vigorous physical activity for 48 hours following the procedure. No water immersion for 5 days.
- You may remove the dry dressing and shower the next day. Leave the skin tapes in place.
- If applicable, you must notify your oncologist prior to having the T or T + anastrozole pellets placed.
- Implants or pellets are not removable.
- If you are a PRE-MENOPAUSAL female, you **must** use birth control while on pellet therapy. *Theoretically*, testosterone could masculinize a female fetus. You must notify the office if you become pregnant.

**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 and Testosterone-Anastrozole pellets are not FDA approved in women. I agree to allow Sarah Roberson, MSN, FNP-C to implant the pellets. I understand that Sarah will not be assuming my healthcare or gynecologic care unless she and I have mutually agreed that she will be assuming the role of my primary care provider. 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.**

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Witness

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Patient Name

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
DOB

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

Abbreviation: T = testosterone