

Consent for BIOIDENTICAL HORMONE REPLACEMENT THERAPY

Thank you for choosing Alazzo Med Spa, LLC. This form is exclusively related to Bio-Identical Hormone Replacement Therapy also known as BiHRT. Please read this form thoroughly and ask any questions that you may have prior to treatment. This consent will serve for all BiHRT treatments performed and does not need to be renewed. Sign only after you feel comfortable enough to get started.

Informed Consent Testosterone or Testosterone with Anastrozole Implants:

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.

Prior to your first pellet implant you will be given a lab slip to have your blood drawn at a lab of your choice. This is not an additional charge nor is it included in the price of BiHRT, as your insurance will typically cover this cost. The results will be send over to Alazzo Med Spa and we will contact you to discuss the results and formulate a plan to manage your BiHRT.

3-4 days prior to your implant we recommend you refrain from ingesting any blood thinning agents such as Advil, Motrin, St Johns Wart, and or Alcohol. This increases the chance of bleeding or brusing at time of implant.

- o No vigorous physical activity for 48 hours following the procedure. No water immersion for 5 days.
- o You may remove the dry dressing and shower the next day. Leave the skin tapes in place.

If you have any questions after reading these guidelines, please do not hesitate to call us for clarification.

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- o If applicable, you must notify your oncologist prior to having the T or T + anastrozole pellets placed.
- o Implants or pellets are not removable.
- o If you are a PRE-MENOPAUSAL female, you must use birth control while on pellet therapy. 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-Anastrazole pellets are not FDA approved in women. I agree to allow an Alazzo Med Spa Provider to implant the pellets. I understand that Alazzo Med Spa or any of its Providers will not be assuming my healthcare or gynecologic care. I agree to hold Alazzo Med Spa, LLC and any of its Providers harmless for any complications that may occur. My data may be used (anonymously) in a study or for research. I am aware that Alazzo Med Spa, LLC does not accept health insurance.

Witness

Patient signature

DATE

*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

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