INTEGRATED PHYSICAL | MEDICINE

☐ New Lenox phone: 815.717.8355 fax: 815.717.8416
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FEMALE TESTOSTERONE AND/OR ESTRADIOL PELLET INSERTION CONSENT FORM

Bio-identical hormone pellets are concentrated hormones biologically identical to the hormones you make in your own body. Estrogen, progesterone and testosterone are derived from the female ovaries (primarily) and adrenal glands (secondarily) prior to menopause.

Testosterone is a hormone produced by the ovaries and adrenal glands in women. In the medical research, testosterone supplementation in women has been shown to improve fatigue, exercise intolerance, muscle tone, libido, weight, decrease depression, anxiety and mood disorders and other conditions.

Though laboratory assays can support a diagnosis of testosterone deficiency, they should not be used to exclude it as there are multiple problems in the measurement of testosterone (ex. dietary intake, sexual activity, sample storage variables, circadian variations). Greater reliance on the clinical features and consideration of symptoms is suggested as an appropriate tool in treating women with testosterone therapy. There is no generally accepted "normal" level of testosterone for women. It is reasonable to prescribe testosterone to a woman who has symptoms of low and to expect total testosterone values that are supraphysiologic after treatment.

All testosterone use in women is considered "off-label". Off-label use refers to the use of any medication for something other than its FDA approval. Many medications prescribed in the US are prescribed for off-label use. The off-label use of testosterone therapy has not been evaluated by the FDA and any claims of benefit are purely educated opinions that come from consideration of various medical research studies. It is reasonable to expect a supraphysiologic testosterone laboratory value after pellet therapy is initiated.

Hormone pellet production is highly FDA regulated; however, the pellet insertion procedure is not an FDA approved procedure for hormonal replacement.

Goals for treatment with this medication will be discussed at each appointment. If goals are met, then maintenance doses will be discussed. If the treatment is not as effective as anticipated, it might be discontinued; at that time, alternative therapies will be discussed. You are welcome to seek a second opinion or a specialist consultation.

The safety of hormone therapy during pregnancy cannot be guaranteed. Notify your provider if you are pregnant, suspect that you are pregnant or are planning to become pregnant during this therapy. Continuous exposure to testosterone during pregnancy may cause adverse effects in the fetus.

My birth control method is (please check):

__Abstinence __Birth Control Pill __Hysterectomy __IUD __Menopause __Tubal Ligation

__Vasectomy __Other

SIDE EFFECTS: Side effects of subcutaneous hormone pellets will be managed clinically and individually. There have been no reported *irreversible* side effects of subcutaneous pellet therapy noted in the literature.

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Potential side effects of pellet insertion may include, but not limited to: Surgical risks are the same as for any minor medical procedure. Bleeding, bruising, swelling, and pain; extrusion of pellets; infection or abscess formation; seroma formation; scarring at insertion site; keloid scar.

Potential side effects of the hormones may include, but are not limited to:

Estradiol Related: Dysfunctional uterine bleeding**;** growth of estrogen dependent tumors and breast tenderness (estradiol)**.**

Testosterone Related: Hyper-sexuality (overactive libido) increase one's hemoglobin and hematocrit (erythrocytosis), acne, increase in body/facial hair growth, abnormal menstrual cycles, hair loss/thinning and virilization, voice changes or abnormal growth of the female genitals (testosterone).

17-beta estradiol has not been shown in any clinical study to date to increase breast, uterine or ovarian cancer risk; however if a patient has an undiagnosed estrogen/hormone dependent cancer a possible risk of accelerated growth may occur. For this reason mammograms, according to the current clinical guidelines, are required as a baseline prior to the initiation of hormone therapy. Every patient has a right to refuse diagnostic mammogram. ***I understand if I refuse I will be required to sign a mammogram waiver before I am to receive hormone therapy. I understand if I have a uterus and am on estradiol therapy I must take oral micronized progesterone (prescription) daily for protection against uterine cancer.***

CONSENT FOR TREATMENT: I have been informed that I may experience any of the complications related to this procedure. Periodic adjustments are required to fine tune the treatment with this type of medication. Periodic blood tests are necessary to determine if the dose needs to be adjusted. I understand that hormone therapies are available in other forms including creams and oral medications. I understand that I am consenting to testosterone therapy for off label use of my symptoms. I understand the hormone pellet procedure is not FDA approved.

AFTERCARE: I agree to immediately report to my practitioner's office any adverse reaction or problems that might be related to my therapy. Potential complications have been explained to me and I agree that I have received information regarding those risks, potential complications and benefits, and the nature of hormone and other treatments and have had all my questions answered. Furthermore, I have not been promised or guaranteed any specific benefits from the administration of hormone therapy. I accept these risks and benefits and I consent to the insertion of hormone pellets with a dosage regime discussed thoroughly by my hormone pellet provider.

I have read and understand this document in its entirety and have been given the opportunity to ask questions concerning my care. I consent to subcutaneous hormone pellet insertion. **This consent is ongoing for this and all future subcutaneous hormone pellet insertions.**

Patient Name	**Patient Signature**	**Date**

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