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Female Estradiol and Testosterone Pellet Insertion Consent

Patient: _____ Date: _____

Address: _____ DOB: _____

Bio-identical hormone pellets are concentrated hormones, biologically identical to the hormones made by your body prior to menopause. Estrogen and testosterone were both produced by your ovaries prior to menopause. **Bio-identical hormones** have the same effects on your body as your own natural estrogen and testosterone did when you were younger, and without the monthly hormonal fluctuations (ups and downs) of menstrual cycles.

Bio-identical hormone pellets are **FDA monitored, but not FDA approved**, for female hormonal treatment. Pellets are produced by compounding pharmacies that specialize in this form of hormonal medication and they are only available with a prescription. The pellet method of hormone therapy has been used in Europe and Canada and by select Ob/Gyn's in the United States for many years. Since these hormones were circulating in your body prior to menopause, the risks of using them are similar to the natural risks of being pre-menopausal. **Studies done in Canada and Europe found that pellet hormone therapy was safer than traditional oral hormone therapy.**

FYI: The famous (infamous!) WHI study (Women's Health Initiative Study) on hormone replacement therapy, first reported in 2002, had many flaws in the study design. For example, they only studied oral Premarin (made from horse urine) and Provera (a synthetic progestin). Their findings were not consistent with hundreds of other studies done on the safety of HRT.

Pellet hormone therapy is usually suggested for you after other methods of hormone therapy have failed. Some patients choose **bio-identical hormone pellets** because they resemble women's premenopausal hormones and therefore have a more natural effect and are better tolerated by women who have been unable to tolerate other forms of hormone therapy.

WARNINGS

Patients who are not sterilized and not menopausal are advised to continue reliable birth control while participating in hormonal therapy. Testosterone is category X (can cause birth defects) and should not be given to pregnant women or women who might become pregnant. YOU NEED TO BE MENOPAUSAL, HAVE HAD A PRIOR HYSTERECTOMY, HAVE BEEN STERILIZED or USE HIGHLY EFFECTIVE BIRTH CONTROL TO BE ABLE TO RECEIVE HORMONAL THERAPY..

If you have a uterus and receive estradiol pellets, you can develop vaginal bleeding and/or uterine lining hyperplasia (excess tissue growth) and rarely uterine cancer. To prevent bleeding or uterine cancer we must also prescribe progesterone. If bleeding persists, you might end up needing a D&C, hormonal IUD, uterine ablation, or rarely a hysterectomy.

Consent for Procedure and Treatment:

I consent to the insertion of hormone pellets below the skin in or near my hip. I have been informed that I *may* experience one or more of the complications and/or side effects listed below. The hormonal risks and side effects are similar to those related to traditional estrogen and/or testosterone hormone therapy and the procedural risks are similar to other medical procedures.

This consent is ongoing for present and future treatment.

Possible Risks and Side Effects of Estrogen pellet insertion and use

- Bleeding, infection and/or pain at the insertion site
- Lack of effect (from lack of absorption, insufficient dosing, or other reasons)
- Possible pellet expulsion (rare)
- Increased growth of estrogen dependent tumors (liver cancer, endometrial cancer, breast cancer)
- Breast tenderness and swelling especially in the first few weeks
- Blood clots (phlebitis, thrombophlebitis, pulmonary embolism)
- Water retention, bloating
- Pellets cannot be removed after insertion. If pellet therapy is discontinued, it can take up to 6-12 months for the hormone level in the bloodstream to return to baseline.

Potential Benefits of use of Estradiol hormone pellets

- Increased (sex drive) libido, energy, and sense of well-being
- Decrease in mood swings, anxiety and/or irritability
- Improvement in balance
- Improvement of dry eyes
- Improvement in arthritis and fibromyalgia

Possible Risks and Side Effects of Testosterone pellet insertion and use

- Bleeding, infection and/or pain at the insertion site
- Lack of effect (from lack of absorption, insufficient dosing, or other reasons)
- Possible pellet expulsion (rare)
- Birth defects in babies exposed to testosterone during their gestation
- Growth of liver tumors, if already present
- Increase in hair growth on the face (normally reversible, rarely permanent)
- Change in voice (normally reversible, rarely permanent)
- Clitoral enlargement (normally reversible, rarely permanent)
- New or worsening acne
- Pellets cannot be removed after insertion. If pellet therapy is discontinued, it can take up to 6-12 months for the hormone level in the bloodstream to return to baseline.

Potential Benefits of use of Testosterone hormone pellets

- Increased (sex drive) libido, energy, and sense of well-being
- Decreased frequency and severity of hormonal migraine headaches
- Decrease in mood swings, anxiety and/or irritability
- Increase in muscle mass and decrease in subcutaneous fat (cellulite)
- Improvement in balance
- Decreased central obesity
- Improvement of dry eyes
- Improvement in arthritis and fibromyalgia

Agreement

My signature below indicates that I have read and understand the above possible risks and possible side effects of using estradiol and/or testosterone hormone pellet therapy. I acknowledge that I have been encouraged to ask questions regarding testosterone and/or estrogen hormone pellets and all my questions have been answered to my satisfaction. I also acknowledge that the risks and benefits of this treatment and the insertion procedure have been explained to me. I agree to inform Pasadena Pellet Therapy right away if I develop any negative side effects.

By signing below, I attest that I am aware of the following:

- Pharmaceutical estradiol is FDA approved for use in females for relief of menopausal symptoms, prevention of osteoporosis, and other conditions.
- Pharmaceutical testosterone is FDA approved for use in males diagnosed with low-Testosterone syndrome and other conditions.
- Pharmaceutical Testosterone IS NOT FDA APPROVED FOR USE IN FEMALES.
- PHYSICIANS MAY PRESCRIBE FDA-APPROVED MEDICATION FOR NON-FDA APPROVED USES. This is called “off-label” prescribing. It is allowed but requires informed consent by the provider to the patient.
- To achieve satisfactory results, it is common to use higher hormone doses than what are considered “usual” or “normal”, referred to as supraphysiologic doses. The dose and blood levels of your hormones require careful selection and monitoring to help ensure your safety.
- In addition to pellet form, Testosterone can be given as oral lozenges, skin creams, and pills; and Estradiol can be given as skin creams, gels, patches; and oral and vaginal, all determined during your consultation with our physicians.
- We do not advise patients using pellet hormone therapy to abruptly stop treatment. Pellets cannot be removed after insertion. If pellet therapy is discontinued, it can take up to 6-12 months for the hormone levels in the bloodstream to return to baseline. A weaning plan should be established for patients who want to stop receiving pellet hormone treatment.
- **For women with their uterus:** If an estrogen pellet has been placed, it is mandatory to use a progesterone type hormone (or progesterone IUD) for one full year from the date of the last estrogen pellet placement. This is due to the lingering presence of estrogen in the bloodstream which can increase the risk of uterine cancer if a progesterone agent is not taken. This is not the case if only testosterone pellets were placed.
- **There is no guarantee that hormone treatment will provide relief of the symptoms that motivated you to use this treatment.**

This consent is ongoing for present and future treatment. (choose one option below):

 I understand these potential risks and benefits. I am aware of all the information in this informed consent document. I consent to using bio-identical hormone therapy and I agree to undergo the pellet insertion procedure.

 I understand these potential risks and benefits. I am aware of all the information in this informed consent document. I consent to using bio-identical hormone therapy but I do not wish to undergo the pellet insertion procedure.

Patient Signature: _____ Date: _____

August 2022