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

Bio-identical hormone pellets are made from plants. They are **FDA monitored, but not FDA approved**, for female hormonal replacement. The pellet method of hormone replacement 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 just 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. Many experts believe that the WHI study data does not apply to treatment with bio-identical hormone replacement using subcutaneous pellets.

Pellet hormone therapy is usually suggested for you after other methods of hormone replacement 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 were unable to tolerate other forms of hormone therapy.

Patients who are not sterilized and not menopausal are advised to continue reliable birth control while participating in hormonal pellet replacement therapy. Testosterone is category X (will cause birth defects) and should never be given to pregnant women. YOU MUST BE STERILIZED or USE EFFECTIVE BIRTH CONTROL TO USE HORMONAL PELLETS.

If you have a uterus and receive estradiol pellets, you may develop vaginal bleeding and/or uterine lining hyperplasia. To prevent bleeding or uterine cancer we also have to prescribe progesterone. If bleeding persists, you may end up needing a D&C, a uterine ablation, or rarely a hysterectomy, in order to continue using estradiol pellet therapy.

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. These risks and side effects are similar to those related to traditional estrogen and/or testosterone hormone therapy. The surgical risks are the same as for any minor medical procedure.

This consent is ongoing for present and future treatment.

Possible Risks and Side Effects of Estrogen and/or Testosterone pellet insertion and use

- Bleeding, infection and/or pain at the insertion site
- Lack of effect (from lack of absorption or insufficient dosing)
- Increased growth of estrogen dependent tumors (endometrial cancer, breast cancer)
- Breast tenderness and swelling especially in the first few weeks (estrogen pellets)
- Blood clots (phlebitis, thrombophlebitis, pulmonary embolism – estrogen pellets)
- Water retention, bloating (estrogen only)
- Birth defects in babies exposed to testosterone during their gestation
- Growth of liver tumors, if already present (testosterone pellets)
- Increase in hair growth on the face, similar to pre-menopausal patterns (testosterone pellets)
- Change in voice –which is reversible (testosterone pellets)
- Clitoral enlargement—which is reversible (testosterone pellets)
- New or worsening acne (testosterone pellets)

Potential Benefits of use of Estradiol and/or 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 (secondary to hormonal decreases)
- 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 any questions regarding testosterone and/or estrogen hormone pellets and all of 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 am aware that estradiol and testosterone hormone pellets are FDA monitored but not approved for women. This consent is ongoing for present and future treatment.

I accept these risks and benefits and I agree to undergo the pellet insertion procedure and I consent to using bio-identical hormone pellet therapy.

Patient Signature: _____ Date: _____