

## FEMALE BIO-IDENTICAL PELLET INSERTION PROCEDURE CONSENT

**Patient:**

**DOB:**

**Date:**

\_\_\_\_\_

Bio-Identical hormone biologically identical to the hormones you make in your own body prior to menopause. Estrogen and testosterone were made in your ovaries and adrenal gland 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 fluctuations (ups and downs) of menstrual cycles.

Bio-identical hormone pellets are made from plants and are FDA monitored, but not approved for female hormonal replacement. The pellet method of hormone replacement has been used in Europe and Canada for many years and by select providers in the United States. You will have similar risks as you had prior to menopause, from the effects of estrogen and androgens, given as pellets.

**FYI:** The WHI study on hormone replacement therapy that was reported first in 2002 had many flaws in the study (only studied Premarin {horse estrogen} and Provera {a synthetic type of progestin} and had findings that were not consistent with the last 1,500 studies done on HRT. The WHI study is not applicable to treatment with bio-identical hormone replacement pellets.

Hormone pellet therapy is usually suggested after traditional methods for replacement have failed, however some patients choose bio-identical pellets because they resemble women's pre-menopausal hormones, and therefore have a more natural effect.

Patients who have not had a total hysterectomy or tubal ligation and are not menopausal are advised to continue reliable birth control while participating in pellet hormonal replacement therapy. Testosterone is category X (will cause birth defects and possible virilization) and cannot be given to pregnant women.

**YOU MUST BE STERILIZED OR USE AN EFFECTIVE FORM OF BIRTH CONTROL TO USE HORMONAL PELLETS.**

My method of birth control is: (please circle)

ABSTINENCE

BIRTH CONTROL PILLS

HYSTERECTOMY

MENOPAUSE

TUBAL LIGATION

VASECTOMY

IUD

Other \_\_\_\_\_

In addition, we ask that our female patient have had a normal pap smear and mammogram within one year of insertion.

\_\_\_\_\_ **(Initials)** I have had a normal pap smear and mammogram within the past year or I am no longer medically required to have them.

\_\_\_\_\_ **(Initials)** I have NOT had a Pap smear or mammogram within the last year. I voluntarily choose to undergo pellet insertion today. I am aware that if any breast or uterine issues arise and/or develop while on pellet therapy, I release this ReviveMD affiliate clinic, from any liability should this occur.

The risks of estrogen and testosterone pellet insertion that have been explained to me include:

**Fluid Retention:** Fluid entrapment in the muscle from testosterone stimulating the muscle to grow. This may result in weight gain of 2-5 pounds. This is temporary and will last two to three weeks. This happens more frequently with the first insertion, and especially when done in hot and humid weather conditions.

**Swelling of the hands and feet:** More likely to occur in hot and humid weather conditions. This can be treated by drinking lots of water, reducing your salt intake, taking apple cider vinegar capsules (available at most health food stores), or a mild diuretic that a provider can prescribe.

**Breast tenderness and nipple sensitivity:** May occur with the first pellet insertion. This is due to an increased blood supply to the breasts caused by the estrogen, which is desirable because the increased blood supply nourishes the tissue. If it is bothersome, an excellent remedy is evening primrose oil capsules (available at most health food stores).

**Uterine spotting or bleeding:** May Occur in the first two months after an insertion, especially if you forget to take your progesterone or if the dose is not high enough. Our office must be notified of this. The bleeding is usually not an indication of a significant uterine problem. More than likely the uterus is simply releasing old tissue. If the bleeding continues for more than two months, it may be a sign that you have a benign polyp or fibroid of the uterus that needs to be removed.

**Infection:** Infection would be indicated by excessive swelling, bleeding or pus. If this occurs please notify the office (some tenderness at the insertion site can be expected and should not be cause for alarm).

**Extrusion:** After pellets are inserted into the subcutaneous layer of the skin, it is normal to notice a bump that may last until the pellets have completely dissolved (3-6 months). However, in rare cases, a pellet will attempt to come out. This is more likely if you do not follow the post pellet insertion instructions. A pellet attempting to extrude will often feel and look like a pimple. Please inform our office if this is occurring.

**Mood Swings and Irritability:** Usually seen in patients who are very deficient in hormones. This will disappear when enough hormones get into the system.

**Facial Pimples and Facial Hair:** May occur if the body was extremely deficient in testosterone. This lasts a short time and can be handled with good face washing and use of astringents and skin toner. If you are troubled by these side effects, there are good natural and pharmacologic agents which can help. Please inquire about them.

The potential benefits that have been explained to me include:

- Increased libido
- Improvement of vaginal dryness
- Increase in muscle mass
- Improvement in balance
- Improved dry eyes
- Decrease in menopausal symptoms
- Increased energy and sense of well-being
- Decreased frequency and severity of hormonal migraine headaches
- Decrease in mood swings
- Decreased central obesity
- Decreased anxiety and irritability (secondary to hormonal decreases)
- Decrease in subcutaneous fat (cellulite)
- Possible improvement in arthritis in fibromyalgia

I \_\_\_\_\_ (**patient**) authorize this ReviveMD affiliate clinic to perform the following procedure:

## **STERILE SURGICAL PLACEMENT OF HORMONAL PELLETS UNDER THE SKIN.**

I understand the reason for the procedure and the risks associated with this particular procedure. I also understand that local anesthesia also involves risk, most importantly a rare risk of reaction to medication causing death. I consent to the use of such anesthetic as may be considered necessary by the provider for these services. I understand that no guarantee or assurance has been made as to the result of the procedure and that it may not cure the condition.

By signing below, I am consenting to the hormonal pellet insertion. I have read and fully understand this consent form and understand that I should not sign this form if all items, including my questions, have not been explained or answered to my full satisfaction, or if I do not understand any part of this consent form.

All risks and benefits have been explained to me and I do not have any further questions at this time. **This consent is on going for this and all future pellet insertions.**

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Signature of Patient: \_\_\_\_\_

Date: \_\_\_\_\_

Name (PRINT): \_\_\_\_\_