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Female Testosterone Pellet Insertion Consent Form

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 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 soy 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 OB/GYNs 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.

Patients who are pre-menopausal are advised to continue reliable birth control while participating in pellet hormone replacement therapy. Testosterone is category X (will cause birth defects) and cannot be given to pregnant women.

My birth control methods (please circle):

Abstinence Birth control pill Hysterectomy IUD Menopause Tubal Ligation Vasectomy Other: _____

CONSENT FOR TREATMENT:

I consent to the insertion of testosterone and/or estradiol pellets in my hip. l have been informed that I may experience any of the complications to this procedure as described below. These side effects are similar to those related to traditional testosterone and/or estrogen replacement. Surgical risks are the same as for any minor medical procedure and are included in the list of overall risks below.

Bleeding, bruising, swelling, infection, painful extrusion of pellets, hyper sexuality (overactive libido), and lack of effect (from lack or absorption). Increase in hair growth on the face, similar to pre-menopausal patterns, birth defects in babies exposed to testosterone during their gestation; growth of liver tumors, if already present change in voice (which is reversible), clitoral enlargement (which is reversible). Testosterone therapy may increase one's hemoglobin and hematocrit levels. This can be diagnosed with a blood test. Thus, a complete blood count (Hemoglobin & Hematocrit) should be done at least annually.

BENEFITS OF TESTOSTERONE PELLETS INCLUDE:

Increased libido, energy, and sense of well-being. Increased muscle mass and strength and stamina. Decreased frequency and severity of migraine headaches. Decrease in mood swings anxiety and irritability. Decreased weight. Decrease in risk or severity of diabetes. Decreased risk of heart disease. Decreased risk of Alzheimer's and dementia.

I have read and understand the above. I have been encouraged and have had the opportunity to ask any questions regarding pellet therapy. All of my questions have been answered to my satisfaction. I further acknowledge that there may be risks of testosterone and or estrogen therapy that we do not yet know, at

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this time, and that the risks and benefits of this treatment have been explained to me and I have been informed that I may experience complications, including one or more of those listed above. I accept these risks and benefits and I consent to the insertion of hormone pellets under my skin. This consent is ongoing for this and all future pellet insertions.

I understand that payment is due in full at the time of service. I also understand that it is my responsibility to submit a claim to my insurance company for possible reimbursement. I have been advised that most insurance companies do not consider pellet therapy to be a covered benefit and my insurance company may not reimburse me, depending on my coverage. I acknowledge that my provider has no contracts with any Insurance company and is not contractually obligated to pre-certify treatment with my insurance company or answer letters of appeal.

Print Name Signature Date

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WHAT MIGHT OCCUR AFTER STARTING TESTOSTERONE

A significant hormonal transition will occur in the first four weeks after you begin testosterone. Therefore, certain changes might develop that can be bothersome.

FLUID RETENTION: Testosterone stimulates the muscle to grow and retain water which may result in a weight change of two to five pounds. This is only temporary. This happens frequently with the first insertion, and especially during hot, humid weather conditions.

SWELLING OF THE HANDS & FEET: This is common in hot and humid weather. It may be treated by drinking lots of water, reducing your salt intake, taking cider vinegar capsules daily, (found at most health and food stores) or by taking a mild diuretic, which the office can prescribe.

UTERINE SPOTTING/BLEEING: This may occur in the first few months after an insertion, especially if you have been prescribed progesterone and are not taking properly: i.e. missing doses, or not taking a high enough dose. Please notify the office if this occurs. Bleeding is not necessarily an indication of a significant uterine problem. More than likely, the uterus may be releasing tissue that needs to be eliminated. This tissue may have already been present in your uterus prior to getting pellets and is being released in response to the increase in hormones.

MOOD SWINGS/IRRITABILITY: These may occur if you were quite deficient in hormones. They will disappear when enough hormones are in your system.

FACIAL BREAKOUT: Some pimples may arise if the body is very deficient in testosterone. This lasts a short period of time and can be handled with a good face cleansing routine, astringents and toner. If these solutions do not help, please call the office for suggestions and possibly prescriptions.

HAIR LOSS: ls rare and usually occurs in patients who convert testosterone to DHT. Dosage adjustment generally reduces or eliminates the problem. Prescription medications may be necessary in rare cases.

HAIR GROWTH: Testosterone may stimulate some growth of hair on your chin, chest, nipples and/or lower abdomen. This tends to be hereditary. You may also have to shave your legs and arms more often. Dosage adjustment generally reduces or eliminates the problem.

I acknowledge that I have received a copy and understand the instructions on this form.

_____

Print Name **Signature** **Date**

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Post Pellet Instructions

* Your insertion site has been covered with two layers of bandages. The inner layer is a steri-strip and the outer layer is a waterproof dressing.

* We recommend putting an ice pack on the insertion area a couple of times for about 20 minutes each time over the next 4 to 5 hours. You can continue for swelling if needed. Be sure to place something between the ice pack and your bandages/skin. Do not place ice packs directly on bare skin.
* No tub baths, hot tubs, or swimming pools for 7 days. You may shower, but do not scrub the site until the incision is well healed (about 7 days).

* **No major exercises for the incision area for 7 days**. This includes running, elliptical, squats, lunges, etc. You can do moderate upper body work and walking.

* The sodium bicarbonate in the anesthetic may cause the site to swell for 1-3 days.

* The insertion site may be uncomfortable for up to 2 to 3 weeks. If there is itching or redness you may take Benadryl for relief, 50 mg. orally every 6 hours. Caution this can cause drowsiness!

* You may experience bruising, swelling, and/or redness of the insertion site which may last from a few days up to 2 to 3 weeks.

* You may notice some pinkish or bloody discoloration of the outer bandage. This is normal.

* If you experience bleeding from the incision, apply firm pressure for 5 minutes.

* Please call if you have any bleeding (not oozing) not relieved with pressure, as this is NOT normal.

* Please call if you have any pus coming out of the insertion site, as this is NOT normal.

Reminders:

* Remember to go for your post-insertion blood work 6 weeks after the insertion.

* Most men will need re-insertions of their pellets 3-4 months after their initial insertion.

* Please call to make an appointment for re-insertion as soon as symptoms that were relieved from the pellets start to return. The charge for the second visit will be only for the insertion, not a consultation.

I acknowledge that I have received a copy and understand the instructions on this form.

_____

Print Name **Signature** **Date**

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Mammogram Waiver for Testosterone and/or Oral Estradiol Therapy

I, _____, voluntarily choose to undergo implantation of subcutaneous bio-identical Testosterone pellet therapy and/or oral Estradiol Therapy, even though I am not current on yearly mammogram. I understand that such therapy is controversial and that many doctors believe that estradiol replacement in my case is contraindicated. My treating Provider has informed me it is possible that taking estradiol could possible cause cancer or stimulate existing breast cancer (including one that has not yet been detected). Accordingly, I am aware that breast cancer or other cancer could develop while on pellet therapy and/or oral estradiol.

( ) **For today's appointment I DO NOT have a mammogram for the following reason:**
( ) **My decision not to have one.**
( ) **Unable to provide the report at this time.**
( ) **My doctors decision not to have one.** Please provide a note from your treating physician with their rationale as to why they don't want you to have a mammogram.

I am aware that a current report must be sent by mail or faxed to our office prior to my next HRT appointment. The Treating Provider has discussed the importance and necessity of a mammogram since I receive testosterone and/or estradiol. _____ **(initials of patient)**

I have assessed this risk on a personal basis, and my perceived value of the hormone therapy outweighs the risk in my mind. I am, therefore, choosing to undergo the pellet therapy despite the potential risk that I was informed of by my Treating Provider.

I understand that mammograms are the best single method for detection of early breast cancer. I understand that my refusal to submit to a mammogram test may result in cancer remaining undetected within my body. I acknowledge that I bear full responsibility for any personal injury or illness, accident, risk or loss (including death and/or breast, uterine or cancer issues) that may be sustained by me in connection with my decision to not have a mammogram and undergo testosterone pellet therapy and/or oral estradiol including, without limitation, any cancer that should develop in the future, whether it be deemed a stimulation of a current cancer or a new cancer. I hereby release and agree to hold harmless any owner or employee of Apollo Medical Associates, INC., physicians, physician assistants, nurse practitioner, officers, directors, employees and agents from any and all liability claims, demands and actions arising or related to any loss, property damage, illness, injury or accident that nay be sustained by me as a result of testosterone and/or estradiol therapy. I acknowledge and agree that I have been given adequate opportunity to review this document and to ask questions. This release and hold harmless agreement is and shall be binding on myself and my heirs, assigns and personal representatives.

_____

Print Name **Signature** **Date**

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PAP and Transvaginal Ultrasound waiver for Testosterone and/or Estradiol Pellet Therapy

I, _____, voluntarily choose to undergo implantation of subcutaneous bio-identical Testosterone pellet and/or oral Estradiol therapy.

( ) For today's appointment I DO NOT have a PAP Smear for the following reason:

( ) My decision not to have one.
( ) Unable to provide the report at this time.
( ) My doctors decision not to have one. Please provide a note from your treating physician with their rationale as to why they don't want you to have a PAP Smear.

( ) For today's appointment I DO NOT have a Transvaginal Ultrasound for the following reason

( ) My decision not to have one.
( ) Unable to provide the report at this time.
( ) My doctors decision not to have one. Please provide a note from your treating physician with their rationale as to why they don't want you to have a Transvaginal Ultrasound.

I am aware that a current report must be sent by mail or faxed to our office prior to my next HRT appointment. The Treating provider has discussed the importance and necessity of a Pap smear and/or Transvaginal Ultrasound (if indicated) since receive testosterone and/or estradiol.

_____ (initials of patient)

I have assessed this risk on a personal basis, and my perceived value of the hormone therapy outweighs the risk in my mind. I am, therefore, choosing to undergo the pellet therapy despite the potential risk that I was informed of by my Treating Provider.

I understand that PAP smear and/or Transvaginal Ultrasounds are the best single method for detection of early ovarian, endometrial and/or cervical cancer. I understand that my refusal to submit to a Pap smear and/or Transvaginal Ultrasound may result in cancer remaining undetected within my body. I acknowledge that I bear full responsibly for any personal injury or illness, accident, risk or loss (including death and/or cervical, endometrial and/or ovarian cancer issues) that may be sustained by me in connection with my decision to not have a PAP Smear and/or Transvaginal Ultrasound and undergo testosterone pellets and/or oral estradiol therapy including, without limitation, any cancer that should develop in the future, whether it be deemed a stimulation of a current cancer or a new cancer. I hereby release and agree to hold harmless Apollo Medical Associates, INC., physicians, physician assistants, nurse practitioner, officers, directors, employees and agents from any and all liability, claims, demands and actions arising or related to any loss, property damage, illness, injury or accident that may be sustained by me as a result of testosterone pellets and/or oral estradiol therapy. I acknowledge and agree that I have been given adequate opportunity to ask questions. This release and hold harmless agreement is and shall be binding on myself and my heirs, assigns and personal representative.

_____

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Print Name **Signature** **Date**

Ovarian Cancer Waiver for Testosterone and/or Oral Estradiol Therapy

I, _____, voluntarily choose to undergo implantation of subcutaneous bio-identical testosterone pellet therapy and/or oral Estoril Therapy, even though I am not current on yearly mammogram. I understand that such therapy is controversial and that many doctors believe that estradiol replacement in my case is contraindicated. My treating Provider has informed me it is possible that taking estradiol could possible cause cancer or stimulate existing breast cancer (including one that has not yet been detected). Accordingly, I am aware that breast cancer or other cancer could develop while on pellet therapy and/or oral estradiol.

I have assessed this risk on a personal basis, and my perceived value of the hormone therapy outweighs the risk in my mind. I am, therefore, choosing to undergo the pellet therapy and/or oral hormone therapy despite the potential risk that I was informed of by my Treating Provider.

I acknowledge that I bear full responsibility for any personal injury or illness, accident, risk or loss (including death and/or breast, uterine or cancer issues) that may be sustained by me in connection with my decision to not have a mammogram and undergo testosterone pellet therapy and/or oral estradiol including, without limitation, any cancer that should develop in the future, whether it be deemed a stimulation of a current cancer or a new cancer. I hereby release and agree to hold harmless any owner or employee of Apollo Medical Associates, inc., medical physicians, physician assistants, nurse practitioner, officers, directors, employees and agents from any and all liability claims, demands and actions arising or related to any loss, property damage, illness, injury or accident that nay be sustained by me as a result of testosterone and/or estradiol therapy. I acknowledge and agree that I have been given adequate opportunity to review this document and to ask questions. This release and hold harmless agreement is and shall be binding on myself and my heirs, assigns and personal representatives.

Print Name **Signature** **Date**