



### **Male Testosterone Pellet Insertion Consent Form**

Bio-identical testosterone pellets are concentrated, compounded hormone, biologically identical to the testosterone that is made in your own body. Testosterone was made in your testicles prior to-andropause. Bio-identical hormones have the same effects on your body as your own testosterone did when you were younger. Bio-identical hormone pellets are made from yams, and bio-identical hormone replacement using pellets has been used in Europe, the U. S. and Canada since the 1930's. Your risks are similar to those of any testosterone replacement but maybe lower risk than alternative forms. During andropause, the risk of not receiving adequate hormone therapy can outweigh the risks of replacing testosterone.

#### **Risks of not receiving testosterone therapy after andropause (Low-T) include but are not limited to:**

Arteriosclerosis, elevation of cholesterol, obesity, loss of strength and stamina, generalized aging osteoporosis, mood disorders, depression, arthritis, loss of libido, erectile dysfunction, loss of skin tone, diabetes, increased overall inflammatory processes, dementia and Alzheimer's disease, and many other symptoms of aging,

#### **CONSENT FOR TREATMENT:**

I consent to the Insertion of testosterone pellets in my hip. I have been informed that I may experience any of the complications to this procedure as described below. Surgical risks are the same as for any minor medical procedure.

#### **Side effects may include:**

Bleeding, bruising, swelling, infection, and pain. Lack of effect (typically from lack of absorption). thinning hair, male pattern baldness. Increased growth of prostate and prostate tumors. Extrusion of pellets. Hyper sexuality (overactive libido). Ten to fifteen percent shrinkage in testicle size. There can also be a significant reduction in sperm production.

There is some risk, even with natural testosterone therapy, of enhancing an existing current prostate cancer to grow more rapidly. For this reason, a prostate specific antigen blood test is to be done before starting testosterone pellet therapy and will be conducted each year thereafter. If there is any question about possible prostate cancer, a follow-up with an ultrasound of the prostate gland may be required as well as a referral to a qualified specialist. While urinary symptoms typically improve with testosterone, rarely they may worsen, or worsen before improving. Testosterone therapy may increase one's hemoglobin and hematocrit or thicken one's blood. This problem can be diagnosed with a blood test. Thus, a complete blood count (Hemoglobin and 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 (secondary to hormonal decline). Decreased weight (Increase in lean body mass}. Decrease in risk or severity of diabetes. Decreased risk of Alzheimer's and Dementia. Decreased risk of heart disease in men less than 75 years old with no pre-existing history of heart disease.

On January 31, 2014, the FDA issued a Drug Safety Communication indicating that the FDA is investigating risk of heart attack and death in some men taking FDA approved testosterone products. The



risks were found in men over the age of 65 years old with pre-existing heart disease and men over the age of 75 years old with or without pre-existing heart disease. These studies were performed with testosterone patches, testosterone creams and synthetic testosterone injections and did not include subcutaneous hormone pellet therapy.

I agree to immediately report to my practitioner's office any adverse reactions or problems that may 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 bio-identical 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 bio-identical therapy. I certify this form has been fully explained to me, and/or I have read it or have had it read to me and I understand its contents. 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 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.

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**Print Name**

**Signature**

**Date**



## 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.

**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:** Is 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.

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**Print Name**

**Signature**

**Date**



### **Post-Insertion Instructions for Men**

- \* 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 4 weeks after the insertion.
- \* Most men will need re-insertions of their pellets 5-6 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.

#### **Additional instructions:**

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

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**Print Name**

**Signature**

**Date**

**Prostate Cancer Waiver for Testosterone Pellet Therapy**

I, **(patient name)** \_\_\_\_\_, voluntarily choose to undergo implantation of subcutaneous bio-identical testosterone pellet therapy with, **(Treating Provider)** \_\_\_\_\_ even though I have a history of prostate cancer. I understand that such therapy is controversial and that many doctors believe that testosterone replacement in my case is contraindicated. My Treating Provider has informed me it is possible that taking testosterone could possibly cause cancer or stimulate existing prostate cancer (including one that has not yet been detected). Accordingly, I am aware that prostate cancer or other cancer could develop while on pellet therapy.

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 acknowledge that I bear full responsibility for any personal injury or illness, accident, risk or loss (including death and/or prostate issues) that may be sustained by me in connection with my decision to undergo testosterone pellet 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 any Physicians, Physician Assistants, nurses, 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 pellet therapy. I acknowledge and agree that I have been given adequate opportunity to review this document and to ask questions. This release indicated that I hold harmless, any owner or employee of Apollo Medical Associates, INC. This agreement is and shall be binding on myself and my heirs, assigns and personal representatives.

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**Patient Print Name**

**Signature**

**Date**

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**Provider Print Name**

**Signature**

**Date**

