

## MALE BIOIDENTICAL PELLETT PROCEDURE INSERTION CONSENT

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 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.

### **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 case

**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.



I \_\_\_\_\_ (patient) authorize a provider at Fast Clinical Weight Loss 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.

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 on going for this and all future pellet insertions.**

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

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

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