



## MALE Testosterone and/or Estradiol Pellet Insertion Consent Form

Bio-identical testosterone pellets are 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 plant derived 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 may be 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 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, pain, reaction to local anesthetic and/or preservatives, 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 and significant reduction in sperm production.

Possible risks include: 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. This condition can be reversed simply by donating blood periodically.

**POSSIBLE BENEFITS OF TESTOSTERONE PELLETS INCLUDE:**

Increased libido, energy, and sense of well-being; increased muscle mass 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; and 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 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 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 understand Revitalise is a separate cash pay only company for BioTe Nutraceuticals and pellet insertion. 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

Today's Date



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