



## Patient Procedure/Treatment Consent Form Biote Pellet Insertion (Male)

Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_

I hereby authorize and direct \_\_\_\_\_ and assistants, as necessary to perform quality care, to perform the following procedure/treatment on me:

Biote Pellet Insertion (Male)

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 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.

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.

The nature and purpose of the procedure/treatment, alternative methods of treatment, and potential risks and complications have been fully explained to me, including but not limited to:

- Bleeding, bruising, swelling, infection and pain.
- Lack of effect (typically from lack of absorption)
- Thinning hair, male pattern baldness
- Possible extrusion of pellets
- Increased growth of prostate and prostate tumors
- 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. This condition can be reversed simply by donating blood periodically.

A significant hormonal transition will occur in the first four weeks after the insertion of your hormone pellets. 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 hands and 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.

#### 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 I have read it or have had it read to me and I understand its contents.

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.

The care provider has explained my condition to me, the above treatment procedure and alternative methods of treating my condition. As well as discusses with me foreseeable risks of the above stated treatment and that there may be undesirable results.

I have carefully read and fully understand this informed Consent Form and have had the opportunity to discuss my condition and the above procedure(s) with the care provider. All my questions have been answered.

I acknowledge that no guarantees have been made to me as to the outcome of procedure(s) and/or treatment(s). I grant this consent without duress, confusion, or pressure from my physician and/or staff, associates, or colleagues.

Patient/Representative Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_