INTEGRATED PHYSICAL | MEDICINE

☐ New Lenox phone: 815.717.8355 fax: 815.717.8416
☐ Joliet phone: 815.439.2726 fax: 815.439.2741
☐ Roselle phone: 224.655.6555 fax: 224.653.9395
☐ Naperville phone: 331-249-3999 fax: 331-249-4029

MALE TESTOSTERONE PELLET INSERTION CONSENT FORM

Bio-identical hormone pellets are concentrated hormones biologically identical to the hormones you make in your own body. Testosterone is derived from the testicles (primarily) and adrenal glands (secondarily) prior to andropause.

Testosterone supplementation, in the medical research, has been shown to improve fatigue, exercise intolerance, muscle tone, libido, weight, and other conditions. It has been shown in research studies to decrease the risk of cardiovascular disease, diabetes, metabolic syndrome and prostate cancer.

Though laboratory assays can support a diagnosis of testosterone deficiency, they should not be used to exclude it as there are multiple problems in the measurement of testosterone (ex. dietary intake, sexual activity, sample storage variables, circadian variations). Greater reliance on the clinical features and consideration of symptoms is suggested as an appropriate tool in treating men with testosterone therapy. The generally accepted cutoff for low "normal" serum total testosterone is 300 ng/dl. It is reasonable to prescribe testosterone to a man who has symptoms of low testosterone and to expect testosterone values that are supraphysiologic after treatment.

All testosterone use in men with a serum level of greater than 300 ng/dl is considered "off label use". Off-label use refers to the use of any medication for something other than its FDA approval. Many medications prescribed in the US are prescribed for off-label use. The off-label use of testosterone therapy has not been evaluated by the FDA and any claims of benefit are purely educated opinions that come from consideration of various medical research studies.

Hormone pellet production is highly FDA regulated; however, the pellet insertion procedure is not an FDA approved procedure for hormonal replacement in the pellet doses we use for men (200 mg pellet).

Goals for treatment with this medication will be discussed at each appointment. If goals are met, then maintenance doses will be discussed. If the treatment is not as effective as anticipated, it might be discontinued; at that time, alternative therapies will be discussed. You are welcome to seek a second opinion or a specialist consultation.

SIDE EFFECTS: Side effects of subcutaneous hormone pellets will be managed clinically and individually. There have been no reported *irreversible* side effects of subcutaneous pellet therapy noted in the literature to date.

Potential side effects of pellet insertion may include, but not limited to: Surgical risks are the same as for any minor medical procedure. Bleeding, bruising, swelling, and pain; extrusion of pellets; infection or abscess formation; seroma formation; scarring at insertion site; keloid scar.

Potential side effects of testosterone therapy may include, but are not limited to:

> Hyper-sexuality (overactive libido), increase one's hemoglobin and hematocrit (erythrocytosis), acne, increase in body/facial hair growth, hair loss/thinning and virilization, testicular shrinkage, and reduction of sperm production that may take up to a year or more to normalize to baseline.

☐ New Lenox phone: 815.717.8355 fax: 815.717.8416
☐ Joliet phone: 815.439.2726 fax: 815.439.2741
☐ Roselle phone: 224.655.6555 fax: 224.653.9395
☐ Naperville phone: 331-249-3999 fax: 331-249-4029

Evidence linking testosterone therapy to the development of prostate cancer has not been established. There is some risk, even with natural testosterone therapy, of stimulating an *existing* prostate cancer to grow more rapidly. Following the American Urological Association recommendations for the evaluation and management of testosterone deficiency, a prostate specific antigen blood test is to be done before starting testosterone pellet therapy in men over 40 and annual labs may be required at the discretion of your healthcare provider. If there is concern about possible prostate cancer, additional testing and/or follow up with specialist may be required.

CONSENT FOR TREATMENT: I have been informed that I may experience any of the complications related to this procedure. Periodic adjustments are required to fine tune the treatment with this type of medication. Periodic blood tests are necessary to determine if the dose needs to be adjusted. I understand that testosterone supplementation is available in several forms including cream, oral formulation, injections and subcutaneous pellets. I understand that I am consenting to testosterone therapy for off label use of my symptoms if my baseline serum testosterone levels are over 300ng/dl. I understand the hormone pellet procedure is not FDA approved.

AFTERCARE: I agree to immediately report to my practitioner's office any adverse reaction or problems that might 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 hormone 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 hormone therapy. I accept these risks and benefits and I consent to the insertion of hormone pellets with a dosage regime discussed thoroughly by my hormone pellet provider.

I have read and understand this document in its entirety and have been given the opportunity to ask questions concerning my care. I consent to subcutaneous hormone pellet insertion. **This consent is ongoing for this and all future subcutaneous hormone pellet insertions.**

Patient Name	**Patient Signature**	**Date**

☐ New Lenox phone: 815.717.8355 fax: 815.717.8416
☐ Joliet phone: 815.439.2726 fax: 815.439.2741
☐ Roselle phone: 224.655.6555 fax: 224.653.9395
☐ Naperville phone: 331-249-3999 fax: 331-249-4029

References:

Gururani, K., Jose, J., & George, P. V. (2016). Testosterone as a marker of coronary artery disease severity in middle aged males. Indian heart journal, 68, S16-S20.

Lucas-Herald, A. K., Alves-Lopes, R., Montezano, A. C., Ahmed, S. F., & Touyz, R. M. (2017). Genomic and non-genomic effects of androgens in the cardiovascular system: clinical implications. Clinical Science, 131(13), 1405-1418.

Chistiakov, D. A., Myasoedova, V. A., Melnichenko, A. A., Grechko, A. V., & Orekhov, A. N. (2018). Role of androgens in cardiovascular pathology. Vascular health and risk management, 14, 283.

Kay-Tee, K., & Chir, M. B. B. (2007). Endogenous testosterone and mortality due to all causes, cardiovascular disease, and cancer in men. Am Heart Association, 116, 2694-701.

Malkin, C. J., Pugh, P. J., Morris, P. D., Kerry, K. E., Jones, R. D., Jones, T. H., & Channer, K. S. (2004). Testosterone replacement in hypogonadal men with angina improves ischemic threshold and quality of life. Heart, 90(8), 871-876.

Jones, T. Hugh, and Daniel M. Kelly. "Randomized controlled trials–mechanistic studies of testosterone and the cardiovascular system." Asian journal of andrology 20.2 (2018): 120

Goodale, Travis, et al. "Testosterone and the Heart." Methodist DeBakey cardiovascular journal 13.2 (2017): 68

Ohlander, S. J., Varghese, B., & Pastuszak, A. W. (2018). Erythrocytosis following testosterone therapy. Sexual medicine reviews, 6(1), 77-85.

Mithoowani, S., Laureano, M., Crowther, M. A., & Hillis, C. M. (2020). Investigation and management of erythrocytosis. CMAJ, 192(32), E913-E918.

Ohlander, S. J., Varghese, B., & Pastuszak, A. W. (2018). Erythrocytosis following testosterone therapy. Sexual medicine reviews, 6(1), 77-85.

Gordeuk, V. R., Key, N. S., & Prchal, J. T. (2019). Re-evaluation of hematocrit as a determinant of thrombotic risk in erythrocytosis. haematologica, 104(4), 653-658.

Carruthers M, Trinick TR, Wheeler MJ. The validity of androgen assays. The Aging Male. 2007;10:165-172.

Carruthers, M. (2008). The paradox dividing testosterone deficiency symptoms and androgen assays: a closer look at the cellular and molecular mechanisms of androgen action. The journal of sexual medicine, 5(4), 998-1012.

Carruthers, M. (2008). The paradox dividing testosterone deficiency symptoms and androgen assays: a closer look at the cellular and molecular mechanisms of androgen action. The journal of sexual medicine, 5(4), 998-1012