



BIOTE HORMONE PELLETS

What are BioTE Hormone Pellets?

Hormone pellets are a convenient and effective method for hormone optimization for both men and women. Once inserted under the skin, a low dose of natural hormone flows directly into the blood stream on a consistent basis. BioTE pellets are compounded to the highest industry standards using the best quality botanical ingredients as bio-identical hormones.

How often will I need BioTE Therapy?

For men, new pellets are usually inserted every 4 to 6 months, and for women, every 3 to 5 months which includes estrogen as well as testosterone.

Does the insertion hurt?

Insertion takes about 5 minutes, is done under a local anesthetic, and virtually painless.

Are there any side effects and how long does it take the hormones to work?

Side-effects are rare. For women, transient breast tenderness may last from 7 to 10 days but unlikely after the first insertion. Testosterone rarely causes acne or hair loss. Most women report symptomatic improvement within several days while testosterone pellets may take two weeks to reach full benefits.

Why hasn't my doctor suggested hormone pellets as an option?

Most physicians have trained to prescribe synthetic hormones, not on the use of bio-identical hormones.

How does Dr. Birken know what dosage to insert?

BioTe has a special formulation calculation, incorporating many factors, such as age, medical conditions, weight, and hormone levels resulting in extremely accurate dosage recommendations.

Randy A. Birken, MD



BIO-IDENTICAL HORMONE PROTOCOL

Please sign that you have read this information and agree to participate in Dr. Birken's BHRT/PELLET program.

Patient Signature: _____ Date: _____

For further questions, please contact the following by phone or email:

Liz 281.419.3231 liz@drbirken.com

Randy A. Birken, MD



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 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 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. This condition can be reversed simply by donating blood periodically.

Randy A. Birken, MD



TESTOSTERONE PELLET INSERTION CONSENT FORM

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. 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.

Print Name: _____

Patient Signature: _____ Date: _____

Randy A. Birken, MD



WHAT MIGHT OCCUR AFTER A PELLET INSERTION {MALE}

What Might Occur After A Peller Insertion (Male)

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 more so 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.

HAIR GROWTH: Testosterone may stimulate some growth of hair on your chin, chest, nipples and/or lower abdomen. This tends to be hereditary. You may also have to shave your legs and arms more often. Dosage adjustment generally reduces or eliminates the problem.

Print Name: _____

Patient Signature: _____ Date: _____

Randy A. Birken, MD



POST-INSERTION INSTRUCTIONS FOR MEN

- Your insertion site has been closed with steri-strips and covered with a waterproof bandage. Remove the bandage and steri-strips after 5 to 7 days.
- 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.
- Do not take tub baths or get into a hot tub or swimming pool for 3 days. You may shower but do not scrub the site until the incision is well healed (about 7 days).
- No intense lower body exercises for 7 days, this includes running, riding a horse, lower body weight lifting, etc.
- The sodium bicarbonate in the anesthetic may cause the site to swell for 1 to 3 days. Don't worry.....this is normal.
- The insertion site may be uncomfortable for up to 2 to 3 weeks. If there is itching or redness you may take an over the counter antihistamine such as Zyrtec or Claritin. You may also take Benadryl for relief which 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 on 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) or pus coming out of the insertion site that is not relieved by pressure.
- Remember to go for your post-insertion blood work 4 to 6 weeks after the insertion.
- Most men will need re-insertions of their pellets 5 to 6 months after their initial insertion.
- Please call as soon as symptoms that were relieved from the pellets start to return to make an appointment for a re-insertion.

Print Name: _____

Patient Signature: _____ Date: _____

Randy A. Birken, MD