

Name: _____ Date of birth: _____

PELLET INSERTION CONSENT FOR MALES

My physician/practitioner has recommended testosterone therapy delivered by a pellet inserted under my skin for treatment of symptoms I am experiencing related to low testosterone levels. The following information has been explained to me prior to receiving the recommended testosterone therapy.

OVERVIEW

Bioidentical testosterone is a form of testosterone that is biologically identical to that made in my own body. The levels of active testosterone made by my body have decreased, and therapy using these hormones may have the same or similar effect(s) on my body as my own naturally produced testosterone. The pellets are a delivery mechanism for testosterone, and bioidentical hormone replacement therapy using pellets has been used since the 1930's. There are other formulations of testosterone replacement available, and different methods can be used to deliver the therapy. The risks associated with pellet therapy are generally similar to other forms of replacement therapy using bioidentical hormones.

RISKS/COMPLICATIONS

Risks associated with pellet insertion may include: bleeding from incision site, bruising, fever, infection, pain, swelling, pellet extrusion which may occur several weeks or months after insertion, reaction to local anesthetic and/or preservatives, allergy to adhesives from bandage(s), steri strips or other adhesive agents.

Some individuals may experience one or more of the following complications: acne, anxiety, breast or nipple tenderness or swelling, insomnia, depression, mood swings, fluid and electrolyte disturbances, headaches, increase in body hair, fluid retention or swelling, mood swings or irritability, rash, redness, itching, lack of effect (typically from lack of absorption), transient increase in cholesterol, nausea, retention of sodium, chloride and/or potassium, weight gain or weight loss, thinning hair or male pattern baldness, increased growth of prostate and prostate tumors which may or may not lead to worsening of urinary symptoms, hypersexuality (overactive libido) or decreased libido, erectile dysfunction, painful ejaculation, ten to fifteen percent shrinkage in testicular size, and/or significant reduction in sperm production, increase in neck circumference, overproduction of estrogen (called aromatization) or an increase in red blood cell formation or blood count (erythrocytosis). The latter can be diagnosed with a blood test called a complete blood count (CBC). This test should be done at least annually. Erythrocytosis can be reversed simply by donating blood periodically, but further workup or referral may be required if a more worrisome condition is suspected.

All types of testosterone replacement can cause a significant decrease in sperm count during use. Pellet therapy may affect sperm count for up to one year. If you are planning to start or expand your family, please talk to your provider about other options.

Additionally, there is some risk, even when using bioidentical hormones, that testosterone therapy may cause existing cases of prostate cancer to grow more rapidly. For this reason, a prostate specific antigen blood test (PSA) is recommended for men ages 55-69 before starting hormone therapy, even if asymptomatic. Testing is also recommended for younger individuals considered high risk for prostate cancer. The test should be repeated each year thereafter. If there is any question about possible prostate cancer, a follow-up referral to a qualified specialist for further evaluation may be required.

CONSENT FOR TREATMENT:

I agree to immediately report any adverse reactions or problems that may be related to my therapy to my physician or health care provider's office, so that it may be reported to the manufacturer. Potential complications have been explained to me, and I acknowledge that I have received and understand this information, including the possible risks and potential complications and the potential benefits. I also acknowledge that the nature of bioidentical therapy and other treatments have been explained to me, and I have had all my questions answered.

I understand that follow-up blood testing will be necessary four (4) weeks after my initial pellet insertion and then at least one time annually thereafter. I also understand that although most patients will receive the correct dosage with the first insertion, some may require dose changes.

I understand that my blood tests may reveal that my levels are not optimal which would mean I may need a higher or lower dose in the future. Furthermore, I have not been promised or guaranteed any specific benefits from the insertion of testosterone pellets. I have read or have had this form read to me.

I accept these risks and benefits, and I consent to the insertion of testosterone pellets under my skin performed by my provider. This consent is ongoing for this and all future insertions in this facility until I am no longer a patient here, but I do understand that I can revoke my consent at any time. I have been informed that I may experience any of the complications to this procedure as described above.

Witness name: _____ Signature: _____ Date: _____

Print name: _____ Signature: _____ Date: _____

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POST-INSERTION INSTRUCTIONS FOR MEN

- Your insertion site has been covered with two layers of bandages. The inner layer is a steri-strip, and the outer layer is a waterproof dressing.
- **Do not take tub baths or get into a hot tub or swimming pool for 7 days.** You may shower, but do not remove the bandage or steri-strips for 7 days.
- No major exercises for the incision area. No heavy lifting using the legs for 7 days. This includes running, elliptical, squats, lunges, etc. You can do moderate upper body work and normal walking on a flat surface.
- The sodium bicarbonate in the anesthetic may cause the site to swell for 1-3 days.
- The insertion site may be uncomfortable for up to 2 to 3 weeks. If there is itching or redness you may take Benadryl for relief (50 mg orally every 6 hours). Caution: this 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. If the redness worsens after the first 2-3 days, please contact the office.
- You may notice some pinkish or bloody discoloration of 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) not relieved with pressure, as this is NOT normal.
- Please call if you have any pus coming out of the insertion site, as this is NOT normal.
- We recommend putting an ice pack on the area where the pellets are located a couple of times for about 20 minutes each time over the next 4 to 5 hours. You can continue this for swelling, if needed. Be sure to place something between the ice pack and your bandages/skin. Do not place ice packs directly on bare skin.

REMINDERS:

- Remember to have your post-insertion blood work done 4 weeks after your FIRST insertion.
- Most men will need re-insertion of their pellets 4-5 months after their initial insertion. If you experience symptoms prior to this, please call the office.
- Please call as soon as symptoms that were relieved from the pellets start to return to make an appointment for your next insertion.

ADDITIONAL INSTRUCTIONS:

I ACKNOWLEDGE THAT I HAVE RECEIVED A COPY AND UNDERSTAND THE INSTRUCTIONS ON THIS FORM.

Print name: _____

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WHAT MIGHT OCCUR AFTER A PELLETT 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.

- **INFECTION:**
Infection is a possibility with any type of procedure. Infection is uncommon with pellet insertion and occurs in <0.5 to 1%. If redness appears and seems to worsen (rather than improve), is associated with severe heat and/or pus, please contact the office. Warm compresses are helpful, but a prescription antibiotic may also be needed.
- **PELLET EXTRUSION:**
Pellet extrusion is uncommon and occurs in < 5% of procedures. If the wound becomes sore again after it has healed, begins to ooze or bleed or has a blister-type appearance, please contact the office. Warm compresses may help soothe discomfort.
- **ITCHING OR REDNESS:**
Itching or redness in the area of the incision and pellet placement is common. Some patients may also have a reaction to the tape or glue. If this occurs, apply hydrocortisone to the area 2-3 times daily. If the redness becomes firm or starts to spread, please contact the office.
- **FLUID RETENTION/WEIGHT GAIN:**
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, or by taking a mild diuretic, which the office can prescribe.
- **BREAST TENDERNESS OR NIPPLE SENSITIVITY:**
These may develop with the first pellet insertion. The increase in estrogen sends more blood to the breast tissue. Increased blood supply is a good thing, as it nourishes the tissue. Taking 2 capsules of DIM daily helps prevent excess estrogen formation. In males, this may indicate that you are a person who is an aromatizer (changes testosterone into estrogen). This is usually prevented if DIM is taken regularly but can be easily treated and will be addressed further when your labs are done, if needed.
- **MOOD SWINGS/IRRITABILITY:**
These may occur if you were quite deficient in hormones. These symptoms usually improve when enough hormones are in your system. 5HTP can be helpful for this temporary symptom and can be purchased at many health food stores.
- **ELEVATED RED BLOOD CELL COUNT:**
Testosterone may stimulate growth in the bone marrow of the red blood cells. This condition may also occur in some patients independent of any treatments or medications. If your blood count goes too high, you may be asked to see a blood specialist called a hematologist to make sure there is nothing worrisome found. If there is no cause, the testosterone dose may have to be decreased. Routine blood donation may be helpful in preventing this.
- **HAIR LOSS OR ANXIETY:**
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. 5HTP may be helpful for anxiety and is available over-the-counter.
- **FACIAL/BODY BREAKOUT:**
Acne may occur when testosterone levels are either very low or high. 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.
- **AROMATIZATION:**
Some men will form higher-than-expected levels of estrogen from the testosterone. Using DIM 2 capsules daily as directed may prevent this. Symptoms such as nipple tenderness or feeling emotional may be observed. These will usually resolve by taking DIM, but a prescription may be needed.
- **HIGH OR LOW HORMONE LEVELS:**
The majority of times, we administer the hormone dosage that is best for each patient, however, every patient breaks down and uses hormones differently. Most patients will have the correct dosage the first insertion, but some patients may require dosage changes and blood testing. If your blood levels are low, results are not optimal and it is not too far from the original insertion, we may suggest you return so we can administer additional pellets or a "boost" (at no charge). This would require blood work to confirm. On the other hand, if your levels are high, we can treat the symptoms (if you are having any) by supplements and/or prescription medications. The dosage will be adjusted at your next insertion.
- **TESTICULAR SHRINKAGE:**
Testicular shrinkage is expected with any type of testosterone treatment.
- **LOW SPERM COUNT:**
Any testosterone replacement will cause significant decrease in sperm count during use. Pellet therapy may affect sperm count up to one year. If you are planning to start or expand your family, please talk to your provider about other options.

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