

## Hormone Replacement for Improved Health and Quality of Life

Data supports that hormone replacement therapy with pellet implants is the most effective and the most bio-identical method to deliver hormones in both men and women. Implants, placed under the skin, consistently release small, physiologic doses of hormones providing optimal therapy.

### HOW DO I KNOW IF I AM A CANDIDATE FOR PELLETS?

Some of the symptoms you might be experiencing might include excessive weight gain, low libido or sex drive, mood swings, insomnia or trouble sleeping, depression, and or irritability. If you are experiencing any of these symptoms you might be a candidate for BHRT pellet therapy.

### What are Pellets?

Pellets are made up of either estradiol or testosterone. The hormones are pressed or fused into very small solid cylinders. These pellets are larger than a grain of rice and smaller than a 'Tic Tac'. In the United States, the majority of pellets are made by compounding pharmacists and delivered in sterile glass vials. There is a 'FDA approved' 75 mg testosterone pellet.

### Why pellets?

Pellets deliver consistent, healthy levels of hormones for 3-5 months in women and 4-6 months in men. They avoid the fluctuations, or ups and downs, of hormone levels seen with every other method of delivery. Estrogen delivered by subcutaneous pellets, maintains the normal ratio of estradiol to estrone. This is important for optimal health and disease prevention. Pellets do *not* increase the risk of blood clots like conventional or synthetic hormone replacement therapy.

In studies, when compared to conventional hormone replacement therapy, pellets have been shown to be *superior* for relief of menopausal symptoms, maintenance of bone density, restoration of sleep patterns, and improvement in sex drive, libido, sexual response and performance.

Testosterone delivered by a pellet implant, has been used to treat migraine and menstrual headaches. It also helps with vaginal dryness, incontinence, urinary urgency and frequency. In both men and women, testosterone has been shown to increase energy, relieve depression, increase sense of wellbeing, relieve anxiety and improve memory and concentration. Testosterone, delivered by pellet implant, increases lean body mass (muscle strength, bone density) and decreases fat mass. Men and women need adequate levels of testosterone for optimal *mental* and *physical* health and for the prevention of chronic illnesses like Alzheimer's and Parkinson's disease, which are associated with low testosterone levels.

Even patients who have failed other types of hormone therapy have a very high success rate with pellets. There is no other 'method of hormone delivery' that is

as convenient for the patient as the implants. Pellets have been used in both men and women since the late 1930's. There is more data to support the use of pellets than any other method of delivery of hormones.

### **How and where are pellets inserted?**

The insertion of pellets is a simple, relatively painless procedure done under local anesthesia. The pellets are usually inserted in the lower abdominal wall or upper buttocks through a small incision, which is then taped, closed. The experience of the health care professional matters a great deal, not only in placing the pellets, but also in determining the correct dosage of hormones to be used.

### **Are there any side effects or complications from the insertion of the pellets?**

Complications from the insertion of pellets include; minor bleeding or bruising, discoloration of the skin, infection, and the possible extrusion of the pellet. Other than slight bruising, or discoloration of the skin, these complications are very *rare*. Testosterone may cause a slight increase in facial hair in some women.

Testosterone stimulates the bone marrow and increases the production of red blood cells. A low testosterone level in older men is a cause of anemia.

Testosterone, delivered by implants or other methods, can cause an elevation in the red blood cells. If the hemoglobin and hematocrit (blood count) get too high, a unit of blood may be donated.

After the insertion of the implants, vigorous physical activity is avoided for 48 hours in women and up to 5 to 7 days in men. Complications from the insertion of pellets include minor bleeding, bruising, dis-coloration of the skin, infection, and possible extrusion of the pellet. Other than slight bruising, or discoloration of the skin these complications are very rare. Extended exposure to moisture (swimming, hot tubs, bath tubs) is avoided for 4 to 5 days, and vigorous physical activity is avoided for 48 hours in women and up to 5 to 7 days in men.

Early physical activity is a cause of 'extrusion', which is a pellet working it's way out. Antibiotics may be prescribed if a patient is diabetic or has had a joint replaced. However, this is a 'clean procedure' and antibiotics may not be needed

### **Why haven't I heard about Pellets?**

You may wonder why you haven't heard of pellets. Pellets are not patented and have not been marketed in the United States. They *are* frequently used in Europe and Australia where pharmaceutical companies produce pellets. Most of the research on pellets is out of Europe and Australia. Pellets were frequently used in the United States from about 1940 through the late 70's when oral patented estrogens were marketed to the public. In fact, some of the most exciting data on hormone implants in breast cancer patients is out of the United

States . Even in United States , there are clinics that specialize in the use of pellets for hormone therapy.

### **Do men need hormone therapy?**

Testosterone levels begin to decline in men beginning in their early 30's. Most men maintain adequate levels of testosterone into their mid 40's to mid 50's, some into their late 70's to early 80's. Men should be tested when they begin to show signs of testosterone deficiency. Even men in their 30's can be testosterone deficient and show signs of bone loss, fatigue, depression, erectile dysfunction, difficulty sleeping and mental decline. Most men need to be tested around 50 years of age. It is never too late to benefit from hormone therapy.

### **What if my primary care physician or my gynecologist says that there is 'no data' to support the use of pellet implants?**

He or she is wrong. There is a big difference between 'no data' and not having read the data. It is much easier for busy practitioners to dismiss the patient, than it is to question their beliefs and do the research. It's about a patient making an informed choice. After pellets are inserted, patients may notice that they have more energy, sleep better and feel happier. Muscle mass and bone density will increase while fatty tissue decreases. Patients may notice increased strength, co-ordination and physical performance. They may see an improvement in skin tone and hair texture. Concentration and memory may improve as will overall physical and sexual health. There is data to support the 'long term' safety of hormones delivered by pellet implants.

### **Do pellets have the same danger of breast cancer as other forms of hormone replacement therapy?**

Pellets do not carry with them the same risk of breast cancer as high doses of oral estrogens that do not maintain the correct estrogen ratio or hormone metabolites. Nor, do they increase the risk of breast cancer like the synthetic, chemical progestins used in the Women's Health Initiative Trial. Data supports that *balanced*, bio-identical hormones are breast protective.

**Testosterone**, delivered by pellet implantation, has been shown to decrease breast proliferation and **lower the risk of breast cancer**, even in patients on conventional hormone replacement therapy. Clinical studies show that bio-identical testosterone balances estrogen and is breast protective. This is not true of *oral*, synthetic methyl-testosterone found in Estratest®, which gets converted to a potent synthetic estrogen, which can stimulate breast tissue. In the past, testosterone implants have been used to treat patients with advanced breast cancer. In 1940, it was theorized that treating patients with testosterone implants earlier, at the time of diagnosis, would have an even greater benefit, preventing recurrence. Androgens have also been shown to enhance the effect of

Tamoxifen® therapy in breast cancer patients. References supporting these statements can be found in the [data section](#) of the website in the 'Breast Cancer Folder'. A power point presentation 'Nov 07', summarizing the full text references, may be viewed.

### **So, how can my doctor claim that bio-identical hormones are not safer than synthetic, chemical 'hormones'?**

Although some physicians and pharmaceutical companies claim that, 'bio-identical hormones are not safer than synthetic, chemical hormones', this is not true. Bio-identical progesterone (including FDA approved Prometrium®) does not increase the risk of breast cancer like the synthetic progestins. Progesterone, used vaginally, does not negate the beneficial effects of estrogen on the heart like the synthetic progestins. Estriol, an estrogen widely used in Europe is a bio-identical hormone, which has never been submitted for FDA approval in the United States . It does not bind strongly to estrogen receptors and does not stimulate breast tissue. Numerous studies have shown that vaginal estriol does not increase the risk of breast cancer (RR 0.7). It has safely been used in breast cancer survivors where it lowered the risk of recurrence and death. It is important to understand that *balanced* hormones are the key to health and disease prevention. There are FDA approved bio-identical hormones like Prometrium®, estradiol gels and patches, and the testosterone pellet. FDA approval is only required if a pharmaceutical company wants to market a drug to the public.

### **Are there side effects to estrogen delivered by pellet implantation?**

When a patient first starts on hormone therapy there may be mild, temporary breast tenderness, which resolves on its own. Hormone receptors may be very sensitive and take time to adjust. There may be a temporary water weight gain, which will also resolve on its own. Women, especially those who have *not* had a hysterectomy, may choose a different method of delivery of estrogen, as the risk of bleeding is significant.

#### **WHAT CAN I EXPECT AFTER PELLETS INSERTION?**

After pellets are inserted, patients may notice that they have more energy, sleep better and feel happier. Muscle mass and bone density will increase while fatty tissue decreases. Patients may notice increased strength, coordination and physical performance. They may see an improvement in skin tone and hair texture. Concentration and memory may improve as will overall physical and sexual health.

### **Will hormone therapy with estradiol and testosterone pellets help with hair loss?**

Hormone deficiency is a common cause of hair loss and treatment with estradiol and testosterone implants can help to re-grow hair. Hair becomes thicker and less dry with pellet therapy.

## How long until a patient feels better after pellets are inserted?

Some patients begin to 'feel better' within 24-48 hours while others may take a week or two to notice a difference. Diet and lifestyle, along with hormone balance are critical for optimal health. Stress is a major contributor to hormone imbalance and illness.

## How long do pellets last?

The pellets usually last between 3 and 5 months in women and 4-6 months in men. The pellets do not need to be removed. They completely dissolve on their own.

## Do patients need progesterone when they use the pellets?

Most times when estradiol is prescribed, progesterone is also prescribed even if the patient has had a hysterectomy. The main indication for the use of *synthetic* progestins, like Provera®, is to prevent the proliferation (stimulation) of the uterine lining caused by estrogen. However, there are *progesterone* (not progestin) receptors in the bone, brain, heart, bladder, breast and uterus where progesterone has been shown to have beneficial effects. Progesterone can be used as a topical cream, a vaginal cream, an oral capsule (Prometrium®), or sublingual drops. Only oral progesterone (100-200 mg) and vaginal progesterone (45-90 mg) have been studied and shown to protect the uterine lining from estrogen stimulation.

If a patient is pre-menopausal, she uses the progesterone the last two weeks of the menstrual cycle (day 1, the first day of bleeding). Hormone therapy with pellets is not just used for menopause. Women at any age may experience hormone imbalance. Levels decline or fluctuate contributing to debilitating symptoms. Pellets are useful in severe PMS, post partum depression, menstrual or migraine headaches, and sleeping disorders. Pellets may also be used to treat hormone deficiencies (testosterone) caused by the birth control pill.

## **DO PELLETS HAVE THE SAME DANGER OF BREAST CANCER AS OTHER FORMS OF HORMONE REPLACEMENT?**

Pellets do not have the same risk of breast cancer as high doses of oral estrogens, like Premarin, that do not maintain the correct estrogen ratio or hormone metabolites. Nor, do they increase the risk of breast cancer like the synthetic, chemical progestins used in the Women's Health Initiative Trial. In fact, data supports that balanced hormones are breast protective.

## How are hormones monitored during therapy?

Hormone levels will be drawn and evaluated before therapy is started. This will include a FSH, estradiol, testosterone and free testosterone for women. Thyroid

hormone levels may also be evaluated. Men need a PSA, sensitive estradiol, testosterone, liver profile and blood count prior to starting therapy. Levels will be reevaluated during hormone therapy, usually prior to insertion of the next set of pellets, 4-5 months. After the first year of therapy, hormones levels may be followed less frequently. Men must notify their primary care physician and obtain a digital rectal exam each year. Women are advised to continue their monthly self-breast exam and obtain a mammogram and/or pap smear as advised by their gynecologist or primary care physician.

### **How much does this cost?**

Men need a much larger dose of testosterone than women and the cost is higher. Pellets need to be inserted 2 to 4 times a year depending on how rapidly a patient metabolizes hormones.

When compared to the cost of drugs to treat the individual symptoms of hormone decline, pellets are very cost effective. There is more good, 'unbiased' data on pellets and bone density than any pharmaceutical drug on the market. It is beyond the scope of this handout to examine the cost of drugs used for insomnia, depression, sexual dysfunction, obesity, diabetes, hypertension and more.

The cost for the insertion of pellets will vary depending by office. The cost also depends on the dose of the hormones and the number of pellets needed. Men typically need a much larger dose of testosterone than women so the cost is higher. Please ask your clinic for pricing.

### **Will insurance cover the procedure?**

Some insurance companies cover the cost of pellets, especially in men. Others do not. Most physicians require payment for their services. Patients may want to contact their insurance companies to see if their costs will be reimbursed. Prevention is much more cost effective than disease.

### **Is there a role for testosterone implants (pellets) in a pre-menopausal female?**

Testosterone pellets may be used in pre-menopausal females (women who have not stopped menstruating). Testosterone has been shown to; relieve migraine or menstrual headaches, help with symptoms of PMS (pre menstrual syndrome), relieve anxiety and depression, and improve sex drive and libido. If a pre-menopausal female has a testosterone pellet inserted, she must use birth

control. There is a theoretical risk of 'masculinizing' a female fetus (giving male traits to a female fetus).

In conclusion, estrogen and testosterone therapy by implantation of pellets is a safe and effective method of hormone therapy for both men and women. Long, continuous administration of hormones by pellets is convenient and economical for the patient. Pellet implantation has consistently proven more effective than oral, intramuscular, and topical hormone therapy with regard to bone density, sexual function, mood and cognitive function, urinary and vaginal complaints, breast health, lipid profiles, hormone ratios and metabolites.

#### **HOW DO I GET STARTED?**

Once your initial consultation is complete, the physician will review your symptoms and blood labs to determine if you are a candidate for pellet therapy. The initial insertion appointment can be scheduled at that time.