BRONSON

Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Testopel® Pellet Insertion for Women

This information is given to you so that you can make an informed decision about having **Testopel® Pellet Insertion.**

Reason and Purpose of the Procedure:

Testopel® is a small testosterone pellet. It is inserted underneath the skin, below the waist. It delivers a slow, steady release of testosterone over 3 to 5 months.

The procedure is simple and takes less than 10 minutes in the office. An ice pack is placed on the site. A skin numbing medicine is injected under the skin. A small incision is made below your hip and the pellet is placed under the skin. Steri strips are placed on the incision to keep it closed.

This medicine is being used for post-menopausal women. It decreases menopausal symptoms and improves sexual desire in women who no longer have ovaries or have ovaries that aren't working. However, it is considered "off-label" meaning it is not yet approved by the FDA for this use.

Benefits of this procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Improved sleep
- Decreased mood swings
- Increased sex drive
- Increased bone density and muscle strength
- Decreased joint discomfort
- Decreased menopause symptoms such as hot flashes
- Increased energy

Risks of this procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

There have been no consistent studies done to evaluate all the risks, especially for the rare development of certain cancers. Your doctor can discuss this with you.

Most side effects and risks are during the treatment. These effects go away after the pellets wear off.

Women who are pregnant or lactating should NEVER use this product as it can cause harm to the fetus or baby.

Known risks of this procedure:

- Abnormal hair growth on face and body
- Hair thinning
- Acne

Risks associated with smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks associated with obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

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Risks specific to you:

_____

_____

_____

_____

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.

If you choose not to have this treatment:

- Your physician can discuss alternative treatments with you.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure the doctor may need to do more tests or treatment.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

My insurance company may not pay for this device or procedure. I know I am responsible for charges not covered by my insurance.

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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Testopel® Pellet Insertion for Women** _____

  _____
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to surgery. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: ☐ Patient ☐ Closest relative (relationship) _____ **☐ Guardian**

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____

(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____