Affix Patient Label

Patient Name: Date of Birth:

Informed Consent

Macroplastique Transurethral Bulking Agent Injection.

This information is given to you so that you can make an informed decision about having **Macroplastique Transurethral Bulking Agent Injection.**

Reason and Purpose of the Procedure:

Macroplastique is used to treat women who have stress urinary incontinence due to weak urethral sphincter muscles. Macroplastique is a toothpaste-like gel that is injected into the wall of the urethra near the bladder. It bulks the wall of the urethra to help prevent uncontrolled urination.

Women with stress urinary incontinence have uncontrolled urination. This can happen during exercise or other actions like sneezing and coughing. One cause of this is a weakness of the urethral sphincter muscles. These muscles help open and close the tube from the bladder that drains urine from the body (urethra).

Macroplastique helps keep urine from accidentally leaking out of the bladder. Using a small tube to view the bladder (a cystoscope) the doctor injects Macroplastique into the wall of the urethra. Part of the gel is absorbed by the body in a few weeks. The part that stays in the urethra narrows it.

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.

- A decrease in urinary incontinence.

Risks of Procedures:

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.

Risks of this Procedure:

- **Urinary retention** (unable to pass urine). You may need a catheter.
- **Your incontinence may get worse.**
- **Urinary infection**. You may need antibiotics.
- **Blood in the urine**. This is usually mild and temporary.
- **Irritation or inflammation of the urethra** (the tube leading from the bladder). You may need medicine.
- **Allergic reaction to the gel.** You may need to stop treatment.
- **Abscess formation at the injection site**. You may need more treatment or surgery.
- **Unsatisfactory results.** You may need to repeat injections.

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.

Risks Specific to You:

____

____

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Alternative Treatments:

Other choice:

- Do nothing. You can decide not to have the procedure.
- Your doctor can discuss surgery, medications or other treatment options with you.

If You Choose Not to Have this Treatment:

- Your urinary incontinence may continue.

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.
- I agree to release my social security number, my name and address, and my date of birth to the company that makes the medical device that is put in or removed during this procedure. Federal laws and rules require this. The company will use this information to locate me.

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Patient Name: Date of Birth:

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 **Macroplastique Transurethral Bulking Agent**:______________________________
- 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 surgery. 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 procedure. IF so, please obtain consent for blood/product.

Patient Signature______________________________Date:__________Time:_________

Relationship: ☐Patient ☐Closest relative (relationship)__________ ☐Guardian

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

Interpreter:______________________________Date___________Time__________

Interpreter (if applicable)

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

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: ______________________________ (patient signature)

Validated/Witness:______________________________Date:________________Time:__________