BRONSON

Affix Patient Label

Patient Name: DOB:

Informed Consent: BOTOX® Injection for Urinary Incontinence

This information is given to you so that you can make an informed decision about having **Botox™ Injection for Urinary Incontinence.**

Reason and Purpose of the Procedure

BOTOX® is a prescription medicine that is used to treat an overactive bladder. An overactive bladder contracts too often or without warning. This can lead to the constant urge to urinate and/or bladder leakage. **BOTOX®** can be useful in decreasing urges and leakage. It is used when other medicine does not work well enough or cannot be taken. It is also used to treat leakage caused by a neurologic condition. Your doctor will insert a thin viewing instrument called cystoscope into the urethra and guide it up into the bladder. The scope allows your doctor to see inside your urethra and bladder.

After draining the bladder, Lidocaine (a numbing medicine) will be injected into the bladder to decrease discomfort. Then the BOTOX is injected into the bladder muscle.

You will usually need more than one injection. Your doctor will talk to you about how often you will get an injection.

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 the amount or frequency of urinary leakage.
- A decrease in feeling the constant urge to urinate.

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.

Risks of this Procedure

- **Autonomic dysreflexia**. This is a sudden onset of extremely high blood pressure. Sweating, flushing may occur. This can be life threatening and would require emergency care.
- **Urinary tract infection.** You may need antibiotics.
- **Urinary retention (incomplete emptying of the bladder).** You may need to learn to use a catheter to completely empty your bladder.
- **Allergic reactions.** Include itching, rash, red itchy welts, wheezing, asthma symptoms, dizziness or feeling faint. Get medical help right away if you experience symptoms.
- **Respiratory (breathing) problems**. Your doctor will monitor you for breathing problems during your treatment with BOTOX® for overactive bladder associated with a neurologic condition. The risk of pulmonary (lung) effects in patients with breathing problems is higher in patients receiving BOTOX®.
- **General muscle weakness**. If this happens, do not drive a car, or operate machinery.
- **Swallowing problems (dysphagia).** You are at the highest risk if you have this problem before getting the injection. Swallowing problems may last for several months. You may need a feeding tube.
- **Diplopia.** Double vision. These symptoms can happen hours, days, or weeks after you receive an injection of BOTOX®.
- **Blurred vision.**
- **Fatigue.**
- **Insomnia**. Your doctor can discuss treatment options with you.

- **Pain**. You may have pain or a burning feeling when you urinate for a few days after the procedure.
- **Bleeding**. Bleeding may darken the urine color. This usually clears over a few days. Blood clots may block the bladder. A catheter may need to be inserted to flush out the clots. If bleeding continues, you may need more surgery.
- **Inability to Pass the Scope**. A scar or stricture (closure) may prevent the passage of the scope into the bladder. This may need additional surgery.

These symptoms can happen hours, days, or weeks after you receive an injection of BOTOX.

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

_____
_____
_____
_____

Alternative Treatments
Other choices

- **Interstim Device placement or Percutaneous Tibial Nerve Stimulation**. These are ways to stimulate the nerves to your bladder to stop the over activity. Your physician can discuss these with you if applicable.
- **Do nothing.** You can decide not to have the procedure.

If you choose not to have this treatment

- Your urinary symptoms may stay the same.

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.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- 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: **BOTOX® Injection for Urinary Incontinence** ☐ **Cystoscopy**
  _____
- 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 surgery. If so, please obtain consent for blood/products.

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
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: _____