BRONSON

Affix Patient Label

Name_____ Date of Birth_____

Informed Consent:

Insertion of Artificial Urethral Sphincter (AUS)

This information is given to you so that you can make an informed decision about having **Insertion of Artificial Urethral Sphincter (AUS)**

Reason and Purpose of the Procedure:

An insertion of an artificial urethral sphincter is done to correct urinary incontinence, which is the involuntary loss of urine. This procedure is done as when a patient experiences loss of urine with coughing, sneezing, lifting, etc. or has a constant dripping or leakage or urine.

The AUS is like a tiny inner-tube that is wrapped around a short segment of your urethra (the tube that you pass urine through.) When a pump is squeezed, it deflates the inner-tube and allows the urethra to open. Urine will then drain from the bladder. The inner tube then automatically regains its fluid so that it once again squeezes the urethra shut. It may take more than on "squeeze cycle" to fully empty the bladder.

It will take practice to learn how to properly inflate and deflate the sphincter. Your doctor will work with you to teach you this practice.

Benefits of this surgery:

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.

- **Decreased dripping or leakage or urine.**

Risks of Surgery:

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.

General risks of surgery:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke may occur.
- Bleeding may occur. If bleeding is excessive, you may need a transfusion.
- Reaction to the anesthetic may occur. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

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Risks of this surgery:

- Erosion: If the sphincter is pressing up against urethral tissue over an extended period, it can slowly erode (wear down) through the urethra. Part of or the entire device may need to be removed.
- Infection: Infection can occur at the surgical site, within the urethra (urinary tract infection) or in more serious cases, in the bloodstream. If this occurs, you may need antibiotics, or further surgery. Rarely, this may require removal of the artificial urethral sphincter.
- Mechanical Failure: It is possible for the parts of the device to malfunction (not work correctly) or stop working altogether. The prosthesis can often be removed and replaced in the same operation, or there may be too much scarring around the urethra to replace.

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:

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

If you choose not to have this treatment:

- Because this treatment is considered after many other options have most likely been attempted, you may continue to urinary incontinence.

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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.

Implants/explants statement: 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.

Humanitarian device statement: 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: **Insertion of Artificial Urethral Sphincter (AUS)**
- _____
- I understand that my doctor may ask a partner to do the surgery.
- I understand that other doctors, including medical residents; 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 _____

Relationship ☐ Patient ☐ Closest relative (relationship) ☐ Guardian Date/Time

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 (if applicable) 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

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:_____