Informed Consent Urethral Sling

This information is given to you so that you can make an informed decision about having **Urethral Sling**

Reason and Purpose of the Procedure:

This procedure is needed for patients with stress-type or total type urinary incontinence (the inability to hold urine). Stress incontinence is loss of urine from things such as coughing, sneezing, and laughing. In total incontinence, the urethra has lost the ability to close together therefore a patients constantly leaks throughout the day/night.

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.

- Incontinence will be resolved or improved

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.

Risks of this surgery:

- Wound Infection: With any incision infection can occur. You may need antibiotics or it could lead to possible mesh removal if unresolved.
- Urinary Tract Infection or Sepsis: You may need further antibiotics.
- Treatment Failure: The procedure can fail immediately or months to years later. You may need further surgery.
- Urinary Retention: This is the inability to urinate. You may need a urinary catheter or further surgery.
- Development of overactive bladder: This could include an intense urge to urinate followed by an involuntary loss of urine.
- Sling Erosion: The sling material may possibly erode through the tissue that it surrounds.
  Lower Extremity Weakness/Numbness: This can occur due to your position on the operating table. This is a rare occurrence.
- Injury from Suprapubic Tube: During placement the tube can puncture a surrounding organ. You may need further surgery to repair. A suprapubic tube is not always used.
- Chronic Pain: You may experience pain in the area of the procedure.
- Painful intercourse: This may need more surgery or treatments to correct.
- There is a risk of bowel perforation with retropubic sling. This may need more surgery or treatments to correct.

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 choices:

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

If you choose not to have this treatment:

- Urinary incontinence will 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.
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.

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.

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

BRONSON

	Affix Patient Label
	Patient Name: DOB:

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: Urethral Sling □Transobturator □ Retropubic
  ____
- I understand that my doctor may ask a partner to do the surgery.
- 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.

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)

<u>For Provider Use ONLY:</u>

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:___________

<u>Teach Back</u>

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:__________