BRONSON	Affix Patient Label
	Patient Name: Date of Birth:

Informed Consent Cystocele Repair

Reason and Purpose of the Procedure
A cystocele occurs when the front wall of the vagina weakens. This condition may cause discomfort and problems with emptying the bladder.

This surgery brings the vaginal wall back to a more normal position.

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).

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.

Cystocele Repair can assist those patients who have had their vaginal wall sag which may eliminate or decrease:
- Pelvic/vaginal discomfort
- Pain during intercourse
- Vaginal bulging

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
- **Treatment failure:** The procedure may not be able to fully correct the defect and additional surgery may be needed.
- **Urinary Retention**: You may need to have a catheter placed if you cannot urinate
- **Chronic Pain:** You may develop-chronic pain in the area surrounding the surgery site.
- **Dyspareunia (Painful intercourse) and Vaginal Shortening:** The depth of the vagina may be decreased and the angle changed. You may have pain or difficulty with intercourse.
- **Mesh Erosion:** If mesh material is used in the procedure, it may wear through the tissue that surrounds it. If the vaginal tissue breaks down, the mesh can usually be removed with a minimal procedure. Often the vaginal wall is still supported because it has scarred into place.
- **Bleeding/Hematoma:** When a small blood vessel continues to ooze or bleed after the procedure is over, the area of collected blood is referred to as a hematoma. The body normally re-absorbs the collection over a short period of time, and surgical drainage is rarely necessary.

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General Risks of Procedures

- 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 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 choice:

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

If You Choose Not to Have this Treatment

- Your bladder will continue to be in an abnormal position, and the symptoms you are having 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.
- 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.

Medical Implants/Explants

- 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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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 **Cystocele Repair** _____
  _____
- 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:_____