



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent Intravesical Instillation of Gemcitabine

This information is given to you so that you can make an informed decision about having intravesical instillation of gemcitabine.

Reason and Purpose of the Procedure:

Gemcitabine is a chemotherapy drug. In this procedure it is placed into the bladder to kill cancer cells. Gemcitabine is placed in the bladder through a urinary catheter.

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.

- Delay or prevent the reoccurrence of cancer.
- Slow cancer growth.

Possible 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.

- **Urinary symptoms.** You may need medication or antibiotics to treat. These may include:
Pain with urination
Frequency of urination
Urgency of urination
Blood in the urine (hematuria)
Increased urination at night (nocturia)
Urinary tract infection
- **Nausea or vomiting.** You may need medicine to control.
- **Inflammation** of the bladder which can move to the kidneys. You may need antibiotics or hospitalization.
- **Fever or chills** may be signs of a urinary tract infection. Tell your provider if you have fever or chills.

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.



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Risks specific to you:

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.
- Your provider can talk to you about any other treatment options

If you choose not to have this treatment:

Your tumor or cancer may return. There is a higher chance of the tumor returning.

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.

By signing this form I agree:

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Informed Consent Intravesical Instillation of Gemcitabine
ADULT Use Only



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- 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: Intravesical instillation of gemcitabine.
_____.
- 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.

Provider: This patient may require a type and screen or type and cross prior to surgery. 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: _____