



Affix Patient Label

Patient Name: _____ Date of Birth: _____

This information is given to you so that you can make an informed decision about Intravesical Instillation of BCG.

Reason and Purpose of the Procedure:

BCG (Bacillus Calmette and Guerin) is a freeze-dried product made from bacteria. The actual mechanism of action (how it works) is unknown. It is widely thought that the BCG causes the immune system to recognize and then attack cancer cells in the bladder.

BCG is given through a urinary catheter into the bladder.

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.

- May delay or prevent the reoccurrence of cancer
- May 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;
 - Hematuria (blood in the urine);
 - Nocturia (increased urination at night);
 - Urinary tract infection.
- Nausea or vomiting; You may need medicine to control.
- Cramps, muscle or joint pain; Your provider can talk to you about pain medicine.
- Sweating, rash, abdominal pain; Contact your provider if these occur.
- Inflammation of the bladder (cystitis) which can extend to the kidneys; You may need antibiotics or hospitalization to treat.
- Swelling of the testicles; If this lasts more than 2 days, call your provider.
- Sepsis (infection in the blood): You may need antibiotics and hospitalization. Sepsis is rare but can cause death.

Affix Patient Label

Name _____ Date of Birth _____

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
- 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.

Affix Patient Label

Name _____ Date of Birth _____

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 practitioner. My questions have been answered.

I want to have this procedure: **Intravesical Instillation of BCG.**

- I understand that my doctor or practitioner may ask a partner to do the procedure.
- I understand that other doctors, including medical residents, or other staff may help with this procedure. The tasks will be based on their skill level.

Patient

Signature _____

Relationship Patient/Parent of Minor Closest relative (relationship) Guardian/POA Healthcare **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: _____