

Physician's Surgical Procedure Disclosure and Patient's Consent
BCG or Other Chemotherapeutic Bladder Instillations

TO THE PATIENT: You have the right to be informed about your condition and the recommended surgical, medical or diagnostic procedure so that you may make the decision whether or not to undergo the procedure after knowing the risks involved and any treatment alternatives available to you. This information is not meant to alarm you; it is an effort to make you better informed so that you may give or withhold your consent to the procedure. If you do not understand any of the information provided, ask your physician to explain it to you.

1. DIAGNOSIS: I voluntarily request my physician, {Name of Provider}, and such associates, technical assistants, and other health care providers as they may deem necessary, to treat my CONDITION:

Cancer of the bladder

2. PROCEDURE(S): I voluntarily consent to and authorize this PROCEDURE for the following purpose:

In this procedure, Bacillus Calmette Guerin vaccine (BCG) or some other type of chemotherapeutic agent is instilled into the bladder. BCG is a live, but weakened, bacterial preparation that has been found to be successful in treating certain bladder cancers.

For the instillation, the patient lies face up on the procedure table. The area around the urethra (channel that carries urine from the body) is washed with an antiseptic soap.

A lubricated catheter (a long, thin, tube) is passed through the urethra into the bladder to drain all urine. A saltwater solution containing BCG vaccine or another type of Chemotherapeutic agent is then slowly instilled through the catheter into the bladder.

The catheter is removed leaving the therapeutic solution in the bladder. In most cases, the patient is encouraged to hold the solution in the bladder for two hours, if possible.

The treatments will be repeated at various intervals depending on protocol. (BCG Instillation) (BLADDER - BCG INSTILLATION) or other Chemotherapeutic agent.

3. MATERIAL RISKS: Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks related to the performance of the surgical, medical and/or diagnostic procedure(s) planned for me, including:

- No guarantee of cure of cancer.
- Discomfort with instillations.
- Bleeding.
- Need for additional therapy including surgery, radiation, chemotherapy, and other treatments if the cancer returns or if therapy is not tolerated.
- Temporary fever or flu-like symptoms.
- Loss of energy.
- Urinary tract infection from catheterization (tube inserted to remove urine).
- Localized infection caused by BCG in bladder, or infection in other part of body (lung, kidney, prostate, liver, or abdomen), requiring prolonged medication.
- Widespread and possibly life-threatening infection of BCG with shock and need for prolonged therapy.

- Bladder irritation and/or inflammation, which could result in bladder holding less urine, temporarily or permanently, and could result in frequent urination or discomfort.
- Uncommon allergic reaction including skin rash, wheezing with shortness of breath; drop in blood pressure, and possible loss of consciousness.

Additional material risks of surgical, medical and/or diagnostic procedure(s) include: death, cardiac arrest, brain damage, disfiguring scar, paralysis or partial paralysis, loss or loss of function a limb or organ, blood clots in veins or lungs, severe loss of blood, allergic reaction and infection.

4. ALTERNATIVES TO PROCEDURE: The following practical alternatives to this procedure have been discussed with me:

Alternatives include surgical approaches, other medications placed in bladder, vitamin therapy, radiation therapy (using high-dose x-rays or other high-energy rays to kill cancer cells), immunotherapy (using the body's immune system to fight disease), or observation.

5. LIKELY OUTCOME IF NO TREATMENT: I have been informed of the likely outcome if no treatment is provided, as follows: Without instillation of BCG or other agents, there may be recurrence and/or progression of my bladder cancer, which may require surgery, chemotherapy, or radiation therapy, and may be incurable.

CONSENT:

I have been given sufficient opportunity to ask questions about my condition, alternative treatments, risks of treatment, the procedures to be used, and the risks and hazards involved. All of my questions have been answered to my satisfaction, and I have sufficient information to give this informed consent. I hereby consent to the above-described procedure.

I certify that this form has been fully explained to me, and that I have read it, or have had it read to me, that the blank spaces have been filled in and that I understand its contents.

 Signature of Patient or Legally Responsible Person
 (A.M./P.M.)

Date: _____
 Time: _____

 Printed Name of Patient or Legally Responsible Person

 Signature of Witness (Include Position / Title)

 Printed Name of Witness