

## Bladder Wall Thermo-chemotherapy (BWT)

### Patient's information

#### 1. Introduction

It was found that you are suffering from non-muscle-invasive (“superficial”) bladder cancer with intermediate or high risk for recurrence (tumors re-appearance after removing them by surgery). In such risk categories for recurrence, it is customary to flush the bladder (bladder instillations) with mitomycin-C (bladder chemotherapy instillation) to reduce the rate of recurrence. When Hyperthermia (temperature of 40°C to 45°C) is combined to chemotherapy instillation it is called thermo-chemotherapy.

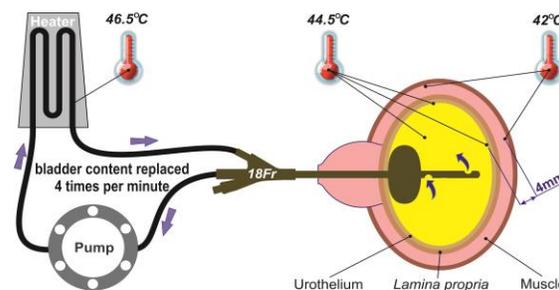
#### 2. General

2.1 Bladder thermo-chemotherapy instillation is well known for more than 20 years.

2.2 Clinical experience with thermo-chemotherapy showed that these combined treatments are more effective in reducing tumor recurrence than the stand-alone drug instillations to the bladder due to two factors:

- Heat enhances drug uptake by cells (increased permeability of cell wall; better drug distribution; accelerated drug metabolism).
- Heat selectively damages cancer cells and not the healthy tissue.

2.3 The system (CE mark) combines hyperthermia and mitomycin-C for bladder instillations and indicated to treat patients with non-muscle invasive bladder cancer (NMIBC) to reduce the rate of tumor recurrence.



#### 3. Clinical Protocols

There are two protocols and your doctor will decide which one of them to implement.

##### Standard protocol:

Comprises 6 weekly induction instillations followed by 6 monthly maintenance instillations.

##### 3.1 Enhanced protocol:

Comprises 6 weekly induction instillations followed by 10 monthly maintenance instillations.

##### 3.2 Follow-up cystoscopies (looking into the bladder and examining it):

Performed, in both protocols, about 4 weeks after the 6 induction instillations and every 3 months thereafter (here, as well, about 4 weeks delay required between last BWT procedure and cystoscopy). In addition, urine and blood tests might prescribe.

##### 3.3 Urine and Blood tests:

Will be performed according to the treating doctor decision.

4. **How to prepare toward procedure**

- 4.1 No need to fast.
- 4.2 To reduce the desire to urinate during the procedure, patient is requested to avoid caffeinated foods (coffee, tea, cola, chocolate) in the day before and the morning of the procedure and to stop fluids intake from the evening before the procedure (from about 20:00) but, half a glass of water in the morning of procedure is OK.
- 4.3 If the treatments are painful, the patient might take a standard pain-killer one to two hours before the procedure.
- 4.4 On recommendation of your doctor: 3-day before procedure anticholinergic drug might prescribe.

5. **Procedure**

- 5.1 Before the procedure you will requested to undress and dress a gown, and to lie down on the treatment bed.
- 5.2 Your genitalia will be cleaned, anesthetic gel will be put into your urethra and the treatment catheter (thin tube) will be inserted to your bladder.
- 5.3 Bladder will be emptied totally through the catheter.
- 5.4 Drug solution will be inserted through the catheter into your bladder and the treatment will start.
- 5.5 Treatment temperature will reach gradually to 44°C-44.5°C and the system will continue treatment for a total of 50 minutes and stops by itself.
- 5.6 Your bladder content (drug and urine) will be drained in an environment-clean way. Then, after the catheter removed, you will redress your clothes and sent home.

6. **Possible Side Effects**

- 6.1 Because the heat is “confusing” the physiology of normal desire to urinate, some patients might feel, during the procedure, a strong desire to urinate (urgency) although their bladder content is small.
- 6.2 Some pain might occur during the procedure.
- 6.3 After the procedure, you might feel, for few days, irritation during urination (dysuria) or increased frequency of the need to urinate.
- 6.4 Some allergic reaction can occur due to the mitomycin drug.
- 6.5 After the procedure you might feel some pain and you can use some standard pain-killer.
- 6.6 After the procedure, some blood might appear in the urine. If blood in the urine and fever come together, please consult with your doctor.

7. **After treatment**

- 7.1 At home you will shower thoroughly your genitalia with water and soap to avoid irritation if drug spilled around.
- 7.2 Drink plenty of clear fluids over the first couple of days to help flush your bladder and reduce your risk of getting a urinary infection.
- 7.3 Avoid becoming pregnant or father a child while having bladder treatment with mitomycin as the effect of the treatment on a developing baby is not known. It is recommended to use contraception during your treatment and for six weeks afterwards. Ask your doctor for more information. For the first 48 hours after a procedure, a condom should use during sex. This will also protect your partner from any medicines that may be present in your semen (if you are a man), or from your vaginal fluid (if you are a woman).