

INSTRUCTION GUIDE for Instillation of JELMYTO® (mitomycin) for pyelocalyceal solution With a Nephrostomy Tube

Important Information

Please refer to the FDA-approved Prescribing Information and Instructions for Administration (IFA) for information about JELMYTO.

This Instruction Guide contains supplemental information on how to instill JELMYTO via a nephrostomy tube. These instructions are derived from materials from the OLYMPUS clinical trial and techniques published from real-world clinical practice.¹⁻³ It is important to note that in the OLYMPUS clinical trial, no investigators utilized a nephrostomy tube as the mode of administration.

Important Information Regarding Nephrostomy Tube Materials and Healing Time Prior to JELMYTO Instillation

Note: Follow practice/institutional protocol regarding placement of the nephrostomy tube as well as the time allowance for healing before proceeding with JELMYTO instillation. Also follow nephrostomy tube removal protocol following treatment course.

- A percutaneous nephrostomy tube (not nephroureteral stent) with molded Luer Lock connector and locking loop must be placed prior to instillation of JELMYTO. Latex catheters or nephrostomy tubes made of latex should not be used during JELMYTO administration due to the risk of deformation attributed with pressure changes, which can impede flow of the hydrogel admixture

JELMYTO Instillation Instructions

A. Measure the Kidney Volume Before the First Instillation

The instillation volume will be equal to the patient's kidney volume.

Note: The kidney volume may be measured either retrograde or antegrade. If the volume was measured antegrade, then subtract 2 mL from each measurement prior to averaging to account for the internal dwell volume in the nephrostomy tube (dead space). There is no need to subtract 2 mL if measured retrograde.

If the kidney volume is already known, proceed to Section B.

If the kidney volume is NOT known, or needs to be reassessed, use the following steps:

1. Perform volumetric measurements using pyelography with diluted contrast so that the entire renal pelvis and calyces are observed, and contrast starts to flow below the ureteropelvic junction (UPJ).

Note: Slow administration of the contrast may facilitate a more accurate measurement since contrast could be drained into the ureter.

2. Record the volume of contrast injected at this point.

3. Allow the contrast to drain from the kidney. This may take about 5 minutes.

Note: Do not withdraw contrast back into the syringe.

4. Repeat steps 1 through 3 two more times, for a total of 3 measurements to improve accuracy.

Note: If the volume was measured antegrade, then subtract 2 mL from each measurement prior to averaging to account for the internal dwell volume in the nephrostomy tube (dead space).

5. Select the kidney volume OR 15 mL, **whichever is lower**, as the instillation volume.

Note: Maximum instillation volume is 15 mL. Record the volume for future instillations.

Sections B and C on next page. 


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B. Chilling JELMYTO and Preparing the Administration Syringe

Please refer to Sections C and D from the JELMYTO Instructions for Administration (IFA) (pictured below).

C CHILL THE JELMYTO


- 1 Place the JELMYTO vial in the ice bath for at least 10 minutes, but no longer than one hour.



- 2 After at least 10 minutes, advance the ureteral catheter over the guidewire towards the target anatomy in the pyelocalyceal system.

D PREPARE THE ADMINISTRATION SYRINGE

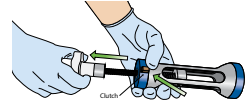
Once the vial is removed from the ice bath, you have 4 minutes to draw JELMYTO into the administration syringe before it solidifies.



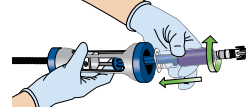
After 4 minutes, recap and place the components back in the ice bath for no more than 15 minutes to liquify the JELMYTO.

- 1 Remove the JELMYTO vial from the ice bath and dry it off.
- 2 Swirl the vial upright to ensure that JELMYTO is uniformly mixed.
- 3 Connect the syringe adaptor to the 20 mL Luer Lock syringe. This will be the administration syringe.
- 4 Slowly withdraw the calculated Instillation Volume of JELMYTO into the administration syringe.

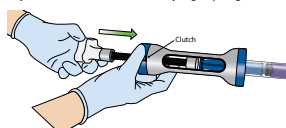
- 5 Press the "Clutch" button on the Uroject12 and pull the knob out.



- 6 Insert the administration syringe into the Uroject12 Syringe Lever and rotate it clockwise until it locks in place.



- 7 While pressing the "Clutch" button, advance the lever to just above the administration syringe's plunger.



Immediately proceed with the instillation steps in Section E to avoid JELMYTO solidification.

JELMYTO is a hazardous drug. Follow applicable special handling and disposal procedures.

C. Instill JELMYTO

Prior to administration, implement your clinic's practice for reviewing patients' labs, inspecting the nephrostomy tube for leakage/malposition, draining the patient's urine, and verifying nephrostomy tube patency.

1. Remove the syringe adaptor from the administration syringe.
Note: If JELMYTO gets on the syringe tip or the catheter's Luer Lock port, wipe it off immediately with sterile gauze, so it does not solidify and prevent a secure connection. (Refer to Frequently Asked Questions in the JELMYTO IFA).
2. Connect the administration syringe to the nephrostomy tube's Luer Lock port by rotating the syringe only.
3. Hold the syringe barrel firmly in its position and dock the syringe into the Uroject12 Syringe Lever by rotating only the Uroject12 Syringe Lever clockwise until it is locked in place.
4. Gradually instill the JELMYTO into the patient by turning the knob of the Uroject12 Syringe Lever at a rate of 1 to 2 seconds per stroke. **The entire syringe must be emptied within 1 minute.**
5. Following completion of the JELMYTO administration, disconnect the syringe from the nephrostomy tube.
6. Fill a 2.5 mL – 5 mL Luer Lock syringe with 2 mL of saline, connect the syringe to the nephrostomy tube, and flush the nephrostomy tube.
Note: Chilling the saline may help flush the nephrostomy tube.
7. Disconnect the 2.5 mL – 5 mL syringe from the nephrostomy tube.
8. Clamp and cap the nephrostomy tube.
9. Remove the administration syringe from the Uroject12 by rotating the syringe barrel counterclockwise.
10. Discard the administration ancillaries according to your facility's disposal procedures.
11. Send the Uroject12 to be processed according to your facility's procedures and the Uroject12 Syringe Lever Instructions for Use.

Provide patient education on home chemotherapy precautions and nephrostomy drainage supplies/adaptors in the event the patient requires drainage. Monitor patients for signs of obstruction.

References: 1. Rosen GH, Nallani A, Muzzey C, Murray KS. *J Urol*. 2022;207(6):1302-1311. 2. Kleinmann N, Matin SF, Pierorazio PM, et al. *Lancet Oncol*. 2020;21(6):776-785. 3. Rose KM, Narang G, Rosen G, et al. *BJU Int*. Published online October 26, 2022. doi: 10.1111/bju.15925

Please [click here](#) for Full Prescribing Information, Instructions for Pharmacy, and Instructions for Administration.



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