

Medical Information Request: JELMYTO® (mitomycin) for pyelocalyceal solution.

Thank you for your question regarding the cleaning, disinfection, and sterilization procedures for the Uroject12 Syringe Lever used with the instillation of JELMYTO.

The Uroject12 Syringe Lever is intended for use in the administration of sterile materials under aseptic conditions, in a clinical urology setting.

Please refer to the **Uroject12 Syringe Lever** Instructions for Use (IFU) for detailed information on the cleaning, disinfection, and sterilization procedures available from: <https://www.urogen.com/download/pdf/uroject12-syringe-lever-instructions.pdf>

Sterilization of the Uroject12 Syringe Lever was qualified utilizing both the gravity and prevacuum cycles in the autoclave. **The Uroject12 Syringe Lever should not be subject to temperatures higher than 279°F (137°C).** The recommended temperature is based on the upper limit of the plastic knob-handle on the Uroject12 Syringe Lever.

Sterilize the Uroject12 according to the autoclave settings described below:

Sterilizer Type:	Gravity	Prevacuum
Sterile Barrier:	Wrap according to hospital policy	Wrap according to hospital policy
Temperature:	250°F (121°C)	270°F (132°C)
Cycle Time:	30 minutes	4 minutes
Dry Time:	30 minutes	45 minutes

- **Please note: The cleaning, disinfection, and sterilization instruction as described in the Uroject12 Syringe Lever IFU are the only methods that have been qualified and reviewed by the FDA. To date, UroGen has not directly evaluated alternative cleaning, disinfection, and sterilization procedures beyond the information presented in the Uroject12 Syringe Lever IFU.**
- **The additional information below are technical evaluations (by literature or internal test) to assess functional impact/damage to the Uroject12 Syringe Lever.**

Additional Information for your review:

- STERRAD® Systems is a plasma hydrogen peroxide sterilization process. The Uroject12 Syringe Lever plastic knob handle was processed using the Sterrad NX standard cycle and was undamaged. This was also expected from evaluation of the Sterrad NX literature.
 - An additional cycle was performed with the Uroject12 Syringe Lever parts, including the plastic knob-handle, that were exposed to a disinfectant that contains peracetic acid. This resulted in the pitting of the plastic knob. Please be aware that **disinfection with solutions containing peracetic acid and potentially other acids followed by Sterrad may damage the plastic knob**, especially if not rinsed and dried thoroughly. UroGen has received reports of plastic knob-handle damage following Sterrad 100 processing, possibly without previous exposure to solutions containing peracetic or other acids.
- Medivators [Cantel] Automated Endoscope Reprocessors and Revital-Ox® RESERT® High Level Disinfectant. Based on literature review of information from Revital OX and Medivators, this combination appears to be compatible with the plastics and metal materials comprising the Uroject12 Syringe Lever (and is also well below the 279°F temperature limit). It is concluded that this process should not damage the Uroject12 Syringe Lever.

- A search of the safety data sheet was conducted for the Renuzyme PLUS and Renuzyme WR, both appear to be compatible with the materials of construction of the Uroject 12 device as they are enzymatic based detergents (mild by definition). From the point of view of material compatibility and upon a review of safety data sheets (SDS) both PowerCon Neutral pH Detergent and Renuzyme Ultra are also compatible with Uroject12 syringe lever materials (anodized aluminum, Stainless steel and Plastics) and are pH neutral (mild by definition). However, no claim could be made of efficacy of these products for cleaning efficacy of the Uroject12 syringe lever medical device as the use of Neodisher MediClean Forte solution should be validated as noted in the instructions for use of automatic cleaning equipment.
- High-level disinfection with Cidex® OPA has been qualified and reviewed by the FDA as an alternative to steam sterilization for the Uroject12 syringe lever, including the plastic knob, as well as the metal knob.
- The use of PeridoxRTU® or Rapicide® PA instead of Cidex OPA for high-level disinfection was assessed by UroGen. All materials of the Uroject12 Syringe Lever were determined to be compatible except for the plastic knob-handle at higher concentrations of PeridoxRTU®. It was concluded that PeridoxRTU® or other similar materials containing less than 5% hydrogen peroxide and less than 0.25% peracetic acid should not damage the Uroject12 Syringe Lever, at least in the short term. Repicide® PA should also be expected to be compatible with Uroject12 materials. No claim could be made about the efficacy of these products in cleaning the Uroject12 syringe lever medical device.
- The use of the following with the Uroject12 Syringe Lever **have not** been assessed by UroGen: MetriCide™ instead of Cidex OPA for high-level disinfection; Prolystica® HP Enzymatic manual cleaner; ASEPTI-ZYME™ Neutral pH enzymatic instrument presoak/cleaner and automatic washer detergent as a substitute for Enzol® Enzymatic Detergent.
- During manual cleaning procedures of the Uroject12 Syringe Lever, a soft-bristled nylon brush is used to aid in soil removal. The Spectrum soft nylon (M-16) brush is recommended, since it is very common and widely used for cleaning at healthcare establishments. Any similar soft-bristled brush may be used. Please refer to the complete cleaning procedure described in the IFU.

DO NOT USE the Uroject12 Syringe Lever if one or more of the following are observed:

1. Visual signs of wear and tear
 - a. broken parts
 - b. loose or out of place parts
 - c. corrosion
2. Uroject12 Syringe Lever shows signs of reduced performance, such as
 - a. grinding when turning the knob
 - b. clutch failure to engage or disengage

After sterilization of the Uroject12 Syringe Lever, please follow your institution's policies and procedures for handling, packaging, and storing sterilized devices.

Please refer to the attachments below for detailed information on the preparation and administration of JELMYTO:

- INSTRUCTIONS FOR PHARMACY (IFP)
- INSTRUCTIONS FOR ADMINISTRATION (IFA)

Please refer to the package insert and www.jelmyto.com for the full Prescribing Information.

As described in the JELMYTO® (mitomycin) for pyelocalyceal solution Prescribing Information:

- **INDICATIONS AND USAGE:** JELMYTO is an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).
- **ADVERSE REACTIONS:** The most common adverse reactions ($\geq 20\%$) are ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, nausea, abdominal pain, fatigue, dysuria, and vomiting.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.

References:

1. JELMYTO[®] (mitomycin) for pyelocalyceal solution. Prescribing Information 2024. UroGen Pharma, Princeton, New Jersey.
2. STERRAD[®] Systems. Accessed on September 10, 2020. Available from: <https://www.asp.com/products/terminal-sterilization/sterrad-100nx>
3. Revital-Ox[®] RESERT[®] High Level Disinfectant. Accessed on November 6, 2020. Available from: <https://www.steris.com/healthcare/products/endoscope-reprocessing/high-level-disinfection/revital-ox-resert-high-level-disinfectant>
4. Medivators [Cantel] Automated Endoscope Reprocessors. Accessed on November 6, 2020. Available from: <https://www.medivators.com/products-and-services/endoscope-reprocessing/automated-endoscope-reprocessors>
5. High Level Disinfectant Rapicide[®] PA. Safety, Efficacy, and Microbiological Considerations. Accessed October 31, 2022. Available from: <https://www.medivators.com/sites/default/files/minntech/documents/50096-959%20REV%20D.pdf>
6. Renuzyme PLUS SDS. Accessed August 12, 2022. Available from: https://www.medline.com/media/catalog/Docs/MSDS/MSD_SDS12719.pdf
7. Renuzyme WR SDS. Accessed August 12, 2022. Available from: https://www.medline.com/media/catalog/Docs/MSDS/MSD_SDS12716.pdf
8. Getinge Cleaning Chemistry. Accessed October 31, 2022. Available from: https://www2.getinge.com/us/product-catalog/cleaning_chemistries/
9. Cidex[®] OPA. ADVANCED STERILIZATION PRODUCTS[®], division of Ethicon Inc., a Johnson & Johnson Company.
10. PeridoxRTU[®] (Sporicidal Disinfectant and Cleaner). Accessed on September 10th, 2020. Available from: <https://www.contechealthcare.com/products/peridoxrtu-sporicidal-disinfectant-and-cleaner/>
11. MetriCide[™]. Accessed on November 25, 2020. Available from: <https://www.metrex.com/en-us/products/high-level-disinfectants/metricide>
12. Prolystica[®] HP Enzymatic Manual Cleaner: Accessed on November 25, 2020. Available from: <https://www.steris.com/healthcare/products/surgical-instrument-cleaning-chemistries/prolystica-surgical-instrument-cleaning-chemistries/prolystica-2x-concentrate-cleaning-chemistries/prolystica-hp-enzymatic-manual-cleaner>
13. ASEPTI-ZYME[™]. Accessed on November 25, 2020. Available from: <http://www.sanitaryindustry.com/products/ecolab/asepti-zyme-.html>
14. JELMYTO[®] and UroGen[®] are trademarks of UroGen Pharma, Ltd. All other trademarks are the property of their respective owners.

Attachments:

- JELMYTO[®] (mitomycin) for pyelocalyceal solution. Prescribing Information 2024.
- JELMYTO[®] (mitomycin) for pyelocalyceal solution. Instructions for Pharmacy (IFP)



- JELMYTO® (mitomycin) for pyelocalyceal solution. Instructions for Administration (IFA)
- Uroject12 Syringe Lever. Instruction for Use (IFU)