



UROJECT12 SYRINGE LEVER

INSTRUCTIONS FOR USE



READ THE FOLLOWING PRECAUTIONS,
WARNINGS, AND INSTRUCTIONS FOR USE
CAREFULLY

GLOSSARY OF SYMBOLS

	Catalogue number		Prescription only
	Serial number		Caution, consult accompanying documents
	Lot number		Do not use if damaged
	Manufacturing date		Device has not been sterilized
	Manufacturer		Consult instructions for use



Manufactured for:

UroGen Pharma Ltd.
9 HaTa'asiya St.
Ra'anana 4365405
Israel

Intended Use

The Uroject12 Syringe Lever Device is intended for use in the administration of sterile materials under aseptic conditions, in a clinical urology setting, by a clinician and in accordance with the best judgment of a physician.

Contraindications

There are no contraindications for the Uroject12 Syringe Lever.

Warnings and Precautions

- The Uroject12 should be cleaned and thereafter either sterilized or high-level disinfected prior to its first use and after every single use.
- The Uroject12 is intended to be used only with the syringes listed in these Instructions for Use.
- Caution: Federal Law restricts this device to sale by or on the order of a physician.
- The Uroject12 is provided non-sterile and must be either sterilized or high-level disinfected before every use.
- Prior to operating the Uroject12, visually inspect the device for any damage or signs of wear. DO NOT USE THE UROJECT12 if visual signs of wear are observed, if it does not move smoothly, or if the clutch mechanism does not work.
- Clean the Uroject12 using the recommended cleaning instructions in these Instructions for Use.
- Sterilize or high-level disinfect the Uroject12 using the recommended instructions in these Instructions for Use.
- Do not expose the Uroject12 to temperatures above 266° F (130° C).

Device Description

The Uroject12 Syringe Lever (Figure 1) is a reusable device that is intended to assist in the delivery of fluids from a standard 20 mL syringe during urinary tract procedures. It contains a housing for holding a standard 20 mL syringe and a lever that pushes the syringe's plunger when the user rotates its knob. A clutch mechanism allows the user to quickly move the lever to the syringe plunger's position.



Figure 1 - Uroject12 Syringe Lever

How Supplied

- Plastic case
- Non-sterile

Required Materials Not Supplied with the Uroject12

The following syringes should be used with the Uroject12:

- Medallion® 20 mL Syringe. Cat.#: MSS121.
Manufactured by: Merit Medical Systems, Inc., Dallas, TX
- COP Medallion® 20 mL Syringe. Cat.#: COP121PC.
Manufactured by: Merit Medical Systems, Inc., Dallas, TX

Storage and Reuse

The Uroject12 should be stored, in a clean and dry place according to healthcare facility sterile medical device procedure.

Prior to each use:

Visually inspect to ensure there are no visual signs of wear.

Verify smooth rotational motion and operation of the clutch mechanism moves smoothly. DO NOT USE THE UROJECT12 DEVICE if one or more of the following have been observed:

- Visual signs of wear, such as:
 - broken parts,
 - loose or out of place parts,
 - corrosion.
- Device shows signs of reduced performance, such as:
 - grinding when turning the knob
 - clutch failure to engage or disengage

A CLEANING, HIGH-LEVEL DISINFECTION AND STERILIZATION INSTRUCTIONS

The Uroject12 Syringe Lever should be cleaned and thereafter either sterilized or high-level disinfected prior to its first and subsequent use.

Cleaning Instructions

Manual Cleaning Instructions

- Rinse the Uroject12 under cold running tap water for 2 minutes to remove gross soil.
 - Prepare Enzo® Enzymatic Detergent per manufacturer's recommendation at 1 oz. per gallon of tap water, or an equivalent cleaning agent.
 - Fully immerse the Uroject12 into the prepared detergent and allow it to soak for 1 minute.
 - While immersed, brush the Uroject12 with a soft-bristled brush (Spectrum M16) to aid in soil removal.
 - Remove the Uroject12 from the prepared detergent and rinse it under cold running tap water for 1 minute.
 - Dry the Uroject12 with clean cloth.
 - Visually inspect the Uroject12 for visible soil. If visible soil is observed, repeat the cleaning procedure.
- Enzo® Enzymatic is a registered trademark of ADVANCED STERILIZATION PRODUCTS®, division of Ethicon Inc., a Johnson & Johnson Company.

Automated Cleaning Instructions

- Pre-clean the Uroject12 as described below:
 - Rinse under cold running tap water for 2 minutes to remove gross soil.
 - Prepare a bath of Neodisher® MediClean Forte® solution following manufacturer's recommendation of 5-20 mL/L using warm tap water.
 - Fully immerse the Uroject12 into the prepared detergent and allow to soak for 10-30 minutes.
- Transfer onto an appropriate rack system contained inside the washer for processing.
- Select the appropriate cycle as listed below:

PHASE	RECIRCULATION TIME (Minutes)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION (If Applicable)
Pre-wash 1	02:30	Cold tap water	N/A
Wash	10:30	113°F (45°C)	Neodisher® MediClean Forte® 2-10 mL/L
Rinse 1	02:30	Warm water 199°F (93°C) (Set Point)	N/A
Pure Water Rinse	01:30	194°F (90°C)	N/A
Dry Time	07:30	Hot air	N/A

Neodisher® MediClean Forte is a registered trademark of Chemische Fabrik Dr. Weigert GmbH & Co. KG.

- After the cleaning cycle is completed, inspect with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood protein substances and other debris) has been removed from surfaces, lumens, crevices and serrations. If visible soil is seen, repeat the cleaning procedure.

B HIGH-LEVEL DISINFECTION AND STERILIZATION INSTRUCTIONS

High-Level Disinfection Instructions

- Equilibrate a water bath of Cidex® OPA* to a minimum of 68 °F (20° C) for Cidex® OPA.
- Ensure minimum effective concentration (MEC) of the Cidex® OPA using Cidex® OPA test strips.
- Fully immerse the Uroject12 in the Cidex® OPA, and agitate to ensure all air bubbles are removed from its surface. Actuate twice through the full range of motion by turning the knob.
- Flush with Cidex® OPA in the hard to reach areas (see Figure 2):
 - All areas of the Lead Screw entry into the clutch cover
 - Clutch button area
 - All sides of exposed Lead Screw surface
 - Slider surface - all sides

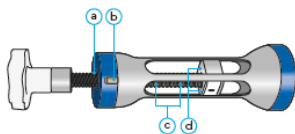


Figure 2 – Flush Areas

- Allow to soak for at least 12 minutes.
- Thoroughly rinse: Fully immerse in pure water, agitate to remove bubbles, and flush with a sterile syringe. Actuate through the full range of motion by turning the knob and allow to sit for a minimum of 1 minute. Repeat two additional times for a total of 3 rinses.
- Dry using a sterile lint-free cloth.

* Cidex® OPA is a registered trademark of ADVANCED STERILIZATION PRODUCTS®, division of Ethicon Inc., a Johnson & Johnson Company.

Sterilization Instructions

Sterilize the Uroject12 according to the autoclave settings in Table 1.

! THE UROJECT12 SHOULD NOT BE SUBJECT TO TEMPERATURES HIGHER THAN 266°F (130°C).

Table 1 Autoclave Settings

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

B OPERATING PROCEDURE

- Before using the Uroject12:

- Visually inspect the device for signs of wear, including broken parts, loose or out of place parts, or corrosion. Do not use if it exhibits signs of wear.
- Verify the lever moves smoothly by pressing and holding the clutch button, then moving the lever back and forth (Figure A). Do not use if it does not move smoothly (grinding when turning the knob) or the clutch does not work.

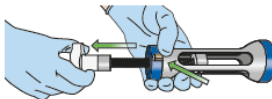


Figure A Prepare the Uroject12

- Press and hold the clutch button, then pull the knob backwards, until there is enough space to install a syringe filled with fluids.
- Insert the syringe into the syringe housing (Figure B).

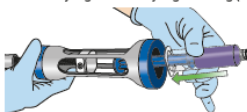


Figure B Install Syringe

- Turn the syringe clockwise (Figure C) until it clicks to lock.

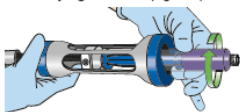


Figure C Turn Syringe Clockwise

- By turning the knob or using the clutch, advance the lever (Figure D) to just above the syringe plunger (Figure E).

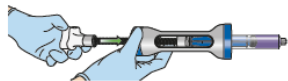


Figure D Move the Lever Down

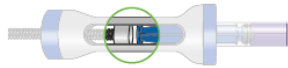


Figure E Advance the Lever to Just Above the Syringe Plunger

- Dispense the fluid by holding the Uroject12 body in one hand and rotating the knob clockwise with the other hand, until the required volume is dispensed (Figure F).



Figure F Dispense the Fluid

- Remove the syringe from the Uroject12 by rotating the Uroject12 body counter-clockwise while holding the syringe (Figure G).

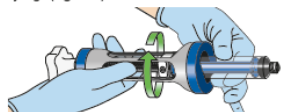


Figure G Unload the Syringe

- Dispose of the syringe according to standard procedures for biohazardous waste (Figure H). DO NOT DISPOSE OF THE MULTI-USE UROJECT12.

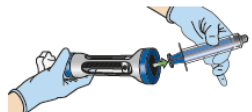


Figure H Dispose of the Syringe

Continue to the Cleaning Instructions for the Uroject12.