REF AD-US

Uroplasty Administration Device

For the delivery of injectable materials contained in standard 3 cc syringes.

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DESCRIPTION OF SYMBOLS

Rx Only	Prescription Use Only
REF	Product Reference Number
SN	Serial Number
	Consult Instructions for Use
LATEX	Not made with natural rubber latex
15°C 30°C	Store at room temperature
	Manufacturer
EC REP	Authorized Representative in a European Community

INDICATION

The Administration Device is indicated for the delivery of injectable materials contained in standard 3 cc syringes.

DESCRIPTION

The Administration Device (AD) is a chrome-plated die cast zinc instrument with a chrome-plated brass adapter, and a stainless steel lever, syringe dosage rod, and pivot point with pin. This device will hold and deliver the contents of Uroplasty 3 cc syringes.

WARNINGS/PRECAUTIONS

» The adapter is the only removable component. To remove the adapter from the Administration Device, hold the rotating collar while turning the adapter a quarter turn, then pull it off from the main body of the device. Do not use tools to remove the adapter or any other parts. Damage will occur if the adapter is removed improperly. Return damaged or faulty units to your distributor.

» Do not soak the Administration Device with other soiled/contaminated devices. Contamination from other devices may accumulate in the Administration Device crevices/moving parts making it more difficult to thoroughly clean. Inadequate cleaning may result in malfunction of the Administration Device release mechanism or restricted movement of the syringe dosage rod.

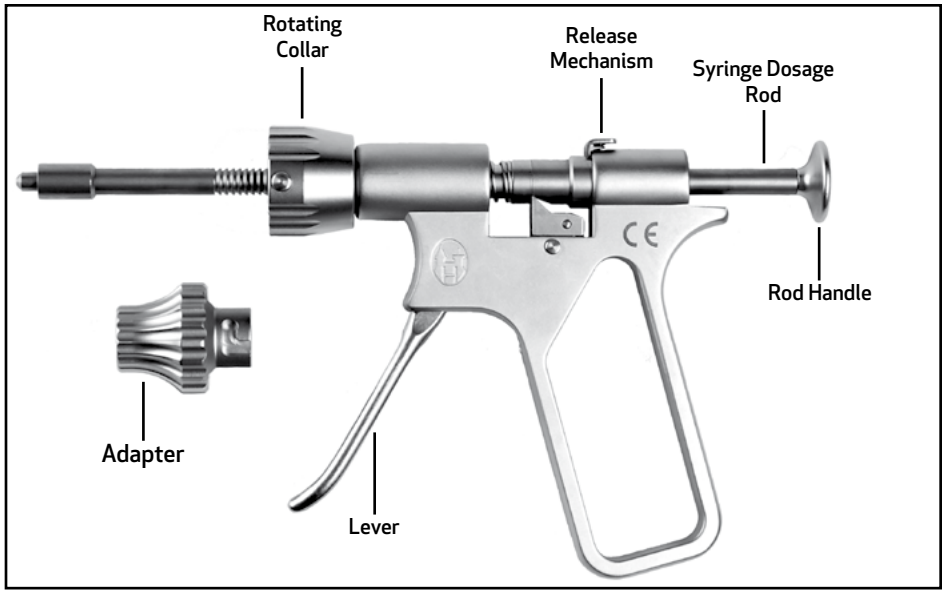
» To avoid pitting or corrosion of the metal surfaces, avoid contact with chloride or oxidizing solutions (i.e., saline, bleach, hydrogen peroxide, peracetic acid, etc.).

» Avoid cold soaks or prolonged exposures in high-level disinfectants beyond the time or concentration specified by the manufacturer. These materials may damage the instrument finish and affect the functioning of the device.

» Detergent residue may result in staining and may interfere with sterilization if not thoroughly rinsed after cleaning.

LIMITATIONS

After cleaning and disinfection or sterilization, verify functionality prior to re-use. End of life is normally determined by wear and damage due to use.



INSTRUCTIONS

Please read and understand all instructions prior to reprocessing the Administration Device. Select the preferred cleaning method, followed by disinfection or sterilization.

Point of Use	The device is supplied non-sterile with one adapter.
Containment and Transportation	Transport the soiled device in a closed container/wrapping to a designated cleaning area. Remove/rinse visible debris from the device before it dries. Do not soak the device in a disinfectant prior to cleaning. Do not soak the device with other soiled devices as this may increase the amount of soil or contaminants in the crevices prior to reprocessing.
Preparation for Cleaning	Remove the adapter by holding the rotating collar while turning the adapter a quarter turn, then pull it off from the main part of the device. Extend the dosage rod fully to the back position by pressing the release mechanism and pulling the rod handle. During cleaning move the dosage rod to the front position by pressing the release mechanism and pushing the rod handle forward.
Cleaning: Manual	» Rinse each component for at least 2 minutes under warm water to remove all visible debris. Manipulate the dosage rod, alternating between the front and back positions during rinsing. Use an irrigation syringe to flush all crevices. » Soak each component for at least 5 minutes in a lukewarm water bath containing an enzymatic detergent per the manufacturer's instructions. » Brush each component for at least 2 minutes under the surface of the enzymatic detergent bath using a soft-bristle brush to remove any visible soil. Manipulate the dosage rod, alternating between the front and back positions, to access all crevices with the brush. » Rinse all parts of the device for at least 2 minutes under warm running water to remove all detergent residues. Use an irrigation syringe to flush all device crevices. NOTE: Detergent residue may result in staining and may interfere with sterilization if not rinsed completely. » Visually inspect each component under normal lighting conditions to verify all debris is removed. » Repeat cleaning steps if debris is still visible on the device. » Dry each component with a lint-free cloth or filtered compressed air.

Cleaning: Automated	» Rinse and brush each component for at least 2 minutes with a soft-bristle brush under warm water to remove all visible debris. Manipulate the dosage rod, alternating between the front and back positions during rinsing. Use a syringe to flush all crevices. » Place each component in an automated washer with the dosage rod on the Administration Device in the back position at an angle to allow draining. » Run the automated wash cycle with the following MINIMUM parameters: - 1 minute cold water prewash - 1 minute hot water enzymatic wash - 2 minute detergent wash at 66°C (150°F) - 1 minute hot water rinse - 7 minute drying at 115°C (239°F) » Visually inspect each component under normal lighting conditions to verify all debris is removed. » Repeat cleaning steps if debris is still visible on the device. Dry each component with a lint-free cloth or filtered compressed air.
High Level Disinfection: Manual	» After cleaning, immerse the adapter and the Administration Device, with the dosage rod in the back position, in a 2% high-level disinfectant solution (e.g., alkaline glutaraldehyde) per the manufacturer's instructions. » Rinse each component for at least 1 minute by immersing in purified water with agitation. Repeat rinse step 3 times. » Dry each component with a lint-free cloth or filtered compressed air.
Low Level Thermal Disinfection: Automated	» Place the adapter and the Administration Device, with the dosage rod in the back position, in an automated washer-disinfector at an angle to allow drainage. » Run the thermal rinse disinfection cycle for a MINIMUM of 2 minutes at 82.2°C (180°F). » Dry each component with a lint-free cloth or filtered compressed air.
Packaging	See sterilization instructions below.
Sterilization	The Administration Device has been validated for the following steam sterilization methods:

Autoclave Type & Device Wrapping	Minimum exposure time at 132°C (270°F)	Minimum exposure time at 121°C (250°F)	Drying Time
Gravity (unwrapped)	3.5 minutes	20 minutes	0 – 1 minutes
Gravity (wrapped)		20 minutes	15 – 30 minutes
Pre-vacuum (unwrapped)	3 minutes		0 – 1 minutes
Pre-vacuum (wrapped)	3 minutes		15 – 30 minutes

ETO, STERRAD® and chemical sterilization are NOT validated.

Maintenance, Inspection, & Testing	Inspect for damage before and after each use. If damage is observed, do not use. There is no maintenance required if thoroughly cleaned and disinfected or sterilized according to these manufacturer's instructions.
Storage	Reassemble the device by inserting the adapter into the rotating collar so the adapter grooves align with the rotating collar pins and turning the adapter so the pins lock into the grooves. Store the dried device at room temperature in a dry environment.

WARRANTY

Uroplasty warrants that reasonable care has been used to design and manufacture this product. Product will be replaced if Uroplasty determines its material or workmanship is defective. This is Uroplasty's only warranty, and it excludes all other warranties (including those implied by operation of law). Uroplasty is not responsible for matters within the control of the user or others, such as product handling, cleaning, disinfecting, sterilization and storage, patient selection and diagnosis and treatment procedures. This Limited Warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, UROPLASTY IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

(2) THIS LIMITED WARRANTY IS MADE ONLY TO THE PURCHASER OF THE PRODUCT. AS TO ALL OTHERS, UROPLASTY MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

Any implied warranties of merchantability or fitness are specifically excluded. Statements and descriptions in marketing literature, while generally describing product, do not constitute any warranties.

DISCLAIMER OF WARRANTIES

Uroplasty excludes all warranties and responsibilities for:

» Improper use and/or tampering, and failure to follow instructions in this insert and for the Uroplasty bulking agent with which the device is used.

ORDERING INFORMATION

The Administration Device is supplied non-sterile with one adapter.

For more information, contact Uroplasty Customer Service:

Uroplasty

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