### **OLYMPUS**



# Reprocessing Thermolabile Flexible Urological Endoscopes & Accessories

Elevating Patient Care. Together.

## **Disclaimer**

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# **Objectives**

### **Objectives**

Describe the essential steps in cleaning, disinfection and sterilization inclusive of manual and automated actions for reprocessing flexible urological endoscopes



Describe the essential steps in cleaning, disinfection and sterilization inclusive of manual and automated actions for reprocessing the MAJ-207, MAJ-891 & MAJ-2092

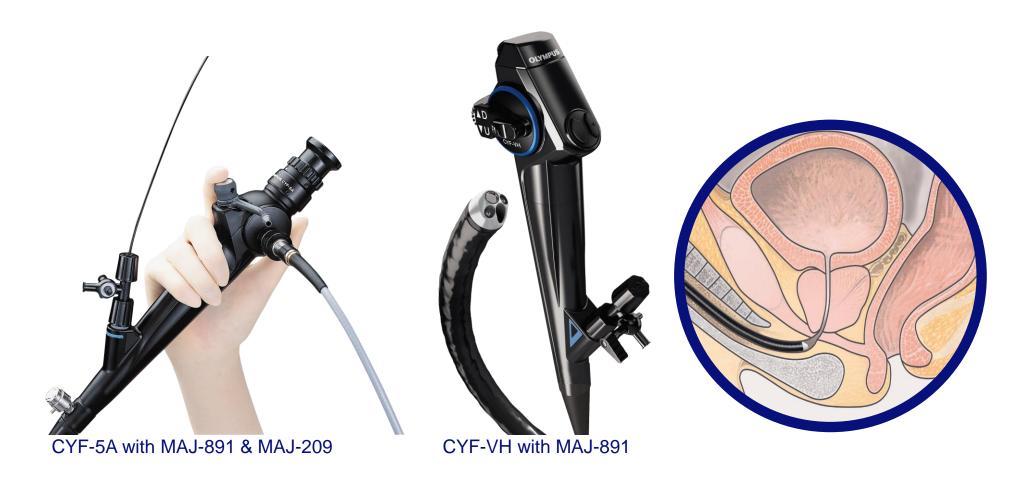


# 01

# Essential Steps in Reprocessing Endoscopes used in Urological Procedures

# **Flexible Cystoscopes**

- CYF-5
- CYF-5R
- CYF-5A
- CYF-VH
- CYF-VHA
- CYF-VHR
- CYF-V2
- CYF-V2R
- CYF-VA2



# **Flexible Ureteroscopes**

- URF-P6
- URF-P6R
- URF-P7
- URF-P7R
- URF-V
- URF-V2
- URF-V2R
- URF-V3
- URF-V3R



# Reprocessing Practices Based on Spaulding Classification\*\*

### **Critical Devices (Cleaning + Disinfection + Sterilization)**

All objects that **enter sterile tissue** or the vascular system E.g.: Flexible Ureteroscopes, surgical instruments, etc.

### **Semi-Critical Devices (Cleaning + Disinfection)**

Items that come into contact with mucous membranes or non-intact skin\*

E.g.: Flexible endoscopes (e.g., cystoscopes\*\*, gastroscopes, colonoscopes, duodenoscopes), etc.

### **Non-Critical Devices (Cleaning / Disinfection)**

Objects that come into **contact with intact skin** (= sufficient barrier against microorganisms) but not mucous membranes

E.g.: Blood pressure cuffs, etc.



<sup>\*</sup>KRINKO / BfArM Recommendation, 2012

<sup>\*\*</sup>Local regulations might differ from this list and classify single medical devices in a higher category

# Reprocessing Overview | Essential Steps

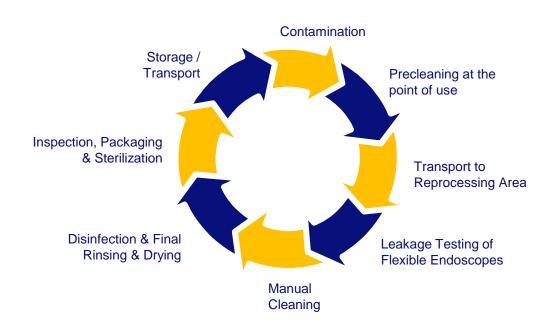
### Always refer to model specific IfU\*

- Precleaning (at the point of use)
- Secure transport to the reprocessing area
- Leakage testing (flexible endoscopes)
- Manual Cleaning
  - Rinsing
  - Drying
- Disinfection (automated or manually)

### AND/OR\*

- Sterilization
- Storage

Quality Assurance
Perform visual inspection throughout the process



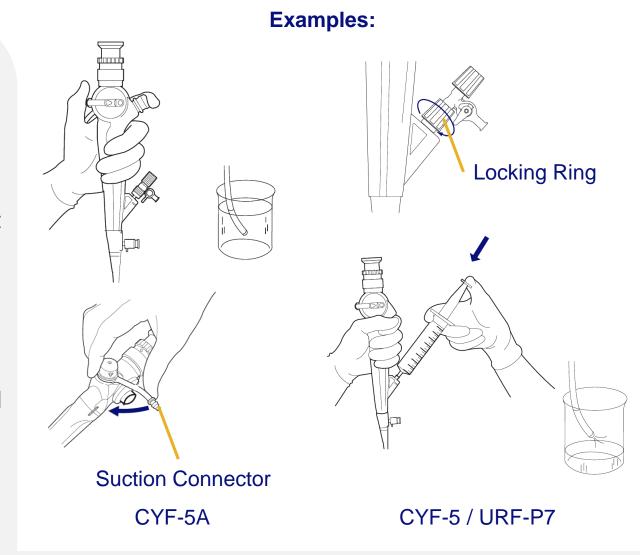


<sup>\*</sup> Steps might differ depending on local regulations, medical device or application

# **Precleaning at the Point of Use**

Performed **immediately** after patient procedure to remove gross debris with endoscope still connected to the video system center

- Use of detergent or water (acc. to IfU)
- Wipe external surface of insertion tube with a lint free wet cloth/sponge
- Detach any accessories that are attached to the endoscope after aspiration but before rinsing
- Rinse **all** channels
  - Aspiration through instrument/suction channel
  - Flush channels with fluid and air



# **Precleaning at the Point of Use**



Wipe Insertion section





Remove MAJ-891 (top picture) or MAJ-2092 (lower picture) and immerse in detergent







Rinse all channels with detergent or water

# **Transport**

- Do not transport endoscopes manually
- Keep the endoscope in a container with a lid to avoid possible environmental or personnel contamination during transportation
- Do not transport endoscopes and accessories together in the same container to avoid damages
- Always comply to time between use and reprocessing (refer to IfU)







**ETS Plus** 

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# Preparation before Cleaning | Leakage test (1/4)

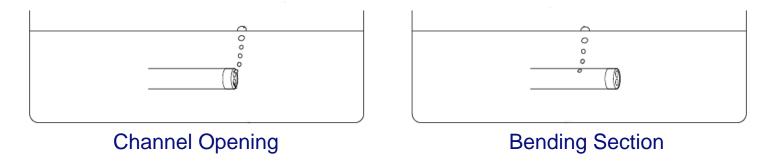
- Before immersing the endoscope in any liquid, confirm that:
  - All components and accessories are detached from the endoscope
- Connect leakage tester (MB-155) to Maintenance Unit (MU-1)
- Make sure that **both** leakage tester cap and endoscopes' venting connector are completely dry
  - Attach/detach the MB-155 always while the endoscope is NOT immersed



# **Preparation before Cleaning | Leakage test (2/4)**

Check for leakages for approx. 30 sec. while deflecting the bending section of the endoscope by turning the UP/DOWN angulation control lever







# Preparation before Cleaning | Leakage test (3/4)

- Check for leakages for approx. 30 sec. while deflecting the bending section of the endoscope by turning the UP/DOWN angulation control lever
- After leakage test:
  - 1. Remove the endoscope from the water
  - 2. Disconnect the leakage tester (MB-155) from the Maintenance Unit (MU-1) or release pressure of manual leak tester
  - 3. Wait 30 sec. until the rubber cover of the bending section deflates to its pre-expansion size
  - 4. Detach the leakage tester from the endoscope
  - 5. Dry the leakage tester cap thoroughly



# **Preparation before Cleaning | Leakage test (4/4)**



In case of a leak

Continuous series of bubbles

Immediately stop further reprocessing

- Dry the endoscope
- Wrap into a foil
- Initiate shipment to next Olympus repair center



# **Manual Cleaning**

- Preparation of detergent solution
  - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
  - Change at least every working day; immediately in case of visible contamination
- Fully immerse the endoscope / instrument in detergent solution
  - Do not immerse the endoscope with objects other than the equipment used for reprocessing the endoscope
- Thoroughly wipe or brush all **external** surfaces



# Manual Cleaning | Brushing & Flushing

# Brush instrument / suction channel and channel opening while immersed



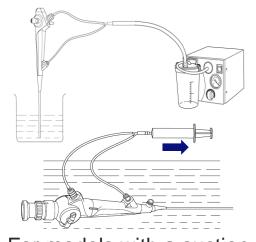
Brush the instrument channel and channel port

Repeat until all debris is removed

# Flush the instrument / suction channel



Fill a syringe with detergent solution and flush the solution through the instrument channel three times



For models with a suction channel a cleaning adapter is used to aspirate detergent and to fill all channels with detergent afterwards with a syringe

### Wipe & allow to soak



Using a lint-free cloth, gently wipe all debris from the external surfaces, while the endoscope is immersed in detergent solution

Soak in the detergent solution for the recommended time



Always refer to the model-specific Instructions for Use for complete and accurate instructions

# Manual Cleaning | Rinsing & Drying

### **Immerse Endoscope in** clean water

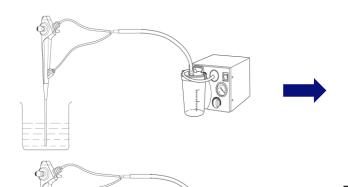


Gently sway the Endoscope to thoroughly rinse it

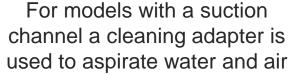
### Flush the instrument / suction channel



Fill a syringe with instrument channel three times



clean water and flush the water through the



### Dry the entire **Endoscope**



Place the Endoscope in a clean basin Using a lint-free cloth, gently dry all external surfaces



Always refer to the model-specific Instructions for Use for complete and accurate instructions

# **Disinfection**

### **Manual Disinfection**

- Possible but not state-of-the-art
- Disinfection not followed by sterilization
  - Use of virucidal disinfectant (high level disinfection (HLD)), e.g. Cystoscopes\*, Gastroscopes, Colonoscopes etc.
- Disinfection followed by sterilization
  - Limited virucidal disinfectant is enough, e.g. Surgical instruments, Ureteroscopes etc.

Take care of the ingredients of your chemicals and talk to your chemical distributor

### Rinsing

With adequate water quality, depending on following steps:

- Disinfection not followed by sterilization
  - Rinsing to be done with disinfected, soft sterile filtered or DI water
- Disinfection followed by sterilization
  - Rinsing to be done with water of drinking water quality

Immersion: take care on contact time and make sure, that all surfaces (inside and outside of the instruments) have contact with disinfection solution

<sup>\*</sup> Depending on local regulations

### **Manual Disinfection**

# Immerse Endoscope in disinfection solution



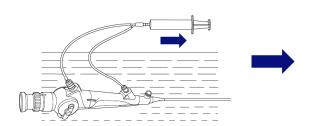
Test the Minimum Effective Concentration (MEC) of the disinfectant prior to each use (if applicable)

Immerse the Endoscope in the disinfection solution

# Flush the instrument / suction channel & allow to soak



Fill a syringe with disinfection solution and flush the solution through the instrument channel Detach syringe or adapters and leave the endoscope immersed in the covered basin for the recommended contact time



For models with a suction channel there are special cleaning adapters available to aspirate disinfection solution into the channels

# Dry the entire Endoscope



Remove the endoscope from the disinfectant solution

Fill a sterile syringe with air and flush the air through the instrument channel

Detach the syringe from the endoscope



Always refer to the model-specific Instructions for Use for complete and accurate instructions

# **Final Rinsing & Drying**

# Immerse Endoscope in water of defined quality



Immerse the Endoscope in the water

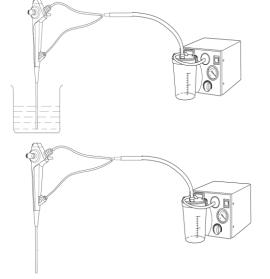
Wipe with sterile lint-free cloths and gently sway the Endoscope to thoroughly rinse it

# Flush the instrument / suction channel



Fill a syringe with water and flush the water through the instrument channel three times

Remove the endoscope from the rinse water and place them in a sterile basin



For models with a suction channel a cleaning adapter is used to aspirate water and air

# Dry the entire Endoscope



Fill a sterile syringe with air and flush the air through the instrument channel 3 times

Dry the external surfaces of by wiping with sterile lint-free cloths
Dry the inside of the instrument channel port, using sterile cotton swabs



Always refer to the model-specific Instructions for Use for complete and accurate instructions

# **Automated Cleaning & Disinfection**

- Automated in an Endoscope Washer-Disinfector (EWD) according to EN ISO 15883
  - Chemo-thermal at max. temperature 60°C
  - Glutardialdehyde (GDA) or Peracetic acid (PAA)
- Advantage of automation is standardization
- Full Documentation
- Eliminate human factors









PAA Process Chemistry



**GA Process Chemistry** 

**OLYMPUS** 

# Packaging | Sterile Barrier Systems (EN ISO 11607-1,2)

# To enable sterilization and to guarantee sterility at adequate storage until reuse

### **Rigid Packaging**

Container made of chrome / steel, aluminium, plastics

### **Soft Packaging**

Fleece, foil bags













# Packaging | Sterile Barrier Systems (EN ISO 11607-1,2)

### After cleaning, disinfection, rinsing & drying

#### Attention:

- Not all packaging material is compatible with all sterilization methods!
- Refer to the sterilizer manufacturers' advice for packaging and follow your medical device manufacturers' IfU
- If containers are used as the sterile barrier system
  - Cleaning and disinfection process has to be compatible with containers' material (e.g. high alkaline cleaners and aluminium containers!)





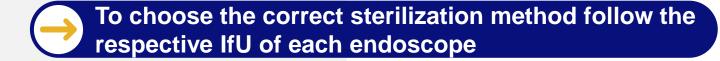


# **Sterilization**

Required for **critical** medical devices (Spaulding classification)

- Use appropriate packaging
- Different sterilization methods available
  - Ehtylene oxide (ETO) at 55°C
  - Low temperature steam formaldehyde (LTSF) at 55°C to 60°C
  - Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) at approx. 50°C

Always refer to the endoscope's IfU for Olympus-approved sterilization methods. Also refer to customer letters for methods not listed in the IfU or the appropriate sterilization programs



# **Storage**

#### **Disinfected items**

- Confirm that all surfaces of the reprocessed items are dry and store the reprocessed items properly in closed, dust-free cabinets (e.g., drying cabinet)
- Vertically hanging recommended
  - In case of horizontal storage: do not coil the endoscope insertion tube or universal cord with a diameter < 20 cm</li>

### Sterilized items

- Record the sterile expiration date on the sterile packaging. Do not damage the packaging
- Store the sterilized items in a proper storage cabinet, following your institutional guidelines

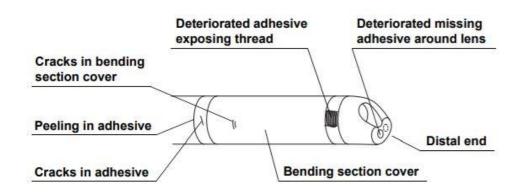


**EDC Plus** 

# **Pre-Procedure Inspection**

### Prior to each use inspect the following:

- Visual inspection of the entire endoscope and ancillary products, checking for any irregularities such as excessive scratching, deformation, and loose parts
- Inspect the entire distal end of the endoscope including the objective lens and examination light outlet for any irregularities such as scratches, chips, cracks, stains, discoloration, deformation, and gaps around the lens
- Inspect the adhesives attaching the bending section cover to the insertion section for any irregularities
- Inspect the bending mechanism
- Attach the accessories to the endoscope and connect the endoscope to the video system center
- Perform a function check of the complete endoscope



Please refer to the Model-Specific Instructions for Use on the Inspection Protocol

## What to be on the lookout for



Dented or damaged Insertion Tube



Discoloring of the Insertion Tube or Bending Section



Peeling glue



Damaged Bending Section



Discolored Peeling glue



**Damaged Lenses** 



# **Essential Steps in Reprocessing**Flexible Endoscope Accessories

# Reprocessing Flexible Endoscope Accessories

### Reprocess the accessories according to the IfU\*

- Dispose in detergent solution
- Secure transport to reprocessing area
- Manual cleaning (possibly US cleaning)
  - Disassembling
  - Rinsing
  - Drying
- Manual disinfection

### AND/OR\*

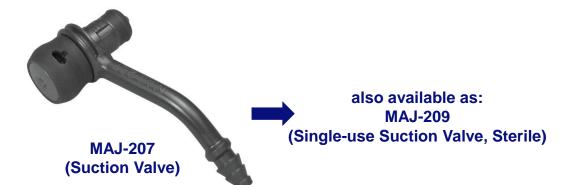
- Sterilization
- Storage







MAJ-2092 (Luer-Split)



<sup>\*</sup> Depending on local regulations the steps might differ

# **Manual Cleaning | MAJ-891**

**MAJ-891** 

- Preparation of detergent solution
  - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
  - Change at least every working day;
     immediately in case of visible contamination
- Disassemble MAJ-891 in 4 parts
- Fully immerse all parts in detergent solution
- Thoroughly wipe or brush all **external** surfaces



**Completely Disassemble** 



Completely immerse in detergent solution

# Manual Cleaning | Brushing

**MAJ-891** 

- Thoroughly brush all internal surfaces of all parts
- Visually inspect all parts
  - If debris remains, ultrasonically clean at 40kHz for 5 minutes
- Leave all parts immersed for the recommended contact time





Note: to pass the brush through the biopsy valve, press it between your fingers in order to open its slit

# Manual Cleaning | Rinsing & Drying



**MAJ-891** 

- After complying to the recommended contact time remove all parts from the detergent solution and place them in clean water
- Gently agitate them to thoroughly rinse
- Use a lint-free cloth to thoroughly wipe and dry the external surfaces of each part
- Use sterile cotton swabs to dry the internal surfaces of each part





### **Manual Disinfection**

**MAJ-891** 

- Preparation of disinfectant solution
  - Follow instructions of process chemical manufacturer (e.g., SekuseptTM Aktiv, ECOLAB or Cidex® Activated Dialdehyde Solution, ASP) in terms of concentration, exposure time and temperature
  - Change at least every working day; immediately in case of visible contamination
- Fully immerse all parts in disinfection solution solution
- Thoroughly flush all internal surfaces



Fill a 30ml syringe with disinfectant solution and flush the forceps/irrigation plug

## **Manual Disinfection**

**MAJ-891** 

- Ensure the contact of all internal and external surfaces with disinfectant solution
- Cover the basin and leave all parts immersed for the recommended contact time



Open the slit of the biopsy valve in the disinfectant solution



# **Final Rinsing & Drying**



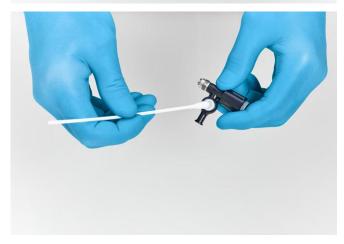
**MAJ-891** 

- Remove all parts from the disinfection solution and place them in a basin with sterile water or water of defined quality based on local regulation\*
- Immerse all parts in clean water. Flush all internal parts with water
- Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of each part
- Use sterile cotton swabs to dry the internal surfaces of each part
- \* Depending on local regulations non-sterile water and alcohol rinse might be used instead



Flush the forceps/irrigation plug utilizing a 30ml syringe

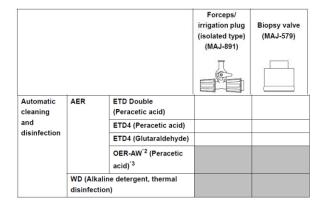


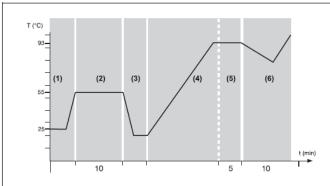


#### **Automated Processing in WD**

**MAJ-891** 

- Ensure that all manual cleaning steps
   have been completed before loading the
   WD
- Ensure that **all** parts are placed into the WD
- WD according to EN ISO 15883
  - Alkaline enzymatic detergent, e.g., neodisher® Mediclean forte, Dr. Weigert
  - Thermal disinfection
  - The drying temperature for which Olympus confirmed material compatibility is 110 °C





Step	Description		
1	Pre-cleaning (≤25°C)		
2	Cleaning (with detergent, 55°C, 10 min)		
3	Rinsing (with or without neutralizer)		
4	Heating (hot water)		
5	Thermal disinfection which serves as the final rinsing (without detergent and neutralizer, 93°C, 5 min)		
6	Drying (95°C, 10 min) (setting values)		

WD program parameters



#### Packaging & Sterilization



MAJ-891

- Ensure all parts are completely dry
- Seal the disassembled parts in separate packages
- Sterilize the packages
- Steam sterilization
  - Refer to recommended steam sterilization parameters and the sterilizer manufacturer's instructions
  - Allow all components to gradually cool down to room temperature
- Low Temperature Sterilization (V-PRO® maX/STERIS)
  - For the microbiological efficacy, contact STERIS Corporation and refer to the "V-PRO® maX" IfU

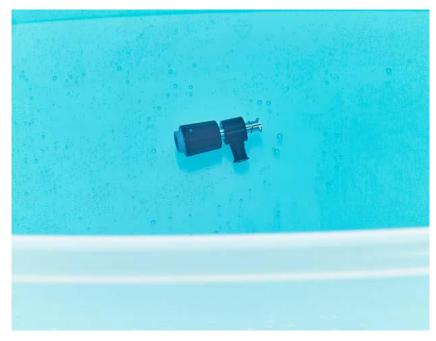
			Forceps/ irrigation plug (isolated type) (MAJ-891)	Biopsy valve (MAJ-579)
Sterilization	Hydrogen peroxide*4	V-PRO <sup>®</sup> maX (Flexible cycle)		
		STERRAD <sup>®</sup> NX <sup>®</sup> with ALLClear <sup>™</sup> Technology (Advanced cycle)		
		STERRAD <sup>®</sup> NX <sup>®</sup> (Advanced cycle)		
		STERRAD <sup>®</sup> 100NX <sup>®</sup> with ALLClear <sup>™</sup> Technology (Duo cycle)		
		STERRAD® 100NX® (Duo cycle)		
		STERRAD® 100S (Long cycle with booster)		
		STERRAD® 100S (Long cycle)		
	Steam (auto	oclaving)		
	Ethylene ox	ide gas		
	Low Tempe formaldehy	rature steam and de (LTSF)		
		compatible	l l	t compatible

### **Manual Cleaning | MAJ-2092**



**MAJ-2092** 

- Preparation of detergent solution
  - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
  - Change at least every working day; immediately in case of visible contamination
- Fully immerse in detergent solution
- Thoroughly wipe or brush all external surfaces



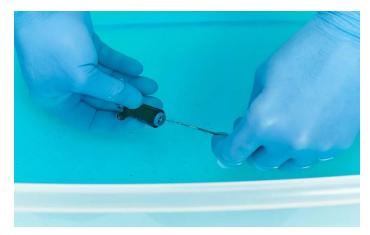
Completely immerse in detergent solution

# Manual Cleaning | Brushing & Flushing



**MAJ-2092** 

- Thoroughly brush all internal surfaces
- Using a clean 30ml syringe, flush the interiors, the openings, and the holes of the Luer-Split with the detergent solution
- Leave all parts immersed for the recommended contact time
- Visually inspect all parts
  - If debris remains, ultrasonically clean at 40kHz for 5 minutes





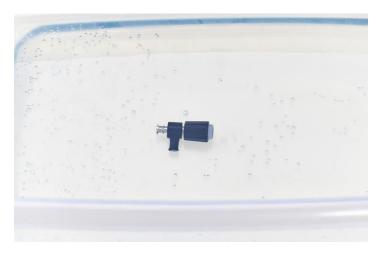
Flush the interiors, the openings, and the holes

### Manual Cleaning | Rinsing & Drying



**MAJ-2092** 

- After complying to the recommended contact time remove MAJ-2092 from the detergent solution and place it in clean water
- Gently agitate it to thoroughly rinse
- Use a lint-free cloth to thoroughly wipe and dry the external surfaces of each part of the MAJ-2092





#### **Manual Disinfection**

**MAJ-2092** 

- Preparation of disinfectant solution
  - Follow instructions of process chemical manufacturer (e.g., SekuseptTM Aktiv, ECOLAB or Cidex® Activated Dialdehyde Solution, ASP) in terms of concentration, exposure time and temperature
  - Change at least every working day; immediately in case of visible contamination
- Fully immerse the MAJ-2092 in disinfection solution solution
- Thoroughly flush all internal surfaces





Fill the channel with disinfectant solution and flush the interiors

#### **Manual Disinfection**



**MAJ-2092** 

- Ensure the contact of all internal and external surfaces with disinfectant solution
- Cover the basin and leave the MAJ-2092 immersed for the recommended contact time



#### **Final Rinsing & Drying**

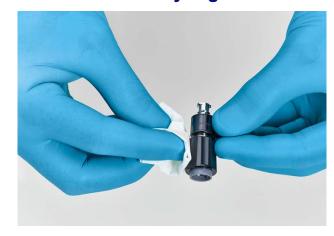
**MAJ-2092** 

- Remove the MAJ-2092 from the disinfection solution and place it in a basin with sterile water or water of defined quality based on local regulation\*
- Immerse the MAJ-2092 in clean water. Flush all **internal** parts with water
- Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of the MAJ-2092

 Depending on local regulations non-sterile water and alcohol rinse might be used instead



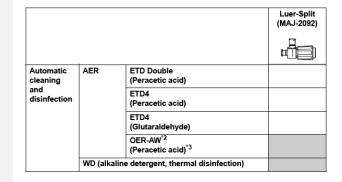
Flush the Luer split utilizing a 30ml syringe

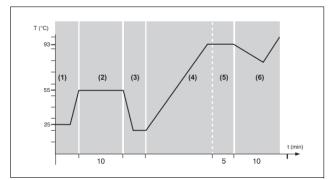


#### **Automated Processing in WD**

**MAJ-2092** 

- Ensure that all manual cleaning steps have been completed before loading the WD
- Connect the adapter (LuerLock) with the WD
- WD according to EN ISO 15883
  - Alkaline enzymatic detergent, e.g., neodisher® Mediclean forte, Dr. Weigert
  - Thermal disinfection
  - The drying temperature for which Olympus confirmed material compatibility is 110 °C





Step	Description		
1	Pre-cleaning (≤25°C)		
2	Cleaning (with detergent, 55°C, 10 min)		
3	Rinsing (with or without neutralizer)		
4	Heating (hot water)		
5	Thermal disinfection which serves as the final rinsing (without detergent and neutralizer, 93°C, 5 min)		
6	Drying (95°C, 10 min) (setting values)		

WD program parameters



#### Packaging & Sterilization



**MAJ-2092** 

- Ensure the MAJ-2092 is completely dry
- Seal the MAJ-2092 in an individual package
- Sterilize the package
- Steam sterilization
  - Refer to recommended steam sterilization parameters and the sterilizer manufacturer's instructions
  - Allow all components to gradually cool down to room temperature
- Low temperature sterilization (Sterrad/ASP, V-PRO® maX/STERIS)
  - Refer to recommended sterilizers/cycles in the IfU and the sterilizer manufacturer's instructions

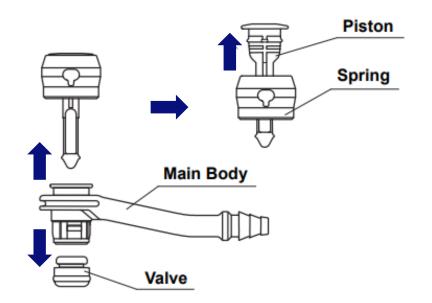
			Luer-Split (MAJ-2092)
Sterilization	Hydrogen	V-PRO® maX (Flexible cycle)	
	peroxide*5	STERRAD <sup>®</sup> NX <sup>®</sup> with ALLClear™ Technology (Advanced cycle)	
	,	STERRAD® NX® (Advanced cycle)	
		STERRAD <sup>®</sup> 100NX <sup>®</sup> with ALLClear™ Technology (Duo cycle)	*4
	,	STERRAD <sup>®</sup> 100NX <sup>®</sup> (Duo cycle)	*4
		STERRAD® 100S (Long cycle with booster)	
	,	STERRAD <sup>®</sup> 100S (Long cycle)	
	Steam (auto	claving)	
	Ethylene ox	ide gas	
	Low Temper	rature steam and formaldehyde (LTSF)	

compatible not comp
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#### **Manual Cleaning | MAJ-207**

MAJ-207

- Preparation of detergent solution
  - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
  - Change at least every working day;
     immediately in case of visible contamination
- Disassemble MAJ-207
- Fully immerse all parts in detergent solution
- Thoroughly wipe or brush all **external** surfaces



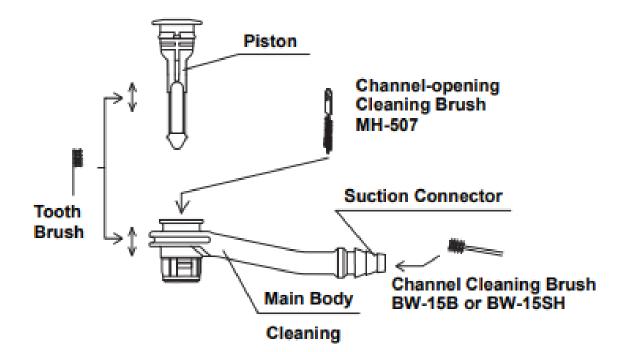
**Completely Disassemble** 



#### Manual Cleaning | Brushing

MAJ-207

- Thoroughly brush all **internal** and **external** surfaces of all parts (for all steps see IfU)
- Ultrasonically clean at 40kHz for 5 minutes
- Visually inspect all parts



**Cleaning** 

## Manual Cleaning | Rinsing & Drying

MAJ-207

- Fill a clean basin with water and immerse all parts in the water
- Gently agitate all parts in the water
- Fill and attach a syringe to the openings of the suction valve parts and flush the with water
- Remove all parts from the water
- Wipe and dry the internal and external surfaces of all parts, using clean lint-free cloths
- Inspect all accessories for residual debris. If debris is found on any accessory, repeat the cleaning procedure until all debris is removed

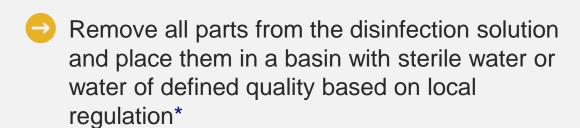
#### **Manual Disinfection**

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- Preparation of disinfectant solution
  - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
  - Change at least every working day; immediately in case of visible contamination
- Fully immerse all parts in disinfection solution solution
- Ensure the contact of all internal and external surfaces with disinfectant solution
- Cover the basin and leave all parts immersed for the recommended contact time



#### **Final Rinsing & Drying**



- Gently agitate all parts in the water
- Use a sterile, lint-free cloth to thoroughly wipe and dry the external surfaces of each part

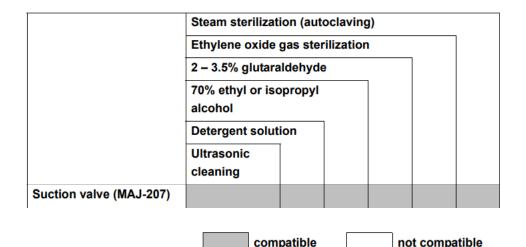
\* Depending on local regulations non-sterile water and alcohol rinse might be used instead



#### **Packaging & Sterilization**

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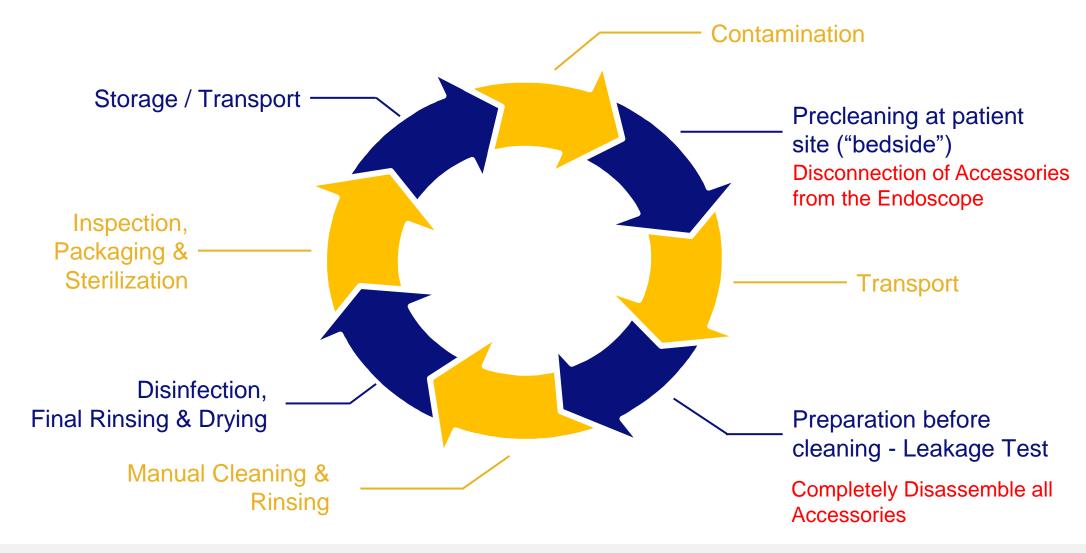
- Ensure all parts are completely dry
- Seal the **disassembled** parts in separate packages
- Sterilize the packages
- Steam sterilization
  - Refer to recommended steam sterilization parameters and the sterilizer manufacturer's instructions
  - Allow all components to gradually cool down to room temperature
- Ethylene oxide sterilization (ETO)
  - Refer to ETO gas exposure parameters in the IfU and the ETO manufacturer's instructions





# Key Take Home Messages

#### **Essential Steps in Reprocessing**



### **Key Take Home Messages**

1 Know the Endoscope

2 Get Familiar with the Instructions for Use (Endoscopes & Accessories)

**3** Be Aware of Local Regulations / Guidelines



Continious Education & 4

Training

**Establish Facility Guidelines** 5

**Know your Vendor Support** 6



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