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## Products

These Instructions for Use apply to the products listed below:

1002-TS 001  
1002-TS 002  
1002-TS 003  
1002-TS 004  
1002-TS 005



## Important Information



*Read these Instructions for Use carefully before each use and keep them for the user or the relevant specialist personnel in an easily accessible place.*



*Read the warnings indicated by this symbol carefully. Improper use of the products may cause serious injury to patients, users or third parties.*

## 1 Usage Information

### Intended Use

Maxmorespine® endoscopes are intended for illumination and visualization in diagnostic and therapeutic endoscopic minimally invasive surgical procedures.

### Indication

Maxmorespine® endoscopes are indicated for application in endoscopic, minimal invasive diagnostic and/or therapeutic surgical procedures on the spine.

### Contraindication

Maxmorespine® endoscopes are not intended to be used in direct contact with central nervous system. This includes the brain, meninges and spinal cord.

### Side Effects and Complications

- Infection (see "Infection Risk" in chapter 2)
- Burn (see "Risks of Burn" in chapter 2)
- Tool breakage (see "Safe handling" in chapter 2)
- Nerve root irritation
- Wound infection
- Postoperative haemorrhage
- Hematomas

### Intended User

Endoscopes shall only be used by trained and qualified doctors. Adequate training, knowledge and experience in the clinical application of endoscopic techniques is required

## 2 Precautions and Warnings

### Infection Risk

In endoscopic studies, the risk of infection is of particular importance. Risk factors should be considered before application. Factors that increase the risk of infections can be divided into two groups:

#### Process-related risk factors

- Nature and extend of tissue damage in therapeutic procedures;
- Circumstances of the endoscopic surgery (emergency or elective surgery)
- Expertise and experience of examiner / user;
- Proper cleaning and disinfection of endoscopes and accessories.

#### Patient-related risks factors

- Reduced immune status or immunosuppression of patient (HIV, Leukemia, Lymphoma, Immunosuppressive therapy, advanced liver or kidney disease, advanced age)

### Light source combination

maxmorespine® endoscopes can be connected to all common light sources for medical endoscopy by adapters. The correct connection shall be checked before each use.

### Risk of Burn

During endoscopic surgeries, the distal end and the light cable connection can become very hot due to the emission of light and thermal energy. Any direct contact with tissue and flammable materials should be avoided. Illumination settings should be adjusted to the necessary brightness, maximum setting should not be used by default.

When operating with HF electrodes, it should be ensured, that the active electrode is always within the field of view and that there is no contact with the endoscope or other metal components of the instruments.

For laser surgery, it should be avoided to direct the laser beam towards endoscope and to use reflective objects in the working area.

### Material Incompatibility

Cleaners and disinfectants can cause substantial damage to the endoscopes. They should not contain the following components:

- Oxidising agents
- Organic, mineral and oxidizing acids (minimal permissible pH value: 5)

- Strong alkalis (maximum permissible pH value: 5)
- Phenols or halogens (e.g. chlorine, iodine bromine)
- Aromatic/halogenated hydrocarbons

Cleaners or disinfectants used in combination shall be compatible with one another. Neutral or slightly alkaline cleaners are recommended.

- The cooling process of endoscopes should never be accelerated (e.g. with cold water); sudden temperature fluctuations can result in the destruction of optical components.
- Endoscopes should not be exposed to temperatures exceeding 137°C (279°F).
- Abrasive cleaners, steel wool or metal brushes should not be used for cleaning purposes.
- Hot-air sterilization, flash sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or plasma sterilization shall not be used.



### Delivery Condition

The medical devices are supplied in non-sterile condition and must be reprocessed and sterilized by the user before the first and every further application according to the following instructions.

### Safe handling

When using the endoscopes in a trocar, bending/pressure during insertion and withdrawal should be avoided

### Visual and functional inspection

Visual and functional inspection shall be conducted after each cleaning and disinfection process prior to sterilization. Inspection instructions in chapter "Inspection" shall be followed

Improperly functioning or defective and over worn endoscopes or endoscopes with unrecognizable markings, missing or removed (abraded) part numbers shall be immediately disposed.

In case of an endoscope getting damaged during application a second sterile endoscope should be available as replacement.

## 3 Limitation of Reprocessing, Disposal

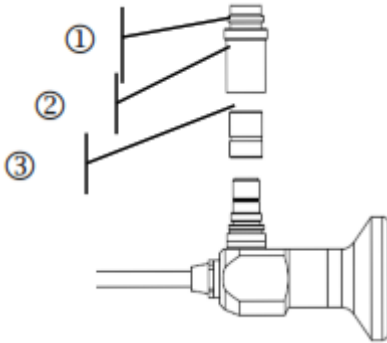
If the Instructions are abided, the number of reprocessing cycles has little effect on the service life of the endoscopes. The durability of endoscopes depends mainly on the proper care, handling and use.

Please dispose of the surgical instruments properly or recycle them at the end of the product's life. The national regulations and waste disposal guidelines must be observed!

## 4 Assembly/ Disassembly

The endoscopes shall be completely disassembled prior to cleaning and disinfection. After disinfection and prior to sterilization they shall be completely reassembled.

### Light cable connection



- ① Storz® / Aesculap® / Olympus®-adapter
- ② Wolf®-adapter
- ③ ACMI®-connection

### Disassembly:

- Unscrew adapter ① or ② from endoscope
- On working channels - if present:
  - Detach sealing cap.
  - Unscrew valve body.
  - Remove valve.

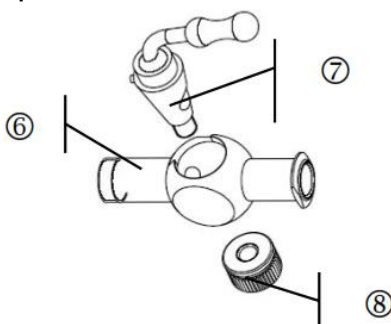
### Assembly:

- Screw on adapter ① or ②.
- On working channels- if present:
  - Insert a new valve.
  - Screw on valve body.
  - Attach sealing cap.

### ⚠ Possible cause of infection

To avoid infections special care should be taken when disassembling contaminated endoscopes.

### Stop-cocks



- ⑥ Stop-cock
- ⑦ Conical valve
- ⑧ Spring cap

### Disassembly:

- Unscrew the spring cap ⑧ and remove the conical valve ⑦ from the stop-cock ⑥.

### Assembly:

- In order to protect against corrosion and to maintain operability, the conical valve ⑦ should be treated with a lubricant before each sterilization.
- When inserting the conical valve, ensure that the guide pin engages in the guide and that the lever points towards the opening in open condition.
- Screw the spring cap ⑧ onto the conical valve ⑦.
- Check stop-cocks for correct functioning.

## 5 Reprocessing

### Preparatory treatment

⚠ **Shall be performed immediately after use:**

- Endoscopes shall be completely disassembled (see section 4 "Disassembly/Assembly").
- Rinse with cold, running water (max. 20°C) until all coarse contamination is removed from the endoscopes.
- Remove adhering contamination using a soft synthetic brush.
- Abrasive cleaners or metal brushes shall not be used. Avoid applying excessive force during the manual removal of contamination.
- Reassemble the stop-cocks, if present (see section 4 "Disassembly/Assembly") and flush out all working channels five times using a disposable syringe (minimum volume: 50 ml).
- Final rinsing of the endoscope with fully desalinated water to prevent formation of residue.
- Complete drying with compressed air (cavities) or a lint-free cloth.

### ⚠ Warning

- Only cleaning agents tested according to the national public health and local guidelines shall be used
- For endoscopes with instrument channels (irrigation and working channel) the inner lumen shall be carefully cleaned and disinfected to avoid the fixation and preservation of organic residues by aldehydes.

### Preparation of Cleaning / Disinfection

#### Prerequisites for suitable washer/disinfectors:

- Choose a programme for optimal endoscope cleaning with sufficient cleaning cycles.

- Controlled programme for thermal disinfection (A0 value > 3000 or at least 5 minutes at 90°C) with proven effectiveness.
- Regular maintenance and verified effectiveness (e.g. DGHM or FDA approval or CE mark certification according to DIN EN ISO 15883).
- Final rinsing with water that is sterile or of low microbiological contamination (max. 10 bacteria/ml) and low in endotoxins (max. 0,25 endotoxin units/ml) (e.g. purified water/ highly purified water).
- Controlled drying phase.

#### Prerequisites for suitable cleaning agents and disinfection agents:

- Approval for the cleaning of endoscopic instruments with verified effectiveness
- (e.g. DGHM or FDA approval or CE mark certification)
- Compatibility of cleaners/disinfectants with one another
- Listed chemicals (see section "Material stability") should not be present.
- An enzyme-based agent with neutral pH value should be used.
- An increased chloride concentration in the tapwater circuit can result in material damage (pitting corrosion). The rinsing water must be prepared in such way that recontamination with bacteria is avoided. The manufacturer's specifications regarding concentration, temperature and exposure time for the cleaners and disinfectants must be observed.

### Pre-Cleaning

1. Remove all light adapters and disassemble all stop cocks (see chapter "Stop-cocks").
2. Rinse thoroughly with cold tap water (max. 20°C) to remove gross contamination.
3. Persistent contamination shall be removed by soaking items in cleaning solution suitable for medical endoscopes (see chapter "Material Incompatibility").
4. Do not use coarse abrasive cleaners, metal brushes and avoid excessive force when manually removing contamination.
5. Assemble all cocks again (see chapter "Stop-cocks") and rinse all channels for five times using a syringe (50ml minimum volume)
6. Rinse endoscopes using DI water

## Cleaning / Disinfection

1. Endoscopes shall be fastened to the inserts of the washer/disinfector. Impairment of rinsing and contact between the endoscopes and other instruments shall be prevented.
2. Stop-cocks (if present) shall be opened and all endoscope channels shall be connected to the special inserts with rinsing device.
3. The washer/disinfector shall not be overloaded.
4. Start the program\*
5. Endoscope shall be removed from the disinfection device immediately after completion of automatic cleaning, in order to prevent corrosion. Avoid accelerated cooling (e.g. water).
6. Inspection and maintenance shall be conducted.

Proof of the basic suitability of the endoscopes for effective mechanical cleaning and disinfection was provided by an independent accredited testing laboratory, using the G 7836 GD disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and Neodisher mediclean cleaner (Dr. Weigert GmbH & Co.KG, Hamburg). The above-described process was observed for this purpose.

\*The applied program parameters are described in the following table:

Step	Parameter	
Pre-rinsing	Rinsing Temperature	Cold tap water
	Soaking time	60 s
Cleaning	Temperature	55°C
	Soaking time	300 s
	Cleaning agent	neodisher mediclean
	Concentration:	0,5%
Post-rinsing	Temperature	Cold DI water
	Soaking time	120 s
Thermal disinfection	Temperature	90°C (A <sub>0</sub> 3000)
	Duration	300 s

## Inspection

Prior to sterilization after cleaning, the endoscopes must be thoroughly inspected for the following aspects:

- External damage (shaft deformed, dents, sharp edges, wear, corrosion, bent, loose or broken components)
  - macroscopically clean (free of visible soil, free of stains)
  - Cleaner or disinfectant residues
  - Condition of the three optical surfaces using reflected light or magnifying glass (smooths, clean and undamaged)
1. Objective window
  2. Ocular window

## 3. Light cable connection

- Loss-free light transmission from light cable connection to light output (compare with new device, if necessary)
  - Unobstructed working channels
- Improperly functioning or defective and over worn endoscopes or endoscopes with unrecognizable markings, missing or removed (abraded) part numbers shall be immediately disposed.

## Maintenance

- The stop-cocks must be lubricated following each cleaning and prior to sterilization (see section chapter 4 Assembly/Disassembly).
- Only lubricants which have verified bio-compatibility may be used. The lubricant must be suitable for this application and must be approved for steam sterilization.

## Packaging

- Endoscopes shall be assembled (see chapter 4 Assembly/Disassembly)
- All stop-cocks shall be opened (if present).
- Only disposable sterilization packaging and/or sterilizing containers which are suitable for steam sterilization shall be used (adequate temperature resistance, air and steam permeability - DIN EN ISO/ANSI AAMI ISO 11607).
- The packaging shall ensure optimal protection of the sterile endoscopes during transport and storage
- Reusable sterilizing containers must be maintained in accordance with manufacturer's specifications
- The endoscopes shall be fixed securely in the containers and protected against damage.
- As the suitability of the packaging considerably influences the sterilization results, this shall be checked within the process and determination of sterilization parameters.

## Sterilization

Sterilization of endoscopes shall be conducted by applying a fractionated pre-vacuum process (according to DIN EN ISO 17665-1) taking into account the respective national requirements.

Sterilization shall be carried out using a fractionated pre-vacuum process with the following parameters:

134°C / 273.2°F,

≥5 minutes hold time,

3 pre-vacuum cycles

Drying in the vacuum for at least 20 minutes.

The autoclave manufacturer's instructions for use and the recommended guidelines for maximum loading with sterilization material must be observed. The autoclave must be properly installed, maintained, validated and calibrated.

## ⚠ Additional Information

It is the responsibility of the reprocessor to ensure that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the process and the equipment used.

## 6 Service and Repair

### ⚠ Service and Repair

Repairs or modifications shall only be performed by Hoogland Spine or by authorized service facilities using original spare parts. In case of complaints or comments regarding the products please contact us directly.

### ⚠ Return Transport

Defective or non-conforming products must have undergone the entire reprocessing process before being returned for repair/service.

## 7 Storage and Transportation










- Store instruments in a clean, cool and dry place.
- Protect from mechanical damage.
- Store and transport in safe containers / packaging.
- Handle with utmost care, do not throw or drop.

## 8 Liability and Warranty

The endoscopes may only be used for their intended purpose in the specified medical fields by appropriately trained and qualified personnel. The attending physician or user shall be responsible for the selection of devices for specific applications or surgical use, the appropriate training and information and an adequate level of experience for the handling of the devices.

The use of damaged and/or contaminated endoscopes is in the responsibility of the user. Disregarding these instructions for use will void the guarantee or warranty claims. We accept no liability in the case of improper handling, incorrect or inadequate preparation or unauthorized repairs

## 9 Description of Used Symbols

Symbol	Description
	Manufacturer
	Catalogue number
	Serial number
	Consult instructions for use
	Caution
	Non-sterile
	CE Marking of Conformity
	Quantity
	Prescription device