maxmorespine® BY HOOGLAND SPINE PRODUCTS

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## Products

These Instructions for Use apply to the products listed below:

REF

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 “Riks of Burn” in chapter 2)
- Tool breakage (see “Safe handling” in chapter 2)
- Nerve root irritation
- Wound infection
- Postoperative haemorhage
- 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.

**⚠ Pump combination**

maxmorespine® endoscopes can be connected to suction and irrigation pumps via luer lock connectors. 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)
- Phenols or halogens (e.g. chlorine, iodine bromine)
- Aromatic/halogenated hydrocarbons
- 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.

**NON STERILE 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, frequent reprocessing cycles has little effect on the endoscopes. The product service life is normally determined by wear and damage in product use. The durability of endoscopes depends mainly on the proper care, handling and use.

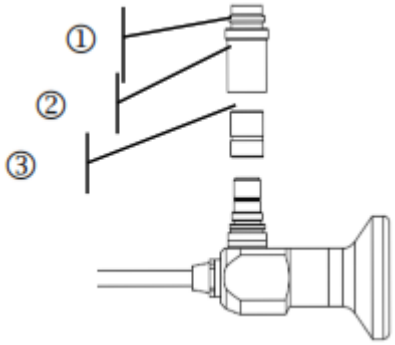
At the end of the product service life, please dispose of the endoscopes properly or

recycle them at the end of the product's life. The national regulations and waste disposal guidelines must be observed!

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.

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## 4 Reprocessing

**Preparatory treatment**

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

- Endoscopes shall be completely Disassembled (see section 0 “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.
- 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 Instability”) should not be present.
- An enzyme-based agent with alkaline pH value should be used.
- Used concentration of cleaning agent has to comply with specifications of the cleaning agent manufacturer.
- 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.
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. Rinse all channels five times using a syringe (50ml minimum volume)
6. Rinse endoscopes using DI water

**Cleaning**

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. 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

| 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 |

5. Endoscope shall be removed immediately after completion of automatic cleaning, to prevent corrosion. Avoid accelerated cooling (e.g. water).

**Disinfection**

1. Automatic drying according to the automatic drying process of the washer-disinfector for at least 15 minutes (at 90° C in the rinsing room). If necessary, subsequent manual drying with a lint-free cloth if moisture can be detected on the device.

| Step | Parameter | |
|---|---|---|
| Thermal disinfection (Drying) | Temperature | 90°C ($A_0$3000) |
| | Duration | 300 s |

2. Holding time of atleast 5-10 minutes shall be considered before the next step.
3. 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.

**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.

**Packaging**

- Endoscopes shall be assembled (see chapter 0 Assembly/Disassembly)
- 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.

Sterilisation shall be carried out by a fractionated pre-vacuum process with three pre-vacuum cycles and drying in a vacuum for at least 20 minutes. The following parameters must be taken into account:

| | |
|---|---|
| Prevacuum: | 3 cycles |
| Sterilization temperature: | 134°C / 273.2°F |
| Sterilization time | 4 min |
| Drying time | 20 min |

Holding Time: Allow the device to stabilize for atleast 10-15 mins before handling.

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.

## 5 Service and Repair

⚠ **Service and Repair**

Repairs or modifications shall only be perfomed 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.

## 6 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.

## 7 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

## 8 Description of Used Symbols

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