maxmorespine®
BY HOOGLAND SPINE PRODUCTS

CE

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Products

These Instructions for Use apply to the products listed below:

REF

1001-ABR X	1001-EK XXX/S
1001-AI XXX	1001-EK XXX/S.2
1001-AS XXX	1001-EP XXX
1001-BB XXX	1001-EP XXX/XX
1001-BD XXX	1001-EP XXX/XXX
1001-BD XXXB ½	1001-ES XX
1001-BD XXXC	1001-ES C
1001-BDSS-XX	1001-FE XXX
1001-BH XXX	1001-FF XXX
1001-CD XXX	1001-FF XXX-X
1001-CF XXX	1001-FF XXX-X-D
1001-CF XXX-D	1001-FP XXX
1001-CH XX	1001-GW XXX
1001-CS XXX	1001-GW XXXN
1001-CT XXXA	1001-HS XXX
1001-CW XXX	1001-HS XXX-D
1001-DC XXX	1001-IC XXX
1001-DF XXX	1001-MDA XXX
1001-DF XXX-D	1001-MF XXX
1001-DR XXX	1001-MF XXX-D
1001-DI XX	1001-MDT-XXX
1001-EF XXX	1001-NRR XX
1001-EF XXX-D	1001-RF XXX
1001-EF XXX/1	1001-RF XXX-D
1001-EF XXX/1-D	1001-S XX
1001-EF XXX/B	1001-SF XXX
1001-EF XXX/B-D	1001-SF XXX-D
1001-EF XXX/1L	1001-SK XXX
1001-EF XXX/1L-D	1001-SK XXX/H
1001-EF XXX/1MD	1001-SK XXX/S
1001-EF XXX/1M-D	1001-SK XXX/S.2
1001-EF XXX/1MU	1001-TH XXX
1001-EF XXX/1U	1001-TS XXX
1001-EF XXX/S	1001-TS XXX-1
1001-EK XXX	1001-UH XXX

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® Instruments are used in combination to assist in endoscopic minimally invasive surgical procedures. Maxmorespine® Instruments are intended for cutting, drilling, scratching, scraping, clipping, dilating, grasping and guiding

Indication

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

Contraindication

Maxmorespine® instruments 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)
- Tool breakage (see “Safe handling” in chapter 2)
- Nerve root irritation
- Wound infection
- Postoperative haemorhage
- Hematomas
- Paralysis

Intended User

Maxmorespine® Instruments may only be used by trained and qualified doctors.

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 instruments.

Patient-related risks factors

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

Material Incompatibility

Cleaners and disinfectants can cause substantial damage to the instruments. 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.

- 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 instruments inside a trocar or working channel, 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 instruments or instruments with unrecognizable markings, missing or removed (abraded) part numbers shall be immediately disposed.

3 Limitation of Reprocessing, Disposal

If the Instructions are abided, the number of reprocessing cycles has little effect on the service life of the instruments. The durability of instruments 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 Reprocessing

Preparatory treatment

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

- Instruments shall be Disassembled as far as possible.
- Rinse with cold water with drinking quality (max. 40°C) until all coarse contamination is removed from the instruments. Continously move all moveable parts at least 10 times.
- 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 lumen five times with water of drinking water quality (max. 40°C) using a disposable syringe (minimum volume: 50 ml).
- Rinse all lumina, gaps, springs and crevices with a water jet pistol for at least 60 seconds with cold water of drinking water quality (max. 40°C).
- Final rinsing of the instruments 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 instruments with lumen, it shall be carefully cleaned and disinfected to avoid the fixation and preservation of organic residues by aldehydes.

Preparation of Cleaning / Disinfection

Ultrasound cleaning

- Place in an ultrasonic bath (max. 40°C) with a mild alkaline cleaner and a frequency of approx.. 35 kHz. The ultrasonic exposure time must correspond to the specification of the cleaning agent manufacturer. A cleaner suitable for ultrasonic cleaning must be used. The instructions of the cleaning agent manufacturer must be followed.
- All surfaces shall be covered. The instruments shall not touch each other.
- Rinse instruments under cold water of drinking water quality (max. 40°C) at least three times for at least 1 minute.
- Flush out all lumen three times with water of drinking water quality (max. 40°C) using a disposable syringe (minimum volume: 50 ml).
- Rinse all lumina, gaps, springs and crevices with a water jet pistol for at least 30 seconds with cold water of drinking water quality (max. 40°C).
    - All movable parts shall be moved forth and back at least ten times

Prepregisites 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 incompatibility”) 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.

Cleaning / Disinfection

1. Instruments shall be fastened to the inserts of the washer/disinfector. All joints and hinges shall be fixed in an open state. Instrument shall be positioned to allow the water to flow in and out of the lumen. Impairment of rinsing and contact between shall be prevented.
2. All rinsing connections shall be connected to the special inserts with rinsing device.
3. The washer/disinfector shall not be overloaded.
4. Start the program (washing disinfector, WD according to EN ISO 15883):
    - 5 minutes pre-rinse with cold water (drinking water quality; max. 40°C)
    - Water drain
    - Clean for 10 minutes with deionized water (55°C) with 0,5% mild alkaline detergent (200 ml)
    - Water drain
    - 1 minute rinse with deionized water
    - Water drain
    - 1 minute rinse with deionized water
    - Water drain
5. Automatic thermal disinfection in washer-disinfector taking into account the national requirements for the A0 value; e.g. A0-value 3000:
    - 3 minutes disinfection with demineralized water 90°C
    - Water drain
6. Automatic drying according to the automatic drying process of the washer disinfector for at least 15 minutes. If necessary, subsequent manual drying with a lint free cloth if moisture can be detected on the instrument.
7. Inspection and maintenance shall be conducted.

Inspection

Prior to sterilization after cleaning, the instruments 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, corrosion, discoloration)
- Cleaner or disinfectant residues
- Unobstructed working channels

Soiled instruments muss be send to reprocessing. Improperly functioning or defective and over worn instruments or instruments with unrecognizable markings, missing or removed (abraded) part numbers shall be immediately disposed.

Maintenance

- Allow instruments to cool to room temperature
- Reassemble disassembled instruments.
- All movable parts shall be treated with steam sterilizable care products based on paraffin oil.
- Applied paraffin oil must comply with the currently valid pharmacopoeia and be physiologically safe.

Packaging

- 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 11607-1).
- The packaging shall ensure optimal protection of the sterile instruments during transport and storage
- Reusable sterilizing containers must be maintained in accordance with manufacturer’s specifications
- The instruments 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 instruments 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,

≥4 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 is 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 instruments 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 instruments 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
	Quantity
	Prescription device