



Feringastrasse 4
85774 Unterföhring
Germany
Tel: +49 (0) 89 95 76065-0
Fax: +49 (0) 89 95 76065-2
<https://www.max-more.com>
info@max-more.com

Products

These Instructions for Use apply to the products listed below:

1001-BE 001/H
1001- BE 001/s
1001- BE 002
1001-BE 003
1001-BE 004/S
1001-BE 004



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

The maxmorespine Bipolar Electrodes are indicated for the coagulation of soft tissue during open or minimally invasive surgical procedures when used in conjunction with a compatible radio frequency generator. The maxmorespine Bipolar Electrodes have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Indication

Maxmorespine® bipolar electrodes are indicated for application on soft tissue in endoscopic, minimal invasive surgical procedures.

Device description

Maxmorespine® bipolar electrodes are designed with a rounded distal end, an ergonomic handle in various designs and a flat plug connection. The electrodes are sold as one-piece electrodes (1001-BE-003) or consist of a three-piece construction (shaft, electrode and handle). The one-piece electrode and the electrodes 1001-BE 002 and 1001-BE 004 are sold as sterile single

use devices. The handle and shafts are intended for reuse.

Usage

The fully assembled device (if assembly is necessary) is connected to a generator by means of a suitable cable. For operating the device must be inserted through a working channel with the appropriate diameter.

Maximum output voltage of the generator U_{max}:

250 V_p

Suitable connection cables for bipolar electrodes:

Maxmorespine® bipolar electrodes can be connected to HF generators that have the permissible V_p voltage via a flat plug using the standard bipolar connection cables.

Contraindication

Maxmorespine® bipolar electrodes 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 with the use of electrosurgical systems

- Tissue and nerve damage in the wrong location
- Perforation of organs
- Sudden heavy bleeding
- Burns and thermal damage
- Fire in connection with surgical drapes and other inflammable materials
- Wound infection

Intended User

Maxmorespine® bipolar electrodes shall only be used by trained and qualified doctors. Adequate training, knowledge and experience in the clinical application of Bipolar Electrode techniques is required. 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.

2 Precautions and Warnings



- Non-observance of these application and safety instructions can lead to injuries, malfunctions or other unexpected incidents.
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N₂O) and oxygen) or in close proximity to

volatile solvents (such as ether or alcohol), as explosion may occur.

- DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- INSPECT instruments and cables for damage prior to each use, especially the insulation of laparoscopic / endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
- Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
- DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
- The intensity should be set as low as is necessary to achieve the desired effect. [unless there is a risk associated with low settings, e.g., argon coagulation]
- Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.
- Never use damaged devices.
- Overloading of the devices must be avoided. Overloading can lead to deformation or breakage and thus to loss of functionality of the devices.
- Do Not contact electrodes with other metallic instruments, trocar sleeves, optics, etc.

Risk of Burn

- Fire in connection with drapes and other flammable materials.
- Alternating current paths leading to burns in places where the patient or user comes into contact with uninsulated components.
- Explosions caused by sparks in the vicinity of flammable gases.

 **Material Incompatibility**

Cleaners and disinfectants can cause substantial damage to the maxmore spine[®] bipolar electrodes. They should not contain the following components:

- Oxidizing agents
- Organic, mineral and oxidizing acids (minimal permissible pH value: 5)
- Phenols or halogens (e.g. chlorine, iodine bromine)
- Aromatic/halogenated hydrocarbons

Delivery Condition

The following individual parts of the maxmore spine[®] bipolar electrodes are single use products and sterilized by ethylene oxide. The products are supplied in sterile condition and may not be used, when the package is damaged:



1001- BE 002

1001- BE 003

1001- BE 004

The following individual parts of the maxmore spine[®] bipolar electrodes 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 instructions in section 5:



1001- BE 001/S

1001- BE 001/H

1001-BE 004/S

Visual and functional inspection

It is very important to check each maxmore spine® bipolar electrode before each use for visible damage and wear and tear, e.g. cracks, fractures or defects on the isolation. Especially areas like moving parts, isolations and ceramic elements must be checked carefully.

In case of an electrode damaged during application a second sterile electrode 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 maxmore spine® bipolar electrodes. The durability of the electrodes depends mainly on the proper care, handling and use.

Please dispose of the electrodes 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 product 1001-BE 003 must not be assembled and disassembled. The following instructions only apply to the following components:

1001- BE 002

1001-BE 004

1001- BE 001/S

1001- BE 001/H

1001-BE 004/S

The maxmore spine® bipolar electrodes shall be completely disassembled prior to cleaning and disinfection. After disinfection and prior to sterilization they shall be completely reassembled.

1. Insert the probe from the tip of the shaft.



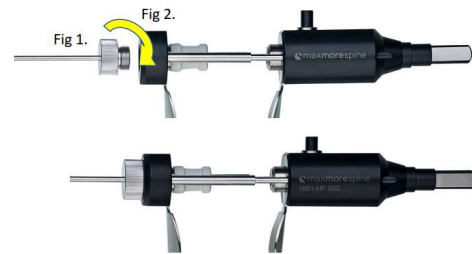
Only the following components can be used together:

- 1001-BE 001/s with 1001-BE 002
- 1001-BE 004/s with 1001-BE 004

2. Insert the probe until it reaches the back of the handle (Fig.1)
3. Press down and hold the black button (Fig.2)
4. Keep sliding the probe into the handle while holding down the black button until it goes no more.
5. Release the button



6. Make sure you line up the threads with the shaft and handle and turn clockwise until you cannot turn anymore.



ATTENTION

Forcing the turn or improper alignment will destroy the thread and void warranty.

5 Reprocessing

Warning

- Only cleaning agents tested according to the national public health and local guidelines shall be used
- Inner lumen shall be carefully cleaned and disinfected to avoid the fixation and preservation of organic residues by aldehydes.

Prerequisites for suitable cleaning agents and disinfection agents:

- Approval for the cleaning of the shaft and handle of the maxmorespine® bipolar electrodes 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 alkaline 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

- The Handle and Shafts of the maxmorespine® bipolar electrodes shall be fastened to the inserts of the washer/disinfector. Impairment of rinsing and contact between the shaft and handle of the maxmorespine® bipolar electrodes and other instruments shall be prevented.
- The washer/disinfector shall not be overloaded.
- Start the program (washing disinfector, WD according to EN ISO 15883):
 - 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
- 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
- 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 device.

Inspection and maintenance shall be conducted.

Inspection

Prior to sterilization after cleaning, the shaft and handle of the maxmorespine® bipolar electrodes 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
- Unobstructed shaft

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

Maintenance

- Allow components to cool to room temperature
- Reassemble disassembled components.
- 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 shaft and handle of the maxmorespine® bipolar electrodes during transport and storage
- Reusable sterilizing containers must be maintained in accordance with manufacturer's specifications
- The shaft and handle of the maxmorespine® bipolar electrodes 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 shaft and handle of the maxmorespine® bipolar electrodes 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 is actually carried out with the equipment, materials and personnel able to achieve 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 devices 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.

















Further storage and transport conditions for sterile devices

- Keep away from  sunlight
- Keep dry 

8 Liability and Warranty

The use of damaged and/or contaminated electrodes 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
	Symbol for "Manufacturer"
	Symbol for "Catalogue number"
	Symbol for "Batch code"
	Symbol for "Serial number"
	Symbol for "Quantity"
	Symbol for "Consult instructions for use"
	Symbol for "Caution"
	Symbol for "Do not re-use"
	Symbol for "Use-by date"
	Symbol for "Do not use if package is damaged"
	Symbol for "Keep away from sunlight"
	Symbol for "Keep dry"
	Symbol for "Sterilized using ethylene oxide"
	Symbol for "Non-sterile"
	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Community European. CE marking for Europe