

Instructions for Use

Endoscopic tube shaft instruments with and without HF connection



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SURGICAL INSTRUMENTS

Suppliers of Fine Quality Instruments

116 Cutler Road • Jandakot WA 6164 • AUSTRALIA
 Phone: (08) 9417 3565 • Fax: (08) 9417 3571 • Fax: (08) 9414 8996
 www.inksurgical.com.au



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Instructions for Use

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CE 0483

Symbol	Symbol description
	Manufacturer
	Production date
	Wear suitable protective clothing, gloves and eye protection
	Caution
	Follow the instructions for use
	Non-sterile

- Products**
- LAP dissecting scissors with and without HF connection
 - LAP grasping forceps with and without HF connection
 - LAP spoon forceps with and without HF connection
 - LAP clamps with and without HF connection
 - LAP biopsy punch with and without HF connection
 - LAP needle holder with and without HF connection
 - Insulated tube shafts
 - plastic handle with and without HF connection

Precautions and warning notices



- Persons using electro-surgical instruments must have the required special knowledge of the subject.
- Instruments could be damaged by excessive force, particularly at the working inserts.
- Damaged instruments may not be used.
- The instrument may not be used in the presence of flammable or explosive substances.
- The instrument may not be placed on or beside the patient.
- Activation may only be carried out if the contact surfaces are located within one's field of vision. Contact with other electrically conductive medical devices must be avoided.
- Instruments are not intended to be leaned on or to provide support.
- Insert the instrument carefully through the working channel to avoid damage on the working part.
- Maintain visual contact at all times during usage.
- Deactivate the automatic switch-on mode of HF instruments when using laparoscopic or endoscopic accessories.
- Do not use any non-insulated instruments for HF surgery.
- Take note of the instructions for use and the safety information for HF devices.

Intended purpose

Endoscopic tube shaft instruments made by **BEMA** are used in minimally invasive surgery, but especially in laparoscopy. The instrument is, depending on the diameter, inserted into a 3,0 mm, 5,0 mm or 10,0mm trocar sleeve. The instruments are used to grasp, cut, dissect and coagulate tissue and organs, as well as for pinching off vessels using electric energy produced by an HF generator for electric surgery.

Needle holders serve as hold- and leading instruments for needles during surgical sutures. They must not be connected to HF current.

Indications

Endoscopic tube shaft instruments of **BEMA** are used in laparoscopic applications with diagnostic and operative purposes. The trained, qualified staff decides whether the endoscopic tube shaft instrument can be used.

Contraindications

Endoscopic tube shaft instruments made by **BEMA** must not be used if a minimally invasive surgery is contraindicated.

Application

Index finger and ring finger hold the main part of the instrument. The moveable handle part is held by the thumb. Jaw parts are navigated analog by movement of the thumb. When the handle is closed, the jaw part also closes.

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The monopolar endoscopic tube shaft instruments made by **BEMA** are suitable for the use of monopolar HF current. All tube shaft handles with HF connection are provided with an extra protection against undesired discharges of electricity (blowout). The HF connection integrated in the handle serves to connect an HF cable, which is connected to an HF generator.

Information, instructions and regulations provided by the respective manufacturers of HF devices have to be regarded. The rated peak voltage for the BEMA monopolar endoscopic tube shaft instruments with HF connection in spray coagulation mode is 3kVp. In cutting and coagulation mode, the rated peak voltage is 2kVp. The settings of a HF device must be configured in such manner that the maximum output voltage is equal to or smaller than the rated peak voltage. Contact surfaces of jaw parts are to be kept clean during surgery. Dried-on tissues or body fluids may be wiped off with soft towels.

The accessory voltage rating must exceed or match the peak output voltage the BEMA monopolar laparoscopy instrument with HF connection in conjunction with a suitable HF device configured to run with an appropriate operating mode / setting (see IEC/DIN EN 60601-2-2) is operated with.

The instruments can be connected to the HF generators from Aesculap, Berchtold, Erbe, KLS/Martin, Olympus, Siemens, Storz, Valleylab and other similar HF generators. The connection possibilities are dependent on the plug of the connection cable. A monopolar cable is connected to the connector of a \varnothing 4 mm socket on the instrument panel. The corresponding connection for the HF device must be selected depending on the device's socket. When inserting the connection cable ensure that the plug-in connection guarantees a permanent contact. This is achieved by inserting the plugs completely into the sockets of the HF generator until slight resistance is met or by plugging them onto the HF accessories.

In order to avoid burns, the largest possible neutral electrode should be used, positioned correctly and be in good contact with the muscle tissue. The neutral electrode is connected to the HF generator. Pay regard to the notes on the use of the neutral electrode in the operating instructions, the notes on the packaging of the neutral electrode as well as to the operating instructions of the HF generator.

The trained and experienced surgeon is responsible for the decision concerning the suitability of the instrument for the intended use. We assume no liability for improper use and wrong reprocessing.



Caution: Activation of the HF voltage can lead to capacitive coupling when the working insert is not in contact with the target tissue or not in position to deliver energy to the target tissue (fulguration). HF current and lasers should never be activated simultaneously. If the laser is used during the same procedure, the working end must be drawn back behind the laser fiber to avoid inadvertently pointing the laser at the working end or the shaft insulation of the instrument. Consequently, the laser fiber must be drawn back before activating the working end of the monopolar instrument in order to prevent arcing, particularly if the laser fiber is surrounded by metal. Please take note of the instructions regarding the use of the laser system for the sake of properly operating the device. A concurrent activation of the HF current and a suction/irrigation appliance should be avoided at all costs - the electrical HF current could be diverted away from the tissue targeted to undergo coagulation.

Functional test

Prior to each use of the instruments, their correct assembly, their fulfillment of a predefined function as well as the absence of damage to them (rough surface, cracks, fractures, scratches, notches, sharp edges, bent or worn parts) has to be ascertained.

If the product exhibits externally visible defects or does not operate as described in this manual, it must be discarded immediately, may not be used anymore and shall be returned to manufacturer.

Initial commissioning

Immediately after receiving, the instruments are to be examined for transportation damage and checked with regard to their proper function.

Potential damage should be reported immediately. The brand new medical device should be taken out of the polyethylene bags. They are to be stored under moisture-free, clean and dry conditions within a protective container until the initial treatment to avoid condensate formation. The medical devices are delivered **non-sterile**. A new medical device is to be inspected visually and functionally after its delivery and prior to each use.

Compatibility

Members of the product family comprised of **BEMA** endoscopic tube shaft instruments (with and without HF connection) are compatible with one another.

To ensure safe use, individual components such as HF plastic handles (with or without ratchet), tube shafts and various working inserts are to be combined exclusively with components of **BEMA**.

Combination with Other Products/Instruments

Products of **BEMA** should under no circumstances be combined with products, components and/or instruments of other manufacturers. Combinations with products composed of different materials and originating from other manufacturers are not permitted and can negatively affect the result of the procedure, as the components used may not be compatible with one another. It is recommended only to use instruments and accessories of **BEMA**.



Precautionary Measures:

In order to ensure a smooth procedure of the examination, the size of the endoscopic access canal and the size of the instrument should be geared to one another.

Preparation

The dismantlable and undismantlable laparoscopy instruments of **BEMA** are to be processed properly before first use and after each use. In the case of manual reprocessing, the individual parts of the instruments must be immersed in an active cleaning and disinfection solution. All surfaces, including those of internal cavities, lumina and openings, must come into contact with the solution. Take note of the instructions of the disinfectant manufacturer.

Caution



Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.

Do not use metal cleaning brushes or abrasive cleaners that could damage the product surfaces due to the resulting risk of corrosion.

Potential damage to the product can be caused by unsuitable cleaning agents and

disinfectants and/or excessively high temperatures!

Use only appropriate cleaning and disinfectant agents, certified for use on stainless steel and plastic, in accordance with the manufacturer's instructions.

Pay regard to the information concerning concentration, temperature and exposure time.

Automated reprocessing should be favored over manual cleaning as it brings forth better and more consistent results.

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Endoscopic tube shaft instruments with and without HF connection



Procedure:	Manual and automated cleaning process			
Products:	Dismantlable and undismantlable endoscopic tube shaft instruments <ul style="list-style-type: none"> with and without HF connection with and without LUER lock with shaft \varnothing 5 mm, \varnothing 10 mm and \varnothing 3 mm 			
ADVICE:	On the basis of the product design and the used materials, one hundred reprocessing cycles have been determined for BEMA endoscopic tube shaft instruments with and without HF connection. Inappropriate handling may lead to reduction of durability. The products are to be checked prior to and after each preparation. In case of damage the device should be cleaned, disinfected and sterilized before being returned to the manufacturer for repair.			
Reprocessing instructions				
Preparation at point of use:	Remove coarse dirt by submerging the instrument in cold water immediately after use. Don't use fixation agents or hot water (>40°C) as this can cause the fixation of residues, which may negatively impact the result of the cleaning and sterilization procedure.			
Transportation:	Safely store and transport the device to the reprocessing site within a closed container in order to avoid damage to instruments and contamination of the environment.			
Preparation for decontamination:	Open or disassemble the instruments without LUER lock for reprocessing, see "Disassembly".			
Manual pre-cleaning:	Immerse the instrument in cold tap water for at least 10 minutes. Ensure that all surfaces and cavities are covered. Scrub the instrument under running tap water with a soft bristled brush until all visible residues have been removed. Then rinse the instrument with a water jet gun for at least 20 seconds.			
Manual cleaning				
Ultrasound cleaning:	Immerse the instrument in an ultrasound bath filled with 0.8% enzyme-based cleaning solution and pre-heated to a temperature of 35°C and subject it to ultrasonic irradiation at 35 kHz for a duration of 10 minutes. Ensure that all accessible surfaces of the instrument are covered and acoustic shadows are avoided. Fully drain any remaining liquid.			
Intermediate rinse	Rinse the product thoroughly (all accessible surfaces) under running water. Put non-rigid components, such as hinges, etc. through their full range of motion during rinsing. Fully drain any remaining liquid.			
Disinfection	Fully immerse the product in the disinfectant solution. Put non-rigid components, such as hinges, etc. through their full range of motion. Ensure that all accessible surfaces are covered with the disinfectant.			
Final rinse	Rinse the product thoroughly (all accessible surfaces) under running water. Put non-rigid components, such as hinges, etc. through their full range of motion during rinsing. Rinse lumens with a water jet gun (spray gun) for at least 20 seconds. Fully drain any remaining liquid. In order to optimize the cleaning process we recommend the use of distilled, demineralized or fully desalinated water.			
Drying:	Drying of a product with suitable equipment, e.g. lint-free towel, medical compressed air. After manual cleaning/disinfection, perform a visual check of visible surfaces for residues. Repeat the cleaning /disinfection process if necessary.			
Automated Cleaning				
Automated Pre-Cleaning:	Immerse the instrument in cold tap water for at least 5 minutes. Scrub the disassembled instrument with a soft bristled brush under cold tap water until all visible residues have been removed. Inner lumens, threads and holes must be flushed with a water jet gun for a minimum of 10 seconds in the pulse mode. Immerse the instrument in an ultrasonic bath filled with alkaline (0,5%) and pre-heated to a temperature of 40°C and subject it to ultrasonic irradiation for 15 minutes. Thereafter, remove the instrument from the bath and rinse with cold tap water.			
Automated Cleaning:	Recommended cleaning procedure: Place the disassembled instrument on an instrument tray and establish a connection between the LUER lock port and the MIC rinsing system. Utilize the dividers of the MIC cart's trays to lock the disassembled instruments in place. Instruments incompatible with such inserts must be opened and loaded loosely into trays of the MIC cart. <ol style="list-style-type: none"> 1 min pre-rinsing with cold water Liquid drainage 3 min pre-rinsing with cold water Liquid drainage 5 min cleaning at 55°C with 0,5 % alkaline Liquid drainage 3 min neutralization with warm water (40°C-60°C) and a neutralizing agent Liquid drainage 2 min rinse with warm water (40°C-60°C) Liquid drainage Pay regard to the operating and loading instructions issued by the washer / disinfectant manufacturer as well as to the recommendations for the use of cleaning agent.			
Disinfection:	Automated Thermal Disinfection in accordance with the national A ₀ -Value requirements (see ISO 15883) We recommend that instruments should undergo a final rinsing with distilled, demineralized or fully desalinated water.			
Drying:	Dry the outer surfaces of the instruments during the drying cycle of the washer/disinfectant. Let instruments cool down to room temperature. If necessary, additional manual drying can be performed by means of a lint free towel. Use medical compressed air for cavities in instruments.			
Functional Testing, Maintenance:	Visual inspection for cleanliness. If necessary, repeat the reprocessing steps until the instrument presents itself free of visual soil. Assemble the instrument (see assembly) and confirm that it fulfills its predefined function. Discard damaged instruments immediately. Conduct maintenance of joint and sliding surfaces by treating them with an adequate instrument oil. Remove excess oil. Only use liquid paraffin/white oil based instrument oils with verified biocompatibility which have been approved for steam sterilization.			
Packaging:	Appropriate packaging for sterilization in accordance with ISO 11607 and EN 868.			
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Sterilization:	<p>The instrument can be sterilized in its assembled state.</p> <p>Subject the instruments to fractionated pre-vacuum steam sterilization (in accordance with ISO 13060 / ISO17665), taking into account specific national requirements and facility guidelines.</p> <p>3 pre-vacuum phases with at least 60 millibar pressure Sterilization at a minimum of 132°C / maximum of 137°C Exposure time: at least 5 min Drying time: at least 10 min</p> <p>Open the Luer Lock flushing port cap for proper steam penetration. Sterilize instruments with a fully opened ratchet. Ensure that the maximum load capacity of the steam sterilizer is not exceeded. Please follow the operation instructions of the steam sterilizer manufacturer.</p>																
Storage:	Store sterilized instruments in a dry, clean and dust-free location at moderate temperatures (5°C to 40°C).																
Reprocessing validation study information:	<p>The recommended sterilization parameters were validated using the following test devices, materials & machines:</p> <table border="0"> <tr> <td>Detergent(automated)</td> <td>Neodisher Mediclean forte; Dr. Weigert; Hamburg (alcalic)</td> </tr> <tr> <td>Detergent(manual)</td> <td>Cidezyme/Enzol (ASP); Mucadont Zymatic (Merz Hygiene GmbH)</td> </tr> <tr> <td>Neutralizing agent:</td> <td>Neodisher Z; Dr. Weigert, Hamburg</td> </tr> <tr> <td>Washer / disinfecter:</td> <td>Miele G7835 CD</td> </tr> <tr> <td>Program:</td> <td>Design Vario TD AD</td> </tr> <tr> <td>Details see report:</td> <td>Manual cleaning: 15812</td> </tr> <tr> <td></td> <td>Automated cleaning: 1005.0627</td> </tr> <tr> <td></td> <td>Sterilization: 1006.2927</td> </tr> </table>	Detergent(automated)	Neodisher Mediclean forte; Dr. Weigert; Hamburg (alcalic)	Detergent(manual)	Cidezyme/Enzol (ASP); Mucadont Zymatic (Merz Hygiene GmbH)	Neutralizing agent:	Neodisher Z; Dr. Weigert, Hamburg	Washer / disinfecter:	Miele G7835 CD	Program:	Design Vario TD AD	Details see report:	Manual cleaning: 15812		Automated cleaning: 1005.0627		Sterilization: 1006.2927
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Additional Instructions:	Should the described chemicals and devices not be available, it is up to the user to validate the process accordingly.																
<p>The user is obligated to ensure that the cleaning and sterilization procedures, including the responsible personnel, the used resources, materials and equipment are adequate and capable of achieving the required results.</p> <p>The State-of-the-art and national legal guidelines dictate that validated processes are to be followed.</p>																	

Maintenance and repair

A warranty period of two years from the date of purchase is provided for all **BEMA** products. This warranty is limited to the repair or replacement of instruments free of charge when these are sent to **BEMA**. **BEMA** is not responsible for the risk of transportation as well as covering shipping costs and must be presented with a statement testifying that each instrument being returned for repair has been thoroughly cleaned and sterilized.

BEMA is neither liable for direct nor consequential damages. The warranty expires if the instrument is used, reprocessed or maintained improperly, if instructions and requirements stated in the manual are disregarded and if the instrument is repaired or modified by the user or another unauthorized service center.

Accessories and spare parts

Following parts can be ordered separately:

- Handle (with or without ratchet),
- Tube shaft
- Diverse working inserts.

Disposal

The instrument can be disposed of via the hospital's individual disposal system. Adhere to national regulations when disposing the product.

Manufacturer



BEMA GmbH + Co. KG
Endosurgical Instruments
 Rudolf-Diesel-Str.12
 78576 Emmingen
 Tel.: +49 (0)7465/9299-0
 FAX: +49 (0) 7465 /9299-29
 E-Mail: mail@bemamedical.com

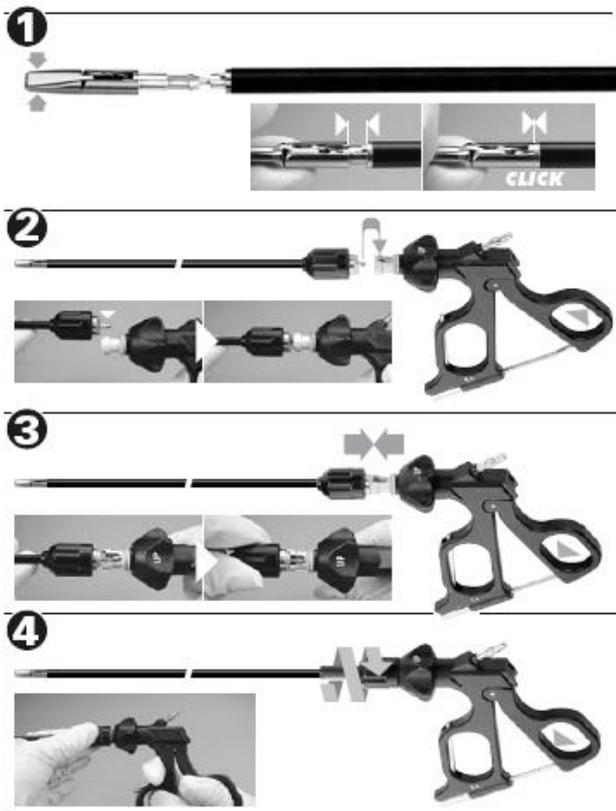
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Assembly

- Ensure that the end effector is closed. The protrusions of the tubular shaft and the notches on the insert must be lined up. The working end must audibly click into the tubular shaft.
- Open the handle entirely. Connect the ball retainer of the insert into the coupling of the handle.
- Close the handle completely.
- Tighten the union nut by hand.



Disassembly

- Loosen the union nut.
- Open the handle completely. Disconnect the working part.
- Release the working end from the tubular shaft by pressing the ball retainer towards the working end.
- Remove the insert completely from the tubular shaft.

