

Instructions for use

Endoscopic tube shaft instruments with and without HF connection

Symbol Symbol description SRN: DE-MF-00000592

CE 0297



Legal 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
- Accessories like plastic handle with and without HF connection

Item No: 47223-30 bis 47327-03, 656-3612M-184 und -185, 912-292-3605 bis 912-292-4505, R030-000000 – R631-030160-246H

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.
- Activate only if the contact surfaces are located in the field of vision. Contact with other electrically conductive medical devices must be avoided.
- Instruments are not supposed to be used to lean or support on.
- Insert the instrument carefully through the working channel to avoid damage on the working part.
- Use only under visual contact.
- 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.
- Pay attention to the instructions for use and safety information of HF devices.

Intended purpose

Endoscopic tube shaft instruments made by Reda Instrumente GmbH are used in minimally invasive surgery, but especially in laparoscopy. The instrument is, depending on the diameter, inserted in 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 holder serve as hold- and leading instrument for needles during surgical sutures. They must not be connected to HF current.

Contraindications

Endoscopic tube shaft instruments made by Reda Instrumente GmbH 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.

The monopolar endoscopic tube shaft instruments made by Reda Instrumente GmbH 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 REDA 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 HF device must be set in such way 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 with which the REDA monopolar laparoscopy instrument with HF connection is operated in combination with a suitable HF device at an appropriate operating mode / setting (see IEC/DIN EN 60601-2-2).

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



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 pointing the laser inadvertently at the working end or the shaft insulation of the instrument. In turn, 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 observe the instructions for use of the laser system for correct application of the laser. HF current and a suction/irrigation device should never be activated at the same time - the electrical HF current could be diverted away from the tissue to be coagulated.

Functional test

Prior to each use, instruments have to be checked for correct assembly, function and damages (rough surface, cracks, fractures, scratches, notches, sharp edges, bent or worn parts).

If the product shows 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 inspected for transportation damages and checked for proper function.

Possible damages should be reported immediately. The brand new medical device should be taken out from the polyethylene bags. They are to be stored open, dry and clean in a protective container until initial treatment to avoid formation of condensate. 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

The product family of REDA endoscopic tube shaft instruments with and without HF connection is compatible with each other.

To ensure safe use, individual components with HF plastic handle (with or without ratchet), tube shaft and various working inserts are just to be combined with components of Reda Instrumente GmbH

Combination with Other Products/Instruments

Products of Reda Instrumente GmbH should under no circumstances be combined with products, components and/or instruments of other manufacturers. The combination with products made of other materials and by other manufacturers can affect the result of the intervention negatively and is not permitted, as the components used may not be compatible with one another. It is recommended only to use instruments and accessories of Reda Instrumente GmbH.



Precautionary Measures:

In order to ensure undisturbed operative examination, the size of the endoscopic access canal and the size of the instrument should match one another.

Preparation:

The demountable and not demountable laparoscopy instruments of Reda Instrumente GmbH are to be prepared properly before first use and after each use. In the case of manual cleaning, the individual parts of the instruments must be soaked in an active cleaning and disinfection solution. Observe the instructions of the disinfectant manufacturer. All surfaces, including those of internal cavities, lumens and openings, must come into contact with the solution.

Caution:



No use of metal brushes or scouring agents for cleaning which may damage the surface. Disregarding can lead to risk of corrosion. Possible damage to the product through unsuitable cleaning agents and disinfectants and/or excessively high temperatures! For plastic and stainless steel approved cleaning agents and disinfectants are to be used according to the instructions of the manufacturer. Note the information for concentration, temperature and exposure time.

Procedure:	Manual and automated cleaning process
Products:	Demountable and not demountable endoscopic tube shaft instruments with and without HF connection with and without LUER lock with shaft Ø 5 mm, Ø 10 mm and Ø 3 mm
ADVICE:	Because of the product design and the used materials, one hundred processing cycles have been determined for REDA 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 the point of use:	Remove coarse dirt by submerging the instrument in cold water immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residue, which may influence the result of the cleaning and sterilization procedure.
Transportation:	Store and transport the device safely in a closed container to the cleaning area to avoid any damage and contamination to the environment.
Preparation for decontamination:	Open or disassemble the instruments without LUER lock for preparation, see "Disassembling"
Manual pre-cleaning:	Immerse the instrument in cold tap water for at least 10 minutes. Pay attention that all surfaces and hollow spaces are wetted. Brush the instrument under running tap water with a soft brush until all visible residues have been removed. Then rinse the instrument with a water pistol for at least 20 seconds.
Manual cleaning	
Ultrasound cleaning:	Immerse the instrument in an ultrasonic bath with enzymatic cleaner (0,8%) and treat with ultrasound for 10 minutes at 35°C. Avoid acoustic shadows during the process. Flush the instrument thoroughly with a water pistol for a minimum of 20 seconds. Let residual water drip off sufficiently.
Drying:	Dry the instrument using a lint-free towel and/or medical compressed air.

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Manual Disinfection:	Immerse the instrument completely in the disinfectant. Observe the manufacturer's instructions. Rinse the instrument thoroughly. Let residual water drip off sufficiently.																
Automated Cleaning																	
Automated Pre-Cleaning:	Immerse the instrument in cold tap water for at least 5 minutes. Brush the disassembled instrument under cold tap water until all visible residues have been removed. Inner lumens, threads and holes must be flushed with a water jet pistol for a minimum of 10 seconds in the pulse mode. Immerse the instrument in an ultrasonic bath with alkaline (0,5%) and treat with ultrasound for 15 minutes at 40°C. Take the instrument out of the bath and rinse with cold tapwater.																
Automated Cleaning:	<p>Recommended method of cleaning: Place the disassembled instrument on an instrument tray and connect the LUER lock connection with the MIC flushing system. Put the disassembled instruments on the inserts of the MIC cart. Instruments not suited for this type of tray must be opened and placed on an instrument tray on the MIC cart.</p> <ol style="list-style-type: none"> 1. 1 min pre-cleaning with cold water 2. Draining 3. 3 min pre-cleaning with cold water 4. Draining 5. 5 min cleaning at 55°C with 0,5 % alkaline 6. Draining 7. 3 min neutralization with warm water (40°C-60°C) and neutralizer 8. Draining 9. 2 min rinse with warm water (40°C-60°C) 10. Draining <p>Hinweise von den Herstellern der Geräte und Reinigungsmittel beachten.</p>																
Disinfection:	Automated Thermal Disinfection under consideration of national requirements regarding A ₀ -Value (see ISO 15883)																
Drying:	Dry the outer surfaces of the instruments in the drying cycle of the washer/disinfector. Let instruments cool to room temperature. If necessary, additional manual drying can be performed through a lint free towel. Use medical compressed air for cavities in instruments.																
Functional Testing, Maintenance:	Visual inspection for cleanliness. If necessary, repeat the reprocessing process until the instrument is optically clean. Assemble the instrument (see assembling) and check its function. Discard damaged instruments immediately. Maintain and repair joint and sliding surfaces with a suitable oil for instruments. Remove excess oil. Only use instrument oils (white oil) which have been approved for steam sterilization and have a tested biocompatibility.																
Packaging:	Appropriate packaging for sterilization according to ISO 11607 and EN 868.																
Sterilization:	<p>The instrument can be sterilized in assembled condition.</p> <p>Sterilize the instruments by applying a fractionated pre-vacuum process (according to 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 132°C , maximum 137°C Holding time: at least 5 min Drying time: at least 10 min</p>																
Storage:	Store sterilized instruments in a dry, clean and dust-free place 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>Neutralizer:</td> <td>Neodisher Z; Dr. Weigert, Hamburg</td> </tr> <tr> <td>Washing device and disinfectant:</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: 01707011901-2 / 01707011901-3</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)	Neutralizer:	Neodisher Z; Dr. Weigert, Hamburg	Washing device and disinfectant:	Miele G7835 CD	Program:	Design Vario TD AD	Details see report:	Manual cleaning: 15812		Automated cleaning: 01707011901-2 / 01707011901-3		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																
It is the duty of the user to ensure that user facility cleaning and sterilization procedures, resources, materials, equipment and personnel are adequate and capable of achieving the required results. State-of-the-art and national legal guidelines require following of these validated processes.																	

Maintenance and repair:

Reda Instrumente GmbH products have a guarantee of two years from the date of purchase. This guarantee is limited to repair or replacement of instruments free of charge, if the instrument is sent to Reda Instrumente GmbH. REDA is not responsible for shipping costs and dispatch risk. Instruments returned to REDA for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized.

Reda Instrumente GmbH is not responsible for direct damages or consequential damages. The guarantee expires if the instrument is used, prepared or maintained improperly, if instructions and requirements of the manual are neglected, if the instrument is repaired or modified by the user or another not authorized service center.

Accessories and spare parts:

Following parts can be ordered separately:

Handle (with or without ratchet), tube shaft and diverse working inserts.

Disposal:

The instrument can be disposed through the hospital's own disposal system. Adhere to national regulations when disposing the product.

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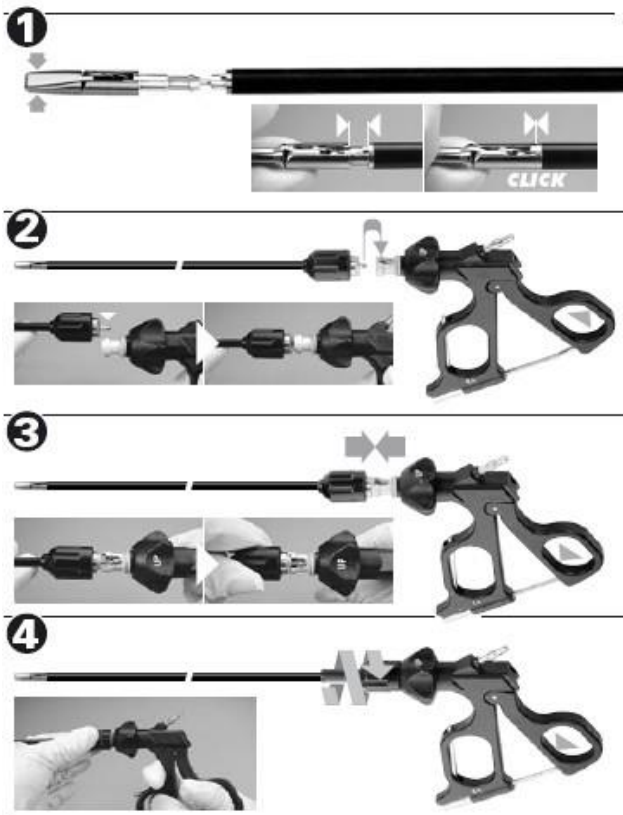
Endoscopic tube shaft instruments with and without HF connection

Manufacturer: Reda Instrumente GmbH
 Gänsäcker 34
 78532 Tuttlingen
 Germany



Assembling:

- Ensure that the working part is closed. The nose of the tubular shaft and the notches on the insert must be on top of each other. The working end must audibly engage into the tubular shaft.
- Open the handle completely. Connect the ball retainer of the working part into the coupling of the grip.
- Close the handle completely.
- Tighten the union nut by hand.



Disassembling:

- 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 working insert completely from the tubular shaft.

