Instructions for use
DOC902 Endoscopes

CE 0297

Table of Contents

1 General Info

This instructions for use refer to:

RZ Medizintechnik GmbH
Unter Hasslen 20
78532 Tuttlingen
Germany
Tel.: 0049-7462-9470-0
Fax: 0049-7462-9470-50
Website: www.rz-medizintechnik.com
Email: sales@rz-medizintechnik.com

Every user is required to read this instruction for use carefully. Patient must be informed about any contraindications, warning and side effect. Always keep this instruction accessible to all users.

REF

100-500-3XX; 100-6XX-XXX; 100-8XX-XXX;
100-9XX-XXX; 225-019-XXX; 225-1XX-XXX;
225-14X-XXX; 225-22X-XXX; 225-240-XXX;
225-440-XXX; 225-540-XXX; 225-727-XXX;
225-740-XXX; 225-804-XXX; 251-104-XXX;
252-104-XXX; 252-127-XXX; 253-2XX-XXX;
253-804-XXX; 253-82X-XXX; 253-900-XXX;
253-905-XXX, 253-910-XXX; 253-915-XXX;
259-375-XXX; 259-430-XXX; 259-710-XXX;
260-104-XXX; 260-105-XXX; 260-110-XXX;
300-09X-XXX; 300-100-4XX; 300-155-4XX;
300-200-4XX; 300-255-4XX; 351-200-XXX;
351-720-XXX; 351-804-XXX; 351-827-XXX;
351-829-XXX; 410-004-XXX; 410-027-XXX;

⚠ ***Warning:*** Noncompliance with these instructions for use might lead to injuries of the users/patients and/or damages to the endoscopes

⚠ ***Warning:*** Described endoscopes may only be used in combination with RZ Medizintechnik products/accessories

2 Device Description

Rigid endoscopes are slim, optical devices which allow imaging of body structures and organs through natural or artificial cavities. Minimally invasive, endoscopic diagnosis or intervention is widely established and causing considerably less patient risks compared to open surgery. Rigid endoscopes are available and individually designed for various surgical specialties such as laparoscopy, hysteroscopy, arthroscopy, spinal endoscopy, and many others. The widespread use created various types of endoscopes, which differ in rigidity, length, diameter, working channel, rinsing and flushing channels, direction of view and working angle. Although many types of different endoscopes exist, the general principle and functional build-up remain the same: To address specific needs of different endoscopic procedures, RZ Medizintechnik GmbH provides various types of rigid endoscopes

3 Intended Use

The use of RZ Medizintechnik endoscopes is indicated for visualization of the intraoperative site during endoscopic procedures and minimally invasive surgery.

3.1 Indications for Use

Device	Representative Picture Indications for use
Arthroscopes	 Are intended for endoscopic procedures involving joints
Bronchoscopes	 Are intended for endoscopic procedures involving lungs
Cystoscopes	 Are intended for endoscopic procedures involving urinary tract
Laryngoscopes	 Are intended for endoscopic procedures involving larynx
Nephroscope	 Are intended for endoscopic procedures involving urologic tract
Hysteroscopes	 Are intended for endoscopic procedures involving uterus / cervix channel
Laparoscopes	 Are intended for endoscopic procedures involving abdominal or pelvic area
Oesophagoscopes	 Are intended for endoscopic procedures involving oesophagus
Otoscopes	 Are intended for endoscopic procedures involving ears
Rhino-Pharyngoscope	

	Are intended for endoscopic procedures involving the rhino
Sinuscopes / Nasoscopes	 Are intended for endoscopic procedures involving nose and sinus cavity
Spinal Endoscopes	 Are intended for endoscopic procedures involving spine
Thoracoscope	 Are intended for endoscopic procedures involving area between the lungs and the chest wall (thorax)
Uretero-Renoscope	 Are intended for endoscopic procedures involving atraumatic access of the urethra via renal access

⚠ ***Warning:*** Due to the high energy radiated light emitted from the illumination fiber, the distal end of the endoscope may reach temperatures exceeding 41ºC (108ºF).

⚠ ***Precaution:*** To avoid burns to the patient, do not leave the tip of the endoscope in direct contact with tissue or heat-sensitive materials. Lower the light source output when working in close proximity to the object.

⚠ ***Precaution:*** Endoscopes are fragile optical devices that need to be handled with caution

⚠ ***Precaution:*** To avoid fogging during surgery, the rear proximal portion of the scope must be entirely free of moisture before it is attached to the camera or coupler

⚠ ***Precaution:*** Always hold the endoscope at the housing body and/or eyepiece

⚠ ***Precaution:*** Do not bend the shaft of the rigid endoscopes

⚠ ***Precaution:*** Avoid shaking or dropping the endoscope.

⚠ ***Warning:*** Intolerance of CO2 during laparoscopy

3.2 Patient Population

There is no restriction concerning the patient population other than the ones provided in the section "Contraindications". Devices intended to be used for specific population such as paediatric, are clearly identified on the label description.

3.2.1 Contraindications

Endoscopes are not intended to be used in direct contact with human central circulatory system and nervous system.

3.2.2 Residual Risks, Side Effects and Complications

- Risk of burns due to the use of light source with too much power.
- Risk of injury due to defective endoscopes
- Risk of infection to patient or medical staff
- The visual field can be disrupted by condensation and debris. Condensation of water vapor on the lens occurs when moving the Endoscope/laparoscope from a cold operating room into a 37°C humidified body cavity. Debris from inside the body cavity and smoke from cautery tools can collect on the laparoscope during the surgery and increase the risk of surgical error, leading to increased possibility of injury to the patient.
- Post-operative pain and fever
- Port site hernias could develop from a few hours to several months after laparoscopic surgery

3.3 Intended Users and Use Environment

RZ Medizintechnik endoscopes must be used by physician that is familiar and sufficiently trained, informed about current state of the art and having sufficient experience in the choice and use of endoscopes. Physician is responsible for patient selection and surgical procedure to apply. Endoscopes must be only used in hospital and/or appropriate centers in sterile state.

3.4 Combination with other Medical Devices

The connection of other equipment or supplies (such as TV adapter, light sources, optical fibre cables, cameras, monitors, printers, video recorder, image processing systems, filing systems, pumps, shavers, insufflator, RF devices, work items, laser devices, pneumatic or electro hydraulic lithotripters etc.) opens up a variety of therapeutic applications. Follow the instructions and security advices of the used devices and accessories. Make sure that users are adequately trained. In case of doubt, contact your dealer or the manufacturer.

Protective measures for RF applications, including laser application, high-energy applications are not integrated in the RZ Medizintechnik GmbH device. Note that only the devices which are permitted for medical purposes may be adapted!

⚠ A thorough understanding of procedures used for endoscopic laser and electrosurgical treatment, applied principles and methods is needed to avoid shock and burn risks for patients and users as well as damage to other equipment and instruments. Liability claims arising from improper use or combination with other devices and instruments are excluded.
Make sure when joint operation of an endoscope with electronic medical devices is performed, that the BF conditions (isolated, floating applied part) are observed.

If endoscopes should be used with electronic medical devices and / or energy-powered endoscopic usable accessories, leakage currents may added up

Notes for use with light sources

⚠ RZ Medizintechnik rigid endoscopes can be adapted to all common light sources for medical endoscopy. The malfunction of a used light source might lead to hazards. Keep an operational replacement light source available, or use light sources that have a spare bulb. If bulb change is necessary during endoscopic application do not move the endoscope during the bulb change. Only if it is possible pull out the endoscope carefully for bulb change. Remember that light is an energy source that can heat each

endoscope optics. The application time is limited by the selection of the light source.

In combination with high intensity light sources, both the light source side and the instrumental side optical fibre end can achieve temperatures that can cause burns. In addition, light of high energy radiation can lead to a temperature increase in tissue. During invasive application temperatures above +41 °C should be avoided, as this can cause tissue damage! Therefore, avoid direct tissue contact and if applicable, pay attention to adequate irrigation of the operative field and the respective device-specific instructions and safety precautions.

Notes for use with high frequency surgical equipment

Prior to application of endoscopic high frequency treatment, surgical patients should be prepared in a suitable manner for the intended intervention. This includes activities to eliminate and to prevent the formation of ignitable gases in particular. In contrast to conventional high-frequency surgery inappropriate (particularly to low) power settings in high-frequency endoscopic surgery can cause a distinctive depth effect in the surrounding tissue.

⚠ The power adjustment should be made according to the users experience with respect to appropriate clinical references and / or appropriate training.

To avoid burns and / or unwanted depth effects in the surrounding tissue and to avoid endoscope damage, the high-frequency current should be switched on only if the appropriate application part (electrode) can be seen through the endoscope. The corresponding manuals, specifications and security advices should be respected.
Never touch the endoscope while operating with an active electrode.

Notes for use with lasers

⚠ If endoscopes or endoscopic accessories are used with laser devices, suitable protective glasses have to be worn to avoid potential damage to the eyes.

To avoid burns and / or unwanted depth effects in the surrounding tissue or damage of the endoscope, the laser power should be activated only if the tip of the laser fibre can be seen through the endoscope. The respective device-specific instructions and safety precautions have to be observed.
Never touch the endoscope while operating with an activated laser fibre

Notes for use with lithotripters

⚠ To avoid danger and in relation to possible restrictions on use of ultrasonic, electro-hydraulic, pneumatic and mechanical lithotripsy device-specific instructions and safety precautions have to be observed. Appropriate surgery sheaths may be used for stone extraction with stone forceps. The required dimensions of suitable instrument can be gathered from technical specifications of the respective single devices. Never touch the endoscope while operating with an activated Lithotripsy unit.

CT (Computer tomography)

⚠ Certain metals of the endoscope can be dangerous due to heating during the application, so that an X-ray examination may be contraindicated in such patients. Due to X-radiation, optical components can discolour and thus can lead to endoscope damage. Concomitant use of CT (computed tomography) / X-ray and endoscopes can lead to hazards. Note therefore appropriate manufacturers and safety instructions.

MRT (Magnetic resonance tomography)

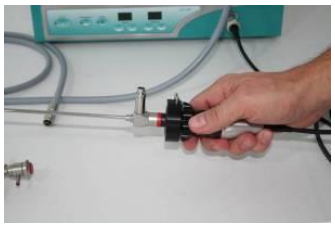
⚠ Due to magnetic field induced movements / relocations or heating some metals of the endoscope can be dangerous during the investigation, so that an MRI scan may be contraindicated in such patients. The optical and electrical medical devices for endoscopy may be damaged by magnets. Metals of the endoscope can cause side effects and visual disturbances. Concomitant use of MRI / magnetic resonance imaging and endoscopes can lead to hazards. Note therefore appropriate manufacturers and safety instructions.

4 Assembling

Setup of minimum configuration in endoscopy (due to different combination of units this may vary)

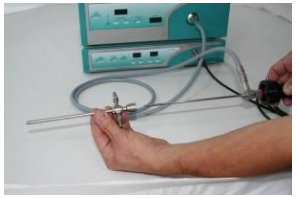
TV-Adapter connection to a Camera

TV-Adapter connection to an endoscope



Fibre optics connection

Instrument connection



5 Reprocessing Procedures

5.1 Handling before the First / Subsequent Use

Please carefully inspect the devices at the time of delivery and prior to each use. Special regard should be given for damages, such as cracks, bends and discoloration of the optical surfaces.

NON STERILE

RZ Medizintechnik´s endoscopes of are supplied non-sterile and therefore require reprocessing prior to first and any subsequent use. Please follow the instructions for reprocessing given below.

⚠ ***Warning:*** These devices are reusable and can be reprocessed up to 100 times. However, the devices are by nature subject to wear depending on the type and time of use. Therefore, inspect the devices thoroughly prior to each further use in particular for integrity of optical surfaces, discoloration, deformation and corrosion.

⚠ ***Warning:*** Extreme heat from steam autoclaving and the high intensity lamp will cause debris on the optical surfaces to possibly discolor, burn and harden if not properly cleaned and removed

5.2 Pre-Cleaning

5.2.1 General Notes

⚠ ***Warning:*** Never use metal brushes for cleaning

⚠ ***Precaution:*** When using cleaning or disinfection agents, make sure not to exceed the manufacturer's specification on temperature, immersion time and concentration. Use only cleaning and disinfectant agents that have been approved by their manufacturer for cleaning and disinfection of endoscopes or optical devices and which feature processes in accordance with national and local guidelines

⚠ ***Precaution:*** Remove visible contamination and heavy debris from the devices immediately after each use by wiping with an appropriate, single-use lint-free cloth or sponge. Use cold water to prevent incrustation of contamination on the device

⚠ ***Precaution:*** Transportation of the devices to the reprocessing area should be performed by immersion in liquid in a containment device to prevent damages

⚠ ***Precaution:*** Prepare the devices for later reprocessing directly in the operating room. Complete device reprocessing must be performed within 1 hour after use. Do not leave used instruments overnight before reprocessing

⚠ ***Precaution:*** In order to avoid incrustations formed by residual blood or proteins, the devices must be reprocessed immediately after use

⚠ ***Warning:*** During transport, cleaning, care, sterilization and storage, the devices should be handled with maximum care

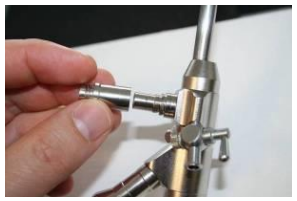
5.2.2 Disassembly

⚠ ***Warning:*** Do not use excessive force; this will damage the instruments

Please follow the below procedures (Please consider that only representative images have been reported):

a) Remove all sealing caps and valves

b) Remove all adaptors



c) Preclean working and irrigation channels with brushes, blow through with air and rinse with sterile water afterwards. Dry all channels with compressed air

5.2.3 Manual Pre-Cleaning

⚠ ***Warning:*** Never use ultrasonic cleaners as this will cause damage to the optical system

Please strictly follow the below procedures:

- Closely follow the manufacturer's instructions for appropriate chemical concentrations and immersion time. However, the maximum immersion time of 1 hr. should not be exceeded (this statement only refers to material compatibility and does not indicate any germicidal effectiveness level)
- After immersion time, the outside surface of the device must be cleaned with a soft bristled brush
- The lumens and flush ports should be brushed by using RZ Medizintechnik's lumen brushes. When brushing the lumen, introduce the brush into the proximal end and ensure the brush is exiting the distal end of the device
- Flush each flush port and lumens with the prepared cleaning solution
- Thoroughly rinse the endoscope and fittings under lukewarm tap water to remove the cleaning solution. Repeat this step three (3) times to ensure total removal of detergent residuals.
- Let all parts of the instrument drain completely
- Use an appropriate soft single-use and lint-free cloth or sponge to wipe off remaining water
- Completely dry the instrument

⚠ ***Precaution:*** After manual pre-cleaning carefully inspect the optical surface with reflective light for foreign particles and scratches that could have a negative effect on the image quality.

⚠ ***Precaution:*** If residual debris are visible, repeat the pre-cleaning procedure

5.2.4 Automated Cleaning

⚠ ***Precaution:*** Use only washer/disinfectors which are intended specifically for cleaning and disinfection of endoscopies by the washer/disinfector's manufacturer. It is recommended that a legally marketed washer-disinfector is used. Refer to the washer/disinfector's instructions for use

Please strictly follow the below procedures:

- Place the devices individually in the washer. Make sure that the devices have been securely fixed to the unit's trays or baskets
- Ensure that flushing ports are opened
- Some automated washers contain flushing connections for lumens. If your washer incorporates this feature, connect the devices to respective connectors, as this will improve cleaning efficacy
- Start cleaning program with the following parameters:
  - Pre-rinse for 2 min. with cold tap water
  - Enzymatic wash for 4 min. at with hot tap water (enzymatic detergent 1 oz. per gallon*)**
  - Neutralizing wash for 2 min. at 65°C (neutral detergent ¼ oz. per gallon*)***
  - Rinse for 15 sec. with hot tap water
  - Dry for 6 min. at 98°C

Notes:
* Use only agents that are certified by their manufacturers as safe for surgical instrument cleaning/ disinfection. Make sure not to exceed the specification of the agent's manufacturer.
** 1 oz. per gallon = 7.489 mg/l
*** ¼ per gallon = 0.25 ml/l

⚠ ***Precaution:*** To prevent corrosion, remove the instruments from the washer/ disinfector immediately after the automatic procedure has stopped. Visually inspect the instrument for residual moisture. Remove residual moist by using a lint free cloth or sterile compressed air

⚠ ***Precaution:*** Visually inspect the instrument for cleanliness and residual moisture. Remove residual moist by using a lint free cloth or sterile compressed air. If necessary, repeat the reprocessing process until the instrument is visually clean.

⚠ ***Precaution:*** A visual inspection for damages and wear, in particular with regard to the optical surfaces has to be performed after each cleaning process

5.2.5 Disinfection

Thermal disinfection with hot water (≥ 93°C) holding time of at least 1 minute.

5.3 Packaging

Prior to sterilization, place the cleaned and disinfected devices in appropriate instrument trays and wrap or seal them by using a suitable wrap (double layer) in accordance with ISO 11607-1. The instrument tray and the sterilization wrap should be labeled and legally marketed for the recommended cycle specifications below.

5.3.1 Sterilization

⚠ ***Warning:*** The devices are not suitable for flash sterilization, dry heat sterilization, radiation sterilization, sterilization with formaldehyde or ethylene oxide, or plasma sterilization. Sterilization with respective methods may cause damage to the devices and / or increased wear

⚠ ***Warning:*** Optical devices must be carefully cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases effectiveness of the sterilization process. After cleaning, make sure that the instrument is carefully dried.

⚠ ***Precaution:*** To ensure permeance of sterilizing agent, ensure that all valves and flushing ports are in open position

The devices are compatible to be sterilized with the following cycles:

Prevacuum Steam Sterilization

Parameter	All markets		USA only
Temperature	121°C 250°F	132°/134°C 270°/274°F	132°C 270°F
Exposure Time	20 min	3 min	4 min
Drying Time	-	-	30 min

⚠ ***Warning:*** After sterilization, make sure that the sterile package of the endoscope is not damaged. If the package has been perforated, sealing has been opened, packaging is wet or damaged in any other way, re-sterilize the endoscope

⚠ ***Precaution:*** After sterilization, ensure gradual cool-down to room temperature without use of any additional cooling. Sudden changes of temperature may damage the devices

⚠ ***Warning:*** When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded

⚠ ***Precaution:*** The reprocessing instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials, and personnel in the processing facility, achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences

6 Storage

Endoscopes must be stored until first or any subsequent use in a suitable environment. After complete reprocessing and drying, the devices must be placed in a suitable container/box for sterile storage.

Keep away from sunlight

Keep dry

7 Warranty

RZ Medizintechnik provides 12 months warranty on the function of the endoscope. The duration of this warranty is limited to claims that are submitted within the specified warranty period from date of purchase of the endoscope, stating the invoice number. This warranty applies only to defects that are not normal wear and tear, abuse, mishandling, improper or inadequate treatment. In cases of maintenance or repair, please contact RZ Medizintechnik service or an authorized repair specialist.

7.1 Repairs

- If any failure has developed, always consult specialist or service personnel. Attach appropriate information to the defective equipment and call qualified service personnel.
- The user should not modify the equipment.
- If possible, always use the original packaging for return purposes.
- Please ensure, that returned devices are properly Reprocessed

8 Disposal

All national regulations on disposal must be observed. Discard non-conforming products according to the respective national laws.

9 Explanation of Used Symbol

Following symbols have been used either in this IFU or in our labels:

Symbol	Description
	Symbol for "Manufacturer"
	Symbol for "Consult the Instruction for Use"
REF	Symbol for "Catalog Number"
LOT	Symbol for "Batch Code"
pcs.	Symbol for "Number of pieces"
	Symbol for "Caution, consult accompanying documents"
NON STERILE	Symbol for "Non-Sterile"
	Symbol for "Keep away from sunlight"
	Symbol for "Keep dry"
	Bar identification code
	UDI/GTIN identification code
CE 0297	Symbol for "European conformity to the essential requirements with notified body number"