Instruction Manual
Rigid endoscopes
with and without working / irrigation channel

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2. Legal advices

This technical manual contents ownership protected information, which underlay copyright conditions. All rights are protected. This technical manual must not be copied, neither by photocopies, microfilms or other procedures and must not be distributed or saved, neither complete nor in extract without explicit written authorization of REDA Instrumente GmbH.

Nomenclature which is at the same time a registered trade mark is not especially marked. In absence of trademark declaration it may not be gathered that a designation will be a free trademark.

REDA Instrumente GmbH would greatly appreciate being informed about any errors or omissions that may be found in the content of this instruction manual.

With regard to continuous development and improvement of our products we reserve the right to alter technical features without written notice.

3. Signs and Symbols

Please take notice!

Caution: Indicates to possible dangerous situations. Non-observance can lead to dead or serious injuries.

Attention: Indicates to possible dangerous situations. Non-observance can cause injuries or product damages.

Read the instruction manual!

Attention! Please consider the accompanying documents.

Non-sterile – sterilize before use.

CE 0297

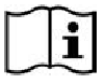
CE-Marking with identification number of notified body for medical devices of risk class IIa and higher according to Council Directive 93/42/EEC.

CE-Marking
The CE marking certifies that the product complies with the following directives:

Medical Device Directive 93/42/EEC
Medical Device Act (Medizinproduktegesetz (MPG))

4. Introduction

Thank you for purchasing a rigid endoscope of REDA Instrumente GmbH. Endoscopes are medical devices that are manufactured at the highest technical level and require careful handling, care and storage.

 Read this instruction manual carefully before using your new product. You preserve the patient and any third party thereby from damage which can result from improper connection or improper operation.

Keep the instruction manual in a conspicuous place near the device.

5. Security advices / warnings

Improper use of the device and non-observance of the given instructions, warnings and precautions can lead to serious risks and consequences in the application or to injury, damage and even death of the patient, user and any third parties or damage to the endoscope!
This manual is designed to get familiar with the equipment and its intended capabilities in detail and use. The manual has to be enclosed with the device therefore always.
The instruction manual contains important information needed for safe, proper and efficient operation of the device.
We reserve the right to alter technical features, so that deviations of the content or pictorial representation are possible.
This manual should help to make the use of rigid endoscopes of REDA Instrumente GmbH easier, but it is not designed as guidance for endoscopic procedures and does not contain detailed description of endoscopy, and is not suitable for beginners' introduction to this endoscopic/surgical technique!
This device may only be used by technically competent and trained persons who are instructed to handle the instrument.
All persons using the devices have to read these instructions carefully first.
Handling of the device has to be carried out in accordance with these instructions.
Use the endoscope for endoscopic purposes only!
Inspect the endoscope, the appropriate endoscopic accessories and all devices connected to optical and mechanical parts for possible damages to exclude the risk of injury before every use! Defect and loose parts affect the function and safety and have to be removed immediately!
Damaged or defective parts of endoscopes must not be used any longer. The full function and intended use of the medical device has to be ensured and

verified by the user when using accessories and other components before use.
In case of doubt, contact your dealer or the manufacturer.
The device is not intended for use in potentially explosive areas!
Mechanical stress due to falling off, strong buckling, bending in a narrow winding, strong shocks and torsion, tensile load or compressive stresses can result in damage or destruction of the endoscope and thus lead to malfunction!
We are not responsible for damages caused by misuse of the endoscope, no liability!
Endoscopic procedures should be performed by trained professionals (e.g. physicians) with appropriate training and experiences in performing endoscopic procedures only. To continuously learn about indications, contraindications, potential complications, risks and the development of endoscopic procedures is the responsibility of the user.

Notes on combinations 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, HF 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 HF applications, including laser application, high-energy applications are not integrated in the REDA Instrumente GmbH device. Note that devices which are permitted for medical purposes may be adapted only!
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.
Provided that the endoscope is used with electronic medical devices and / or energy-powered endoscopic usable accessories, leakage currents may added up.

Notes for use with light sources

REDA Instrumente GmbH 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 respective 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.
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.

6. Intended use

REDA Instrumente GmbH rigid endoscopes are optical devices which allow inspecting the body's interior through natural body openings or artificial cavities and the visualization of organs, tissues and structures.
The following parameters of rigid endoscopes optics are variable:
Sizes, working length, probe diameter, direction of view and field of view.
Rigid endoscopes can be used in the following applications:

- Arthroscopy
- Cystoscopy
- Diskectomy
- Hysteroscopy
- Laparoscopy
- Nephroscopy
- Thoracoscopy
- Ureterorenoscopy

Indications:
The use of rigid endoscopes of REDA Instrumente GmbH is indicated for endoscopic procedures and other procedures in minimally invasive surgery.

Contraindications:
The use of rigid endoscopes of REDA Instrumente GmbH is contra-indicated if endoscopic procedures are contraindicated.

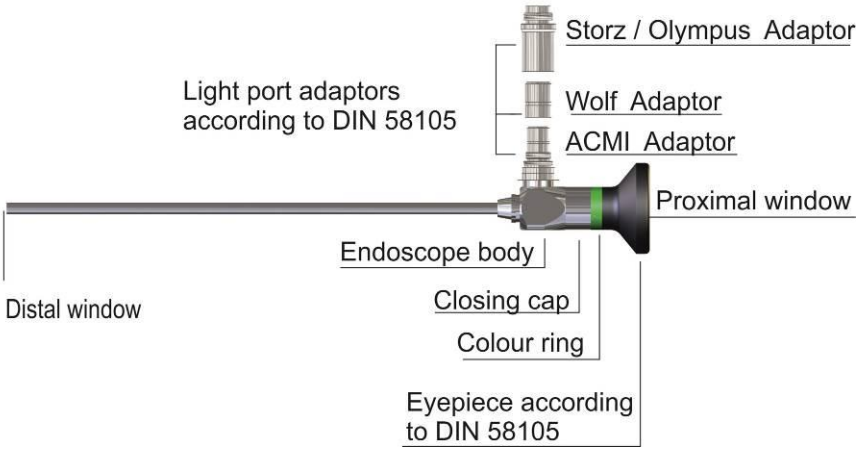
7. Device description / sketch / part description

The model / type, serial number and item number for identifying the medical product can be found on the product labelling (on packaging / device).

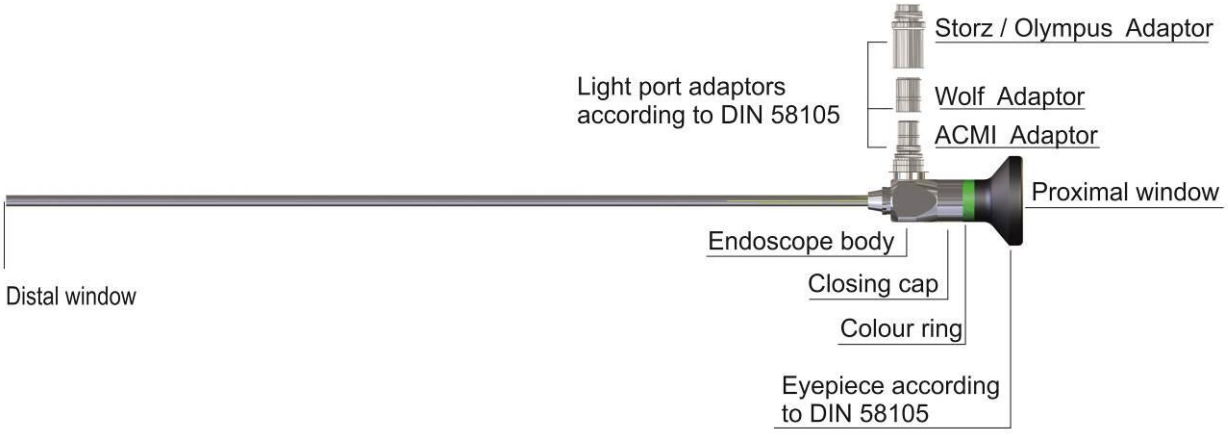
Models with a direction of view of 0° are shown in the following illustrations exemplary. Please note that devices with different directions of view may differ slightly from the illustrated products.

a) Models without working channel

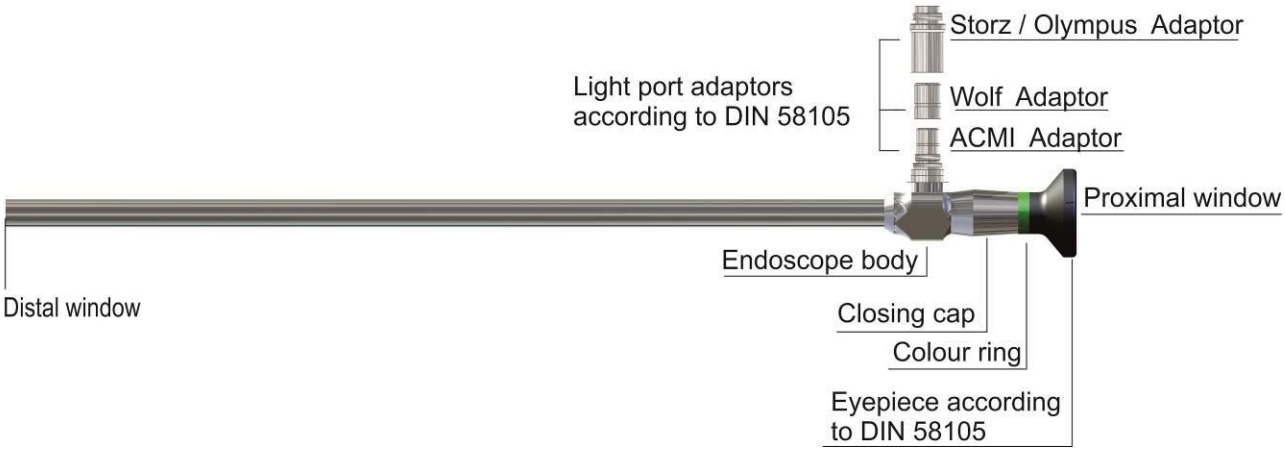
Arthroscope



Cystoscope / Hysteroscope

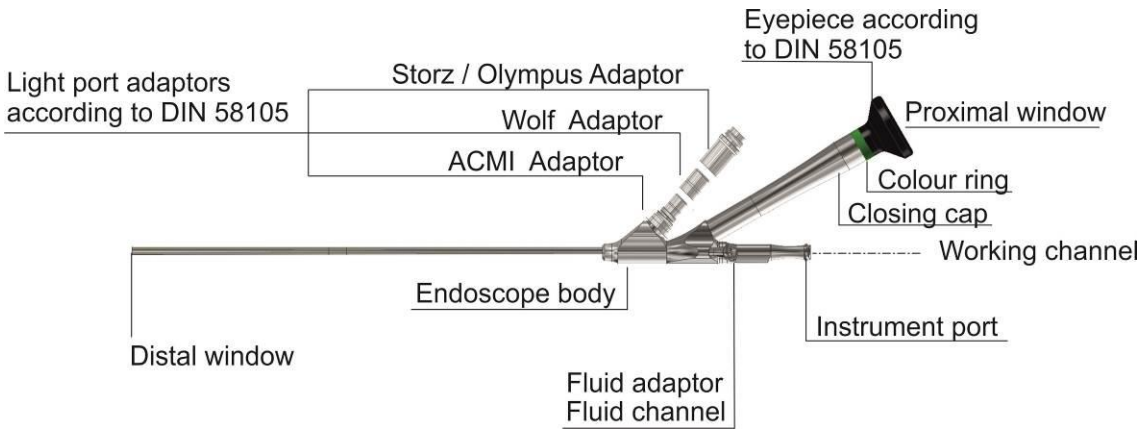


Laparoscope / Thoracoscope

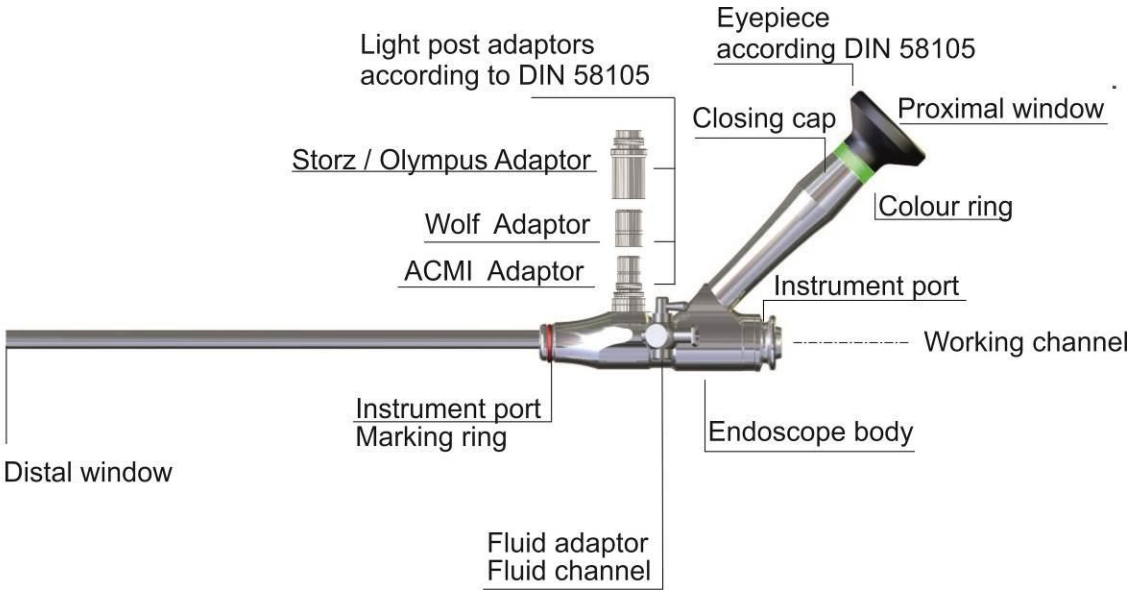


b) Models with working channel

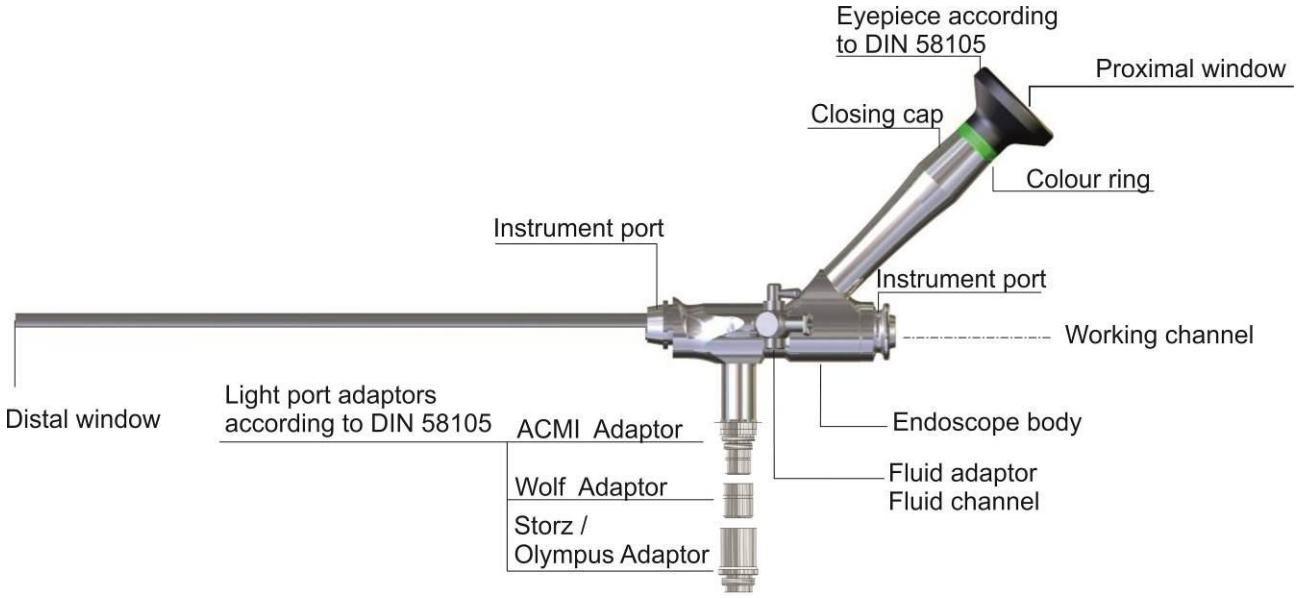
HD MINI Compact Cystoscope (MCC)



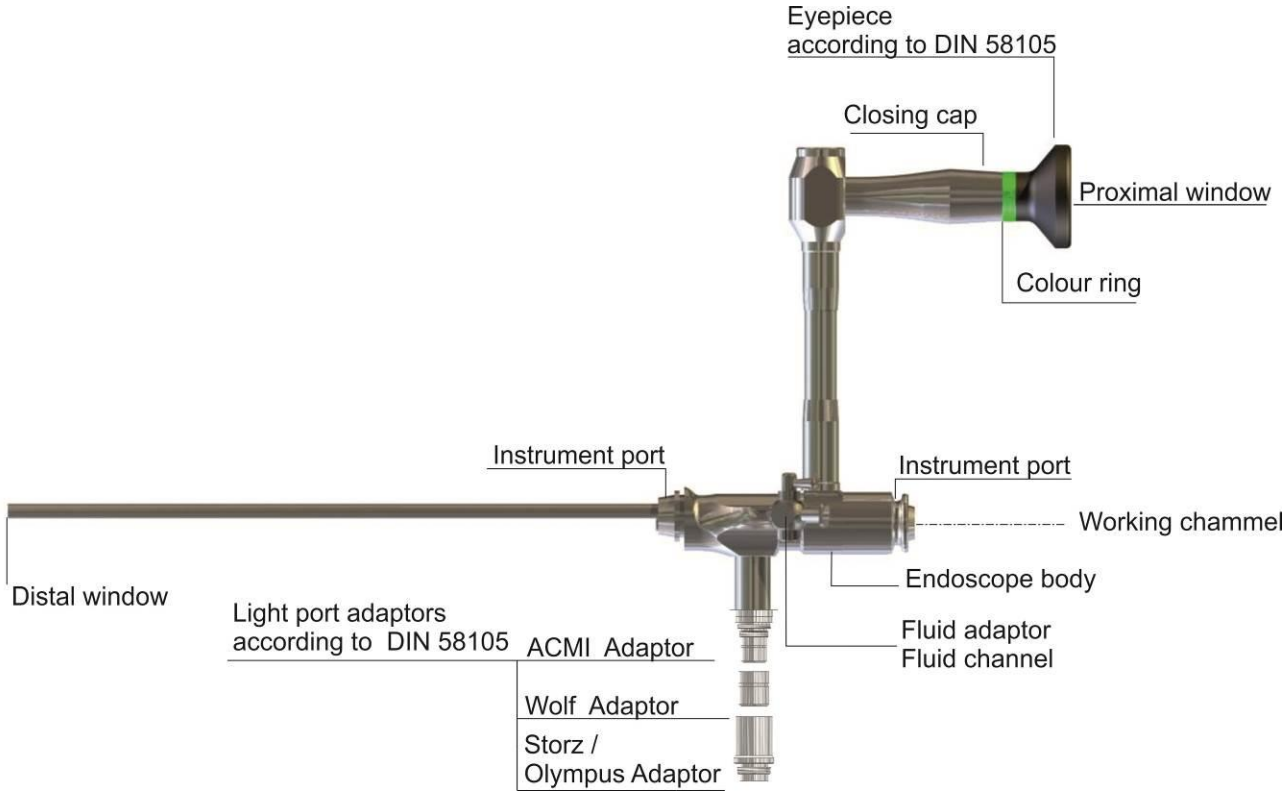
Diskectomy system


Eyepiece
according DIN 58105
Light post adaptors
according to DIN 58105
Closing cap
Proximal window
Storz / Olympus Adaptor
Colour ring
Wolf Adaptor
ACMI Adaptor
Instrument port
Working channel
Instrument port
Marking ring
Endoscope body
Distal window
Fluid adaptor
Fluid channel

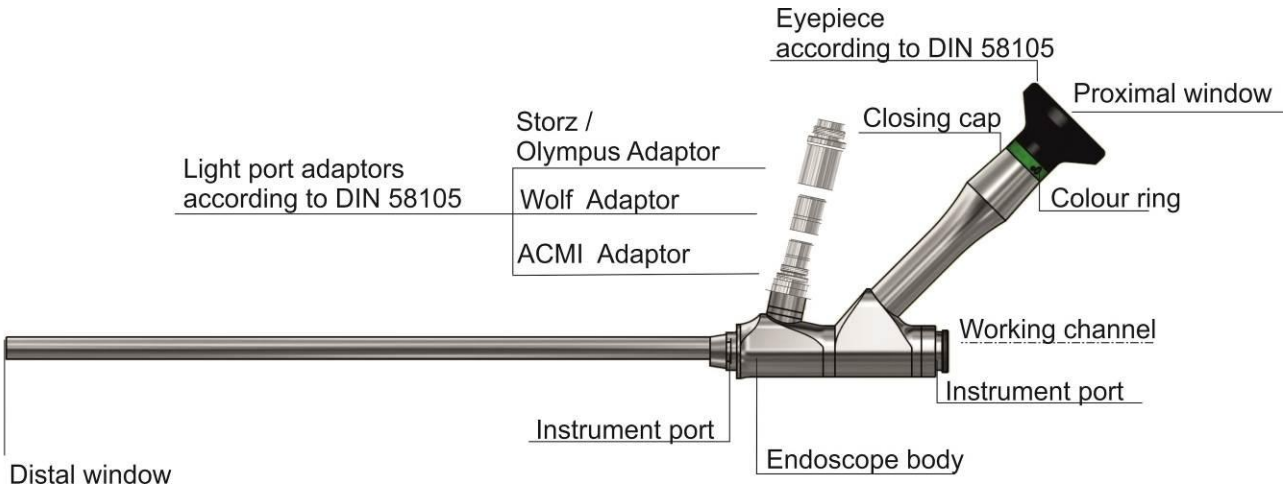
Nephroscope



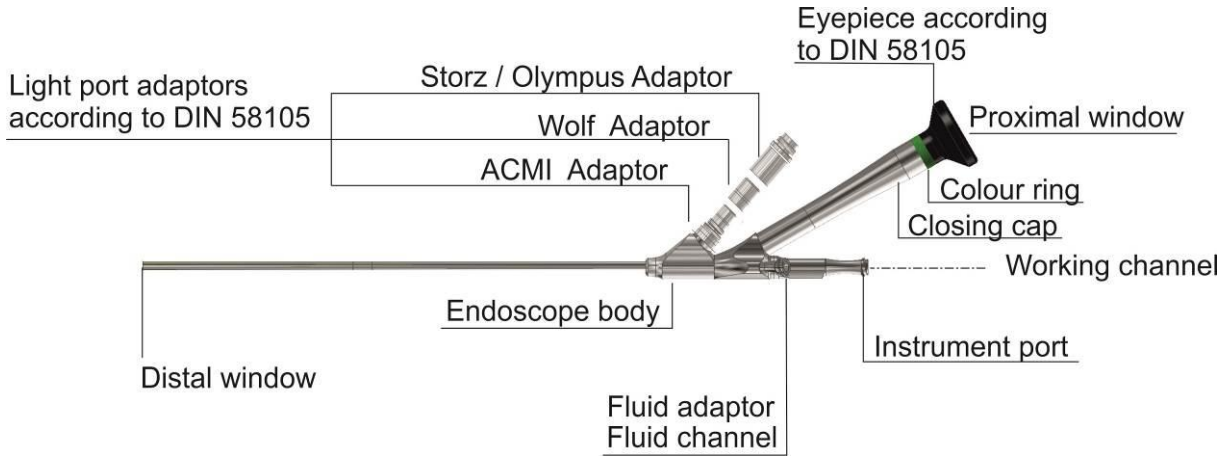
Nephroscope



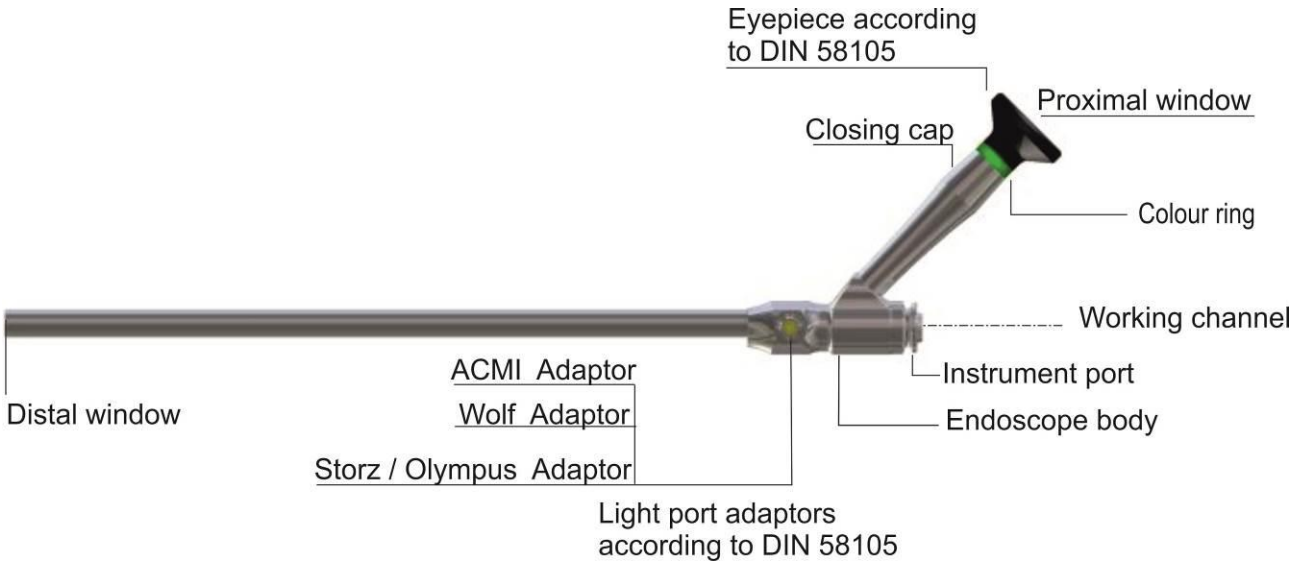
HD Compact Nephroscope (CN)



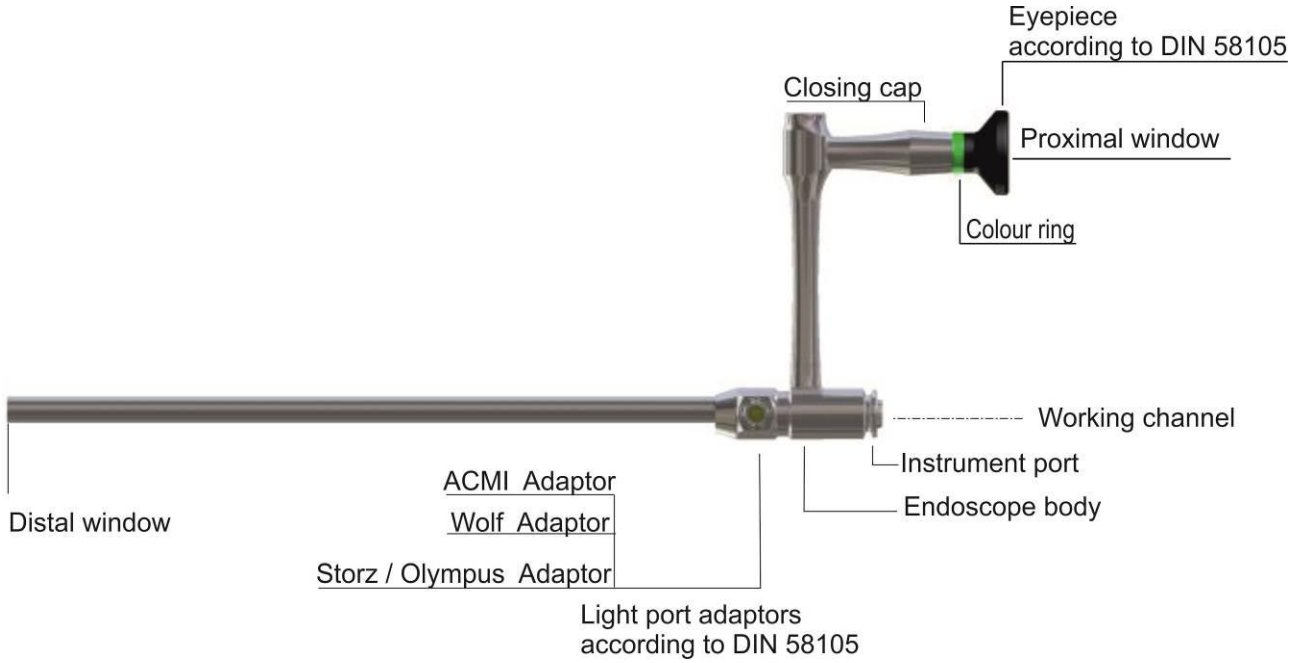
HD MINI Compact Nephroscope (MCN)



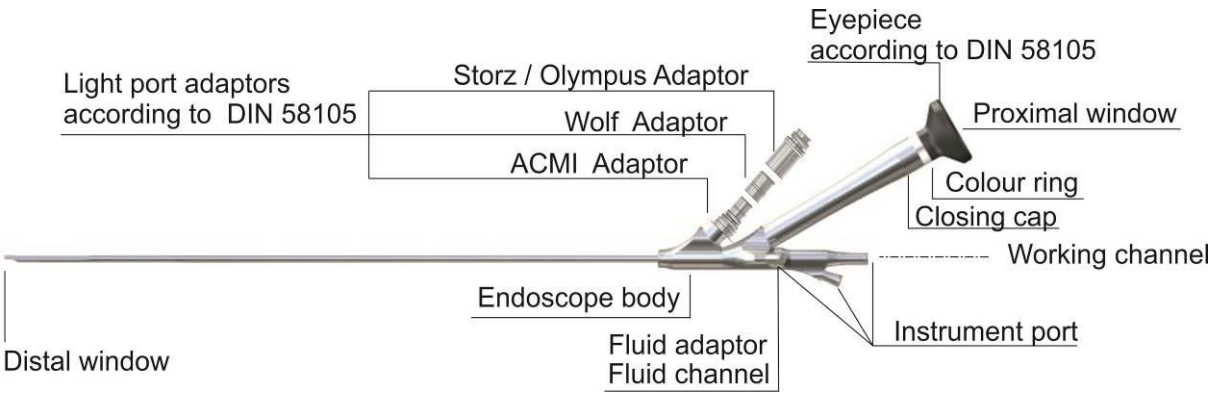
Surgical Laparoscope



Surgical Laparoscope



Ureterorenoscope



Accessories:

Light port adaptor	Storz – Adaptor Wolf - Adaptor
Eyepiece	Eyepiece combined
Colour ring	Direction of view

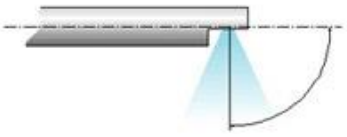
0° Colour code green

15° Colour code white/silver

30° Colour code red

45° Colour code blue

70° Colour code yellow



90° Colour code black

8. Initial operation

Remove the REDA Instrumente GmbH rigid endoscope and its accessories from the packaging and carefully remove all packing materials.

The delivery includes:	1 piece	Rigid Endoscope
	1 piece	Wolf-Adaptor
	1 piece	Storz-Adaptor
	1 piece	Cleaning brush (for endoscopes with working channel provided only)

Rigid endoscope and accessories have to be checked promptly for completeness and obvious damage after unpacking. Damage can be claimed only if the supplier is notified immediately (within 24 hours).
Please use for any necessary return of equipment or accessories the original packaging. Describe the problem, identify the malfunction and designate a contact person for possible inquiries.

Caution:
If equipment or other medical devices are connected to the endoscope please note references made in chapter 5. “combinations with other medical devices”

Follow the instructions and safety advices of used devices and the accessories strictly.

REDA Instrumente GmbH rigid endoscopes are supplied non-sterile and have to be cleaned before first use and after every use according to the reprocessing instructions. Rigid endoscopes have to be disinfected or sterilized according to the medical indication (please note chapter 10. “cleaning, disinfection, sterilization”).

9. Operation

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

Connectivity options of different endoscope models are shown below:

a) Endoscopes without working channel (e. g. arthroscopes, cystoscopes, hysteroscopes, laparoscopes, thoracoscopes)

The following figures show the connection options for endoscopes without working channel exemplary. Please note that depending on the endoscope model and the used accessories the connection options may vary.

TV-Adapter connection to a Camera (optional)

TV-Adapter connection to an endoscope

Pay attention to the eyepiece adjustment!

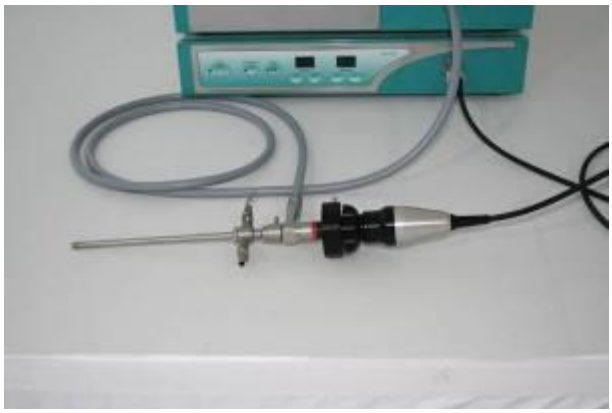
Fibre optics connection

Pay attention to fibre optics adjustment!

Instrument connection (optional)

⚠ **Pay attention to the correct positioning of the instrument to the optics!**

⚠ **Pay attention to instrument adjustment!**



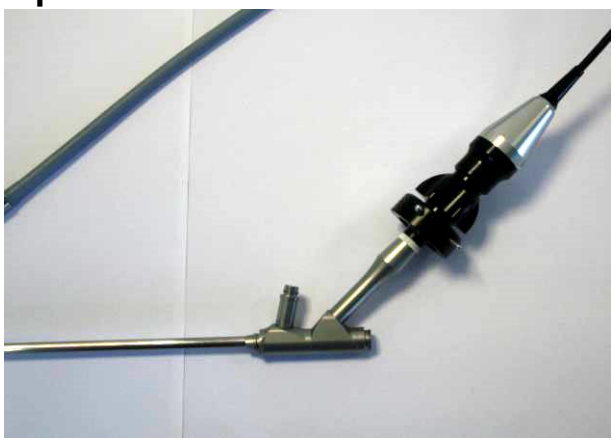
b) Endoscopes with working channel (e. g. cystoscopes, diskectomy systems, nephroscopes, surgical-laparoscopes, ureterorenoscopes)

The following figures show the connection options for endoscopes with working channel exemplary.

The following figures show the connection options for endoscopes with working channel exemplary. Please note that depending on the endoscope model and the used accessories the connection options may vary.

TV-Adapter connection to a Camera (optional)

TV-Adapter connection to an endoscope

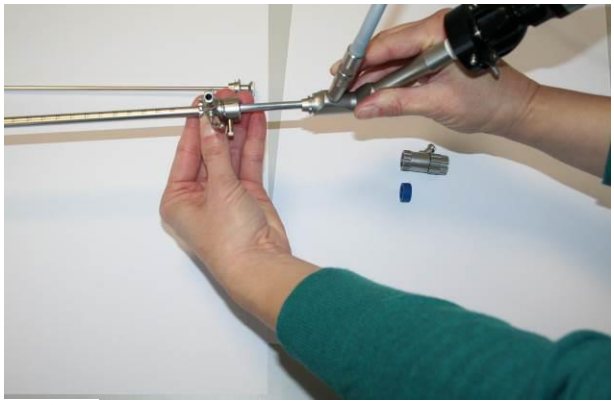


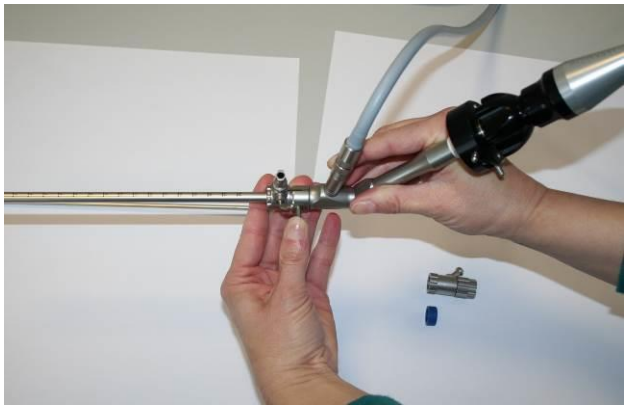
Pay attention to the eyepiece adjustment!

Fibre optics connection

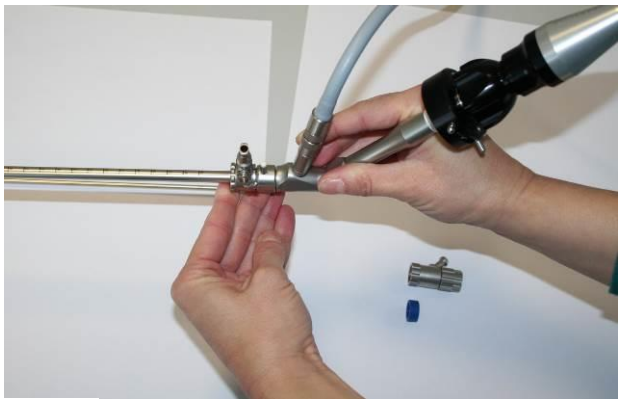
Pay attention to fibre optics adjustment!

Instrument connection (optional)



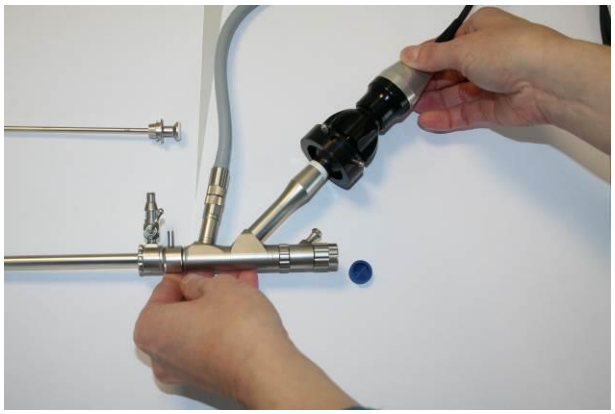


Pay attention to the correct positioning of the instrument to the optics!

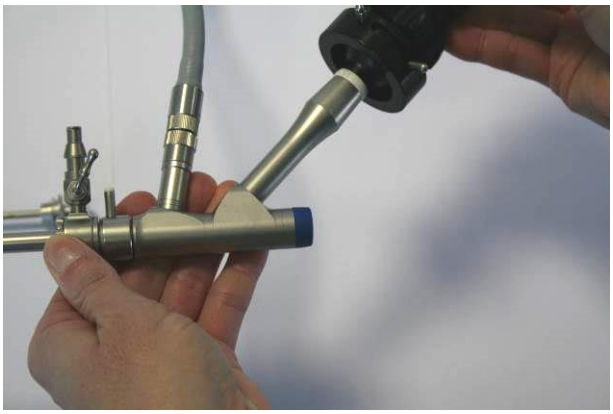


Pay attention to instrument adjustment!

Flushing adaptor with flush valve connection (optional)



Sealing cap connection (optional)



10. Cleaning, disinfection, sterilization

General Principles / preliminary remarks

Note that the manner of processing can have significant impact on the life of endoscopes, the safety of the patient, user and any third parties.
Check your endoscope optics function (such as adequate lighting of the fibres, clear, sharp, bright and round picture) and check your endoscope for possible damage (such as sharp edges, loose parts or visible deformation of materials) before each use.

REDA Instrumente GmbH endoscope optics have to be cleaned, disinfected and sterilized before each use, and this is especially true for first-time use after delivery, because all instruments are supplied non-sterile (cleaning and disinfection after removal of the protective packaging; packaging after cleaning and disinfection, sterilization after packaging). An effective cleaning and disinfection is an essential prerequisite for effective sterilization.

As part of your responsibility for the sterility of the instruments / devices in use always ensure:

- that adequate equipment and product-specific validated procedures for cleaning / disinfection and sterilization are used in principle only,
- that used equipment (disinfector, sterilizer) is serviced and checked regularly and
- that the validated parameters are strictly adhered to in each cycle.

During the application please pay special attention to the collection and separation of soiled / contaminated instruments. Keep them separated and do not place them back on the instrument tray in order to avoid higher contamination of the assembled instrument tray. Clean / disinfect contaminated instruments. Place them back on the instrument tray and sterilize the instrument tray fully stocked afterwards.

The endoscope optics should be cleaned immediately after each use. To avoid adverse effects on the components of the endoscope lens use demineralised water for cleaning if possible only.
An effective cleaning and disinfection is an essential prerequisite for effective sterilization.
Before each use, the endoscope optics has to be cleaned, disinfected and sterilized. Please observe the applicable regulations of your country as well as the hygiene directives applicable to medical practices/hospitals.
This especially applies to the different guidelines / requirements for effective prion inactivation.

Procedure according to DIN EN ISO 17664: Sterilization of medical devices - reprocessing of resterilizable medical devices

10.1. Instructions for reprocessing

A mechanical process (disinfector) should be used for cleaning and disinfection wherever possible. A manual method should be used in case of non-availability of an automated procedure only due to the significantly lower efficacy and reproducibility.
Preparation at the location of use and preparation prior to cleaning should be carried out in both cases.
For endoscope optics provided with irrigation and aspiration stopcocks, these should be disassembled for sterilization. We recommend a **steam sterilization / autoclave process**.

10.2. Limitations and restrictions on reprocessing, durability

Frequent reprocessing of rigid endoscope optics has an impact on their usability. The end of product lifetime is usually determined by wear and damage caused by use.
If damages are found during inspection (please see chapter 10.7 “inspection, maintenance, testing”) the device should be send in for inspection or replacement to our service address.

10.3. Preparation at the location of use

In clinical practise used endoscope optics get might get into contact with corrosive etching agents and drugs.
Endoscopes have to be disconnected from other equipment after use immediately. Surface contamination should be cleaned with a lint-free soft coarse cloth / paper towel.

Please note:
"Dropping" of instruments (optics) during surgery in a collecting container will inevitably lead to damage. Please pay special attention to place down gentle the device after use.

In order to avoid contamination of the environment a closed container (e.g. tub with lid) should be used for transport of the used device to the reprocessing / cleaning room.

10.4. Preparation prior to cleaning

In clinical practise used endoscope optics might get into contact with corrosive etching agents and drugs.
Coarse impurities on the instruments have to be removed directly after use (within 2 h).

A wet clean up should be performed immediately after surgery in order to avoid drying out of blood, protein and other substances on the endoscope and to protect personnel. Dried protein complicates the cleaning, disinfection and sterilization.

Procedure:

- Use running water or a disinfectant solution. The disinfectant should be free of aldehyde (otherwise fixation of blood smears), exhibit proven efficacy (e.g. VAH/DGHM - or FDA approval or CE marking) and suitability for the disinfection of instruments.

- For manual removal of impurities use a soft brush or a clean soft cloth only, which is used for this purpose only. Never use metal brushes or steel wool or other sharp objects.

- Rinse all lumens of the instruments five times using a disposable syringe (minimum volume of 10-50 ml, according to the instrument size).
  Degrease the irrigation/aspiration stopcocks.

Please note:
The disinfectant used in the pre-treatment serves for personal security only. It does not replace the next disinfection step carried out after cleaning.

Caution:
Endoscopes must not be cleaned in an ultrasonic bath.

Caution:
Use approved cleaning agents only.
Do not put the endoscope in alcohol or other corrosive liquids.

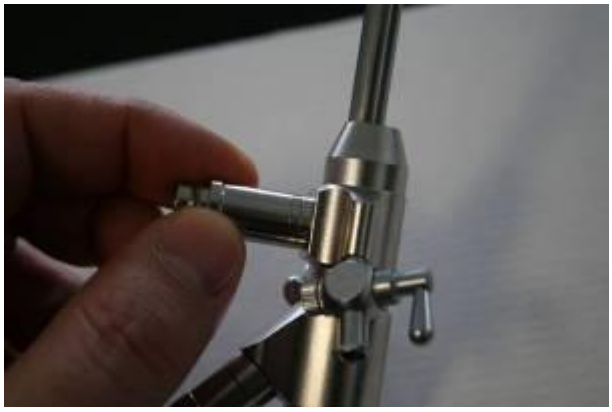
- Remove, if present, all sealing caps, valves, bushing grommets from the endoscope (discard disposable items immediately).

Picture 1

Picture 2

- Remove all adaptors, and if present, all stopcocks from the endoscope (discard disposable items immediately).

Picture 3

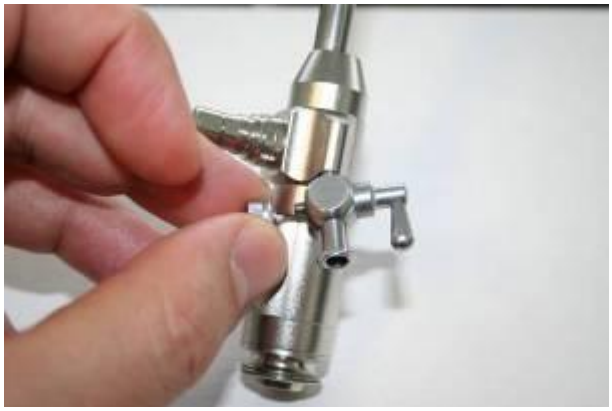


Picture 4

Picture 5

Picture 6

Picture 7



Picture 8

- For endoscopes with working / irrigation channel, preclear working and irrigation channels with brushes, blow through with air and rinse with sterile water afterwards. Dry all channels with compressed air.

Picture 9

Picture 10

- Rinse the endoscope with sufficient deionized water.

10.5. Cleaning and disinfection

Please note!
A mechanical process (disinfector) should be used for cleaning and disinfection whenever possible. Because of the significantly lower efficacy and reproducibility a manual method should be used in case non-availability of an automated procedure only.

The pre-treatment has to be carried out in both cases.

Separate the endoscope from connections (flushing and suction hose, fibre optics cable, and camera head). If endoscopes are equipped with an optical bridge or one-way cock, they have to be removed.

Light guide adapters and screw caps of stopcocks, plug valves, protecting caps of valves and bridges must be removed. Clean coarse contamination of the surface with a damp, soft lint-free cloth.

Cleaning is necessary for hygienic reasons.

Caution:
Endoscopes must not be decontaminated and cleaned in an ultrasonic bath.

Caution:
Use approved cleaning agents. Do not put the endoscope in alcohol.

10.5.1 Mechanical cleaning / disinfection (disinfector / CDD (cleaning and disinfection device)

Endoscopes with and without working / irrigation channel can be cleaned in appropriate cleaning and disinfection devices. Working/ irrigation channels have to be cleaned prior to mechanical cleaning according to chapter 10.4 “Preparation prior to cleaning”.

When selecting the disinfector ensure,
- that the disinfector has been tested for efficacy (e.g. DGHM or FDA approval or CE marking according to DIN EN ISO 15883),
- that if possible a tested program for thermal disinfection is used (A0-value> 3000 or - for older machines - at least 5 min at 90 ° C) (the use of chemical disinfection harbours the risk of disinfectant residues on the instruments),
- that the program used is suitable for the instruments and contains sufficient rinse cycles,
- that only sterile or germ-poor (max. 10 bacteria / ml) and endotoxin-poor (max. 0.25 endotoxin units / ml) water (e.g. purified water / highly purified water) is used,
- that the air used for drying is filtered, and
- that the used disinfector is maintained and checked regularly.

When choosing the cleaning agents ensure,
- that this is basically suitable for the cleaning of instruments made of metals and plastics,
- that - if thermal disinfection is used - in addition a suitable disinfectant with proven efficacy (e.g. VAH/DGHM- or FDA approval or CE marking) is used which is compatible with the cleaning agent ,

- that chemicals used are compatible with the instruments (see chapter 10.11 "material resistance")
- the declared concentrations of the cleaning, and if indicated, disinfection agent must be strictly adhered.

Procedure:
Cleaning / disinfection

1. Disassemble the endoscopes as far as possible (light-guide, handle, irrigation stopcocks).
2. Place the disassembled instruments in the disinfector. Make sure that the instruments do not touch each other.

   If applicable: Connect all lumens of the instruments using the existing connection of the Luer lock flush port to an appropriate irrigation adaptor of the disinfector.
3. Start the program.
4. Remove the instruments from the disinfector at the end of the program.
5. Check and pack the instruments after removal from the disinfector as soon as possible (see chapter 10.7 "control, maintenance and testing" and chapter 10.8 "packaging"), possibly after additional drying in a clean place.

The evidence for the suitability of the instruments/devices for an effective automated cleaning and disinfection has been provided by an independent accredited test laboratory using a disinfector G 7836 CD (thermal disinfection, Miele Cie. GmbH & Co., Gütersloh) and the detergent Neodisher mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above has been considered.

10.5.2 Manual cleaning and disinfection

When choosing the cleaning agent and disinfectant ensure,
- that these are basically suitable for the cleaning and disinfection of instruments made of metals and plastics,
- that the cleaning agent - is suitable for ultrasonic cleaning (no foam) - if applicable,
- that a disinfectant with proven efficacy (e.g. VAH/DGHM- or FDA approval or CE mark) is used and that it is compatible with the cleaning agent,
- that chemicals used are compatible with the instruments (see "material resistance").

Combined cleaning / disinfecting agents should not be used if possible. Only in cases of very low contamination (no visible impurities) can combine cleaning / disinfecting agents are used.

Cleaning and disinfectant concentrations and contact times which are specified by the manufacturer must be strictly adhered.

Use freshly prepared solutions only. Use sterile or germ-poor (up to 10 bacteria / ml) and endotoxin-poor (max. 0.25 endotoxin units / ml) water (e.g. purified water / highly purified water) only. Use filtered air for drying only.

Procedure:
Cleaning

1. Disassemble the instruments as far as possible (fibre optic light-guide, handle, irrigation stopcocks)
2. Place the disassembled instruments air bubble-free in the cleaning bath for a predefined exposure time. Make sure that the instruments covered adequately (possible carefully brushing with a soft brush). Pay attention that the instruments do not touch. Move movable parts several times back and forth.

   If applicable: Rinse all lumens of the instruments five times at the beginning or the end of the exposure using a disposable syringe (minimum volume of 10-50ml (according to the instrument size)) and the existing Luer lock connector and an appropriate irrigation adaptor.
3. Remove the instruments from the cleaning bath and rinse them thoroughly at least three times with water.
4. Check the instruments (see chapter 10.7 "control, maintenance and testing").

Disinfection

5. Place the disassembled, cleaned and inspected instruments for specified contact time in the disinfectant, so that the instruments are sufficiently covered.

   If applicable: Rinse all lumens of the instruments five times at the beginning or the end of the exposure using a disposable syringe (minimum volume of 10-50 ml (according to the size of the instrument)) and the existing Luer lock connector and an appropriate irrigation adaptor.
6. Place the disassembled instruments for a predefined contact time air bubble-free in the cleaning bath, so that the instruments are adequately covered.

7. Remove the instruments from the cleaning bath and rinse them thoroughly at least five times with water.
8. Dry the instruments by using filtered compressed air.
9. Pack the instrument as soon as possible after removal (see chapter 10.8 "packaging", possibly after additional drying in a clean place).

The evidence of the general suitability of the instruments/devices for effective manual cleaning and disinfection has been provided by an independent accredited test laboratory using the detergent Cidezyme / Enzol and the disinfectant Cidex Opa (Johnson & Johnson GmbH, Norderstedt). The method described above has been considered.

10.6. Drying

Endoscopes and if present its working and irrigation channels or cavities have to be dried completely and then stored in appropriate containers.

10.7. Inspection, maintenance and testing

Check all instruments after cleaning respectively cleaning / disinfection for corrosion, damaged surfaces, chips and contamination. Exclude damaged instruments (limited number of reuse, please see chapter 10.12 "reuse"). Adherent contaminations of the optics glass surface and mechanic parts might remain even after careful cleaning and disinfection. Still contaminated instruments have to be cleaned and disinfected again.

Inspection of the mechanics and endoscope surface

• The endoscope surfaces have to be undamaged and in particular free of sharp edges. Check for dents, bends, mechanical / thermal damage caused by high frequency or laser surgery equipment as well as for cracks and spalling**.**

Inspection of the fibre optics

• Hold the distal endoscope end toward a lighted window or a bright ceiling light.

Caution:
Do not use a cold-light source for this test. Direct view into the radiated light from a cold light sources can cause eye damage.

Look at the light guide connector. The individual fibres appear now bright. Move the bright ceiling light facing side slightly up and down. The brightness of the fibres changes a bit. It is uncritical if individual fibres remain dark. A

fracture rate of about 20 to 30% impedes the endoscopic procedures strongly.

- The surfaces of the light entry and exit surfaces should be smooth and clean. Rough surfaces with deposits, tangible or withdrawn individual fibres may lead to insufficient lighting. Further application and processing may result in progressive endoscope damage.

Caution:
Endoscopes with damaged fibre optics should be send in to the manufacturer or an authorized service specialist for checking.

Verification of the proximal and distal areas of glass

- Glass surfaces have to be clean and debris-free. Persistent encrustation, observed during visual examination, should be removed with appropriate cleaning pastes or alcohol-soaked cotton swab or toothpick. Inadequate rinsing of the optics after cleaning and disinfection is often the cause of precipitates.

- Corresponding to the indications appropriate working distance the image has to be sharp and clear. A fuzzy, non-circular, cloudy, foggy, image points out to damage.

Caution:
Endoscopes with indelible persistent encrustations should be send in to the manufacturer or an authorized service specialist for checking.

Caution:
Endoscopes with damaged glass surfaces (e.g. chips), impaired image quality or striking surface damage and deformation may no longer be used. They should be discarded or send in to the manufacturer or an authorized service specialist for checking.

Maintenance:
Put the disassembled endoscopes (fibre optic light guide, handles) together again.

Caution:
Irrigation stopcocks must not be installed on the endoscope prior to sterilization of the endoscope.

Instrument oils may not be used prior to sterilization of the endoscopes.
Greasing the rinsing taps is only permitted after sterilization. Use sterile fat that has a proven biocompatibility only.

Please note:
Endoscopes do not require regular maintenance carried out by the manufacturer.

10.8. Packaging

Pack the endoscope immediately after cleaning, disinfection and maintenance in appropriate packaging material for sterilization.
The packaging of the device protects the content and serves the sterile transport. The packaging material has to match legally required features.
The durability of the material to saturated steam, temperature differences and pressure changes has to be guaranteed.

Sort and place the cleaned and disinfected instruments on the corresponding sterilization tray.

Please pack the respective instruments or sterilization trays in disposable sterilization packaging (single or double pack) and / or sterilization containers, which meet the following requirements:
- DIN EN ISO/ANSI AAMI ISO 11607
- Suitability for steam sterilization (temperature stability up to at least 141 ° C (286 ° F) sufficient vapour permeability)
- Adequate protection of instruments and sterilization packaging against mechanical damage
- Regular maintenance according to the manufacturer's instructions (sterilization container)

The packaging has to be labelled with the date of sterilization, the batch number and expiration date.

10.9. Sterilization

Since the success of sterilization depends on the previous state of cleaning, unclean endoscope optics should never be sterilized! Prior to sterilization convince yourself that the endoscope, the optical surfaces in particular are clean. Make sure that the examination according to chapter 10.7 “control, maintenance and testing” does not indicate to usability limitations of the endoscope.
It is the user’s responsibility to implement the listed sterilization processes in order to achieve the desired and required sterilization effects. Prior to thermal sterilization the optical lenses have to be cleaned with pure alcohol. It is essential to ensure that optical components are not in contact with hot metal surfaces during thermal sterilization as thermal bridges might lead to destruction of materials and leakage of the entire system.

Steam sterilization / autoclaving
The following sterilization procedures should be applied only; other sterilization methods are not permitted:

Steam sterilization
- fractionated vacuum procedure[1] (with sufficient product drying)
- steam sterilizer according to DIN EN 13060 or DIN EN 285
- according to DIN EN ISO 17665-1 ANSI/AAMI ISO 17665-1 (until now: DIN EN ISO 11134 554/ANSI AAMI) validation (valid IQ / OQ (picking) and product-specific performance (PQ))
- maximum sterilization temperature 138 ° C (280 ° F, plus tolerance according to DIN EN ISO 17665-1 ANSI/AAMI ISO 17665-1 (formerly DIN EN ISO 11134 554/ANSI AAMI))
- sterilization time (exposure time at sterilization temperature) at least 20 min at 121 ° C (250 ° F) and at least 3[2] min at 132 ° C (270 ° F) / 134 ° C (273 ° F).

[1] The use of less effective gravitational method is permitted for non-availability of the fractionated vacuum method only. This method may have significantly longer exposure times and has to be validated by the user as to suitability and effectiveness.

[2] and 18 min (for prion inactivation)

The evidence of the general suitability of the instruments/devices for effective steam sterilization has been provided by an independent accredited test laboratory using the steam sterilizer Systec V-150 (System GmbH Labor Systemtechnik, Wettenberg) and the fractionated vacuum procedure. At this, typical conditions in clinics and medical practices as well as the method described above has been considered.

Caution:
Flash sterilization is not permitted.

Caution:
Do not apply hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide, or plasma sterilization.

Caution:
Other settings of autoclave and autoclave cycles might have negative effects on the device or its components.

Caution:
Weight and load of the sterilization material must not be exceeded as it may cause excessive condensate and result in rust damage.

Caution:
When sterilizing multiple instruments in a sterilization cycle, do not exceed the maximum load of the sterilizer.

Caution:
Please note that with increasing number of instruments in a sterilization cycle the success of sterilization will be decreased.
Please refer to the manufacturer's instructions.

Caution:
The dryness of the optics has to be achieved after cooling to room temperature.

Caution:
Please follow the sterilizer manufacturer's instructions, especially the ventilation times after sterilization. The relevant national legal regulations have to be observed.

In thermal sterilization it has be adhered to the cooling time. An acceleration of the cooling time can cause damage to the optical components!

The instructions of the sterilizer manufacturer have to be strictly adhered to.

Advice:

It is the user's responsibility to implement the listed sterilization processes in order to achieve the desired and required sterilization effects.

Note:
Please do not forget to attach the adapter, the one-way cocks and other accessories after sterilization again. The one-way cocks have to be greased after sterilization always. Use approved medical sterile fats only.

10.10. Storage

Optics need to be dried completely.
Store sterilized endoscopes in sterile and appropriate containers always. Store closed containers in a sterile area or cabinet safely protected against heat, radiation, dust, moisture, temperature fluctuations and contamination.

Store non-sterilized endoscopes in appropriate containers always. Store closed containers protected against heat, radiation, dust, moisture, temperature fluctuations and contamination.

10.11. Material resistance

Be careful in the selection of cleaning and disinfecting agents. Ensure that the following components are not contained:
- organic, mineral and oxidizing acids (minimum admissible value pH 5.5)
- strong alkalis (maximum admissible value pH 11, neutral / enzymatic or slightly alkaline detergent recommended)
- organic solvents (for example: alcohols, ethers, ketones, benzenes) oxidizing agents (for example: hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic / halogenated hydrocarbons
- oils

Clean all instruments, sterilization trays and sterilization containers with metal brushes or steel wool.

All instruments, sterilization containers and sterilization trays must not be exposed to temperatures higher than 141 ° C (286 ° F)!

10.12. Reusability

The rigid endoscopes can - with appropriate care and, if undamaged and unpolluted – be used up to 100 times.
Any further reuse or the use of damaged and / or contaminated instruments/devices is the responsibility of the user.
After 100 sterilization cycles the endoscopes must be sent for maintenance in our service center (**Chapter 13**). Following the results from our maintenance, the endoscope can be reused for 50 cycles.

In case of non-observance any liability is excluded.

10.13. Exceptions

For the following list please refer to the reprocessing instructions:
The following rigid endoscopes or parts thereof are, for technical reasons, partly made of chrome-plated parts. Therefore, please do not place them into the thermal disinfector or ultrasonic bath. Use appropriate cleaning and disinfection agents only.
• Interchangeable one-way cocks

Be careful when selecting cleaning and disinfecting agents. Ensure that components described in chapter 10.11. “material resistance" are not contained.

10.14. Additional information

The above listed instructions have been validated by the manufacturer of medical devices for the preparation of a medical device whose reuse is deemed suitable. It is the responsibility of the processor to ensure that the effective reprocessing of instruments/devices is carried out with appropriate equipment, materials and personnel in a reprocessing facility in order to achieve the desired results.
Therefore validation and routine monitoring of the process is required normally. Any deviation from the instructions should be carefully evaluated by the processor for their effectiveness and possible adverse consequences likewise.

11. Trouble shooting

Problem	Possible cause	Remedying of defect
Picture cloudy, foggy	- Glass surfaces contaminated	- Cleaning of glass surfaces according to section 10.5 (manual cleaning)
	- Deposits, coarse encrustations of glass surfaces	- Remove deposits according to section 10.5, check water quality
	- Leaky, defective lens system	- Send in the endoscope for repair
Picture too dark, too small illumination	- Glass surfaces contaminated	- Cleaning of glass surfaces according to section 10.5 (manual cleaning)
	- Deposits, coarse encrustations of glass surfaces	- Remove deposits according to section 10.5, check water quality
	- Wrong light conducting cable connector	- Check light conducting cable connector, replace if necessary
	- Fibre optics defect	- Check fibre optics according to section 10.8
	- Defect light conducting cable, light source	- Check light conducting cable, light source

Problem	Possible cause	Remedying of defect
Yellowish lighting	- Dirty fibre optics	- Cleaning of glass surfaces according to section 10.5 (manual cleaning) If necessary send in the endoscope for service.
	- Dirty, broken light conducting cable	- Check light conducting cable (for example, shine on white surface), replace if necessary
Staining, discolouration	- Inadequate cleaning (for example, remaining protein residues)	- Clean up, possibly with thorough scrubbing
	- Inadequate rinsing of endoscope between treatment phases (especially before sterilization)	- Ensure thorough rinsing between the treatment phases (see section 10.5 and 10.6)
	- Contaminated, too often used disinfectants and cleaning solutions	- Replace disinfection and cleaning solutions regularly
Leakage	- Leaking connections	- Check connections between sealing cap and irrigation stopcock
	- Defect irrigation stopcocks	- Send in the endoscope for repair

12. Warranty, service and repair

The REDA Instrumente GmbH grants 12 months warranty on the function of rigid endoscopes.
The duration of this warranty is limited to claims that are submitted within the specified warranty period from date of purchase of the endoscope, possibly related to repairs, stating the invoice number.
This warranty applies to defects only that are not normal wear and tear, misuse, mishandling, improper or inadequate treatment or due to force majeure. In cases of maintenance or repair, please contact the REDA Instrumente GmbH service or an authorized repair specialists:

In the interest of rapid processing of service requests, we ask you to send in the product with the following information:

- Item number (REF)
- Serial number (SN)
- Detailed fault description

Please use the original packaging for any necessary return of endoscopes or accessories.

Caution:
To protect your personnel and REDA Instrumente GmbH staff, please clean and sterilize the endoscope (possibly related accessories) thoroughly before sending in.

Should this be impossible for urgent reasons, process the endoscope the greatest extend and mark accordingly.

For safety reasons REDA Instrumente GmbH service can decline the repair of soiled or contaminated products.

All warranty and guarantee claims will be lost if the user himself or an unauthorized repair/service facility repairs the endoscope.

Unauthorized opening, repair and modifications of the device release the manufacturer from any liability for the reliability of the system. All warranty will void during warranty period therefore.

The manufacturer is obliged to warrant the function of the device for a period of 12 month.
This warranty is limited to claims made within the warranty period, which begins with the date of purchase**.** This warranty applies to defects that are not normal wear and tear, misuse or mishandling, lack of care or force majeure only. This warranty excludes wear parts.

13. Waste management

The implementation of European legislation into national laws and regulations obliges you to dispose medical devices appropriately.
Dispose the medical devices separately from household/consumer waste. Please dispose medical device waste according to national and local regulations.
Dispose used and contaminated medical equipment at a collection point of a suitable waste authority.
Medical waste is classified according to dangerous goods legislation (for transportation) to the UN number UN 3291 (Medical Waste).
Please dispose medical waste according to national and local regulations.
Packaging material, as long as not contaminated, dispose according to relevant national and local regulations.

Date: 02/2021

REDA
INSTRUMENTE GMBH

TUTTLINGEN/GERMANY