INNOVIEW

Instructions For Use

Rigid Endoscopes

Contents

CE 0483

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Products

These Instructions for Use apply to the specifications of the following products with registration numbers from DIMDS:

Indication	DIMDS-Registration number
Arthroscope	**DE/CA39/00006871**
Hysteroscope	**DE/CA39/00006874**
Laparoscope	**DE/CA39/00006862**
Bronchoscope	**DE/CA39/00006879**
Thoracoscope	**DE/CA39/00006872**
Cystoscope	**DE/CA39/00006875**
Ureterorenoscope	**DE/CA39/00042974**
Otoscope	**DE/CA39/00006865**
Laryngoscope	**DE/CA39/00006878**
Sinuscope	**DE/CA39/00006877**

Read the Instructions for Use carefully before each use and keep them for the user or the relevant specialist in an easily accessible place.

Read the warnings indicated by the safety symbols carefully. Improper use of the products may cause serious injury to patients, users or third parties.

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1 Usage Information

Read the instructions for use carefully and follow the instructions.

1.1 Intended Use

The endoscopes manufactured by Innoview GmbH are intended for the illumination and visualization in diagnostic and therapeutic endoscopic, minimally invasive surgical procedures within the ten (10) indications mentioned above.

The functional capacity of the device can only be guaranteed if it is used as intended. Inappropriate use may damage the device and result in injury to the patient and/or the user and/or third parties.

1.2 Intended User

Endoscopes should only be used by physicians or medical professionals supervised by a physician (medical professionals in accordance with MPBetreibV §4). Adequate training, know-how and experience with the clinical use of endoscopic techniques are required. This also includes reprocessing of the endoscopes.

1.3 Indication for use

Innoview GmbH manufactures rigid endoscopes with different specifications regarding dimensions, length, and field of views. The specifications determine the indication of the respective endoscopes. Innoview rigid endoscopes are CE marked and are indicated for applications in endoscopic, minimally invasive surgical procedures, also for diagnostic procedures which are in conjunction with instruments used in operative arthroscopic procedures as well as; bronchoscopy, hysteroscopy, laparoscopy, laryngoscopy, otoscopy, rhinoscopy, thoracoscopy; ureterorenoscopy; cystoscopy.

The main aim of endoscopic diagnostics and endoscopic surgery is to conserve the tissue and thus improve the preservation of function.

The instructions for use do not present or explain any clinical applications.

1.4 Contraindications

There are no known contraindications directly related to using an endoscope. In principle, the use of rigid endoscopes for a single endoscopic procedure are contra-indicated if endoscopic procedures in general are contraindicated.

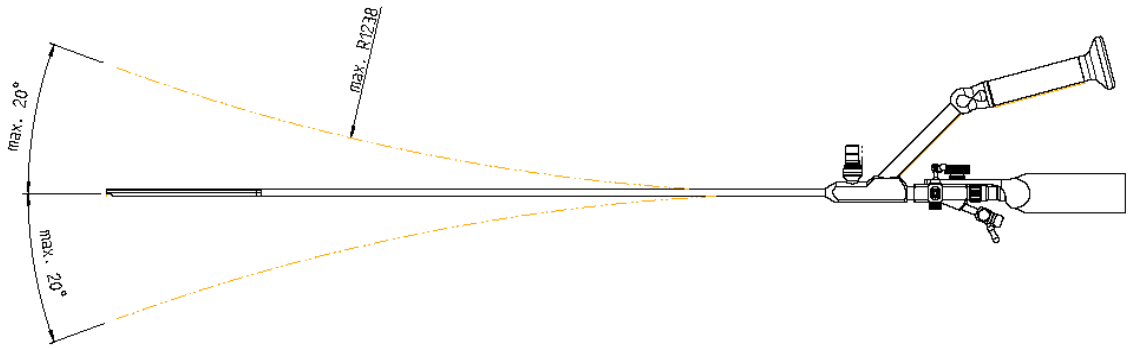
Only materials suitable for use in the medical field are used for the rigid endoscopes. In rare cases, hypersensitised patients may experience pseudo-allergic reactions during prolonged contact. Having this in mind, you must ensure the patient does not have an allergy to silicone, nickel and possibly brass before the endoscopic procedure.

2 Safety Precautions and Warnings

The safety of patients and users is the highest priority when it comes to the correct use of medical devices. To ensure this safety, there are several aspects to keep in mind:

2.1 Safe handling

- Reprocess a brand-new endoscope before initial use and every subsequent use (the device is delivered non-sterile). This also applies to devices that are no longer correctly stored in a sterilisation package that has been opened.
- Before every use, check the endoscope for sharp edges as well as bent, loose or broken parts.
- Check the endoscope for potential damage and verify its function after every reprocessing cycle.
- Damaged endoscopes must be discarded immediately.
- When using the endoscope in a trocar, avoid any bending stress during insertion and removal.
  Semi-flexible endoscopes are designed for minor flexural loads, a deflection of the tubing is admissible up to **max. 20°!**
- Higher bending forces cause permanent deformation and damage of the product (**see diagram below**).



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2.2 Hazard symbols

These instructions for use contain the following hazard symbols that must be observed to ensure safe use:

Symbol	Meaning
	General warning
	Hot surface
	Eye protection to be used
	Hand protection to be used

2.3 Product Specific Warnings

 Risk of burns	**Certain parts of the endoscope may heat up considerably during operation, meaning there is a risk of burns. Wear suitable protective equipment to avoid injury.**
 Risk of infection	**Use of the endoscope in a clinical setting increases the risk of infection. Therefore, every precaution must be taken to prevent infection.**
 Risk of burns	**Due to the release of light energy and thermal energy, the distal end and the fibre-optic connection may heat up considerably during use. Avoid direct contact with fabric and easily combustible materials. If possible, only use the brightness level that is necessary rather than the maximum illumination setting.**
 Risk of burns	**When using HF electrodes, ensure that the active electrode is always in your line of vision and is not in contact with the endoscope or other metal parts of the instrument.**
 Risk of burns	**During laser surgery, avoid using reflecting objects in your working area and never point the laser beam at the endoscope.**
 Risk of infection	**Before initial use and every subsequent use, the endoscopes must be reprocessed in accordance with the instructions for use.**
 Risk of infection	**To avoid infections, all staff must wear the following personal protective equipment: a protective hood to completely cover the hair as well as eye protection, mouth and nose protection, gloves, a protective gown, and suitable moisture-proof shoes. Further guidelines from the institution on hygiene must be followed.**
 Risk of injury	**Never use damaged endoscopes (see chapter 'Visual and functional checks')**
 Wear personal protective equipment.	**When using chemical detergents, the occupational safety instructions on the respective safety data sheet must be observed.**

<u>Please note:</u>
In case an endoscope is damaged during use, it is helpful to have a second sterile backup endoscope available.

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In addition to the regulations mentioned in the instructions for use, it is necessary to observe the country-specific regulations and internal company instructions.

2.4 Symbols on the label

Symbol	Description		
	Manufacturer	InnoView GmbH Bruckmatten 35,79356 Eichstetten	Telephone +49 / (0)7663 / 91425-0 Telefax +49 / (0)7663 / 91425-25 Email mail@innoview.info Web www.innoview.info
	Catalogue number		
	Serial number		
	Date/year of manufacture		
	Non-sterile		
	Consult instructions for use		
CE 0483	Conformity marking with the fundamental requirements with the number of the medical device certification GmbH, Stuttgart, Germany		
UDI	UDI delta matrix code for uniform product identification for medical products + in human readable form.		

2.5 Risk of infection/complications/contraindications

Depending on the area of application, complications that may arise due to the result of the procedure must be considered.
The risk of infection during endoscopic examinations is particularly important.
Risk factors causing an increased risk of infection may be divided into two categories:

Procedure-related risks:

- the nature and extent of tissue damage during therapeutic interventions.
- circumstances surrounding the endoscopic intervention (emergency or planned procedure).
- incompetence and low experience of the examiner/user.
- incorrect cleaning and disinfection of the endoscopes and accessories.

Patient-related risks:

- patients with impaired immune status or immunosuppression (HIV, leukaemia, lymphoma, immunosuppressive therapy, advanced liver or kidney disease, old age).
- presence of specific sources of infection or anatomical conditions.
- conditions facilitating the adhesion of bacteria in the organism (heart valve defect, heart valve replacement, endoprostheses, permanent intravenous catheters).

Endoscopic examinations may cause endogenous displacement of the body's own microorganisms, followed by bacteraemia. In this context, the national and international recommendations regarding prophylactic administration of antibiotics before certain interventions must be observed (ESGE Guidelines).

2.6 Service

To ensure the safety of users and patients, maintenance and repair work on the endoscope should only be carried out by the manufacturer and specialist companies authorised by the manufacturer using original spare parts.
To avoid transport damage, use the original packaging when shipping the devices.

2.7 Hygiene

For safety reasons, thoroughly clean, disinfect and sterilise any defective endoscopes before shipping them back to us. If the shipment is not accompanied by any proof, we reserve the right to reprocess the device at the owner's expense.

2.8 Storage

The packaging must guarantee optimum protection of the sterile endoscopes during transport and storage. The requirements of the relevant standard DIN EN ISO 11607 must always be complied with.

2.9 Visual and functional checks

Examination for:

- external damage (shaft deformation, dents, or sharp edges).
- residues of detergents or disinfectants. Condition of the three optical surfaces – 1. Lens window, 2. Ocular window, 3. Fibre-optic connection - using reflecting light or a magnifier (smooth, clean, and intact).
- optimum image quality (a bright and clear image with high definition).
- loss-free light transmission from the fibre-optic connection to the light output (Possible comparison with a new device).
- free passage of the endoscope's working channels.
- material changes on the metal and plastic surfaces.
- legibility of the device labelling.

Defective endoscopes must be taken out of service immediately.

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2.10 Material resistance

Detergents and disinfectants can cause considerable damage to endoscopes. These agents must not contain the following components:

- organic acids, mineral acids, and oxidising acids (minimum pH 5)
- strong alkalis (maximum pH 10)
- phenols or halogens (such as chlorine, iodine, bromine)
- aromatic/ halogenated hydrocarbons

Agents used in combination must be compatible with each other. Neutral or slightly alkaline detergents are recommended.

- Never forcefully accelerate the endoscope cooling process (for instance with cold water); sudden changes in temperature may destroy the optical components.
- The endoscopes may only be exposed to temperatures below 137°C (279°F).
- Never use abrasive detergents, steel wool or metal brushes for cleaning.
- Never clean endoscopes in an ultrasonic bath (damage to the optical system).
- Never use hot air sterilisation, flash sterilisation, or radiation sterilisation.

2.11 Service life

If the instructions for use are observed, the number of reprocessing cycles has only a minor effect on the service life of the products. The reprocessing methods as well as the products used for this purpose have a significant impact on the service life. When used as intended, no damage to the product is expected. Thus, visual, and functional checks in accordance with section 2.9, must be performed before every use. If the device is defective, it must be taken out of service immediately.

*As proof of the service life of the endoscopic optics, an endoscopic optic of the type "Arthroscope 4.0mm, 0°, 175mm" was subjected to all steps of cleaning and disinfection according to the instructions for use as part of the reprocessing in the laboratory. This was validated and documented as part of the project "**P201702**_Cleaning endurance test (cleaning, disinfection and sterilization)".and the results proved to have no negative effect on the device.*

3 Operating / Maintenance Instructions

3.1 Rigid endoscopes

InnoView manufactures different types of endoscopes.

Models with working channels particularly, the (inner lumen) require very thorough cleaning to prevent the build-up of deposits in the delicate channels.

During cleaning and disinfection, all detachable endoscopic attachments must be removed to uncover any concealed surfaces. This is the only way to ensure adequate reprocessing.

3.2 Fibre-optic connection

Risk of infection	**Be careful when dismantling contaminated endoscopes.**

Disassembly:

Unscrew adapters ① and ② and remove them from the endoscope.
In case of working channels – if applicable –

- Remove the sealing cap.
- Unscrew the valve body.
- Remove the valve.

- Ventile valves and valve caps are disposable items for single use. Multiple use is not intended and is not validated.

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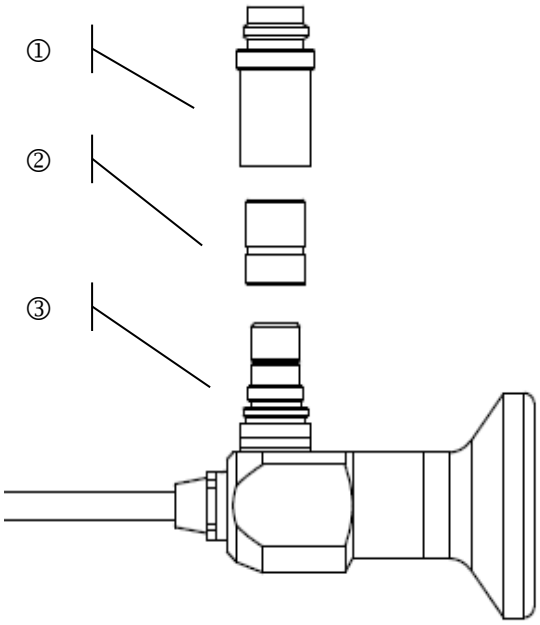
Assembly:

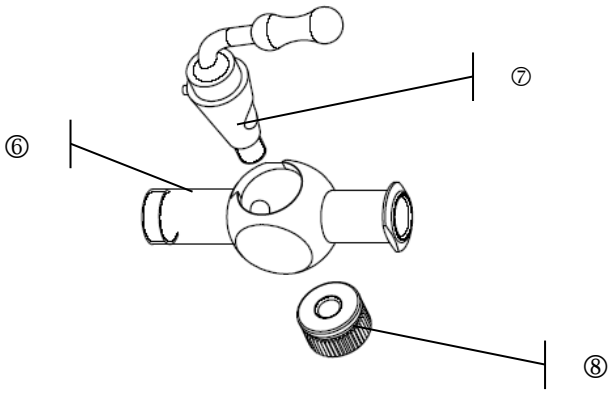
- Screw on adapters ① and ② adapter.
- In case of working channels – if applicable –
  - Insert a new valve.
  - Screw on the valve body.
  - Attach the sealing cap.

[replacement valves are available from InnoView]



① Storz® / Aesculap® / Olympus® adapter
② Wolf® adapter
③ ACMI® connection

3.3 Stopcocks



⑥ Stopcock
⑦ Plug valve
⑧ Spring cap

Disassembly:

- Unscrew the spring cap ⑧ and remove the plug valve ⑦ from the stopcock ⑥.

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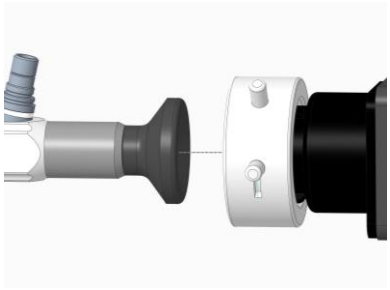
Assembly:

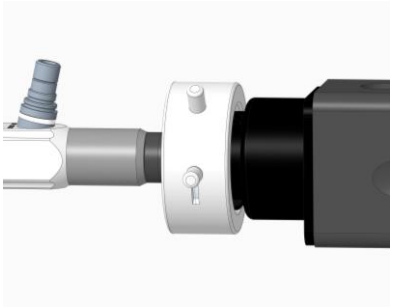
- Prior to every sterilisation, the plug valve ⑦ must be treated with a lubricant that is approved for the purpose in question and the respective reprocessing technique. This is to provide corrosion protection and to retain the functional capacity.
- When inserting the plug valve, make sure that the guide pin runs smoothly in the guide and the lever points toward the opening when it is open.
- Screw the plug valve ⑦ into the spring cap ⑧.

- Check the stopcocks to see whether they function correctly.

3.4 Camera head



(1)



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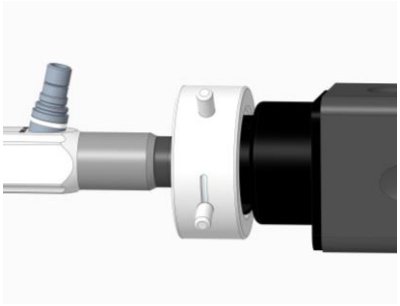
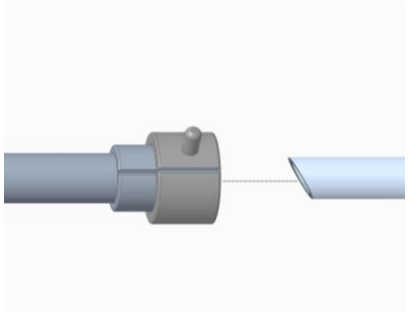


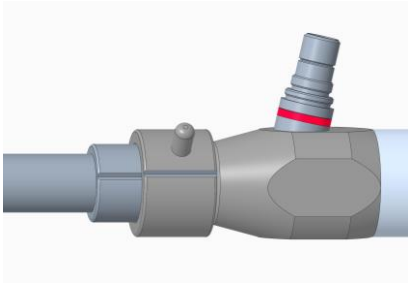
(3)

- Unlock the camera head (1) as shown in the picture and put it on the eyepiece funnel (2) and lock it (3). Due to the different compatible systems, the instructions for use from the manufacturer must be followed.
  The eyepiece funnel for coupling the camera head complies with the ISO/TS 18339 specifications.

3.5 Instrument coupling



(1)



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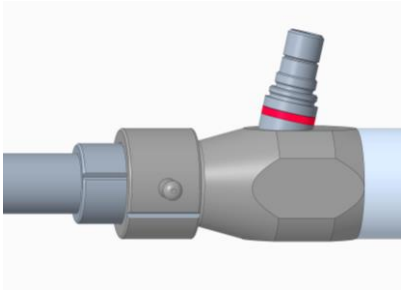

(3)

- Unlocking the camera head (1), placing it on the eyepiece funnel (2) and locking the camera head (3). as shown in the picture. Due to the different systems, the instructions for use from the instrument manufacturer must be followed.

Due to the different compatible systems, the manufacturer's instructions for use must be observed. The eyepiece funnel for coupling the camera head complies with ISO/TS 18339 specifications.

4 Reprocessing

4.1 Basic principles

The endoscopes must be cleaned, disinfected, and sterilised before every use, especially brand-new devices, since all endoscopes are delivered in a non-sterile condition (cleaning and disinfection after removing the transport packaging;(sterilisation in suitable sterilisation packaging) is very important. The following conditions must be met to ensure effective reprocessing:

- Cleaning and reprocessing immediately after use (max. 1h after the last use) to avoid encrustation and corrosion during dry removal. If they are expected to be left for a while, the optical systems are to be kept in a detergent/disinfection solution to stop them drying up.
- Wet removal should be done only in non-corrosive solutions at the specified concentration.
- Determining the configurations for the handling of the used devices and compliance with the manufacturer’s instructions.
- Regular maintenance and checking of the used devices.
- Validated procedures for all reprocessing steps.
- Adherence to the standardised parameters for each reprocessing cycle.
- Verifying the disinfection and sterilisation efficiency based on corresponding indicators.

In addition, the applicable national hygiene regulations and
the local guidelines of the doctor's practice or hospital must be observed,
especially the various requirements regarding effective prior inactivation.

4.2 Cleaning and disinfection

The mechanical method described here for the washer-disinfector should be given priority.

Effective cleaning and disinfection are an essential prerequisite for effective sterilisation.
The pre-treatment must always be carried out separate from this. (section 4.3- “Pre-treatment”).

 Risk of infection	**Only use detergents that have been tested and approved according to the respective national hygiene regulations and the local guidelines.**
 Risk of infection	**In endoscopes with a channel system (rinsing and/or working channels), the inner lumens must be carefully cleaned and disinfected to prevent fixation and preservation of organic residues by aldehyde.**
 Risk of infection	**If not cleaned properly, there is a risk of infection. Spraying of germs must be prevented.**
 Risk of infection	**To avoid infections, all staff must wear the following personal protective equipment: a protective hood to completely cover the hair as well as eye protection, mouth and nose protection, gloves, a protective gown and suitable moisture-proof shoes.** **Further guidelines from the institution on hygiene must be followed.**

4.3 Pre-treatment

Working steps immediately after application:

- Remove all fibre-optic adapters before reprocessing! If applicable, disassemble all stopcocks (see section 3.3 ‘Assembling/disassembling the stopcocks’).
- All cleaning steps must be performed below the surface of the liquid to prevent squirting of contaminated liquids.
- Rinse thoroughly with cold running purified water (max. 20°C) to remove coarse impurities from the endoscopes.
- Remove adhering contaminations with a mild detergent solution approved for medical endoscopes (see chapter ‘Material resistance’).
- All empty channels must be rinsed at least five times using a disposable syringe (with a volume of at least 50 ml).
- Never use abrasive cleaners or metal brushes and avoid excessive force when manually removing contaminants.
- Finally rinse the endoscopes with purified water (demineralised water in accordance with DIN EN ISO 15883-1) for one minute to prevent staining and pitting.
- Dry fully with compressed air (especially cavities) or a lint-free cloth.

Evidence of the basic suitability of the endoscopes for effective cleaning was provided by an independent accredited test laboratory using Neodisher Mediclean detergent (Dr.Weigert GmbH & Co. KG, 20539 Hamburg) with an immersion time of 5 minutes in a 0.5% solution as part of the validation of the mechanical reprocessing technique (project number 12336). In doing so, the procedure described above was used.

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4.4 Manual cleaning & disinfection

The mechanical method described below for the washer-disinfector should be given priority.
If no corresponding device is available, a manual procedure can also be used. However, the lower effectiveness and reproducibility must be considered here. As well as this, the manual cleaning and disinfection procedure must be secured under the responsibility of the user (additional product-specific and procedure-specific standardisation).

The pre-treatment must always be carried out separate from this.

Procedure:

- The disinfectant solution is prepared according to the instructions from the manufacturer of the chemical. Subsequently, the pre-treated devices are inserted completely covered by the solution.
- You may only use disinfectants that have been approved for endoscopes (see also section 2.10: Material resistance) and where their effectiveness has been tested. In this case, the disinfectant manufacturer's specifications regarding concentration, temperature, service life and application duration must be observed depending on the product. Cavities must be filled, (free of bubbles) and, if necessary, rinsed (towards the distal end).
- Small parts such as detachable stopcocks, fibre-optic adapters and rubber parts must be dismantled and fitted separately.
- Finally, the device must be rinsed sufficiently with demineralised water or sterile water to prevent the chemicals from adhering to the device even more.
- Then dry the device immediately using a compressed air gun and lint-free cloths.

Evidence of the basic suitability of the endoscopes for effective manual disinfection was provided by an independent accredited test laboratory using Bomix® plus disinfectant (PAUL HARTMANN AG, 89522 *Heidenheim) with an immersion time of 15 minutes in a 1% solution as part of the validation of the reprocessing technique (project number 12337). In doing so, the procedure described above was used.*

4.5 Mechanical cleaning + disinfection

Requirements for suitable cleaning and disinfecting equipment:

- Program selection for optimised endoscope cleaning with enough rinsing cycles. The manufacturer's specifications regarding loading of the receiving wash basins must not be exceeded.
- The device must be equipped with suitable racks and connections that allow safe cleaning and disinfection with the enabled program. This must be verified by the operator of the washer-disinfector.
- Controlled thermal disinfection program (A_0 value > 3000 or at least 5 min. at 90°C) with proven efficacy.
- Regular maintenance and proven efficacy. The devices must meet the EN ISO 15883-1:2014 requirements. Country-specific requirements must be observed.
- Final rinsing with cold demineralised water (in accordance with DIN EN ISO 15883-1) for at least 120 sec.
- Controlled drying phase. The program must be verified by the operator of the washer-disinfector.

With chemo-thermal disinfection there is a risk of disinfectant residues remaining on the endoscopes.
A quarterly microbiological check for quality assurance of the reprocessing method is recommended.

Requirements for suitable detergents/disinfectants:

- Approval for the cleaning of endoscopic instruments with proven efficacy
- Compatibility of the used detergents/disinfectants (especially in the case of chemo-thermal disinfection).
- Listed chemicals (see section 2.10 - 'Material resistance') should be avoided.
- If powders are used, it must be ensured that they have been safely and completely dissolved before cleaning. Potential residues may, for instance, block the inner lumens.
- Use enzyme-based agents with a neutral pH value.

Increased chloride concentrations in the feed water cycle may damage the material (pitting). The rinsing water must be carefully reprocessed to prevent recontamination.
The manufacturer's instructions for the cleaning agent and, if applicable, disinfectant regarding concentration, temperature and exposure time must be observed.

Procedure:

- Safely attach the endoscopes to the inserts of the disinfection unit. Avoid rinse residue and do not allow the endoscopes to be in contact with other instruments.
- Open the stopcocks – if applicable – and connect all lumens of the endoscopes to the special inserts with a rinsing system to guarantee complete and thorough rinsing of all cavities.
- Do not overload the disinfection unit.
- Start the program.

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- After completing the program, check whether the program was run in accordance with the specifications and whether all control parameters are met.
- As soon as the automatic cleaning cycle is completed, immediately remove the endoscopes from the disinfection unit to avoid corrosion. Make sure your hands are disinfected or you are wearing fresh disposable gloves. Avoid accelerated cooling (for instance in water).
- Dry the tubes and channels with compressed air and, if necessary, wipe the devices dry with a lint-free cloth.
- Checking and maintenance (see section 4.6. below).
- Packaging the endoscopes (see chapter 'Packaging').

4.6 Checking

After cleaning and disinfection, the endoscope can then be assembled (see section:3 'Assembly instructions'). The following checks must be carried out:

- Visual check of the three optical surfaces (see section 2.9 :**. The requirements of** the relevant standard DIN EN ISO 11607 must always be complied with.

- **2.9 Visual and functional checks**), and, if necessary, cleaning with an alcohol-soaked swab (70%). Deposits on the light guide can cause considerable loss of light and may also affect the optical system.
- Checking the surfaces for corrosion, wear, general damage, sharp edges, or chipping in the distal area.
- If there are still any residues or contaminations left, repeat the disinfection after manual pre-treatment.
- Damaged endoscopes must be discarded or can be sent to Innoview GmbH for inspection/repair.

4.7 Maintenance

- After each cleaning and disinfection cycle, the stopcocks must be lubricated before sterilisation (see section 3.3 'Assembling/disassembling the stopcocks').
- Only lubricants with verified biocompatibility should be used. The lubricant must be suitable for this application and approved for steam sterilisation.
- Cleaning the optical surfaces with 70% alcohol (ethanol, isopropanol) prevents deposits from setting/burning in.

Evidence of the basic suitability of the endoscopes for effective automatic cleaning and disinfection was provided by an independent accredited test laboratory using the Neodisher Mediclean cleaner (0.5% solution, 5min immersion) for pre-cleaning and then the Lautenschläger ZentraCert disinfector (thermal disinfection), and the Neodisher Mediclean detergent (Dr. Weigert GmbH & Co. KG, Hamburg) in the Miele PG 8535 washer-disinfector (cleaning, Miele Professional, Princeton), as part of automatic reprocessing validation (project number 12336). In doing so, the procedure described above was used.

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5 Sterilisation

Proceed as follows before sterilising the components.

5.1 Preparation and packaging for sterilisation

- Open all stopcocks if applicable.
- Only use disposable sterilisation packaging and/or sterilisation containers that are suitable for steam sterilisation (sufficient temperature resistance, air, and steam permeability according to DIN EN ISO 11607).
- The packaging must guarantee optimum protection of the sterile endoscopes during transport and storage. The storage location must be dust-free, low on germs, dry, dark, and free from temperature fluctuations.
- Reusable sterilisation containers must be maintained in accordance with the manufacturer's specifications; they must offer secure fixation of the endoscopes and protect them from damage.

Since the suitability of the packaging has a significant impact on the sterilisation result, this must be checked when defining the sterilisation parameters.

Make sure that only completely cleaned, well maintained, dry and disinfected devices are being sterilised in the user's process cycle.

The following sterilisation procedure was validated for its germicidal effect:

5.2 Steam sterilisation

- Fractionated vacuum process (with 3x pre-vacuum) for endoscopes with and without an empty channel.

Steam sterilisation conditions:

- Sterilisation temperature: from min. 132°C to max. 134°C (273°F); in accordance with DIN EN ISO 17664
- Sterilisation time at sterilisation temperature: 3-5 min at 132°C (270°F)
- Steam steriliser, approved according to DIN EN 13060 and DIN EN 285 and tested according to DIN EN ISO 17665
- Observe the cooling time. Accelerated cooling (e.g., with cold water) may destroy the endoscopes.
- According to the KRINKO/BfArM-RKI recommendations, saturated steam sterilization at 134°C/5 min is recommended.

The steriliser manufacturer's instructions regarding preparation, packaging and execution of the sterilisation process must be carefully observed.

Other sterilisation procedures are prohibited (see section 2.10 'Material resistance').

Evidence of the basic suitability of the endoscopes for effective steam sterilisation was provided by an independent accredited test laboratory using Lautenschläger ZentraCert (F. & M. Lautenschläger GmbH & Co. KG, Köln) in a half-cycle process (1.5 min/132°C) within the scope of the validation of the sterilisation technique (project number 12338). Typical conditions in clinics and medical practices were assumed and the endoscopes were tested under laboratory conditions in a half-cycle process. This also pertains to other parameters with a longer holding time and/or higher temperature.

6 Warranty

Innoview rigid endoscopes comes with 24 months (2 years) warranty.

7 Repair / Maintenance

Innoview GmbH offers professional repair of damaged endoscopes to its customers and only repairs endoscopes from its own production.
Repairs and modifications performed by unauthorized persons or professionals will lead to expiration of warranty**.**
Using damaged and/or contaminated endoscopes is the user's responsibility. Failure to observe these instructions for use will result in the warranty becoming null and void. We accept no liability for improper handling, incorrect or inadequate reprocessing or unauthorised repair.

For reasons of hygiene and infection prevention, endoscopes must be cleaned, disinfected and where necessary, sterilized before they are sent in for repairs.
Innoview GmbH reserves the right to return contaminated devices to the sender.

8 Serious Incidents

Professional operators and users (physicians) as well as persons who hand over medical devices to end users for their own use in the course of their professional or commercial activities or in order to comply with legal requirements or obligations are obliged under the provisions of the Medical Devices User Reporting and Information Ordinance **(MPAMIV**) to report incidents that have occurred in Germany (under certain conditions also incidents that have occurred in third countries) to the Federal Institute for Drugs and Medical Devices or, in accordance with its area of responsibility, to the Paul Ehrlich Institute (PEI).

Incidents are malfunctions, failures or changes in properties or performance or inaccuracies in the labelling or instructions for use of a medical device that have led, could have led , or could lead directly or indirectly to the death or serious deterioration of the health status of a patient, user or other persons.

The notification shall be addressed to:
Federal Institute for Drugs and Medical Devices
Medical Devices Department- Kurt-George-Kiesinger
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