

INSTRUCTION FOR USE

Precisely yours,



Rigide autoclavable endoscopes



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1 Applicable standards and guidelines

Hygiene Requirements for the Reprocessing of Medical Devices –

Date: 10/2012 – KRINKO/RKI/BfArM -

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Aufb_MedProd/Aufb_MedProd_node.html

DIN EN ISO 17664:2018-04: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017)

DIN EN ISO 15883-1:2014-10: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006 + Amd 1:2014); German version EN ISO 15883-1:2009 + A1:2014

DIN EN 13060:2019-02: Small steam sterilizers; German version EN 13060:2014+A1:2018

DIN EN 285:2016-05: Sterilization - Steam sterilizers - Large sterilizers; German version EN 285:2015

DIN EN ISO 17665:2006-11: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006); German version EN ISO 17665-1:2006

DIN EN ISO 11607:2017-10: Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006 + Amd 1.:2014); German version EN ISO 11607-1:2017

MPBetreibV: Medizinprodukte-Betreiberverordnung (Medical Device Operating Regulations), most recently amended by Art. 9 V, 29 Nov. 2018

DIN EN ISO 15223-1:2017-04: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

2 Safety

The safety of patients and users is the highest priority when it comes to the correct use of medical devices. In order 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.
- Endoscopes may 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.
- Read the instructions for use carefully and follow the instructions.

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2.2 Hazard symbols

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

 Risk of burns	<p>Certain parts of the endoscope may heat up considerably during operation, meaning there is a risk of burns. Wear suitable protective equipment in order to avoid injury.</p>
 Risk of infection	<p>Use of the endoscope in a clinical setting increases the risk of infection. This is why every precaution must be taken to prevent infection.</p>
 Risk of burns	<p>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 really necessary rather than the maximum illumination setting.</p>
 Risk of burns	<p>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.</p>
 Risk of burns	<p>During laser surgery, avoid using reflecting objects in your working area and never point the laser beam at the endoscope.</p>
 Risk of infection	<p>Before initial use and every subsequent use, the endoscopes must be reprocessed in accordance with the instructions for use.</p>
 Risk of infection	<p>In order 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.</p>
 Risk of injury	<p>Never use damaged endoscopes (see chapter 'Visual and functional checks')</p>

 <p>Wear personal protective equipment</p>	<p>When using chemical detergents, the occupational safety instructions on the respective safety data sheet must be observed.</p>
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Please note:

In case an endoscope is damaged during use, it is helpful to have a second sterile backup endoscope available.

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

2.3 Symbols on the label

Explanation of symbols used:	
	Symbol for "Batch Code"
	Symbol for "Catalog Number"
	Symbol for "Caution, consult accompanying documents"
	Symbol for "Non-Sterile"
	Symbol for "Manufacturer"
	Symbol Date/year of manufacture
	Conformity to the essential requirements with notified body number of DQS Medizinprodukte GmbH, Frankfurt, Germany

2.4 Risk of infection/complications/contraindications

Risk of infection/complications

Depending on the area of application, complications that may come about as a result of the procedure must be taken into account.

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 elective procedure);
- competence and experience of the examiner/user;
- correct 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 particular 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 bacteremia. In this context, the national and international recommendations regarding prophylactic administration of antibiotics before certain interventions must be observed (ESGE Guidelines 1998).

- Endoscopes may only be used by physicians or medical staff supervised by a physician. Adequate training, know-how and experience with the clinical use of endoscopic techniques are required. Read the instructions for use carefully and follow the instructions.

Contraindications

There are no known contraindications directly related to using an endoscope. In principle, using rigid endoscopes is contraindicated for the individual endoscopic procedures if endoscopic processes are generally contraindicated.

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

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2.5 Service

In order to ensure the safety of users and patients, maintenance and repair work on the endoscope may only be carried out by the manufacturer and specialist companies authorised by the manufacturer using original spare parts.

In order to avoid transport damage, use the original packaging when shipping the devices.

2.6 Hygiene

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

2.7 Storage

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.

2.8 Visual and functional checks

Checking 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.

If the device is defective, it must be taken out of service immediately.

In many cases the device can be repaired as described in chapter 2.5 Service.

2.9 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 cleaners are recommended.

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- 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.

2.10 Service life

As long as 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 chapter 2.8 must be performed before every use. If the device is defective, it must be taken out of service immediately.

3 Definitions

3.1 Indications and area of application

Endoscopes are used for illumination and visualisation during diagnostic and therapeutic-surgical interventions in the following endoscopic procedures:
arthroscopy; bronchoscopy; hysteroscopy; laparoscopy; laryngoscopy; otoscopy; sinuscopy; thoracoscopy; urethroscopy; 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.

3.2 Rigid endoscopes

INVIDIA Medical manufactures different types of endoscopes.

Models with working channels (inner lumen) in particular require very thorough cleaning so as to prevent the buildup of deposits in the delicate channels.

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

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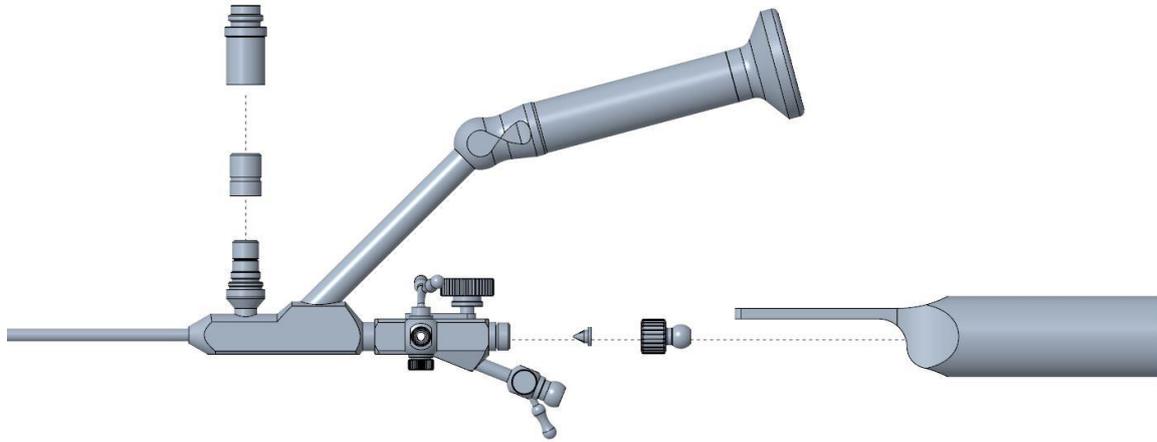


Figure 1: Endoscope with an insertion sheath for guided entry of a lithotripsy generator

4 Use

4.1 Intended use

The endoscopes were developed and manufactured for the specified purpose only. Thus, the functional capacity of the device can only be guaranteed if it is used as intended. Inappropriate use may damage the device and cause personal injury to the patient and/or the user.

4.2 Qualification

- Endoscopes may 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.
- Read the instructions for use carefully and follow the instructions.

4.3 Assembly/disassembly

 Risk of infection	Be careful when disassembling contaminated endoscopes.
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Fibre-optic connection

Disassembly:

Unscrew adapters ① and ② and remove them from the endoscope.

In case of working channels – if applicable –

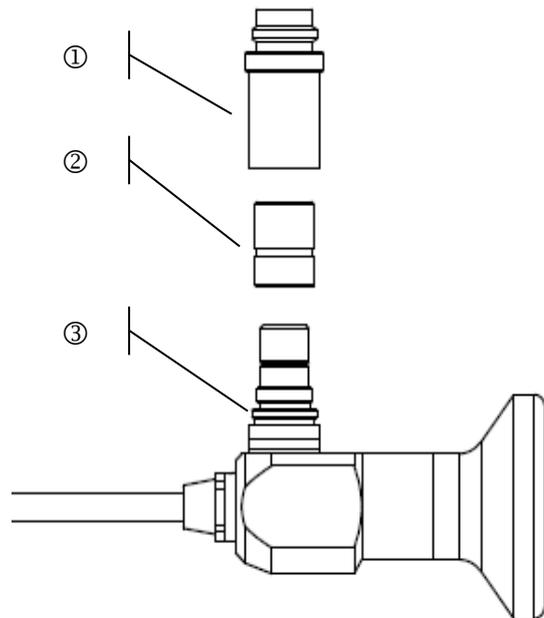
- Remove the sealing cap.
- Unscrew the valve body.
- Remove the valve.
- Duckbill valves and valve caps are disposable items for single use. Multiple use is not intended and is not validated.

Assembly :

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- 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 INVIDIA]



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

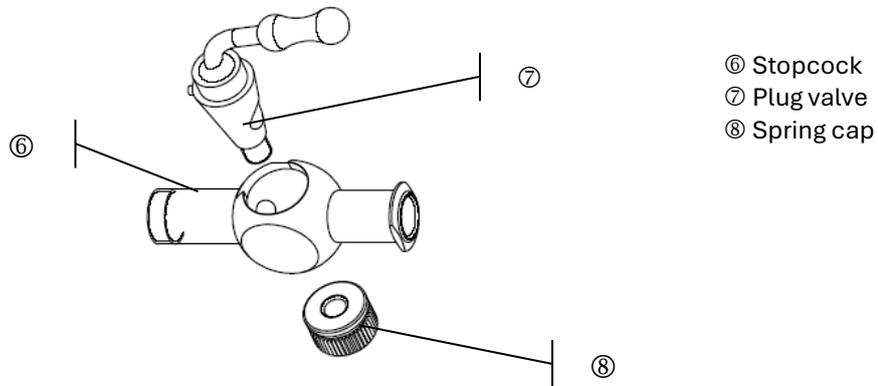
Stopcocks

Disassembly:

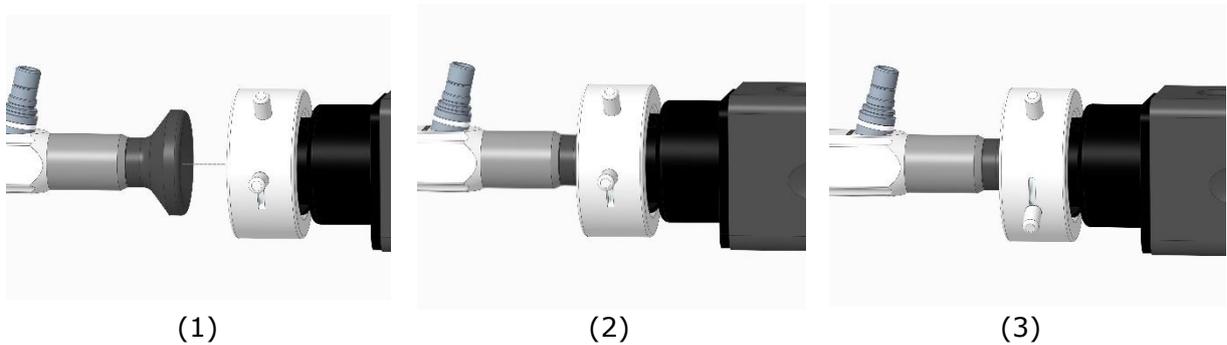
- Unscrew the spring cap ⑧ and remove the plug valve ⑦ from the stopcock ⑥.

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.

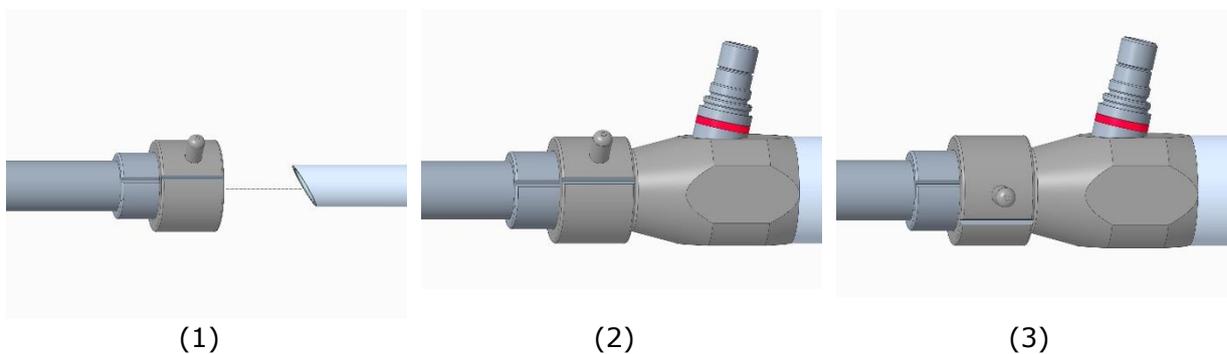


Camera head



- 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.

Instrument coupling



- The endoscope is inserted (2) and locked (3) into the unlocked instrument (1) as shown in the picture. Due to the different systems, the instructions for use from the instrument manufacturer must be followed.

5 Reprocessing

5.1 Basic principles

The endoscopes must be cleaned, disinfected and sterilised before every use, especially brand new devices, since all endoscopes are delivered in non-sterile condition (cleaning and disinfection after removing the transport packaging; sterilisation in suitable sterilisation packaging).

The following conditions must be met to ensure effective reprocessing:

- Cleaning and reprocessing immediately after use (max. 1h after the last use) so as 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 so as to stop them drying up.
- Wet removal 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 prion inactivation.

5.2 Cleaning and disinfection

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

Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

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

 Risk of infection	<p>Only use detergents that have been tested and approved according to the respective national hygiene regulations and the local guidelines.</p>
 Risk of infection	<p>In endoscopes with a channel system (rinsing and/or working channels), the inner lumens must be carefully cleaned and disinfected in order to prevent fixation and preservation of organic residues by aldehyde.</p>
 Risk of infection	<p>If not cleaned properly, there is a risk of infection. Spraying of germs must be prevented.</p>
 Risk of infection	<p>In order 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.</p>

Pre-treatment

Working steps immediately after application:

- Remove all fibre-optic adapters before reprocessing! If applicable, disassemble all stopcocks (see chapter 'Assembling/disassembling the stopcocks').
- All cleaning steps must be performed below the surface of the liquid in order 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 so as to prevent staining and pitting.
- Dry fully with medical compressed air (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.

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 taken into account 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 chapter 2.9 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 completely 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.

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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.

Mechanical cleaning + disinfection

Requirements for suitable washer-disinfectors:

- Program selection for optimised endoscope cleaning with a sufficient number of rinsing cycles. The manufacturer's specifications regarding loading of the receiving baskets 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 chapter 'Material stability') 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 so as to prevent recontamination.

The manufacturer's instructions for the cleaning agent and, if applicable, disinfectant regarding concentration, temperature and exposure time must be observed.

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Procedure:

- Safely attach the endoscopes to the inserts of the disinfection unit. Avoid rinse residue and do not allow the endoscopes to come into contact with other instruments.
- Open the stopcocks – if applicable – and connect all lumens of the endoscopes to the special inserts with a rinsing system in order to guarantee complete and thorough rinsing of all cavities.
- Do not overload the disinfection unit.
- Start the program.
- 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 so as 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 chapter 2.8).
- Packaging the endoscopes (see chapter ‘Packaging’).

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.

Checking

After cleaning and disinfection, the endoscope may be attached (see chapter ‘Assembly instructions’). Now the following checks have to be carried out:

- Visual check of the three optical surfaces (see chapter 2.8 Visual and functional checks), and, if necessary, cleaning with an alcohol-soaked swab (70%). Layers on the fibre optics may cause considerable loss of light and may also affect the optical system.
- Checking the surfaces for corrosion, wear, sharp edges or chipping in the distal area.
- If there are still any residues or contaminations left, repeat the disinfection after manual pretreatment.
- Damaged endoscopes must be discarded.

Maintenance

- After each cleaning and disinfection cycle, the stopcocks must be lubricated before sterilisation (see chapter ‘Assembling/disassembling the stopcocks’).
- Only lubricants with verified biocompatibility may 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.

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5.3 Sterilisation

Proceed as follows before sterilising the components.

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 considerable effect on the sterilisation result, this should have been 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:

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 17664:2018-04
- Sterilisation time at sterilisation temperature: 3 min at 132°C (270°F)
- Steam steriliser, approved according to DIN EN 13060:2019 and DIN EN 285:2016 and tested according to DIN EN ISO 17665:2006.
- Observe the cooling time. Accelerated cooling (e.g. with cold water) may destroy the endoscopes.
- According to the KRINKO/BfArM-RKI recommendation (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**), saturated steam sterilisation at 134°C/5 min is recommended

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.

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

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Other sterilisation procedures

Sterrad

The endoscopes were successfully tested in a low-temperature plasma procedure (**STERRAD System 100S, 200, 50, NX, 100NX**) for the resistance of the materials used and their microbiological efficiency. The basic suitability of the endoscopes and the effectiveness of reprocessing have been proven in laboratory tests using the systems listed above.

Endoscopes with narrow lumen cavities may need to be sterilised with suitable conditions. Application-specific instructions and compatibility lists are available directly from **Advanced Sterilization Products® (ASP)**.

The steriliser manufacturer's instructions regarding preparation, packaging and execution of the sterilisation process must be carefully observed. This may vary from product to product.

Evidence of the basic suitability of the endoscopes for effective Sterrad sterilisation was provided by ASP as part of the sterilisation validation (project number RPT03167). Typical conditions in clinics and medical practices were assumed and the endoscopes were tested under laboratory conditions.

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

6 Loss 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.

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