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2 Introduction

Our products are exclusively intended for professional use by appropriately trained and qualified personnel and may only be acquired by them.
By purchasing this instrument, you are now the owner of a high-quality product whose use and correct handling are described in the following. In order to minimize possible risks to patients and users, please observe these instructions carefully. Use, disinfection, cleaning and sterilization may only be performed by suitably trained specialist personnel.

3 Scope

The use of optical instruments is mainly in the following areas:

Anuscopes; Proctoscopes; Sphincteroscopes: The instrument is used for anal and rectal examinations. The examination may only be carried out by suitably trained and qualified specialist personnel.

Laryngoscopes; Otoscopes; Sinuscopes: The instrument is used for ENT examinations. The examination may only be carried out by suitably trained and qualified specialist personnel.

3.1 Intended Use

Anuscopes; Proctoscopes: A rigid endoscope used for visual examination and treatment of anal sphincter muscle. It is introduced into the body via the anus during the examination / treatment. The inserted part is very short and has a large diameter. An obturator is inserted through the lumen. The anatomical image is thus directly visible. The product is used for the examination / diagnosis of patients with abnormal function of the sphincter, internal haemorrhoids or anal fissures. It is a reusable instrument intended for transient use.

Sphincteroscopes: An endoscope with a fixed, internal part, used for visual examination and treatment of the anal sphincter. It is introduced into the body via the anus during the examination / treatment. The inserted part is very short and has a large diameter. An obturator is inserted through the lumen. The anatomical image is thus directly visible. The product is used for examination / diagnosis of patients with abnormal sphincter function, internal haemorrhoids or anal fissures. It is a reusable instrument intended for transient use.

Laryngoscopes; Otoscopes; Sinuscopes: A rigid endoscope used for the visual examination of the nasal cavity and larynx regions. It is introduced into the body through the nasal wing during the neck / nose / throat examination. Anatomical images are transmitted through a lens system or fiber bundle.

3.2 Contraindications

Endoscopes should not be used for coagulopathies or unstable hemodynamics.

4 Warning

!	Medical products are delivered in a non-sterile condition and must be cleaned, disinfected and sterilized prior to their initial use.
!	The use of faulty instruments is in principle forbidden and they have to go through the whole cleaning process before return.
!	Please take into consideration that through higher power a bigger damage of the tissue can result: f.e. on forceps: the power at the end of the jaw is higher than at the tip of the jaw
!	Please observe the additional information enclosed with the products.
!	Remove all protective sleeves and films prior to first using or preparation for use.
!	The safe combination of different products or of products with implants must be reviewed prior to clinical application by the user.
!	Avoid improper throwing or dropping of instruments
!	Avoid mechanical overstressing of the instrument beyond the structural design, this can lead to breakage and deformation!
!	A visual inspection of the instrument for damage and contamination must be carried out before each use!
!	To prevent all contact corrosion, instruments with damaged surfaces must be separated immediately.
!	If the products are used on patients with transmissible spongiform encephalopathy or HIV infection, we decline any responsibility for their reuse.
!	After ophthalmical use, please pay attention to water quality during treatment (according to the specifications of AAMI TIR34 and the recommendations of the Rober-Koch-Institute on preparation of medical devices)!
!	Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5 Handling

The type of treatment must be determined in each individual case by the surgeon in cooperation with the internist and the anaesthetist.

For operational use in various surgical disciplines must be done by appropriately trained and qualified personnel.

6 Preparation

The person in charge of preparatory treatment is responsible for ensuring that the treatment is duly carried out using the relevant equipment, materials and personnel in the treatment facility and so achieves the desired result. This necessitates validation and routine monitoring of the process used. We urge you to take note of the national regulations dealing with instrument preparation.

The validated parameters refer to reusable surgical instruments. The validated parameters should also be observed for the other products described, unless a different procedure is explicitly described.

6.1 Reutilization restrictions

Frequent repeat preparatory treatment has minimal effects on the product. The end of the product life is normally determined by wear and damage due to use

6.2 Information on instrument preparation

- Use cleaning and/or disinfection agents with a pH-value within 9-10. Please observe manufacturer instructions regarding dosage, exposure time and renewal of solutions.
- Do **not** use hard brushes (e.g. metal brushes or metal sponges) or coarse abrasive cleaners.
- Never leave instruments in cleaning or disinfection agents for longer than the specified time.
- Only used demineralized water for rinsing.
- Rinse and dry carefully through channels and pipes.
- Sensitive instruments must be cleaned in a storage or clamping fixture.
- Observe manufacturer instructions of cleaning – and sterilizing equipment.

6.3 Preparation at the place of use

Directly after using remove coarse dirt of the instruments and rinse out the working cannulas. Do not use fixing agents or hot water (> 40°C), as this results in residues becoming fixed and can affect the success of the subsequent cleaning operation
Dismantle and/or open instruments as far as possible. Within short time after use the instruments clean the instruments for reducing a drying of the residues.
This enables an easier cleaning. If instruments come into contact with corroding medicines or cleaning agents, wash these up with water immediately after use.

Longer drying times, e.g. for dry disposal are not validated and therefore not recommended.


The drying time during validation was 1 hour.

6.4 Ultrasound bath (optional)

All instruments must be opened, dismantled and any cavities rinsed through.
Place instruments in the screen basket in such a way that overlaps and contact between instruments are avoided. Add cleaning agent to the water and adjust the temperature of the solution in line with the cleaning agent manufacturer's instructions.
The cleaning in the ultrasound bath should be at 35-40 kHz, 5 minutes at least.

To validate cleaning in an ultrasonic bath, the test items were ultrasonically treated in Neodisher Mediclean forte 0,5 % for 5 minutes.

Subsequently rinse instruments including all cavities before cleaning and disinfection.
Medicine products which are possessing a bad ultrasound transmission, e.g. soft materials are not usable for the ultrasound bath.

6.5 Manual cleaning

Since mechanical processes can be standardizied, reproduced and therefore validated, mechanical cleaning/disinfection should be preferred to manual processes.
Manual cleaning and disinfection process ist not validated and therefore needs to be validated additionally by the end user.

6.6 Mechanical cleaning

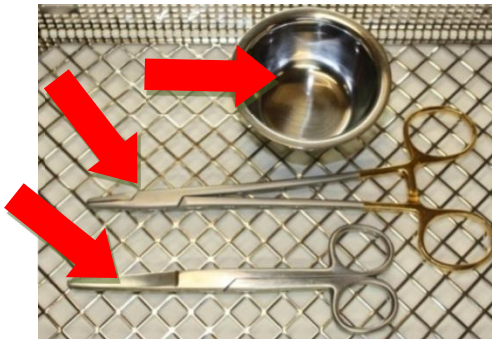
Based on international standards (EN ISO 15883) and national directives, only validated machine cleaning and disinfection methods may be used. For the mechanical cleaning we recommend a standard programme for surgical instruments, f.e. instruments from Miele.

Only completely deminieralized water should be used for cleaning, neutralisation and rinsing, in accordance with the „Guidance Complied by the DGKH (Germany Society for Hospital Hygiene), DGSV (German Society for Sterile Supply) and AKI (Working Group on Instrument Reprocessing) for the Validation and Routine Monitoring of Automated Cleaning and Thermal Disinfection Processes for Medical Devices as well as Advice on Selecting Washer-Disinfectors“ (which refers to DIN EN ISO 15883-1 Point 6.4.2)

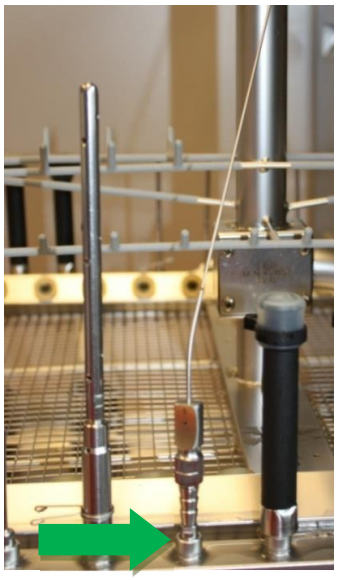
Flexible (complex) instruments with invisible surfaces must be pre-cleaned manually before mechanical cleaning.
We recommend for all push shafts, -and pipe shafts instruments and instruments whose surfaces are on top of each others during the cleaning (f.e.bone forceps and gouge forceps) a manually pre-cleaning for an optimal cleaning result without residues.

Observe the following by loading:

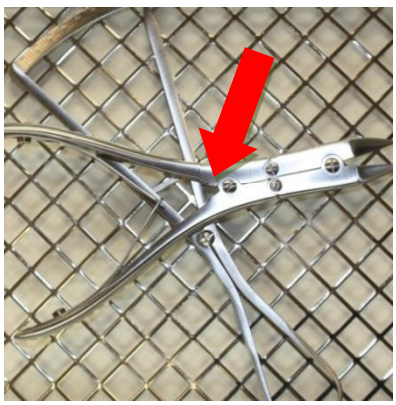
- Place the dismantled/opened instruments securely in the tray.
- Instruments with openings and gaps have to be faced down with the opened side so that they can be cleaned and no water of the cleaning process is collecting inside them. If available use balanced devices for rinsing

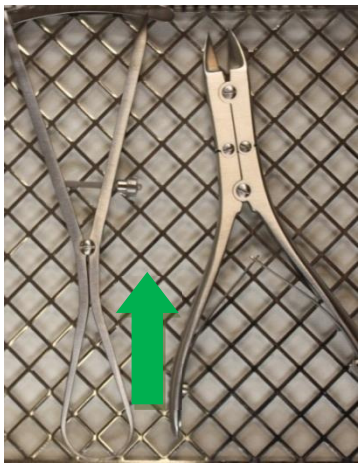


- Place the instruments with joints in an opened position into the cleaning,-and disinfection machine.
- If needed use an adapter for the cleaning



- Do not overload trays, avoid creating any overlaps.





Preliminary rinsing (cold, if applicable fully demineralized water without additives) is followed by chemical. The chemical cleaning should take place at **40°C -60°C** for at **least 5 minutes**.

We recommend products with a **pH-value within 9-10,** e.g. Neodisher MediClean forte from Dr. Weigert. The cleaning agents used should be selected depending on the material and properties of the instruments and in accordance to national regulations: If there is a high chloride concentration in the water, pitting and tension crack corrosion can occur on the instruments. The occurrence of this type of corrosion is minimized by using alkaline cleaning agents and demineralized water. By adding an acid-based neutralization medium, the rinsing off of alkaline cleaning agent residues is facilitated during the first intermediate rinsing process (warm or cold water).

In order to prevent the formation of deposits, it is advisable to use neutral cleaners where the water quality is unfavourable. After the second intermediate rinsing process, thermal disinfection takes place. The thermal disinfection should take place at temperatures of between **80 and 95°C**, with an **exposure time as outlined in EN ISO 15883**.

After the finishing of the programme take the good out of the machine because corrosion can arise if the instrument remains in the machine.

Parameters used for the validation of preparation	
Pre-rinsing	1 minute with cold tap water
Cleaning	Temperature: 55 °C
	Soaking Time: 5 minutes (worst case)
	Neodischer Mediclean forte 0,4% (worst case)
Neutralization	Temperature: cold DI water
	Soaking Time: 2 minutes
	Neodisher Z 0,1%
Post-rinsing	2 minutes with cold DI water
Disinfection	Temperature: 90 °C (A_0 3000)
	Soaking Time: 5 minutes

6.7 Drying

Ensure adequate drying by the cleaning and disinfection device or using other suitable measures.

Drying was omitted in the validation (worst case condition)

7 Maintenance, inspection

After cooling to room temperature, the instruments must be visually inspected for protein residues and other contamination, paying particular attention to cavities, blocks, inclusions, pipes, and other inaccessible areas. Instruments which are not free of residues must be returned for a complete retreatment process.

Carry out the functional check mentioned above. Instruments with stains, which are blunt, bent, no longer function or which are otherwise damaged must be segregated!
To help identify faulty instruments that need to be sorted out, we recommend the brochure "Instrument Reprocessing" from the Working Group “Instrumenten Aufbereitung”. This includes Chapter 8 " Checks and Care" and Chapter 12 " Surface Changes: Deposits, Discoloration,
Corrosion, Aging, Swelling and Stress Cracks".

7.1 Functional check

A newly purchased product must be subjected to a thorough visual and function check after its delivery and before each use.
Products must be checked for irregularities. Paying attention to cracks, fractures and the occurrence of corrosion.

The joints of the instruments should be oiled with a care product before the functional test. We recommend a medical white oil based on paraffin oil.
Check instruments with joints for ease of movement. Carry out a function check in accordance with the intended application of the instrument.

Defective products must not be used and must have undergone the complete preparatory treatment process again before being returned.

8 Sterilization

Prior to sterilization, products must undergo cleaning and disinfection, be rinsed off without residue using demineralized water and subsequently dried. HEBUmedical recommends using a validated steam sterilization process (e.g. sterilizer in compliance with EN 285 and validated in accordance with DIN EN ISO 17665-1).
The validated parameters refer to reusable surgical instruments. The validated parameters should also be observed for the other products described, unless a different procedure is explicitly described.

On using the fractionated vacuum method, **sterilization** must be performed with at least **134°C (USA 132° C)** with a **minimum dwell period of 3 minutes.** Vacuum drying must then be carried out for at least 20 minutes.

Except for the following products:

!	Sinuskope	Otoskope	Nasopharnygoskop, flexibel
HB-Nr. 	HB 6523-00 HB 6523-30	HB 6526-71	HB 6550-00

Parameters used for the validation of steam sterilization	
Prevacuum	3 times
Sterilization temperature	132 °C
Sterilization time	1,5 minutes (half cycle method)
Drying time	20 minutes

The vapour must be free of ingredients, recommended limiting values of feed water and vapour condensate are determined through EN 285.
Other sterilization processes are compatible but not validatet from HEBUmedical.
When loading, observe the recommended total weight. After the sterilization, check the sterile product packaging for damage, and inspect the sterilization indicators

8.1 Sterilization of Laryngoscopes

Sterilization of blades with bulbs
All blades are either autoclavable up to 134 ° C (3 bar g) or can be sterilized in hot air up to 140°C without contact damage. The bulbs and light carriers must be removed prior to sterilization. Sterilize bulbs and carriers separately in gas or a disinfective solution.

Sterilization of cold light blades
All cold light blades are autoclavable up to 134° C (3 bar g). To enhance the working life of the in-built glass fibres, gas sterilization or disinfection in solution is recommended. Do not clean cold light blades in an ultrasonic cleaner. Never apply them to flash-autoclavers, hot air sterilization, or chemicals.

Sterilization of Handles
The battery handles should neither be autoclaved nor sterilized in hot air. Only sterilize in gas or a disinfective solution. For this procedure, do not forget to take out the batteries.

To avoid corrosion or insufficient contact use only non-leaking Alkaline batteries. Concerning handles with cold light equipment only gas sterilization or disinfection in solution are applicable. Remove the bulbs before sterilization.

8.2 Packaging

Compliant packaging of products for sterilization in line with ISO 11607. Packaging used must be suitable for the instruments and protect them from microbiological contamination during storage. The seal must not be under tension. HEBUmedical recommends container or hospital common sterilization paper/film packagings for sterilized packaging.

During validation the instruments were packaged in hospital common sterilization packagings (paper/film packagings) and steam sterilized.

9 Lifetime

The steam sterilization procedure was validated by laboratory tests. The products were sterile validated at a pre-vacuum of at least 5min duration and a temperature of 134°C for a lifetime of 50 cycles.
You can continue to use the instruments at your own responsibility over this cycle value if the tests described in chapter 7 have been successfully completed.

10 Storage

Store products in a dry, clean and dust-free environment at moderate temperatures from 5°C to 40°C. Protect from the effects of the sun's rays and artificial light.

11 Warranty / Repair

Our products are manufactured from high-grade materials and carefully checked prior to dispatch. However, even if used properly in accordance with their intended purpose they are subject to a greater or lesser degree of wear depending on their intensity of use.
This wear is technically induced and unavoidable.
Should faults occur independently of wear, please contact our customer services. Defective products should no longer be used.
They must undergo the complete preparatory treatment process before being returned.

12 Manufacturer and servicing address

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