Manufacturer's information

for the processing of resterilizable medical devices according to EN ISO 17664

Products: **FS Rhodium Laryngeal Mirrors** (front surface rhodium mirrors)
Handles for laryngeal mirrors

For processing in a disassembled state.

WARNINGS:  **Fig. 1 – Scratches**  **Fig. 2 – Water spots**	⚠ **Observe the standard German accident prevention regulations (UVV)** We are not aware of any warnings if the instructions for the devices and disinfection and cleaning agents to be used are followed. ⚠ **Glass breakage** The mirror glass can break and/or splinter if processed or used incorrectly, e.g., if pressure is applied to the glass. Therefore, take **precautionary measures** – especially with difficult patients and children – such as using a rubber dam or saliva ejector, which prevents biting or clenching. If necessary, remove the mirror pieces using appropriate tools, e.g., tweezers or an aspirator. **Ensure proper protection against glass particles with regard to risk of injury and infection.** ⚠ **Mechanical impairment (scratches)** Do not use **hard brushes** or sponges because they can scratch the surface of the mirror and damage the coating of all front surface laryngeal mirrors (Fig. 1) ⚠ **Mounting the laryngeal mirror on a handle** When mounting the laryngeal mirror on a handle, bear in mind that very high forces are generated especially during final tightening of the mirror, which can have an adverse affect on the welding. **Therefore, always hold the laryngeal mirror by the stem – <u>not the frame</u>.** This way, you can screw on the handle and firmly tighten the screw thread with one last strong twist without impairing the welding. ⚠ **Also observe the point "Inspection and Functional Check" before initial use.**
Limitations on reprocessing:	Repeated processing has minimal effect. The end of a product's service life is determined by wear and tear and damage due to use, such as: - Scratches caused by mechanical cleaning (Fig. 1) - Damage caused by rotating instruments - Lime residues (Fig. 2), e.g., if the decalcification of the thermal disinfector is not correctly adjusted **The end of a product's service life varies and is therefore to be determined by the user.** FS Rhodium laryngeal mirrors are acid resistant. Acidic cleaners (e.g., neodisher N) are used with devices such as thermal disinfectors.

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	Our tip: Rhodium acts as a non-stick coating. As a precious metal, rhodium is acid resistant like gold. In combination with the non-stick action, lime residues can therefore be easily removed using acidic cleaners (e.g., neodisher N).

INSTRUCTIONS:
The procedures described are well known and based on standard equipment and consumable materials.

Point of use:	Carry out reprocessing only in the rooms/areas designated for this. Observe the effective hygiene measures in accordance with the country-specific guidelines.
Storage + Transport:	Storage and transport must be carried out in the rooms and containers designated by the practice. Immediately after the instruments have been used on a patient, place them in a disinfection bath filled with a suitable cleaning/disinfection agent (e.g., ID 212 without aldehyde from DÜRR, alkaline cleaning agent with a pH of 10). This prevents the surface drying of residues (protein fixing). Follow the ID 212 directions for use regarding dosage and exposure time. Alternatively: **Dry disposal** Collection of medical devices (dry disposal) after appropriate pretreatment or after patient treatment **LZK BW (Baden-Württemberg State Chamber of Dentists): AA02-1, 06/2018:** **Procedure:** **1. Storage of instruments** into suitable collection containers, e.g., plastic boxes to be locked Careful storage (no throwing in) of the instruments, if necessary with the aid of instrument forceps. Personal protective equipment (e.g., hand, eye, mouth and nose protection) must be observed. Long preparation times should be avoided (recommendation: The 6-hour regulation during the waiting period should not be exceeded; manufacturer's instructions must be observed.) 2. **Waste separation** In sufficiently resistant, impermeable and if necessary moisture-resistant garbage bags.

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Preparation for decontamination:	Follow the standard instructions for instruments in your practice. No other special requirements need to be followed for laryngeal mirrors and handles. The Robert Koch Institute recommends: Disassembling instruments in accordance with personal protection measures.
Cleaning, disinfection and drying: **- Automatic**	Processing should preferably be done by machine in accordance with the recommendation of the Robert Koch Institute (RKI). Observe standards DIN EN ISO 15883-1 and DIN EN ISO 15883-2 **Equipment:** 1. Washer/disinfector (W/D) e.g., from Miele with Vario program. It must reach an A_0 value of at least 3000. 2. neodisher® MediClean Dental from the Dr. Weigert company. 3. Suitable instrument rack or sieve tray. **Procedure:** Also follow the instructions for use at all times for the products and devices to be used. 1. Take the instruments out of the disinfection bath and rinse thoroughly under running potable water immediately before the automated processing (at least 10 seconds). No residue of the cleaning/disinfection agent should be transferred to the W/D. 2. Place the instruments in a suitable instrument rack or sieve tray. 3. Place the instrument rack/sieve tray in the W/D so that the spray jet comes into direct contact with the instruments. 4. Start the Vario program including thermal disinfection. Thermal disinfection is carried out with an A_0 value of at least 3000. 5. Program: ▪ 1 min. pre-washing with cold water ▪ Emptying ▪ 3 min. pre-washing with cold water ▪ Emptying ▪ 10 min. washing at 55°C with 0.5% neodisher® MediClean Dental alkaline cleaning agent ▪ Emptying ▪ 3 min. neutralization with warm tap water (>40°C) and 0.1% neodisher® Z neutralizer; Dr. Weigert, Hamburg ▪ Emptying ▪ 2 min. intermediate flushing with warm tap water (>40°C) ▪ Emptying ▪ Thermal disinfection with demineralized water, at 92°C for at least 5 min. ▪ Automatic drying, around 60°C for 30 min. 6. Remove the instruments at the end of the program cycle and dry them with compressed air according to the RKI recommendation. With instrument racks/sieve trays, pay special attention to the drying of hard-to-reach areas.

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	7. Check for intactness and cleanliness with a suitable magnifying glass. An 8X magnification is usually sufficient for a visual check. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated. Only absolutely dry instruments must be placed in the sterilizer in order to prevent limescale and/or water spots (Fig. 2). **Make sure the decalcification is correctly adjusted,** **Our tip:** Rhodium acts as a non-stick coating. As a precious metal, rhodium is acid resistant like gold. In combination with the non-stick action, lime residues can therefore be easily removed using acidic cleaners (e.g., neodisher N).
Cleaning: **- Manual**	Cleaning supplies: e.g., a soft brush Treatment chemicals: ID 212 from DÜRR, alkaline cleaning and disinfection concentrate with a pH of 10. Clean the instruments according to the usage directions for the treatment chemicals and cleaning agents. **Clean all edges (e.g., mirror to frame) and transitions (e.g., frame to welded stem) as well as the threaded sections on the laryngeal mirror and the threaded opening on the handles very thoroughly. It is necessary to ensure that all areas of the instrument are reached.** However, do not use any mechanical scrubbing devices because they would scratch the coating (Fig. 1). ▪ Pre-wash for 1 minute under running potable water with a soft brush to remove coarse impurities ▪ Place in ID 212 cleaning solution at 2% concentration for 5 min. ▪ Clean transitions and threaded areas with a soft brush ▪ Rinse threaded openings with syringe After cleaning, rinsing should be done with fully desalinated, deionized water for 1 minute in order to prevent limescale residues on the instrument, which leave behind white deposits or water spots (Fig. 2). Check for intactness and cleanliness with a suitable magnifying glass. An 8X magnification is usually sufficient for a visual check. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.
Disinfection: **- Manual**	Treatment chemicals: ID 212 from DÜRR, alkaline cleaner and disinfection concentrate with a pH of 10. Disinfect the instruments according to the usage directions for the treatment chemicals and cleaning agents. Place cleaned instruments for disinfection in a second disinfection bath containing

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	ID 212. Application concentration 2%, exposure time 5 minutes. ▪ Rinse threaded openings with syringe **It is necessary to ensure that all areas of the instrument are reached. Clean all edges (e.g., mirror to frame) and transitions (e.g., frame to welded stem) as well as the threaded sections on the laryngeal mirror and the threaded opening on the handles very thoroughly.** After disinfecting, rinsing should be done with fully desalinated, deionized water for at least 15 seconds in order to prevent limescale residues on the instrument, which leave behind white deposits or water spots (Fig. 2).
Drying: **- Manual**	Preferably with compressed air according to RKI recommendation. With instrument racks, pay special attention to the drying of hard-to-reach areas. Only absolutely dry instruments must be placed in the sterilizer in order to prevent limescale and/or water spots (Fig. 2).
Maintenance:	The product does not require maintenance.
Inspection and functional check:	Carry out a visual inspection for flaws, damages and wear and tear. It is recommended to use a device with optical magnification for better visual inspection. Flawed and/or defective instruments should be discarded. This includes: Instruments with 1. rough and/or protruding edges 2. defects in the mirror glass, e.g., cracks, broken edges 3. weakened welding from stem to the frame (see warning on page 1: "Mounting the laryngeal mirror on a handle") Check that the laryngeal mirror is securely connected in the handle, twist to tighten if necessary.
Packaging:	Use standardized packaging material (DIN EN ISO 11607-1) designed for this purpose. The packaging must be large enough so that no stress is placed on the seal.
Sterilization:	**Equipment:** Steam sterilizer Only put completely dry instruments in the sterilizer in order to prevent limescale deposits and/or water spots. **Procedure:** Steam sterilization using a fractionated vacuum method at 134°C in a device in accordance with EN 13060:

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	1. Fractionated pre-vacuum method (at least 3-fold) 2. Sterilization temperature 134°C 3. Exposure time: 5 minutes (full cycle) 4. Drying time: 10 minutes Observe standard EN 17655 for sterilization with moist heat. In addition, EN 554 was also valid until September 1, 2009. In order to prevent spot formation and corrosion, the steam must not contain any other substances. The maximum load for the sterilizer must not be exceeded when sterilizing several instruments. Observe the device manufacturer's instructions for use.
Storage:	The packaged sterile goods must be protected from dust, humidity and (re)contamination during transport and storage.

Additional information:	Ensure that the maximum load of the devices is not exceeded. The entire procedure must also be carried out before initial use.
Manufacturer contact:	**Fentex *medical* GmbH** Take-off Gewerbepark 2 DE-78579 Neuhausen ob Eck Fon +49 7467 949620 Fax +49 7467 9496217 Email **info@fentexmedical.com**

Observe your country's applicable legal requirements for the reprocessing of medical devices. You can find information about this at www.rki.de

Also observe the standard German accident prevention regulations (UVV).

The instructions provided above have been validated by the medical device manufacturer as being SUITABLE for the preparation of a medical device for reuse. It is the responsibility of the operator to ensure that the actual processing performed in the processing facility – including the equipment, materials and personnel used – achieves the desired result. This usually requires validation and routine monitoring of the procedure in the processing facility.

Any deviation from the instructions provided should be carefully evaluated for effectiveness and any possible negative consequences by the practice's safety officer.

Date: 2018-09