Hygienic Reprocessing

HEINE F.O. 4 NT/F.O. Laryngoscope Handles (LED or XHL)

HEINE Standard F.O. 4 (LED) NT, Standard F.O. (LED),
F.O. 4 SLIM (LED) NT, Small F.O. (LED),
F.O. 4 SHORT (LED) NT, Short F.O. (LED)

General warning and safety information:

WARNING! This symbol draws attention to **a potentially dangerous situation**. Non-observance can result in moderate to major injuries.

NOTE! This symbol indicates valuable advice. Notes are important, but not related to hazardous situations.

	Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines. The described reprocessing measures do not replace the specific rules applicable for your institution/ department.
	After each use and charging, carry out hygienic reprocessing.
	Equipment where there is a suspicion of exposure to Creutzfeld-Jakob disease (CJD) pathogens or variants must not be reprocessed under any circumstances.
	Please consider the instructions of the manufacturer for the applied reprocessing media.
	HEINE Optotechnik GmbH & Co. KG only approves the agents and procedures listed in this instruction.
	Hygienic reprocessing is to be carried out by persons with adequate hygienic expertise.
	The handle inserts, bottom inserts and rechargeable and dry cell batteries are not suitable for automated reprocessing, immersion disinfection or steam sterilization.
	HEINE rechargeable batteries and their bottom inserts are not suitable for reprocessing using a STERRAD procedure.
	Before using it again, ensure that the handle is completely dry after reprocessing.
	Hold the insert with the contact pointing downwards during wiping to prevent liquid entry.
	Liquid should not enter the insert during reprocessing because this could damage the device.
	In order to avoid recontamination of the processed parts during reassembly, the batteries should remain within the laryngoscope handle insert during reprocessing of the STANDARD handle.
	After cleaning, the handle must be rinsed free of residue in order to avoid reactions with subsequent treatment stages/ damage to the materials.
Limitations on reprocessing	• As long as the product meets the requirements of ISO 7376. • Periodically check the integrity of the device and that the illumination is sufficient.

HEINE Optotechnik GmbH & Co. KG • Dornierstr. 6 • 82205 Gilching • Germany
E-Mail: info@heine.com • **www.heine.com**

med 113715 06/04.2021

Choice of the reprocessing procedure

The hygienic classification (Spaulding classification) of the laryngoscope handles, as well as the decision for one of the offered reprocessing procedures, is the responsibility of the user or the qualified person(s) responsible for reprocessing. Internal regulations of your hospital/ institution, national directives, recommendations, standards and laws need to be considered.

For highly infectious cases (previous or following patients) (e. g. in case of a proven existence of a dangerous infectious disease (symptomatic or asymptomatic), the reprocessing guidelines in this document are superseded by processes of your institution / practice-internal regulations, national directives, recommendations, standards and laws.

The laryngoscope insert and the bottom insert, need to be reprocessed as shown in Chapter A.

Choose one of the following reprocessing methods for the handle shell:

		Cleaning and disinfection		
		Automated cleaning and disinfection	**Manual cleaning (brushing)**	**High-level manual disinfection (immersion)**
Sterilization	**No Sterilization**	Chapter B	Chapter C	
	Low Temperature STERRAD / VHP (Steris)	Chapter D	Chapter E	
	Steam	Chapter F	Chapter G	

HEINE Optotechnik GmbH & Co. KG • Dornierstr. 6 • 82205 Gilching • Germany
E-Mail: info@heine.com • **www.heine.com**

med 113715 06/04.2021

Chapter A: Intermediate-level wipes disinfection of the laryngoscope insert and bottom insert

1. **Containment and transportation**
   Reprocess as soon as possible following use.
2. **Preparation**
   Disassemble the blade from the handle and reprocess separately.
   Disassemble the handle for reprocessing.
   Reprocess the handle shell as described in chapter B-G.
3. **Manual cleaning and disinfection**

   Pay attention that all surfaces are completely moistened for the complete exposure time specified by the disinfectant manufacturer. If necessary, increase the number of wiping procedures and or the number of wipes.
   Avoid liquid entry in the laryngoscope insert and the bottom insert of the laryngoscope handle.
   Equipment
   - Intermediate level disinfection wipes: alcohol and/or quarternary ammonium compounds (e. g. Super Sani-Cloth by PDI) having an EPA-registered claim for activity against *Mycobacterium tuberculosis* and Hepatitis B.

   Implementation
   - Wipe the laryngoscope insert and bottom insert three times with a fresh wipe.
   - Pay particular attention to recesses, ridges, difficult to access areas.
   - For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.
4. **Reassembly**
   Insert the laryngoscope insert and bottom insert into the handle shell and close it.
5. **Inspection and function testing**

   - Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
6. **Storage**
   Store it in such a way that it is protected from recontamination, dust and moisture.

Chapter B: Automated cleaning and disinfection of the handle shell

1. Point of use

Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.

2. Containment and transportation

Reprocess as soon as possible following use.

3. Preparation

Disassemble the blade from the handle and reprocess separately.
Disassemble the handle for reprocessing.
Clean and disinfect the laryngoscope handle insert and bottom insert as described in Chapter A.

4. Cleaning and disinfection

If it is required in your institution or your country, you can perform manual cleaning of the handle shell by brushing before automated cleaning and disinfection.

4.1 Automated cleaning and disinfection

Equipment

- Washer/disinfector that conforms to the requirements of ISO 15883 or has a validated procedure corresponding to ISO 15883.
- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP).
- Neutralizing agent if specified by the cleaning agent manufacturer.

Implementation

- The instructions from the manufacturer of the cleaning agents and the washer/disinfector must be followed.
- Chose a suitable cleaning agent and cleaning program (according to ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 min. at 93 °C or an alternative, comparable program.

5. Reassembly

Insert the laryngoscope insert and bottom insert into the handle shell and close it.

6. Inspection and function testing

- Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Perform functional testing after reprocessing.

7. Storage

Store it in such a way that it is protected from recontamination, dust and moisture.

Chapter C: Manual cleaning (brushing) and high-level manual disinfection (immersion) of the handle shell

1. **Point of use**
   Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.
2. **Containment and transportation**
   Reprocess as soon as possible following use.
3. **Preparation**
   Disassemble the blade from the handle and reprocess separately.
   Disassemble the handle for reprocessing.
   Clean and disinfect the laryngoscope handle insert and bottom insert as described in Chapter A.
4. **Manual cleaning by brushing**
   Equipment
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP).
   - Warm (30 - 40 °C) demineralized water, soft plastic brushes.

   Implementation
   - Soak the handle shell for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces of the handle shell by brushing (submerged in the cleaning solution).
   - Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism, below the hinge and the inner surfaces of the handle shell.
   - For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.
5. **Manual immersion disinfection**
   Equipment
   - High level disinfectant for immersion disinfection (compatible with cleaning agent):
     Quarternary ammonium compounds (e. g. neodisher Septo MED)
     or agent ortho-phthalaldehyde (e. g. CidexOPA)

   Implementation
   - Immerse the handle shell in the disinfectant solution as specified by the manufacturer of the disinfectant.
   - Pay particular attention to maintain the specified concentrations, temperatures and the contact times.
   - For removing the disinfectant and drying afterwards, follow the instructions provided by the manufacturer of the disinfectant.
6. **Reassembly**
   Insert the laryngoscope insert and bottom insert into the handle shell and close it.
7. **Inspection and function testing**
   - Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
8. **Storage**
   Store it in such a way that it is protected from recontamination, dust and moisture.

Chapter D: Automated cleaning, disinfection and low temperature sterilization STERRAD / VHP (Steris)

1. Point of use
Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.

2. Containment and transportation
Reprocess as soon as possible following use.

3. Preparation
Disassemble the blade from the handle and reprocess separately.
Disassemble the handle for reprocessing.
Clean and disinfect the laryngoscope handle insert and bottom insert as described in Chapter A.

4. Cleaning and disinfection of the handle shell
If it is required in your institution or your country, you can perform manual cleaning of the handle shell by brushing before automated cleaning and disinfection.

4.1 Automated cleaning and disinfection of the handle shell

Equipment

- Washer/disinfector that conforms to the requirements of ISO 15883 or has a validated procedure corresponding to ISO 15883.
- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP).
- Neutralizing agent if specified by the cleaning agent manufacturer.

Implementation

- The instructions from the manufacturer of the cleaning agents and the washer/disinfector must be followed.
- Chose a suitable cleaning agent and cleaning program (according to ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 min. at 93 °C or an alternative, comparable program.

5. Reassembly
The handle can be reassembled before packaging for hydrogen peroxide low-temperature sterilization:
Insert the laryngoscope insert and bottom insert into the handle shell and close it.
(with the exception of HEINE rechargeable batteries and their bottom inserts)

6. Inspection and function testing

- Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Perform functional testing after reprocessing.

7. Packaging of the handle for sterilization
Pack the items individually in single or double standardized sterilization pouches suitable for the selected sterilization process.

8. Sterilization

8.1 STERRAD sterilization of the handle

Equipment

- STERRAD NX, 100NX or 100S Sterilizer

Implementation
Perform the STERRAD NX Standard or Advanced cycle.

8.2 VHP (Steris) sterilization of the handle

Equipment

- V-PRO 60 Sterilizer, V-PRO maX Sterilizer
- VAPROX HC Sterilant

Implementation
Perform the V-PRO 60 or V-PRO maX Sterilizer's Lumen Cycle.

9. Storage
Store it in such a way that it is protected from recontamination, dust and moisture.

HEINE Optotechnik GmbH & Co. KG • Dornierstr. 6 • 82205 Gilching • Germany
E-Mail: info@heine.com • **www.heine.com**

med 113715 06/04.2021

Chapter E: Manual cleaning (brushing), Low temperature Sterilization STERRAD / VHP (Steris)

1. **Point of use**
   Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.
2. **Containment and transportation**
   Reprocess as soon as possible following use.
3. **Preparation**
   Disassemble the blade from the handle and reprocess separately.
   Disassemble the handle for reprocessing.
   Clean and disinfect the laryngoscope handle insert and bottom insert as described in Chapter A.
4. **Manual cleaning of the handle shell by brushing**
   Equipment
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP).
   - Warm (30 - 40 °C) demineralized water, soft plastic brushes.

   Implementation
   - Soak the handle shell for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces of the handle shell by brushing (submerged in the cleaning solution).
   - Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism, below the hinge and the inner surfaces of the handle shell.
   - For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.
5. **Reassembly**
   The handle can be reassembled before packaging <u>for hydrogen peroxide low-temperature sterilization</u>:
   Insert the laryngoscope insert and bottom insert into the handle shell and close it.
   (with the exception of HEINE rechargeable batteries and their bottom inserts)
6. **Inspection and function testing**
   - Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
7. **Packaging of the handle for sterilization**
   Pack the items individually in single or double standardized sterilization pouches suitable for the selected sterilization process.
8. **Sterilization**

8.1 STERRAD sterilization of the handle

Equipment
- STERRAD NX, 100NX or 100S Sterilizer

Implementation
Perform the STERRAD NX Standard or Advanced cycle.

8.2 VHP (Steris) sterilization of the handle

Equipment
- V-PRO 60 Sterilizer, V-PRO maX Sterilizer
- VAPROX HC Sterilant

Implementation
Perform the V-PRO 60 or V-PRO maX Sterilizer's Lumen Cycle.

9. **Storage**
   Store it in such a way that it is protected from recontamination, dust and moisture.

Chapter F: Automated cleaning and disinfection, steam sterilization of the handle shell

1. Point of use
Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.

2. Containment and transportation
Reprocess as soon as possible following use.

3. Preparation
Disassemble the blade from the handle and reprocess separately.
Disassemble the handle for reprocessing.
Clean and disinfect the laryngoscope handle insert and bottom insert as described in Chapter A.

4. Cleaning and disinfection
If it is required in your institution or your country, you can perform manual cleaning of the handle shell by brushing before automated cleaning and disinfection.

4.1 Automated cleaning and disinfection
Equipment
- Washer/disinfector that conforms to the requirements of ISO 15883 or has a validated procedure corresponding to ISO 15883.
- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP).
- Neutralizing agent if specified by the cleaning agent manufacturer.

Implementation
- The instructions from the manufacturer of the cleaning agents and the washer/disinfector must be followed.
- Chose a suitable cleaning agent and cleaning program (according to ISO 15883).
- Recommendation: A program with disinfection lasting at least 5 min. at 93 °C or an alternative, comparable program.

5. Inspection and function testing
- Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Perform functional testing at the end of the reprocessing.

6. Packaging for sterilization
Only the handle shell can be steam sterilized.

Pack the items individually in single or double standardized sterilization pouches suitable for the selected sterilization process.

7. Steam sterilization
Equipment
Steam sterilizer (Class B according to DIN EN 13060)
Implementation
Use one of the following programs (ISO 17665):
Fractionated vacuum procedure (at least 3 pre-vacuum cycles) and gravitation procedure:
- Sterilization temperature: at least 132 °C (max. 134 °C)
- Exposure time/holding time: at least 3 min.
- Drying time: at least 20 min.
-

8. Storage
Store it in such a way that it is protected from recontamination, dust and moisture.

9. Reassembly
Insert the laryngoscope insert and bottom insert into the handle shell and close it.

Chapter G: Manual cleaning (brushing) and steam sterilization of the handle shell

1. **Point of use**
   Gross contamination must be removed soon after use, e. g. with a disposable wet wipe or enzymatic pre-cleaner.
2. **Containment and transportation**
   Reprocess as soon as possible following use.
3. **Preparation**
   Disassemble the blade from the handle and reprocess separately.
   Disassemble the handle for reprocessing.
   Clean and disinfect the laryngoscope handle insert and bottom insert as described in Chapter A.
4. **Manual cleaning by brushing**
   Equipment
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME by ASP).
   - Warm (30 - 40 °C) demineralized water, soft plastic brushes.

   Implementation
   - Soak the handle shell for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces of the handle shell by brushing (submerged in the cleaning solution).
   - Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism, below the hinge and the inner surfaces of the handle shell.
   - For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent. Pay particular attention to remove residues from recesses and ridges.
5. **Inspection and function testing**
   - Check the handle for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing at the end of the reprocessing.
6. **Packaging for sterilization**
   Only the handle shell can be steam sterilized.

   Pack the items individually in single or double standardized sterilization pouches suitable for the selected sterilization process.
7. **Steam sterilization**
   Equipment
   Steam sterilizer (Class B according to DIN EN 13060)
   Implementation
   Use one of the following programs (ISO 17665):
   Fractionated vacuum procedure (at least 3 pre-vacuum cycles) and gravitation procedure:
   - Sterilization temperature: at least 132 °C (max. 134 °C)
   - Exposure time/holding time: at least 3 min.
   - Drying time: at least 20 min.
8. **Storage**
   Store it in such a way that it is protected from recontamination, dust and moisture.
9. **Reassembly**
   Insert the laryngoscope insert and bottom insert into the handle shell and close it.

HEINE Optotechnik GmbH & Co. KG • Dornierstr. 6 • 82205 Gilching • Germany
E-Mail: info@heine.com • **www.heine.com**

med 113715 06/04.2021