

Hygienic Reprocessing

HEINE® EasyClean LED Laryngoscope Handles

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 in terms of set up, operation or maintenance, as applicable. Notes are important, but not related to hazardous situations.

	<p>Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines. They must be implemented in the hospital / practice internal rules and guidelines.</p>
	<p>After each use, carry out hygienic reprocessing.</p> <p>If you use reprocessing programs with temperatures above 60 °C (e. g. automated cleaning and disinfection or steam sterilization), you need to remove the batteries and the casing (if available) first OR refer to the battery manufacturer's instructions.</p> <p>Equipment, where there is a suspicion that they have been in contact with Creutzfeld-Jakob disease (CJD) pathogens or variants thereof must not be reprocessed under any circumstances.</p> <p>Please consider the instructions of the manufacturer for the applied reprocessing media.</p> <p>HEINE Optotechnik only approves the agents and procedures listed in this instruction.</p> <p>The reprocessing is to be carried out by persons with adequate hygienic expertise.</p> <p>The described reprocessing measures do not replace the specific rules applicable for your institution/ department.</p> <p>If the valve on the bottom insert opened during reprocessing, or if the bottom insert has not been completely closed, the handle inside shall dry with opened bottom insert, the valve shall be closed (pressed in) and the reprocessing shall be repeated.</p> <p>The described reprocessing procedures are represented alongside the corresponding material compatibilities. Reprocessing must be carried out in accordance with an approved processing procedure. HEINE Optotechnik GmbH & Co. KG cannot guarantee the sterility and disinfection of these procedures. This has to be validated by the user e. g. Hospital or the manufacturers of the reprocessing equipment.</p>
	<p>Before using it again, ensure that the handle is completely dry after reprocessing.</p> <p>Ensure that the bottom insert is completely closed during reprocessing to avoid liquid entry.</p> <p>For important details regarding the processing procedures, please refer to the FAQs for Hygienic Reprocessing on our Website.</p>
<p>Limitations on reprocessing</p>	<p>Hygienic reprocessing only has a minor influence on the product life as this is determined mainly by wear and tear during use.</p> <p>Periodically check the integrity of the device and that the illumination is sufficient!</p>



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.

If you, the user or the qualified person responsible for reprocessing,

- have classified the handle as **“non-critical”** (Spaulding classification)
 - i.e. the handle **contacted only intact skin and did not penetrate it** or it did not directly contact the patient
 - and is **not visibly contaminated with microorganisms and organic soil (e. g. blood, body fluids)**

then intermediate level wipe disinfection can be performed (see chapter A).

Otherwise, high-level disinfection (i.e. manual cleaning with immersion-disinfection or automated cleaning and disinfection) and/or sterilization shall be performed (see chapter B-G).

Choose one of the following reprocessing methods:

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



Chapter A: Intermediate-level wipes disinfection

1. Containment and transportation

Reprocess as soon as possible following use.

2. Preparation

Disassemble the blade from the handle and reprocess separately.

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.

Equipment

- Intermediate level disinfection wipes: alcohol and/or quaternary ammonium compounds (e. g. Super Sani-Cloth® by PDI®) having an EPA-registered claim for activity against *Mycobacterium tuberculosis* and Hepatitis B.

Implementation

- Using the disinfectant wipe, start from the top of the handle and wipe down 3 times while turning the handle. This procedure is to be repeated 3 times, each with a new disinfectant wipe.
- Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism, below the hinge and the bottom insert.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.

4. 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.

5. Storage

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



Chapter B: Automated cleaning and disinfection with removing of the battery

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.



Remove the batteries and the casing (if available) before automated reprocessing and/or steam sterilization. Before automated reprocessing, screw in the bottom insert.

4. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning of the handle 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® or neodisher® MediClean Forte).
- 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 after reprocessing.

6. Reassembly

Insert the batteries and the casing (if available) into the handle and close it.

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)

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.



If you use reprocessing procedures with temperatures below 60 °C (Low-Temperature Procedures) or if the battery manufacturer's instructions allow the temperatures of the used procedures, you can reprocess the handle without removing the batteries.

4. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® by ASP® or neodisher® MediClean Forte).
- Warm (30 - 40 °C) demineralized water
- Soft plastic brushes: surface brush and small round plastic brush Ø 5mm

Implementation

- Use the detergent at the maximum recommended concentration.
- Soak the closed handle (with screwed bottom insert) completely for at least 5 min. submerged in the cleaning solution (30 - 40 °C).
- Clean all surfaces of the closed handle by brushing (submerged in the cleaning solution):
- Brush all surfaces thoroughly until no more contamination is visible and at least 5 times (in total at least 3 min.).
- Then brush with the small round plastic brush at least 5 times the recesses, ridges and areas at the handle head, the snap-in mechanism, below the hinge, at the lamp and at the bottom insert (in total at least 3 min.).
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times specified by the manufacturer of the cleaning agent.
- 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): agent ortho-phthalaldehyde (e. g. Cidex®OPA)

Implementation

- Immerse the closed handle completely 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 specified by the manufacturer of the disinfection agent.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the manufacturer of the disinfectant.

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 they are protected from recontamination, dust and moisture.

Chapter D: Low temperature procedure without removing the battery:

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.



If you use reprocessing procedures with temperatures below 60 °C (Low-Temperature Procedures) or if the battery manufacturer's instructions allow the temperatures of the used procedures, you can reprocess the handle without removing the batteries.

4. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® by ASP® or neodisher® MediClean Forte).
- Warm (30 - 40 °C) demineralized water
- Soft plastic brushes: surface brush and small round plastic brush Ø 5mm

Implementation

- Use the detergent at the maximum recommended concentration.
- Soak the closed handle (with screwed bottom insert) completely for at least 5 min. submerged in the cleaning solution (30 - 40 °C).
- Clean all surfaces of the closed handle by brushing (submerged in the cleaning solution):
- Brush all surfaces thoroughly until no more contamination is visible and at least 5 times (in total at least 3 min.).
- Then brush with the small round plastic brush at least 5 times the recesses, ridges and areas at the handle head, the snap-in mechanism, below the hinge, at the lamp and at the bottom insert (in total at least 3 min.).
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times specified by the manufacturer of the cleaning agent.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

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. Packaging for sterilization

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

7. Low temperature sterilization

7.1 STERRAD®

Equipment

- STERRAD® NX®, 100NX® or 100S® sterilizer

Implementation

Perform one of the following cycles:

STERRAD NX / 100NX Standard cycle, STERRAD 100NX Express cycle oder STERRAD 100S Short cycle.



7.2 VHP® (Steris)

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.

8. Storage

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



Chapter E: High temperature procedure with removing the battery: Automated cleaning and disinfection, steam sterilization

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.



Remove the batteries and the casing (if available) before automated reprocessing and/or steam sterilization.

Before automated reprocessing, screw in the bottom insert.

4. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning of the handle 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® or neodisher® MediClean Forte).
- 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 after reprocessing.

6. Packaging for sterilization

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

7. Steam sterilization



The real drying time depends on various parameters. Its determination and validation is in the responsibility of the user.

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 4 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 batteries and the casing (if available) into the handle and close it.



Chapter F: Procedure with removing the battery: Automated cleaning and disinfection, 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.
Remove the batteries and the casing (if available) before automated reprocessing.
Before automated reprocessing, screw in the bottom insert.
4.  **Cleaning and disinfection**
If it is required in your institution or your country, you can perform manual cleaning of the handle 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® or neodisher® MediClean Forte).
 - 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 after reprocessing.
6. **Reassembly**
Insert the batteries and the casing (if available) into the handle and close it.
7. **Packaging for sterilization**
Pack the items individually in single or double standardized sterilization pouches suitable for the selected sterilization process.
8. **Low temperature sterilization**
- 8.1 **STERRAD®**
Equipment
 - STERRAD® NX®, 100NX® or 100S® sterilizer*Implementation*
Perform one of the following cycles:
STERRAD NX / 100NX Standard cycle., STERRAD 100NX Express cycle oder STERRAD 100S Short cycle.
- 8.2 **VHP® (Steris)**
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 G: Procedure with removing the battery: Manual cleaning (brushing), steam sterilization

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.



Remove the batteries and the casing (if available) before reprocessing.

Before reprocessing, screw in the bottom insert.

4. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® by ASP® or neodisher® MediClean Forte).
- Warm (30 - 40 °C) demineralized water
- Soft plastic brushes: surface brush and small round plastic brush Ø 5mm

Implementation

- Use the detergent at the maximum recommended concentration.
- Soak the closed handle (with screwed bottom insert) completely for at least 5 min. submerged in the cleaning solution (30 - 40 °C).
- Clean all surfaces of the closed handle by brushing (submerged in the cleaning solution):
- Brush all surfaces thoroughly until no more contamination is visible and at least 5 times (in total at least 3 min.).
- Then brush with the small round plastic brush at least 5 times the recesses, ridges and areas at the handle head, the snap-in mechanism, below the hinge, at the lamp and at the bottom insert (in total at least 3 min.).
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times specified by the manufacturer of the cleaning agent.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

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. Packaging for sterilization

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

7. Steam sterilization



The real drying time depends on various parameters. Its determination and validation is in the responsibility of the user.

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 4 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 batteries and the casing (if available) into the handle and close it.

