

# Hygienic Reprocessing

## HEINE visionPRO video laryngoscope

### 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.

	<p>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.</p>
	<p>After each use, carry out hygienic reprocessing.</p> <p>Dispose of the video laryngoscope blade before reprocessing. It is a disposable product and must not be reprocessed and reused under any circumstances.</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 and has to be disposed.</p> <p>If you use reprocessing agents that are not described by HEINE, pay attention to the information provided by the manufacturer of the reprocessing agents.</p> <p>Regularly check the validity of all manufacturer's instructions.</p> <p>HEINE Optotechnik GmbH &amp; Co. KG 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>HEINE Optotechnik GmbH &amp; Co. KG has validated the effective reprocessing for the procedures and agents recommended in this document.</p> <p>If a reprocessing procedure other than that described in these instructions is used, an approved and validated reprocessing procedure must be carried out. This must be validated by the user e.g. hospital or the manufacturers of the reprocessing equipment.</p> <p>The reprocessing agents of the list MED 236208 have been checked regarding material compatibility.</p> <p>Wear suitable gloves during reprocessing.</p> <p>Use disinfection wipes having an EPA-registered claim for activity against Mycobacterium tuberculosis and Hepatitis B.</p> <p>Do not use agents containing hydrogen peroxide.</p> <p>Do not press in the visionPRO latching balls under water.</p> <p>Remove any dirt from the pins.</p> <p>Do not switch on the device during preparation.</p> <p>Steam sterilization or machine reprocessing must not be carried out.</p>
	<p>Avoid the penetration of liquids.</p>
<p>Limitations on reprocessing</p>	<ul style="list-style-type: none"> <li>• Regularly check that the device is intact.</li> <li>• Regularly check the function of the camera and the illumination.</li> </ul>

## 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.

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 following reprocessing procedures are available:

- For the handle and the display unit assembled: wipe disinfection (**see chapter A**).
- For the handle:
  - Cleaning and disinfection (fungicidal, bactericidal (including mycobacteria) and virucidal) (manual cleaning and immersion disinfection) (manual cleaning with immersion-disinfection) (**see chapter B**)
  - sterilization (**see chapter C**).

Component	Intermediate Disinfection	High level Disinfection	Sterilization
 Single use blade	Intermediate-level wipes disinfection —	Manual cleaning (brushing) and high-level manual disinfection —	Sterilization STERRAD —
 Handle and display unit assembled	✓ (Chapter A)	—	—
 Handle (disassembled)	—	✓ (Chapter B)	✓ (Chapter C)
- = not applicable	✓ = suitable		

## Chapter A: Intermediate-level wipes disinfection

### 1. Containment and transportation

Reprocess as soon as possible following use.

### 2. Preparation

Remove the blade from the handle and dispose of the blade.

Use disinfectant wipes that are fungicidal, bactericidal (including mycobacteria) and virucidal, and have confirmed efficacy against hepatitis B.

### 3. Point-of-Use Processing

Wipe the components with a microfibre cloth soaked in cleaning agents immediately after use to prevent contamination from drying. Use disinfectant wipes containing either enzymatic or neutral to mildly alkaline.

Use soft and suitable brushes for the hard-to-reach places, niches and crevices.

Remove the residue of the cleaning agent and dry the display tray as required by the manufacturer of the cleaning agent.

Wipe the components with a microfibre cloth soaked in cleaning agents immediately after use to prevent contamination from drying. Use disinfectant wipes containing either enzymatic or neutral to mildly alkaline.

### 4 Manual cleaning and disinfection of the video laryngoscope



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.

Dispose of the wipes according to local and hospital regulations.

#### Equipment

Intermediate level disinfection wipes:

- Super Sani-Cloth (Quarternary ammonium compounds + alcohol)

*Implementation (This procedure must be repeated 3 times).*

#### Area 1:

Wipe with a disinfectant wipe starting below the on/off button (3) three times down to the transition to the handle. Turn the handle while doing so.

#### Area 2:

Wipe the joint area of the display unit three times with the disinfectant wipe. Pay attention to rotating movements. Pay particular attention to niches, crevices and the hard-to-reach areas around the joint, under the joint and at the transitions.

#### Area 3:

Then wipe the on/off button thoroughly three times with the disinfectant wipe. Pay attention to circular as well as horizontal and vertical movements.

#### Area 4:

Wipe the edges and the glass side of the display three times. Pay attention to vertical and horizontal movements. Pay special attention to niches and crevices.

#### Area 5:

Wipe the back of the display three times with a new disinfectant wipe. Pay attention to horizontal and vertical movements.



#### Area 6:

Using the disinfectant wipe, start at the top of the black part of the handle and wipe down three times until you reach the grey material at the bottom of the camera handle. Turn the handle while doing this. Pay particular attention to niches, crevices and the hard-to-reach places and to the material transitions.

#### Area 7:

Using the disinfectant wipe, wipe the grey part of the handle three times with rotating as well as horizontal and vertical movements. Pay particular attention to the clip on which the spatula is attached. For stronger contaminations, the use of a brush may be necessary.

#### Area 8:

Finally, wipe the area of the camera with the cloth and with horizontal and vertical movements. Pay particular attention to niches and crevices and make sure that you do not scratch the camera.

- If you still see residues after wiping disinfection, brush the affected areas with surface brushes soaked in disinfectant.
- Remove the residues (especially in the cameo area) with a cloth soaked in distilled water or water of at least potable quality (according to the disinfectant manufacturer's instructions) and dry the video laryngoscope as required by the disinfectant manufacturer.

#### **5. Inspection and function testing**



- Check the components for visible contamination or wear and tear and reprocess if necessary or dispose of in case of non-removable contamination.
- A functional test must be carried out after reprocessing. First let the video laryngoscope to dry. Then check the function of the device, especially the function of the camera and the illumination.

#### **6. Storage**

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

## Chapter B: High level disinfection

### Manual cleaning (brushing) and high-level manual disinfection (immersion) (handle)

#### 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.



The handle must be rinsed without residue after the manual cleaning to avoid reactions with subsequent treatment steps or impairment of the materials.

#### 4. Point-of-Use Processing

Wipe the disassembled handle immediately after use with a microfibre cloth soaked in cleaning agents to prevent contamination from drying.

Use cleaning agents that are either enzymatic or neutral to mildly alkaline.

Use soft and suitable brushes for the hard-to-reach places, niches and crevices.

Remove the residue of the cleaning agent and dry the handle as required by the manufacturer of the cleaning agent.

#### 5. Manual cleaning by brushing

##### Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (neodisher MediClean Forte).
- Warm (30 - 40 °C) demineralized water
- Soft plastic brushes: surface brush (2,3 x 0,1 x 0,5 cm w x l x h)
- Sufficiently large and material-resistant basin

##### Implementation

- Use the detergent at the maximum recommended concentration.
- Soak the handle completely for at least 5 min. submerged in the cleaning solution (30 - 40 °C).
- Clean all surfaces of the 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 the niches, crevices and the areas around the transitions, the spatula clip and the camera area at least 5 times with a surface brush (in total at least three minutes).
- Pay particular attention to maintain the specified concentrations, temperatures and the contact times specified by the manufacturer of the cleaning agent.
- Remove the residue of the cleaning agent completely with water (preferably fully de-salted) and as required by the detergent manufacturer and dry the handle.

#### 6. Manual immersion disinfection

##### Equipment

- High level disinfectant for immersion disinfection (compatible with cleaning agent): Cidex OPA (ortho-phthalaldehyde)

##### Implementation with Cide OPA

- Completely immerse the handle in the disinfectant solution according to the disinfectant manufacturer's instructions.
- Pay special attention to the concentrations (min. 0.55%), temperatures (min. 20°C) and exposure times (min. 12 minutes) specified by the disinfectant manufacturer.
- After removing the handle from the CIDEX OPA solution, immerse it completely in plenty of water and rinse it thoroughly. Use sterile water or potable water specified by the manufacturer of the disinfection solution.
- Leave the handle fully immersed for at least 1 minute.
- Remove the handle and discard the rinse water. Always use fresh water for all rinses. Dispose of the water after each rinse. Do not reuse the water for other rinses or any other purpose.

- Repeat this procedure TWO (2) more times for a total of THREE (3) RINSES in plenty of fresh water to remove all CIDEX OPA solution residue.
- Allow the handle to air dry sufficiently before reusing it

**7. Inspection and function testing**



- Check the handle for visible contamination or wear and reprocess if necessary or dispose of in case of non-removable contamination.
- A functional test must be carried out after reprocessing. To do this, first allow the handle and the display unit to dry completely. Then assemble the two components and check the function of the unit, especially the function of the camera and the illumination.

**8. Storage**

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

## Chapter C: Sterilization STERRAD (handle)

### 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.

Disconnect the display unit and the handle.



The handle must be rinsed after manual cleaning to avoid reactions with subsequent treatment steps or impairment of the materials.

### 4. Point-of-Use Processing

Wipe the mounted handle with a disinfectant wipe immediately after use to prevent contamination from drying.

Use disinfectant wipes containing either alcohol or quaternary ammonium compounds.

Use soft and suitable brushes for the hard-to-reach places, niches and crevices.

Remove the residue of the cleaning agent and dry the handle as required by the manufacturer of the cleaning agent.

### 5. Manual cleaning by brushing

#### Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (neodisher MediClean Forte).
- Warm (30 - 40 °C) demineralized water
- Soft plastic brushes: surface brush (2,3 x 0,1 x 0,5 cm w x l x h)
- Sufficiently large and material-resistant basin

#### Implementation

- Use the cleaning agent in the maximum recommended concentration.
- Fully immerse the handle in cleaning solution (30 - 40 °C) for at least five minutes to soak.
- Clean all surfaces of the handle by brushing (immersed in cleaning solution):
- Brush all surfaces thoroughly until no more dirt is visible and at least 5 times (in total at least three minutes).
- Then brush with a surface brush at least 5 times the niches, crevices and the places in the area of the transitions, in the in clip of the blade and in the area of the camera (in total at least three minutes).
- Pay particular attention to compliance with the concentrations, temperatures and exposure times specified by the manufacturer of the agent.
- Remove the residue of the cleaning agent completely with water (preferably fully de-salted). and as required by the detergent manufacturer and dry the handle.

### 6. Manual immersion disinfection

#### Equipment

- High level disinfectant for immersion disinfection (compatible with cleaning agent): Cidex OPA (ortho-phthalaldehyde)

#### Implementation with Cide OPA

- Completely immerse the handle in the disinfectant solution according to the disinfectant manufacturer's instructions.
- Pay special attention to the concentrations (min. 0.55%), temperatures (min. 20°C) and exposure times (min. 12 minutes) specified by the disinfectant manufacturer.
- After removing the handle from the CIDEX OPA solution, immerse it completely in plenty of water and rinse it thoroughly. Use sterile water or potable water specified by the manufacturer of the disinfection solution.
- Leave the handle fully immersed for at least 1 minute.
- Remove the handle and discard the rinse water. Always use fresh water for all rinses. Dispose of the water after each rinse. Do not reuse the water for other rinses or any other purpose.
- Repeat this procedure TWO (2) more times for a total of THREE (3) RINSES in plenty of fresh water to remove all CIDEX OPA solution residue.

Allow the handle to air dry sufficiently before reusing 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. Packaging for sterilization**

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

**9. Low temperature sterilization**

Choose one of the following sterilization methods.

**STERRAD**

*Equipment*

- STERRAD NX, 100NX or 100S sterilizer

*Implementation*

Perform one of the following cycles:

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

**10. Storage**

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