

Hygienic Reprocessing

HEINE Finoff transilluminator

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. Equipment where there is a suspicion of exposure to Creutzfeld-Jakob disease (CJD) pathogens or variants must not be reprocessed under any circumstances. Follow the instructions of the manufacturers of the reprocessing agents and equipment. 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.</p>
	<p>Before using it again, ensure that the device is completely dry after reprocessing. No ultrasonic reprocessing. The optical fibres could be damaged beyond repair. In case of questions regarding the processing procedures, please refer to the FAQs on our Website.</p>
<p>Limitations on reprocessing</p>	<ul style="list-style-type: none"> • Periodically check the integrity of the device. • Steam sterilization: Max. 1000 cycles Beyond these cycles, the product may continue to be used if it is in a safe and good condition.



Choice of the reprocessing procedure



The hygienic classification (Spaulding classification) of the instruments, 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.

If you, the user or the qualified person responsible for reprocessing, have classified the Finoff transilluminator as “**non-critical**” (Spaulding classification) then wipe disinfection can be performed (**see chapter A**).

Otherwise (e.g. for scleral illumination with aperture cap), fungicidal, bactericidal (including mycobacteria) und virucidal disinfection (i.e. manual cleaning with immersion-disinfection or automated cleaning and disinfection) and/or sterilization shall be performed (**see chapter B-E**).

Choose one of the following reprocessing methods:

		Cleaning and disinfection			
		Wipe disinfection	Automated cleaning and disinfection	Manual cleaning (brushing)	Fungicidal, bactericidal (including mycobacteria) und virucidal manual disinfection (immersion)
Sterilization	No sterilization	Chapter A	Chapter B	Chapter C	
	Steam		Chapter D	Chapter E	



Chapter A: Wipe disinfection

1. Preparation

Disassemble the aperture cap with Cobalt blue filter from the Finoff transilluminator and reprocess it separately just like the Finoff transilluminator.

2. 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

- Disinfection wipes: alcohol and/or quarternary ammonium compounds (e. g. Super Sani-Cloth by PDI or Clinell Universal Wipes) which are fungicidal, bactericidal (including mycobacteria) und virucidal and have confirmed efficacy against Hepatitis B

Implementation

- Clean and disinfect the device manually.
- Pay particular attention to difficult to access areas.
- Thoroughly wipe the touched areas.
- For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.

3. Inspection and function testing



- Check the Finoff transilluminator and the aperture cap with Cobalt blue filter for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the product, especially the aperture cap with Cobalt blue filter for sharp edges.
- Do not use the product if there are visible signs of damage.

4. Storage

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



Chapter B: Automated cleaning and disinfection

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 Finoff transilluminator from the handle and reprocess the handle separately.

Remove the lamp from the Finoff transilluminator. It won't be reprocessed.

Disassemble the aperture cap from the Finoff transilluminator and reprocess it separately just like the Finoff transilluminator.

4. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning 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).
- Neutralizing agent if specified by the cleaning agent manufacturer.

Implementation

- 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. (e. g. Vario TD program by Miele)

5. Remounting

Insert the lamp back into the Finoff transilluminator

6. Inspection



- Check the Finoff transilluminator and the aperture cap for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the product, especially the aperture cap for sharp edges.
- Do not use the product if there are visible signs of damage.

7. Storage

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



Chapter C: Manual cleaning (brushing) and 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 Finoff transilluminator from the handle and reprocess the handle separately.

Remove the lamp from the Finoff transilluminator. It won't be reprocessed.

Disassemble the aperture cap from the Finoff transilluminator and reprocess it separately just like the Finoff transilluminator.

4. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME).
- Warm (30 - 40 °C) demineralized water, Soft plastic brushes.

Implementation

- Soak the Finoff transilluminator and the aperture cap for 1 min. submerged in the cleaning solution (30 - 40 °C).
- Clean all surfaces of the Finoff transilluminator and the aperture cap by brushing (submerged in the cleaning solution).
- Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

5. Manual immersion disinfection

Equipment

- Disinfecting agent (fungicidal, bactericidal (including mycobacteria) und virucidal) 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 Finoff transilluminator and the aperture cap 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. Remounting

Insert the lamp back into the Finoff transilluminator

7. Inspection



- Check the Finoff transilluminator and the aperture cap for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the product, especially the aperture cap for sharp edges.
- Do not use the product if there are visible signs of damage.

8. Storage

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



Chapter D: 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 Finoff transilluminator from the handle and reprocess the handle separately.

Remove the lamp from the Finoff transilluminator. It won't be reprocessed.

Disassemble the aperture cap from the Finoff transilluminator and reprocess it separately just like the Finoff transilluminator.

4. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning of the Finoff transilluminator and the aperture cap 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).
- Neutralizing agent if specified by the cleaning agent manufacturer.

Implementation

- 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 (e. g. Vario TD program by Miele).

5. Inspection



- Check the Finoff transilluminator and the aperture cap for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the product, especially the aperture cap for sharp edges.
- Do not use the product if there are visible signs of damage.

6. Packaging for sterilization

Pack the Finoff transilluminator and the aperture cap 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. Remounting

Insert the lamp back into the Finoff transilluminator



Chapter E: Manual cleaning (brushing), manual disinfection (immersion) and 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 Finoff transilluminator from the handle and reprocess the handle separately.

Remove the lamp from the Finoff transilluminator. It won't be reprocessed.

Disassemble the aperture cap from the Finoff transilluminator and reprocess it separately just like the Finoff transilluminator.

4. Manual cleaning by brushing

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME).
- Warm (30 - 40 °C) demineralized water, Soft plastic brushes.

Implementation

- Soak the Finoff transilluminator and the aperture cap for 1 min. submerged in the cleaning solution (30-40 °C).
- Clean all surfaces of the Finoff transilluminator and the aperture cap by brushing (submerged in the cleaning solution).
- Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism.
- For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.

5. Manual immersion disinfection

Equipment

- Disinfecting agent (fungicidal, bactericidal (including mycobacteria) und virucidal) 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 Finoff transilluminator and the aperture cap 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. Inspection



- Check the Finoff transilluminator and the aperture cap for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the product, especially the aperture cap for sharp edges.
- Do not use the product if there are visible signs of damage.

7. Packaging for sterilization

Pack the Finoff transilluminator and the aperture cap individually in single or double standardized sterilization pouches suitable for the selected sterilization process.

8. 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.



9. **Storage**
Store it in such a way that it is protected from recontamination, dust and moisture.
10. **Remounting**
Insert the lamp back into the Finoff transilluminator

