

Hygienic Reprocessing

HEINE FlexTip®+ F.O. Blade




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 blade 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"> • Steam sterilization: Max. 4000 cycles Beyond these cycles, the product may continue to be used if it is in a safe and good condition. • For all other reprocessing methods: As long as the product meets the requirements of ISO 7376.





Choice of the reprocessing procedure

Choose one of the following reprocessing methods:

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



Chapter A: 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 blade from the handle and reprocess the handle separately.
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.
5. **Inspection**

 - Check the blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
 - Check the safe functionality of the mobility of the blade tip and lever.
 - Do not use the product if there are visible signs of damage.
6. **Storage**
Store it in such a way that it is protected from recontamination, dust and moisture.



Chapter B: 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 the handle separately.

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 blade for 1 min. submerged in the cleaning solution (30-40 °C).
- Clean all surfaces of the blade by brushing (submerged in the cleaning solution).
- Pay particular attention to recesses, ridges, difficult to access areas of the snap-in mechanism and the moving elements.
- 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 blade 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 blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the safe functionality of the mobility of the blade tip and lever.
- 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: 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 the handle separately.

4. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning of the blade 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.

5. Inspection



- Check the blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the safe functionality of the mobility of the blade tip and lever.
- Do not use the product if there are visible signs of damage.

6. Packaging for sterilization

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

7. Sterilization

7.1 STERRAD sterilization

Equipment

- STERRAD NX, 100NX or 100S Sterilizer

Implementation

- Perform the STERRAD NX Standard or Advanced cycle.

7.2 VHP (Steris) sterilization

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“ or „Non Lumen cycle“.

8. Storage

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



Chapter D: 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 the handle separately.

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

5. Inspection



- Check the blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the safe functionality of the mobility of the blade tip and lever.
- Do not use the product if there are visible signs of damage.

6. Packaging for sterilization

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

7. Sterilization

7.1 STERRAD sterilization

Equipment

- STERRAD NX, 100NX or 100S Sterilizer

Implementation

- Perform the STERRAD NX Standard or Advanced cycle.

7.2 VHP (Steris) sterilization

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“ or „Non Lumen cycle“.

8. Storage

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



Chapter E: 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 the handle separately.

4. Cleaning and disinfection



If it is required in your institution or your country, you can perform manual cleaning of the blade 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.

5. Inspection



- Check the blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the safe functionality of the mobility of the blade tip and lever.
- Do not use the product if there are visible signs of damage.

6. Packaging for sterilization

Pack the blade 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.



Chapter F: Manual cleaning (brushing) 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 blade from the handle and reprocess the handle separately.

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

5. Inspection



- Check the blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Check the safe functionality of the mobility of the blade tip and lever.
- Do not use the product if there are visible signs of damage.

6. Packaging for sterilization

Pack the blade 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.

