Hygienic Reprocessing

HEINE Classic+ Fiber Optic (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.

	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, 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.
	Before using it again, ensure that the blade is completely dry after reprocessing.
	No ultrasonic reprocessing. The optical fibres could be damaged beyond repair.
Limitations on reprocessing	• 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.

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Choice of the reprocessing procedure

Choose one of the following reprocessing methods:

		Cleaning and disinfection		
		Automated cleaning and disinfection	**Manual cleaning (brushing)**	**Fungicidal, bactericidal (including mycobacteria) und virucidal manual disinfection (immersion)**
Sterilization	**No Sterilization**	Chapter A	Chapter B	
	Low Temperature STERRAD / VHP (Steris)	Chapter C	Chapter D	
	Steam	Chapter E	Chapter F	

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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

- Choose 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 blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- 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.

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Chapter B: 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 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.
   - 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):
     Based on succinic acid dialdehyde (e.g. gigasept FF (new))
     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.
   - 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.

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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
- Choose 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 blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- 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.

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Chapter D: Manual cleaning (brushing), manual disinfection (immersion) 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. 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.
- 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):
  Based on succinic acid dialdehyde (e.g. gigasept FF (new))
  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.
- Do not use the product if there are visible signs of damage.

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

8. Sterilization

8.1 STERRAD sterilization
Equipment
- STERRAD NX, 100NX or 100S Sterilizer

Implementation
Perform the STERRAD NX Standard or Advanced cycle.

8.2 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“.

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

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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
- Choose 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 blade for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- 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. 137 °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.

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Chapter F: 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 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.
   - 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):
     Based on succinic acid dialdehyde (e.g. gigasept FF (new))
     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.
   - Do not use the product if there are visible signs of damage.
7. **Packaging for sterilization**
   Pack the blade 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. 137 °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.

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