HEINE QUALITY MADE IN GERMANY

Hygienic Reprocessing

HEINE® Classic+ and Modular+ Fiber Optik (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 in terms of set up, operation or maintenance, as applicable. Notes are important, but not related to hazardous situations.

	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.
	After each use and charging, 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.
	Please consider the instructions of the manufacturer for the applied reprocessing media.
	HEINE Optotechnik only approves the agents and procedures listed in this instruction.
	Hygienic reprocessing is to be carried out by persons with adequate hygienic expertise.
	The described reprocessing measures do not replace the specific rules applicable for your institution/ department.
	Modular Macintosh blades are not suitable for reprocessing using Hydrogen Peroxide.
	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.
	Before using it again, ensure that the blade is completely dry after reprocessing.
	No ultrasonic reprocessing. The optical fibres could be damaged beyond repair.
	After cleaning, the blade must be rinsed free of residue in order to avoid reactions with subsequent treatment stages/ damage to the materials.
	For important details regarding the processing procedures, please refer to the FAQs for Hygienic Reprocessing on our Website.
Limitations on reprocessing	Hygienic reprocessing only has a minor influence on the product life as this is determined mainly by wear and tear during use. Periodically check the integrity of the device and that the illumination is sufficient!

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Choice of the reprocessing procedure

The hygienic classification (Spaulding classification) of the laryngoscope blades, 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.

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	

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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.
Classic+ blades cannot be dismounted.
Modular+ Blades shall be dismounted for reprocessing:
Mac: Grasp the blade with one hand and push out the light module with the thumb of the other hand.
Miller: Grasp the blade with one hand, press the light module at the top with the thumb of your other hand out of the lock and pull it out of the socket.

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

- 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 blade or its modules for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Do not use the device if there are visible signs of damage.
- Perform functional testing after reprocessing.

6. Storage

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

7. Reassembly

Reassemble the Modular+ blade in hygienic environment: Insert the light module in its blade module.

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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.
   Classic+ blades cannot be dismounted.
   Modular+ Blades shall be dismounted for reprocessing:
   Mac: Grasp the blade with one hand and push out the light module with the thumb of the other hand.
   Miller: Grasp the blade with one hand, press the light module at the top with the thumb of your other hand out of the lock and pull it out of the socket.
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 or its modules for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces of the blade or its modules 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
   - High level disinfectant for immersion disinfection (compatible with cleaning agent):
     Quarternary ammonium compounds (e. g. neodisher® Septo MED)
     or agent ortho-phthalaldehyde (e. g. Cidex®OPA)

   Implementation
   - Immerse the blade or its modules 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 and function testing**
   - Check the blade or its modules for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Do not use the device if there are visible signs of damage.
   - Perform functional testing after reprocessing.
7. **Storage**
   Store it in such a way that it is protected from recontamination, dust and moisture.
8. **Reassembly**
   Reassemble the Modular+ blade in hygienic environment: Insert the light module in its blade module.

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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.
Classic+ blades cannot be dismounted.
Modular+ Blades shall be dismounted for reprocessing:
Mac: Grasp the blade with one hand and push out the light module with the thumb of the other hand.
Miller: Grasp the blade with one hand, press the light module at the top with the thumb of your other hand out of the lock and pull it out of the socket.

4. Cleaning and disinfection

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

- 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 blade or its modules for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Do not use the device if there are visible signs of damage.
- Perform functional testing after reprocessing.

6. Packaging for sterilization
Pack the blade or its modules 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.

9. Reassembly
Reassemble the Modular+ blade in hygienic environment: Insert the light module in its blade module.

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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.
   Classic+ blades cannot be dismounted.
   Modular+ Blades shall be dismounted for reprocessing:
   Mac: Grasp the blade with one hand and push out the light module with the thumb of the other hand.
   Miller: Grasp the blade with one hand, press the light module at the top with the thumb of your other hand out of the lock and pull it out of the socket.
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 or its modules for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces of the blade or its modules 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. **Inspection and function testing**
   - Check the blade or its modules for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Do not use the device if there are visible signs of damage.
   - Perform functional testing after reprocessing.
6. **Packaging for sterilization**
   Pack the blade or its modules 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.
9. **Reassembly**
   Reassemble the Modular+ blade in hygienic environment: Insert the light module in its blade module.

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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.
   Classic+ blades cannot be dismounted.
   Modular+ Blades shall be dismounted for reprocessing:
   Mac: Grasp the blade with one hand and push out the light module with the thumb of the other hand.
   Miller: Grasp the blade with one hand, press the light module at the top with the thumb of your other hand out of the lock and pull it out of the socket.
4. **Cleaning and disinfection**
   If it is required in your institution or your country, you can perform manual cleaning of the blade or its modules 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

- 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 blade or its modules for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Do not use the device if there are visible signs of damage.
   - Perform functional testing after reprocessing.
6. **Packaging for sterilization**
   Pack the blade or its modules 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. **Reassembly**
   Reassemble the Modular+ blade in hygienic environment: Insert the light module in its blade module.

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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.
   Classic+ blades cannot be dismounted.
   Modular+ Blades shall be dismounted for reprocessing:
   Mac: Grasp the blade with one hand and push out the light module with the thumb of the other hand.
   Miller: Grasp the blade with one hand, press the light module at the top with the thumb of your other hand out of the lock and pull it out of the socket.
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 or its modules for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces of the blade or its modules 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. **Inspection and function testing**
   - Check the blade or its modules for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Do not use the device if there are visible signs of damage.
   - Perform functional testing after reprocessing.
6. **Packaging for sterilization**
   Pack the blade or its modules 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. **Reassembly**
   Reassemble the Modular+ blade in hygienic environment: Insert the light module in its blade module.

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