

# 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.

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | <p>Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines.<br/>The described reprocessing measures do not replace the specific rules applicable for your institution/ department.</p>                                                                                                                                                                                                                                                                                |
|    | <p>After each use carry out hygienic reprocessing.<br/>Equipment where there is a suspicion of exposure to Creutzfeldt-Jakob disease (CJD) pathogens or variants must not be reprocessed under any circumstances.<br/>Follow the instructions of the manufacturers of the reprocessing agents and equipment.<br/>HEINE Optotechnik GmbH &amp; Co. KG only approves the agents and procedures listed in this instruction.<br/>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.<br/>No ultrasonic reprocessing. The optical fibers could be damaged beyond repair.</p>                                                                                                                                                                                                                                                                                                                                             |
| <p>Limitations on reprocessing</p>                                                  | <ul style="list-style-type: none"> <li>• Steam sterilization: Max. 4000 cycles<br/>Beyond these cycles, the product may continue to be used if it is in a safe and good condition.</li> <li>• For all other reprocessing methods: As long as the product meets the requirements of ISO 7376.</li> </ul>                                                                                                                                                                                                                  |

## Choice of the reprocessing procedure (According to FDA)

Choose one of the following reprocessing methods:

|               |                                              | Cleaning and disinfection              |                               |                                                     |
|---------------|----------------------------------------------|----------------------------------------|-------------------------------|-----------------------------------------------------|
|               |                                              | Automated<br>cleaning and disinfection | Manual cleaning<br>(brushing) | High-level<br>manual<br>disinfection<br>(immersion) |
| Sterilization | No Sterilization                             | Chapter A                              | Chapter B                     |                                                     |
|               | Low Temperature<br>STERRAD /<br>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*

- 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.

### 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.

## 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.
- 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):  
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.

## 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.

### 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.

## 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.
- 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.
- 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*

- 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.

### 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.

## 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.
- 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.
- 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.