HEINE QUALITY
MADE IN GERMANY

Hygienic Reprocessing

HEINE UniSpec® Instrument head

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, carry out hygienic reprocessing.
	Please consider the instructions of the manufacturer for the applied reprocessing media.
	HEINE Optotechnik only approves the agents and procedures listed in this instruction.
	The 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.
	UniSpec Tubes are for single use only. After use, they must not be reused. An attempt to reprocess them could result in damage to the tube or obturator and injury to the patient.
	In case of suspected contamination inside the insufflation bulb, discard it.
	The insufflation bulb cannot be sterilized.
	The micro-bacterial efficiency is only valid for the recommended hygienic reprocessing methods. Information to alternative reprocessing methods do not guarantee micro-bacterial efficiency and the absence of residual agents.
	Before using it again, ensure that the device is completely dry after reprocessing.
	After cleaning, the components 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	The reprocessing of the instrument heads over 65 °C could reduce the light transmission and life expectancy of the optical fibers.

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

Choice of the reprocessing procedure

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

For the Instrument head, choose one of the following reprocessing procedures:

		Cleaning and disinfection		
		Automated cleaning and disinfection	**Manual cleaning (brushing)**	**Manual disinfection (immersion)**
Sterilization	**No Sterilization**	Chapter A*	Chapter B	
	Steam	Chapter C*	Chapter D	

*Validated

For the insufflation bulb wipe disinfection has to be performed (Chapter E)

For the sponge holder manual cleaning (brushing) and manual disinfection (immersion) has to be performed (Chapter F)

For the illumination adaptor wipe disinfection has to be performed (Chapter G)

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

Chapter A: Automated cleaning and disinfection of the instrument head

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

Remove the tube from the instrument head and dispose it.
For reprocessing, open the viewing window of the instrument head and remove the swivel lens.

⚠ Remove the light source before reprocessing

4. Cleaning and disinfection

4.1 Manual pre cleaning

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® or neodisher® MediClean)
- Soft plastic brushes

Implementation

- Soak the instrument head and the swivel lens for 1 min. submerged in the cleaning solution (30 - 40 °C).
- Brush off visible contamination on the outer and inner surfaces at least 3 times (immersed in cleaning solution) with a plastic brush.
- Then rinse the components with running demineralised water.

4.2 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: alkaline (e.g. neodisher® FA)
- Neutralizing agent: based on citric acid (e.g. neodisher® Z)

Implementation

- Place the instrument heads in the washer-disinfector in a tilt resistant manner without touching each other.
- The connector for the insufflation bulb has to be connected to flushing connections of the washer/disinfector, to flush the lumen sufficiently.
- 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. e. g.
  - pre-rinsing
  - alkaline cleaning
  - neutralisation / based on citric acid
  - rinsing / without additive
  - final rinsing,
  - disinfection 93°C
  - drying

5. Inspection and function testing

⚠
- Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Perform functional testing after reprocessing.

6. Storage

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

Chapter B: Manual cleaning (brushing) and manual disinfection (immersion) of the instrument head

(alternative reprocessing procedure)

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**
   Remove the tube from the instrument head and dispose it.
   For reprocessing, open the viewing window of the instrument head and remove the swivel lens.

Remove the light source before reprocessing

4. **Manual cleaning by brushing**
   Equipment
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® by ASP®).
   - Warm (30 - 40 °C) demineralized water, Soft plastic brushes.

   Implementation
   - Soak the instrument head and the swivel lens for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces by brushing (submerged in the cleaning solution).
   - Pay particular attention to recesses, ridges and difficult to access areas.
   - For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.
   - Optics may be wiped using a micro-fibre cloth.

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. Cidex®OPA)

   Implementation
   - Immerse the instrument head and the swivel lens 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 device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
7. **Storage**
   Store it in such a way that they are protected from recontamination, dust and moisture.

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

Chapter C: Automated cleaning and disinfection, steam sterilization of the instrument head

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

Remove the tube from the instrument head and dispose it.
For reprocessing, open the viewing window of the instrument head and remove the swivel lens.

⚠ Remove the light source before reprocessing

4. Cleaning and disinfection

4.1 Manual pre cleaning

Equipment

- Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® or neodisher® MediClean)
- Soft plastic brushes

Implementation

- Soak the instrument head and the swivel lens for 1 min. submerged in the cleaning solution (30 - 40 °C).
- Brush off visible contamination on the outer and inner surfaces at least 3 times (immersed in cleaning solution) with a plastic brush.
- Then rinse the components with running demineralised water.

4.2 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: alkaline (e.g. neodisher® FA)
- Neutralizing agent:
  based on citric acid (e.g. neodisher® Z)

Implementation

- Place the instrument heads in the washer-disinfector in a tilt resistant manner without touching each other.
- The connector for the insufflation bulb has to be connected to flushing connections of the washer/disinfector, to flush the lumen sufficiently.
- 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. e. g.
  - pre-rinsing
  - alkaline cleaning
  - neutralisation / based on citric acid
  - rinsing / without additive
  - final rinsing,
  - disinfection 93°C
  - drying

5. Inspection and function testing

⚠
- Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
- Perform functional testing after reprocessing.

6. Packaging for Sterilization

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

7. Steam Sterilization

The real drying time depends on various parameters. Its determination and validation is in the responsibility of the user.

Equipment

Steam sterilizer (Class B according to DIN EN 13060)

Implementation

Use the following program (ISO 17665):

Fractionated vacuum procedure (at least 3 pre-vacuum cycles):

- 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 D: Manual cleaning (brushing), manual disinfection (immersion) and steam sterilization of the instrument head

(alternative reprocessing procedure)

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**
   Remove the tube from the instrument head and dispose it.
   For reprocessing, open the viewing window of the instrument head and remove the swivel lens.

Remove the light source before reprocessing

4. **Manual cleaning by brushing**
   Equipment
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® by ASP®).
   - Warm (30 - 40 °C) demineralized water, Soft plastic brushes.

   Implementation
   - Soak the instrument head and the swivel lens for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces by brushing (submerged in the cleaning solution).
   - Pay particular attention to recesses, ridges and difficult to access areas.
   - For removing the cleaning agent and drying afterwards, follow the instructions provided by the manufacturer of the cleaning agent.
   - Optics may be wiped using a micro-fibre cloth.
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. Cidex®OPA)

   Implementation
   - Immerse the instrument head and the swivel lens 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 device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
7. **Packaging for Sterilization**
   Pack the items individually in single or double standardized sterilization pouches suitable for the selected sterilization process.
8. **Steam Sterilization**

   The real drying time depends on various parameters. Its determination and validation is in the responsibility of the user.

   Equipment
   Steam sterilizer (Class B according to DIN EN 13060)
   Implementation
   Use the following program (ISO 17665):
   Fractionated vacuum procedure (at least 3 pre-vacuum cycles):
   - Sterilization temperature: at least 132 °C (max. 134 °C)
   - Exposure time/holding time: at least 3 min.
   - Drying time: at least 20 min.

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

9. Storage

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

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

Chapter E: Wipe disinfection of the insufflation bulb

(Material compatible procedure)

1. **Containment and transportation**

   Reprocess as soon as possible following use.

   For highly infectious cases (previous or following patients) e. g. in case of a proven existence of a dangerous infectious disease (symptomatic or asymptomatic), dispose the insufflation bulb directly after use.

   The insufflation bulb cannot be sterilized.

2. **Preparation**

   Remove the insufflation bulb from the UniSpec instrument head and dispose of the hygiene filter.

3. **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

   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. neodisher® MediClean or Cidezyme®)
   - Disinfectant:
     quarternary ammonium compounds (e. g. Cleanisept® Wipes , Mikrobac® Tissues or Sani-Cloth® AF3),
     alcoholic (e. g. Incides® N) or
     hydrogen peroxide (e. g. PREempt™ Wipes)

   Implementation

   - Wipe all outer surfaces with wipes at least 3 times.
   - Pay particular attention to difficult to access areas.
   - For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.

4. **Inspection and function testing**

   - Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.

5. **Storage**

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

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

Chapter F: Manual cleaning (brushing) and manual disinfection (immersion) of the sponge holder

(Material compatible procedure)

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**
   The sponge holder must be reprocessed with the pliers open.
4. **Manual cleaning by brushing**
   Equipment
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. CIDEZYME® by ASP®).
   - Warm (30 - 40 °C) demineralized water, Soft plastic brushes.

   Implementation
   - Soak the sponge holder for 1 min. submerged in the cleaning solution (30-40 °C).
   - Clean all surfaces by brushing (submerged in the cleaning solution).
   - Pay particular attention to difficult to access areas.
   - Thoroughly brush the areas touched by the patient or the user.
   - 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. Cidex®OPA)

   Implementation
   - Immerse the sponge holder 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 device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
7. **Storage**
   Store it in such a way that they are protected from recontamination, dust and moisture.

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018

Chapter G: Wipe disinfection of the illumination adaptor

(Material compatible procedure)

1. **Preparation**
   In the event of suspected contamination, carry out hygienic reprocessing of the instrument.
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
   - Cleaning agent: enzymatic or neutral to mildly alkaline (e. g. neodisher® MediClean or Cidezyme®)
   - Disinfectant:
     quarternary ammonium compounds (e. g. Cleanisept® Wipes, Mikrobac® Tissues or Sani-Cloth® AF3) or alcoholic (e. g. Incides® N)

   Implementation
   - Wipe all outer surfaces with wipes at least 3 times.
   - Pay particular attention to difficult to access areas.
   - For removing the disinfectant and drying afterwards, follow the instructions provided by the disinfectant manufacturer.
3. **Inspection and function testing**
   - Check the device for any visible contaminants or abrasions. Reprocess again if necessary. Dispose if the contaminants cannot be removed.
   - Perform functional testing after reprocessing.
4. **Storage**
   Store it in such a way that it is protected from recontamination, dust and moisture.

HEINE Optotechnik GmbH & Co. KG • Kientalstr. 7 • 82211 Herrsching • Germany
Tel. +49(0)8152/38-0 • Fax +49(0)8152/38-202 • E-Mail: info@heine.com • **www.heine.com**

med 112719 02/07.2018