KARL STORZ — ENDOSKOPE

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Reprocessing instructions
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NOT APPLICABLE FOR THE US

1 Target group

These reprocessing instructions are intended for personnel with technical knowledge and expertise in the reprocessing of medical devices.

2 General information

2.1 Read the reprocessing instructions

If the reprocessing instructions are not followed, patients, users, or third parties may be injured or the product may be damaged.

- ▶ Read the reprocessing instructions for the product and its components carefully and follow all the safety notes and warnings.

2.2 Read the reprocessing instructions for use

If the reprocessing instructions for use are not followed, patients, users, or third parties may be injured or the product may be damaged.

- ▶ Read and follow the “Cleaning, disinfection, care, and sterilization of KARL STORZ instruments” instructions for use (item no. 96216003).

The cleaning, disinfection, and sterilization procedures are explained in detail in the reprocessing instructions for use.

The reprocessing instructions for use can be downloaded from www.karlstorz.com.

2.3 Read the instructions for use for the reprocessing unit

If the instructions for use are not followed, patients, users, or third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use for the reprocessing unit carefully and follow all the safety notes and warnings.
- ▶ Carry out reprocessing in accordance with the instructions for use for the reprocessing unit.

2.4 National laws and regulations

National laws and regulations must be observed in addition to the accompanying documentation.

2.5 Additional information on the product

Additional general information on the product can be requested and downloaded from www.karlstorz.com.

2.6 Description of warning messages

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed. The warning messages describe the following levels of danger.

⚠ WARNING
WARNING

Designates a possible imminent risk. If this is not avoided, it could lead to death or serious injuries.

⚠ CAUTION
CAUTION

Designates a possible imminent risk. If this is not avoided, it could lead to minor injuries.

NOTICE
NOTICE

Designates a possibly harmful situation. If this is not avoided, the products could be damaged.

3 Safety

3.1 Unsterile product

The product is not sterile when delivered. The use of non-sterile products poses a risk of infection for patients, users, and third parties.

- ▶ Reprocess the product in line with the reprocessing instructions before initial use and every subsequent use.

3.2 Contaminated products

During work on contaminated devices, the guidelines for personal safety must be observed.

3.3 Working with process chemicals

Incorrect exposure time, concentration, life span, and range of action of chemicals can lead to a risk of infection for the patient, user, and third parties, as well as damage to the product.

- ▶ Note the information provided by the manufacturer of the chemicals and the microbiological range of action of the chemicals used.

3.4 Creutzfeldt-Jakob disease

Products that come into contact with the central nervous system can become contaminated by organic residue containing prions. Prions lead to infection with Creutzfeldt-Jakob disease.

If Creutzfeldt-Jakob disease has been diagnosed or is suspected:

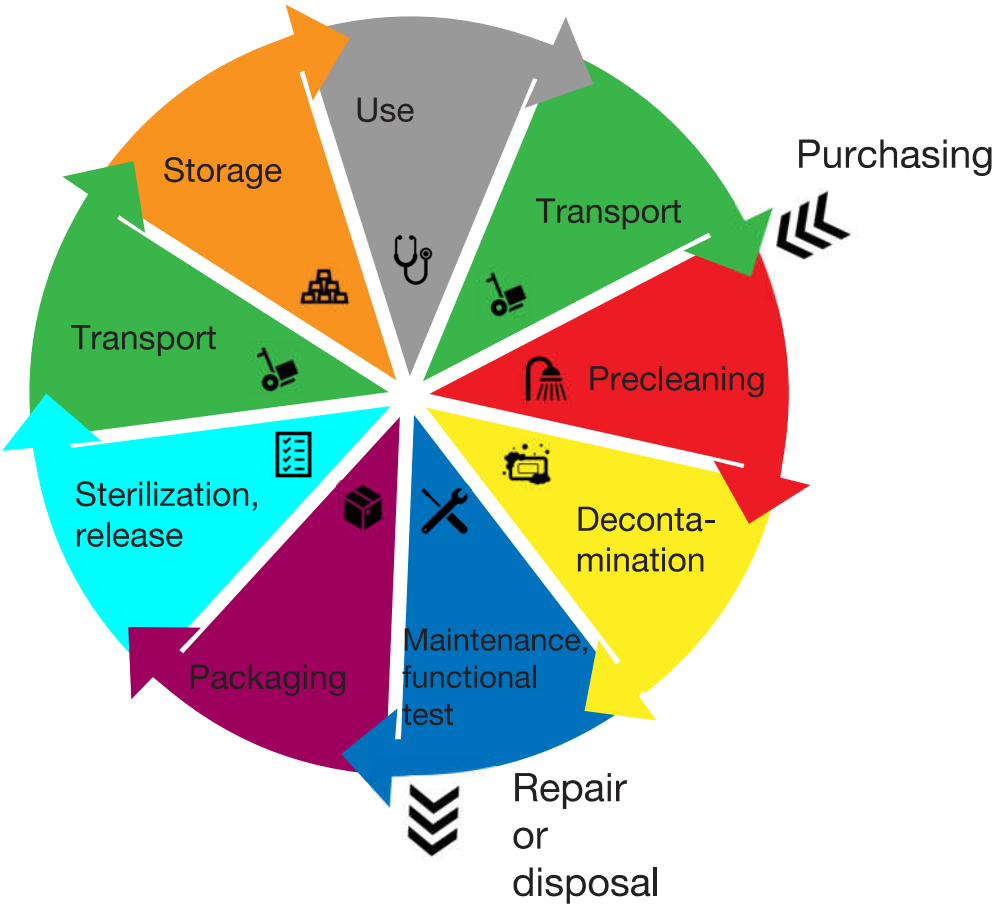
- ▶ Do not continue to use the product.
- ▶ Dispose of the product properly.

4 Overview of processes

The following reprocessing procedures have been approved for the product:

- Reprocessing with manual decontamination

4.1 Reprocessing cycle for standard products



5 Materials for reprocessing

The reprocessing accessories used must be clean and functional.

The reprocessing accessories are listed below:

Application	Material
Initial treatment at the site of use	Moist compresses, possibly disposable cloth
Pre-Cleaning	
Brushing the surfaces	Brush, item no. 27652
Cleaning and disinfection	
Manual drying and/or after-drying	Medical compressed air from compressed air gun, item no. 27660 Alternatively: syringe 60 cc
Maintenance	
Packaging	Standardized and approved packaging

Suitable reprocessing accessories are listed in the following catalog:

- HYGIENE – Care, Sterilization, Storage Techniques (item no. 96211004)

6 Bedside Pre-Cleaning

Reprocessing of the product should start within 2 hours of use to ensure the effectiveness of the reprocessing processes listed in the reprocessing instructions.

1. Wipe the surfaces of the product with a compress or disposable cloth to remove gross soiling, corrosive solutions, and drugs.
2. Rinse surfaces with cold water.

6.1 Transport to the reprocessing site

1. Right after using / bedside pre-cleaning of the product, place it in a suitable dry transport container.
2. Transport the securely positioned product to the site of reprocessing.

7 Cleaning and disinfection

The following procedures are validated and approved for cleaning and disinfection of the product:

- Manual cleaning and disinfection

7.1 Reprocessing with manual decontamination

7.1.1 Pre-Cleaning

The product is not suitable for ultrasonic treatment.

7.1.1.1 Brushing surfaces

Requisite materials:

- Brush, item no. 27652

1. Clean the surfaces of the product under cold running water with a brush.
2. Mobile parts must be brushed under running water.
3. Brush the surfaces until residue can no longer be seen and then brush for a further minute.
4. Irrigate the surfaces with cold running water.

7.1.2 Manual cleaning

Required materials:

1. Immerse the product completely in the cleaning solution.
2. Allow to take effect in accordance with the specifications of the chemicals manufacturer.
3. Irrigate the product with cold water for at least one minute for neutralization.

7.1.3 Manual disinfection

Required materials:

- Water of at least drinking water quality according to country-specific regulations

1. Immerse the product completely in the disinfectant solution.
2. Allow to take effect in accordance with the specifications of the chemicals manufacturer.
3. Use the water gun and rinsing attachment to rinse the product.
   Alternative: Use the syringe and adaptor to rinse the product at least 3 times with sterile water.

   ⚠ WARNING

   Risk of infection due to residual liquid!

   If devices are not adequately dried following disinfection, the effectiveness of the validated reprocessing processes is not guaranteed.

   ▶ Use compressed air or a syringe filled with air to dry devices fully following disinfection.
4. Dry all surfaces, joints, openings, channels, and lumens completely using compressed air or an air-filled syringe.

8 Visual inspection

1. Check products for the following points:
   – Visible soiling
   – Damage and corrosion
   – Completeness
   – Dryness
2. Subject any products displaying visible soiling to another complete cleaning and disinfection process.
3. Discard damaged and corroded medical devices.
4. Discard incomplete medical devices or replace missing parts.
5. Dry the product by hand if necessary.

9 Life span

The end of the product life is largely determined by wear, reprocessing processes, the chemicals used and any damage resulting from use.

9.1 Functional check

If the device does not fulfill one of the points listed below or if damage can be identified, see chapter ‘Maintenance, repair, servicing and disposal’ in the instructions for use.

The following tests must be carried out to detect functional limitations:

1. Check the surface of the product for mechanical integrity and changes.
2. Check the labeling for legibility.
3. Check the product for mechanical integrity.
4. Check the correct positioning of the assembled components and, if necessary, also check the cleaning connector.
5. Check the mobility of all mobile components, if necessary once the components have been assembled in the case of products that can be dismantled.
6. Check whether the end positions of the application part are reached.
7. Check if the image is transmitted.
8. Check and inspect the product annually.

10 Packaging

The packaging material must always be matched to the sterilization process being used.

Required materials:

- Standardized packaging materials and packaging materials and systems that have been approved for the product (EN 868 Parts 2–10, EN ISO 11607 Parts 1 + 2, DIN 58953)

11 Sterilization

The sterilization processes described below have been validated and approved for this medical device by KARL STORZ.

- ▶ Select the suitable procedure, taking into consideration the country-specific regulations and in consultation with the device manufacturer.

11.1 Hydrogen peroxide (H2O2) – ASP STERRAD

⚠ WARNING

Risk of infection due to inadequate sterilization!

Oiled devices can only be adequately sterilized by means of steam sterilization with fractionated vacuum.

- ▶ Only oil devices if they are sterilized by means of steam sterilization with fractionated vacuum.

Within the scope of validation, the following material was used:

- KIMBERLY-CLARK KC400 KIMGUARD STERILIZATION WRAP

The following STERRAD procedures have been validated and approved by KARL STORZ for the product:

- STERRAD 100S Short Cycle without Booster
  - Tray/container 39301HCT2
- STERRAD NX Standard Cycle
  - Tray/container 39301HCTS
- STERRAD 100NX Standard Cycle
  - Tray/container 39301HCTS
- STERRAD 100NX DUO Cycle

11.2 Hydrogen peroxide (H2O2) – STERIS V-PRO

⚠ WARNING

Risk of infection due to inadequate sterilization!

Oiled devices can only be adequately sterilized by means of steam sterilization with fractionated vacuum.

- ▶ Only oil devices if they are sterilized by means of steam sterilization with fractionated vacuum.

Within the scope of validation, the following material was used:

- H600 HALYARD Sterilization Wrap

The following STERIS V-PRO procedures have been validated and approved by KARL STORZ for the product:

- STERIS V-PRO 1
- STERIS V-PRO 1 Plus lumen cycle
- STERIS V-PRO 1 Plus non-lumen cycle
- STERIS V-PRO maX lumen cycle
- STERIS V-PRO maX non-lumen cycle
- STERIS V-PRO maX flexible cycle
- STERIS V-PRO maX 2 lumen cycle
- STERIS V-PRO maX 2 non-lumen cycle

- STERIS V-PRO maX 2 fast non-lumen cycle
- STERIS V-PRO maX 2 flexible cycle
- STERIS V-PRO 60 lumen cycle
- STERIS V-PRO 60 non-lumen cycle
- STERIS V-PRO 60 flexible cycle

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