KARL STORZ — ENDOSKOPE

en **Reprocessing instructions**
Light Adaptor Video Endoscopes
20045031

02-2021

CE

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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.

ATTENTION

ATTENTION

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 unsterile products poses a risk of infection for patients, users, or third parties.

- Before use, reprocess the product in line with the reprocessing instructions.

3.2 Contaminated products

During work on contaminated products, 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 Creutzfeld-Jakob disease has been diagnosed or is suspected:

- Dispose of the product properly and do not continue to use it.

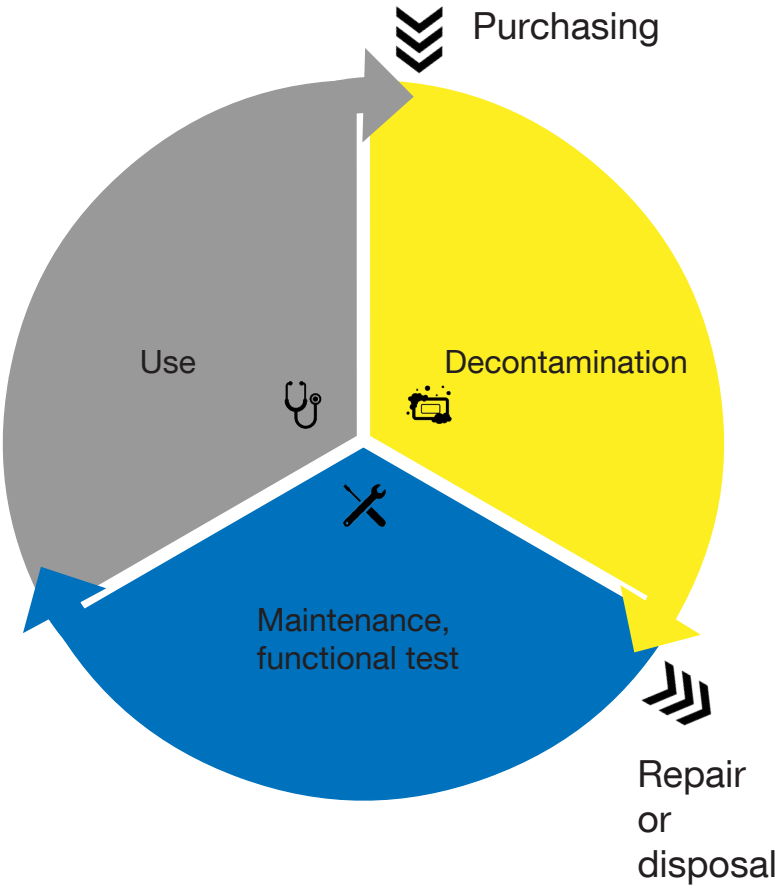
4 Overview of processes

The following reprocessing procedures have been approved for the product:

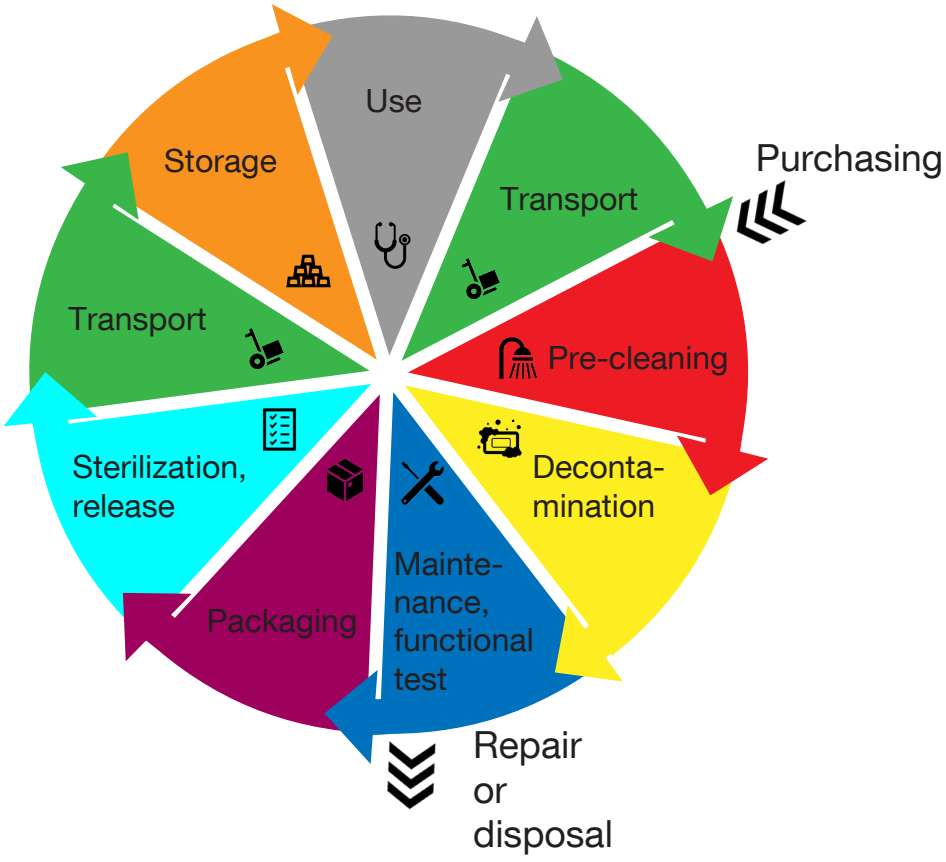
- Manual wipe disinfection
- Reprocessing with automated decontamination

A detailed description of the validated processes is provided in the respective chapters in these instructions.

4.1 Reprocessing cycle for manual wipe disinfection



4.2 Reprocessing cycle for standard products



5 Manual wipe disinfection

Manual wipe disinfection is not a validated reprocessing procedure.

Required materials:

- Disposable cloth and disinfectant
  Alternatively: ready-to-use disinfectant cloth
- Dry, low-lint cloth

1. Use a disposable cloth moistened with disinfectant or a ready-to-use disinfectant cloth to wipe the external surfaces of the product.
2. Take up any excess moisture with a dry low-lint cloth.

6 Requisite materials

The reprocessing accessories used must be clean and functional.

The following reprocessing accessories are required:

Application	Material
Initial treatment at the site of use	Moist compresses, possibly disposable cloth
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)

7 Initial treatment at the site of use

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. Irrigate surfaces with cold water.

7.1 Transport to the reprocessing site

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

8 Cleaning and disinfection

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

– Automated cleaning: thermal disinfection

8.1 Reprocessing with automated decontamination

8.1.1 Automated cleaning / thermal disinfection

A washer-disinfector for thermostable devices must be used for the device. The washer-disinfector must meet the requirements of standard ISO 15883.

The A_0 value of the disinfection process must be observed.

Required materials:

– Suitable slide-in trolley and, if necessary, suitable instrument holder.
The selection must be made in consultation with the manufacturer of the WD.

1. Place the device in the slide-in trolley and, if necessary, in the instrument holder.
2. Use the adaptor to connect the lumina of the device to the slide-in trolley.
3. Connect the lumina of the device using the irrigation facilities of the slide-in trolley.
4. The parameters of the automated cleaning and disinfection process validated by KARL STORZ are specified in the document “Cleaning, Disinfection, Care, and Sterilization of KARL STORZ Instruments” (item no. 96216003).

Steps
1. Pre-irrigation
2. Cleaning
3. Intermediate irrigation
4. Thermal disinfection
5. Drying

⚠ 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.

▶ Check if the device is dry and dry it by hand if necessary, see chapter Checking [p. 14].

9 Visual inspection

1. Check products for the following points:
   – Visible contamination
   – 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.

10 Life span

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

10.1 Functional check

If the product does not fulfill one of the points listed below or if damage can be identified, see chapter “Maintenance, repair, 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.

11 Packaging

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

Required materials:

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

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

▶ Package the product according to the instructions of the packaging manufacturer.

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20045031 • EN • V1.1 • 02-2021 • RI • CE

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