KARL STORZ — ENDOSKOPE

en

Reprocessing instructions
Power LED RUBINA, OPAL1 NIR/ICG
TL400

01-2023

CE 0123

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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 Alcohol-based disinfectants

Alcohol-based disinfectants have a protein-fixing effect and attack materials.

- ▶ Do not use alcohol-based disinfectants.

3.4 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.

3.5 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:

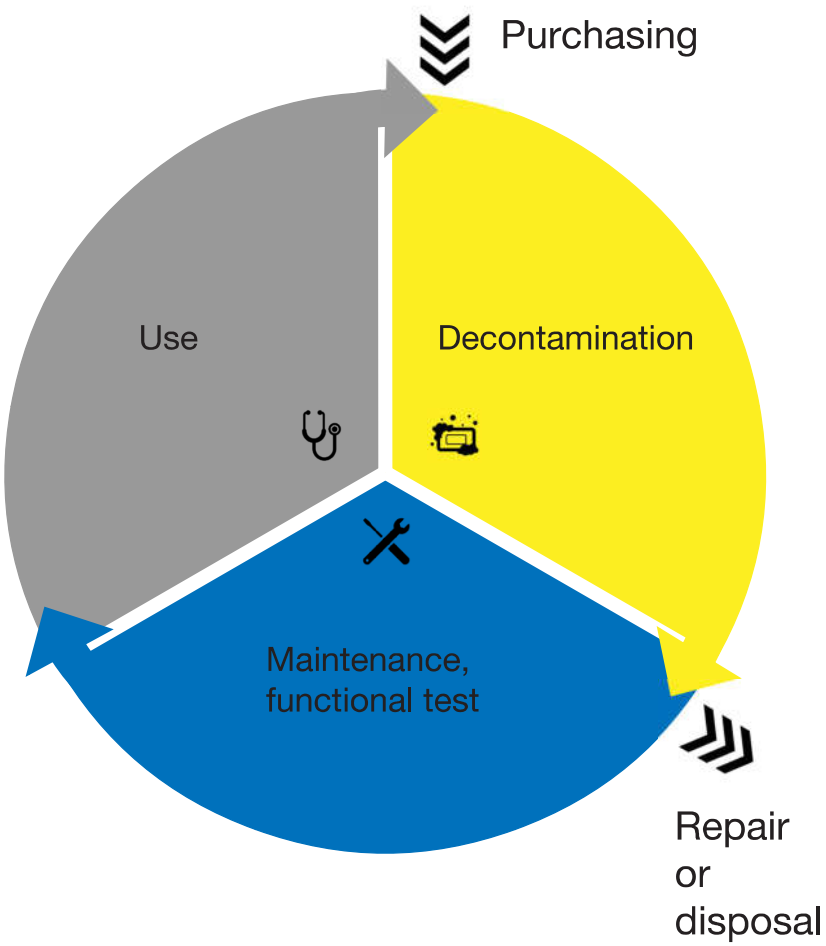
- ▶ Do not continue to use the product.
- ▶ Dispose of the product properly.

4 Overview of processes

The following reprocessing procedures have been approved for the product:

- Manual wipe disinfection

4.1 Reprocessing cycle for manual wipe disinfection



5 Manual wipe disinfection

Manual wipe disinfection is not a validated reprocessing procedure.

Requisite materials:

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

NOTICE

Damage due to ingress of liquid!

Liquid ingress into the product can cause a short-circuit which would damage the product.

- ▶ Do not store any liquids on, above, or close to the product.
- ▶ Do not spray the product directly during disinfection.
- ▶ In the event of ingress of liquid into the product, switch off the product, disconnect it from the power supply, and allow it to dry completely.

NOTICE

Damage due to contact with disinfectant!

Disinfectant impairs the conductivity of electrical connections.

- ▶ Disinfectant must not be allowed to get into electrical connections.

1. Switch off the device before wipe disinfecting and disconnect from the mains.
2. Use a disposable cloth moistened with disinfectant or a ready-to-use disinfectant cloth to wipe the external surfaces of the product.
3. Dry off any excess moisture with a dry low-lint cloth.

5.1 Additional information on reprocessing

Additional general information on reprocessing can be requested from Hygiene@Karlstorz.com.

6 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.

7 Life span

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

7.1 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. During commissioning, the equipment performs a self-test, which checks whether the functionality of the medical device has been fully met. If this self-test indicates an error, proceed as described in chapter Maintenance.
5. Check and inspect the product annually.

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