KARL STORZ — ENDOSKOPE

en

Reprocessing instructions
TELECAM C3
TC100

02-2021

CE

Table of contents

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

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.

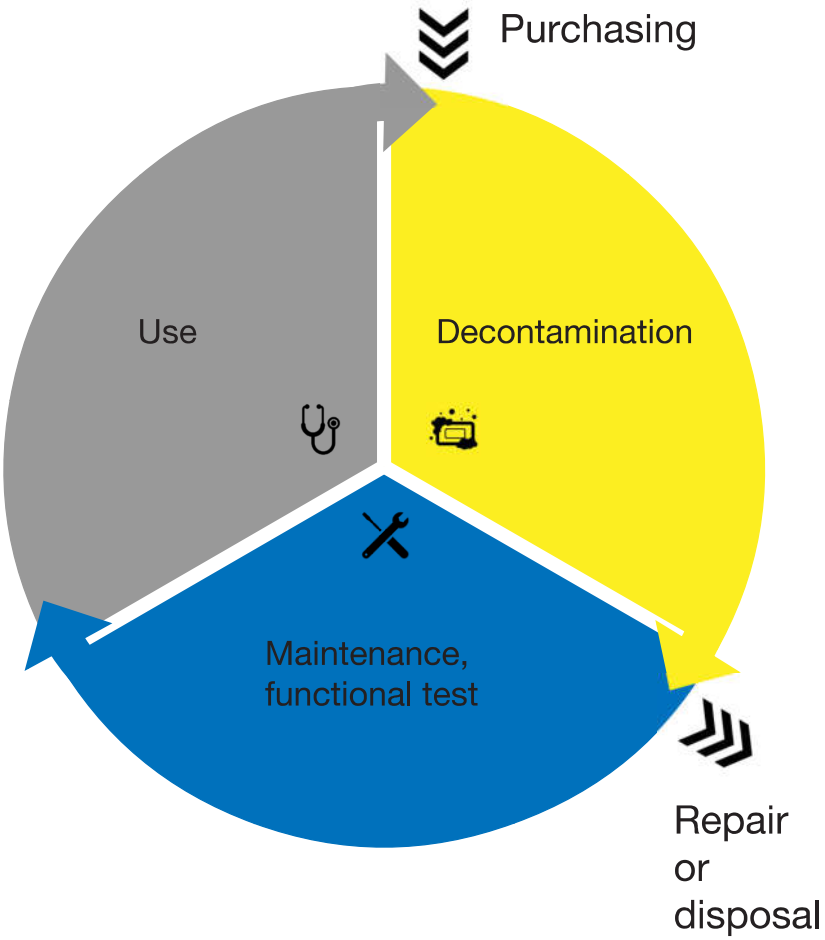
4 Overview of processes

The following reprocessing procedures have been approved for the product:

- Manual wipe disinfection

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

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

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 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.

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 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.
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 whether audiovisual data and patient data is correctly documented by the device.
6. Check and inspect the product annually.

STORZ
KARL STORZ—ENDOSKOPE

TC100 • EN • V1.1 • 02-2021 • RI • CE

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen

Postfach 230
78503 Tuttlingen
Germany

Phone: +49 7461 708-0
Fax: +49 7461 708-105
E-mail: info@karlstorz.com
www.karlstorz.com