Recommendation by the Quality Task Group (130)

# Visual inspection, care and functional testing of surgical instruments

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A vast array of different surgical instruments and other reprocessed devices (termed "medical devices" below) are used every day in operating theatres, outpatient surgical departments and medical/dental practices. These devices must be reprocessed in accordance with the state of the art with validated processes to enable their safe use for patients.

**VISUAL INSPECTION** (inspection of the reprocessing results) for residues/cleanliness/damage/surface changes, which must be performed every time manual and automated cleaning/disinfection and drying are carried out, is one of the measures required for demonstrating that "successful reprocessing is verifiably guaranteed". The German Medical Device Operator Ordinance (MPBetreibV) stipulates that inspection shall be undertaken by qualified persons while taking account of the manufacturer's reprocessing instructions for use (IFU). The pertinent details are set out in the "Hygiene requirements for reprocessing medical devices" jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM).

**VISUAL INSPECTION** for residues/cleanliness/damage/surface changes must be performed every time manual and automated cleaning/disinfection and drying are carried out.

In principle, the following applies: effective **DISINFECTION AND STERILIZATION** can only be achieved if the medical devices are clean (KRINKO/BfArM Recommendation, visual inspection). Following care measures, functional testing must be performed to guarantee safe functioning of the medical devices in accordance with their intended use (see MPBetreibV).

Effective **DISINFECTION AND STERILIZATION** can only be achieved if the medical devices are clean.

The following are recommended:

- the establishment of a risk management system in the RUMED
- the imparting of knowledge to RUMED personnel in relation to Maintenance as stipulated by MPBetreibV
- the compilation of standard operating procedures (SOPs) for visual inspection, care and functional testing of cleaned and disinfected medical devices.

The statements below are recommendations. The measures to be taken must always be reviewed and tailored to the specific application conditions and the medical device manufacturer's instructions.

## Legal basis

According to DIN EN ISO 17664, the medical device manufacturer must provide reprocessing instructions (in the national language) containing at least one validated reprocessing process.

The **MANUFACTURER'S REPROCESSING INSTRUCTIONS** must be observed. The user may use different validated reprocessing processes but, in doing so, must demonstrate that the success of these processes is verifiably guaranteed, while taking account of the material compatibility as per MPBetreibV, and that the safety and health of patients, users or third parties is not endangered.

The **MANUFACTURER'S REPROCESSING INSTRUCTIONS** must be observed.

The KRINKO/BfArM Recommendation stipulates that the design features of medical devices essential for **SAFETY AND FUNCTIONALITY** must be tested. The medical devices must be in perfect functional condition when used.

**SAFETY AND FUNCTIONALITY** of the medical devices must be ensured.

- Appropriate test equipment must be available (see MPBetreibV and KRINKO/BfArM Recommendation) for testing.
- The scope of testing will depend on the respective medical device and must, if necessary, be set out in SOPs on the basis of medical device families (e.g. forceps, retractors and scissors).

- Care agents must lend themselves to the intended use. A care agent is deemed suitable if there is evidence that it does not negatively impact effective sterilization and is biocompatible. The manufacturer's instructions must be taken into consideration when conducting testing (material, function, maximum number of allowable use/reprocessing cycles, etc.).
- Medical devices that are the subject of complaints must be withdrawn from operation.
- If the event of deviation from the manufacturer's reprocessing instructions, evidence of written risk assessment must be available (KRINKO/BfArM Recommendation, Annex 2).

In Germany, the regional governments, public health offices, etc. (depending on the federal state) are responsible for supervision of proper reprocessing of medical devices. A fine may be imposed for significant **DEFICIENCIES** and medical device reprocessing may be prohibited.

For significant **DEFICIENCIES OF MD REPROCESSING** a fine may be imposed and medical device reprocessing may be prohibited.

Each reprocessing step must be described in individual-specific SOPs and is thus part of the quality management system.

Personnel entrusted with reprocessing must have commensurate qualifications. In this respect, both MPBetreibV and the KRINKO/BfArM Recommendation cite participation in specialist training courses, such as those offered by the German Society of Sterile Supply (DGSV ev.).

## General rules for visual inspection, care and functional testing

Visual inspection (inspection of the reprocessing results) must be performed every time manual and automated cleaning/disinfection and drying are carried out. Likewise, functional testing must be performed to guarantee flawless functioning of the medical devices in accordance with their intended purpose.

### Visual inspection

Following automated reprocessing, the medical devices should be left to cool down to room temperature to avoid the risk of metal abrasion and fretting corrosion. First, macroscopic **VISUAL INSPECTION** is carried out for cleanliness and surface changes. A magnifying glass must be used for delicate medical devices, detailed inspection or inspection of macroscopically suspicious sites. Workplace lights and a magnifying glass with 3- to 9-fold magnification are recommended.

**VISUAL INSPECTION** for cleanliness and surface changes is carried out macroscopically and in addition with a magnifying glass.

The medical devices must be free of visible residues. The following critical sites must be inspected in great detail: grooves, serrations, joints and gaps. **LUMENS AND TUBULAR STRUCTURES** must be checked for patency to the extent this is visually possible. (Lumens that do not lend themselves to visual inspection must be checked already before cleaning using a brush, syringe or jet pistol.) Table 1 lists potential residues and ways to remove them.

**LUMENS AND TUBULAR STRUCTURES** must be checked for patency.

Fig. 1: Inspection at the packing station

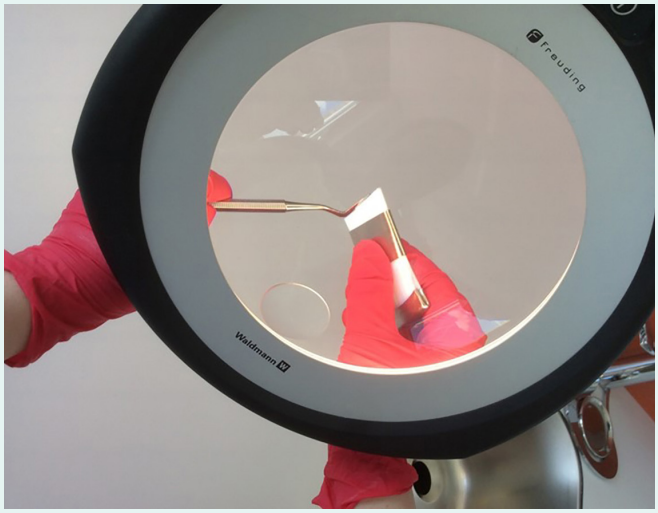


Fig. 2: Inspection using magnification, nylon brush – Do not use metal brushes!

Fig. 3: Example of a surface change with crevice corrosion, surface corrosion

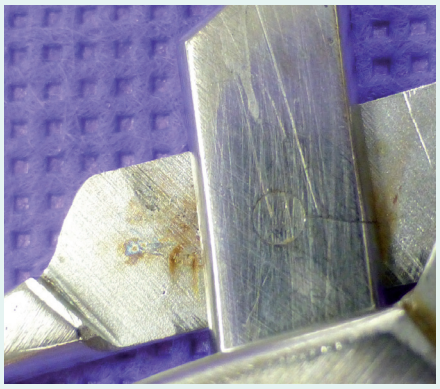

Fig. 4: Example of a surface change with stress corrosion cracking

Fig. 5: Surface discoloration

Fig. 6: Corrosion or residue

Fig. 7: Medical device was not dismantled

Fig. 8: Residues/corrosion below the marking tape – device should not be used

## Surface changes

When carrying out visual inspection for surface changes attention must be paid to e.g. cracks, breakages, deformations, signs of wear, fatigue, ageing and damaged insulation. Particularly delicate and fragile medical devices must be inspected under a work light with magnification.

Corrosion is another type of surface change. Apart from the risk to patients, **CORROSION** presents an economic risk, e.g. through transfer of extraneous rust to intact medical devices. It is often difficult to distinguish between corrosion and residues in everyday practice [1].

**CORROSION** presents a risk to patients, but also an economic risk, e.g. through transfer of extraneous rust to intact medical devices. .

**Table 1: Recommended treatment methods for various residues on medical devices**

| Residues | Treatment methods/recommended treatment agents |
|---|---|
| Tissue residues | manual recleaning, ultrasonic cleaning, use of a steam cleaning appliance under an extractor hood, 3% hydrogen peroxide solution |
| Fats, glue residues | Alcohol, petrol, orange oil |
| Bone cement | Dispose of medical devices and other utensils (bowls, drills, etc.) because removal is difficult and attempts to do so may cause damage |
| Dental cement | Manual removal with cement removal solution and soft brush (no wire brushes) |

*In principle, following manual recleaning medical devices must again undergo a cleaning and disinfection process.*
If a medical device is found to be free of residues on visual inspection, care measures and functional testing can be carried out.

**CARE AGENTS** must be biocompatible, steam permeable and suitable for steam sterilization.

## Care

**CARE AGENTS** for stainless steel medical devices must be produced on the basis of paraffin/white oil and must also be biocompatible (tissue compatible/meet drug standard), steam permeable and suitable for steam sterilization.

The use of silicone oils is not recommended for stainless steel as they could cause sluggishness and compromise the effects of steam sterilization.

The process steps of testing must be set out in **SOPs**.

## Functional testing

The process steps and scope of testing must be set out in **SOPs** on the basis of medical device families. The SOP must also describe the action to be taken for a device that fails functional testing, for example:

- Correct recleaning procedure where this is warranted
- Dispatch for repair
- Information such as cost centre, tray, reason for repair.

Another SOP should specify the action required for incomplete sets:

- If possible, find a replacement from the back-up stocks
- Consult the shift manager or surgical department (how essential is the medical device?)
- Label the set on the outside.

**FUNCTIONAL TESTS** must be designed such that medical devices that no longer meet their intended purpose are reliably identified.

**FUNCTIONAL TESTS** must be designed such that those medical devices that no longer meet their intended purpose, e.g. due to wear or damage, are reliably identified and withdrawn from operation. In cases of doubt, suitable test methods should be agreed with the medical device manufacturer. Feedback from surgeons must also be obtained.

For certain medical devices it may not be practical to perform functional testing in the RUMED (e.g. special ophthalmological medical devices) or the test equipment may not be available (e.g. motors, cameras). Responsibilities (surgical department/RUMED) must be defined in writing in an interdepartmental agreement.

Maintenance of structured, easily accessible back-up stocks tailored to the instruments most susceptible to damage (e.g. cutting or delicate medical devices) has proved to be the best approach.

## References


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