

Recommendation by the Quality Task Group (69)

Problem instruments when it comes to reprocessing (Part 1)

Medical device reprocessing is very complex. Pursuant to the German Medical Devices Act (MPG), reprocessing of medical devices that, at most, may harbour only a low microbial count or be sterile when put to use is understood to mean cleaning, disinfection, sterilisation, their associated tasks as well as testing and restoration of technical safety. The German Medical Devices Operator Ordinance (MP-BetriebV) stipulates that → **REPROCESSING** be performed using validated processes. These measures are aimed at ensuring that the requirements governing cleaning, disinfection and, if applicable, sterilisation are fulfilled each time reprocessing is carried out. → **CLEANING** is a particular challenge which, even in a washer-disinfector (WD), can only be indirectly subjected to parametric release. In all cases, monitoring of the water quantity, temperature, time and dosage quantity must be guaranteed in the WD. Other aspects that are not standardised include positioning of supplies in trays, the nature and quantity of the soils encountered as well as the extent to which the latter will have dried on the devices before reprocessing.

Often, normal automated reprocessing methods are adequate for cleaning standard instruments, but this is not the case for particularly intricate instruments harbouring stubborn soils. This present recommendation by the Quality Task Group focuses on these topics, thus updating Recommendations 19 and 20 from 2001.

→ **REPROCESSING** must be performed using validated processes.

→ **CLEANING** can only be indirectly subjected to parametric release.

1. Medical device designs

The extent to which a medical device is → **AMENABLE TO CLEANING** is determined by its geometry and constructional aspects such as the presence of gaps, joints, cavities, threads, type of surfaces, etc.

It must be ensured that the entire cleaning solution gains access to all internal and external surfaces of the medical device. This calls for appropriate positioning or, possibly, adaptation of the medical devices to the water-conveying systems within the WD. Medical devices can be → **CLASSIFIED** into different groups based on their constructional features:

Group 1:

Instruments that permit visual inspection/verification of the cleaning results. Examples of such instruments: Wound retractors, specula

Groups 2 – 7 do not, or only to an extent, permit visual inspection of the cleaning results.

Group 2:

Jointed instruments. Examples: Scissors, instruments with box lock, double-levered forceps and clamps.

Group 3:

Sliding-shaft instruments. Examples: Punches, rongeurs. A basic distinction can be made between those sliding-shaft instruments that can be dismantled and those that cannot.

Group 4:

Tubular-shaft instruments. Examples: Minimally invasive surgical (MIS) instruments, suction devices, lumened instruments, arthroscopy shavers. A basic distinction can be made between tubular shaft instruments that can be dismantled and those that cannot.

Group 5:

Microsurgical instruments. Microsurgical instruments may have the same design features as jointed, sliding-shaft or tubular-shaft instruments but they are of a filigree construction.

Group 6:

Complex (intricate) instruments. Examples: Implant insertion instruments/systems, motor systems. Complex instruments have a combination of different constructional features and thus often make special demands on reprocessing.

→ **AMENABILITY TO CLEANING** is determined by geometry and constructional aspects.

→ **A CLASSIFICATION** of medical devices can be based on their constructional features.

Group 7:

Flexible instruments. Examples: Intramedullary reamers, gigli saws, flexible biopsy forceps, flexible foreign body forceps.

→ **SOILS** will influence amenability to cleaning according to their nature and quantity.

→ **THE CHOICE OF REPROCESSING METHOD** depends on the nature and quantity of soils.

2. Variety of soils

Apart from the geometry of the medical device, the nature and quantity of → **SOILS** will determine the extent to which the device can be cleaned. In general, dried soils hamper cleaning. Examples of stubborn soils include: bone meal, incrustations on HF instruments, mucus, ointments and fats, drug residues, proteins that have been denatured by disinfectants as well as fibres. These have implications for the → **CHOICE OF REPROCESSING METHOD** used. Combinations of different stubborn soils can also be encountered:

Bone meal

Bone meal is insoluble in water and cannot be dissolved chemically either by conventional process chemicals. Bone meal is also often found in combination with blood and other contaminants and can become hard when exposed to heat.

Incrustations to HF instruments

HF surgical instruments, and in some cases ultrasonic scissors, harbour incrustations which are composed of denatured blood and tissue and cannot be removed with many automated standardised processes.

Mucus

Dried mucus consists mainly of «congealed» carbohydrates and can be broken down and dissolved only after maceration.

Ointments, fats and oils

Ointments, fats and oils are not soluble in water and can only be emulsified and then rinsed off. Solid ointment bases and fats must exceed their melting point, i. e. be present in liquid form, before they can be emulsified.

Drug residues

These include contrast media, dyes, fibrin and other glues, saline solution, bone cement, etc.

Disinfectant-denatured proteins

Proteins call for special cleaning measures if they have been denatured by disinfectants and thus rendered insoluble.

Fibres and particles

Fibres and particles cannot be dissolved or broken down by detergents and can lead to blockage of the systems conveying the reprocessing media within the WD or of instrument lumens.

3. Cleaning processes

Other measures that can be taken additionally to assure automated reprocessing of → **«PROBLEM INSTRUMENTS»** under standard conditions:

1. Manual precleaning using immersion methods, pretreatment with H₂O₂, brushing, water pistols, ultrasonic bath, steam cleaning or a combination of these.
2. More complex automated cleaning processes involving multi-step methods or multi-component detergents, special WDs with integrated ultrasound and/or increased cleaning pressure.

→ **FOR PROBLEM INSTRUMENTS** additional measures may be necessary.

→ **CONSTRAINTS** as regards the range of cleaning/disinfection processes that can be used are possible e. g. due to the materials used.

There may be → **CONSTRAINTS** as regards the range of cleaning/disinfection processes that can be used, e. g. in terms of materials and/or constructional features (e. g. ultrasound not permitted, no immersion, limited pH value range, no oxidative processes, temperature restrictions).

A combination of the following three factors

1. Instrument construction (design)
2. Variety of soil(s) and extent of drying
3. Cleaning process used

have an impact on the cleaning results. The Quality Task Group intends exploring this topic from different angles and issuing recommendations that will make it easier for users to reprocess problem instruments. ■