Recommendations by the Quality Task Group (83)

Reprocessing sterilization containers with synthetic components used for sterile supplies and for contaminated medical devices

➜ **SYNTHETIC MATERIALS** are used for certain container components.

➜ **HIGH DIMENSIONAL STABILITY** is an advantage conferred by appropriate synthetic materials.

➜ **SPECIAL PROPERTIES** must be noted when reprocessing.

This recommendation replaces Recommendation 30 «Hard Packaging» issued in 2003.

Over the past 40 years, sterilization containers have worldwide proved to be a safe and economical packaging system for sterile supplies of varying sizes and design. Depending on their make, they are used to distribute sterile medical devices (MDs) to the final users and/or for closed transportation of contaminated instruments. In the past the majority of sterilization containers were made of aluminium and stainless steel materials.

For well over 10 years now, in addition to these materials ➜ **SPECIAL SYNTHETIC MATERIALS** are also being used for certain container components. Those synthetic materials that are suitable for such applications are characterized, in particular, by their ➜ **HIGH DIMENSIONAL STABILITY** and amenability to steam sterilization. Such materials include PPSU (polyphenyl sulfone) and PEEK (polyether ether ketone) as well as silicone seals specially designed for use in medical settings. Like all other materials, synthetic materials, too, are endowed with ➜ **SPECIAL PROPERTIES** that must be taken into account when reprocessed. This Recommendation is aimed at providing the user with information on appropriate manual and automated decontamination of such synthetic components.

The types of packaging used must be tailored to the medical devices (MDs) to be packed, while observing the manufacturer's instructions (e. g. sterilization must be assured taking account of MD weight and geometry).

In collaboration with users, measures must be taken to ensure sterile use and sterile presentation for the respective type of packaging. Likewise, the feasibility and effectiveness of decontamination and sterilization must be verified and validated in cooperation with the CSSD. In addition, the sterilization container must be checked to ensure it can meet the transportation requirements (mechanical protection) and designated storage (mechanical stress).

Stainless steel containers/trays with silicone supports have proved advantageous, e. g. optics trays or camera sterilization containers. These constitute a gentle transportation means that will preserve the value of the MDs, while providing for good storage as well as sterile presentation.

Provision must be made for clear labelling and for a closure mechanism e. g. by means of lead seals. MD recontamination until the time of use must be ruled out.

Overview of materials used in sterilization containers

Table 1: Materials – properties	
Pros	**Cons**
Aluminium	
• Light	• Can be deformed if dropped or exposed to excessive impact
• High thermal capacity and thermal conductivity provide for good drying results	• Surfaces are sensitive to unsuitable decontamination processes and mechanical scratching
	• Coloured anodized layers can fade over time
Synthetics (PPSU, PEEK)	
• Impact resistant	• Because of lower thermal capacity and thermal conductivity, longer drying times may be needed
• Colourfast	• Unsuitable chemicals, e.g. rinse aids, can damage synthetic materials
• Scratchproof	
• Dimensionally stable	

Decontamination methods used for sterilization containers

Cleaning/disinfection are normally conducted using one of the following processes:

1. Automated decontamination in a washer-disinfection (WD) using a container program and/or in a decontamination facility for sterilization containers with thermal disinfection
2. Automated decontamination in WD using a container program and/or in a decontamination facility for sterilization containers with chemothermal disinfection
3. Manual wipe disinfection

If the sterilization containers are also used to transport contaminated instruments back to the CSSD, ➜ **AUTOMATED CLEANING** and disinfection are recommended. Sterilization containers used for sterile supplies as well as those used to transport contaminated MDs should preferably be decontaminated using processes approved by the sterilization container manufacturer. Attention must also be paid to the instructions issued by the process chemicals' manufacturer, while if necessary testing compatibility with a sample of the relevant materials.

➜ **AUTOMATED CLEANING** is recommended for sterilization containers used for sterile supplies as well as those used to transport contaminated MDs.

Table 2: Overview of suitability/limitations of reprocessing methods for various materials				
Decontamination step	**Process**	**Chemicals**	**Aluminium**	**Synthetics (PPSU/PEEK)**
Cleaning	WD	pH neutral	+	+
		mildly alkaline	+	+
		alkaline	–	–
		oxidative	–	–
		acidic	–	–
	manual	pH neutral	+	+
		alkaline	–	–
		acidic	–	–
Disinfection	WD	thermal > 90 °C	+	+
		chemothermal	+	+
	manual	wipe disinfection	+	+1)
Final rinse with demineralized water	WD and manual	demineralized water	+	+
Final rinse with rinse aid	WD	surfactants (e. g. in rinse aids)	+	–

1) only with 70 % alcohol (only for containers used for sterile supplies)

Reprocessing methods

Aluminium sterilization containers:

Demineralized water and neutral detergents, or special detergents for aluminium, are recommended for anodized sterilization containers (if possible with pH up to 1.5). Depending on the water quality, discoloration of the anodized layer after repeated reprocessing cycles cannot definitely be ruled out. However, this optical defect does not adversely affect functionality. Attention must be paid to the instructions issued by the process chemicals' manufacturer.

Sterilization containers with synthetic components (see also Table 2)

PPSU is used predominantly in such cases. PPSU is thermally stable, and can be reprocessed using thermal disinfection and steam sterilization. Cleaning can be carried out with mildly alkaline or neutral detergents (see aluminium sterilization containers). Rinse aids should not be used since subsequent exposure to steam sterilization of any surfactant residues on surfaces can lead to changes in the structure of synthetic materials and hence to crack formation if the synthetic materials are of a lesser quality and e.g. have not been annealed. Residues of surfactant detergents or acids can also persist because of inadequate rinsing in the WD or inappropriate storage (entrainment) and also due to inadequate rinsing following manual cleaning and disinfection.

➜ **SURFACTANTS** can result in damage if they persist on synthetic surfaces.

➜ **SURFACTANTS**, like acids, can result in damage if they persist on synthetic surfaces. Therefore thorough final rinsing with demineralized water is recommended in principle to remove as far as possible any process chemicals and, if applicable, water constituents from surfaces. This must be verified when validating such reprocessing methods. Attention must be paid to the instructions issued by the process chemicals' manufacturer.