Recommendations by the Quality Task Group (79)

Sterile barrier and packaging systems

The recommendation jointly compiled by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices (BfArM), «Hygiene requirements for medical device reprocessing», and published in Federal Health Gazette 2012; 55:1244–1310 cites the medical device packaging as an integral part of the reprocessing chain. Terms such as «sterile barrier system», «protective packaging» and «packaging system» have been taken from national and international standards.

The packaging system must be compatible with sterilization processes, assure sterility until the time of use and allow aseptic presentation. Recontamination of the medical device once reprocessed must be ruled out until the point of use.

The packaging process should be implemented in accordance with the «state of the art», while observing the «state of the art in science and technology». National and international standards reflect the state of the art in science and technology and, as such, must be implemented into everyday practice.

The Medical Devices Operator Ordinance (MPBetreibV) stipulates that validated reprocessing methods must be used in principle. In addition, standards DIN 58953-7:2010 (*Use of sterilization paper, nonwovens, wrapping material, textile materials, paper bags and sealable pouches and reels*) and DIN 58953-9:2010 (*Use of sterilization containers*) call for validation of all packaging processes[1].

To facilitate conduct of validation in situ, the German Society of Sterile Supply (DGSV) in collaboration with the Central State Body for Health Protection with Regard to Drugs and Medical Devices (ZLG) has compiled an easy to implement guideline for validation of packaging systems pursuant to EN ISO 11607-2. This guideline contains, apart from several checklists, specimen standard operating procedures (SOPs). The guideline can be downloaded free of charge at www.dgsv-ev.de. Based on this guideline, non-validable packaging processes are no longer acceptable in practice.

The aim of the present Quality Task Group recommendation is to give an overview of the packaging systems used in everyday practice, present the pertinent standards, define validability of the packaging processes and demonstrate sterilization compatibility. This recommendation replaces Recommendation 27 «Packaging Systems» published in 2003.

Table 1: Standards regulating packaging systems

	Pouches		Reels	Paper bags	Sterilization containers	Sheet packaging
Sealing method	heat sealable	self-sealable	heat sealable	heat sealable	various	adhesive tape
Sealing process:						
Manual		×			×	×
Automated	×		×	×		
Validable packaging process	yes	no	yes	yes	yes	yes
Standards and Guidelines regulating validation:						
EN ISO 11607-2	×		×	×	×	×
ISO/TS 16775[2]	×		×	×	×	×
DGSV Guideline[3]	×		×		×	×
Packaging system:						
Pertinent standards	EN ISO 11607-1 EN 868-5			EN ISO 11607-1 EN 868-4	EN ISO 11607-1 EN 868-8	EN ISO 11607-1 EN 868-2
Packaging technique and handling:						
Pertinent standards	DIN 58953-7 ISO/TS 16775				58953-9 ISO/TS 16775	58953-7 ISO/TS 16775

1 Pursuant to the current version of the KRINKO/BfArM Recommendation*, the DIN 58953 series of standards is especially important for everyday practice.
(*: *Recommendation for hygienic reprocessing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute [RKI] and the Federal Institute for Drugs and Medical Devices [BfArM]*)

2 Packaging for terminally sterilized medical devices – Guidance for implementation of ISO 11607-1 and ISO 11607-2 (publication planned for 2013)

3 Guideline for validation of packaging processes pursuant to EN ISO 11607-2

Table 2: Compatibility with sterilization processes

	STEAM	EO (ethylene oxide)	FORM (formaldehyde)	VH2O2 (vaporized hydrogen peroxide)	Dry heat (hot air)
Paper (Paper bags, crepe paper)	YES	YES	YES[4]	NO	NO
Nonwovens with cellulose component	YES	YES	YES	NO	NO
SMS material made of 100% PP	YES	YES	YES	YES	NO
Transparent packaging made of paper or nonwoven material with PET/PP foil	YES	YES	YES	NO	NO
Transparent packaging of Tyvek®[5] and PET/PE	NO[6]	YES	YES	YES	NO

4 Paper is in principle suitable for FORM sterilization, but may contain a higher FORM residual content after sterilization. If the packaging is composed exclusively of paper, the FORM residual content following sterilization must be ascertained. If the residual content is non-critical, the packaging system can be released.

5 Tyvek® is the registered trademark for DuPont spunbonded polyethylene.
Tyvek®, itself, can tolerate temperatures and steam sterilization up to 126 °C. The PET/PE film normally used is not compatible with steam sterilization.

6 Specific packaging materials are available for hot air sterilization. In general such materials are made of polyamide film (PA). This publication does not give details of packaging systems for hot air sterilization, since these materials are not included in the DIN EN 868 series of standards. Compliance with the sterile barrier system requirements stipulated by EN ISO 11607-1 is possible. Evidence of this must be provided by the manufacturer/supplier.