Recommendation by the Quality Task Group (125)

Comparison of sterile barrier systems

Authors: T. Appel, S. Bungardt, D. Diedrich, A. Forster, K. Gehrmann, A. Hartwig, A. Jones, J. Metzing, A. van Waveren
qualitaet@dgsv-ev.de

Introduction

The introduction of a new **STERILE BARRIER SYSTEM (SBS)** constitutes a significant change to the instrumentation circuit. This change may impact the process and outcome quality, logistics, storage and, ultimately, the entire cost structure of the reprocessing process.

Therefore, all important aspects and potential effects should be considered and investigated beforehand. This Recommendation is designed to support that undertaking.

The introduction of a new **STERILE BARRIER SYSTEM (SBS)** has several consequences.

Business administration assessment

In principle it is important to ensure that as few different varieties of SBS as possible are used. **REDUCING THE VARIETIES** has many benefits:

- Routine work practices save time and reduce mistakes
- Validation of the packaging process pursuant to DIN EN ISO 11607-2 is less labour intensive (each type of packaging requires separate validation)
- Less intensive training needed
- Standardization of transport and storage
- Less administrative effort (e.g. article numbers, orders, product data sheets)

REDUCING THE VARIETIES has benefits.

Before contemplating changing the SBS, the **COST FACTORS** of the existing and the new systems should be compared:

- Investment costs (e.g. containers or transport baskets for soft packaging)
- Costs for consumables (e.g. non-wovens (fleece), paper film packaging, labels, adhesive tapes, filters, absorbent non-wovens, edge and tip protectors, protective packaging, etc.)
- Maintenance and repair costs (e.g. for containers/transport baskets)
- Reprocessing costs (e.g. for containers/transport baskets)
- Time investment for the actual packaging process, handling (e.g. orders, transport, etc.) and/or for the reprocessing process required
- Disposal costs
  - Transportation of contaminated supplies
  - Waste
- Costs for adapting the storage/transport system to the requirements of the new packaging material

The **COST FACTORS** of the various systems must be calculated.

User involvement

A change to the packaging material has an impact on handling by the user. In the event of a switch from e.g. containers to soft packaging or vice-versa, this decision also has implications for the entire workflow patterns of the nursing personnel in the operating room (OR).

For this reason, all users must be involved in the **DECISION-MAKING** process and trained for any switchover. Additional test runs help to identify any problems at an early stage and provide proof that all important aspects have already been checked in advance of decision-making and that the new system is suitable.

All users must be involved in the **DECISION-MAKING** process.

Technical evaluation

In addition to ensuring that the new product meets all normative and legal requirements, the **TECHNICAL SUITABILITY** for the in-house processes must be tested. These tests should be carried out before validation.

The **TECHNICAL SUITABILITY** must be checked.

Protective function

The SBS must maintain sterility until the time of use or until the expiry date. Sharp or pointed instruments can perforate the SBS and must therefore be protected

against puncture damage by suitable means (e.g. instrument protection caps), and medical device functionality must be preserved. Depending on the packaging material, additional trays and/or fixation systems may be required.

Drying results

The **DRYING RESULTS** must be verified in test runs.

The SBS impacts the drying results achieved in the steam sterilization process. The **DRYING RESULTS** should therefore be carefully investigated in test runs and deemed suitable before purchasing the SBS. If the drying results are not of the standard required, the process and/or load must be optimized. Additional aids, such as suction non-wovens, may be helpful. If these do not help, inadequate drying results can also be a criterion for exclusion, thus obviating the need for any further tests.

Transport

The **REQUIREMENTS** to be met by the SBS during transportation must be considered.

The greater the distance between the rumed and the site of use, the more stringent are the **REQUIREMENTS** to be met by the SBS during transportation.

Soft packaging should generally be additionally protected in a transport box or transport basket during transportation. The risk of perforation when using sheet packaging can be reduced by fitting edge protection aids (e.g. instrument protection caps, protective corners or absorbent non-wovens as anti-slip aids).

Storage

The **STORAGE** must rule out damage to the SBS.

Shelving systems or cabinets should be designed to ensure space-saving **STORAGE CAPACITIES** and at the same time exclude damage to the packaging.

Risk assessment

RISK ASSESSESSMENT must weigh up the advantages and disadvantages of the systems.

The use of every packaging material carries individual **RISKS**. The advantages and disadvantages of the different packaging systems must be weighed up against each other, taking into account the in-house situation.

Containers

- Deformations of the tank or lid
- Defects in the filter holder seals (if fitted)
- Defects in the lid seals (flattened, torn, etc.)
- Tank loading height exceeded, lid does not close tightly
- Damage to the function of permanent filters goes unnoticed
- Drying problems

Non-wovens

- Possibly, manufacturing defects already on delivery
- Defects caused by box cutters when opening cardboard boxes
- Adhesive tapes become detached after sterilization
- Drying problems
- Damage to the packaging during transportation to the user's premises

Shrink-wrap packaging

- Possibly, manufacturing defects already on delivery
- Perforation by sharp or heavy medical devices
- Drying problems
- Burst sealing seams following sterilization
- Possibly, problems when opening (peeling) under ascetic conditions
- Damage to the packaging during transportation to the user's premises

Users

- SBS is released before the correct cooling time (30 minutes) (condensate formation)
- Place flexible SBS on moist surfaces
- Handle with freshly disinfected hands that are not yet completely dry

Quality assurance

QUALITY ASSURANCE measures must be adapted.

If the SBS is switched to a completely new system, the existing **QUALITY ASSURANCE** measures must also be adapted accordingly.

Routine tests

Routine tests are an integral part of operational qualification as stipulated by the guideline for validation of packaging processes according to DIN EN ISO 11607-2. The number of spot checks depends on the total annual number per packaging type.

If specified by the manufacturer, maintenance and servicing tasks for sterile containers must be set out in writing, and all tests/spot checks must be documented.

Quality control

Staff must be trained to detect any visible defects or damage to the SBS already before use during daily handling (see item 5 Risk assessment).

Training

Documented training is part of installation qualification as specified by the guideline for **VALIDATION** of packaging processes according to **DIN EN ISO 11607-2**. The training programme must include all aspects to be tested and special features of the SBS used.

VALIDATION according to **DIN EN ISO 11607-2** includes documented training.

Security of supply

In the event of **SUPPLY BOTTLENECKS** it may be necessary to use a different product as a substitute solution. This can only be done in coordination with the RUMED, because performance requalification of the sterilization and packaging processes for a particular reason cannot be ruled out. Management of supply bottlenecks must be included as a component of the RUMED contingency concept.

The substitute solution must be included in the contingency concept for management of any **SUPPLY BOTTLENECKS.**

References

1. DIN EN ISO 11607-2:2020-05 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly