ISO 11607 – How to translate into action
Sterile container systems

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Annual WFHSS Workshop CSSD, Muscat, Oman
November 1st to November 2nd, 2006
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- ISO 11607, part 1 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices.
- ISO 11607, part 1 also specifies general requirements for all packaging materials.

Important for the manufacturer of materials and packaging systems to provide safe materials and systems

- Manufactures of sterile containers may demonstrate compliance with this ISO 11607, part 1 by using requirements and test methods described in EN 868, part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – requirements and test methods
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The activities described in ISO 11607, part 1 shall be carried out within a formal quality system

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General requirements for reusable sterile containers:

Essential facts and their implication for your daily work with sterile containers

- Sterile containers belong to the group of preformed sterile barrier systems (pouches, bags and reusable containers) and are defined as „rigid sterile barrier systems designed to be repeatedly used.”
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Specific requirements for reusable containers according to ISO 11607, part 1

- Every container shall be equipped with a tamper-evident system to provide a clear indication when the closure integrity has been compromised.
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Specific requirements for reusable containers according to ISO 11607, part 1

- The sterilization agent port and the closure shall provide a barrier to microorganisms during transport and storage of the container.

There is no universally accepted method of demonstrating microbial barrier properties. Suitable methods are listed in the standard.
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Commonly used performance testing for reusable sterile containers:


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Specific requirements for reusable containers according to ISO 11607, part 1

- The container shall be constructed to facilitate inspection of all essential parts.
- Acceptance criteria shall be established for inspection prior to each use

**Visual inspection is the most common procedure, there could be also other acceptable methods**
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4.2 Function checks

- Prior to each use, carry out a visual inspection for damage and correct functioning of all components of the sterile container:
  - Metal parts not deformed
  - Aluminum lid not warped
  - Seals intact
  - Plastic parts not cracked
  - Permanent filter intact
  - Lock functions properly (engages)

- Use sterile containers only if they are in mint condition. Replace any damaged components immediately with original spare parts or have the affected components repaired.

Follow the Instructions for Use (IFU)
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Specific requirements for reusable containers according to ISO 11607, part 1

- Individual components of the same type of containers must be interchangeable or otherwise designed that the components cannot be mixed and interchanged.
- Do not mix parts of containers from different brand and manufacturers

one type of bottom, fully interchangeable lids
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- Cleaning and maintenance information shall be specified by the manufacturer
- Refer to manufacturers information for use
- Aesculap Extranet: Database Care and Maintenance including all Aesculap products

| Material-specific requirements for the cleaning and disinfection of sterile containers |
|----------------------------------------|----------------|----------------|----------------|
|                                        | Disposal container, stainless steel | Standard container, anodized aluminum | Primeline container, plastic |
| Ultrasound treatment in manual and mechanical processing | ✓ | ✓ | ✓ |
| Cleaning/Disinfecting agent* | acid, pH-neutral, alkaline | pH-neutral, mildly alkaline | pH-neutral, mildly alkaline |
| Thermal disinfection with fully desalinated water, 5 min, at 90 °C | ✓ | ✓ | ✓ |
| Mechanical drying with hot air at up to 120 °C | ✓ | ✓ | ✓ |

* Mildly alkaline cleaning/disinfecting may cause surface changes discoloration of the aluminum lids (fading, staining). Such changes do not affect the functionality of the product. For colored aluminum lids use, if possible, a process involving a neutral cleaning and disinfecting agent and fully desalinated water.
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Specific requirements for reusable containers according to ISO 11607, part 1

Maintenance of sterile containers
According to the EN 868, part 8:

- Serviceable life of a container should not be less than 500 cycles.
- Serviceable life of the silicone gaskets should not be less than 100 cycles.

If the service life shall be demonstrated by accelerated ageing procedures, the ageing procedure according to Annex G of EN 868, part 8 shall be used.

Aesculap did a validation for the serviceable life of our containers based on this ageing test for 5000 cycles.
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Specific requirements for reusable containers according to ISO 11607, part 1

- Compatibility with the sterilization process = refer to manufacturers IFU

2.1 Intended use

The Aesculap sterile container system is intended for use as sterile packaging for instruments and textiles due for steam sterilization through a validated steam sterilization process (e.g. in a sterilizer complying with EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993 and validated according to EN 554/ISO 13683).

After sterilization, the sterile materials are stored in the sterile container until they are used.

Note

Please contact your Aesculap representative if your Aesculap sterile containers are to be used in any other steam sterilization process.
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ISO 11607, part 2: Validation requirements for forming, sealing and assembly processes: practical impacts

- Sterile containers are sterile barrier systems
- Sterile containers can be used without additional protective packaging
- Sterile containers are rigid sterile barrier systems and can be used and are most commonly used without wrapping the instrument tray inside.
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ISO 11607, part 2: Validation requirements for forming, sealing and assembly processes: practical impacts

- Sterile containers are already preformed: the user just need to put in his instrument baskets and close the lid.

- However there are still points which needs to be observed in order to achieve the expected result of the entire packaging and sterilization process: a safe and sterile set of instruments.

- It is recommended to install within the quality management system of the sterile supply department Standard Operating Procedures for the necessary working steps and controls.
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ISO 11607, part 2: Validation requirements for forming, sealing and assembly processes: practical impacts

- Processes shall be revalidated if changes are made to the packaging materials.

Permanent filter cartridges for testing with thermocouples are provided by Aesculap
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ISO 11607, part 2: Validation requirements for forming, sealing and assembly processes: practical impacts

After the cleaning process a visual control of the essential parts of the container should be implemented:

- Barrier system in place or intact, disposable filters replaced, no visible damages
- Filter retention system engaged if applicable
- No visible damages of the lid and the upper edge of the bottom part
- Silicone gasket in place and without any visible damages
- Closing latches/system without visible damages
- Closing latches/system engage and not loose
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ISO 11607, part 2: Validation requirements for forming, sealing and assembly processes: practical impacts

Forming process:

- According to EN 285 and EN 868, part 8 the total weight of the instrument load should not exceed 10 kg inside a full-size container.
- After closing the lid the container will be sealed with a tamper evident system.
- A labelling system is used to provide all necessary information for the documentation and follow up of the individual container.
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- For sterilization, transport and on stock rigid containers can be stacked
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- The loss of sterile package integrity is usually regarded as event related than time related.
- To be able to demonstrate that the sterile barrier system maintains integrity over time Aesculap performed event related shelf life testing over the period of 360 days.

The responsibility however for the handling and storage conditions of sterile goods rests with the user.
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Don't be scared, just do it !!!

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