Sterile Container Packaging System

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General requirements for sterile packaging systems

- Protection of contents
- Maintaining of the product quality
- Maintaining sterility during transport and handling
- Information about contents
Why reusable containers for sterile packaging?

- It allows systematic organization of sterile goods in **safe** and **economic** manner.
- Easy and safe handling.
- Safe storage 6-12 months.
- Steam sterilizable.
- Easy packaging, labelling and sealing.
- Safe transport / disposal.
- Safety first.
- Easy to clean and disinfect.
- Inspection, care and function test.
The new standard for medical packaging EN ISO 11607

- Sterile containers belong to the group of **preformed sterile barrier systems** and are defined as „rigid sterile barrier systems designed to be repeatedly used.“

- Due to their constructive details Aesculap sterile containers offer both
  - the sterile barrier system and the protective function

- Sterile containers are rigid sterile barrier systems and **can be used and are most commonly used without wrapping the instrument tray inside**.

Aesculap containers are tested according to EN 868, part 1 and 8 (European Standard for sterile packaging material / sterile containers) without inside wrappings.

European / ISO standards and FDA do not require an additional wrapping of baskets inside sterile containers.
The new standard for medical packaging EN ISO 11607

for example:

preformed barrier system + protective packaging = packaging system
The new standard for medical packaging EN ISO 11607

for example:

1st sheet = barrier system + 2nd sheet = protective packaging = packaging system
Aesculap Sterile Containersystem

Modular container system: universal bottom, three different lid systems

Highly flexible according to different customer needs

Basic  Vario  Primeline

disposable or re-usable, permanent filters
Advantages of using Aesculap sterile containers

Safety first

- Robust design: Storage and transport without risk of damage
- Validated bacterial barrier system (filter) acc. to ISO EN 11607
  (Standard for sterile packaging materials)
- Simple component design: Long service life and low maintenance
- Easy handling: User errors very unlikely
- Shelf-life studies for 12 months (event related)
Advantages of using Aesculap sterile containers

Materials

Aluminium:
- Good drying properties
- Low weight

PPSU (PolyPhenylSulfone): high grade polymer
- Impact-resistant
- Colorfast
- Scratch resistant
Advantages of using Aesculap sterile containers

Organization

- Transportable, in house and outside
- Labeling option
- Stackable
- Color code
- System philosophy
Advantages of using Aesculap sterile containers

Supply of sterile instrumentation to the OR

- Simple, safe and expeditious sterile preparation
- Reduced transport risks connected to damaged packaging
- Reduced amount of waste in the O.R.
- Reduced particle contamination during the handling of the container
Aseptic preparation of Aesculap containers in the OR

- opening
- getting the basket
- removing the lid
- removing the basket
Aseptic preparation in the USA
Advantages of using Aesculap sterile containers

Disposal

- Closed instrument cycle
- Protecting staff against contamination
- Protecting the environment against contamination
- Standardized return transport
- Options for automatic transport
Advantages of using sterile containers

**Economy**
- Reusable containers
- Low/zero disposal costs
- Shorter packing times
- No repeat purchase costs
- No repeat administration costs
- Robustness
- Long service life

![Cost comparison container / soft packing chart](image-url)
Advantages of using Aesculap sterile containers

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

Maintenance of sterile containers

According to the EN 868, part 8 (4.4.1 & 4.4.2)

- 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.
Accelerated aging test, 5,000 cycles, acc. to EN 868, 8

Ageing test acc. to EN 868, Part 8, Annex G:

Continuous-duty sterilization

Incessant pressure changes simulate the mechanical stress on the system.

Microbiological examination of Basic, Vario & PrimeLine Containers prior to the continuous-duty test and after 5,000 cycles
Advantages of using Aesculap sterile containers

Commonly used performance testing for reusable sterile containers:


Aesculap Division
Marketing Sterile Technology
According to EN 285, European Standard for steam sterilizers, the maximum pressure change per min must not exceed 10 bar/min.

Normally a sterilizer would work with a pressure change rate of 3-4 bar/min.

To demonstrate the strength and reliability of PrimeLine we did this test even with a pressure change of 30 bar/min.
Advantages of using Aesculap sterile containers

Long-lasting, stainless steel closing system

Stack ability guaranteed
Advantages of using Aesculap sterile containers

Stackability acc. to EN 868, Part 8

Load: 10kg
Requirement: Lateral pulling force > 40N
Maximum stacking load acc. to EN 868, Part 8

Requirements:

0.5 N/cm²  
(minimum total load: 100 N)  
→ for a standard lid:
  702 N, equivalent ca. 70 kg

Breaking point: ca. 37.000 N ≈ 3.7 tons  
= 52 times better than required
PrimeLine is made of high grade polymer

PPSU = PolyPhenylSulfone

- **Impact resistant** = No deformation, reliable closing, less repair costs
- **Scratch resistant** = Better appearance
- **Color fast** = Better coding function
- **Color selection** = Blue, red, green, grey, yellow, anthracite
Permanent Sterile Protection System

removable cover

removable retainer with PTFE filter

flexible frame for retainer

inside protection

outside protection
Why PTFE filter

- PTFE = PolyTetraFluorEthylene (Teflon® Dupont)
- Highly resistant to chemicals
- Resistant to age
- The properties of the material do not change with time and use
- Stronger than steel
Primeline Clear Lid

- Clearly visible instrument sets = quick control
- Check of indicator change
- Check the set list
- Now 7 different PrimeLine colors available
Aesculap Scope Container
Aesculap Scope Container

- non-anodized version → validation and approval for STERRAD sterilization
- anodized version → validation and approval for steam sterilization
Aesculap Scope Container

- Approved Sealing and Closing Edge
- Indicator Labels
- Identification Labels
- Integrated Protection of Filter
- Indicator Labels
Aesculap Scope Container

Plugging in Silicone Gasket
Aesculap Scope Container

Optic Tray with universal Optic Storage System
Aesculap Universal Storage System
Aesculap Universal Storage System
Aesculap Universal Storage System
Aesculap Sterile Container System

Growing Stronger

Working Together

Products

Services
Aesculap Sterile Container System

Expert Know how for optimized sterile supply

Growing Stronger

Working Together

OR

CSSD
Questions?

Aesculap Sterile Container System