

# 10th World Congress of Sterilization

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Reusable Medical Equipment

Reprocessed in a CSSD – Shelf life times

Pia Hilsberg, Denmark

Can anybody tell me, what  
is the shelf life time of this  
instrument tray??



# Previous Studies

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- Paul G. Standard, Don C. Mackel and G. F. Mallison; *Microbial Penetration of Muslin- and Paper Wrapped Sterile Packs Stored on Open Shelves and in Closed Cabinets*, CDC, Atlanta, Georgia 1971
  - Wrapped in linen: Shelf life time down to 3 days
  - Wrapped in crepe paper: Shelf life time 3-4 weeks
  - Packages further wrapped in sealed plastic bags: Shelf life time up to 9 months

# Previous Studies

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- Paul G. Standard, G. F. Mallison and Don C. Mackel; *Microbial Penetration Through Three Types of Double Wrappers for Sterile Packs*, CDC, Atlanta, Georgia 1973
  - Faster penetration through 1 layer than through 2 layers
  - Double linen: 28 days
  - Linen and crepe paper: 77 days
  - Linen and densely woven cotton: 63 days
  - The time for the microbial penetration is less than half as long if the packages were stored on open shelves rather than in closed cabinets.

# Dutch Guidelines

Evaluation of the wrapping material	Point	Evaluation of a possibly additional protection:	Point
<b>Wrapping material:</b>		Protection against dust (welded paper bag or thin plastic bag tied with a knot)	400
1. Layer		Solid, moulded box + one additional sheet of crepe or non woven	750
One sheet of crepe (pure cellulose)	20	<b>Evaluation of facilities</b>	
One sheet of non woven material	40	Common room or direct with patient	0
One autoclave bag (plastic laminate)	80	Operating room / Outpatient department	50
2. Layer		Ordinary depot room	75
One sheet of crepe (pure cellulose)	60	Sterile store room / depot in ordinary ward	250
One sheet of non woven material	80	Sterile store room / depot at OP?????	300
One autoclave bag (plastic laminate)	100	Sterile store room / depot in STC ????	300
<b>Miscellaneous:</b>		<b>Evaluation of the placing of the equipment:</b>	
Container with inner lining of non woven material	210	Transportation trolley coated with plastic or cloth	0
Double container	250	Open shelves	0
<b>Evaluation of a possibly additional protection:</b>		Closed cabinets	100
Closed box (transportation box with unlocked cover)	250		
Distribution prepacking (one additional sheet of crepe paper or non woven material)	250		

# Present Guidelines – Other Countries

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- AAMI/DS-1 ST79:2005; Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- 8.9.3: Contamination of sterile products is event related and the probability of contamination is increased over time and through increased handling.

# Present Guidelines – Other Countries

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- AS/NZS 4187:2003; Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities:
- The shelf life time is event related and comprises as follows: Wrapping material, storage and handling conditions, probability of material deterioration and packing design.

A sterile package is unusable when incorrectly packed, damaged or open, humid after sterilisation or after contact with a wet surface, polluted or if it indicates that it has not been exposed to a sterilisation process.

# Present Guidelines – Other Countries

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Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008; HICPAC, CDC, Page 75:

- Studies in the 1970s showed that maintenance of the sterility varied and depended on the wrapping material.
- The shelf life time varies in relation to the porousness of the packing and storage conditions.
- Several hospitals have switched to event related shelf life where the evaluation is based on factors that may deteriorate the quality of the product, e.g. the number of microorganisms in the air, air shifts, traffic, location, humidity, temperature, area and type of wrapping.



# Present Guidelines – Other Countries

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- Medical Devices Agency, Part 3: Procedures for decontamination using, cleaning, disinfection and sterilization processes, June 2006, Page 28:
- The shelf life time is event related. In case the protection measures remain intact there are no restrictions in relation to shelf life, and the instruments will remain sterile.

# Present Guidelines – Other Countries

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- DIN 58953-7-9: Instrument containers with/without inner lining: 6 months.
- AWMF (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften) Recommendation Hospital Hygiene; The Processing of Instruments and Materials in Hospital and General Practice; 1998: Due to the great variations of wrapping materials and packing methods it is not possible to make a guideline for shelf life times. However, shelf life times of 3-6 months seem to be realisable.

# Present Guidelines – Other Countries

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- Norway: No available guidelines for the determination of shelf life times.
- On the basis of the examinations in the 1970s Sweden has determined a shelf life time of 1 month for non-woven packs.

# Conclusion – Available Material

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The guidelines of most countries are based on event related shelf life, but what is an event?

- An event comprises any damage or accident that compromises the sterility of the content.
- Events may include: Material quality, factors that may deteriorate the quality of the product, e.g. humidity, air purity, dust, dirt, pressure variations, temperature variations.

# New Study made in 2009

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- **Determination of the Efficacy of Sterile Barrier Systems Against Microbial Challenges During Transport and Storage** concerning the measurement of the sterile barrier efficacy during transport and storage has recently been published in Infection Control and Hospital Epidemiology in February 2009.
- The article concludes, that neither an exclusively event related nor an exclusively time related expiration date is possible.
- The expiration date must be determined on the basis of a scientific risk evaluation of the barrier qualities (the filter efficacy) compared to inevitable environmental conditions. The article requests the manufacturer to present data that indicates the filter efficacy.

# Event Related Shelf Life

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## Overall evaluations:

1. The barrier qualities of the packaging
2. Storage and climate conditions in storerooms
3. Transport conditions
4. Handling conditions

# Overall Evaluations –

## 1. The Barrier Qualities of the Packaging

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- Evaluation of the manufacturer's technical documentation
- Evaluation of the laboratory test made by an independent laboratory
- Evaluation of the manufacturer's instructions

# Overall Evaluations –

## 2. Storage Conditions and Climate Conditions in Storerooms

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- Number of cfu in the room
- Number of air shifts and air directions
- Temperature
- Humidity
- Pressure conditions
- Sunlight
- Traffic
- Placing of products (open shelves, closed cabinets, no stacking)
- Inspection of storerooms
- Application of the FIFU principle
- Training of the staff / Audition of the staff in good handling practice



# Overall Evaluations –

## 3. Transport Conditions

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- Losses, crushing, shakes
- Pressure conditions during transport
- Placing of products (open trucks, closed trucks, no stacking)
- Training of the staff / Audition of the staff in good handling practice

# Overall Evaluations –

## 4. Handling Conditions

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- Number of handlings
- Weight
- Placing in storeroom (easy to pick)
- Training of the staff / Audition of the staff in good handling practice

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- If case the above conditions prove to be examined and considered satisfactory porous sterile packs can be supplied with the following indication:

**The equipment is sterile until use unless the packaging is defective**

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The question is whether it is Cost  
Benefit to control all these event  
conditions?

And are we able to procure all  
relevant information?

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- Aren't the costs for this control too high?
  - And will the costs for the control of e.g. climate conditions not exceed the costs for repacking – e.g. in relation to decentralised stocks in connection with wards?

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- Wouldn't it be better to re-examine shelf life times based on modern used wrapping materials and storage in rooms with temperatures within e.g. 18-30° C and a relative humidity which does not exceed 70 % rH.

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- A way of measuring the filter efficacy is also wanted. The filter efficacy is considered a very efficient tool when determining shelf life times. At present no suitable method seems to be available.  
(No instructions to the method in 11607-1).

Can anybody tell me, what  
is the shelf life time of this  
instrument tray??

Thank you for  
listening!

Further  
questions:  
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