

# REQUIREMENTS FOR PACKAGING

---

**Wim Renders**

# The choice of packaging material is important for

- CSSD: it determines the way of working
- Hospital and patient: it determines the safety of the patient. The packaging has to ensure sterility of the medical devices until the moment of use



# Medical Device Directive




Avis juridique important  
ES CS DA DE ET EL EN FR IT LV LT HU MT NL PL PT SK SL FI SV  
Site map | LexAlert | FAQ | Help | Contact | Links

31993L0042

## Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

*Official Journal L 169 , 12/07/1993 P. 0001 - 0043*

*Finnish special edition: Chapter 13 Volume 24 P. 0085*

*Swedish special edition: Chapter 13 Volume 24 P. 0085*

ES	CS	DA	DE	ET	EL	EN	FR	IT	LV	LT	HU	MT	NL	PL	PT	SK	SI
<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>	<a href="#">html</a>

[MORE INFO](#)

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another: whereas such disparities constitute barriers to trade within the Community:

# Medical Device Directive (1)

- Sterile Barrier Systems (SBS) are accessories class 1
- The responsibility for conformity assessment lies with the manufacturer
- SBS have to meet the essential requirements of MDD and must bear the CE marking of conformity

### *Article 3*

#### **Essential requirements**

The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

#### **▼ M5**

Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery <sup>(5)</sup> shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.

## *ANNEX I*

### **ESSENTIAL REQUIREMENTS**

#### **I. GENERAL REQUIREMENTS**

- 8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.
- 8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.







# Harmonised standards related to medical devices

## Summary list of titles and references of harmonised standards related to medical devices

The information contained in the summary list is a compilation of the references of standards which have been published in the Official Journal of the European Union. Although the lists are updated regularly, they may not be complete and they do not have any legal validity; only publication in the Official Journal produces legal affect.

The following summary list of references of harmonised standards is split into two tables. The first part of the table includes the references of the harmonised standards from EN 285:2006 to EN 27740:1992/A1:1997. The second part of the table starts with the references of harmonised standard EN 60118-13:1997.

First part of summary table (includes the references of the harmonised standards from EN 285:2006 to EN 27740:1992/A1:1997)			
ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard
			<b>Note 1</b>
CEN	EN 285:2006  Sterilization - Steam sterilizers - Large sterilizers	EN 285:1996	30.11.2008
CEN	EN 375:2001  Information supplied by the manufacturer with in vitro diagnostic reagents for professional use	—	
CEN	EN 376:2002  Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing	—	
CEN	EN 455-1:2000  Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	EN 455-1:1993	Date expired (30.04.2001)
CEN	EN 455-2:2000  Medical gloves for single use - Part 2: Requirements and testing for physical properties (including Technical Corrigendum 1:1996)	EN 455-2:1995	Date expired (30.04.2001)

# Medical Device Directive (2)

- Harmonized standards (EN) facilitate compliance with the essential requirements
- Applying the norms = conformity to MDD

## Products meeting the norm offer

- conformity to the regulations
- certainty to the CSSD
- confidence to the user
- safety to the patient!

# Medical Device Directive (3)

## ISO 11607-Packaging for terminally sterilized medical devices

- Part 1:2009: “Requirements for materials, sterile barrier systems and packaging systems”
- Part 2:2006: “Validation requirements for forming, sealing and assembly processes”

# Medical Device Directive (4)

## ISO 11607 DEFINITIONS

**Sterile Barrier System (SBS):** The minimum packaging that prevents the ingress of microorganisms and allows for aseptic presentation at the point of use.

**Preformed sterile barrier system:** The sterile barrier that is supplied partially assembled for filling and final closure or sealing, e.g., pouches, bags, and open reusable containers.

**Protective packaging:** The packaging configuration designed to prevent damage to the sterile barrier system and its content from the time of assembly until the point of use.

**Packaging system:** The combination of sterile barrier system and protective packaging.



# Medical Device Directive (5)

## EN 868 series

- EN 868-2 Packaging materials and systems for medical devices which are to be sterilized - Part 2: Sterilization wrap – Requirements and test methods.
- EN 868-3 Packaging materials and systems for medical devices which are to be sterilized - Part 3: Paper for use in the manufacture of paper bags (specified in Part 4 of this standard) and in the manufacture of pouches and reels (specified in Part 5 of this standard) - Requirements and test methods.
- EN 868-4 Packaging materials and systems for medical devices which are to be sterilized - Part 4: Paper bags - Requirements and test methods.
- EN 868-5 Packaging materials and systems for medical devices which are to be sterilized - Part 5: Heat sealable pouches and reels of material manufactured from paper and plastic – Requirements and test methods
- EN 868-6 Packaging materials and systems for medical devices which are to be sterilized - Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods.
- EN 868-7 Packaging materials and systems for medical devices which are to be sterilized - Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods.
- EN 868-8 Packaging materials and systems for medical devices which are to be sterilized - Part 8: Re-usable containers for steam sterilizers conforming to EN 285 - Requirements and test methods.
- EN 868-9 Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods.
- EN 868-10 Packaging for terminally sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines - Requirements and test methods.

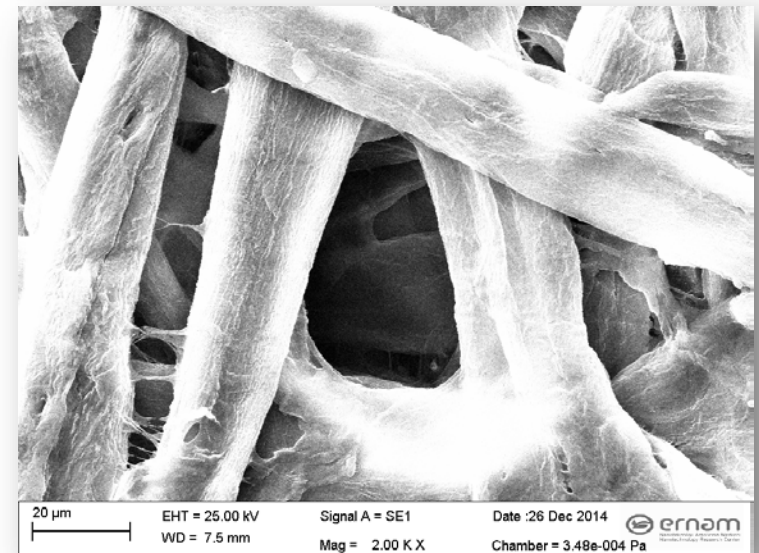
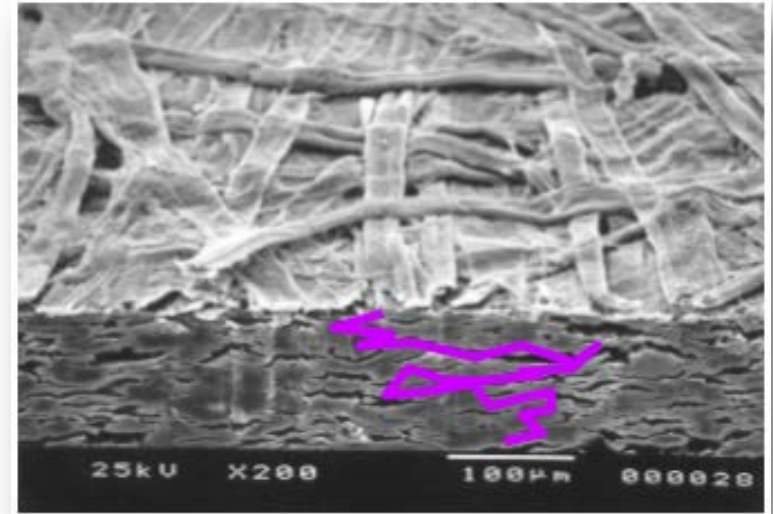


# Overview of packaging material

- Paper
- Creped paper
- Softened creped paper
- Reinforced creped paper
- Wet laid nonwoven
- 100% synthetic fibers
- Tyvek: polyolefines
- Preformed packaging systems
  - Heat sealable pouches and reels
  - Sterilizing containers
- Cotton
- Schimmelbush drums

# Paper

- 100% wood pulp, 1 layer
- Smaller pore size than textile
- Depth effect because of layered structure
- Micro-organisms normally can not penetrate dry paper
- Moisture can be a transport medium
- Wet paper loses much of its strength



## ***Investigation of an increase in surgical site infections among Orthopaedic and Ophthalmology patients***



# Creped paper

- 100% wood pulp, 1 layer
- Adjusting paper's stretch and thickness
- Softer and stronger
- Most cost effective material



# Softened crepe paper

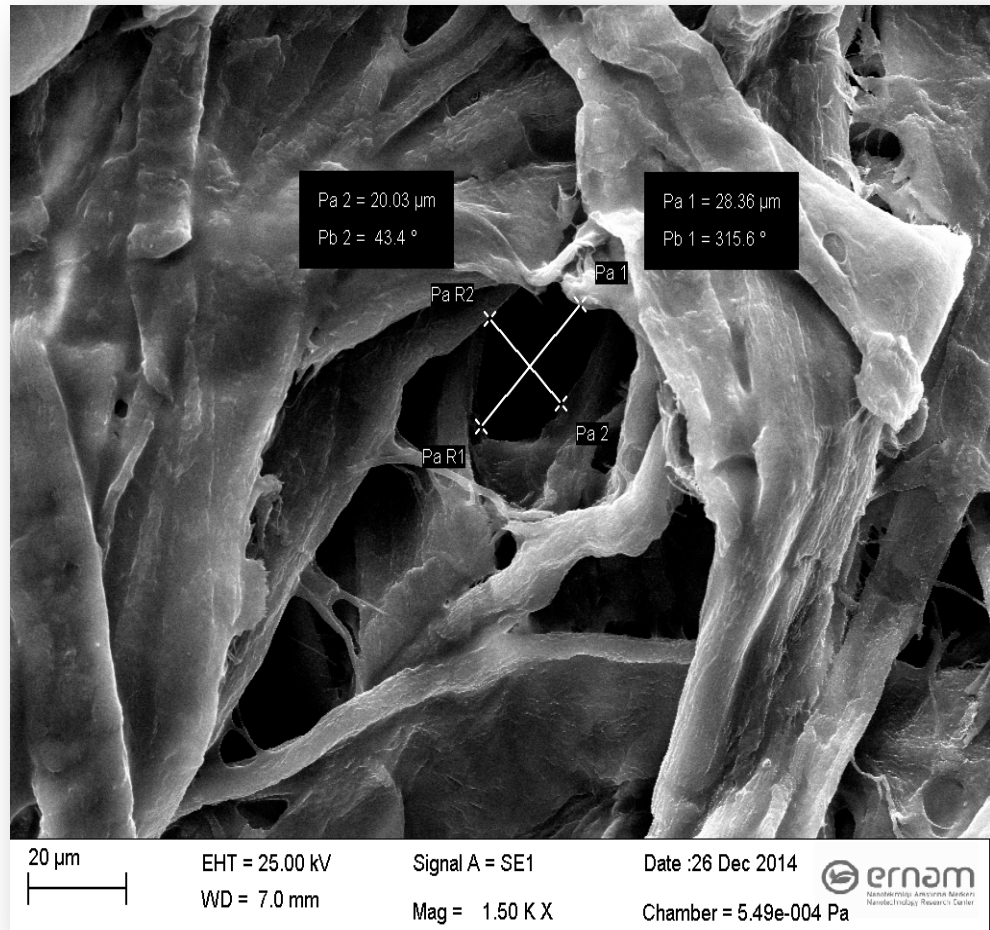
- 100 % wood pulp, 1 layer
- Greater softness and stretch





# Reinforced creped paper

- 80 % wood pulp, synthetic surface binder (Acrylic), 1 layer
- A combination of drape-ability and softness with strength and water repellency





# Paper and Crepe

## Disadvantages

- Low tensile and tear resistance
- Less flexible and more easily permeable to water
- More memory: complicates aseptic technique

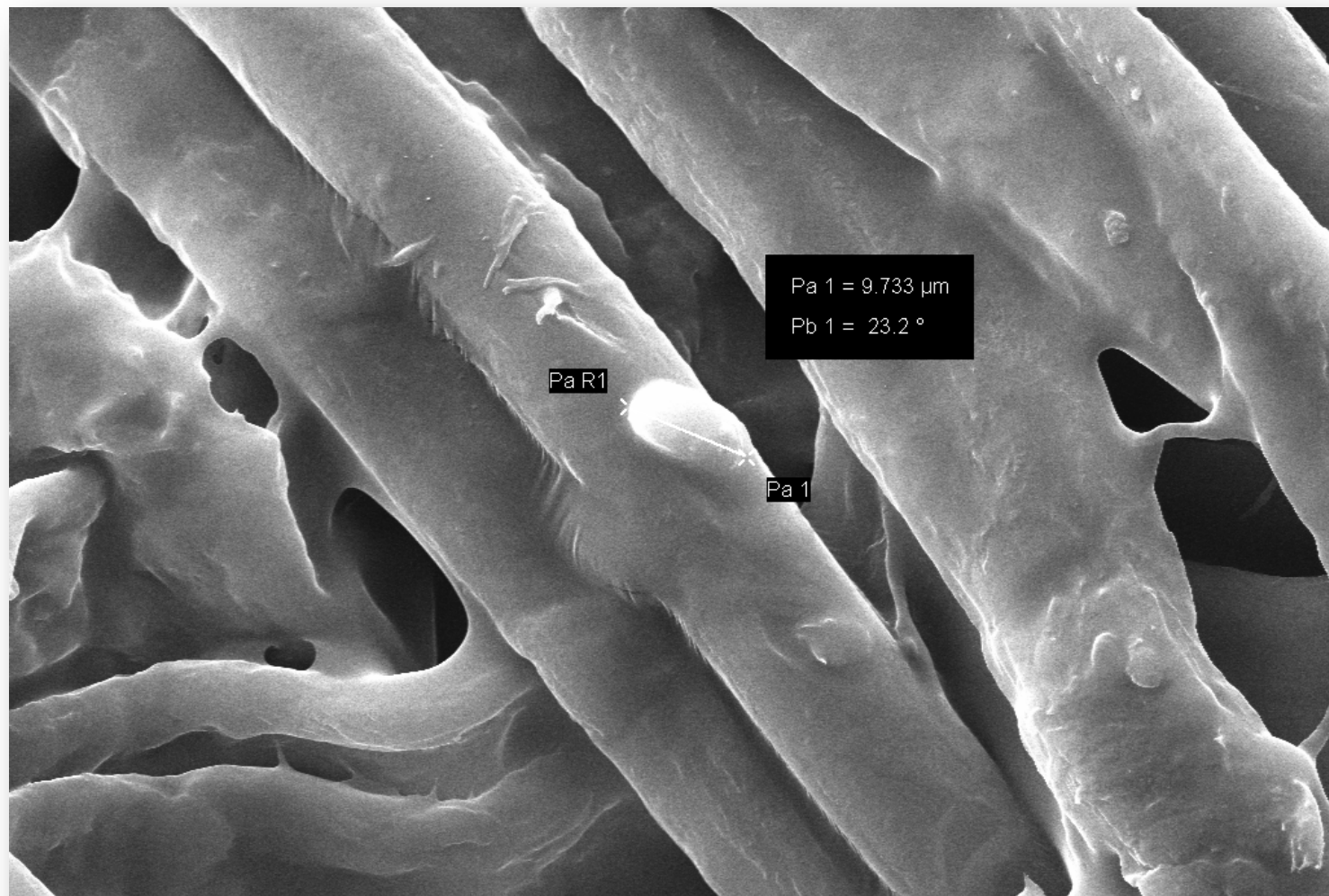
## Advantages

- Excellent moisture regulating and vapor-permeable
- Very good barrier properties

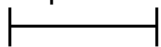
# Wet laid nonwoven

- Wood pulp and synthetic fiber blend (Polyester), 1 layer
- Strong and well drapable
- Good barrier
- Virtually lint free and a higher fluid repellency





10 μm



EHT = 25.00 kV

WD = 7.0 mm

Signal A = SE1

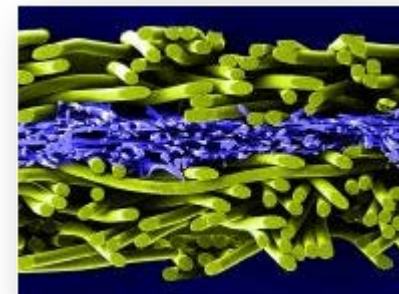
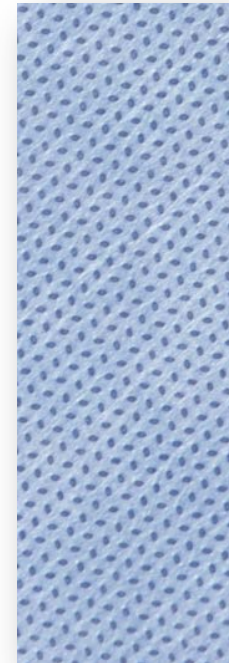
Mag = 3.00 K X

Date :31 Dec 2014

Chamber = 3.87e-004 Pa

# 100 % synthetic fibers

- Spunbound/Meltblown/Spunbound nonwoven, multi-layer
- The material with the highest mechanical resistance
- Far-reaching waterproof, good tensile and tear resistant
- Cave: wet packages
- Also suitable for H<sub>2</sub>O<sub>2</sub> sterilization





# Alcohol repellency

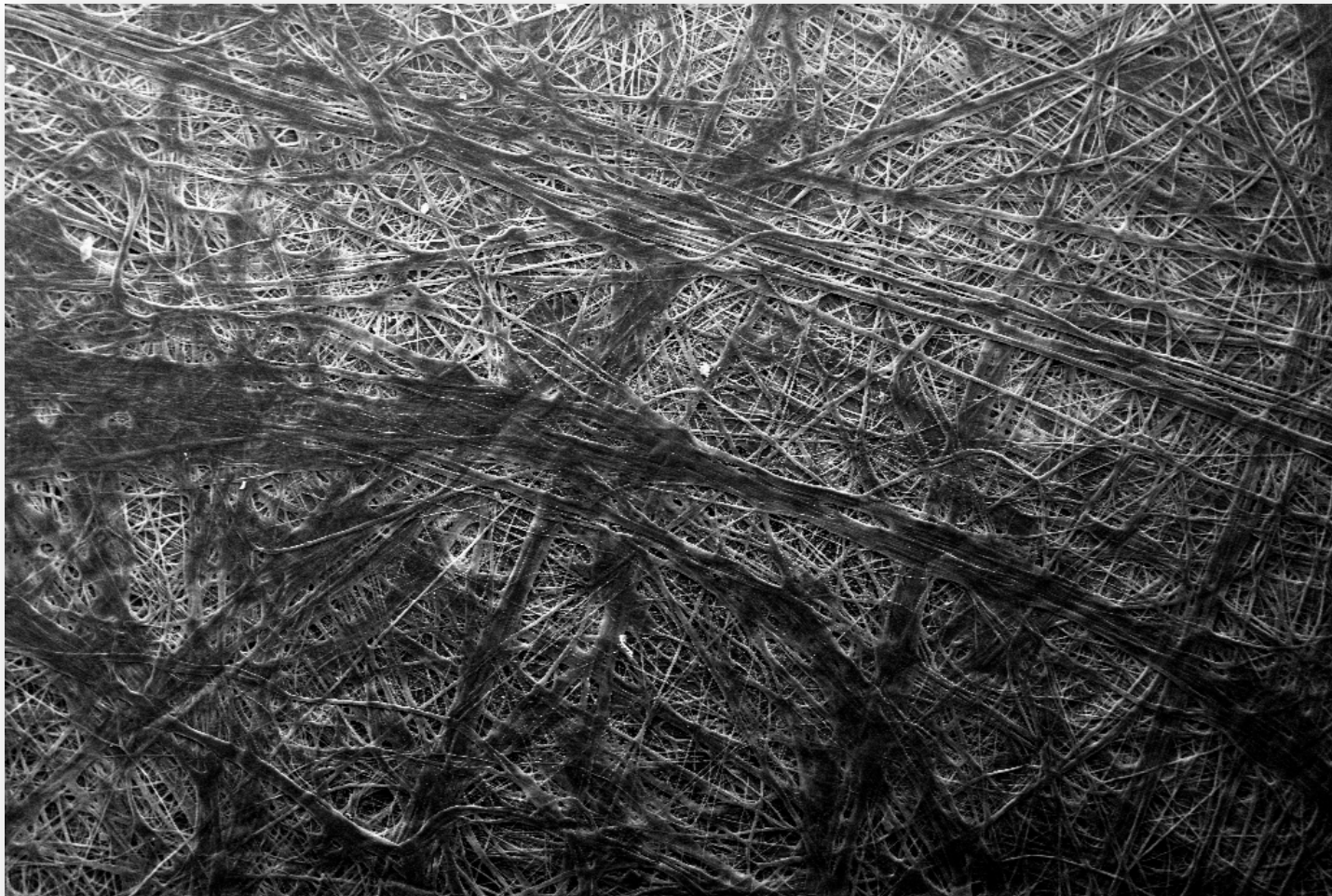



# Tyvek

- Polyethylene fibers
- Combination of tear resistance, durability, breathability and microbial barrier
- Not compatible with steam sterilization at 134° C
- Compatible with EO and low temperature oxidative sterilization







200  $\mu$ m  


EHT = 25.00 kV  
WD = 7.0 mm

Signal A = SE1  
Mag = 70 X

Date :26 Dec 2014

Chamber = 4.41e-004 Pa

# Preformed packaging systems

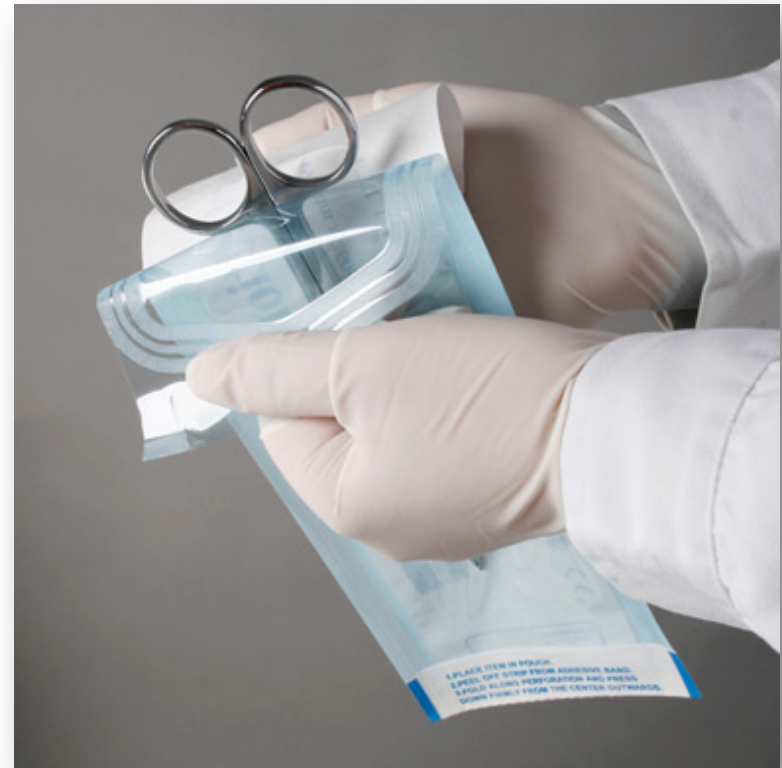
## Heat sealable pouches

- A film on one side and paper, nonwoven or polypropylene/polyolefine on the other
- The content is visible
- Peel-open system assures dust-free, aseptic opening and presentation
- Class 1 chemical indicator



# Heat sealable pouches

- The content should be able to move freely inside the pouch:
- Packages should be filled to no more than  $\frac{3}{4}$  of their length and minimum 2 cm of empty space around the instrument
- The right orientation of the medical device for easy and aseptic removal



# Heat sealable pouches

- In case of double packaging: porous against porous material!
- Inner pouch not folded
- Inner pouch should fit freely in the outer pouch
- Closures that compress the package should not be used





# Sealing

- Sealing is the most critical step
- Seal at least 6 mm wide
- Gusset types are difficult to close
- Self-seal pouches: closing cannot be guaranteed!
- Self making of pouches is not a good idea



T. Kami



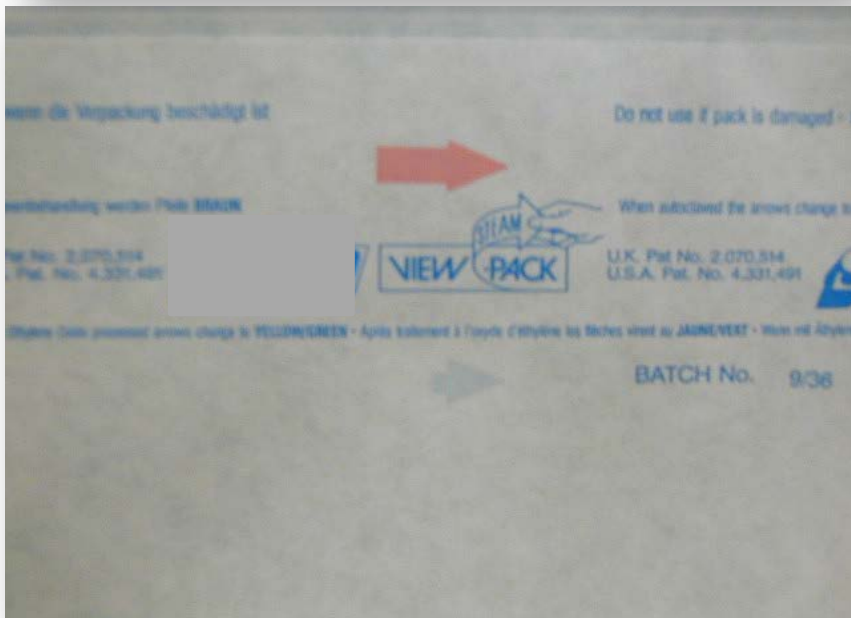
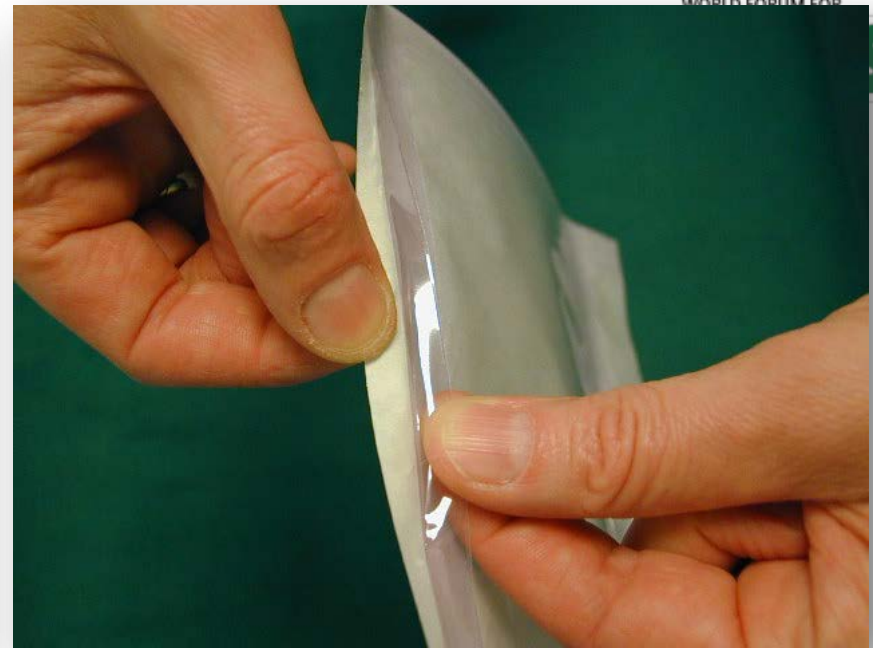




# Heat sealable pouches

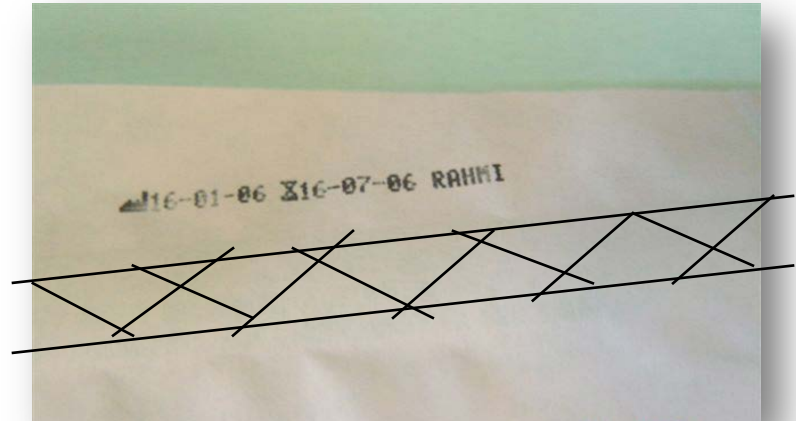
## When you use reels:

- Cut the reel to the desired length
- Allow extra space for sealing and a flap to open the package
- Reels are marked with a symbol indicating the peeling direction



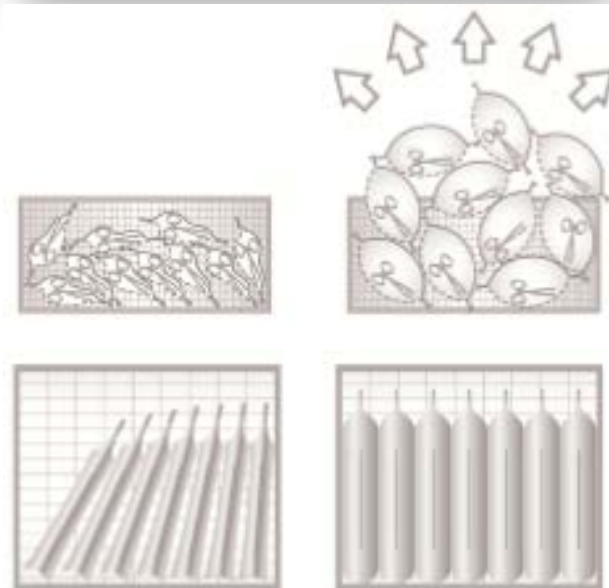
# Heat sealable pouches

- Writing on pouches only on the film side or on the paper side outside the seals
- The writing instrument may not create holes
- Only markers appropriate for the sterilization method
- Labels must not impede the sterilization process



# Heat sealable pouches

- Place upright in the sterilizer:  
vertically on their sides is the best.  
Otherwise flat with the porous side  
facing down
- Not too tight together
- Not folded, not touching the  
chamber walls
- After sterilization: before handling  
let cool down to ambient  
temperature
- 2 layers (Double pouching): better  
protection





# Heat sealable pouches

## Opening:

1. Unattach the seals on the upper corners
2. Pull the laminate from paper side slowly and evenly to prevent fibers from breaking, thereby causing contamination





# Sterilizing containers

Well designed containers offer:

- Air removal and steam access through filters or valves
- Ensure sterility maintenance during storage
- Clear identification by labelling
- A tamper device indicating whether a container was opened



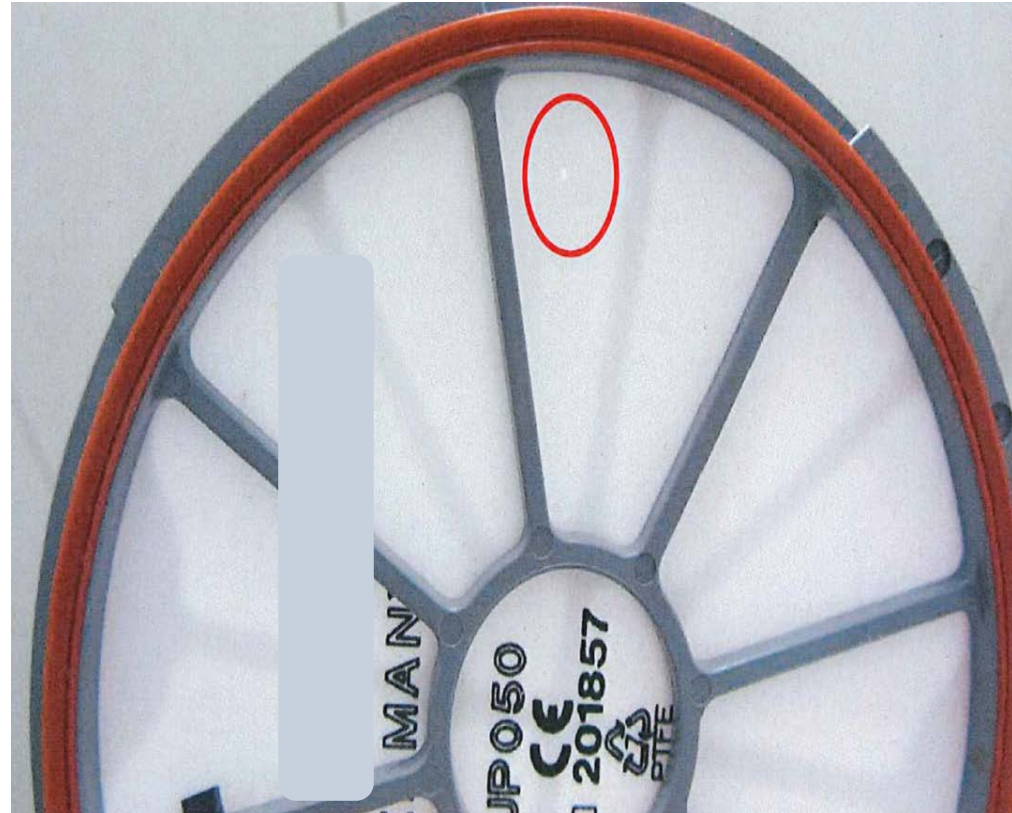
# Sterilizing containers

- Dutch standards: use containers with inner packaging closed with sterilization tape.
- 2-layer concept makes aseptic opening possible
- Inner packaging covers the exterior and creates a sterile field
- Load up to 10 kg (EN 868-8)



# Disadvantages of sterilizing containers

- Danger for wet loads: appropriate sterilization program and load
- Obligatory washing and disinfecting after each use
- Check the seals regularly on integrity and porosity
- 



# Le test à l'eau



Verser un volume défini d'eau dans la cuve du conteneur.

Mettre en place le couvercle



Mettre le conteneur sur la tranche en prenant précaution de ne pas déborder le filtre



Attendre un délai de 20 sec. pour chaque tranche avant de conclure à l'absence de fuite



# Cotton

- Not suitable as SBS: not an adequate microbial barrier
- As protective packaging it should contain its natural humidity:
  - Conditioning at room temperature (18° C to 22° C), relative humidity ranging from 35 % to 70 % for a minimum of 2 hours before sterilization



# Schimmelbush drums

- Not suitable as SBS
- Can be used as protective packaging
- Problems:
  - Metal band is only closed after sterilization
  - The band does not provide an adequate closure
  - The lid does not provide a proper seal
  - Hinged lids are hindering aseptic opening





# Recommendations for use

- Creped papers in double layer:
  - Weight up to 3 kg for small packs
- Reinforced creped paper (double):
  - Weight up to 6 kg for small surgical trays
- Nonwoven (double):
  - Weight up to 12 kg for surgical trays
- In Europe more and more a combination of SMS and nonwoven is used



# Recommendations for use

- Wrapping not too tight, not too loose. The packaging may in relation to the medical devices not be too big
- If sterilization cycle has to be repeated packages must be repacked
- Dutch guidelines:
  - Textile packages: maximum 6 kg
  - Instrument nets: maximum 8,5 kg (without packaging).  
Heavier means validation!

# Single or double wrapping?

ISO 11607

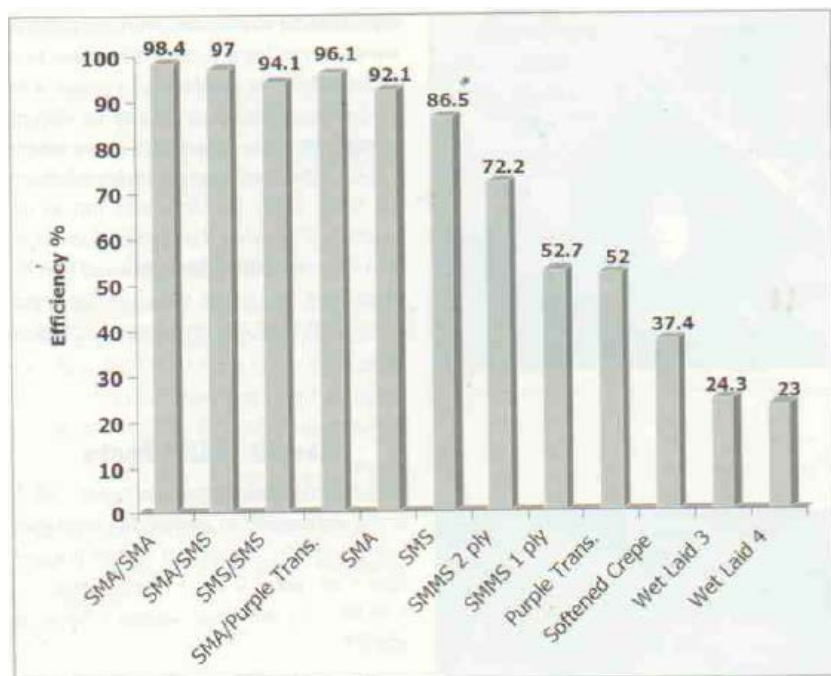
1. SBS of 2 layers + 1 layer protective packaging
2. SBS of 2 layers.  
Outer layer plays a double role: barrier and protection



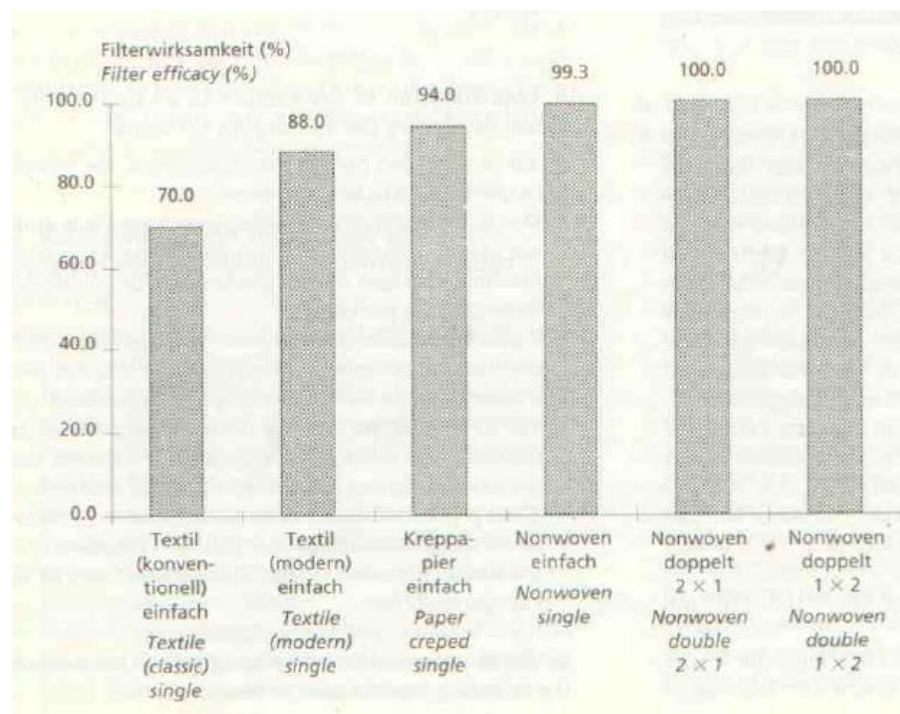
# David Duweltz

	<b>BFE Single Wrapping</b>	<b>BFE Double Wrapping (Interleaved)</b>
<b>Standard, Soft, Reinforced crepe</b>	96 % to 99 %	99,9 %
<b>Wet-laid Non woven</b>	90 %	98 %
<b>SMS Non woven</b>	93 %	99 %
<b>New Linen</b>	48 %	75 %
<b>Re-used Linen</b>	17 %	59 %

## Pack Integrity Test (Airborne challenge) T.I. Overthrow – CS4/2005

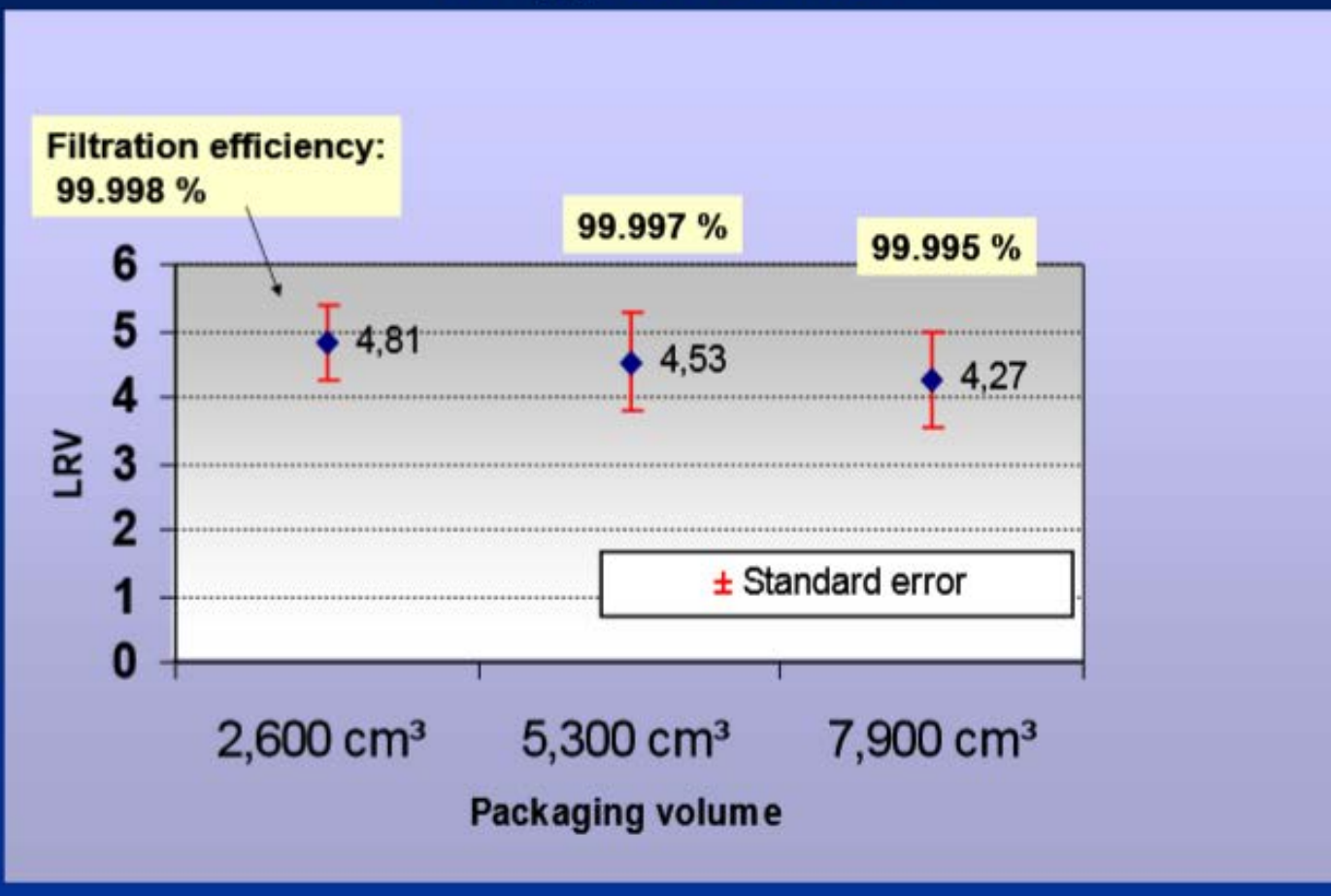


## Single or Multiple Wrapping of Medical Devices: Procedure Assessment Through Research – A.C.P. de Bruijn CS 5/1999



# Dunkelberg

## Logarithmic reduction value (LRV) of double wrapped baskets





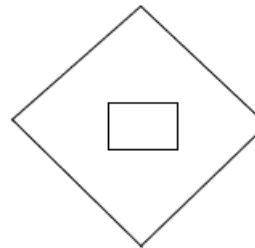
# How to wrap?

- Overthrow: the way in which a sterilization wrap was folded makes a substantial difference to the barrier efficiency
- Double sequential wrapping was recommended. Why?
  - Improved bacterial filtration
  - Guaranteed aseptic opening
  - Combination of different generation wraps possible
  - Possibility of color coding
- New forms of packaging allow simultaneous wrapping. It requires a double-layered material and a recommended way of wrapping

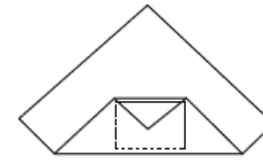


# How to wrap?

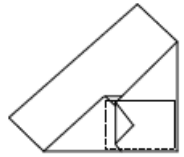
- Traditional methods for sequential wrapping: envelope and parcel method
- Most common: envelope folding. Why:
  - More tortuous path
  - Design validated by event related sterility maintenance studies
  - Reduces handling during opening thanks to the tabs



Packing sequence 1



Packing sequence 2



Packing sequence 3



Packing sequence 4



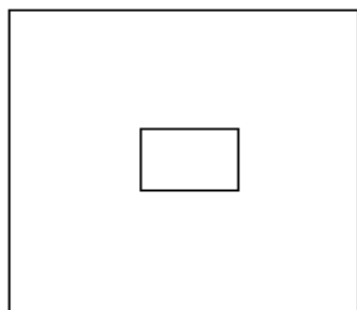
Packing sequence 5



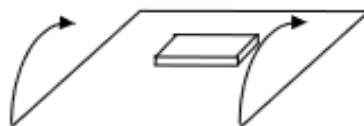
Packing sequence 6



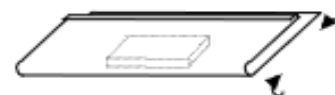
# Parcel method



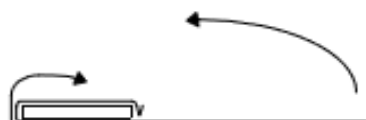
Packing sequence 1



Packing sequence 2



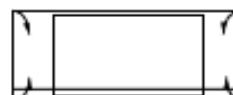
Packing sequence 3



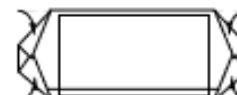
Packing sequence 4



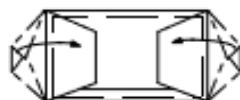
Packing sequence 5



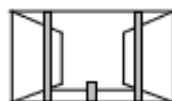
Packing sequence 6



Packing sequence 7



Packing sequence 8

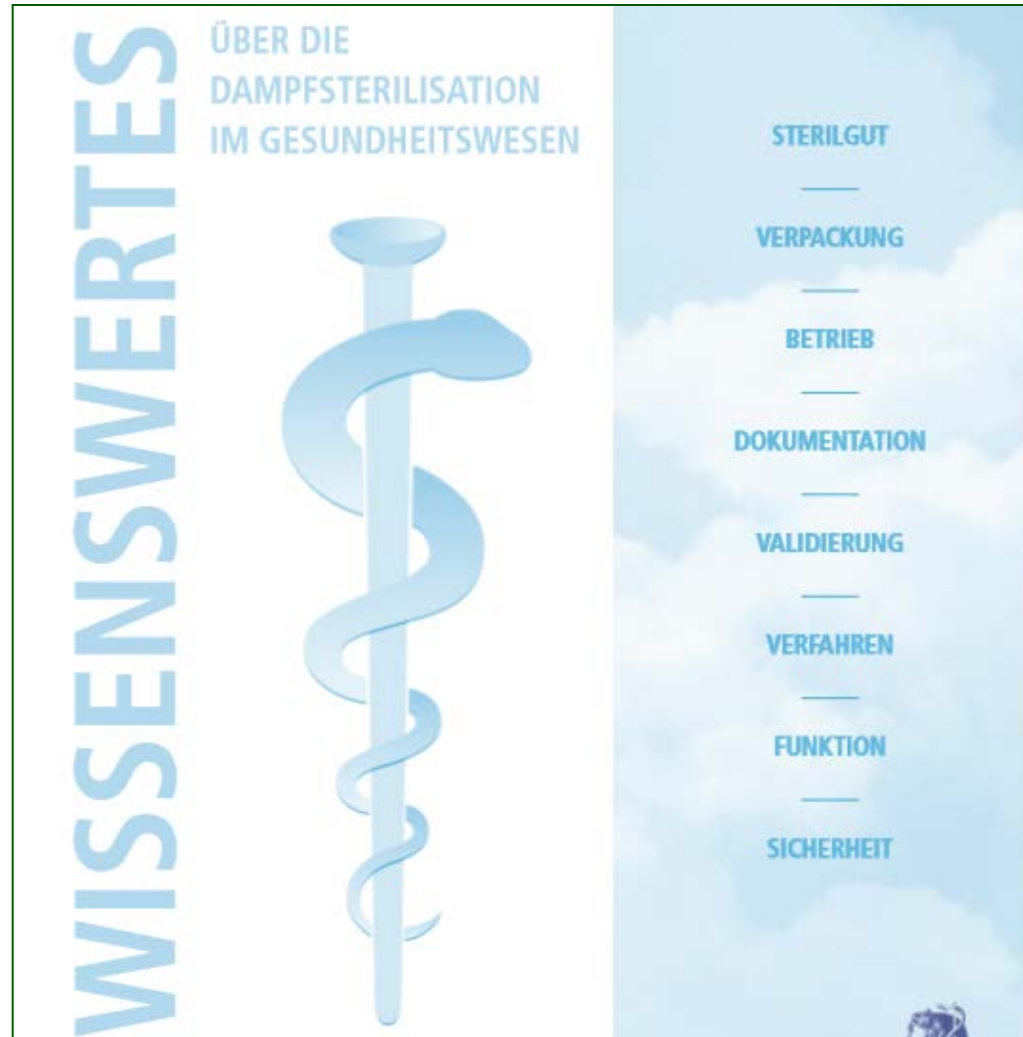


Packing sequence 9





# Recommendations for loading the sterilizers



# Loading

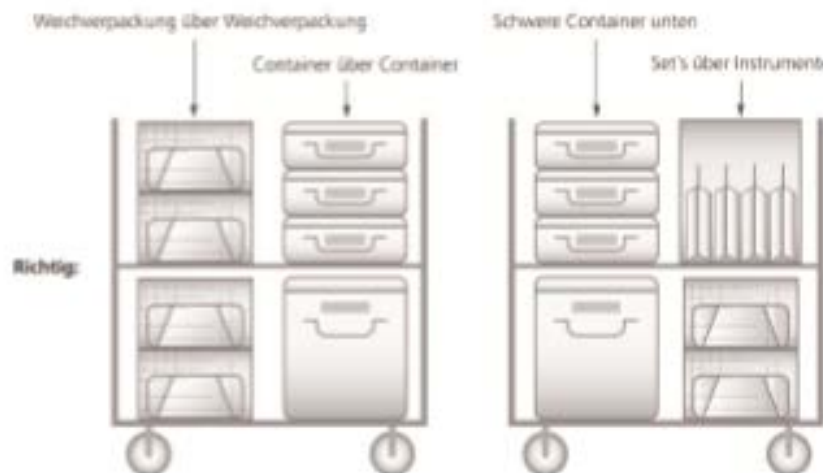
- At the top the material that generates little condensate
- At the bottom heavy products e.g. containers
- Container beneath container is OK. The condensate will flow off.
- Soft packaging under container collects the condensation. Drying will not be sufficient



- Container trocken  
- Container trocken



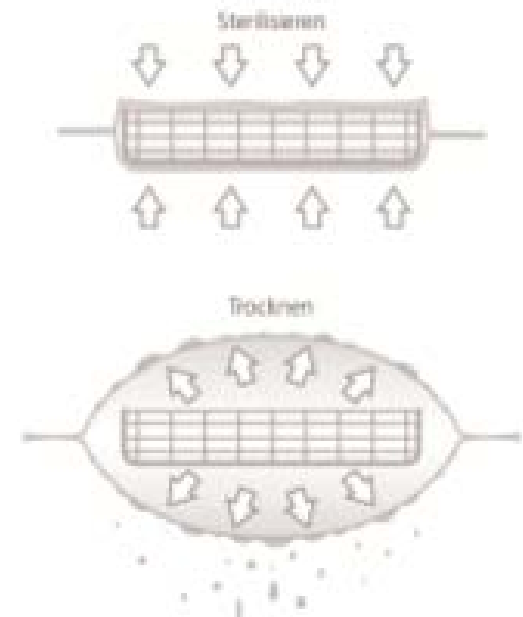
- Paket trocken  
- Paket trocken





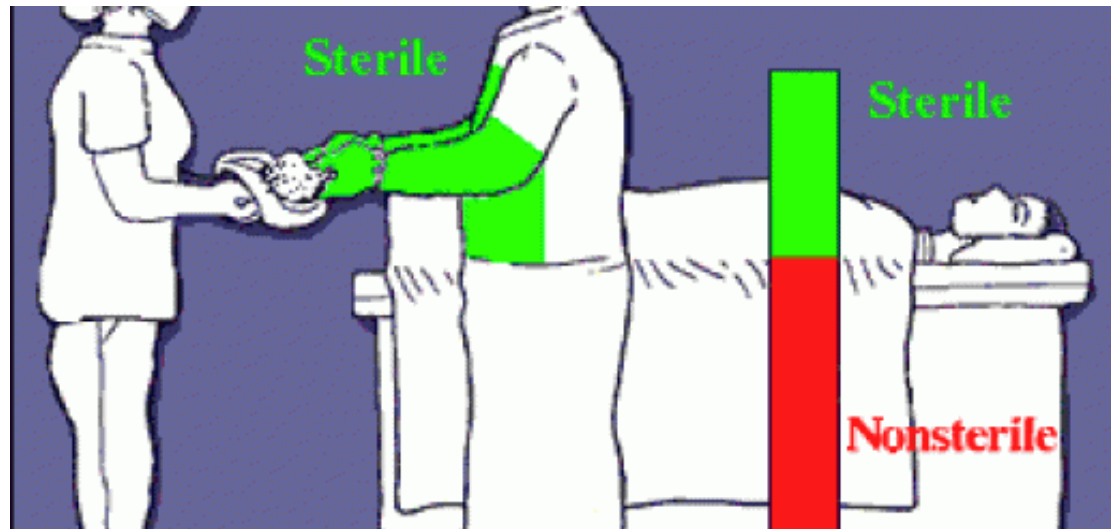
# Recommendations for loading the sterilizers

- Evacuation creates overpressure in each package: inflation. Thereby the condensate is pressed through the paper or nonwoven.
- Soft packaging under soft packaging: condensate flows off this packaging: dry
- Container under soft packaging: cools down too much by condensate. The stored heat is not sufficient to vaporize the amount of water: not dry!
- Soft packaging should not be placed directly on top of each other or on containers: water can stay in between



# Opening sterile packages

1. Inspection for the appropriate appearance of the external indicator and physical integrity
2. Remove outer wrap before entering the OR, not to introduce exterior contaminants



*Thank you!*