



Vereinigte Papierwarenfabriken GmbH, Feuchtwangen



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## Sterile Barrier Systems



## Sterilisation control and documentation products





## Definitions: SBS

### Sterile barrier system (SBS)

- Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product unit at the point of use



SBS – minimum configuration

## Definitions SBS

### Protective packaging

- Packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

### Packaging System

- Combination of the sterile barrier system and protective packaging



Packaging System as a maximum configuration:  
Double SBS + protective packaging (dust cover)

## ISO 11607 - used worldwide as standard for SBS

mandatory for the medical device industry (MDI) and healthcare facilities within the EU

ISO 11607-1:2006  (2014 update of annex ZA: only validated testmethods are mentioned in the ISO 11607)	Part 1 General requirements for materials, design and development of <u>sterile barrier systems</u>
ISO 11607-2:2009	Part 2 Requirements for forming and sealing processes and <u>validation</u> of this processes
ISO / TS 16775:2014 Not mandatory	Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2



## EN 868 – European standards series

widely used for demonstration of compliance with the requirements of ISO 11607

	product groups most relevant for use in hospitals
EN 868-2:2009	Wrapping materials (crepe paper, non-woven, SMS type materials)
EN 868-3:2009	Paper for bags and pouches
EN 868-4:2009	Paper bags
EN 868-5:2009	Heatsealable pouches and reels (=prefabricated SBS) made from permeable material and film
EN 868-6:2009	Uncoated rollstock papers for MDI
EN 868-7:2009	Coated rollstock papers for MDI
EN 868-8:2009	Reusable rigid sterile barrier systems i.e. containers
EN 868-9:2009	Spunbond polyolefin (Tyvek®) sterile barrier systems
EN 868-10:2009	Coated spunbond polyolefin (Tyvek®) sterile barrier systems

## EN 868-2: wrapping materials

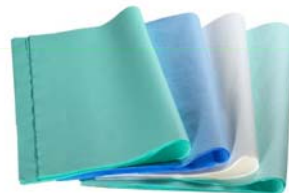
Formatted materials:

- (crepe) paper ( $\approx 60 \text{ g/m}^2$ )
- ‚Wetlaid‘ non woven ( $\approx 50 - 80 \text{ g/m}^2$ )  
made from pulp (blue coloured)  
and plastic fibres (transparent, shiny)  
manufactured like paper



Sterilisation compatibility:

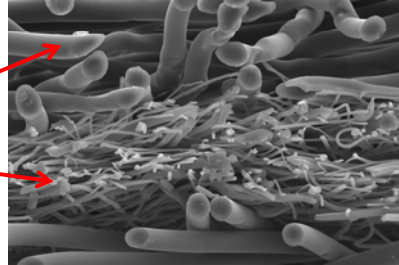
- STEAM
- EO (Ethylenoxide)
- FORM (Formaldehyde)



## EN 868-2: wrapping materials

Materials:

- SMS ( $\approx 35 - 80 \text{ g/m}^2$ )
- Polypropylene multi layer material
- extruded fibres: Spunbond and Meltblown
- Spunbond = strength
- Meltblown = filtration = barrier



Sterilisation compatibility:

- STEAM
- EO (Ethylenoxide)
- FORM (Formaldehyde)
- VH2O2 (Vaporised  $\text{H}_2\text{O}_2$  hydrogen peroxide = 'Plasma')

## EN 868-5: pouches and reels (heatsealable preformed SBS)

Combinations of porous materials

- Medical paper
- Non-woven
- Tyvek® spunbond non woven
- and laminated films:
- PET/PP films (Polyester/Polypropylene)
- PET/PE films (Polyester/Polyethylene)

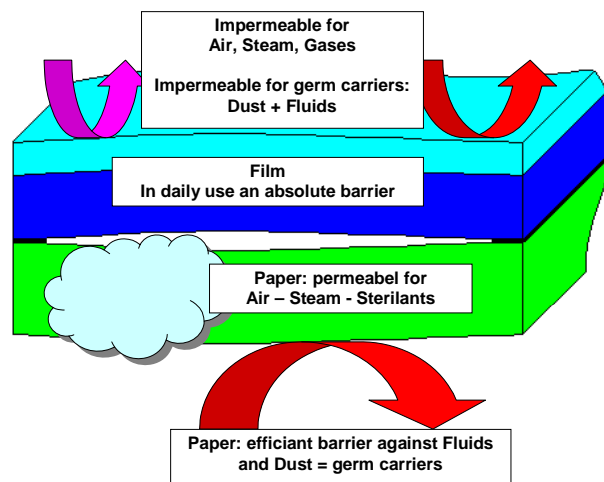


- Heat sealable and peelable
- Facilitates aseptic presentation
- Material combinations predetermine sterilisation compatibility

## Sterilisation compatibility

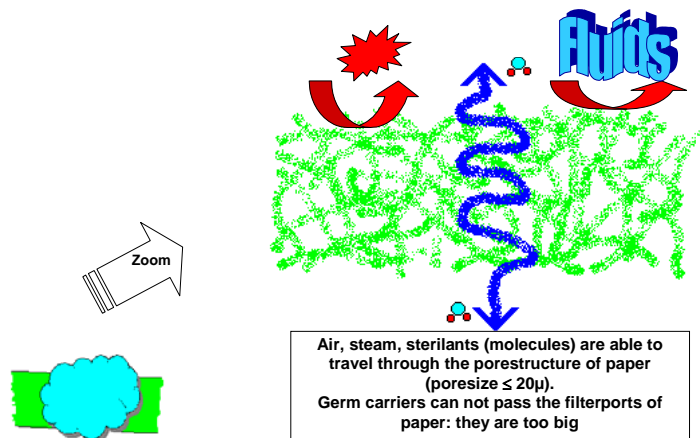
	STEAM	EO & FORM	VH2O2 (Plasma)
Paper/film laminates Non woven/film laminates			
Crepe paper, 'wetlaid' non woven, paper bags		residual FORM concentration should be checked	
Tyvek/film laminates			
SMS wrapping			

## Barrier of materials

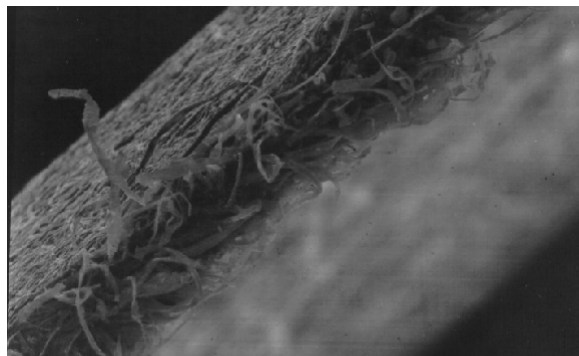




## Filtration



## Cross sectional enlargement of a paper sheet



## Cotton



... is not an appropriate barrier material !

## Application and handling rules

- Flexible sterile barrier systems are intended for single use
- Barrier functions are in question after several repeated sterilisation processes
- Do not sterilise flexible sterile barrier systems a second time!

## Application and handling rules

- Fill pouches and reels to a maximum of 75%:



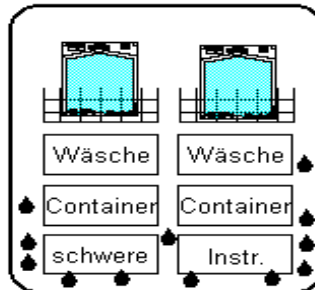
- Double packs: paper on paper // film on film!

## Application and handling rules

- After sterilisation: packs must be completely dry within 30 minutes
- If condensate is still observed after 30 minutes: consider these packs to be non-sterile and reprocess it!



## Application and handling rules



Loading the chamber:

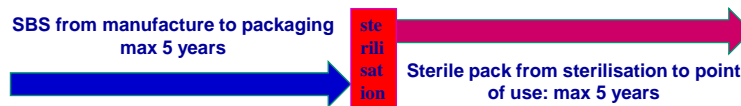
- light packs on top, heavy packs (instrument trays) on bottom

## Storage and transport conditions for SBS

- Temperature: 15° – 25°C
- Relative humidity: 35 – 50%, short term 60%
- Constant environmental conditions
- Be aware of dew point: lowering the air temperature will increase relative humidity to the point where condensation starts (e.g. air of 25°C and 60% r.h. reaches its dew point at 17°C)
- Dedicated storage rooms should have air conditioning and filtration
- Dedicated clean Cabinets
- Protect against condensate, rain, fluids, chemicals etc.
- Protect against direct UV light / sun light, storage area should be dark
- Protect against pest
- Minimize handling and presence of people

## Shelf life of sterile barrier systems

- Manufacturers of SBS have to provide shelf life information
- Stericlin® SBS products have a shelf life of max 5 years from manufacturing date until point of use. Point of use means sterilisation!
- After sterilisation a second shelf life period starts: maximum 5 years storage of sterile products, according DIN 58953-8 (see next slide)



## Storage time recommendations by DIN 58953-8:2010

Storage time table  
according to DIN 58953-7:2009

type of sterile barrier system compliant with ISO 11607 / EN 868	storage unprotected (without dust protection, e.g. on shelves)	storage protected (dust protected, e.g. in cupboards or drawers)
Single or double SBS	intended for immediate use, not to be used for storage.	6 months
single or double SBS + protective packaging = packaging system	max 5 years or maximum shelf life of the product if shorter	

## End of lecture

Thank you for your kind attention!

Useful links:

[www.vp-group.de](http://www.vp-group.de)

[www.sterilebarrier.org](http://www.sterilebarrier.org)