PACKAGING MATERIALS AND EQUIPMENT

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AGENDA

1. What’s the objective of the sterilization process
2. What are the requirements towards sterile packaging material
3. What are my options
4. Rigid Container System
5. Notes on choosing and using container system

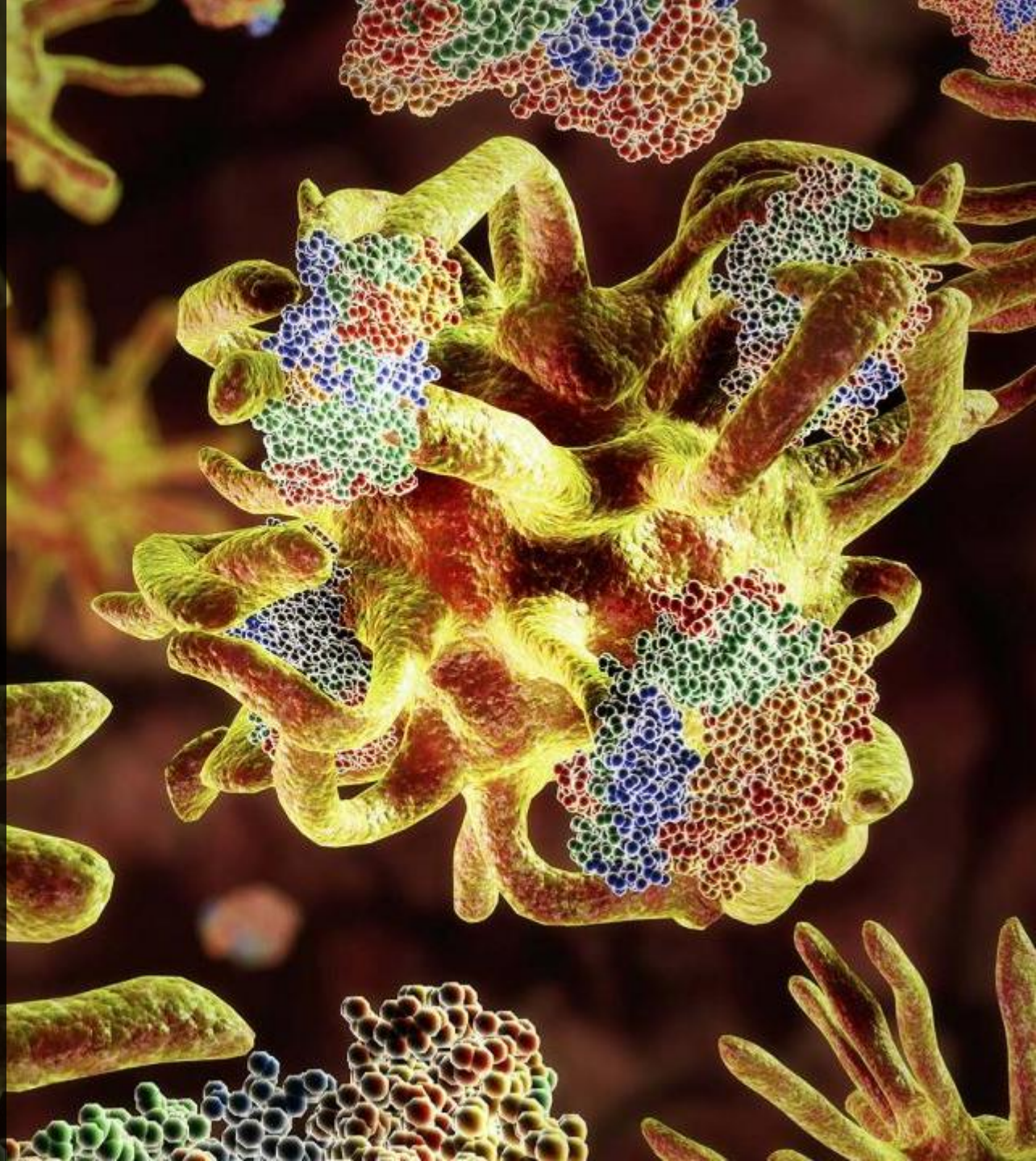
STERILIZATION PROCESS

WHAT'S THE OBJECTIVE

Prevention is the first line of defence in the fight against surgical site infection

As antibiotics & antimicrobials encounter increasing reports of microbial resistance the field of decontamination science undergoes a revival

The sterilization process is the total destruction of all microorganisms



10^x	Result	Log (10^x)	Reduction
10^0	1	**0**	**None = 0 %**
10^1	10	**1**	90 %
10^2	100	**2**	99 %
10^3	1’000	**3**	99.9 %
10^4	10’000	**4**	99.99 %
10^5	100’000	**5**	99.999 %
10^6	1’000’000	**6**	99.9999 %

Definitions & Reduction Factor

Cleaning: Removal of dirt and germs. It’s the measurement to make a surface “visually” clean

Reduction Factor - 10^{-2}

Disinfection: Process in which most or nearly all microorganisms are killed through the use of chemicals, heat or ultraviolet rays

Reduction Factor - 10^{-5}

Sterilization: Process of the total destruction of all microorganisms – especially spores and prions.

Reduction Factor - 10^{-6}

Growth Rate of a E. Coli or Salmonellae

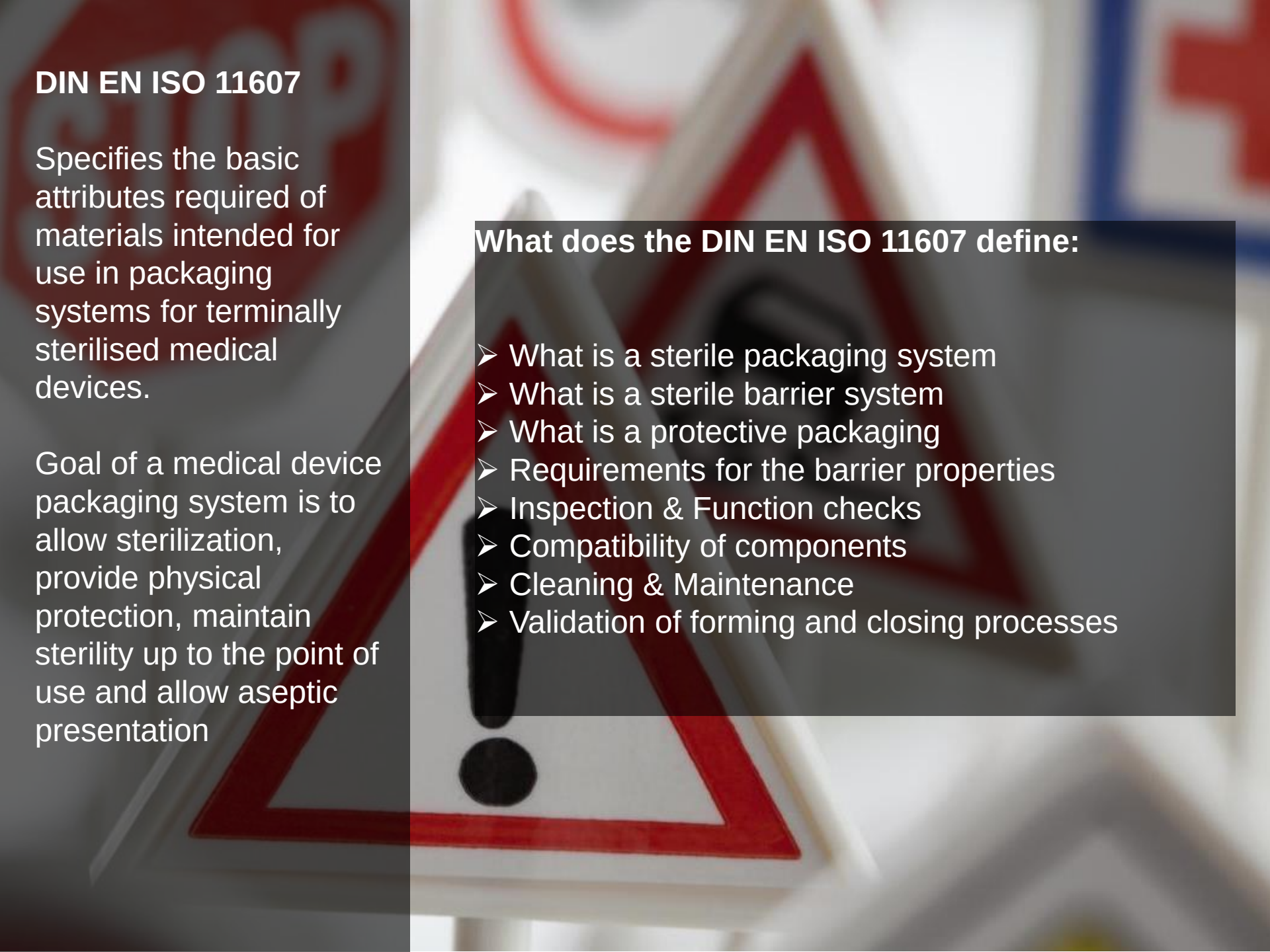
Bacteria's are masters in proliferation…

00 Min.	1	Bacteria	
20 Min.	2		
40 Min.	4		
1 Hour	8		E.Coli or
2 Hours	64		Salmonellae
3 Hours	512		doubling their selves
4 Hours	4.096		every 20 minutes
6 Hours	262.144		
6 Hours 40 Min.	1.048.576	Bacteria's	

After 6.5 hours – Over 1,000,000 Bacteria’s

REQUIREMENTS

TOWARDS A STERILE PACKAGING SYSTEM



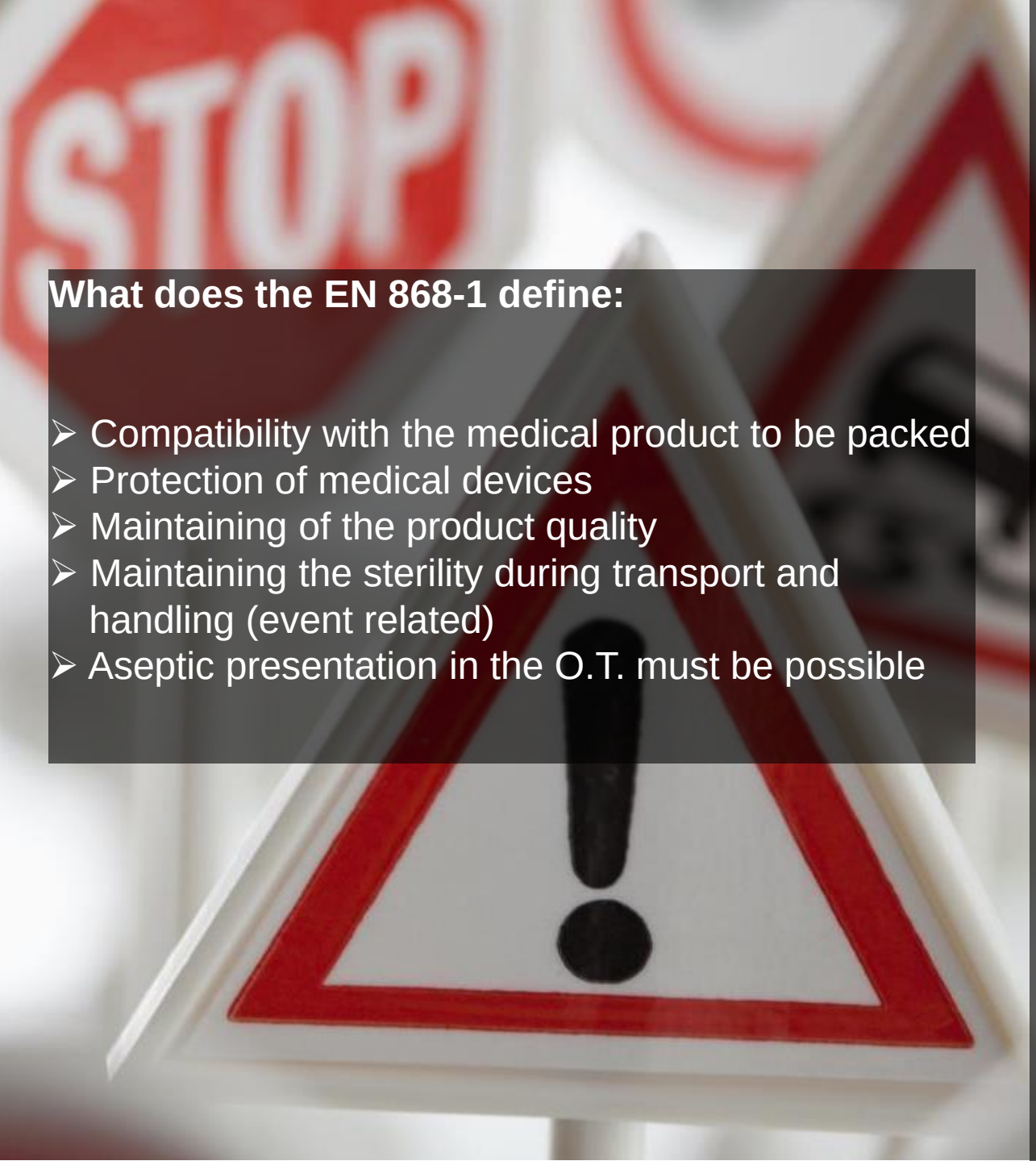
DIN EN ISO 11607

Specifies the basic attributes required of materials intended for use in packaging systems for terminally sterilised medical devices.

Goal of a medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation

What does the DIN EN ISO 11607 define:

- What is a sterile packaging system
- What is a sterile barrier system
- What is a protective packaging
- Requirements for the barrier properties
- Inspection & Function checks
- Compatibility of components
- Cleaning & Maintenance
- Validation of forming and closing processes



What does the EN 868-1 define:

- Compatibility with the medical product to be packed
- Protection of medical devices
- Maintaining of the product quality
- Maintaining the sterility during transport and handling (event related)
- Aseptic presentation in the O.T. must be possible

EN 868-1

Specifies packaging materials and systems for medical devices which are to be sterilized.

Others such as ANSZI / AORN / JCI

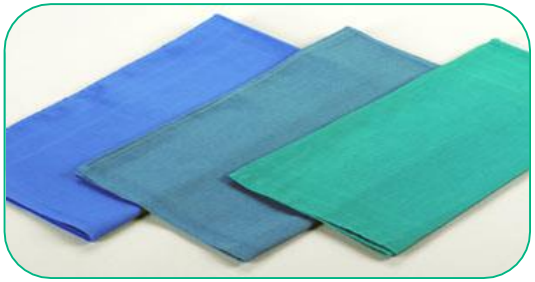
provide recommendations towards a sterile packaging system more in detail such as…

- Adequate barrier to microorganisms and fluids
- Maintain sterility
- Allow sterilant penetration
- Protect adequate against damages
- Provide adequate seal integrity
- Prevent transfer of microorganisms
- Be low-linting
- Favorable cost/benefit ratio
- Packaging needs a validation
- Adequate drying should be given

OPTIONS

OF DIFFERENT STERILE PACKAGING MATERIALS

Types of Sterile Packaging Materials

Type	Properties	Example
Re-Usable Woven Textiles	Textiles are supplied in sheets of woven materials and in a range of different fabrics	
Non-Woven	Non-Wovens consist of a bonded web made of textile and/or non textile fibers. Usually supplied in sheets	
Rigid Containers	Rigid Containers are usually made of aluminum and are a reusable sterile packaging system	

RE-USABLE WOVEN
TEXTILE WRAPS

Facts

used as sterile packaging until 1980

Material: 140-thread-count
- ineffective microbial barrier
- allowing most microorganisms to pass through
- not water repellent

Specifications:
- thickness: 0,40mm ± 0,05%
- weight: 210g/m2 ± 0,05%
- resistance to traction:12,5 daN/cm in warp and 5,5 in fill

Limited to 65 re-uses
- Challenging tracking of reprocessing cycles

Complex reprocessing cycle

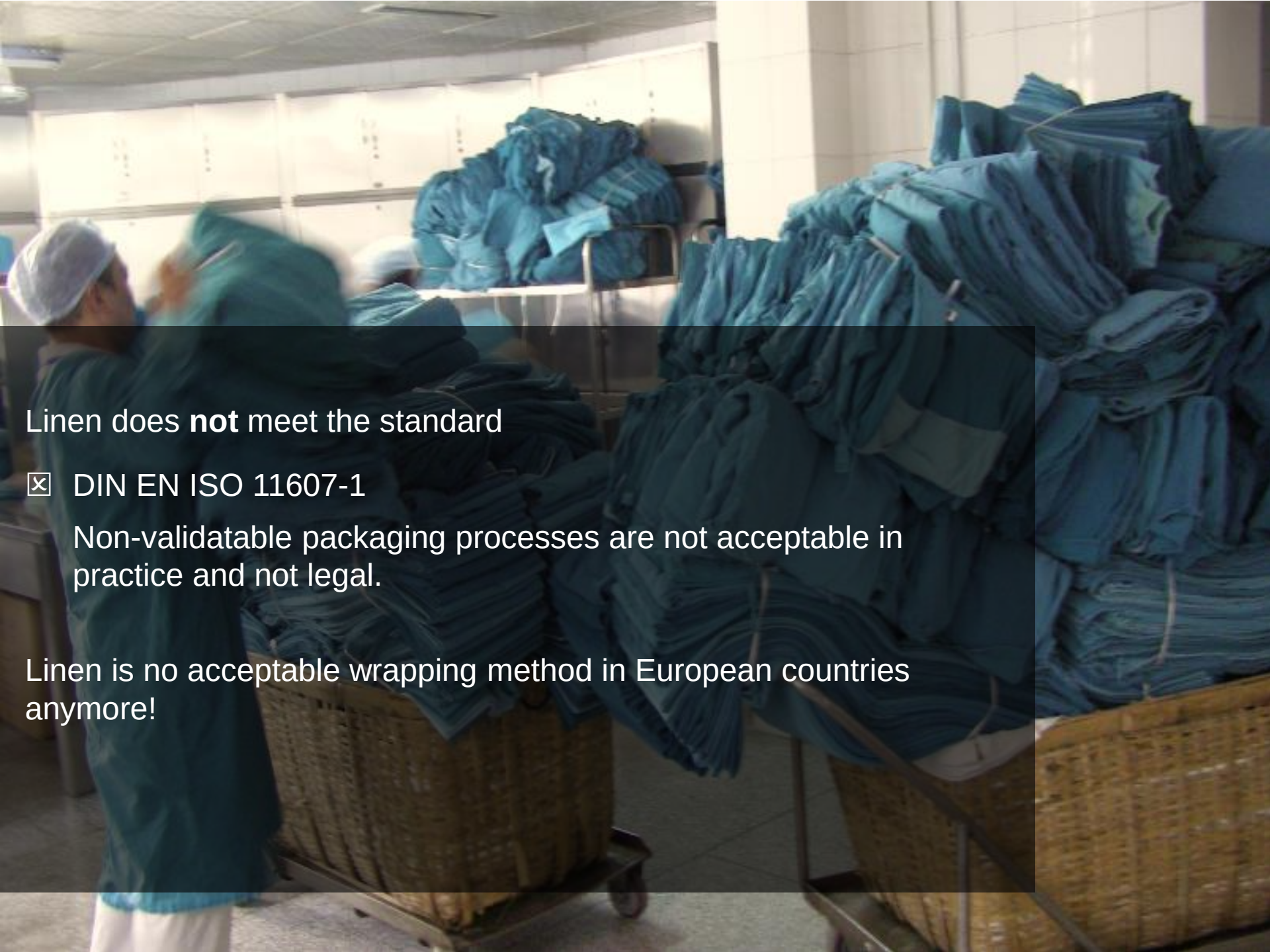
Time & Labour intensive

Expiry date: Double linen 28 days

General Statements

- Layer (acc. to AORN & ISO 11607): Sequential wrapping with two single wraps
- Reusable woven textiles should be laundered after every use to maintain hydration
- Maximum re-usage of 65 times*
- If the material appears very thin, even though there are no patches on the item, the item should be removed from use.
- Increasing number of washing and sterilization cycles increases permeability of the microbial barrier and its air permeability
- Soiled linen shall be processed for washing within 24 hours

* Study: Evaluation of the use and re-use of cotton fabrics as medical and hospital articles wraps in steam sterilization method; Edna Rodrigues; Kazuko Uchikawa Graziano; Brazil.



Linen does **not** meet the standard

☒ DIN EN ISO 11607-1

Non-validatable packaging processes are not acceptable in practice and not legal.

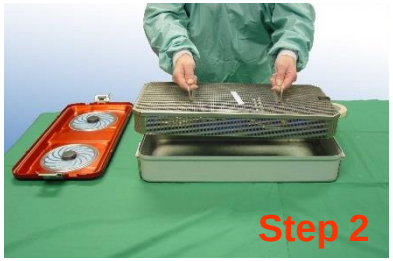
Linen is no acceptable wrapping method in European countries anymore!

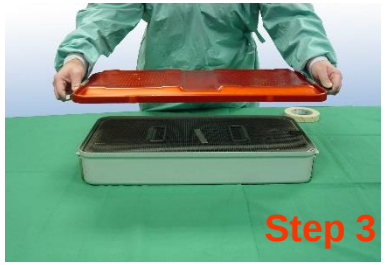
NON WOVEN

SHEET WRAPS

Sterile Technology

PURE SOFT WRAP – NON WOVEN





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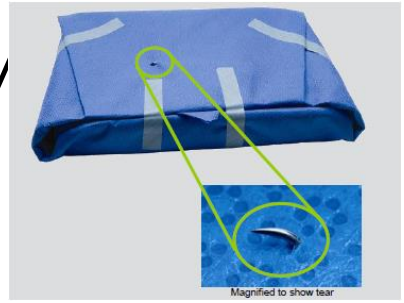
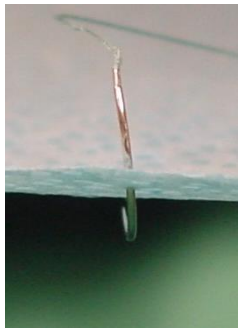


Pure Soft wrap – Non woven

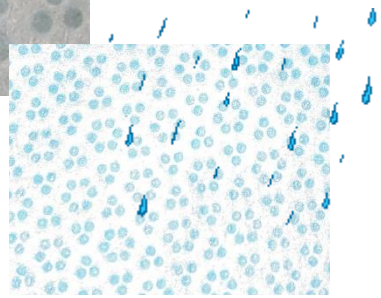
Safety?



Where is the hole?

- Tiny, almost invisible pin holes can cause contamination

- Reprocessing due to tears/puncture in wrap



- No shelter against moisture results in limited shelf-life

Awkward to handle due to integrity as well as potential damages to the sterile packaging system.

Supporting Documents:
Yale Study

Sterile Technology

Pure Soft wrap – Non woven

Eco friendly?

Sterilization wrap makes up as much as 20% of the surgical services waste stream in some medium to large hospitals.

Source: University of Minnesota Medical Center fact sheet

RIGID CONTAINER SYSTEM

GROUP OF PREFORMED PACKAGING SYSTEMS

Sterile Container System

First Container developed by Aesculap 1971

90% of hospitals in Germany are using sterile container

Throughout Europe the golden Standard

Benefits

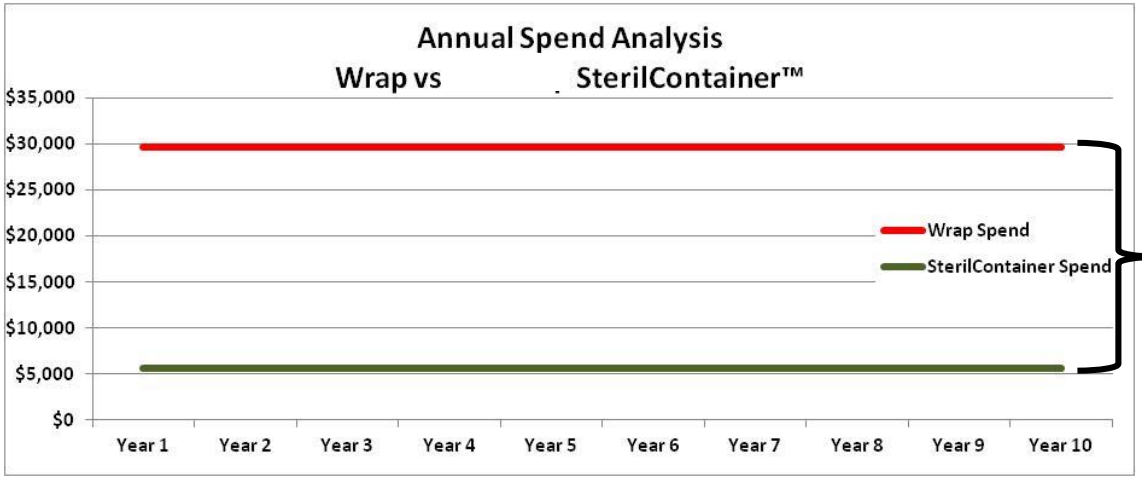
- Complaint to all relevant norms and standards
- Solide, rigid box
- Colour Coding
- Protection of Instruments
- Low operating costs
- Labeling option
- Safe & sound transportation
- Stackable
- Easy aseptic presentation
- Cost Saving
- Decrease of waste during surgery

Status Quo - Common Findings

Status Quo – How it could be

INVESTMENT COST: ROI Calculator Output

Payback Analysis



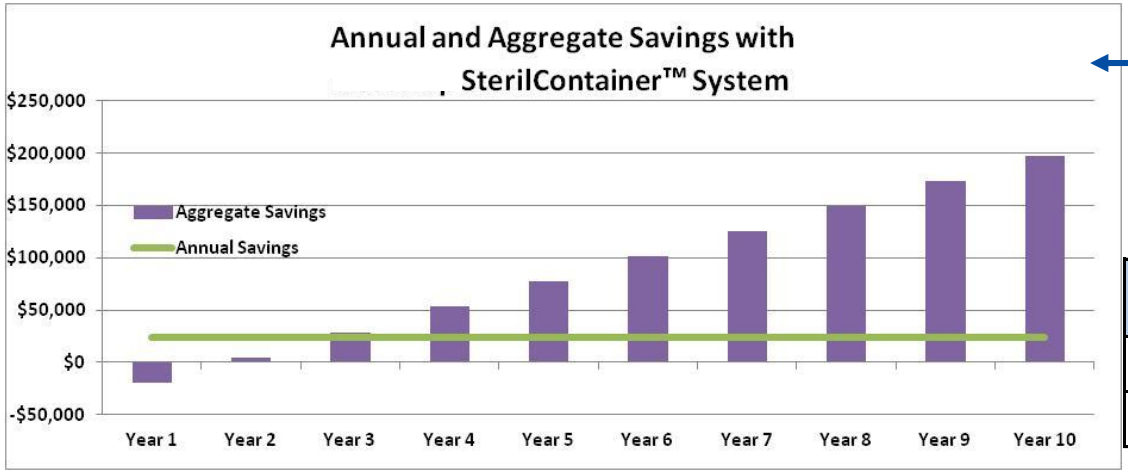
What it Does

Takes annual information and calculates long-term savings and payback period

How to Use it

Shows graphic comparison of operating expenses

Annual and aggregate savings by switching to SterilContainer System



Most importantly, **the estimated payback period**

Results	
Payback Period in Years	1.8
Total Savings Over 10 Years	$197,664

Source: Aesculap USA in – house calculating

Sterile Technology

HOW TO CHOOSE THE OPTIMAL CONTAINER

What does it need – Hard Facts

Some Tips how to define the suitable size for the set in question…

Influence Factors:

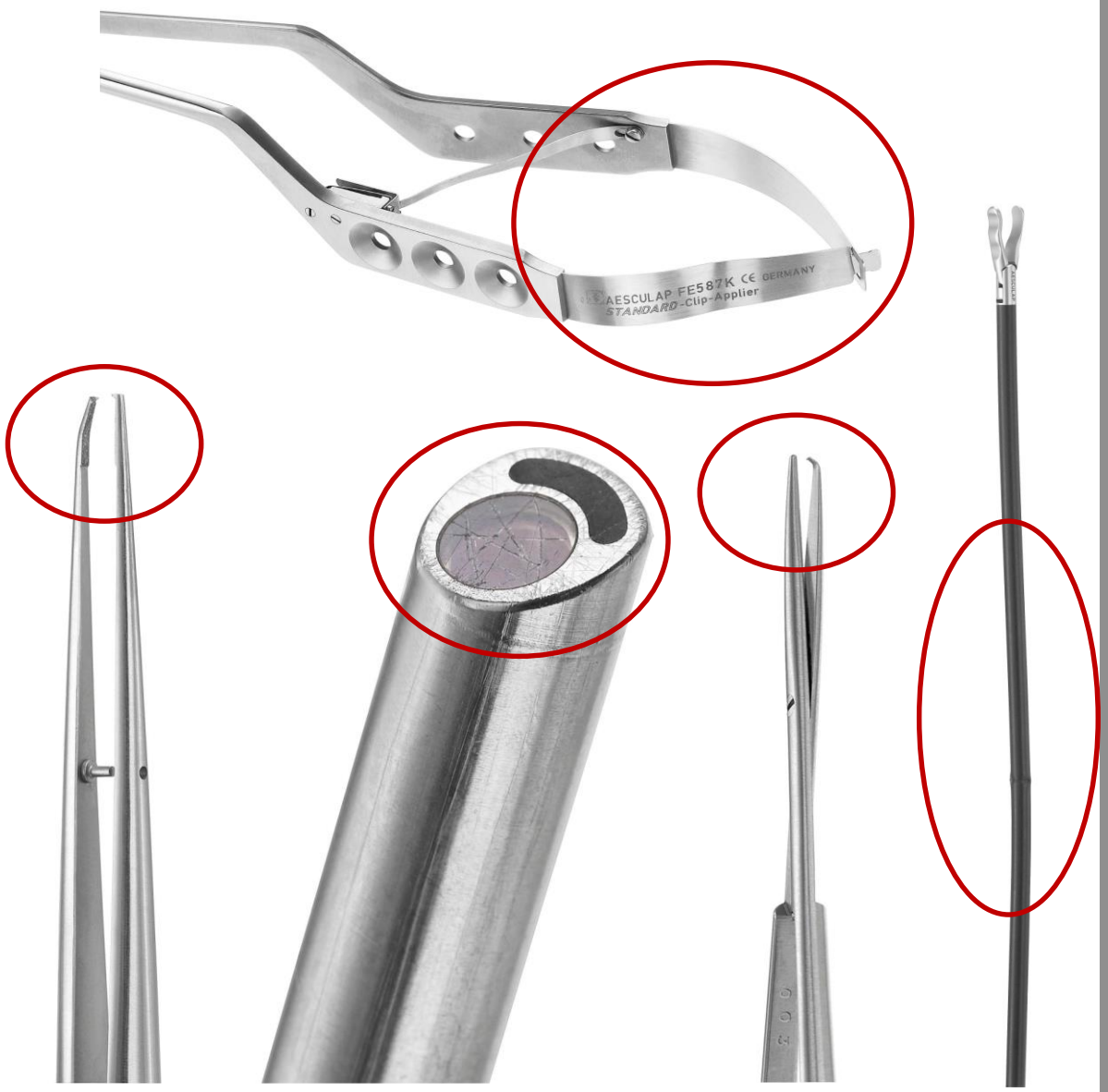
- Number of Instruments
- "Biggest / Longest" Instrument
- Gravitational / Pre Vacuum Steriliser

- 1/1 Container
  - > 50 Instruments
  - 10kg max. loading

- ¾ Container
  - > 30 Instruments
  - 7.5 kg max. loading

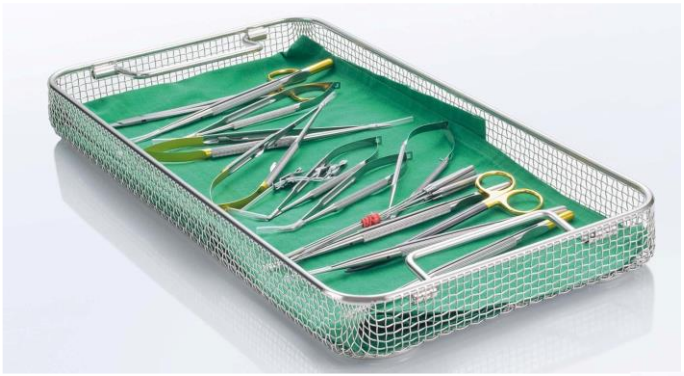
- ½ Container
  - < 30 Instruments
  - 5kg max. loading

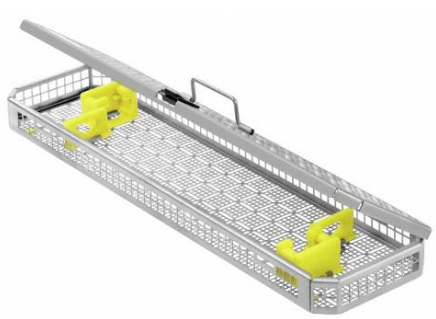
These are "approx." assisting values.

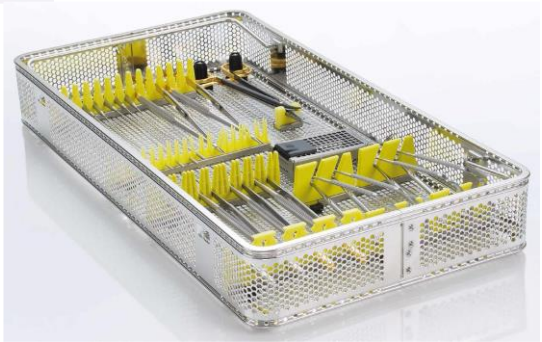


How to protect

- Micro Instruments
- Specialty Instruments
- Expensive Equipment's e.g. scopes



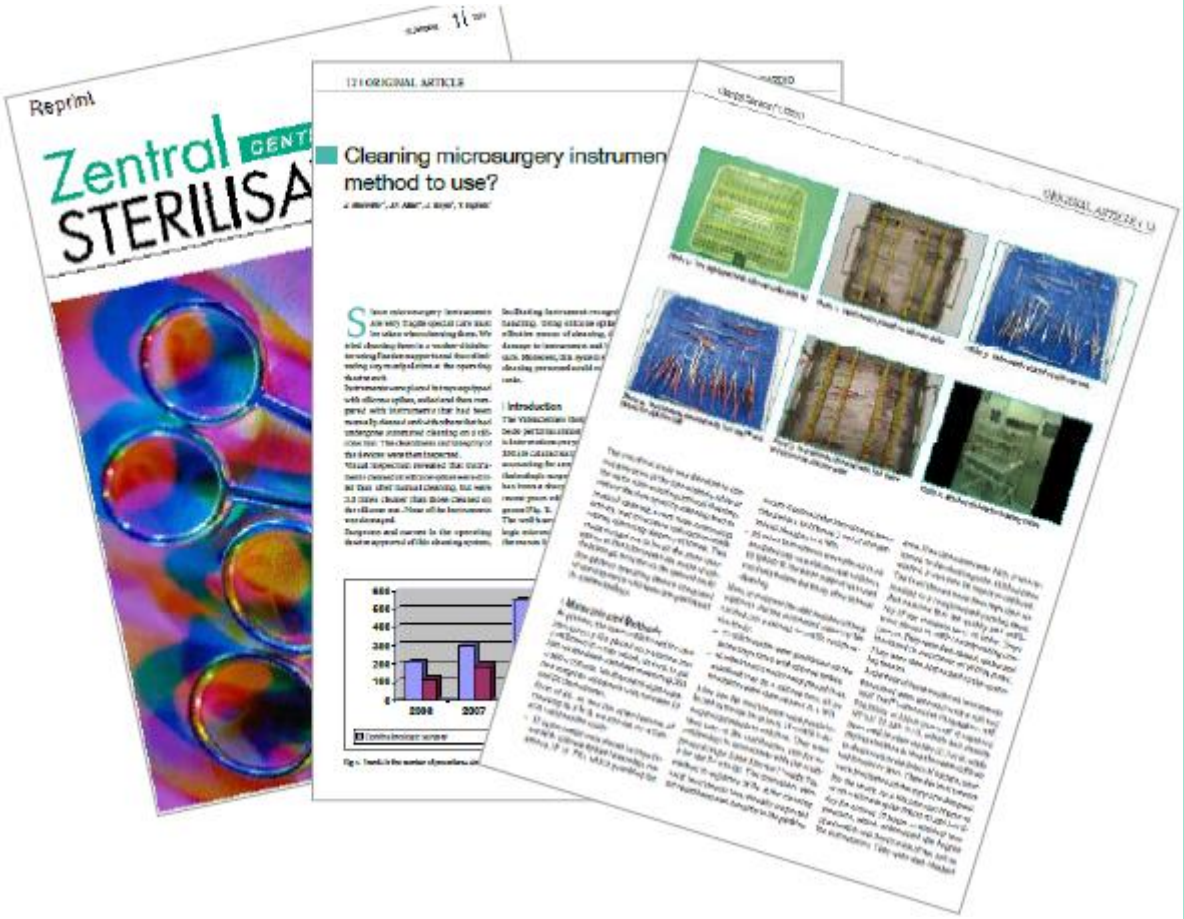




Organisation

- Fast recognition of missing items
- Faster aseptic presentation
- Faster intraoperative counting counting

Cleaning micro instruments: which method to use?



Source: Scientific paper published in the "Zentral Sterilisation – Central Service", the official journal of the German Society for Sterile Supply (DGSV)

- **Cost savings** due to less need of replacement and/or repair of instruments (result of less need of manipulation and alteration of the instruments)
- **Time saving** of more than 20 minutes per set due to switching from manual to mechanical cleaning
- **Optimal cleaning results**, minimizing the risk of contamination of personnel and environment, through mechanical cleaning
- **Increased satisfaction level** among theatre personnel since visual inspection and handling of instruments is facilitated due to perfect organization and overview

TROUBLESHOOTING LIST

Malfunction	Cause	Remedy
Excessive amounts of condensate inside the sterile container	Temperature of sterile materials too low prior to sterilization	Allow materials for sterilization to reach room temperature (approx. 20 °C)
	Textiles too damp	Sterilize dry textiles only.
	Sterile container too heavy	1/1 container: with instruments: max. load 10.0 kg with textiles: max. load 8.0 kg
		1/2 container: max. load 5.0 kg
		3/4 container: max. load 7.5 kg
		Optics container: max. load 3.0 kg
		Dental container: max. load 2.0 kg
		Mini container: max. load 1.5 kg
	Materials for sterilization incorrectly packed	Position hollow materials, dishes, plates, etc with the opening facing downwards at a slant.
		Arrange textiles in loose vertical piles, do not press them together.
	Sterile container incorrectly positioned in sterilizer	Always place heavy sterile containers at the bottom.
	Sterile containers processed immediately after sterilization	Allow sterile containers to cool down to room temperature prior to processing.
	Sterile containers improperly positioned during cooling phase	Do not store sterile containers on a floor or in a drafty place. Store sterile containers in a temperature-controlled room with a constant relative humidity and temperature.
	Sterilizer properties do not comply with DIN EN 285	Have sterilizer serviced regularly. Check drying vacuum. Check drying time.
		Check steam quality and upgrade if necessary.
	Empty-cycle and vacuum test not run daily before sterilization begins	Run empty-cycle and vacuum test daily before beginning sterilization.
	Unsuitable sterilizer cycle selected	Select cycle in accordance with load.
	Sterilizer door left open too long, sterilizer cooled down	Load and unload sterilizer quickly.

THANK YOU

YOUR QUESTIONS…