



20-23
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SANTIAGO-CHILE



Sterilization Wrap

Checklist for CSSD Manager

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Complying with standards for sterilization wrap

Hospitals

- In most countries hospitals must comply with standards (ISO, EN, etc ...) – not an option.

Standards

- Make the lives of manufacturers and end-users easier; the details have been already discussed by standard's committees (i.e. : ISO TC 198 WG 7 & CEN TC 102 WG 4)

National best practices

- In each country are written according to ISO 11607-1 & EN 868-2.

Guidance Document

- Published on WFHSS Web site: [Home – Wfhss Guidelines \(wfhss-guidelines.com\)](https://www.wfhss-guidelines.com)



ISO 11607-1 Terminology

3.11 Packaging System

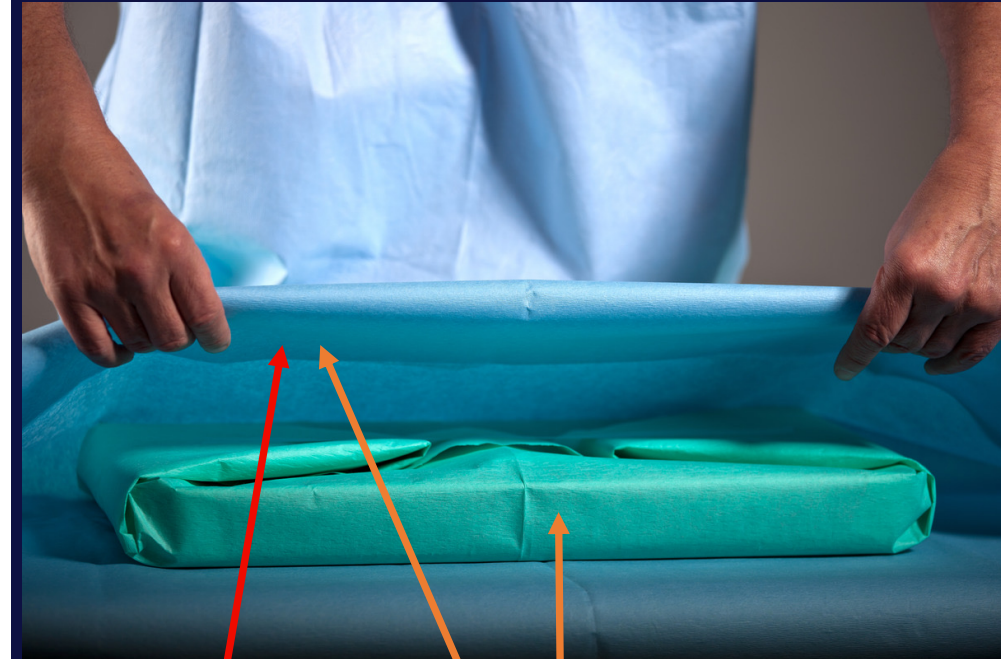
- Combination of the sterile barrier system and protective packaging

3.14 Protective Packaging

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

3.23 Sterile Barrier System

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



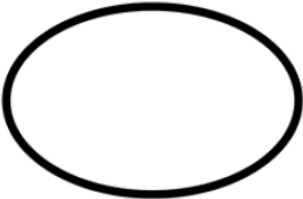


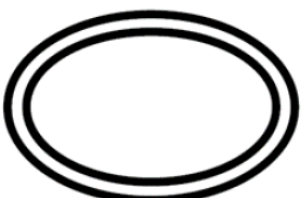
Protective
Packaging

Sterile Barrier System



New symbols for packaging system

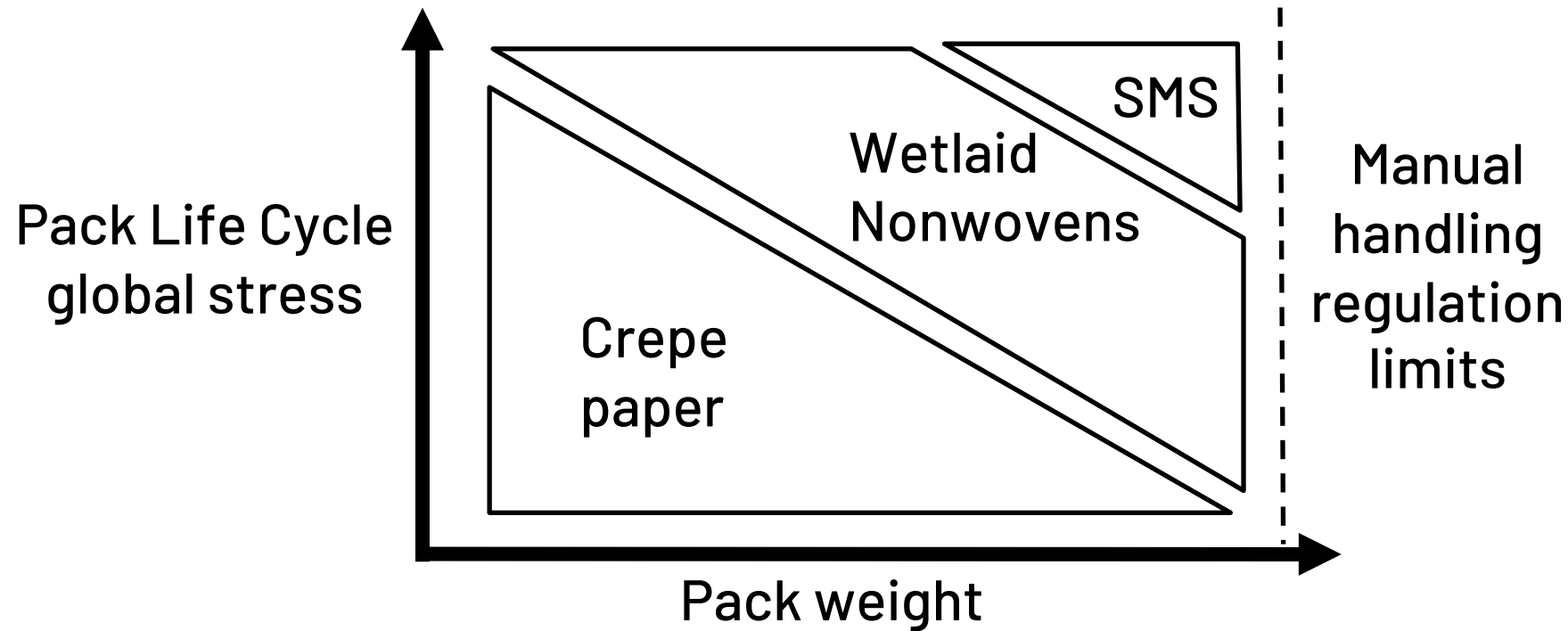
- A **solid line** which indicates a Sterile Barrier System layer (maintaining sterility)
- A **dashed line** which indicates a Protective Packaging layer that is not a validated microbial barrier
- Symbols developed by the Sterile Barrier Association (SBA) and published in ISO 11607-1 & ISO 15223-1

Symbol	What it represents	Recommended handling / usability
	Single sterile barrier system	Aseptic presentation technique requires opening by an assistant nurse. (Sterile) Scrub nurses or surgeons must not touch the outer surface of the packaging. Pack must not be placed on sterile surfaces.
	Single sterile barrier system with protective packaging inside	Aseptic presentation technique requires opening of the outer packaging by an assistant nurse. Sterile nurses or surgeons must not touch the surface of the outer packaging. The inner layer with the sterile product may be handled by sterile personnel. Product in inner layer can be placed on sterile surfaces.
	Single sterile barrier system inside protective packaging	Aseptic presentation technique requires opening by an assistant nurse. Sterile nurses or surgeons must not touch the outer surface of the sterile packaging. Pack must not be placed on sterile surfaces.
	Double sterile barrier system	Aseptic presentation technique requires opening of the outer sterile packaging by an assistant nurse. Sterile nurses or surgeons must not touch the outer surface of the sterile packaging. Outer packaging must not be placed on sterile surfaces. The inner sterile packaging may be handled by sterile personnel and can be placed on sterile surfaces.

[guidance-doc-symbols-201908-1.pdf \(sterilebarrier.org\)](https://sterilebarrier.org/guidance-doc-symbols-201908-1.pdf)



Sterilization Wrap Selection

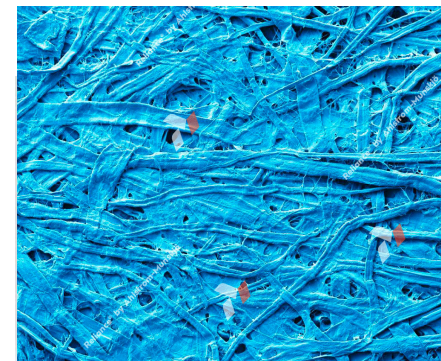


Type of Sterilization Wrap (EN 868-2)

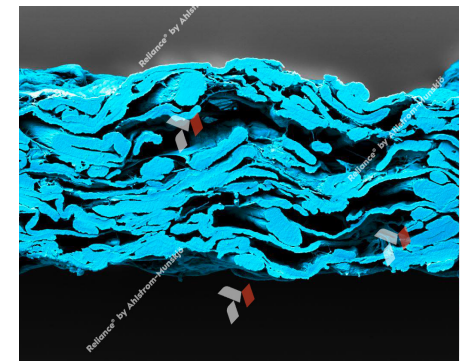
Crepe Paper

Made from more than 97 % of cellulosic fibers with wet strength and sizing agents.

- Excellent barrier properties
- High moisture absorption capacity
- Not slippery for the operator and gentle on the hands (sensitive micrexed version)
- Cost effective
- Best sustainable solution



Surface



Section



STEAM



EO



FORM



IRRAD

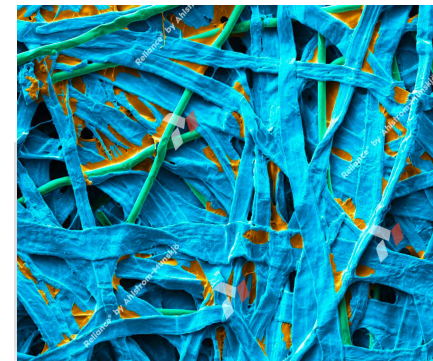


Type of Sterilization Wrap (EN 868-2)

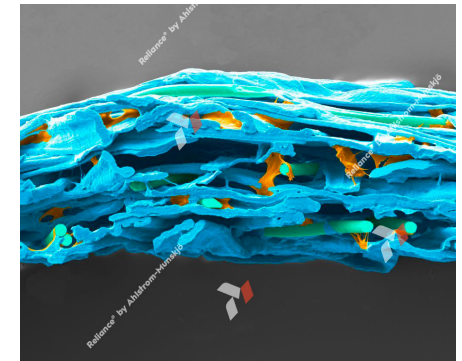
Wetlaid Nonwoven

Made with 70% cellulose, 20% synthetic binder and 10% Polyester fibers. Softer and stronger than crepe

- Strong, flexible and soft for easy folding
- Low Lint
- Can minimize wet-packs due to cellulosic material



Surface



Section



STEAM



EO



FORM



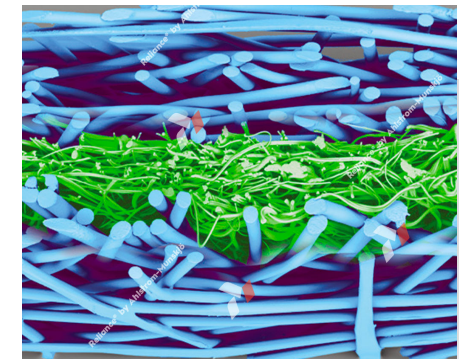
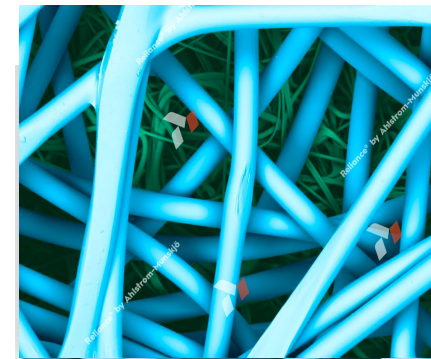
IRRAD



Type of Sterilization Wrap (EN 868-2) SMS Nonwoven

SMS (S for Spunbond and M for Meltbown) is 100% polypropylene nonwoven treated to resist static charge build-up and for repellency

- Very strong and durable
- Low lint
- Excellent drapability, easy to use
- Polypropylene is a recyclable polymer



Section



STEAM



EO



FORM



H2O2



Key Properties : Microbial Barrier



Sterilization wrap acts as a microbial filter:

- Porous to the gaseous sterilizing agent
- Preventing ingress of micro-organisms

WFHSS publication regarding microbial barrier according to DIN 58953-6 :

[PowerPoint Presentation \(wfhss.com\)](http://wfhss.com)

Recommendation of WFHSS : "Cotton textile are not compliant sterile barrier system and prohibited, due to sources of particulate contamination"



Key Properties : Sterilization Compatibility

- What sterilizers do you have ?
- What issues are you having ?



STEAM



EO



FORM



IRRAD



H2O2



Sterilization wrap : Wet Packs



Recent publications in regards to wet packs :

- **Test method to check wet packs in steam sterilization :**
Mouro et al. – SF2S Congress 2023, Marseille, France.
[Présentation PowerPoint \(sf2s-sterilisation.fr\)](https://sf2s-sterilisation.fr)
- **Development of sterilization wrap that reduces the drying time in steam sterilization up to 40 % and decrease the risk of wet packs :** Patent pending - W02023126647
[WO2023126647 STERILIZATION WRAP AND METHODS OF FABRICATION AND USE \(wipo.int\)](https://wipo.int)



Key Properties : Mechanical resistance

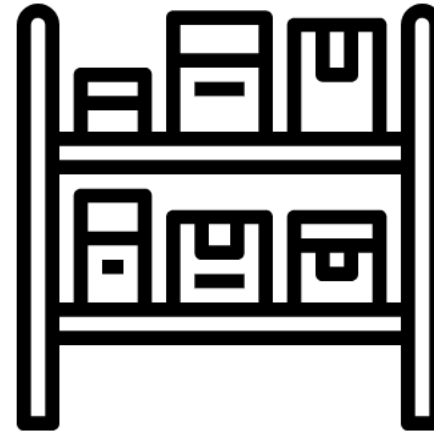
Sterilization wrap should be resistant to :



HANDLING



TRANSPORTION



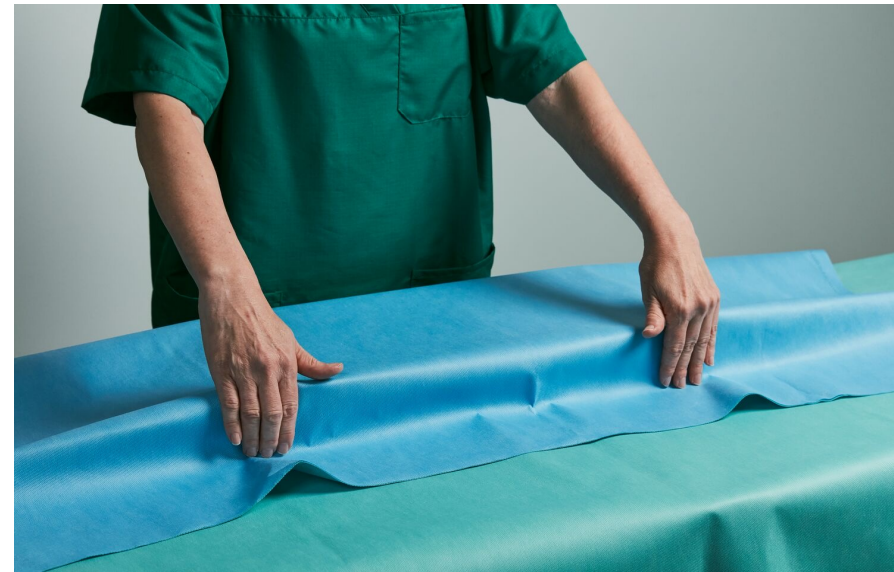
STORAGE
CONDITIONS



STERILIZATION
PROCESS



Folding Instructions



- Folding Instructions of sterilization wrap are presented in ISO TS 16775 (Annex B.4.3 SBS sterilization wrap)
- Two types of wrapping method have been validated by ISO TC 198 WG 7 experts : **Envelope method** & **Square fold** for simultaneous or sequential


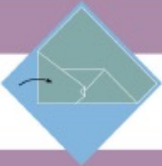




Envelope Folding



ENVELOPE FOLDING - Step 1

- 1**



1. The surgical tray is placed on the middle of the sheet so that its edges form a right angle with the sheet diagonals.
- 2**





2. The sheet is drawn upwards over the broader side and folded back parallel to the longitudinal edge to cover the load. A triangle is formed for aseptic opening.
- 3**




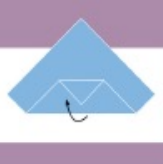
3. The same procedure as shown in step 2 is carried out from the left to the right.
- 4**





4. The same procedure as shown in step 2 is carried out from the right to the left.
- 5**



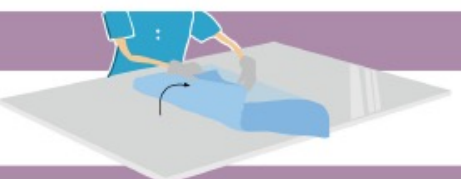

5. The last part of the sheet is now drawn over the tray. The corner is tucked into the envelope until it sticks out.



ENVELOPE FOLDING - Step 2

- 1**



1. The tray is placed on the middle of the sheet so that its edges form a right angle with the sheet diagonals.
- 2**



2. The sheet is drawn upwards over the broader side and folded back parallel to the longitudinal edge to cover the load. A triangle is formed for aseptic opening.
- 3**



3. The same procedure as shown in step 2 is carried out from the left to the right.
- 4**





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- 5**



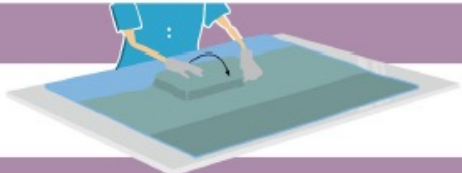
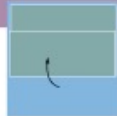
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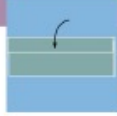


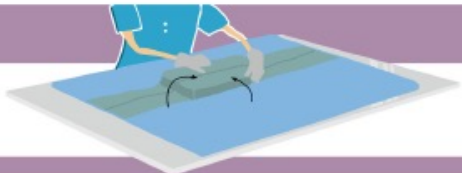
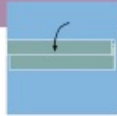
Square Folding


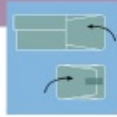
SQUARE FOLDING - Step 1

- 1**



1. The surgical tray is placed in the lower half of the sheet
- 2**





2. The front side of the sheet is wrapped over the surgical tray.
- 3**




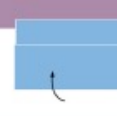
3. The edge of the sheet is folded back outward approximately to the level of the surgical tray.
- 4**




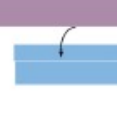
4. The folded edge is folded again to the middle of the tray. The sheet is closed with a suitable closure system.
- 5**




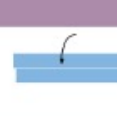
5. The wrap is folded at the sides and laid over the surgical tray.


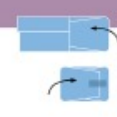
SQUARE FOLDING - Step 2

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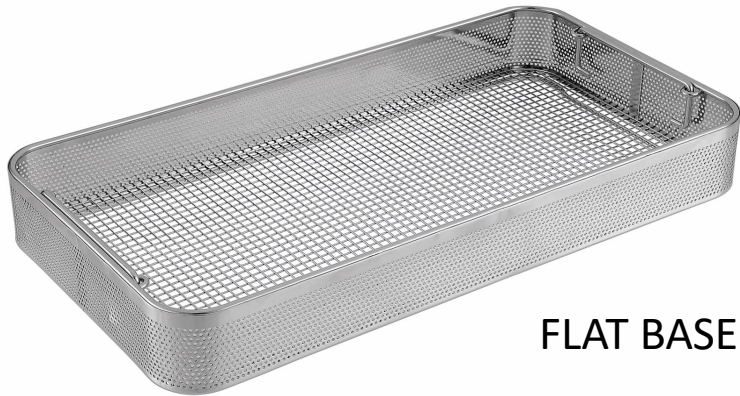
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5. The wrap is folded at the sides and laid over the surgical tray.

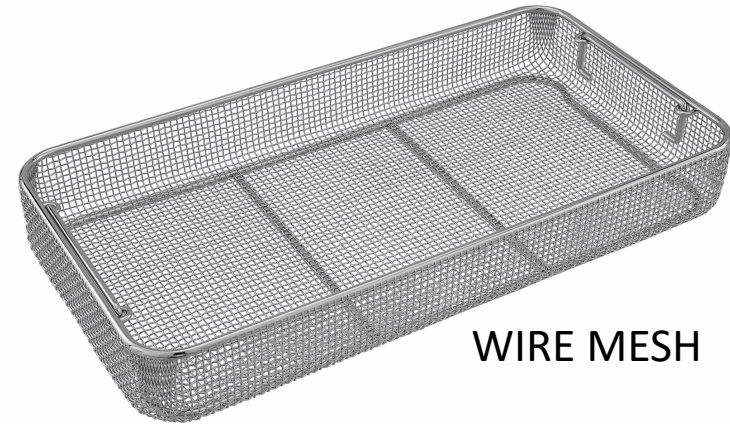


DIN Trays



FLAT BASE

For use with sterilization wrap
(note: Do not wrap too tight, as to not damage the sterilization wrap during steam sterilization)



WIRE MESH

For use with containers
(note: May cause damage to the sterilization wrap if used with it)



Tray Accessories

In order to protect sterilization wrap from DIN tray, different products can be used :



Silicone pad



Corner pad
(Silicone)



Corner pad (Crepe
Paper)



Tray liner (Crepe or
Wetlaid)

Rigid Container Integrity

Water Leak Test



- (FD S98 -053, Fascicule de documentation FD S98-053 (afnor.org)) has been cited in ISO TS 16775 : Paragraph B.9.4. 4 Routine monitoring of reusable container processes
- Test method and results have been presented by Lambert et al. at WFHSS 2017 in Bonn, Germany

Rigid Container Integrity

If container fails the test, recommendation is to use a sterilization wrap as Sterile Barrier System and container as a Protective Packaging : Packaging System



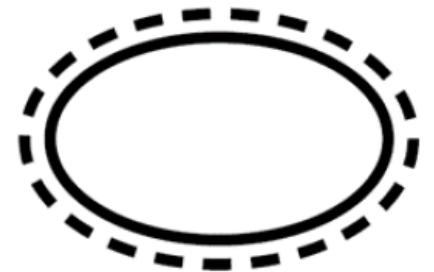
SBS

+



PP

=



PS

Training: Operating Room (OR) Staff

Incorrect



Do not stack wrapped trays

A hole in the sterilization wrap was found in the lower tray

Correct



Key Properties : Shelf life Limitations

Shelf Life:

- Manufacturers should provide shelf life limitation pre-sterilization
- The most common is 5 years

SHELF LIFE
EXP. DATE
<hr/>

Sterility Maintenance:

- More event than time related
- Manufacturers may simulate storage conditions over a time period (up to 365 days) for their wrap
- CSSD managers make their own risk analysis in regards to transport and storage to determine expiration date



Sterilization Wrap Selection Check List

- | | |
|--|---|
| <input type="checkbox"/> Confirm wraps meet standards | <input type="checkbox"/> Select appropriate wrap sizes and weights |
| <input type="checkbox"/> Identify all sterilization methods used at facility | <input type="checkbox"/> Use correct DIN tray (flat base) |
| <input type="checkbox"/> Consider issues faced (i.e. wet packs, abrasions) | <input type="checkbox"/> Have tray accessories available |
| <input type="checkbox"/> Select material compatible with sterilization methods | <input type="checkbox"/> Train all staff on tray handling, including OR |
| <input type="checkbox"/> Review labeling, IFU's and shelf life | <input type="checkbox"/> Test rigid containers for integrity |



Conclusion: Key Takeaways on Sterilization Wrap



CSSD Checklist

Ensure adherence to best practices in sterilization processes and maintain high-quality standards



Wrapping Techniques

Understand and apply the appropriate methods for different types of instruments and packaging requirements



Compliance with Standards

Stay updated on national and international sterilization wrap standards to ensure safety and regulatory compliance



Sterilization Wrap Selection

Choose wraps that offer optimal protection, durability, and compatibility with sterilization methods



Addressing Wet Packs

Implement proper techniques to avoid moisture retention, a critical factor in preventing contamination



Thank You

For any questions do not hesitate to contact me at
menno.dufour@ahlstrom.com

CSSD is key in patient safety, and so the role of the CSSD manager and their dedicated team is crucial

There is a lot to consider when selecting a new sterilization wrap in order to secure the overall process



ANNEXES



Key properties for sterilization wrap

Key properties to be evaluated	Requirements	Standards & Test Methods
Compatibility with respect to the intended sterilization processes	Suitability for use in sterilization processes and cycle parameters Sterilization residue (EO)	EN 868 - 2 after sterilization ISO 10993-7
Biocompatibility & toxicological attributes	Cytotoxicity (after sterilization) Bio-burden control Chemical properties (pH, Chloride, Sulfate)	ISO 10993 -5 ISO 11737-1 ISO 6588-2, ISO 9197, ISO 9198
Physical & chemical properties	Physical & chemical properties follow-up	Standards listed in EN 868-2
Microbial barrier	Porous material shall provide an adequate microbial barrier	Tests listed in ISO 11607-1 Germ Proofness (DIN 58953-6)
Compatibility with respect to forming and sealing processes	Folding	ISO TS 16775
Acceptable shelf-life	Shelf-life limitations for pre-sterilization	EN 868-2 / DIN 58953-6 tests on <u>aged paper</u> , before and after sterilization



Key Properties : Mechanical Resistance

Minimum Requirements in EN 868-2 for mechanical resistance

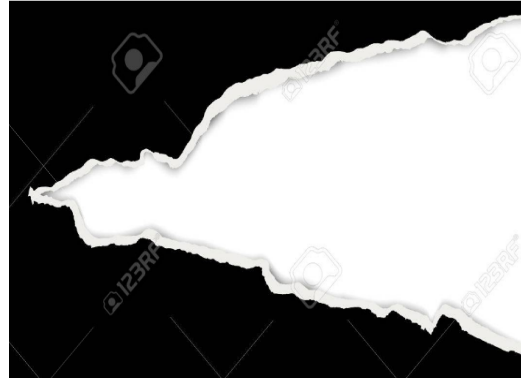
Properties	STANDARDS	Units	EN 868 - 2 Creped Paper	EN 868 - 2 Non Woven
Basis Weight	ISO 536	g/m ²	+/- 5%	+/- 5%
Tearing strength MD	EN 21974	mN		> 750
Tearing strength CD	EN 21974	mN		> 1000
Dry burst strength	ISO 2758	kPa		> 130
Wet burst strength	ISO 3689	kPa		> 90
Tensile strength MD	ISO 1924-2	kN/m	> 1.33	> 1
Tensile strength CD	ISO 1924-2	kN/m	> 0.67	> 0.65
Wet tensile strength MD	ISO 3781	kN/m	> 0.33	> 0.75
Wet tensile strength CD	ISO 3781	kN/m	> 0.27	> 0.5
Stretch MD	ISO 1924-2	%	> 10	> 5
Stretch CD	ISO 1924-2	%	> 2	> 7



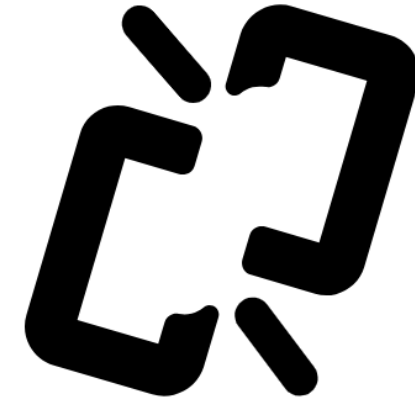
Key Properties : Mechanical Resistance



Burst strength
(Dry & wet)



Initiated tear
resistance



Tensile strength
(Dry & wet)

Important that physical performance before and after sterilization remain above requirements of EN 868-2.

