STERILIZATION WRAP
STERISHEET user guide for the validation of the packaging
ARJOWIGGINS in few words...

- A large range of sterilization wrap from standard creped paper to non-woven
- A large range of standard or reinforced paper for sterile packaging
  - Hospital pouches for Steam or EtO sterilization
  - Packaging of single use Medical Devices for EtO and Irradiation sterilization
Different options of packaging...

<table>
<thead>
<tr>
<th>Wraps</th>
<th>Cellulosic paper</th>
<th>Linen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet laid non-woven</td>
<td>SMS (PP)</td>
<td></td>
</tr>
</tbody>
</table>

Containers

Pouches Cellulosic paper
PEHD (flash spun bond)
## Sterilization Wrap in details

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Crepe Paper</strong></td>
<td>100% wood pulp material. The original wrapping material and the most cost effective.</td>
</tr>
<tr>
<td><strong>Reinforced Crepe Paper</strong></td>
<td>80% wood pulp and synthetic surface binders. The affordable combination of drape ability and softness with strength.</td>
</tr>
<tr>
<td><strong>Wet Laid Non Woven</strong></td>
<td>50% Wood pulp and synthetic fibers blend. The higher fluid repellence, drape ability and strength for the demanding wrapping and draping applications.</td>
</tr>
<tr>
<td><strong>100% synthetics fibers PP SMS Spunbond /Meltblown / Spunbond NW</strong></td>
<td>The material with the highest mechanical resistance, mainly tear strength &amp; the only material adapted to plasma sterilisation.</td>
</tr>
</tbody>
</table>
How to consider the choice of packaging?

Choice of packaging shall depend on:
- Type of sterilization to be used
- Shelf life performance to be achieved
- Type of material to be packed
- Safety of nurses, patients and for hospital environment
- Cost performance

THE AIM: THE SAFEST OPTION FOR THE PATIENT WITH THE OPTIMAL MATERIAL

Hence the following applies:
- Any elected item to wrap/pack must fulfill the objective related to operations in CSSDs:
  - be sterilizable
  - allow efficiency of sterilization process
  - maintain barrier properties after sterilization all the way until use in OR
  - proper physical protection for medical device
- A careful screening of packing/wrapping options should be conducted to allow this at best possible cost performance
How to consider the choice of packaging?

**Question:** How to be sure that the medical device placed in the wrap packaging is still sterile when introduced in operating room?

**Problematic:**
There is no destructive and routine test able to determine if the barrier integrity of the pack is still valid

**Answer:**
Compliance to EN ISO 11607 part 1 & 2

- Part 1: Requirements for material and Packaging System Design
- Part 2: Validation requirements of processes for packaging

3 requested conditions:
1. Have the adequate material
2. Have a validated packaging system design
3. Follow a protocol from packaging to operating room with regular check of the integrity of the packaging
ISO 11607 Standard

- **SCOPE**: Packaging for terminally sterilized medical device
  manufactured industrially or **assembled in a CSSD**

- **Increased responsibilities for the CSSD**

- **Producer ≠ Manufacturer**
  - Producer: Arjowiggins / responsible for the material
  - Manufacturer: CSSD in charge of the packaging and sterilization
Packaging system = SBS (Sterile Barrier System) + Protective packaging

Number of layers for SBS? 1 layer ? 2 layers ?
- Minimum package that prevents ingress of micro-organisms & allows aseptic presentation of the product at the point of use

Packaging system should consist in a SBS and a protective packaging: 2 possible ways:
- SBS made of 2 layers + 1 layer for protective packaging
  => Packaging system is made of 3 layers
- SBS made of 2 layers, outer layer playing a double part:
  - Barrier
  - Protection

ISO 11607 Standard
1- MATERIAL REQUIREMENT

2- PACKAGING SYSTEM DESIGN REQUIREMENTS

3- PROCESSES VALIDATION
1- MATERIAL REQUIREMENT

2- PACKAGING SYSTEM DESIGN REQUIREMENTS

3- PROCESSES VALIDATION
ISO 11607-1 : Material Requirements

- Example of what Arjowiggins done to be in compliance with ISO 11607-1 for material requirements
- Documentation provided by the supplier

<table>
<thead>
<tr>
<th>Key properties to be evaluated</th>
<th>Requirements</th>
<th>Compliance demonstrating Tools: Standards &amp; appropriate Test methods</th>
</tr>
</thead>
</table>
| Microbial barrier             | Porous material shall provide an adequate microbial barrier         | Tests listed in EN 868-2  
Bacterial Filtration Efficiency (ASTM F2101)  
Germ Proofness (DIN 58953-6 § 2.14 & § 2.15) |
| Biocompatibility & toxicological attributes | Biocompatibility  
Sensitisation / Irritation / Cyto-toxicity  
Bio-burden control  
Chemical properties | ISO 10993  
ISO 10993  
EN 11737  
EN 868-2 |
| Physical & chemical properties | Physical & chemical properties follow-up | Tests listed in EN 868-2 |
| Compatibility with respect to forming and sealing processes | Folding  
Drape ability | EN 868-2  
EN 868-2 |
| Compatibility with respect to the intended sterilization processes | Suitability for use in sterilization processes and cycle parameters | EN 868-2 after sterilization |
| Acceptable shelf-life | Any shelf-life limitations for pre-sterilization and post-sterilization storage | EN 868-2  
Bacterial Filtration Efficiency (ASTM F2101)  
Germ Proofness (DIN 58953-6 § 2.14 & § 2.15) on 5 years aged paper, before and after sterilization |
EN 868-2 : Sterilization wraps

- Specific requirements for sterilization wrap

- 4 materials are listed

  - Plain Paper
    - cellulose base

  - Creped paper
    - cellulose base

  - Non woven
    - cellulose base with synthetics fibers (wet laid non woven)
    - 100% synthetics fibers (dry laid non woven)

  - Linen
    - Woven textile material
Role of packaging

Allow sterilization AND provide a high bacterial barrier performance during the storage of the sterilized packs

Bacterial barrier against contamination coming from:
- Air (airborne, micro particles, dust)
- Fluids (drops, aerosols)
Microbial barrier

- The **principle of bacterial barrier** is that bacteria die / burn their energy before crossing barrier material.
  - Tortuous path

- Part of the non-compliant materials are the ones which are not barrier enough to stop bacteria on their way:
  - Film to paper pouches poorly manufactured (no sealing in some areas)
  - Materials with holes or with insufficient tortuous path
Germ Proofness DIN 58953-6

§ 2.15 dry challenge test
§ 2.14 wet challenge test

Pass or fail test performed on sterilized sample
Microbial barrier

Germ Proofness DIN 58953-6
§ 2.15 dry challenge test

Simulates exposure to airborne bacteria by placing a microorganisms powder in contact of a pressurized / depressurized sample. Then are counted the microorganisms passing through the sample on a nutrient medium placed on the opposite side.
Microbial barrier

Germ Proofness DIN 58953-6
§ 2.14 wet challenge test

Simulates exposure to liquid-borne bacteria by placing few microorganisms aqueous droplets in contact of a sample. After drying & incubation are counted the microorganisms passing trough the sample on a nutrient medium placed on the opposite side.

DROPLETS

Bacteria

Sample

Agar medium

MATERIAL PAPER or LINEN
Bacterial Filtration Efficiency test (ASTM F2101)

A microorganisms suspension is dried and sprayed onto the sample. A constant air flow then draws the sprayed microorganisms through the sample. The number of them that have passed through the sample is counted in a nutrient medium placed on the other side.

BFE test performed on material after steam sterilization to simulate exposure to airborne bacteria

BFE testing: 100% is the best possible rating
## Microbial barrier

| Test performed on 1 single sheet |

<table>
<thead>
<tr>
<th></th>
<th>DRY STATE</th>
<th>WET STATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Germ Proofness</td>
<td>Bacterial Filtration Efficiency</td>
</tr>
<tr>
<td>Arjowiggins - crepe paper</td>
<td>PASS</td>
<td>96% to 99%</td>
</tr>
<tr>
<td>Arjowiggins - Wet laid non woven</td>
<td>PASS</td>
<td>90%</td>
</tr>
<tr>
<td>Arjowiggins - SMS</td>
<td>PASS</td>
<td>93%</td>
</tr>
</tbody>
</table>

EN 868-2 Annex B
Sterilization processes - compatibility

- Steam sterilization is the way the most used

- Steam
- Formaldehyde
- EtO
- Irradiation
- Plasma
Sterilization processes - compatibility

100 % steam penetration as percentage of activated sterilization indicators according to ISO 11134

Cycles:
France 18’ @ 134°C
USA 20’ @ 121°C

Steam sterilization is the way the most used
## Sterilization processes - compatibility

<table>
<thead>
<tr>
<th>Packaging</th>
<th>Material</th>
<th>STEAM</th>
<th>EtO</th>
<th>Irradiation</th>
<th>Plasma</th>
<th>FO</th>
</tr>
</thead>
<tbody>
<tr>
<td>wrap</td>
<td>Cellulosic crepe paper</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>Wet laid non-woven</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>SMS (100% PP)</td>
<td>P</td>
<td>P</td>
<td></td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>Linen</td>
<td>P</td>
<td>P</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pouches</td>
<td>Cellulosic paper</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td></td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>Tyvek</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td>container</td>
<td>depending of the type of filter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Topics

1- MATERIAL REQUIREMENT

2- PACKAGING SYSTEM DESIGN REQUIREMENTS

3- PROCESSES VALIDATION
ISO 11607-1: Packaging System Design Requirements

**Condition 1**: Check if the product is normalized (ISO 11607-1 & EN 868-2), answering the following needs:
- Microbial barrier properties
- Biocompatibility & non toxicity products
- Sterilization process compatibility
- Acceptable shelf life

**Condition 2**: Validation of the packaging system design

<table>
<thead>
<tr>
<th>Key properties to be evaluated</th>
<th>Requirements</th>
<th>Compliance demonstrating Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening</td>
<td>Aseptic presentation</td>
<td></td>
</tr>
<tr>
<td>Compatibility with respect to the intended sterilization processes</td>
<td>Efficiency of sterilization</td>
<td></td>
</tr>
<tr>
<td>Packaging system physical protection</td>
<td>Adequate protection to the product through the hazards of handling, distribution and storage</td>
<td><strong>Appropriate Solutions:</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>REAL TESTS &amp; GOOD PRACTICES</strong></td>
</tr>
<tr>
<td>Packaging system microbial barrier</td>
<td>Integrity of the Sterile Barrier System</td>
<td></td>
</tr>
<tr>
<td>Stability testing</td>
<td>Maintenance of sterility integrity over time</td>
<td></td>
</tr>
</tbody>
</table>
How to validate that the design of your packaging system is adapted?

**Condition 2**: Validation of the packaging system design by real test & good practices

- Several wrapping methods
  - Envelope folding
  - Square folding
  - Pasteur folding
  - Roll method

- The most common and recommended folding is envelope folding

- Why?
  - To create the more tortuous path which means a better barrier against penetration of micro-organism
  - Design validated by Event-Related Sterility Maintenance Study
  - Reduce handling during opening thanks to the tab
How to validate that the design of your packaging system is adapted?

- Double sequential wrap is recommended

Why?

- Bacterial filtration efficiency & germproof ness test (DIN 58953-6 § 2.14 & § 2.15) is improved
- Guarantee aseptic opening
- Possibility to combine different generation wraps and offer a combination of the best characteristics and benefits of each generation of products
- Provide the most adapted wrapping solution and a tailored made wrapping system
- Possibility to have a colour coding:
  Security: Superposition of two colours allows to visualise any defect & prevent dust cover entering the operation rooms
## Validation of the double wrapping Vs single wrapping

### Bacterial Filtration Efficiency test (ASTM F2101)

<table>
<thead>
<tr>
<th>Material</th>
<th>Single Wrapping</th>
<th>Double Wrapping (interleaved)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arjowiggins - crepe paper</td>
<td>96% to 99%</td>
<td>99.9%</td>
</tr>
<tr>
<td>Arjowiggins - Wet laid non woven</td>
<td>90%</td>
<td>98%</td>
</tr>
<tr>
<td>Arjowiggins - SMS</td>
<td>93%</td>
<td>99%</td>
</tr>
</tbody>
</table>
How to validate that the design of your packaging system is adapted?

**Condition 2**: Validation of the packaging system design by real test & good practices

- **Efficiency of sterilization**:
  Steam penetration testing thru activating sterilization indicators

- **Integrity of the SBS / Maintenance of sterility integrity over time**:
  
  **Event-Related Sterility Maintenance Study (Nelson laboratories)**
  This test is performed on double-layer packaging after sterilization, and simulates shelf storage – inside a room whose humidity and temperature are regularly recorded – along with weekly handling of the packaged packs. The packs are inspected after period of 180 days and the results is given as the percentage of uncontaminated packs.

  **Microbial aerosol challenge test (Nelson laboratories)**
  aerosolizing high number of Bacillus atrophaeus spores and then testing the contents of the package for ingress of that organism
## Validation of sterility maintenance

### Event-Related Sterility Maintenance Study

<table>
<thead>
<tr>
<th>Wraps</th>
<th>Sterility Maintenance (30 days / 180 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterisheet Creped Paper</td>
<td>100 % / 100%</td>
</tr>
<tr>
<td>Sterisheet Reinforced Creped Paper</td>
<td>100 % / 100%</td>
</tr>
<tr>
<td>Sterisheet Wet Laid Non Woven</td>
<td>100 % / 100%</td>
</tr>
<tr>
<td>Sterisheet SMS</td>
<td>100 % / 100%</td>
</tr>
</tbody>
</table>

Tested on double sequential wrapping
1- MATERIAL REQUIREMENT

2- PACKAGING SYSTEM DESIGN REQUIREMENTS

3- PROCESSES VALIDATION
Our protocol for the validation of packaging process

**Condition 1**: Check if the product is normalized (EN ISO11607-1 & EN 868-2), answering the following needs:

**Condition 2**: Validation of the packaging system design by real test & good practices

**Condition 3**: A written protocol and visual aids for each step

1. Packing preparation
2. Sterilization (Loading)
3. Transportation
4. Storage
5. Opening

Only a visual inspection, will guarantee the integrity of the packaging:

At the end of each stage, a visual inspection should be performed thru a documented quality system including recording, training & qualifying any actor of the chain

Following guideline is based on these 3 conditions and the results of in situ testing, experience & good practices
ISO 11607-2 : Validation of the process

- Necessity of a quality document describing (at least)
  - used material, its characteristics, etc…. (supplier data)
  - type of sterilization used
  - type of Medical Device to be sterilized
  - folding & packing protocol
  - acceptance criteria
  - qualification step (IQ, OQ & PQ)

- Qualification in 3 steps:
  1- Installation Qualification
     - training / installation : table, light, wraps rack, etc...
  2- Operational Qualification
     - check et validation that the packing is appropriate
     (worst case scenario)
  3- Performance Qualification
     - repeatability and reproducibility of the process
Guideline for packaging
1- Packing preparation (1/4)

- All the items must be carefully checked before packing

- Medical devices
  - check the medical devices are clean & dry
  - check the medical devices are not damaged
    - no stain / no corrosion
  - check all items for a given procedure are there

- Sterilization sheets
  - check if packaging product is clean, without any holes & tears
    & secure its tracking number trace ability feature
  - store the wraps on rack

- Packing area
  - prepare a clear & clean area
  - table with an adequate surface
  - tape holder
Guideline for packaging

1- Packing preparation (2/4)

Choose the adapted material to the medical device

- Material adapted to the size and weight of the items to be packed
# Guideline for packaging

## 1- Packing preparation (3/4)

<table>
<thead>
<tr>
<th>Material</th>
<th>Small packs</th>
<th>Medium size packs</th>
<th>Large Packs</th>
<th>Orthopedic sets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crepe</td>
<td>Weight: up to 3 kg (for double layer packaging)</td>
<td>Small and medium-size trays, light packs, instrument kits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reinforced crepe</td>
<td>Weight: up to 6 kg (for double packs)</td>
<td>Small surgical trays, small surgical packs of medium size and weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonwoven</td>
<td>Weight: up to 12 kg (for double packs)</td>
<td>Surgical instrument trays, orthopaedic trays and packs, heavy and large-size packs</td>
<td>Can be used as sterile field operating theatres due to nonwoven material’s resistance to disinfectants</td>
<td></td>
</tr>
<tr>
<td>Interleaved</td>
<td>Combination of various grades and colours to suit every type of application</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interleaved SMS / nonwoven</td>
<td>Weight: up to 15 kg (en double pack)</td>
<td>Orthopaedic trays and packs, very heavy packs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

These weight values are indicative.
Guideline for packaging

1- Packing preparation (2/4)

✓ Chose the adapted material to the medical device

• Material adapted to the size and weight of the items to be packed

• Adapted to the shape of the medical device (Sharp edge, corner)

• Adapted to the number of manipulations

• Add protection to sharp medical devices (the protections shall withstand the sterilization process)

⊙ Place visual aids on the packing area to chose the right material
Guideline for packaging

1- Packing preparation (4/4)

• Visual of the folding procedure in packing area

| 1 | 2 | 3 | 4 | 5 |

• Validation (OQ) : Place sterilization indicator inside the pack to check efficiency of sterilization process
• Check tack and resistance of specific sterilization indicator tape (designed to endure both heat & humidity) to close the pack

• Visual of the aspect of the final pack to prevent gapping, billowing & air pockets from the forming

• First validation of the packaging by comparison with visual aids

• Traceability of the pack
Guideline for packaging

2- Sterilization (1/2)

Loading

- Avoid the sterilization of different kinds of materials:
  - Textiles
  - Plastics
  - Metal
  - sterilization wraps
  - containers

- Make sure all items are oriented in the sterilizer such that water can drip out:
  - Basins and other concave items must be placed on their sides tipped slightly downward
  - Pouches shall be placed vertically, in a way water can drip out

- Do not overcrowd the sterilizer

- Stacked packs = Tear or Puncture risk

- Asperity on the support = risk of Tear
Guideline for packaging
2- Sterilization (2/2)

- The choice of the cycle
  Sterilisation cycle shall be adjusted to the loading

- Unloading
  • Don’t manipulate the packs before the load is fully cooled down
  • Check the sterilization release parameters or indicators to validate the sterilization process
  • Check there is no residual condensation on each pack when unloading
  • Check the integrity of the protective layer: if it has been damaged, sterility state could be compromised and the pack must be processed again
    & Root Causes Analysis should be performed
Guideline for packaging

3- Transportation

shelf life of a package sterile is **event related** and not **time-related**

- Supplies should be handled carefully

- Transportation in clean cabinets, in bins or with trolleys are recommended

- Avoid dragging, crushing, bending, compressing, or puncturing the packaging

- Avoid multiple handling, moisture penetration and exposure to airborne contaminates

- After each manipulation, packaging should be thoroughly inspected

- When hand transport, sterile packages should be maintained in a position parallel with the floor

- Written policies and procedures should be developed for the use of transport equipment and appropriate handling practices.
Guideline for packaging

4- Storage

The shelf life of a package sterile is event related and not time-related

Sterile items should be stored in a manner that reduces the potential for contamination

• Storage area dedicated to sterile supplies
• Temperature and humidity controlled (Room temperature & Humidity does not exceed 70%)
• Away from direct sunlight
• Traffic should be controlled to limit access to sterile items

• Sterile items stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation
• Avoid friction of packs against the shelves during handling

• first in / first out policy

• Written policies and procedures should be developed for the storage, handling and rotation.
Guideline for packaging
5- Opening sterile packages

*The following guidelines should be observed when opening sterile packages:*

- Before it is opened, the **package should be inspected** for the appropriate appearance of the external sterilization indicator and the physical integrity of the packaging
  - **Last and more crucial inspection**
  - **Place visual aids of final packaging & refused package in this area**
    [closely linked to first step: packaging preparation]

- **Remove the outer wrap before entering the OR**
  not to introduce exterior contaminating elements

- **Enter the OR with the inner wrap only**
  - **Aseptic presentation**
  - **If the material is a non woven resistant to disinfectants, it can be used as sterile field**
Guideline for packaging
A new work Item for ISO TC 198 WG 7

The crucial subject of packaging systems assembly validation taken under consideration during the last 2 plenary meeting:

• **Keys decisions:**
  
  • **Educational informative guideline** to be submit to formal vote within 1 year time frame
  
  • Addressing on the same levels, both Medical Devices Manufacturers and healthcare facilities (hospital CSSD, dentists,...) needs
  
  • Covering all kind of currently used packaging systems for hospitals i. e.
    
    • Pouches
    • Containers
    • WRAPS
  
  • Clearly **emphasizing** the KEY need of the ASPETIC presentation of the packed products
Thank you for your attention