Sterilization wraps material trends and conformity to European Standards
Your speaker today: Dr. David DUWELTZ

- Technical Support & Regulatory Affairs Manager
- ArjoWiggins Healthcare

Packaging solutions for the Medical devices and pouch making industry

Arjowiggins participation

- Standardization expert for sterilization packaging
  - AFNOR SR95 GT1
  - CEN TC102 WG4
  - ISO TC 198 WG7

Ready to use solutions for CSSD
PACKAGING SYSTEM INVOLVED IN A BIG PART OF THE OPERATIONS IN THE HOSPITAL

End life of single use packaging
Sterile stores
Sterilization
Prep and pack
Cleaning and disinfection
CHAIN OF ACTIVITIES
TO MAINTAIN STERILITY EACH STEP IS CRUCIAL

Cleaning / disinfection
Packaging
Loading
Sterilization
Unloading
Distribution
Storage
Transport
Unpacking
Sterilization packaging: A considered choice

- Rational to select a packaging system based on:
  - Different practices
  - Scientific literatures
  - Standards
  - Collaboration with suppliers in order to obtain the performances of the packaging
  - Validation
European Directive… Which one & Why?

European Directive for medical devices
MDD 93/42/EEC amended 2007/47/EC

‘MEDICAL DEVICE’ : any instrument, apparatus, appliance, software, material or other article, to be used specifically for diagnostic and/or therapeutic purposes

‘ACCESSORY’ : an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device

For the purposes of this Directive, accessories shall be treated as medical devices in their own right.

Sterilization wrap, pouches .... (Non invasive, non active, non substance release) are considered as accessories for medical device of CLASS I
93/42/EEC directive for medical devices

Main mandatory requirements

- Recognized quality management system (as ISO9001 or EN13485)
- Process traceability
- Official authorities registration with local vigilance correspondent appointment (MOH: AFFSAPS in France)
- CE labelling (based on EN 980) & information notice
- Risk management
93/42/EEC directive for medical devices

Essential requirements for selling on CE market (CE marking)

Based on risk management

Standards = Tools used to demonstrate the conformity of the product to MDD essential requirements

EN ISO 11607 : 2009

ISO 5646-3
EN 868 series
DIN 58953-6
ISO 10993
EN 11737
ASTM F2101
TAPPI T437
And so on…
Packaging materials are ruled by Standards

- What are the standards for Sterilization Wraps?
  - EN ISO 11607-1 & 2
    - Part 1: Requirements for materials, sterile barrier systems and packaging systems
    - Part 2: Validation requirements for forming, sealing and assembly processes
  - EN 868 series
    - Specific requirements
<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>
<tbody>
<tr>
<td>Microbial barrier</td>
<td>Porous material shall provide an adequate microbial barrier</td>
<td>Tests listed in EN 868 series Bacterial Filtration Efficiency (ASTM F2101) Germ Proofness (DIN 58953-6 § 2.14 &amp; § 2.15)</td>
</tr>
<tr>
<td>Biocompatibility &amp; toxicological attributes</td>
<td>Sensitisation / Irritation / Cyto-toxicity Bio-burden control Chemical properties</td>
<td>ISO 10993 (-1, -5 &amp; -10) EN 11737 EN 868</td>
</tr>
<tr>
<td>Physical &amp; chemical properties</td>
<td>Physical &amp; chemical properties follow-up</td>
<td>Tests listed in EN 868</td>
</tr>
<tr>
<td>Compatibility with respect to forming and sealing processes</td>
<td>Folding /Drape ability Seal strength</td>
<td>EN 868 series</td>
</tr>
<tr>
<td>Compatibility with respect to the intended sterilization processes</td>
<td>Suitability for use in sterilization processes and cycle parameters Sterilization residue (EO)</td>
<td>EN 868 series after sterilization ISO 10993-7</td>
</tr>
<tr>
<td>Acceptable shelf-life</td>
<td>Any shelf-life limitations for pre-sterilization and post-sterilization storage</td>
<td>Tests listed in EN 868 / BFE (ASTM F2101) / DIN 58953 tests on <strong>5 years aged paper</strong>, before and after sterilization</td>
</tr>
</tbody>
</table>

- Example of what Arjowiggins done to be in **compliance** with ISO 11607-1 for material requirements
- Documentation provided by the supplier
Sterilization packaging: The standards

- Harmonized norms referential, acting as EC specifications
- Packaging products dedicated standards

  - Part 2: Sterilization wraps (Papers / Non-Woven / Textile)
  - Part 3: Paper for use for paper bags (specified in EN 868-4) and for pouches and reels (specified in EN 868-5)
  - Part 4: Paper bags
  - Part 5: Sealable pouches and reels of porous and plastic film construction
  - Part 6: Paper for low temperature sterilization processes
  - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN285
Sterilization packaging: The standards

- 3 categories of packaging in EN 868-2

  - Wraps
    - Woven, textile (Linen)
    - Paper (plain / crepe / soft crepe / reinforced ….)
    - Cellulose based non-woven
    - Non-Woven (SMS)

  - Preformed Sterile Barrier System: Pouches / Reels
    - Self seal pouches
    - Heat seal pouches
    - Made of a combination of Paper, Tyvek, SMS… with PP, PP/PET film
    - Paper bags

  - Container
    - With re-usable filter
    - With single use filter
Sterilization packaging: The standards

Made in EEC
ISO 11607 - 1 & EN 868-5

En 868-2
ISO 11607-1

Sterilization packaging: The standards

The bacterial barrier for human protection
The 5 key properties for a sterilization pack

1. Compatibility with the sterilization process
2. Protect against re-contamination
3. Resistance to manipulation, handling, storage
4. Allow aseptic opening at the point of use
5. Safe for both the patient & hospital users = Biocompatibility
QUICK FOCUS ON THE DIFFERENT STERILIZATION WRAP MATERIAL
Wraps material

- Woven, textile (Linen)
- Paper (plain / crepe / soft crepe / reinforced ….)
- Cellulose based non-woven
- Non-Woven (SMS)
Packaging material: WRAPS

- **Woven, textiles**
  - Re-usable material / Cotton, linen and blends of cotton and synthetic materials (PET)
  - Used to wrap instruments and linen packs for Steam sterilization
  - Newly listed in EN 868-2 / Specific requirements
    - 
      - ISO 11607-1 requirements on biocompatibility (Washing agent?)
      - Wet & Dry Tensile strength > 300N
      - Wet & Dry Tear strength > 6N
      - Wet & Dry Burst strength > 100kPa
      - Air permeability < 20mm/s
      - Resistance to water penetration (No requirement for the moment)
  - Barrier quality of textiles is represented in "thread counts" per square inch
    - Minimum acceptable thread count for surgical textiles is 140 threads/inch
    - Higher thread count, greater resistance to dust penetration
  - Treated with chemical to increase moisture resistance
Packaging material: WRAPS

- Woven, textiles
  - Limitation
    - Linting
    - Reprocessing results in wear
    - Need to inspect the linen wrapper after each use
    - Deterioration of water-retardant chemicals
    - Washing process (Optical Brighter Agent)
## Packaging material: WRAPS

### Cellulose base wraps

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard and Soft Crepe Paper</strong></td>
<td>100% wood pulp material, original wrapping material and the most cost effective</td>
<td></td>
</tr>
<tr>
<td><strong>Reinforced Crepe Paper</strong></td>
<td>80% wood pulp and synthetic surface binders, affordable combination of drape ability and softness with strength</td>
<td></td>
</tr>
<tr>
<td><strong>Wet Laid Non Woven</strong></td>
<td>50% Wood pulp and synthetic fibers blend, binders reinforced material, higher fluid repellence, drape ability and strength for demanding wrapping and draping applications</td>
<td></td>
</tr>
</tbody>
</table>
Packaging material: WRAPS

- Cellulose base wraps

<table>
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<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanical strength</strong></td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td><strong>Drapeability</strong></td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>Water repellence</strong></td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>Barrier Filtration Efficiency</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>
Packaging material : WRAPS

Cellulose base wraps

- Single use material
- Used to wrap trays for Steam / EtO / FO sterilization
- Listed in EN 868-2 / Specific requirements
  - Mechanical performance
  - Barrier performance
  - Water resistance

Advantages

- Cost effective, no laundering
- Provide better bacterial/moisture barrier
- Many of these products are water repellent (surface treatment by fluoropolymer)
- Can be used as drapes (ref. To EN 13795 standard)

Limitations

- Mechanical resistance (tear) for crepe paper
- Waste (counterbalanced by biodegradability / green product)
Packaging material: WRAPS

- Synthetic Non Woven (SMS)

100% synthetics fibers Polypropylene SMS
Spunbond / Meltblown / Spunbond NW

The material with the highest mechanical resistance, mainly tear strength & the only material adapted to plasma sterilisation

- The spunbond network consist of long, strong and thick PP filaments (foreground)

- The meltblown layer is made of short and thin PP microfibers (background)
Packaging material: WRAPS

- Synthetic Non Woven (SMS)
  - Single use material
  - Used to wrap trays for Steam / EtO / FO / Plasma sterilization
  - Listed in EN 868-2
    - Specific requirements equivalent to wet laid non woven

  - Advantages
    - High mechanical resistance
    - Plasma sterilization
    - Lint free

  - Limitations
    - Wet packs
    - Waste
Packaging material: WRAPS

- And always keep your analytical mindset open!
  - Track the “false safety”! Track the “apparent safety”!
Wrapping Techniques

- Several wrapping methods
  - Envelope folding
  - Square folding (parcel)
  - Pasteur folding
  - Roll method

- The most common and recommended folding is envelope folding & square folding

- Create the more tortuous path which means a better barrier against penetration of micro-organism

- Envelope folding
  - Reduce handling during opening thanks to the tab
  - Design used for Event-Related Sterility Maintenance Study
Packaging material: WRAPS

- Wrapping Techniques
  - Envelope folding
  - Square folding or parcel fold
Packaging material: WRAPS

- Wrapping Techniques
  - Double sequential wrap is recommended
Wrapping Techniques

- Double sequential wrap is recommended
  - Bacterial filtration efficiency & germproofness test improved

<table>
<thead>
<tr>
<th>BFE</th>
<th>Single Wrapping</th>
<th>Double Wrapping (interleaved)</th>
</tr>
</thead>
<tbody>
<tr>
<td>paper based wraps</td>
<td>85% to 99%</td>
<td>95% to 100%</td>
</tr>
<tr>
<td>New Linen</td>
<td>48%</td>
<td>75%</td>
</tr>
<tr>
<td>Re-used linen</td>
<td>17%</td>
<td>59%</td>
</tr>
</tbody>
</table>
Wrapping Techniques

- Double sequential wrap is recommended
  - Bacterial filtration efficiency & germproof ness test 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
  - Possibility to have a color coding
  - Security: Superposition of two colors allows to visualize any defect & prevent dust cover entering the operation rooms
Packaging material: WRAPS

- Risk analysis / material selection matrix
  - Wraps used to pack big trays
  - General guideline for wraps, to be challenged thru local validation
Sterility Maintenance Evaluation

- Producer’s technical documentation
- Event Related Sterility Maintenance Study

- This test is performed on sequential double-layer packaging after sterilization, and simulates shelf storage of sterilized packs facing « normal life » events.

- The test protocol includes:
  » Control of the sterilization efficacy
  » One post sterilization handling & transfer to the storage area made of open shelves (no dust cover added)
  » A weekly manual checking simulating an inventory.
  » Environmental bio-burden & the storage conditions (°C / %RH) are monitored.
  » Bacteriologic expertise of inside located gauzes or devices after 180 days
  » Results expressed in % of non contaminated sites after a given period of time

Packaging material : WRAPS
Packaging material : WRAPS

**Sterility Maintenance Evaluation**

- Producer’s technical documentation
- Event Related Sterility Maintenance Study

<table>
<thead>
<tr>
<th>Wraps</th>
<th>Sterility Maintenance (30 days / 180 days) Uncontaminated gauzes/devices</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>
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</table>
Sustainable Developpement :
A new criteria
Packaging material selection

- New criterion for certification in hospital: Sustainable Development

- 3 axes
  - Economical
  - Social
  - Environmental

- Environmental criteria
  - Eco-friendly purchasing
  - Waste management
  - Diminution of greenhouse gas emissions (carbon footprint)
  - Energy saving
  - Water management
  - Eco-construction / protection of biodiversity
Changing the way to look at sterilization wrap

New generation of sterilization wraps

Bio-designed

To better protect the environment

Without compromising on patient’s safety
A sterilization wrap should be …

BIODEGRADABLE

RENEWABLE

SUSTAINABLE

CARBON COMPENSATED
Environmental impact analysis

What people usually see: end life of a product

But there is more to it: transport, chemistry, manufacturing process, extraction and renewal of raw materials

END LIFE
END USE
TRANSPORT
CONVERTING
MANUFACTURING
RAW MATERIALS

REDUCE & COMPENSATE
**Hidden part of the iceberg**

**Raw material & Process**

- Maximization of renewable raw material
  - Pulp from sustainable managed forests (FSC label)
Hidden part of the iceberg

Raw material & Process

- Maximization of renewable raw material
  - Pulp from sustainable managed forests (FSC label)
  - Replacement of the synthetic plastic fiber in non-woven by Polylactic acid based fiber
    - PLA (poly-lactic acid) is a biodegradable aliphatic polyester derived from cereal (corn)
    - PLA fiber is resulting from a polymerization process
    - PLA is a heat resistant thermoplastic suitable for sterilization applications

![Diagram showing the process from Cereal to PLA]

- Extraction
- Fermentation
- Monomer production
- Polymerization
- RENEWABLE
- SUSTAINABLE
Hidden part of the iceberg

Raw material & Process

- Maximization of renewable raw material
  - Pulp from sustainable managed forests (FSC label)
  - Replacement of the synthetic plastic fiber in non-woven by Polylactic acid based fiber

- Minimized raw material
  - Grammage optimization to save trees (pulp = trees)

- Minimized use of chemical additives in final product
  - Use of non bleached pulp to reduce chlorine derivated chemicals
  - Natural colors selection down gauging pigments global content
  - Extreme minimization of non renewable chemical additives / example: no fluorocarbon
Visible part of the iceberg

- **End life of sterilization wraps**
  - Incineration: lowest CO$_2$ emission
  - Biodegradability = 45 days
    - Aerobic conditions
    - Compost at 58°C
    - Following standards ISO 14855 (2005)
    - And ASTM D 5338-98:2003
Visible part of the iceberg

- **End life of sterilization wraps**
  - Incineration: OK with lowest CO₂ emission
  - Biodegradability = at start
Visible part of the iceberg

- End life of ArjoGreen™ sterilization wraps
  - Incineration: OK with lowest CO₂ emission
  - Biodegradability = after 4 days
Visible part of the iceberg

- End life of ArjoGreen™ sterilization wraps
  - Incineration: OK with lowest CO₂ emission
  - Biodegradability = after 1 week
Visible part of the iceberg

- **End life of ArjoGreen™ sterilization wraps**
  - Incineration: OK with lowest CO$_2$ emission
  - Biodegradability = after 2 weeks

![Visible part of the iceberg image](image-url)
Visible part of the iceberg

- End life of ArjoGreen™ sterilization wraps
  - Incineration: OK with lowest CO₂ emission
  - Biodegradability = after 3 weeks
Visible part of the iceberg

- **End life of sterilization wraps**
  - Incineration: OK with lowest CO$_2$ emission
  - Biodegradability = after 4 weeks
Compensating for remaining carbon emissions through carbon projects

For more information on these projects:

Thank you for your attention!