Pack Safely!
Properties and Demands of Good Packaging Materials

Hanna-Kaisa Kyyrönen
Clinical Specialist
Wipak Medical, Health Care Products
Sterile packaging provides for

1. Easy packing
2. Effective sterilization
3. Reliable storage
4. Safe handling
5. Sterility of products until they are used
6. Aseptic presentation
Packaging for terminally sterilized medical devices

Part 1
Requirements for materials, sterile barrier systems and packaging systems

Part 2
Validation requirements for forming, sealing and assembly processes
European norms EN 868:2-10/1999
Packaging materials and systems for medical devices which are to be sterilized

Part 3: Paper for use in the manufacture of pouches and reels
-Requirements and test methods

Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction
-Requirements and test methods
An excellent multilayer film maintains its mechanical strength and does not crystallize easily before and after heat exposure.
Structure of the film has a great effect on the crystallization grade of PP

When crystallized, the film is brittle and breaks easily.
For example Multi-X

Multilayer film

High heat resistance
Advanced sealing and peeling properties
Superior tear strength

1. PET - Outer layer
2. TIE - Adhesive layer
3. PP - Middle layer, elasticity
4. PP - Bulk layer, mechanical strength
5. PP - Middle layer, profile stability
6. PP - Sealing layer, against paper
The performance of Multi-X is far superior to that of conventional films
Improved film toughness and flexibility

Pinholes in packing materials compromise the bacteria barrier properties

The flex-crack test wrinkles the material during 900 cycles causing damage and pinholes in the material.

Comparison of test results shows the superiority of the Multi-X.
Typical film performance tests

**Tensile strength**
ISO 527-3 (N/mm²) after autoclaving

- **Sterikind® Multi-X**: MD 65, CD 70
- **Conventional film**: MD 60, CD 65

**Elongation at break**
ISO 527-3 (%) after autoclaving

- **Sterikind® Multi-X**: MD 140, CD 130
- **Conventional film**: MD 120, CD 110
Film strength and toughness are demonstrated by testing the elasticity and practical peel performance.
Seal strength requirements

Sterile barrier systems are supposed to remain sealed during autoclaving and provide a clean, fiber-free peel when opened.

<table>
<thead>
<tr>
<th>Heat seal strength requirements</th>
<th>0,5</th>
<th>1</th>
<th>1,5</th>
<th>2</th>
<th>2,5</th>
<th>3</th>
<th>3,5</th>
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<td>(N/15mm)</td>
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<td>EN 868-5 (1999)</td>
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<td>Steriking flat packs</td>
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<td>Other products, average</td>
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</tbody>
</table>
Medical paper

Barrier and water repellent properties as well as mechanical strength have certain requirements.

<table>
<thead>
<tr>
<th>Performance comparison</th>
<th>EN 868-3 (1999)</th>
<th>Grade 60 g</th>
<th>Grade 70 g</th>
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</thead>
<tbody>
<tr>
<td>Tensile strength dry</td>
<td>MD kN/m</td>
<td>≥ 4.40</td>
<td>6.71</td>
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<tr>
<td></td>
<td>CD kN/m</td>
<td>≥ 2.20</td>
<td>3.27</td>
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<tr>
<td>Tensile strength wet</td>
<td>MD kN/m</td>
<td>≥ 0.90</td>
<td>1.28</td>
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<tr>
<td></td>
<td>CD kN/m</td>
<td>≥ 0.45</td>
<td>0.68</td>
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<tr>
<td>Tear strength</td>
<td>mN</td>
<td>≥ 550</td>
<td>690</td>
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<tr>
<td>Water repellency</td>
<td>sec</td>
<td>≥ 20</td>
<td>26</td>
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<tr>
<td>Air permeance</td>
<td>µm/ Pa*sec</td>
<td>≥ 3.4</td>
<td>9</td>
</tr>
</tbody>
</table>
High-weight medical paper

The average mass of 1 m$^2$ of the conditioned paper when tested accordance with ISO 536 shall be within 5% of the nominal value stated by the manufacturer.

**Microscopic pictures**

- 70 gram paper
- 60 gram paper

The 70 gram paper makes a more challenged tortuous path for bacteria penetration.
Design qualities
EN 868-5

- Width of the seal shall be not less than 6 mm
- One web of the materials shall either be provided with a thumb notch or be lipped
- Marking of pouches and reels:
  - Do not use if the pack is damaged – or equivalent phrase
  - LOT number (traceability)
  - Manufacturers name or trade mark
  - Process indicator(s), if applicable (complies with ISO 11140-1)
  - Direction of peel
  - Nominal dimensions and/or identification code

- The product shall not be printed on any surface which comes into direct contact with the item
- Process indicator (shall not be less than 100 mm² in area)
Correct use of the packaging materials assures sterility

- A pouch should not be packed too full
- The seals need to be made strong enough
- When loading into an autoclave complete air removal from the packs and proper penetration of the sterilizing agent must be ensured
- When taken into use aseptic opening is performed
Conclusion

Good packaging materials:
- comply with the international norms and standards EN ISO 11607 and EN 868.
- have manufacture traceability

Safe packing is provided with:
- educated personnel
- appropriate facilities
- good quality products
Contact information:

Hanna-Kaisa Kyyrönen
Clinical Specialist
Health Care Products
Wipak Medical
hanna-kaisa.kyyronen@wipak.com
www.steriking.fi

WIPAK OY
P.O. Box 45
15561 NASTOLA
FINLAND
Tel. +358 (0)20 510 311
www.wipak.com

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