Recommendations by the Quality Task Group (30): Packaging Systems – Part 2: Hard Packaging

When it came to processing medical devices little attention was paid for a long time to sterile supply packing. The psychological sense of security conferred by the visible presence of packaging was more important than the actual requirements and the underlying process. Neither the correct choice of packaging nor the consequences of inadequate packaging warranted much reflection.

The Quality Task Group, a working group composed of experts, is now dealing with this topic. Its goal is to give users an easily understood guide, presented in tabulated form, to enable them to assign the different types of packaging to their respective standards as well as to evaluate them in economic terms.

Safety aspects and user friendliness are also taken into consideration. Particular attention is also paid to validation. This is because in view of the markedly more stringent quality requirements (see ISO 17664), anywhere in the world, each manufacturer of medical devices, each hospital as well as anyone dealing with medical device packaging and sterilisation must focus in detail on this aspect of quality management.

In the context of standard ISO 11607, validation is understood to mean “the provision of documented proof that all quality requirements addressed to the process are fulfilled and that the process repeatedly produces devices that meet the given specifications”.

As far as the packing process is concerned, this means that the process must be reproducible. Processes that unfold differently on each occasion do not lend themselves to validation.

Binding procedural directives and standard operating procedures, as stipulated by a quality management system, as well as specialist personnel who undergo regular training are a prerequisite for validable processes.

These recommendations are divided into three parts:
Part 2: Hard Packaging Systems and
Part 3: Comparison of the Systems

By consulting the tables, the user should be able to select the appropriate system.

Sigrid Krüger
Quality Task Group Coordination

### Hard Packaging

<table>
<thead>
<tr>
<th>Packaging material</th>
<th>Hard Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent standards</td>
<td>DIN EN 868-1 EN 868-8</td>
</tr>
<tr>
<td></td>
<td>EN 868-1 868-8</td>
</tr>
<tr>
<td>ISO</td>
<td>11607¹</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Packing technique</th>
<th>manual automated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation</td>
<td>Reproducible yes</td>
</tr>
<tr>
<td></td>
<td>Validable yes</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Application technology</th>
<th>Competent standards</th>
<th>DIN 58953-9</th>
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</thead>
<tbody>
<tr>
<td>ISO</td>
<td>ISO 17664 (draft)</td>
<td>11607¹</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sterilisation process</th>
<th>Steam yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde no</td>
<td></td>
</tr>
<tr>
<td>Ethylene oxide yes²</td>
<td></td>
</tr>
<tr>
<td>Gas plasma yes²</td>
<td></td>
</tr>
<tr>
<td>Hot air no</td>
<td></td>
</tr>
<tr>
<td>Liquid media no</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Economic efficiency</th>
<th>Material investment high</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment investment none⁴</td>
<td></td>
</tr>
<tr>
<td>Labour low⁴</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Hard packaging systems

¹ contains no specific information for the operator
² the operating manual produced by the container manufacturer giving a list of the processes permitted must be observed
³ this is determined by the design (guided control), no deviation possible
⁴ depends of the type of processing
Classifying Medical Devices before Processing (as of October 2003)

based on the Recommendation (by the RKI and BfArM) *Hygienic Requirements for Processing of Medical Devices* (published in: *Bundesgesundheitsbl. 2001; 44: 1115–1126.*

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**Medical Device**

- Only contact with intact skin?
  - Yes: Non-critical medical device
  - No: Contact with mucosa or pathologically altered skin?
    - Yes: Semi-critical medical device
    - No: Skin or mucosal penetration?
      - Yes: Critical medical device Group A, B or C
      - No: For using blood, blood products, sterile medicinal products?
        - Yes: Critical medical device Group A, B or C
        - No: No medical device e.g. feeding bottle/teat

**Semi-critical medical device**

- Are there any lumens or parts that are difficult to access?
  - No: Semi-critical A no special processing requirements
  - Yes: Semi-critical B increased processing requirements

**Critical medical device Group A, B or C**

- No medical device e.g. feeding bottle/teat

**Non-fixing**

- Cleaning/Disinfection preferably automated
  - Non-fixing pre-cleaning as required
  - Non-fixing pre-cleaning immediately after use

**Semi-critical A**

- No special processing requirements
  - Cleaning/Disinfection preferably automated
  - Sterilisation as required

**Semi-critical B**

- Increased processing requirements
  - Cleaning/Disinfection preferably automated
  - Sterilisation as required

**Agent/Processes used**

- Must be endowed with bactericidal, fungicidal and virucidal activity.
- Spectrum of action AB
- Preferably thermal or automated

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Agent/Processes used must be endowed with bactericidal, fungicidal and virucidal activity.

Spectrum of action AB

Preferably thermal or automated
Critical Medical Device

Are manufacturer's instructions available? Yes → No → End of process

Can a documented, validated process be chosen based on existing knowledge? Yes → No → End of process

Are there any lumens or parts that are difficult to access? No → Yes → End of process

Critical A
no special processing requirements

Non-fixing pre-cleaning as required

Cleaning: preferably alkaline
Disinfection: preferably thermal
preferably automated in WD

Limited number of processing cycles specified by manufacturer? Yes → Yes → Suitable validated LT sterilisation process

Label

Steam sterilisation possible? Yes → No → Steam sterilisation

Suitable validated LT sterilisation process

Critical B
with increased processing requirements

Steam sterilisation possible? Yes → Non-fixing pre-cleaning immediately after use

Cleaning: preferably alkaline
Disinfection: thermal automated in WD

Further processing: only in institutions with an externally certified quality management system according to DIN EN ISO 13485/DIN EN ISO 13488

Critical C
with particularly stringent processing requirements

Non-fixing pre-cleaning immediately after use

Cleaning: preferably alkaline
Disinfection: preferably thermal
preferably automated in WD

Suitable validated LT sterilisation process

Person entrusted with processing:
Proof of recognised training as sterilisation assistant

Steam sterilisation possible? No

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