Validating the Packaging Process

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• Using Pouches and Reels
  – Checking the conditions in healthcare facilities
  – Checking the material suitability by testing
  – Choosing the right SBS – evaluation criteria
• Standards and Guiding Documents
  – For manufacturers
  – For healthcare facilities

  Packaging Process Validation for Pouches
  – IQ – Installation Qualification
  – OQ – Operational Qualification
  – PQ - Performance Qualification

• Wipak Validation Service
• Routine Control for Checking the Pack Integrity and Documentation
• Corrective Actions
Why Packaging Process Validation?

• For the safety of patients: to reduce number of infections that happen due to lost barrier or bad aseptic presentation

• SBS (primary package) is a minimum package that prevents ingress of microorganisms and allows aseptic presentation at the point of use

• Only intact packaging can serve as sterile barrier

• ISO 11607-2 states that there needs to be a documented validation program in all healthcare facilities where medical devices are packed and sterilized.

• To prove that the sealer makes proper seal and that sealed package can really serve as sterile barrier
  – To prove that SOPs for sealing, wrapping, self-seal and container packing are in place and provide sterile barrier repeaditely
  – To prove that packaging works in the environment it is used
Packaging Process Validation Results in

1. Less claims, less repacking, less broken packages, lower risks → saves money.
2. Good reputation for hospitals.
4. Lower infection rates.
Checking the environment and conditions → Choosing the right pouch → Filling the pouch → Validating the Sealing process (plan, IQ, OQ, PQ) → Checking the pack integrity at different stages of supply cycle → Aseptic Presentation
Choosing Right Sterile Barrier System or Packaging System

For example choosing the right pouch or double pouch or tray wrap

**Material performance testing**
- Evaluating intended processes
- Making a plan for testing and a table for evaluation criteria
- Testing materials in those processes and using also worst case scenarios
- If using the same packaging system for multiple medical devices or a family of medical devices, then a rationale should be developed
- The healthcare facility should follow a plan or criteria for evaluating the choice of sterile barrier systems
- Results of testing should be compared to the acceptance criteria
- The results of the evaluation should be documented

**Material stability testing**
- Manufacturer documents, third party studies
- Evaluation of pack integrity in the facility according to storage, transportation, handling and other conditions
- Evaluate pack dryness
- Think also about the possibility of extractables that may leach out of packaging materials over time. (ASTM D4754)
Choosing Right Sterile Barrier System or Packaging System
Failures that we want to avoid – Evaluation Criteria

• **Holes** often come when packed items or trays are stacked, when stored and/or when pulled out from shelves.
• Sometimes SBSs break already during the autoclave process, handling or transportation
• **Hole in the pack means that the items inside are unsterile**
  – This **increases** the packaging related **costs** in OR
  – This **reduces the productivity** of OR team
  – Holes may lead into **delays** in operations
  – Hole in the pack creates **significant risk** for the patient safety
  – Holes also increases the number of claims CSSD is getting
Choosing Right Sterile Barrier System or Packaging System
Failures that we want to avoid – Evaluation Criteria
Choosing Right Sterile Barrier System or Packaging System

Failures that we want to avoid – Evaluation Criteria

Bad Peel, fibers coming out. Loose particles. Risk for the patient! Happens due to bad material choices or due to wrong sealing parameters either at the manufacturer facilities or in the hospital.

Loose particles can contaminate the sterile item upon opening.
Choosing Right Sterile Barrier System or Packaging System
Failures that we want to avoid – Evaluation Criteria

• **LEAKAGE IN THE SEALING AREA**
  – This allows a path for microbes to enter

• **DYE PENETRATION TEST FAILING – SEALS ARE NOT INTEGRITY**
  – Leakage may be due to wrong material choice or due to wrong sealing parameters or defected sealer. Leakage may occur also after sterilization as autoclave vacuum pulses are very powerful.
Choosing Right Sterile Barrier System or Packaging System

Failures that we want to avoid – Evaluation Criteria

- Too low Seal Strength levels (EN868-5, ASTM F88 or as reasonable for the process)
- RISK OF OPENING PACKAGE DURING THE AUTOCLAVE PROCESS AND AFTER WHEN TRANSPORTING OR HANDLING THE PACKAGE
Choosing Right Sterile Barrier System or Packaging System
Failures that we want to avoid – Evaluation Criteria

WET LOADS (PACKS)
- Moisture in the pack after sterilization means it is unsterile
- Moisture can also create water path for microbes to enter into the pack
- Moisture is good growth place for the microbes
  - May create significant infection risk for the patients
  - Wet loads increase the packaging related costs in OR
  - Wet packs decrease the productivity of OR team
  - May lead to delays in operations
  - Increases the number of claims to CSSD
Choosing Right Sterile Barrier System or Packaging System
Failures that we want to avoid – Evaluation Criteria

CONTAMINATION RISK from printing inks or other extractables

- the possibility that inks may leak into the packaging over time, potentially contaminating the medical device or the environment
- (ASTM D4754)

...printing on or in nonporous film
The markings and prints that are in indirect contact with the packed items may migrate through the polymeric film construction.
Standards and Guiding documents for Manufacturers

Responsibilities of the Manufacturer

- Material conformance. Only virgin medical grade materials can be used. No recycled paper or recycled plastics
- Print safe (outside of packing area), safe inks
- To produce in clean environment. Quality systems in place: ISO13485, ISO 9001, ISO14001, ISO22000 etc.
- Follow minimum ISO 11607-1 and 2
  - EN868 (parts 2-10)
  - ISO 11140-1
- Declaration of conformity and studies for material compatibility, microbial properties, double pouching validation etc.
- Manufacturer’s instructions needed
  - Sterilization method, safety considerations, batch visibility, barrier properties. Mentioned in IFUs, technical specifications, MSDSs etc.
Standards for Packaging and Validation

<table>
<thead>
<tr>
<th>Packaging for terminally sterilized medical devices</th>
<th>Published (valid)</th>
<th>Withdrawn (expired)</th>
</tr>
</thead>
</table>

  - Under review at the moment
Sealing Validation for pouches should include protocol and results:

- **Validation Plan**
- **IQ:** appropriate and correctly installed sealing device, defining critical process parameters, controlling and monitoring systems for critical parameters, calibration schedules etc.
- **OQ:** defining correct process parameters and quality criteria, and then challenging these process parameters
- **PQ:** demonstrating that the process is constantly producing acceptable quality of seal under specified conditions (OQ), three validation runs including "worst case –scenario"
- Procedure for addressing failures and corrective actions
- Process control and routine monitoring
- Plan for revalidation

According to ISO 11607 there should be a documented validation program demonstrating the efficacy and reproducibility of all sterilization and packing processes (pouches, wrapping, containers).
Validation Plan

- Validation plan checklist: Heat Sealing Process Preformed Sterile Barrier Systems (SBS: Pouches, Reels, etc.)
  - Including: Responsible persons, description of SBS systems, assembly process, description of pouches and reels (or wrapping, containers or self-seal), description of sealing devices, description of sterilization processes, description of possible protective packaging, challenges of handling, distribution and storage, acceptance criteria and qualification steps, validation report and approval
  - Extensive question lists available in ISO TS 16775:2014 guiding document
Review of the process, SBS or packaging system should be considered periodically to ensure that multiple minor changes, which did not require revalidation, have not affected the packaging system.
Steriking® Seal Validation Service helps healthcare facilities to validate their packaging process in accordance with the ISO 11607-2 requirements.

The Wipak Validation Service for one sealing machine comprises of:

- Instructions for Validation
- Templates for documenting Installation (IQ), Operational (OQ) and Performance Qualifications (PQ)
  - Available at website [http://sealvalidation.steriking.com](http://sealvalidation.steriking.com)
  - Also available as word files if computer not available in CSSD
- Testing the seals of sterilized pouches/packs (Wipak laboratory)
- Pinhole testing for sterilized pouches (Wipak laboratory)
- Peel testing/evaluation (Wipak laboratory)
- One Multi Seal test kit (MS300) for routine control
- Validation report with conclusions and recommendations
Checklists for IQ, OQ & PQ Qualification steps
## Actual Qualification steps: Short Checklist IQ

<table>
<thead>
<tr>
<th>Sealing Device</th>
<th>Model</th>
<th>Serial number</th>
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</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Name</td>
<td>Address</td>
</tr>
<tr>
<td>CE Conformity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ yes</td>
<td>☐ no</td>
<td>☐ evidence</td>
</tr>
<tr>
<td>Service/Maintenance</td>
<td>Company</td>
<td>Contact details</td>
</tr>
<tr>
<td>Documentation</td>
<td>Available</td>
<td>Where? Archiving</td>
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<tr>
<td>Operation Manual</td>
<td>☐ yes</td>
<td>☐ no</td>
</tr>
<tr>
<td>Spare Part –list</td>
<td>☐ yes</td>
<td>☐ no</td>
</tr>
<tr>
<td>Maintenance and Cleaning Schedule</td>
<td>☐ yes</td>
<td>☐ no</td>
</tr>
<tr>
<td>Documented Training of Users</td>
<td>☐ yes</td>
<td>☐ no</td>
</tr>
<tr>
<td>Written procedures</td>
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<td>☐ no</td>
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</table>

### Conditions and features

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<thead>
<tr>
<th>Correctly installed? Volts, Hz, etc.</th>
<th>☐ yes</th>
<th>☐ no</th>
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</thead>
<tbody>
<tr>
<td>Free of visual and functional defects?</td>
<td>☐ yes</td>
<td>☐ no</td>
</tr>
</tbody>
</table>

### Critical process parameters

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Pressure/Force</th>
<th>Speed/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>± °C</td>
<td>± N</td>
<td>± m/min /s</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Are these monitored?</th>
<th>☐ yes</th>
<th>☐ no</th>
<th>Evidence:</th>
</tr>
</thead>
</table>

**Signature:**

| Date: |  |  |  |

**Remarks:**

- Volts
- Hz
- Critical process parameters
  - Temperature
  - Pressure/Force
  - Speed/Time
- Evidence:
## Actual Qualification steps: Short Checklist OQ

<table>
<thead>
<tr>
<th>Testing conditions</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Calibration /Check up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature:</td>
<td></td>
<td></td>
<td>yes/no</td>
</tr>
<tr>
<td>Pressure:</td>
<td></td>
<td></td>
<td>yes/no</td>
</tr>
<tr>
<td>Speed/Time:</td>
<td></td>
<td></td>
<td>yes/no</td>
</tr>
<tr>
<td>Sampling quantity</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality criteria</th>
<th>Before and after sterilization</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely intact seal</td>
<td>yes/no</td>
<td></td>
</tr>
<tr>
<td>No channels or open seals</td>
<td>yes/no</td>
<td></td>
</tr>
<tr>
<td>No punctures or tears</td>
<td>yes/no</td>
<td></td>
</tr>
<tr>
<td>No delamination or separation</td>
<td>yes/no</td>
<td></td>
</tr>
<tr>
<td>Other: specify</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seal strength</td>
<td>Min.</td>
<td>Max.</td>
</tr>
</tbody>
</table>

Signature: ___________________________ Date: ________________
OQ – Operational Qualification
With Seal Control-Sheet and/or actual pouches

• Made visually and by using for example Steriking® Smart Dye Test or Sterking® MS300 or some other ASTM F1929 type of Dye Penetration test
• Using seal control sheets SC250 for Steriking® or pouches if validating other materials than Steriking

• **NOTE!** Seal Control Sheet serves very well as a document prove of a the daily test
Seal Control Sheets - 
For visual check of seal quality

Seal Control sheets (SC250) are constructed of same materials than See-Through packages. Seal Control sheets are also available of LT-Blueline materials (TSC200).
Seal Validation Service – PQ steps

1. Select 30 items and pack them.
2. Seal the packs, by using different temperatures.  
   - 160°C, 170°C, 180°C, 190°C, 200°C
3. Sterilize in 3 different cycles.
4. Take instruments out and collect empty packages.
5. Analyses and report made by Wipak.
# Actual Qualification steps: Short Checklist PQ

<table>
<thead>
<tr>
<th>Defined parameters (OQ)</th>
<th>Temperature</th>
<th>Pressure</th>
<th>Speed / Time</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Sterilization cycle (Run) A</th>
<th>Sterilization cycle (Run) B</th>
<th>Sterilization cycle (Run) C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/time of sterilization (according to SOPs)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visual (as per OQ)</th>
<th>Compliance</th>
<th>Compliance</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material A</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Material B</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Material C</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Seal strengths / Intactness</th>
<th>Test method and institute:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material A</td>
<td><img src="" alt="OK Value" /></td>
</tr>
<tr>
<td>Material B</td>
<td><img src="" alt="OK Value" /></td>
</tr>
<tr>
<td>Material C</td>
<td><img src="" alt="OK Value" /></td>
</tr>
</tbody>
</table>

**Signature:**

**Date:**
VIDEO OF THE SEALING VALIDATION WIPAK
Stericking® Seal Validation Service Platform

Stericking® service platform

Welcome to Wipak’s Stericking® service platform for the validation of the sealing process. The Stericking® Validation Service can be ordered through Wipak’s distributor network.

The sterile barrier system (SBS) is the minimum packaging configuration that prevents microorganisms from entering and allows aseptic presentation at the point of use. Only intact packaging can serve as a sterile barrier and the loss of package integrity can compromise patient safety. ISO 11607-2 standard for sterilization packaging states that there needs to be a documented validation program in all healthcare facilities where medical devices are packed and sterilized. The aim of this validation program is to demonstrate the efficacy and reproducibility of all sterilization and packaging processes.

The validation of the sealing process according to ISO 11607-2 includes Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). The validation process includes verifying that the sealer makes a proper closing seal and that the final sealed package performs as a safe sterile barrier system. To support healthcare facilities in their validation programs, Wipak is now offering a new service to assist in the validation of the sealing process.

The Wipak Validation Service for one sealing machine comprises of:
- Templates for documenting Installation (IQ), Operational (OQ) and Performance Qualifications (PQ)
- Testing of the seals of sterilized pouch/packs
- Periodic testing for sterilized pouches
- Paw/leak evaluation
- One Multi Seal Test kit (MST500) for routine control
- Validation report with conclusions and recommendations

To order the validation service, please e-mail your contact details to specagent.stericking@wipak.com.

After we have processed your order, you will receive a username and password for the service and be able to start your validation.
Steriking® Seal Validation Service Platform
Steriking® Seal Validation Service Platform

Validation progress and navigation:

Step 1/3  Step 2/3  Step 3/3

Checklist OQ

Testing conditions

Temperature:
- Upper limit: 17°C  
- Lower limit: 20°C
- Calibration / Check up: ○ Yes ○ No

Pressure:
- Upper limit:  
- Lower limit:  
- Calibration / Check up: ○ Yes ○ No

Speed/Time:
- Upper limit: 10  
- Lower limit:  
- Calibration / Check up: ○ Yes ○ No

Sample quantity:
- 25 pieces

Quality criteria:
- Completely intact seal
- Before and after sterilization: Test method:  
  ○ Pass ○ Fail  
  Visual inspection

Lab results

Upload files

Lab results will appear here once they have been uploaded by Wipak.

Inform
Steriking® Seal Validation Service Platform

Validation progress and navigation:
Step 1/3  Step 2/3  Step 3/3

Checklist PQ
Defined parameters (OQ)
Temperature:
170°C, 190°C, 160°C, 200°C
Pressure:
Speed/Time:
10 m/min
Tested material:
Steriking® S33, lot 0315

Sterilization cycle A (Run):
Date/time of sterilization (according to SOPs):
10.8.2017 11:51 - 12:05
Cycle parameters (temperature, time):
140°C, 5 min, max

Visual (as per OQ):
Dye Penetration test:
Peel test, fiber free opening:
Compliance:
Yes ☐ No ☐

Lab results
Upload files

Uudenmaa sairaalapesula_validointi S33 lot 0315 11.8.2017.pdf
Uudenmaa sairaalapesula_validointiraportti 20170810.doc

Inform
Validation Report from Wipak

- Report of findings. Giving instructions to do corrective actions when needed.
- Giving recommendations for improvements.
- Giving the sealing window and the highest and lowest seal strength limits for the hospital for the specific SBS and specific sealing device.
- Should be put into files or can be kept in Wipak Sealing validation platform.
Pouches shall be inspected for intact seals and barrier integrity before and after sterilization and before use.

Routine tests available from Wipak Steriking®:

**MS300**

**Recommended Use:**
- *Daily* testing and reporting with **Seal Control Sheets (SC250)**
- *Once a week* dye penetration test or every time when suspecting a problem
- Works very well after sterilization. Can be done in sterile area, sterile storage or even up at the theaters

**Contents of a Kit:**
- 300 pcs Seal Control Sheets
- 1 stopwatch
- 80 ml dye solution (drop flacon and pipette)
- Instructions For Use

Sufficient for testing one sealing device for 1 year.
Routine Control for Checking the Pack Integrity and Documentation Steriking® Smart Dye Test

Dye penetration test is easy and clean format

- Ink is packed in single dosages into special aluminum package from where it is easy to release inside the sterilization package without any risk of ink transmission

There are two versions of Smart Dye test:

- One for paper/laminate packs (blue ink), SDTB
- One for Tyvek/laminate packs (red ink), SDTP
- Seal integrity can be detected within 5 seconds
Typical problems found during validation and routine testing + corrective actions

Wet Packs -> What to do?

• Checking packaging procedures:
  – Check how loading the autoclave
  – Decrease the number of items packed into tray
  – Use of tray liners

• Changing autoclave parameters.
  – Longer drying or more vacuum pulses after the sterilization holding time etc.

• Checking the water quality

• Maintenance of the autoclave

• Using separate steam generators for autoclaves

• Switch from container or linen to single use wrapping or pouches
Typical problems found during validation and routine testing + corrective actions

Avoiding Wet Packs - Load related matters

- Do not load too many heavy sets to the same load. (Check manufacturer IFU about the limits)
- Avoid stacking containers or wrapped trays
- Leave enough space between the trays
- Put peel pouches on their edges or paper side down to allow condensate drop down
- Usually autoclave manufacturers instruct to load containers on the bottom shelves, wrapped items on bottom or second shelve and peel pouches on top.
- Sometimes recommendation is to place the biggest and heaviest sets as far from the drain as possible. Reason being that they create the most condensate and this way it is easiest to get them dry
- Do not put too heavy load into containers or trays (follow IFUs or for example AAMI or EN standard documents)
Avoiding Wet Packs – Tray Liners
Avoiding Wet Packs – Tray Liners

For absorbing moisture and for extra protection

- For use with surgical instrument trays and containers
- Absorbs excessive condensation during autoclave process
  - To be placed into a tray under the instruments and/or under the tray
  - Sometimes also under containers or wrapped trays
  - Protects the sterilized package against damage
  - Protects sharp instruments or tray edges from sticking thru the wrapping material
- Protects items falling in between the mesh tray holes

WIPAK STERIKING® TRAY LINERS ARE:

- TL – Standard Tray-Liner - 70 g – absorbs 4 times its own weight
- TLWE – Tray-Liner with Edge – 107 g – absorbs 4 times its own weight
- TLNW – Nonwoven Tray-Liner – 45 g – absorbs 6 times its own weight
Autoclave Process
Avoiding Wet Packs
Changing autoclave process parameters

- Drying happens in last phases with residual heat
- With the heat that has been transferred from steam to the packed items
- If items are wet, heat has not been enough for drying
- 1. Drying can be influenced with vacuum pulses where water boils out more easy in lower pressure (usually good for textiles and items that dry easy)
- 2. Drying can be intensified with air pulses in between the vacuum pulses (usually used for rubber, plastic and medium sized instrument loads)
- 3. Drying can be further intensified with steam pulses in between the vacuum pulses
- here items are heated with steam with purpose that items get the needed heat to dry the residual water
- This is used usually for heavy instrument loads (metal)
Typical problems found out during routine testing or validation + corrective actions

Broken packages
• Checking packaging procedures:
  – Handle packaging with care, see critical points and areas in the hospital. Change the way of working or try to fix the environment when possible
  – See if instrument could be packed so that sharp parts would touch the stronger part of the package – normally film
  – Use package with stronger paper or Tyvek. 60g/m2 → 70g/m2, 59g/m2 → 75g/m2
  – Use tyvek or Nonwoven if still stronger package needed
  – Crepe → Nonwoven → Synthetic (SMX)
  – Use inner pouch to protect from sharp edges
  – **USE BETTER/ MORE SUITABLE MATERIALS**
Broken packages

- Checking packaging procedures and quality system:
  - If using linen or other reusable textiles, there might be holes already after one use. Checking of the holes is mandatory each time when wrapping and when opening the pack
  - Use tray liner or protective corner cards
  - Use tip protectors for sharp instruments (small pouch or special protector)
  - Consider disposable materials

Linen wears out during the use
- How to identify possible pinholes
Weak Seals

- Checking packaging procedures:
  - Do not pack too tight. Only \( \frac{3}{4} \) of the pack should be filled. 2cm per side free space.
  - See that paper side is down
  - If packing pouch edge down, paper against paper and film against film. Leave space between the packs
  - Do not pack to the trays which do not have holes
  - Pack bowls and such items so that condensate water may drop out
  - Check the seal integrity by doing validation and by doing routine control
Thank you

Contact Wipak
wipak.com
steriking.com

Visit also:
http://sealvalidation.steriking.com

Join Our Winnovations Network
winnovations.wipak.com