Study on Sealing Quality and Reliability of Pouch Package Sterilized in Hospital

Takako Kami, MS. RN.  Hiroyoshi Kobayashi, MD. PhD.  
Division of Infection Prevention and Control  
Tokyo Healthcare University Postgraduate School
Introduction

The ultimate goal of all packaging systems is to maintain sterile and aseptic conditions until the package contents are used for patients.

Pouch packages, containers, and wraps are used to maintain the aseptic condition. Sterility of all packages should be ensured before they are opened to use.
Method

Pouch packages opened in clinical settings have been collected from thirteen facilities. Package barrier integrity of the opposite unopened edge other than the opened was tested by dye penetration method.
Results

- No. of facilities cooperated: 13
- No. of pouches collected: 1,000

**148 pouches that failed**

- 25cm width: 11 pouches (fail)
- 30-52cm width: 137 pouches (fail)
- Of 148 pouches:
  - 108 pouches with side gusset
Dye penetration test

Dye penetration test is performed in order to check Package barrier integrity.

No channel: pass  Channel: fail

Dye penetration test / Recommendation: 1 × / day
PASS & FAIL

PASS

FAIL
Blue ink penetration the seal
PASS
Creation of Leakage Narrow Channel by surgical sutures

Surgical suture of different size 4-0, 1, 2,

The pouch is heat-sealed after fixing the sutures by adhesive tapes apart from sealing site
It is difficult to find a channel macroscopically.

Marks for suture channels.
Seal Leak Test
The diameter of braided silk 2 is regulated to be between 0.500 and 0.599mm by US Pharmacopeia, 24th edition.
Channel visible due to ink penetration
A big Hole !
Pouches with gussets
Pouches with gussets
Pouches with gussets
Pouches with gussets (all failed)
Many Leak Channels by Incomplete Sealing
Multiple Leak Channels
Soiled Pouches  

Folded Pouches
Plastic films were completely peeled
Large pouches
40cm W, Ca 80cm L
In used large pouches plastic film is completely peeled
Was it possible to remove the instrument from the large pouch aseptically?
Conclusion

- Ca 1000 pouches already opened were gathered from thirteen facilities.
- Opposite side of sealing was tested by dye penetration method.
- 148 were revealed the exist of leaks.
- Among them 108 were side gusset.
• On the double folded part of pouch side, the heat of sealer does not penetrate evenly. This is the reason why leak channels are often observed in the double folded side-sealing.

• Large pouches are apt to result in incomplete sealing because it is too large to handling adequately at heat sealing and the gusset may makes easily folds of the sealing part. So the large pouch should be carefully reevaluated to select for use.
• Periodical maintenance of the sealer, and routine leak test of sealing should be required for the sterility maintenance.
• Education of the personnel engaged in central services is important factor for the package barrier integrity.
• When sterilizing pouch is selected, adequate size and shape should be considered.
• Handling and preservation of the pouches after sterilization should be also considered carefully.
We thank the healthcare personnel for their kind cooperation to provide us the clinically used sterilization pouches.

Thank you very much for your kind attention.