Incomplete closure of the gusset type sterilization pouch in clinical use

-Reliability of the pouch with side gusset type of after steam sterilization-

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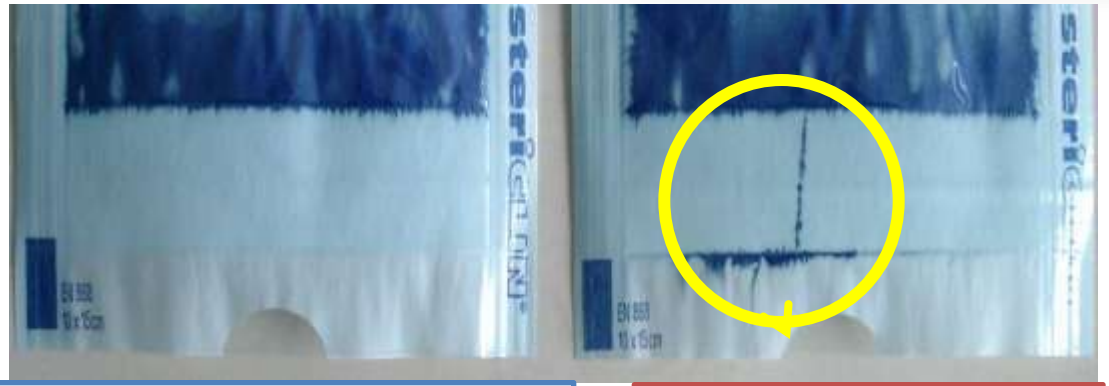
BACKGROUND

Introduction

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.

In our results of blue ink test, Kami et al. (2012) found that the gusset type sterilization pouch developed the leak channel more easily than normal type sterilization pouches. This study examines the cause and prevention.

Blue ink test



No channel: pass

Channel: fail

The parts which were failed called “ channel”.

Try the Blue ink test

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

◆ 148 pouches that failed

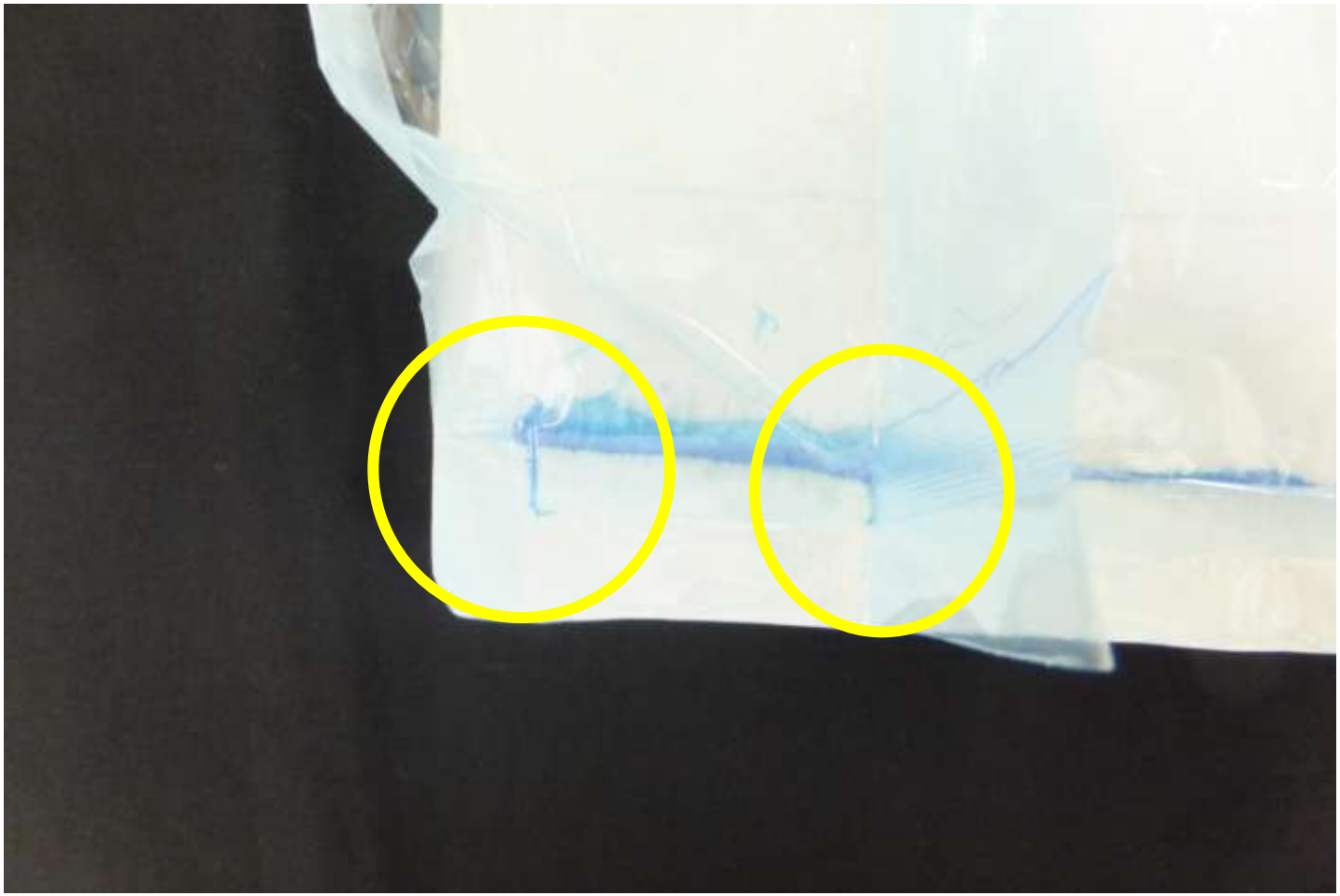
- ➢ 25cm width:11poudhes (fail)
- ➢ 30-52cm width:137poudhes (fail)
- ➢ Of 148 pouches:
  - ✓ **108 pouches with side gusset**

Gusset type pouch are often used in Japan.

Normal type pouch

Gusset type pouch

Channels of gusset type pouch



Method

- Temperature distribution of the heat sealers was studied with Thermoscale® (Fujifilm business supply K.K.).
- Three sealing temperature (180 ℃ : 190 ℃ : 200 ℃) were compared after steam sterilization.
- Possibility of contamination through the tunnel was evaluated.

Temperature distribution Thermoscale®

Conventional sealer

NEW conventional sealer

Color is not uniform ⇒ Temperature distribution is not uniform

Comparison of sealing temperature before and after steam-sterilization: Number of channels

Gusset Type Pouch Sealing Investigation (New Conventional Sealer)			
Temperature	Pouch width	Sterilization (AC)	
		Before	After
180℃	15cm	0/10	2/10
190℃	15cm	0/10	2/10
200℃	15cm	0/10	0/10
180℃	30cm	0/10	21/21
190℃	30cm	0/10	18/20
200℃	30cm	0/10	22/25

Possibility of contamination through the channel was evaluated

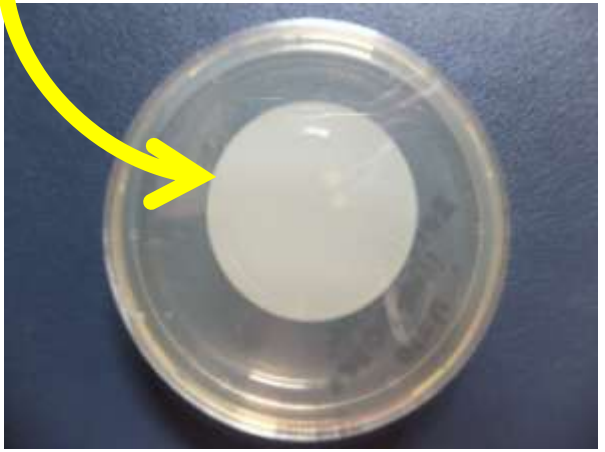
18G Needle (0.94mm in inner diameter)

The filter holder of air sampler with membrane filter (19mmϕ, pore size: 0.3µm Nuclepore®, Track-Etched Membranes Whatman)

Room air trapped in the holder 1cf 30min.

Possibility of contamination through the channel was evaluated

Membrane filter (19mmϕ, pore size: 0.3µm Nuclepore®, Track-Etched Membranes Whatman)



Cultured 48 hours

n	Air Trapping 30cf (Cell count)	18G Needle Air Trapping 1 cf (Cell count)	Indoor falling number of bacteria 30min (colony count)
1	3	0	0
2	3	0	0
3	5	0	0
4	6	0	0
5	6	0	0
6	6	0	0
7	4	0	1
8	3	0	0
9	6	1	0
10	6	1	1
11	4	1	0
12	4	0	1
13	6	0	0
14	2	0	1
15	6	0	0
16	15	1	1
17	12	1	0
18	13	2	0
19	13	0	0
20	17	1	0

cf = cubic feet

1-15: Nobody in the room

16-20:one person in the room

Conclusion

- Conventional type sealer can not seal the gusset type pouch. It can be used to seal the normal type pouches.
- For sterility maintenance of pouches with gusset after sterilization, the heat sealing method should be further examined more carefully to improve the maintenance.

If you have farther questions,
please send an e-mail to me.

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Thank you very much
for your kind attention !