

Incomplete closure of the gusset type sterilization pouch in clinical use

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

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Background & Objectives

The ultimate goal of all packaging systems is to maintain sterility 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.

In the result of previous study on one thousand of used pouches to test the unpeeled sealing opposite to the opened, 148 pouches had leaked channels. 108 of them were the gusset type of pouches. So this time the sealing assurance of sterilizing pouch after heat sealing is experimentally studied. (Figure 1)

Methods

- 1, compared before and after steam sterilization at each temperature of the sealer.
(The numbers of channels of gusset.) (Figure 2)
- 2, The indoor air trapped from the injection needle was cultured for 48 hours.
(Diameter of 18G injection needle > Gusset parts channel (Figure 3. 4)

Results

- 1, There was no channel in gusset parts before steam-sterilization. However, the following steam-sterilization result is bad.
- 2, There are a lot of channels when the width of the pouches is wide.
- 3, As a result of trapped indoor air from the 18G injection needle, bacteria penetrate from the channel.

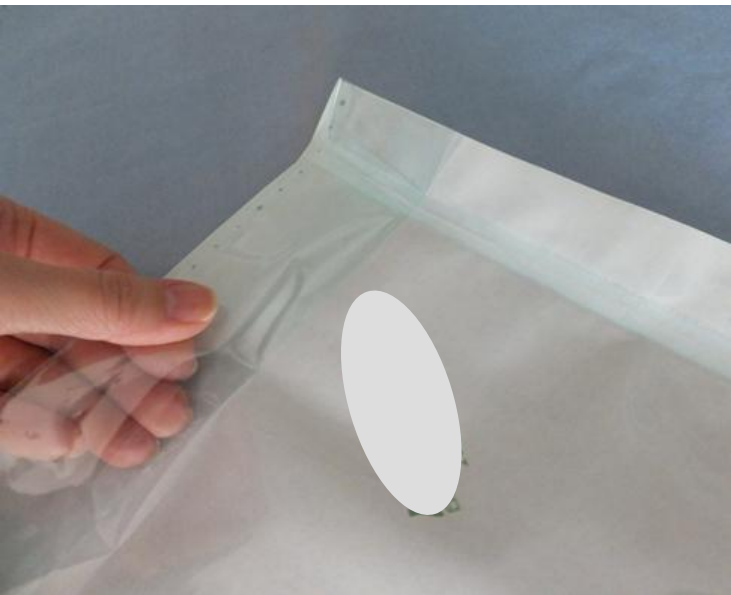
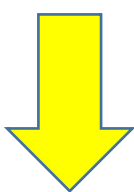


Figure1 : Gusset type pouch



Before steam sterilization : Powder in the Gusset type pouch

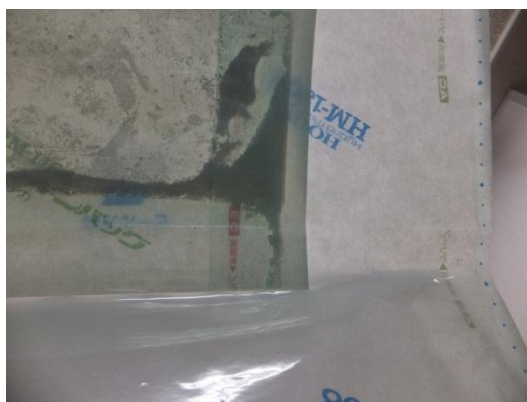
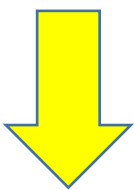


Figure3 : Put the powder

After steam sterilization : Powder were outside from channel of Gusset parts



Figure2 : New conventional type sealer (Sealer for Gusset)



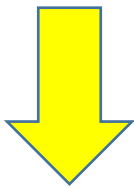
Comparison of sealing temperature, before and after steam-sterilization: Number of channels

Gusset Type Pouch Sealing Investigation (New Conventional Sealer)

Temperatur e	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



Figure4 : For air trapping Filter and holder



Collecting air for 30min
The number of colonies after 48hs (n=20)

n	Air Trapping 30cf (Cell count)	18G Needle Air Trapping 1 cf (Cell count)	Indoor falling number of bacteria 30min (Cell 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. Re-sterilization is recommended if the gusset type pouch is moved once to prepare the operation.