

■ Research Brief

A Study on the Reliability of Sterilizing Pouch and the Sealing Quality of Slide Gusset Bags

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Background : The ultimate goal of all packaging systems for sterilizations is to guarantee the sterility assurance and to keep sterility maintenance in clinical settings. More than twenty years ago, the sterility maintenance of packaging items after sterilization changed from time related to evident related. However, the evidence of contamination through narrow channel artificially made in the sterilizing bag is not clear evident yet.

Objective : To examine the security of sterilizing bag and the possible contamination through a narrow channel that may occur by incomplete heat sealing on a sterilizing bag.

Method :

1. Sealing securities of one thousand bags after use was tested by using blue ink.
2. A peeling test on a part of the gusset sealing by tensiometer (Strograph®, Toyoseiki).
3. Powder of 0.2µm in average size was employed for pressure penetration test.
4. Sampling test of airborne bacteria through 18 gage injection needle (the inner diameter of 0.94mm) was carried out in order to study the possible air contamination inside the bag through a leak channel.

Results : One thousand pouches previously opened were gathered from thirteen facilities. Among their unpeeled seals on the other side of the opened one, 148 bags were found to have leak channels. One hundred and eight bags were the gusset types. Among them, 108 had leak channels inside, and 11 showed the channel in large 25-cm-wide pouches.

In the peeling test, some leak channels were found in the gusset parts.

In the powder tests, powder leakages were observed when a negative pressure through artificially made channels was placed on with 3-0 surgical suture in the heat sealed parts.

Air contamination through the injection needle shows poor sterility maintainance through leal channel after the sterilization.

Conclusion : This study shows that narrow leak channel on a sterilizing bag may cause the contamination of airborne bacteria even though the possibility of the contamination is not so high. The results of this study propose that much precaution should be paid in clinical settings. Healthcare professionals have to recognize that even such narrow artificial channel should be seen as potentially dangerous and that the prevention it is crucial.