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Performance Evaluation of Propper Chex-All Pouches.

## Double-pouch packaging for sterilization in steam cycles.

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The new regulations [1] require that manufacturers of paper-plastic pouches should validate the use of their pouches for double-pouch packaging.

Pouches tested: Propper Chex-All® II and Chex-All® III
Steam cycles: Pre-vacuum steam sterilization at 272°F for 4 min
Gravity displacement steam sterilization at 250°F for 30 min
Half-cycle exposures at 272°F in pre-vacuum and at 250°F in gravity sterilizers[2]

**Methods:**

The double-pouching sets were assembled according to the recommended practices: we used two consecutive sizes of pouches, put a smaller one inside a larger one in the way that paper side of the smaller one was positioned to the paper side of the larger one. The internal pouches were put inside the larger ones flat with no bending. The study was performed on three different lots of each type of pouche.
The steam penetration and sterilization conditions inside internal pouches were tested using Strate-Line® chemical indicators and Duo-Spore® biological indicators. Both indicators were positioned inside the small pouches in the way that allows monitoring different parts of the pouches. Then the pouches were sealed and placed vertically on a rack in the sterilizer without bending. This practice is done according to the AAMI recommended practices ST-79:2006, Section 8.5.2, Paper-plastic pouches. Then the pouches were subject to either gravity displacement or pre-vacuum steam sterilization in standard and half-cycles.
After processing, the pouches were checked for their external and internal pre-printed (only for Chex-All® II pouches) indicators. Also, Strate-Line® chemical indicators inside the smaller pouches are checked and the Duo-Spore® strips are incubated at 56°C for 48 hours in a tryptic soy broth to see if any bacterial growth occurs after sterilization. All data are recorded and information on the cycle, time, and location of experiment is recorded for verification and future validation. To evaluate how typical size metal content (heat sink) can affect the performance of the pouches, the experiment was repeated in both, pre-vacuum and gravity cycles with the internal pouches, containing standard surgical instruments, suitable for these sizes of the pouches. The attainment of sterilization conditions was monitored using Strate-Line® indicators, positioned in a way that allows monitoring different parts of the pouches.

**Summary:**

In the experiments all chemical and biological indicators inside internal Chex-All® II and Chex-All® III pouches demonstrated attainment of adequate sterilization conditions in gravity (250°F) and pre-vacuum (272°F) standard recommended cycles and half-cycles. The chemical indicators changed colors to the end-point in all tested parts of the pouches, and the biological indicators demonstrated no growth after the exposure. The results were reproducible on three different lots of each type of pouche.

**References:**

1. ANSI/AAMI/ST-79: 2006 with addendums 2007 and 2008. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Pages 66-72, Section 8.5.2 Paper-Plastic Pouches. Arlington 2009.
2. US Department of Health and Human Services. FDA guidance for industry – Premarket notification [510k] submissions for medical sterilization packaging systems in health care facilities.