

Paper Pouch, Soaker Sheet and Tray Liner Steam Sterilization Verification Summary

Title: Healthmark (Wipak) brand paper pouches, (Clinipak) brand soaker sheets and tray liners for use in a High-Vac Steam Sterilization Cycle.

Purpose: To demonstrate the sterilization efficacy and validate the use of paper pouches, soaker sheets and tray liners in case containers or wrapped trays (single use wrap).

Materials:

Tray Design:

Test in Wrapped Instrument trays: A full set of instruments was used. A Biological Indicator and Chemical indicator were placed in each bag. A bag was placed in each corner and the center of the tray.

Test in Rigid Containers: full sets of instruments were used. A Biological Indicator and a Chemical indicator were placed in each bag. A bag was placed in each corner and the center of the tray.

Two sizes of paper pouches were used along with the tray liner and soaker sheet if appropriate. Each tray liner, soaker sheet, biological, wrapper and chemical indicator had a consistent lot number.

Experimental Procedure:

Load Configuration Design:

Maximum load test: Two test trays/containers were placed on the bottom shelf over the drain and two test trays/containers on each of the other sterilizer shelves. For example, to test a sterilizer with three shelves, six trays/containers are used. The chamber otherwise is fully loaded with conventionally packaged items (they are documented on log sheet). A total of 6 instruments sets per test cycle ran. A total of two load configurations were used each with a different style of wrap (rigid containers & single use wrapped tray). However, the sets were identical in instrument size.

Small load test: One test tray/container was placed on the bottom shelf over the drain in an otherwise empty chamber. Two cycles ran, one of rigid containers and the other of wrapped.

The biological indicators were placed in the most difficult-to-sterilize and accessible location within the loads as determined by AAMI ST33 guidelines.

The maximum and small load tests are described in AAMI ST 33 and are suggested test methods to be used by healthcare professionals for testing products.

Test Results: All 70 biological indicators from the sets were sterile at the end of the 48-hour incubation period. The controls showed positive growth.

Conclusion: The Healthmark (Wipak) brand of paper pouches, (Clinipak) brand of soaker sheets and tray liners have been verified for use in rigid case containers and wrapped instrument sets.

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