Healthmark Paper Sterilization Bags-
Validation for use in a Wrapped Tray or Rigid Container
PB1-10/PBTO

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Steam Sterilization Efficacy-To validate the sterilization efficacy of Healthmark Paper Sterilization Bags.

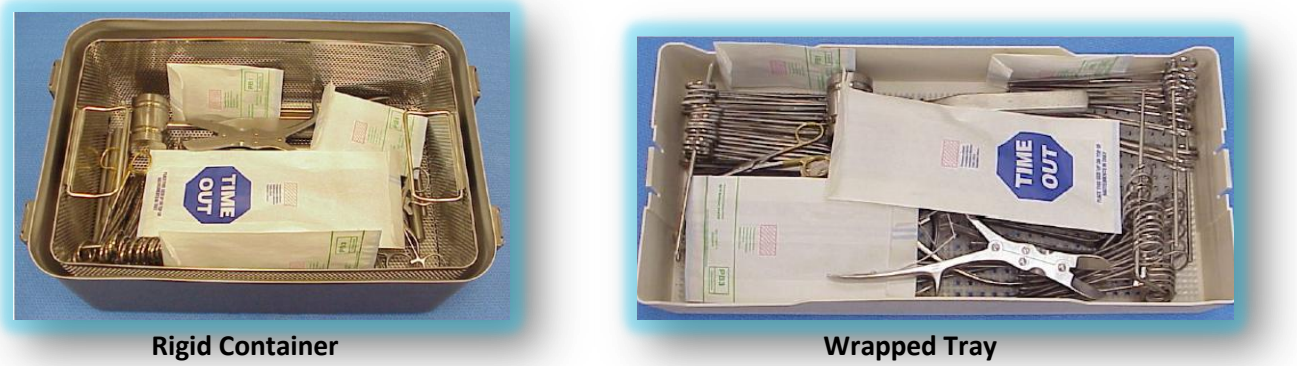
Materials:

Healthmark Sterilization Bags (PBTO, PB1, PB3)
Solid Bottom Rigid Container
Full set of instruments
Biological Indicators
Chemical Indicators

Procedure:

Steam sterilization efficacy was validated using the biological indicator (BI) overkill method.

- Devices were inoculated with *Geobacillus stearothermophilus* spores
- Devices were placed both within Healthmark Paper Sterilization Bags and loaded into a tray or rigid container. (See Fig) Inoculated devices were also placed outside of the bags to determine whether they impeded sterilization of other items.
- Integrators were included to assess adequate steam penetration
- Each was processed for one-half cycle (270°F, 2 min exposure, 20 min dry)
- Inoculated devices were tested for viability of microorganisms



Rigid Container **Wrapped Tray**

Figure 1. Load Configuration

Results:

All test samples were:

- ✓ ***Negative for growth***
- ✓ ***Penetrable to steam***

Controls were positive for growth.

Dry Time

Healthmark Paper Bags meet or exceed the minimum criteria for a validated 30 minute dry time.

Biocompatibility

Healthmark Paper Sterilization Bags are ***Non-Toxic.*** Biocompatibility was determined using the MEM Elution Cytotoxicity Assay for a fully loaded tray containing three count sheets (printer: HP930c, ink: 45 HP inkjet cartridge, paper: Staples® 30% Recycled Copy Paper, 8 1/2"x11") within a Healthmark Paper Sterilization Bag.

All validation tests meet AAMI, ISO, and USP guidelines. If you would like more detailed data please contact Healthmark INDUSTRIES at Healthmark@hmark.com.