

# Product Technical Data Sheet

Form No.: FTP-082 Rev.:A

## Product Name: SteriTec US Steri-Pak LF Bowie-Dick Test Pack

**Product Type:** Bowie-Dick Indicator

**SteriTec Reorder No.:** BD 111

**Description:** The US Steri-Pak LF Bowie-Dick Test Pack is designed as an environmentally safe lead free method for daily monitoring of pre-vacuum steam sterilizers to detect air leaks, inadequate steam penetration and vacuum pump failures. The Steri-Pak LF is designed to simulate a large towel pack as defined by AAMI ST66 and meets the EN 867-3 test methods for detecting temperature drops and the presence of air. The test pack is placed in the sterilizer in the most difficult to sterilize area and run through a sterilization cycle for 3.5 minutes at 132° C. A test pack consists of blotter sheets, and one test sheet sandwiched between layers in the approximate middle of the pack. On the outside of the test pack box is a process indicator label that informs the user of the test pack sterilization status.

### Performance Characteristics:

If no appreciable air is present in the sterilizer chamber after vacuums are drawn, the steam will penetrate to the middle of the test pack and turn the indicator sheet a uniform black color. If a small amount of air is present, sufficient to cause a 2° C temperature drop, the air will migrate to the middle leaving the center of the sheet a blue color rather than uniform black. The process indicator label spot on the outside of the test pack box, turns black when exposed to steam sterilization.

**Color Change:** Indicator sheet - Blue to Black for complete change and no air leak  
Process Indicator Spot – Blue to Black

**Complete Color Change Time:** 3.5 minutes at 132° C with no air leaks

**Indicator Stability:** Before and After Exposure = Excellent

### Physical Characteristics:

**Background Print Color:** Black

**Dimensions:** Indicator = 4.99" X 3.75. Test Pack = 5.065" X 3.825" X 0.6875"

**Substrate Material:** Indicator = 70 pound text. Pack Sheets = Blotter paper

**Quantity / Box:** 1

**Boxes / Case:** 20

**Selling Unit:** Case

### Environmental Limitations:

**Storage:** 60° - 90° F (15° - 30° C) at 35 - 60% humidity

**Shelf Life:** 3 years from date of manufacture

**FDA 510(k) Release to Market Date:** June 10, 1999, K990246

### Standards Classifications:

AAMI ST60, Class 2

EN 867-1, Class B

ISO 11140-1, Class 2