



## Product Technical Data Sheet

Form No.: FTP-082 Rev.: E

### 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 standard towel pack as defined by ANSI/AAMI/ISO 11140-5 test methods for evaluating the sterilizer's effectiveness of steam penetration and air removal. 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 in a standard towel pack, 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 on outside of box – Blue to Black

**Critical Parameters:** (in a standard hospital pre-vacuum steam sterilizer)  
3.5 minutes at 132°C

**Stated Values:** Not applicable for Bowie-Dick tests

**Indicator Stability:** Before Exposure = Excellent  
After Exposure = Good, when stored away from a light source

#### Physical Characteristics:

**Background Print Color:** Black

**Dimensions:** Indicator = 4.9" X 3.75. Test Pack = 5.065" X 3.825" X 0.6875"

**Substrate Material:** Indicator = 80 pound Cover. Pack Sheets = Blotter paper

**Quantity / Box:** 1

**Boxes / Case:** 20

**Selling Unit:** Case

#### Environmental Limitations:

**Storage:** 50° - 100°F (10° - 38°C) at 10 - 70% humidity. Store exposed indicator sheets away from light sources.

**Shelf Life:** The expiry date is printed on the product packaging.

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

#### Standards Classifications:

ANSI/AAMI/ISO 11140-5