



## Product Technical Data Sheet

Form No.: FTP-052 Rev.: F

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

**Product Type:** Bowie-Dick Indicator

**Reorder Number:** BD 108/S-T

**Description:** Steri-Pak LF Sub-Trans Bowie-Dick Test Packs are designed as an environmentally safe lead free method for daily monitoring of pre-vacuum steam sterilizers that run sub-atmospheric and/or trans-atmospheric cycles as defined in the ISO 11140-4 test methods for detecting temperature drops and the presence of air. The Test Pack was designed to detect air leaks, inadequate steam penetration and vacuum pump failures. 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 134°C. A test pack consists of several blotter sheets, and a test sheet packaged in a box. The correctly assembled test pack simulates the resistance of a Bowie-Dick test pack.

#### 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 two-degree temperature drop in a Bowie-Dick towel pack, the air will migrate to the middle of the test pack turning the center of the sheet as indicated by a bluish color rather than a uniform black.

**Color Change:** Blue to Black for complete change and no air leak

**Critical Parameters:** *(in a standard pre-vacuum steam sterilizer)*  
134°C for 3.5 minutes with no air leaks (end point achieved)

**Stated Value:** *(as determined in a steam resistometer)*  
Not Applicable for bowie-dick test packs.

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

#### Physical Characteristics:

**Lamination:** Two blotter sheet and indicator sheet laminated on one side.

**Dimensions:** 4.90" X 3.75"

**Indicator Substrate Material:** 80 pound cover

**Quantity / Box:** 1

**Boxes / Case:** 20

**Selling Unit:** Case

#### Environmental Limitations:

**Storage:** 32° - 104°F (0° - 40°C) at 10 - 70% humidity. After exposure to a steam sterilization cycle, do not expose to light sources for extended periods of time.

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

**FDA 510(k) Release to Market Date:** Not released for U.S. marketing.

#### Standards Classifications:

EN ISO 11140-1, Class 2

ISO 11140-4

**ITEM:** SteriTec Steri-Pak LF Sub-Trans Bowie-Dick Test Pack, BD 108/S-T

**PRODUCT TECHNICAL DATA SHEET, FTP-052**

**Change History**

<b>CO Number</b>	<b>Rev</b>	<b>Change Description</b>	<b>Date Released</b>
1506	E	Updated standards to ISO 11140-4.	04/21/2008