



Product Technical Data Sheet

Form No.: FTP-082 Rev.:C

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 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: 32° - 104° F (0° - 40° C) at 10 - 70% humidity. Store exposed indicator sheets away from light sources.

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

ISO 11140-1:2005, Class 2