



Product Technical Data Sheet

Form No.: FTP-093 Rev.: D

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

Product Type: Bowie-Dick Indicator

Reorder Number: BD 109/S-T

Description: Steri-Pak Kit LF Sub-Trans Bowie-Dick Test Packs are 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 Kit LF Sub-Trans Test Pack is designed to meet the ISO 11140-4 test methods for detecting temperature drops and the presence of air in sub-atmospheric and trans-atmospheric steam sterilization cycles. 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 kit consists of several blotter sheets, and 30 test sheets 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, the center of the sheet will display a bluish color rather than a uniform black.

Color Change: Blue to Black with no air leak

Critical Parameters:(in a standard hospital pre-vacuum steam sterilizer)
3.5 minutes at 134°C

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

Indicator Stability: Excellent before and after sterilization.

Physical Characteristics:

Each kit consists of two sets of blotter cards and 30 indicator sheets. One indicator sheet is placed in the middle of a blotter card set to form a test pack. The test pack is then placed in the kit holding frame (REF BD 105) and clamped. Blotter card sets can be used for 15 test runs. The Cover Card has numbers designating each time the set has been tested. The test run number is marked off after each use.

Dimensions: 5.6875" X 4.5"

Indicator Substrate Material: 80 lb Cover

Quantity / Box: 30 indicators and 2 blotter card sets

Boxes / Case: 16

Accessories: Test Pack Holding Frame (REF BD 105). Sold separately.

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, when stored at the conditions listed above.

FDA 510(k) Release to Market Date: None. Not for distribution in US.

Standards Classification:

ISO 11140-1: 2005, Class 2

ISO 11140-4: 2007

ITEM: SteriTec Steri-Pak Kit LF Sub-Trans Bowie-Dick Test Pack, BD 109/S-T

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Change History

CO Number	Rev	Change Description	Date Released
1509	D	Updated standards.	04/24/2008