



Product Technical Data Sheet

Form No.: FTP-062 Rev.: F

Product Name: SteriTec EU PLUS Bowie-Dick Test Pack

Product Type: Bowie-Dick Indicator

SteriTec Reorder Number: BD 113 (wrapped) & BD 113+ (boxed)

Customer Name: ID&CO

Customer Catalog No.: BD 113 (wrapped) & BD 113+ (boxed)

Description: The EU PLUS Bowie-Dick Test Packs are designed as a 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 paper sheets, and a laminated indicator sheet that are wrapped and sealed. 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, the air will migrate to the middle of the test pack turning the center of the sheet as indicated by a blue color rather than a uniform black.

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

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

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

Indicator Stability: Before and After Exposure = Excellent

Physical Characteristics:

Lamination: Indicator sheet

Dimensions: 4.9" X 3.75"

Indicator Substrate Material: 80 pound cover

Quantity / Pack or Box: 1

Pack or 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:

ISO 11140-1, Class 2

ISO 11140-4

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