

3M™ Comply™ Bowie-Dick Type Test Pack 1233LF

Product Description

The 3M™ Comply™ Bowie-Dick Type Test Pack 1233LF is equivalent in performance to the Bowie-Dick towel pack described in AAMI ST-79. The test pack consists of a lead-free steam-sensitive chemical indicator test sheet positioned in a package of layered porous materials. The test sheet consists of a lead-free steam-sensitive chemical indicator ink printed on paper as a yellow-colored diagonal pattern and is positioned near the center of the porous pack. The test sheet will turn a uniform dark brown/black color except when air removal failures such as air leaks occur. An air removal failure is indicated by a lighter-colored area in the indicator ink pattern of an otherwise dark-colored test sheet. 3M™ Comply™ Bowie-Dick Test Packs meet ISO 11140-5:2007 and are Type 2 (Category s2) Special Indicators as categorized by ISO 11140-1:2014.

Indications for Use

The 3M™ Comply™ Bowie-Dick Type Test Pack 1233LF is designed for testing air removal efficiency of 132- 134°C (270- 273°F) dynamic-air-removal steam sterilizers.

Contraindications

Do not use the 3M™ Comply™ Bowie-Dick Type Test Pack 1233LF for air removal monitoring of gravity displacement steam, dry heat, ethylene oxide, or other low temperature sterilization processes.

Instructions for Use

1. Test Frequency

The Bowie-Dick test must be carried out each day in an empty sterilizer before the first processed load. A warm-up cycle (dry time may be omitted) should be run first to properly heat the sterilizer prior to the Bowie-Dick test. If the sterilizer is in use for 24 hours each day, the test may be done at any time but preferably at the same specified time each day. The Bowie-Dick test should also be performed as part of qualification testing following sterilizer installation, relocation, malfunction, major repairs, and sterilization process failures.

2. Test Cycle

Before putting the 3M™ Comply™ Bowie-Dick Type Test Pack 1233LF in the sterilizer, inspect the lead-free indicator on the label of the test pack. If any part of the indicator on the label has changed from yellow to light brown or darker, the test pack should not be used. Place the test pack horizontally, label side up, on the bottom shelf of the rack, over the drain in an otherwise empty, dynamic-air-removal steam sterilizer. Run the sterilizer for 3.5 minutes at 132- 134°C (270- 273°F). If timer must be set for full minute intervals, the test may be run for 4 minutes. (Do not process for more than 4 minutes; results will be invalid.)

3. Interpretation of Results

Promptly remove the test pack from the sterilizer after completion of the cycle. Once processed, the indicator ink on the label will change from yellow to light brown or darker. Allow the test pack to cool; retrieve and examine the test sheet.

Pass - A satisfactory test result is indicated by a test sheet that shows uniform dark brown/black color development. A uniform color change result indicates rapid steam penetration, adequate air removal, and lack of significant air leaks. (See picture for example)

Fail - An unsatisfactory test result is indicated by a test sheet that shows non-uniform color development with a lighter-colored area in the indicator ink pattern, usually near the center of the test sheet. A non-uniform color change result is caused by residual air in the sterilizer chamber and indicates incomplete air removal from the chamber or failure of the sterilizer to hold a vacuum during the test cycle. (See picture for example) If a non-uniform color change is noted, it should be reported immediately to the supervisor and the sterilizer should not be used until it is examined for possible malfunction.

4. Maintain all test sheets in records.

Storage

- Best stored under normal room conditions: 59-86°F (15-30°C), <50% relative humidity.
- Protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents.
- After use the indicator sheet will not change visually within 24 months when stored at above conditions.

Explanation of Symbols:

 Catalogue Number


 Caution, see instructions for use

 Do not reuse

 Use by date

 Batch code

 Manufacturer

 Date of manufacture

 Product is designed for testing air removal efficiency in dynamic-air-removal steam cycles.

 Product is designed for use with steam sterilization cycles.

Made in U.S.A. by

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