

3M™ Comply™ Bowie-Dick Plus Test Pack 00135LF

Product Description

The 3M™ Comply™ Bowie-Dick Plus Test Pack 00135LF is equivalent in performance to the Bowie-Dick towel pack described in AAMI ST-79. The test pack consists of lead-free steam-sensitive chemical indicator test sheets positioned in a package of layered porous materials. The primary 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 primary 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. The test pack also contains an Early Warning sheet which is placed at a lower point in the pack than the primary test sheet. The Early Warning sheet has a lead-free steam-sensitive chemical indicator circle that turns from yellow to dark brown/black for early detection of air removal failures before they appear on the primary 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 Plus Test Pack 00135LF 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 Plus Test Pack 00135LF 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 Plus Test Pack 00135LF 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 conducted for 4 minutes. (Do not process for more than 4 minutes; results will be invalid.)

3. Interpretation of Results

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

4. Primary Test Sheet

Pass - A satisfactory test result is indicated by a primary 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 primary test sheet that shows non-uniform color development with a lighter-colored area on the test sheet, usually near the center of the indicator ink pattern. 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.

5. Early Warning - If the yellow indicator ink circle on the Early Warning test sheet does not turn to a color that is as dark as or darker than the color standard, impending sterilizer failure is indicated; routine sterilizer maintenance should be scheduled soon.

Note: A color interpretation chart is available upon request from the 3M Health Care Helpline at 1-800-228-3957.

6. 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 sheets 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

 **3M Health Care**

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3M.com/infectionprevention

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