# **Product Description**

The 3M<sup>TM</sup> Comply<sup>TM</sup> Bowie-Dick 00130LF test sheets are large-sized sheets printed with a lead-free steam-sensitive chemical indicator ink in a diagonal pattern to be used in a standard Bowie-Dick towel pack as described in AAMI ST79. 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 brown/black test sheet.

## **Indications for Use**

The 3M™Comply™ Bowie-Dick Test Sheet 00130LF is designed to be used as the indicator sheet placed inside a facility-assembled Bowie-Dick towel pack for testing air removal efficiency of 132- 134°C (270- 273°F) dynamic-air-removal steam sterilizers.

## Contraindications

Do not use the 3M<sup>™</sup> Comply<sup>™</sup> Bowie-Dick Test Sheet 00130LF 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 Pack Assembly

Prepare a test pack of 100% cotton surgical towels that are clean and preconditioned. The towels should be folded to a size 9 inches (250 mm  $\pm$  20 mm) in one direction and 12 inches (300 mm  $\pm$  20 mm) in the other direction, and placed one above another. The height of the test pack should be 10 to 11 inches (250 and 280 mm) and the weight of the pack should be 8.8 pounds (4 kg  $\pm$  5%).

Place a single 3M<sup>™</sup> Comply<sup>™</sup> Bowie-Dick Test Sheet 00130LF in the geometric center of the test pack; the test sheet should be oriented ink side up. Place the towel pack containing the test sheet in a single loosely applied wrap and tape securely.

#### 3. Test Cycle

Place the test pack horizontally, 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.)

#### 4. Interpretation of Results

Promptly remove the test pack from the sterilizer after completion of the cycle. Allow the test pack to cool, retrieve and examine the test sheet.

Pass - A satisfactory 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.

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. If a non-uniform color change is noted for the first test, retest the sterilizer. If the second test also shows a non-uniform color change, it should be reported immediately to the supervisor and the sterilizer should not be used until it is examined for possible malfunction.

#### 5. Maintain all test sheets in records.

#### Storage

Best stored in original packaging in a dry (<50% RH) condition at room temperature [15-30°C (59- 86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents. After use the indicator will not change visually within 24 months when stored at above conditions.

#### **Explanation of Symbols:**

**REF** Catalogue Number

A Caution, see instructions for use

(2) Do not reuse

Vise by date

LOT Batch code

Manufacturer

M Date of manufacture

[AR REMOVAL] Product is designed for testing air removal efficiency in dynamic-air-removal steam cycles.

**STEAM** Product is designed for use with steam sterilization cycles.

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JM Health Care 🖬

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