

Steri-Pak Kit LF Sub-Trans Bowie-Dick Test Pack

BD 109/S-T

Indications for Use

The Steri-Pak LF Sub-Trans Bowie-Dick Test Pack is designed for daily monitoring of pre-vacuum steam sterilizers operating at 134°C for 3.5 minutes and 121°C for 11 minutes with sub-atmospheric or trans-atmospheric cycles as defined in ISO 11140-4 to detect the presence of residual air. The pack materials were designed for use in multiple test cycles.

Color Change

The indicator will change from blue to black when exposed to a steam sterilization cycle with acceptable vacuum cycles.

Instructions for Use

The Bowie-Dick test is conducted each day in an empty sterilizer prior to processing any loads.

1. Run a warm up cycle to properly heat the sterilizer.
2. Place one Steri-Pak LF Bowie-Dick indicator sheet between two reusable test pads.
3. Record date of test on test record card (numbered circles 1-15).
4. Insert test packet with indicator centered into the metal holder (BD 105) and close clamps on both ends.
5. Place metal holder with test pack on bottom of the sterilizer nearest to the drain. The holder must lay horizontal.
6. Run the sterilizer for 3.5 minutes at 134°C or 11 minutes at 121°C.
7. Remove the test pack from the sterilizer and allow the pack to cool.
8. Remove indicator from between the pads. Leave pads in holder, unclamped, for use with the next test. Allow the pack to dry prior to next use.
9. If the indicator sheet is still warm upon removal from the pack, do not place it on a cold surface. The indicator may return to original color if a cold surface is encountered prior to indicator equilibration.

Interpretation

1. If the sterilizer is functioning properly, the indicator will show a uniform black color change throughout the entire pattern.
2. If a significant amount of residual air is present, the indicator shows a blue area in the center.
3. On rare occasions, bubbling of the laminate may occur. If this happens, analyze the card for appropriate color change as instructed above.

Safety Precautions

CAUTION: the metal test pack holder will be hot and should be handled carefully to avoid thermal injury. Wear insulated gloves to protect hands.

Storage

- Store at normal room temperature 10° - 38°C and 10-70% R.H.
- Store exposed indicator sheet away from light sources

Expiry Date

The expiry date is printed on the product packaging. Do not use after expiration date listed on the packaging.

LOT Number

A unique identification code, [LOT], is printed on each indicator and packaging labels.

Interfering Substances or Conditions

There are no known interfering substances or conditions that could affect the intended use of the indicator or adversely affect the indicator performance.

Release of Toxic Substances

The indicator releases no known toxic substances in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

Declaration of Conformity

The Steri-Pak Kit LF Sub-Trans Bowie-Dick Test Pack indicator conforms to all applicable portions of ISO 11140-1 Type 2 indicators for use in specific tests and ISO 11140-4.

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Steri-Tec Products Mfg. Co., Inc.
Member of the Getinge Group
74 Inverness Drive East
Englewood, CO 80112 USA

www.getinge.com/steritec