



4/10 Load Challenge Pack

REF LT 111

Directions For Use

INDICATIONS FOR USE

The SteriTec 4/10 Load Challenge Pack was designed for use in pre-vacuum steam sterilizers operating at 132° or 135°C (270° or 275°F). It allows the operator to verify sterilizer performance with standard and extended hold times set by hospital personnel.

COLOR CHANGE

During steam sterilization the indicators will change from Purple to Green when exposed to the appropriate sterilization process parameters.

CRITICAL PARAMETERS (in hospital steam sterilizer – color change end points of the integrator card inside the challenge pack)

TEMP.	4 MIN	10 MIN
132°C (270°F)	4 minutes	10 minutes
135°C (275°F)	3 minutes	8 minutes

STATED VALUES (as determined in a steam sterilization resistometer –color change end point of the integrator card only)

TEMP.	4 MIN	10 MIN
132°C (270°F)	4.9 minutes	12 minutes
135°C (275°F)	4 minutes	9 minutes

INSTRUCTIONS FOR USE

1. Load the sterilizer as normal.
2. Place the Test Pack on the lowest shelf or most difficult-to-sterilize location.
3. Process the load, normal cycle.
4. Remove the Test Pack from the sterilizer.
5. Open the Test Pack by pulling the tab across the front of the box, remove the pack, and examine integrator card located in the middle of the pack.
6. Record the appropriate information on the front of the card and circle the temp/time the test pack was exposed to.

SAFETY PRECAUTIONS

CAUTION: The test pack may be hot and should be opened carefully to avoid thermal injury.

INTERPRETATION

Each indicator changes color from purple to green at or near the end point of each chosen cycle. The color change end point times may vary slightly from sterilizer to sterilizer and cycle-to-cycle depending upon the length and temperature of the pre-vacuum phase and length of the drying phase.

- With exposure to extended pre-vacuum sterilization cycles of 4 minutes at 132° or 3 minutes at 135°C, the 4 MIN indicator will change to Green and the 10 MIN indicator may change to a Gray/Purple incomplete color change. If the sterilizer has a long come up time the 10 min spot may turn green.
- With exposure to extended pre-vacuum sterilization cycles of 10 minutes at 132° or 8 minutes at 135°C, both indicators will change to Green.

STORAGE

Store at temperature ranges of 50°-100°F (10° - 38°C) and 10 - 60% R.H. Protect from moisture and excess humidity.

EXPOSED INDICATOR STABILITY

The integrator card color change is stable after exposure to steam sterilization conditions. The indicator will not revert back to the original color and can be utilized as a permanent record.

EXPIRY DATE

The expiry date is printed on product packaging.

LOT NUMBER

A unique identification code, **LOT**, is printed on each indicator card, box, and case labeling. Any color change observed in the lot number should be ignored. The lot number is NOT meant for use as a chemical indicator.

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

SteriTec Products Mfg. Co., Inc. declares that the integrator card conforms to the emulator performance requirements listed in ISO 11140-1 Class 6 indicators.

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