

# Heli-Check FORM

## LT 112

### Indications for Use

Heli-Check FORM is for LTSF (low temperature steam/formaldehyde) sterilizers to verify air removal, formaldehyde exposure and deep vacuum achievement necessary for the sterilization of hollow lumen instruments. The Heli-Check FORM is suitable for daily LTSF sterilizer monitoring.

### Color Change

The indicator will change from red to green when exposed to a LTSF sterilization cycle with acceptable vacuum cycles.

### Instructions for Use

1. Unscrew the indicator containment capsule from the threaded end cap.
2. Fold the indicator in half with the indicator ink facing inward.
3. Insert the indicator into the indicator capsule with the fold first.
4. Reconnect the indicator containment capsule to the end cap by screwing clockwise until snug.
5. Place the assembled Heli-Check device into the sterilizer, in a horizontal position, near the coolest location in the sterilizer.
6. Run the cycle as recommended by manufacturer.
7. Dispose of the helix device after 250 cycles.

### Interpretation

1. At the end of the cycle, remove the Heli-Check device from the sterilizer and allow the device to cool before opening.
2. Unscrew the indicator containment capsule and remove the indicator.
3. Color change from red to green indicates satisfactory air removal and formaldehyde exposure within the load. The presence of any red color remaining indicates insufficient sterilization conditions and re-sterilization is recommended.
4. Remove protective adhesive backing by bending the indicator. Adhere individual processed indicators to records as specified by hospital policy.
5. Allow the device to cool and dry prior to next use. Look for residual moisture that could block the free transmission of air or formaldehyde gas throughout the entire length of the lumen. Do not use if water is present. Place the open device in a warm dry area.

### Safety Precautions

*CAUTION: the Heli-Check device will be hot and should be handled carefully to avoid thermal injury.*

### Storage

- Store at normal room temperature between 10° – 38°C and 10-70% R.H.
- Protect from moisture and excess humidity.

### 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.