Heli-Check Hollow Load PCD

REF LT 104

Directions for Use

INDICATIONS FOR USE
Heli-Check Hollow Load Process Challenge Device (PCD) (Figure 1) is compliant with EN 867-5 for pre-vacuum steam sterilization of hollow loads. Heli-Check hollow load PCD verifies air removal, deep vacuum achievement necessary for lumens, steam penetration, and exposure levels. It is a reusable device that can be utilized in each sterilization load, as an independent control device for decisions regarding load release or for daily release of pre-vacuum steam sterilizers should hollow load tests be required.

CRITICAL PARAMETERS *(in a standard hospital steam sterilizer)*
3.5 minutes at 134°C

PACKAGING
The Heli-Check can be reused for 250 cycles and consists of 1 Heli-Check PCD device and 1 re-sealable foil pouch containing 250 Heli-Check monitors.

DESCRIPTION
The disassembled Heli-Check Process Challenge Device consists of the following parts: a standardized lumen connected to an end-cap (Figure 2), an indicator capsule with sealing "O' ring, Class 2 ink chemistry.

INSTRUCTIONS FOR USE
1. Unscrew the indicator capsule from the lumen end cap.
2. Remove a Heli-Check indicator from the protective pouch and fold it in half at the score line with the indicator ink facing inward.
3. Insert it into the indicator capsule with the fold first. (Figure 3)
4. Replace the indicator capsule by twisting by hand until snug. *NOTE: DO NOT over tighten the cap using tools.*
5. Place the assembled Heli-Check device in the sterilizer, in a horizontal position, near the coolest location in the sterilizer (usually on a shelf, near the drain, next to the door).
6. Conduct the intended sterilizer cycle.
7. At the end of the cycle, remove the Heli-Check PCD from the sterilizer and wait one minute to allow the device to cool before opening. ***CAUTION: The Heli-Check device may still be hot. Use hand protection if necessary.***
8. Open the indicator capsule and remove the Heli-Check monitor. Read the results. (Figure 4)
9. Document the results as required by hospital procedures.
10. Allow the device to cool and dry prior to next use. Look for one or more slugs of water that could block the free transmission of air or steam throughout the entire length of the lumen. Do not use if water slugs are present. Placing the open device in a warm dry place can accelerate drying.

INTERPRETATION OF RESULTS
Color change from Pink to Black indicates satisfactory air removal and steam penetration within the load. The presence of any pink color remaining indicates insufficient sterilization conditions and re-sterilization is recommended. Follow hospital procedures for re-sterilization of the load.

REMOVING THE RELEASE LINER
Remove release liner by bending the folded monitor back on itself, which will cause the release liner to pull away from the monitor slightly at the fold line (Figure 5). Grasp the release liner and pull to remove (Figure 6). Adhere individual monitors to records as specified by hospital policy.

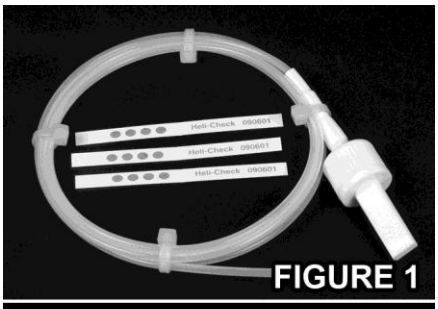
STORAGE
Store at room temperature 50° - 100°F (10°- 38°C). Do not remove Heli-Check monitors from protective foil pouch until ready for processing. Protect from moisture and excess humidity by resealing the foil bag after each use. Once processed, the monitor strips are stable and require no special storage conditions.

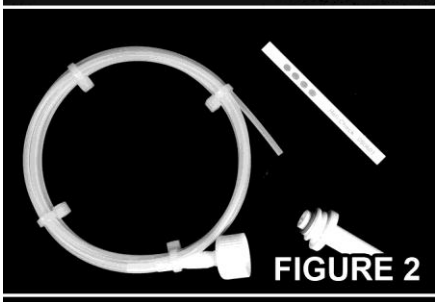
EXPIRY DATE
The expiry date is printed on the product packaging.

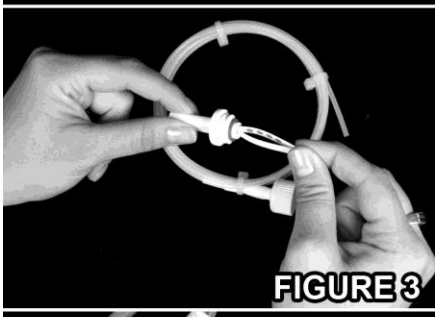
LOT NUMBER
A unique identification code, LOT, is printed on each indicator and packaging labels.

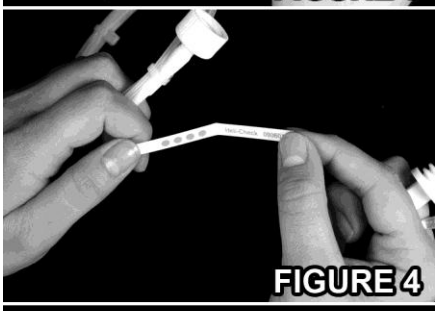
INTERFERING SUBSTANCES OR CONDITIONS
There are NO KNOWN INTERFERING SUBSTANCES OR CONDITIONS that could affect the intended use of the indicator or adversely affect the indicator performance.

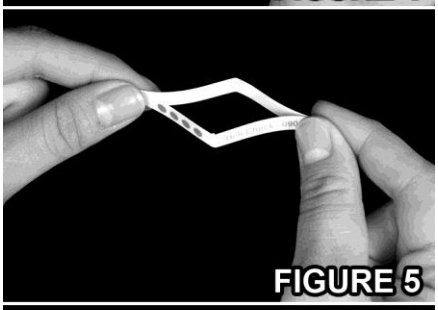
RELEASE OF TOXIC SUBSTANCES
The indicator releases NO KNOWN TOXIC SUBSTANCES in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

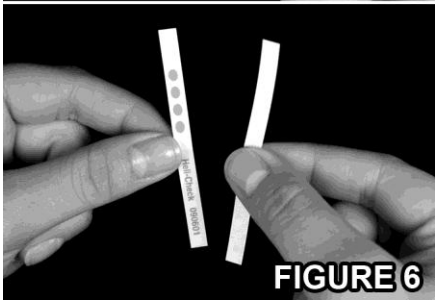












SteriTec Products, Mfg. Co., Inc.
74 Inverness Drive East
Englewood, CO 80112 USA
(303)660-4201 FAX (303)660-4213