



Product Technical Data Sheet

Form No.: FTP-182-1 Rev.: C

Product Name: SteriTec HeliPac PCD –
134 Refill Kit

Product Type: Chemical Indicators & HeliPac Process Challenge Device

SteriTec Reorder Number: LT 102/134/RF

Description: The SteriTec HeliPac Refill Kit supplies additional test monitors, Leak Test monitors, silicone gaskets, and porous pads for continuous use of the HeliPac Process Challenge Device. The SteriTec HeliPac test monitor provides an integrated response to steam sterilization at 134°C for pre-vacuum sterilizers. The HeliPac test monitor is design to function within the HeliPac load challenge device. The HeliPac test monitor gives a visible confirmation of the attainment of sterilization conditions at the location within the sterilizer chamber. A Leak Test monitor is supplied with the test monitor and gives an early warning of possible problems with the steam penetration of the HeliPac load challenge device.

Performance Characteristics:

The HeliPac test monitor has two different timing indicator inks printed for each indicator. The user can determine:

1. If only the first indicator square turns green, the integrator has been subjected to insufficient steam sterilization conditions.
2. If both the indicator spots turn green, sufficient steam sterilization conditions were present.
3. If the Leak Test monitor has changed color to black, the HeliPac load challenge device was not properly sealed.

Color Change: Test Monitor: Purple to Green, Leak Test: Blue to Black

Critical Parameters: (in a standard hospital steam prevacuum sterilizer)

First Square – 1.7 minutes (-15/+0 sec) @ 134°C (-1/0 C)

Square Arrow – 5 minutes (-45/+0 sec) @ 134°C (-1/0 C)

Stated Values: (as determined in a steam resistometer) Special Tests not applicable

Indicator Stability: Before and After Sterilization = Excellent

Physical Characteristics:

The HeliPac test monitor is packaged in humidity resistant white foil bags along with one bag of HeliPac Leak Test monitors.

Background Print Color: Green PMS 557U

Dimensions: 1.34" X .51"

Substrate Material: Print Blotter

Lamination: Indicator side

Units / Bag: 20 test monitor cards (15 test strips/card) and 300 Leak Test monitors.

Units / Box: 1 bag of monitors, 20 porous pads, and 1 silicone gasket.

Selling Unit: Box

Environmental Limitations:

Storage: 50° – 100°F (10° – 38°C) in resealable moisture barrier bag provided.

Shelf Life: The expiry date is printed on the product packaging

SteriTec FDA 510(k) Release to Market Date: Not for sale in USA.

Standards Classification:

ISO 11140-1, Class 2