



Ethylene Oxide Helix PCD Test

Ref Code:C-1045

Product Description

Helix PCD test strips (process challenge test) is used as a daily test for pre-vacuum hospital sterilizers and for bench-top gas sterilizers Class B for gas penetration. The Helix PCD test is an excellent test to detect even the smallest amounts of inert gases capabilities.

Helix PCD strips are not replacing routine monitoring of sterilization cycles. This should be done by lot control sets and within pack integrators.

Physical Parameters

Process	Ethylene Oxide
Strip Dimensions	0,5 cm x 7,5 cm
Packaging	250 indicators / pack
Chemical Indicator	Initial color: Yellow Signal color: Brown %100 Toxic Heavy Metals Free

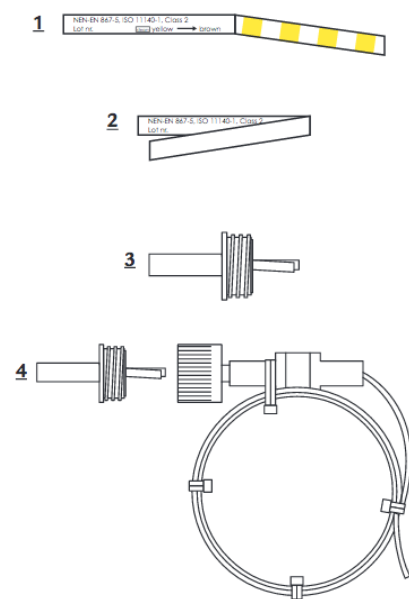
Intended Use

The strips are intended to monitor all cycles within the vaporized ethylene oxide sterilizers. The ethylene oxide strips are intended to be used with sterilization wraps, containers, cassettes, rails or pouches to distinguish between processed and unprocessed units for both Healthcare and Industrial applications.

The strips are for use in all Ethylene Oxide processes.

Instructions for Use




Separate one strip from the indicator board. Insert the STERISTAR C-1045 to C-1131 coded helix tube (80 cm) by folding it through the perforated line in the middle. The test tube complicates the process and the vapor passes through the tube and reaches the indicator strip. The 4 yellow indicator zones on the indicator strip should turn brown.



Upon exposure to Ethylene Oxide, the strips will transition from yellow to a shade of brown. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from yellow to a shade of brown provides indication of exposure to Ethylene Oxide. If signal color is not achieved, this suggests ideal sterilization conditions may not have been met. Colors other than brown should be treated as a process failure.

The endpoint color (brown) of the strip will remain stable for a minimum of 45 days from the date of processing when stored according to the products labeled storage conditions.

Performance Characteristics

Results Availability	Immediately following exposure to E.O. processes
Unexposed*	After E.O. Sterilization Process*
	
Potential Fail Color	
	

*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.



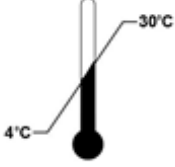
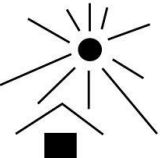

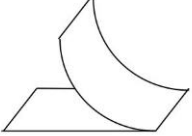


! The signal color achieved from exposure to E.O. may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.).

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators

ISO 13485:2016 Medical devices - Quality management systems

Storage and Shelf Life

	<p>Do not reuse</p>		<p>Keep dry</p>
	<p>4°C to 30°C</p>		<p>Keep away from sunlight</p>
	<p>10% - 40% RH</p>		<p>Self-Adhesive</p>
	<p>Shelf life 4 years from the date of manufacture</p>		
	<p>Keep away from sterilants.</p> <p>Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date.</p> <p>Do not expose this product to Dry Heat, H2O2 or any sterilization processes other than EO.</p>		

Disposal

Discard as general waste.