



PCD Helix Test, Big Scale (6 Indicators)

Ref Code: C-1033

Product Description

Helix PCD test strips (process challenge test) is used as a daily test for pre-vacuum hospital sterilizers and for bench-top steam sterilizers Class B for steam penetration. The Helix PCD test is an excellent test to detect even the smallest amounts of steam penetration 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	Steam
Strip Dimensions	0,6 cm x 13,5 cm
Packaging	250 strips / pack
Chemical Indicator	Initial color: Pink Signal color: Dark Brown / Black %100 Toxic Heavy Metals Free

Intended Use

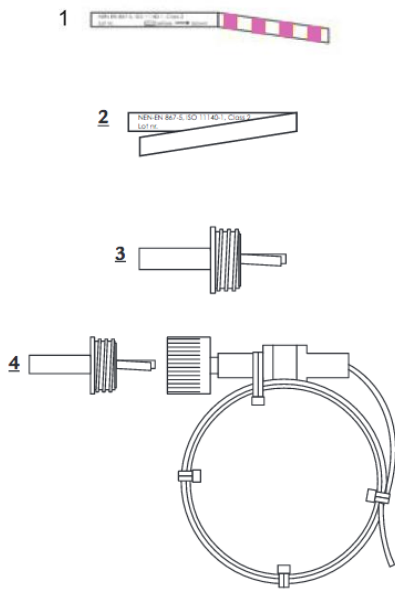
The strips are for use in all Steam sterilization processes.

Steam Process Strip Requirements

- 134 °C 3,5 min. – 121 °C 15 min.



Instructions for Use

Separate one strip from the indicator board. Insert the STERISTAR C-1033 to C-1031 coded helix tube (1,5 M) 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 6 pink indicator zones on the indicator strip should turn black.



Process the packages/items as instructed in the sterilizer validation or manual. Upon exposure, the indicator will transition from pink to dark brown/black. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from pink to a shade of dark brown/black provides indication of exposure. If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 1 minute. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met.

Performance Characteristics

Results Availability:	Immediately following exposure to Steam processes.
Unexposed*	Exposed to 134°C 3,5 min. – 121 °C 15 min. *
	

Potential Fail Color



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





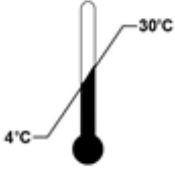
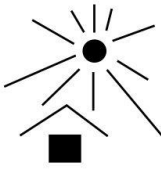

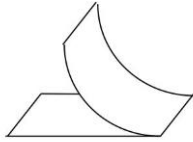


The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a strips, any color change produced during exposure to steam which is close to signal color is considered acceptable.

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, EO, H2O2 or any sterilization processes other than Steam,</p>		

Disposal

Discard as general waste.