



TDS-1031-1 / Rev.00 / 09-2021

PCD Helix Test Tube (1,5M)

Ref Code: C-1031



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
Dimensions	1,5 M
Packaging	1 pieces / pack





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Intended Use

The strips are for use in all Steam sterilization processes with STERISTAR PCD Helix Tests.

Steam Process Strip Requirements

• 134 °C 3,5 min. – 121 °C 15 min.

Instructions for Use

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- Ensure the Helix Tube is dry and not warm. Unscrew the cap from the Helix Tube.
- Take an indicator strip out of the package (image 1) and fold it in the middle with the text on the inside (image 2).
- Insert the middle fold part of the indicator strip first into the closure cap as far as it will go into the cap (image 3).
- Screw the closure cap back into the Helix Tube (image 4) and place in the autoclave; Run a sterilization process as indicated on the strip: 134 °C 3.5 min or 121 °C 15 min; At the end of the sterilization process, remove the tube from the autoclave. Be careful, the tube may be hot.
- Unscrew the cap and check the indicator strip. If the indicator shows dark / black it can be assumed that the autoclave is functioning properly and sterilizes successfully.
- Note that the test tube should be renewed after 250 batches.

STERISTAR C-1030, C-1032 and C-1033 coded products can be used with Helix Tube.





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Compliance

- ISO 11140-1:2014 Sterilization of health care products Chemical Indicators
- ISO 13485:2016 Medical devices Quality management systems

Storage and Shelf Life

$(\underline{\mathbb{X}})$	Do not reuse	Ť	Keep dry	
4°C	4°C to 30°C		Keep away from sunlight	
40 %	10% - 40% RH		Shelf life 5 years from the date of manufacture	
	 Keep away from sterilants. Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date. Do not expose this product to Dry Heat, EO, H2O2 or any sterilization processes other than Steam. 			

Disposal Discard as general waste.