

PCD 4.7

PCD 4.7 - Steris BI Spore Strip in Glassine, NA005

PCD 4.7 is an external Process Challenge Device for Ethylene Oxide (EO) sterilization containing a glassine wrapped Steris BI Spore Strip, NA 005. The unique, patented packaging is convenient to use and consistently demonstrates consistent sterilization resistance for a wide range of medical devices in industrial EO cycles.

Component Materials

Product Label: Polyolefin plastic with removable pressure sensitive adhesive test tube label.

Mounting Card: PVC plastic with a pressure sensitive adhesive strip for mounting on the outside of sterilizer load boxes.

EO Resistant Barrier Pouch: This PCD uses our type 4 pouch material configuration. This pouch is formed from a proprietary multi-layer plastic film that yields consistent resistance to EO sterilization processes.

Biological Indicator: Steris BI Spore Strip in glassine, NA005



PCD EO Performance

The nominal D_{EO} value for this PCD is approximately 32 minutes. This D_{EO} value was derived from multiple studies performed in ISO certified laboratory BIER vessels using the standard Stumbo-Murphy Carr (SMC) Fraction Negative method. Commercial results will differ depending on EO product/process variables.

Quality Systems Conformance

Every PCD lot is supplied with a Certificate of Quality Conformance and the BI manufacturer's certification. Mesa's biological indicator manufacturing facilities are in compliance with ISO-13485 manufacturing standards.

Shelf Life and Storage Conditions

Storage conditions and expiry are based on the biological manufacturer's certificate supplied with every PCD lot.

Do not use PCDs if they are past the BI manufacturer's labeled expiration date.

PCD EO Process Validation

Please review our Validation Guideline at biologicalindicators.mesalabs.com

Packaging

All PCDs are packaged in corrugated shippers with appropriate cushioning to assure clean, damage free transport to the customer.