



Mesa PCD[®] Technology **Selection Guide**



Why do more manufacturers choose Mesa PCD® Technology?

1

Wide Product Range

- » Process challenge device (PCD) ethylene oxide (EtO) Resistances (D_{EO}) of 3 to 58 minutes are readily available.
- » Self-contained biological indicators (SCBI) reduce incubation and release times, help minimize total process turnaround times and need for clean bench.
- » For support on selecting the right solution, contact bi-support@mesalabs.com.

2

Reduced Costs

- » Elimination of inhouse-produced, internal test packs greatly reduces material, labor and overhead costs.
- » External mounting of PCDs on each load minimizes recovery costs.
- » Release times using SCBI technology reduces product inventory in the pipeline.

3

Quality and Safety

- » All PCD components are manufactured in ISO 13485: 2016 certified facilities. Mesa has critical supplier agreements with numerous large and small medical devices companies world-wide.
- » Each PCD is supplied with a certificate of quality conformance. All critical components are fully traceable.
- » PCD identification is unique and load specific for sterilization and microbial qualification in case of BI failure.
- » Employee EtO exposure is minimized during BI recovery.
- » PCDs are shelf stable per manufacturer's certification and confirming studies.

4

Reduced Risk

- » Eliminate the risk of inconsistency, inherent in homemade PCDs.
- » Reduce the risk of healthcare-associated infections with simple to use commercially manufactured PCD.



Mesa's PCD Technology provides the ultimate in convenience, sterilization efficiency, reliability and cost savings for industrial sterilization users.

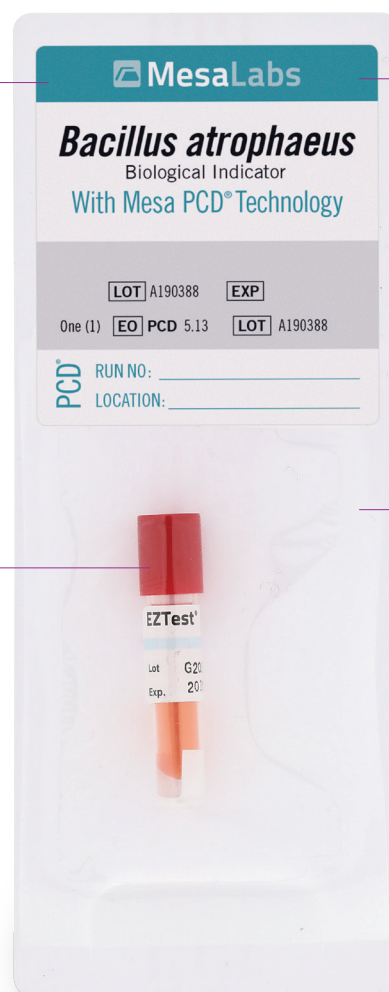
Mesa PCD® Technology is a unique, patented package of biological indicators (BIs) or self-contained biological indicators (SCBIs) for use in ethylene oxide (EtO) sterilization processes. As defined in ISO 11135:2014, these process challenge devices (PCDs) are used for validation and to routinely monitor sterilization processes for medical devices.

Label

- » Contains lot-specific information: PCD Type, PCD Lot Number, BI Type, BI Lot Number, PCD/BI Expiration Date

Biological Indicator

- » Mesa, 3M, Steris
- » SCBIs which do not require clean bench for activation
- » Strips in glassine or naked
- » Discs



Backer Card

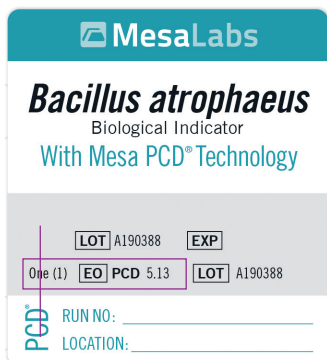
- » White PVC card with a thumb notch at the bottom to hold the pouched BI in place
- » Contains a pressure-sensitive adhesive strip on the back to allow for adherence of the PCD to the exterior of the load

Pouch

- » Proprietary formulation of plastic films that allow EtO gas to penetrate at different rates (3 to 58 min range of products)

Introducing the New PCD Selection Set V.13

The New Selection Set Contains 25 Each of PCD 2.13, PCD 4.13, PCD 6.13, PCD 7.13



All PCDs are identified by a N.X nomenclature. The “N” prefix delineates a particular polymeric film/pouch specification called a PCD ‘Type’. This type is indicative of a particular EtO resistance range. The “.X” suffix defines a particular BI or SCBI. The D_{eo} values listed are nominal values and are for reference and comparison only. These values were derived by laboratory testing using a Biological Indicator Evaluator Resistometer (BIER) vessel.

| Reorder No. | BI Manufacturer | D _{eo} min |
|---------------------------------|------------------------------------|---------------------|
| Type 2 — Most Resistance | | |
| PCD 2.1 | Mesa Spore Disc, 1-10006MM | 28 |
| PCD 2.12 | Mesa Spore Strip w/out Glassine | 28 |
| PCD 2.13 | Mesa EZTest EZG/6 SCBI | 58 |
| PCD 2.2 | Steris BI Strip, NAO05 | 28 |
| PCD 2.5 | Mesa BI Strip in Glassine, SGMG/6 | 37 |
| PCD 2.6 | 3M Attest™ 1264-S SCBI | 58 |
| PCD 2.7 | Steris BI strip in glassine, NAO05 | 37 |
| PCD 2.9 | 3M Attest™ 1294-S RRBI | 58 |

| | | |
|----------------------------------|-----------------------------------------|---|
| Type 3 — Least Resistance | | |
| PCD 3.13 | Mesa EZTest EZG/6 SCBI | 3 |
| PCD 3.2 | Steris BI Spore Strip, NA 005 | 3 |
| PCD 3.5 | Mesa BI Spore Strip in Glassine, SGMG/6 | 4 |
| PCD 3.6 | 3M Attest™ 1264-S SCBI | 5 |
| PCD 3.9 | 3M Attest™ 1294-S RRBI | 5 |

| | | |
|-----------------------------------|------------------------------------|----|
| Type 4 — Medium Resistance | | |
| PCD 4.1 | Mesa Spore Disc, 1-10006MM | 21 |
| PCD 4.13 | Mesa EZ Test EZG/6 SCBI | 50 |
| PCD 4.2 | Steris BI Strip, NAO05 | 21 |
| PCD 4.5 | Mesa BI Strip in Glassine, SGMG/6 | 32 |
| PCD 4.6 | 3M Attest™ 1264-S SCBI | 50 |
| PCD 4.7 | Steris BI strip in glassine, NAO05 | 32 |
| PCD 4.9 | 3M Attest™ 1294-S RRBI | 50 |

| Reorder No. | BI Manufacturer | D _{eo} min |
|--------------------------------|-----------------------------------|---------------------|
| Type 5 — Low Resistance | | |
| PCD 5.1 | Mesa Spore Disc, 1-10006MM | 4 |
| PCD 5.13 | Mesa EZ Test EZG/6 SCBI | 13 |
| PCD 5.2 | Steris BI Strip, NAO05 | 4 |
| PCD 5.5 | Mesa BI Strip in Glassine, SGMG/6 | 5 |
| PCD 5.62 | 3M Attest™ 1264-S SCBI | 13 |
| PCD 5.92 | 3M Attest™ 1294-S RRBI | 13 |

| | | |
|-----------------------------------|------------------------------------|----|
| Type 6 — Medium Resistance | | |
| PCD 6.1 | Mesa Spore Disc, 1-10006MM | 12 |
| PCD 6.13 | Mesa EZ Test EZG/6 SCBI | 35 |
| PCD 6.2 | Steris BI strip, NAO05 | 12 |
| PCD 6.5 | Mesa BI Strip in Glassine, SGMG/6 | 17 |
| PCD 6.6 | 3M Attest™ 1264-S SCBI | 35 |
| PCD 6.7 | Steris BI strip in glassine, NAO05 | 17 |
| PCD 6.9 | 3M Attest™ 1294-S RRBI | 35 |

| | | |
|-----------------------------------|------------------------------------|----|
| Type 7 — Medium Resistance | | |
| PCD 7.1 | Mesa Spore Disc, 1-10006MM | 9 |
| PCD 7.13 | Mesa EZ Test EZG/6 SCBI | 26 |
| PCD 7.2 | Steris BI Strip, NAO05 | 9 |
| PCD 7.5 | Mesa BI Strip in Glassine, SGMG/6 | 14 |
| PCD 7.6 | 3M Attest™ 1264-S SCBI | 26 |
| PCD 7.7 | Steris BI Strip in Glassine, NAO05 | 14 |
| PCD 7.9 | 3M Attest™ 1294-S RRBI | 26 |

| | | |
|---------------------------------------------------|------------------------|----------------------------------|
| Type 8 — H₂O₂ Cycles | | |
| PCD 8.13 | Mesa EZTest EZH/6 SCBI | (H ₂ O ₂) |