



Product Technical Data Sheet

Form No.: FTP-368 Rev.: A

Product Name: 4/10 Load Challenge Pack

Product Type: Process Challenge Device - PCD

Reorder Number: LT 111

Description: The SteriTec 4/10 Load Challenge Pack was designed specifically for process challenge testing of steam sterilizers using standard and extended cycles. The Test Pack verifies exposure to steam sterilization conditions in each load by means of an Integrator card. The Test Pack consists of a chemical indicator test card placed inside a package of porous and non-porous materials. The pack provides resistance to the penetration of steam during the sterilization cycle.

Performance Characteristics:

When exposed to the appropriate extended steam sterilization cycle, the appropriate indicator changes color.

Color Change: Purple to Green

Critical Parameters – Pack: (in a standard hospital steam pre-vacuum sterilizer)

Temperature	4 MIN spot Time	10 MIN spot Time
132°C	4 minutes	10 minutes
135°C	3 minutes	8 minutes

Indicator Stability: Excellent Before and After Sterilization

Physical Characteristics:

Dimensions: 2.47" W X 3.97" L

Substrate Material: Indicator Card = Print Blotter
Pack Sheets = Bio Index

Quantity / Box: 1

Boxes / Case: 40

Selling Unit: Case

Environmental Limitations:

Storage: 50° - 100°F (10° - 38°C) at 10 – 60% humidity

Shelf Life: The expiry date is printed on the product packaging.

SteriTec FDA 510(k) Release to Market Date: K080136 (8/15/08)

Standards Classifications:

Integrator Card

ISO 11140-1, Class 6