ProChem O.K. Cycle Integrator

REF CI-OK

Ref. Dutscher : **132290**

Directions for Use

INTENDED USE

The *ProChem O.K. Cycle* chemical integrator strips are designed for use in pre-vacuum steam sterilizers operating at 121°C and at 134°C. Used as directed, the *ProChem O.K. Cycle* integrator strips give visual confirmation that sterilization conditions were met at point of placement in the sterilizer chamber.

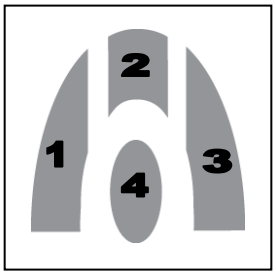
COLOR CHANGE

During steam sterilization, the four indicators spots change from purple to green.

STATED VALUES

(As determined in a steam sterilization resistometer)

Spot	121°C	134°C
1	8 min.	3.25 min.
2	11 min.	4.5 min.
3	17 min.	7 min.
4	30 min.	11 min.



INSTRUCTIONS FOR USE

1. Place a *ProChem O.K. Cycle* strip in each pack, peel-pouch or tray for sterilization. Place strip at a location in the package considered most difficult for steam to reach. For larger packs, place strips at several locations in pack.
2. Sterilize package as usual in a steam sterilizer.
3. Following the sterilization cycle:
   For 121°C cycles, verify that indicator spots 1, 2, and 3 have turned from purple to green. Spot 4 will change to green in sterilization cycles exceeding 30 minutes. If spot 3 is not green, it suggests inadequate sterilization conditions. Follow in-house protocol for failed cycle.
   For 134°C cycles, verify that indicator spots 1 and 2 have turned from purple to green. Spot 3 changes to green after spot 2 giving the user more information about the cycle. See chart. Spot 4 will change to green in sterilization cycles exceeding 11 minutes. If spot 2 is not green, it suggests inadequate sterilization conditions. Follow in-house protocol for failed cycle.

SAFETY PRECAUTIONS

- *If there is any doubt about sterility of item, it must be considered NOT sterile.*
- *Do not use any strips whose indicator spots are not purple in color prior to exposure to steam sterilization processing.*
- *Not recommended for use in a "flash" sterilization cycle.*

STORAGE

ProChem O.K. Cycle steam sterilization integrator strips should be stored between 10°- 38°C (50°-100°F) in the re-sealable bag provided. No special storage conditions are necessary after exposure to steam sterilization conditions. Keep unexposed indicator strips in the sealed bag provided.

EXPIRY DATE

The expiry date is printed on the product packaging.

LOT NUMBER

A unique identification code LOT is printed on each indicator strip and package labeling.

INTERFERING SUBSTANCES OR CONDITIONS

There are NO KNOWN INTERFERING SUBSTANCES OR CONDITIONS that could affect the intended use of the indicator or adversely affect the indicator performance.

RELEASE OF TOXIC SUBSTANCES

The indicator releases NO KNOWN TOXIC SUBSTANCES in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

DECLARATION OF CONFORMITY

Mesa Labs declares that the ProChem O.K. Cycle integrator conforms to all applicable portions ISO 11140-1, Type 5 pertaining to integrators.

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