

STERI-DOT® PROCESS INDICATORS FOR ETHYLENE OXIDE (EO) STERILIZATION

INSTRUCTION FOR USE

Steri-Dot process indicator is an Ethylene Oxide indicator, designed to display a distinct color change after exposure to EO sterilization. The indicator consists of EO-sensitive chemical ink printed on one surface of a circular-shaped adhesive paper ("Dot"). The chemical ink will change color from purple-red to green during EO sterilization exposure. The endpoint color is stable and will not revert under specified conditions of storage, although some minor fading may occur over time.

Sterilization parameters necessary to change color of the indicator are the following:

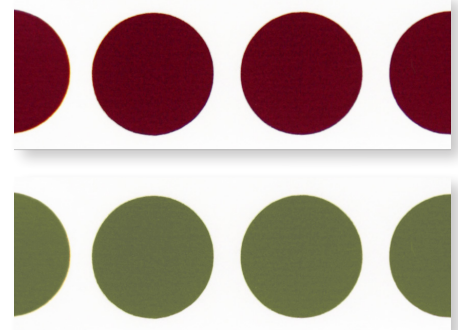
1. The concentration of Ethylene Oxide
2. The relative humidity level
3. Exposure temperature
4. Time of exposure

The Steri-Dot process indicator is certified by Propper to perform in accordance with the requirements of ISO 11140:2014-1, Type 1 with the following stated values:

54°C, 600mg EO, 20 min, 60%RH
37°C, 600mg EO, 25 min, 60%RH

The indicator is suitable for the following typical cycles used in healthcare:

TEMPERATURE	ETHYLENE OXIDE	RH%	EXPOSURE TIME
37°C	736 mg/l	≥35%	3 hours
37°C	759 mg/l	≥35%	3 hours
54°C	600 mg/l	40-60%	45 min or longer
54°C	736 mg/l	≥35%	1 hour
55°C	759 mg/l	≥35%	1 hour
55°C	600 mg/l	40-60%	4 hours



HOW TO USE STERI-DOT® PROCESS INDICATOR AND INTERPRET THE RESULTS:

One or more Steri-Dot process indicators should be placed on the external (exposed) surfaces of each package in a load. Each indicator on each package should be positioned to allow sufficient contact of the indicator with the processing environment. An indicator color change from purple-red to any shade of green indicates exposure to EO process, but not necessarily an adequate sterilizing exposure. Failure of the indicator to achieve the green color indicates:

- 1) The package or load was not processed at all
- 2) The package was sterilized in a wrong process (Steam, VHP, Dry heat)
- 3) Substantially inadequate exposure to one or more of the critical process variables

Process failure must be reported to the supervisor. Hospital protocol for reprocessing loads must be observed.

Indicator disposal should be in accordance with existing laws and regulations for disposal of non-hazardous chemical waste.

Unprocessed Steri-Dot indicators should be stored below 32°C and 70% relative humidity. When stored as indicated, this product has 42 months shelf life from the date of manufacture. For record keeping purposes, use the same storage conditions and protect from light.

