

STERI•DOT® Process Indicator for Ethylene Oxide Sterilization

Technical Data Sheet

Introduction:

Propper Steri-Dot is a Type 1 process indicator for use in EO sterilization. Steri-Dot indicator displays a distinct color change after exposure to EO processing. The indicator consists of a proprietary EO-sensitive chemical ink printed on a paper label material. The back side is coated with a pressure-sensitive adhesive. The chemical ink changes color from purple-red to green when exposed to EO gas.

The color change is reproducible and depends on the following four critical variables of EO sterilization process:

1. Concentration of Ethylene Oxide
2. Humidity level
3. Exposure temperature
4. Time of exposure

Performance:

Steri-Dot process indicators are certified by Propper to perform in accordance with the requirements of ISO 11140-1:2014 for Type 1 indicators. All performance testing was conducted in a specially designed sterilizer (BIER vessel, or Resistometer) in accordance with the requirements of ISO 18472 – Sterilization of Healthcare Products – Biological and Chemical Indicators – Test Equipment.



FIGURE 1. PROPPER MANUFACTURING COMPANY STERI•DOT® ETHYLENE OXIDE STERILIZATION PROCESS INDICATOR UNIT BOX.



FIGURE 2. LEFT IMAGE SHOWS UNPROCESSED INDICATOR DOTS. RIGHT IMAGE SHOWS PROCESSED INDICATOR DOTS.

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

Interpretation of Results:

Steri-Dot indicator will only react to process conditions in the immediate vicinity of the indicator. Since it was designated to demonstrate exposure to EO sterilization process, the correct placement of the indicator is essential. One or more indicators should be placed on the external (exposed) surfaces of each package in a load. The adhesive backing is suitable for applying the indicator on paper, sterilization wrap, metal and plastic surfaces. Each indicator should be positioned to allow exposure of the indicator to the processing environment. The chemical ink changes color from purple-red to green when exposed to EO gas. Any shade of green demonstrates exposure to the sterilization conditions. The endpoint color is stable but may slowly fade after extended storage under recommended conditions. It demonstrates exposure to EO process, but not attainment of sufficient sterilization conditions.

Failure of the indicator to achieve the green endpoint color indicates:

- 1) The package or load was not processed yet;
- 2) 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.

Ink Safety Testing:

Steri-Dot indicators are sold affixed to a silicone-coated Kraft release paper. There is no natural rubber latex, lead or metals used in the composition of this product. There are no known hazards associated with this product when used as directed. The third-party safety testing of Steri-Dot indicators was performed by NAMSA – North American Science Associates, Inc. The study found that the indicator did not impact cytotoxic properties to the various substrate samples sterilized in contact with them (NAMSA Lab #84T-04651-00, Propper PIR84-5).

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

Quality Compliance: Propper Manufacturing Company, Inc. and the medical products manufactured therein are subject to the jurisdiction of the United States of America Food and Drug Administration (FDA). As such, Propper's manufacturing facility is subject to periodic inspection by the FDA. During the most recent inspection, the FDA found Propper's facility to be in substantial compliance with current Good manufacturing Practices (GMP's). Propper's FDA Establishment Registration Number is 2410251.

Shelf-life and Storage Conditions:

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.

Product Order Information:

- Reorder No.: 36100100 – Box of 2000 Steri-Dot® Indicators 9/16" - Ethylene Oxide
- Reorder No.: 36100200 – Box of 1000 Steri-Dot® Indicators 1" - Ethylene Oxide