143C

PROCESS INDICATOR TAPE FOR STEAM STERILIZATION - TYPE 1

INTERTAPE POLYMER GROUP®

TECHNICAL DATA SHEET

DESCRIPTION

The process indicator tape is designed to seal packs that are exposed to steam sterilization. The tape distinguishes between items processed and unprocessed in both gravity discharge and prevacuum steam sterilization processes. Made of a saturated crepe paper printed with non-lead based ink, the green indicator lines turn black once exposed to the steam process. It is coated with a synthetic, solvent-free adhesive. **This**

product is not made with natural rubber latex. Lead is not used in the manufacturing of the ink of indicator lines.

PRODUCT APPLICATION

Designed to use on disposable wraps. The tape requires pressure upon application in order to provide proper contact, assuring that the tape will stay in place throughout the steam autoclave process. After use, the tape removes easily.

STANDARDS

Meets International Standard ISO 11140-1:2014. Approved as a Medical Device per FDA 510(K) #K161024.

STORAGE

The tape should be stored at room temperature (15°-30°C / 59°-86°F) in its original packaging/container. It should not be stored in humid environment (RH should be below 50%) or exposed to sunlight and should be kept away from chemical, cleaning and disinfecting products. The shelf life of this product is 36 months from the date of manufacture, when stored at the recommended conditions.



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EFFECTIVE: 08/24

NOMINAL VALUES

The following data are nominal values based on PSTC, ASTM and other standard tests. The data should not be considered as specifications.

Backing Saturated Crepe Paper

Adhesive Synthetic, Solvent-free

Thickness 5.5 mil (0.14mm)

Adhesion to Steel70 oz/in (19N/25mm)Tensile Strength20 lb/in (87N/25mm)

Elongation 7%

Indicator Non-Lead Based Ink

Color Blue (with printed green

indicator lines)

TEST CYCLES

Gravity sterilizers operating at 121°C (+3°C) for 30 minutes, 132°C for at 3 minutes, 132°C for at 10 minutes, 132°C for at 15 minutes, 135°C for 3 minutes and 135°C for 10 minutes. Pre-vacuum sterilizers operating at 132°C for 3 minutes, 132°C for 4 minutes, 134°C for 3 minutes, 134°C for 4 minutes and 135°C for 3 minutes.

INTERPRETATION

Tape is a single use device that is interpreted for appropriate signal color after processing. Indicator lines on the tape turn black when exposed to proper steam sterilization conditions (refer to interpretation guide).

