Instructions for Use

Lead-free Steam Indicator Tape
Lead-free Blue Steam Indicator Tape

Product Description
The process Lead-Free Indicator Tape consists of an adhesive, backing and chemical indicator lines. The adhesive is a resilient, pressure sensitive adhesive designed for use on disposable wraps. After the steam sterilization process, the tape is designed to keep wrapped items secured and removes easily. The backing is a natural or blue colored saturated crepe paper and provides the elongation needed for pack expansion during sterilization. The chemical indicator lines will show a visual color change from beige to dark brown/black when proper levels of moisture and temperature have been achieved. The Lead-Free Steam Indicator Tape is compliant to ISO 11140-1:2014 Type 1.

This product is not made with natural rubber latex, and free of any lead or solvents.

Intended Use
A physical/chemical sterilization process indicator tape is a single use device intended to be used by a health care provider to distinguish between sterilization processed and unprocessed units.

Indications for Use
Lead-Free Steam Indicator Tape is indicated for use in holding sterilization packs together and has been validated in the following steam sterilization cycles.

Gravity	Dynamic Air Removal (Pre-vacuum/SFPP)
121°C (250°F) 30 minutes	132°C (270°F) 3 minutes
132°C (270°F) 3 minutes	132°C (270°F) 4 minutes
132°C (270°F) 10 minutes	134°C (273°F) 3 minutes
132°C (270°F) 15 minutes	134°C (273°F) 4 minutes
135°C (275°F) 3 minutes	135°C (275°F) 3 minutes
135°C (275°F) 10 minutes	

Instructions for Use
When using Crosstex Lead-free Steam Indicator Tape to secure sterilization wraps it is recommended to follow written policies and procedures, the manufacturer's written IFU for the sterilization wrap and/or follow the ANSI/AAMI ST79:2017 (Section 9.5) guideline for proper use and placement of the indicator tape.

1. Remove the product label and plastic packaging and install the tape roll in a compatible tape dispenser.*
2. Unwind a section of Lead-free Steam Indicator Tape long enough to secure the pack.
3. Place one end of the Lead-free Steam Indicator Tape on the package and apply finger pressure across the length of the tape to secure the pack. DO NOT STRETCH THE TAPE.
4. Repeat steps 2 and 3 if the method of pack wrapping / size requires two or more strips of indicator tape for secure closure. Do not allow any openings in the folds.
5. When the steam sterilization cycle is complete, the chemical indicator lines will show a visual color change from beige to dark brown/black.
6. When the sterile pack is ready for use, open by using aseptic technique to avoid contaminating the internal contents.

*A multiple tape dispenser (part number TD-001) is available from Crosstex

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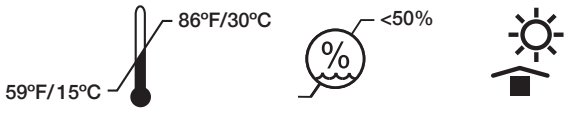
Note: The Crosstex Lead-Free Steam Indicator Tape is compliant to ISO 11140-1:2014 Type 1. It is not to be used inside other packaging materials such as wrapped goods and pouches. The indicator tape is designed for use by health care providers to accompany wrapped packs to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. Tape surface can be written on with indelible non-toxic ink to document appropriate information (e.g. date, sterilizer, contents, load/cycle).

Storage Conditions:



Do not freeze. Keep away from sterilants and excessive heat.

Shelf-Life: Unused: 24 Months from date of manufacture

AAMI ST79 2017 Section 11.1.3 Shelf Life States: The health care facility should establish policies and procedures for determining shelf life. The shelf life of facility-sterilized items is event-related and should be based on the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount and conditions of handling.

Contraindication: Routine end user sterilization process validation requires use of other additional chemical and/or biological indicators and monitoring of proper sterilization process parameters prior to sterile load release.

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

www.crosstex.com/resources

Crosstex International, Inc.
6789 W. Henrietta Road, Rush, NY 14543 USA
585.359.0130 | www.crosstex.com

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