

Getinge Assured

Green Tape

Product Description

Getinge Assured Green Tape tape is made utilizing a saturated natural color crepe paper that is printed on one side with green indicator lines and coated with solventless pressure-sensitive adhesive on the other side. The adhesive is specifically formulated to adhere to disposable wrap. After the steam sterilization process, the green indicator lines will turn black/dark brown indicating that the wrapped unit was processed. Green Tape is specially designed to endure the high heat and moisture conditions that are present before, during, and after the sterilization/autoclave process while keeping items securely sealed. The product is not made with natural rubber latex. Lead is not used in manufacturing of the chemical indicator lines ink. The tape is cleared as a Medical Device per FDA 510(K)#K161024.

Intended Use

The product is a physical/chemical sterilization process indicator, Type 1, is a single use device intended to be used by health care providers to show the unit has been directly exposed to sterilization process and to distinguish between processed and unprocessed items. Compliant with ISO 11140-1:2014

Indications for Use

The product is designed for use in both gravity discharge and pre-vacuum steam sterilization process.

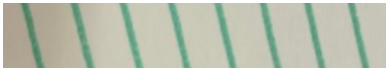
Gravity	Dynamic Air Removal (Pre-vacuum)
121°C (250°F) 30 min	132°C (270°F) 4 min
	135°C (275°F) 3 min

Instructions for Use

1. Remove all labels and plastic packaging from the roll, install in the appropriate tape dispenser.
2. Wrap the pack as instructed by hospital procedure.
3. Apply finger pressure across the length of the tape, assuring that the tape will secure the unit throughout the process. DO NOT STRETCH THE TAPE.
4. Load the sterilizer as recommended by manufacturer.
5. After steam sterilization, the chemical indicator lines will turn black/dark brown.
6. When the unit is ready for use, open at the wrapped items by using aseptic technique approved by hospital procedure.

Interpretation

When exposed to complete sterilization cycle conditions the indicator lines turn black/dark brown.



Before cycle



Cycle completed (all examples show acceptable "exposed" results)

Color change is stable for six months if the facility-sterilized unit is stored at conditions described in the storage section of the document.

Safety

After sterilization the load can be hot and should be cooled to safe temperature before handling.

Contradictions

None.

Storage

Recommended to be stored at normal room 15°-30°C/59°-86°F temperatures in its original packaging/container. It should not be stored in humid environment (RH < 50%) or exposed to sunlight and should be kept away from chemical, cleaning, and disinfecting products (for example, hydrogen peroxide).

Expiry Date

The shelf life of the product is 36 months from the date of manufacture when stored at the recommended conditions.

Symbols

Intertape Polymer Inc. provides information on Lot # and manufacturing date for the tape. All symbols used by Contract providers, on an individual roll core, or a label/packaging, shall be further explained by the Contract provider.