

Getinge Assured

ChemiSix Pack Extended

Indications for Use

The Getinge Assured ChemiSix Pack Extended is a process challenge device containing a Type 6 emulating indicator designed for use in monitoring pre-vacuum steam sterilizers operating at 132°C for 10 or 20 minutes or 135°C for 8 or 16 minutes. When used as directed the Getinge Assured ChemiSix Pack Extended PCD gives instant visual confirmation that sterilization conditions in the load were met, providing instant results for load release. The ChemiSix Pack Extended PCD is not a substitute for Biological Monitoring.

Color Change

During exposure to steam sterilization conditions the appropriate indicator dot will change from purple to green. If the appropriate indicator dot shows an incomplete color change to a gray/purple or has purple specks, this demonstrates that the load was exposed to insufficient sterilization conditions. If the appropriate indicator dot changes completely to green, this demonstrates the load was exposed to acceptable sterilization conditions.

Stated Values

Values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer and determined in a steam sterilization resistometer (BIER) with the indicator card only.

- 132°C – 12 minutes and 21 minutes
- 135°C – 9 minutes and 18 minutes

Instructions for Use

1. Place a Getinge Assured ChemiSix Pack Extended PCD in each load. Place the PCD in the area of the sterilizer determined to be the most difficult to sterilize.
2. Sterilize the load as usual in a steam sterilizer.
3. At the completion of the sterilization cycle open the test pack and verify that the appropriate indicator dot has turned to green.
4. If the appropriate indicator dot has changed completely to green it indicates that sterilization conditions have been met in the load. Follow hospital policy for load release.
5. If the appropriate indicator dot is not completely green, it suggests inadequate sterilization conditions and the items must be re-sterilized (per hospital policy) with a new/unprocessed PCD.

Precautions

- If there is any doubt about the sterility of an item, it must be considered NOT sterile
- Getinge Assured ChemiSix Pack Extended PCD is not recommended for use in Gravity sterilization cycles

Storage

Store at normal room temperature 50° - 86°F (10° - 30°C) and 10% - 60% RH. Protect from excessive humidity and moisture.

Expiration

Expiration date is printed on the test pack box. Use of indicators beyond the expiration date is not recommended.

LOT Number

The lot number LOT is printed on each test pack box.

Exposed Indicator Stability

The Getinge Assured ChemiSix Pack Extended emulator card will not revert back to its original color and may be used as a permanent record.

Release of Toxic Substances

Getinge Assured ChemiSix Pack Extended PCD is lead free. The indicator releases no known toxic substances in sufficient quantities to cause either a health hazard or a hazard to the intended properties of the product being sterilized.

Standards Conformity

ChemiSix Pack Extended emulator card ISO 11140-1, Type 6