

SAFE CHECK

INSTRUCTION FOR USE

Product Name: Helix Test Indicator & Helix Test Tool

Product Description:

MEDSTER Safecheck Helix Test Indicator has a self-adhesive structure and conforms to sterilization records. Helix Test Apparatus (Holder) has a 150±1cm long hose. There are 250 helix test indicators in each package.

This product is used for load control, the adhesive indicator is placed at the end of the test tool, where only steam can enter from the beginning of the hose and the steam can reach the chemical indicator by passing through a single point at the end of the hose. When exposed to steam sterilization conditions of 134°C-3.5 min and 121°C -15 min, the indicator ink will change from the initial color to the reference color. If the color change of the chemical indicator is achieved despite the difficult conditions, it means that the sterilizer is working successfully.

LOT and expiry date information can be found on the product label.





The shelf life of our product is 3 years.

Our product meets the performance specifications of ISO 11140-6 "Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers.

Helix test tool can be used 250 times.

Instruction:

- Check the device for visible damage and make sure that the device is dry. Also make sure the sterilizer is not hot.
- Open the tube by removing the capsule from the device.
- Get a strip from the sheet. Fold the indicator strips in half and make sure the indicator is facing in.
- Insert the strip into the capsule of the device. The folded side should be inside the capsule chamber and the open end should face the open end of the capsule.
- Make sure that the indicator is fixed in the capsule.
- Run a sterilization cycle as indicated on the Helix test strip. (134°C (270°F) for 3,5 min. or 121°C for 15 min.)
- Remove the indicator at the end of the sterilization cycle. Check the indicator. If the chemical indicator changes to the reference color, the test is successful.
- The indicator strip has a self-adhesive structure and can be applied to sterilization records.

| Color Conversion Chart | |
|---|--|
| Before Sterilization | After Sterilization |
|  |  |
|  |  |

Warnings and Precautions:

- Helix test indicators are disposable, do not reuse. Helix test tools can be used 250 times in a controlled manner.
- Check the product before using it. Do not use the product that is deformed or has a color change in the indicator color.
- Do not use expired products.

















Storage, Storing and Disposal Information:

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose of in accordance with the place of use and local regulations.

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Symbols and their meanings on the product label and user manual:

| Symbols | Meaning | Symbols | Meaning | Symbols | Meaning |
|---|----------------------------------|---|------------------------------|---|----------------------------|
|  | Manufacturer Information |  | Production Date (Month/Year) |  | Single Use Only |
|  | Product Lot Information |  | Expiration date |  | CE Symbol |
|  | Reference No |  | Unique Device ID |  | Medical Device |
|  | Do not expose to sunlight |  | Keep Dry |  | Store between 0°C and 40°C |
|  | Max. 70% RH |  | Metal free |  | Lead free |
|  | Suitable for steam sterilization | | | | |

Packaging and Product Information:

| Product Code | Product Description | Package Contents | Inner Box Quantity |
|--------------|----------------------|------------------|--------------------|
| 90.200 | Helix Test Indicator | 250 pcs | 100 packs |
| 90.201 | Helix Test Tool | 1 pc | - |