INSTRUCTIONS FOR USE
KRCI-107 EO Chemical Indicator, Type 5

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Product code	**KRCI-107**	**Brand**	**EEP**
Indicator	Type 5 EO integrating indicator	**Dimensions**	10 × 70 mm
Pack contents	250 indicators per pack	**Use**	One indicator in each instrument pack
EO concentration	600 mg/L	**Cycle temperature**	54 °C
Relative humidity	60 % RH	**Exposure time**	50 minutes
Initial color	Blue	**Acceptable endpoint**	Black; complete change
Shelf life	36 months from manufacture	**Storage**	15–30 °C; original zip-lock pouch
Device status	Non-sterile	**Classification**	Class B per product list

1. Intended purpose

KRCI-107 is a Type 5 integrating chemical indicator intended for internal monitoring of ethylene oxide (EO) sterilization cycles. It is designed to respond to the critical EO process variables for the specified cycle. Place one indicator inside each instrument pack at the location considered most difficult for the sterilizing agent to reach. The indicator does not by itself establish sterility or replace required sterilizer monitoring, validation, or load-release procedures.

2. Product configuration and specified cycle

Each pack contains 250 single-use indicators. Each indicator measures 10 × 70 mm and is intended for one use only. The specified EO exposure conditions are: 600 mg/L EO concentration, 54 °C, 60 % relative humidity, and 50 minutes exposure time. Use only with the specified, validated EO cycle. Do not extrapolate the result to other cycle combinations.

3. Instructions for use

Check that the indicator pack is intact, the indicators are clean and dry, and the expiry date has not passed.

Before sterilization, place one unused indicator inside each instrument pack at the location considered most difficult for EO to reach.

Prepare and close each instrument pack according to the facility’s approved packaging procedure.

Process the packs in an EO sterilizer using the specified cycle conditions: 600 mg/L EO, 54 °C, 60 % RH, and 50 minutes exposure time. Follow the sterilizer manufacturer’s instructions and the facility’s validated EO process.

After completion of the EO cycle and any required aeration, retrieve the packs according to facility procedures. Open each pack safely and examine the indicator under adequate lighting.

Record the result according to the facility's documentation procedure.

4. Interpretation of results

PASS: The indicator color changes completely from blue to black.

FAIL: The color change is incomplete, non-uniform, unclear, or remains blue. Do not consider the contents of the affected pack sterile and do not release them for use.

5. Action after a failed result

Keep the affected pack out of use. Follow the facility's nonconforming-load procedure and applicable national requirements. Reprocess the items using the facility's approved procedure and a new, unused indicator. Investigate and document the failure before releasing the items.

6. Storage and transport

Store unused indicators at ambient temperature (15–30 °C) in the original zip-lock pouch. Keep the pouch closed between uses. Protect indicators from direct sunlight and other strong light, moisture, detergents, oxidizing agents, and disinfectants. Transport indicators in the closed original pouch and protect them from contamination, crushing, and environmental exposure. Do not use damaged, contaminated, wet, or expired indicators.

7. Warnings and limitations

For professional use by trained sterilization personnel only.

Use one indicator in each instrument pack and one time only. Do not reuse processed indicators.

Use only with the specified EO cycle conditions and within the expiry date.

A passing indicator result does not independently confirm sterility. Continue all required process monitoring, validation, and release procedures.

Follow the EO sterilizer manufacturer's instructions, the facility's validated process, and applicable national requirements.

8. Disposal

Dispose of used indicators and affected packaging according to facility procedures and applicable local requirements. Do not return used indicators to the unused-indicator pouch.

9. Manufacturer and contact

Legal manufacturer: Krinmed Khavarmianeh Inc.
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