KRINMED
THE STERILIZATION SPIN-OFF

EEP
EXCELLENT ELITE PROCESS

INSTRUCTIONS FOR USE
KRCI-108 L Steam Chemical Indicator, Type 5

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Product code	**KRCI-108 L**	**Brand**	**EEP**
Indicator	Type 5 steam integrating indicator	**Dimensions**	70 × 20 mm
Pack contents	250 single-use indicators	**Use**	One indicator in each instrument pack
Cycle A	121 °C / 18 min	**Cycle B**	134 °C / 4 min
Initial color	Yellow	**Acceptable endpoint**	Black, dark gray, or dark brown; no yellow remains
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-108 L is a single-use Type 5 integrating chemical indicator for internal monitoring of steam sterilization cycles. It is intended to indicate whether the specified steam exposure conditions were reached at the location of the indicator inside a sterilization pack. It does not by itself establish sterility or replace required sterilizer monitoring, validation, or load-release procedures.

2. Product configuration and cycle conditions

Each pack contains 250 indicators. Each indicator measures 70 × 20 mm and is for one use only. Use KRCI-108 L only with one of the following specified cycles: 121 °C for 18 minutes, or 134 °C for 4 minutes. Do not extrapolate results 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 a location considered most difficult for steam to reach.

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

Process the pack using one of the specified cycles: 121 °C for 18 minutes or 134 °C for 4 minutes. Follow the sterilizer manufacturer’s instructions and the facility’s validated process.

After the cycle, retrieve the pack according to facility procedures. Open it 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 changes completely and uniformly from yellow to black, dark gray, or dark brown. No yellow may remain.

FAIL: Any yellow remains, or the color change is incomplete, non-uniform, or unclear. 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. Replace the packaging as required by facility procedures, prepare the pack again, and repeat the sterilization process using a new, unused indicator. Investigate and document the failure before releasing the instruments.

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 CSSD and sterilization personnel only.

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

Use only with one of the specified steam cycles and within the expiry date.

Any residual yellow color means the indicator acceptance criterion was not met. Do not use or release the instruments in that pack.

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

Follow the 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.
Brand: EEP
Address: Qarchack Industrial Zone, Tehran, Iran
Email: info@krinmed.com
Telephone: +98 21 4126 9999