KRINMED
THE STERILIZATION SPIN-OFF

EXCELLENT ELITE PROCESS

INSTRUCTIONS FOR USE
KRCI-150 L Steam Chemical Indicator, Type 6

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Product code	KRCI-150 L	Brand	EEP
Indicator	Type 6 steam chemical indicator	**Available sizes**	35 × 65 mm; 17 × 65 mm
Pack contents	250 indicators per pack	**Use**	One indicator in each instrument pack
Cycle A	134 °C / 4 min	**Cycle B**	121 °C / 18 min
Initial color	Yellow	**Acceptable endpoint**	Black, dark gray, or dark brown; no yellow remains
Shelf life	48 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-150 L is a single-use Type 6 steam chemical indicator intended for internal monitoring of steam sterilization cycles. Place one indicator inside each instrument pack before sterilization. The indicator provides a visual response to the specified cycle conditions. It does not by itself establish sterility or replace required sterilizer monitoring, validation, or load-release procedures.

2. Product configuration and cycle conditions

The indicator is supplied in two sizes: 35 × 65 mm and 17 × 65 mm. Both sizes have the same intended use, cycle conditions, interpretation criteria, and shelf life; only the dimensions differ. Each pack contains 250 indicators. Each indicator is for one use only.

Use only for one of the following specified steam cycles: 134 °C for 4 minutes, or 121 °C for 18 minutes. Use the cycle that matches the product label and the validated sterilization process. Do not extrapolate results to other cycle combinations.

3. Instructions for use

Confirm the indicator is within its expiry date and that the pouch and indicator are intact, clean, and dry.

Before sterilization, place one unused indicator inside each instrument pack. Position it within the pack according to the facility’s validated packaging and monitoring procedure.

Close and prepare the pack using the facility’s approved packaging procedure. Load and process it using the applicable validated cycle: 134 °C for 4 minutes or 121 °C for 18 minutes.

After the cycle, retrieve the pack according to facility procedures. Open it safely and inspect the indicator under adequate lighting.

Interpret the color response and record the result as required by the facility’s documentation procedure.

4. Interpretation of results

PASS: The yellow indicator areas have changed completely and uniformly to black, dark gray, or dark brown. No yellow may remain.

FAIL: Any yellow remains, or the color change is incomplete, uneven, or unclear. Do not use or release the instruments in the affected pack. Follow facility procedures, replace the packaging as required by applicable rules and validated procedures, and repeat the sterilization cycle with a new indicator.

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, prepare the pack again, and repeat the complete sterilization process using a new indicator and an appropriate validated cycle. 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 per instrument pack and one time only. Do not reuse processed indicators.

Use only with the specified steam cycles and within the indicator's expiry date.

Any residual yellow color means the pack did not meet the indicator's acceptance criterion. 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 procedures, 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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