KRINMED
THE STERILIZATION SPIN-OFF

EXCELLENT ELITE PROCESS

INSTRUCTIONS FOR USE
KRCI-161 L Steam Chemical Indicator, Type 4

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Product code	**KRCI-161 L**	**Brand**	**EEP**
Indicator	Type 4 steam chemical indicator	Dimensions	10 × 70; 15 × 70; 20 × 70 mm
Pack contents	250 indicators per bag	Use	Single-use; one in each package
Specified reference cycle	134 °C	Exposure time	3.5 minutes
Initial color	Yellow	Acceptable endpoint	Black; significant change
Shelf life	48 months from manufacture	Storage	15–30 °C; original zip-lock aluminum pouch
Device status	Non-sterile	Classification	Class B per product list
Documentation	Place on indicator for record retention	Package material	Resealable aluminum pouch

1. Intended purpose

KRCI-161 L is a Type 4 chemical indicator intended for internal monitoring of steam sterilization processes. It provides a visual indication that the indicator was exposed to the specified sterilization conditions. Use it only in compatible steam sterilization processes and follow the sterilizer manufacturer's instructions and the facility's validated process. The indicator does not by itself establish sterility or replace sterilizer monitoring, process validation, or load-release procedures.

2. Product configuration and specified cycle

Each bag contains 250 single-use indicators. KRCI-161 L is available in 10 × 70 mm, 15 × 70 mm, and 20 × 70 mm sizes. The specified reference cycle is 134 °C for 3.5 minutes.

3. Instructions for use

1. Check that the aluminum zip-lock pouch is intact, the indicator is unused, and the expiry date has not passed.
2. Before sterilization, place one unused indicator inside each package to be monitored. Position it according to the facility's validated packaging and monitoring procedure.
3. Prepare and close each package according to the facility's approved packaging procedure.
4. Process the package in a steam sterilizer using the specified cycle of 134 °C for 3.5 minutes, where this cycle is compatible with the load and packaging. Follow the sterilizer manufacturer's instructions and the facility's validated process.
5. After completion of the cycle, retrieve the packages according to facility procedures. Examine the indicator under adequate lighting.
6. If the result is acceptable, peel the indicator from its backing and retain it in the patient or operation record as required by the facility's documentation procedure.

4. Interpretation of results

PASS: The indicator shows a significant color change from yellow to black.

FAIL: The indicator remains yellow, shows an incomplete or unclear change, or does not reach the expected black endpoint. Do not consider the contents of the affected package sterile and do not release them for use.

5. Action after a failed result

Keep the affected package out of use. Follow the facility's nonconforming-load procedure, the sterilizer manufacturer's instructions, and applicable national requirements. Investigate and document the failure. Reprocess the items only under the facility's approved procedure, using a new, unused indicator.

6. Storage and transport

Store unused indicators at ambient temperature (15–30 °C) in the original zip-lock aluminum 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. Do not use damaged, contaminated, wet, or expired indicators.

7. Warnings and limitations

- For professional use by trained sterilization personnel only.
- Use one indicator once only. Do not reuse processed indicators.
- Use only for steam sterilization and within the expiry date printed on the packaging.
- A passing indicator result confirms exposure to the monitored process conditions only. It does not independently confirm sterility. Continue all required process monitoring, validation, and release procedures.
- Follow the steam 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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