INSTRUCTIONS FOR USE
KRCI-115 Plasma Chemical Indicator, Type 4

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Product code	KRCI-115	Brand	EEP
Indicator	Type 4 H_2O_2 gas plasma chemical indicator	Dimensions	20 × 70 mm
Pack contents	See quantity on product packaging	Use	Single-use strip
Intended process	H_2O_2 gas plasma sterilization	Process response	Time and H_2O_2 concentration
Initial color	Orange	Acceptable endpoint	Yellow; visible change
Shelf life	48 months from manufacture	Storage	15–30 °C; original resealable aluminum pouch
Device status	Non-sterile	Classification	Class B per product list
Traceability	LOT and expiry on each strip/packaging	Documentation	Used strip may be retained as a record

1. Intended purpose

KRCI-115 is a Type 4 chemical indicator intended for internal monitoring of hydrogen peroxide (H_2O_2) gas plasma sterilization processes. It provides a visual indication that the monitored item was exposed to the sterilization process variables, including time and H_2O_2 concentration. It does not by itself establish sterility or replace sterilizer monitoring, process validation, or load-release procedures.

2. Product configuration and specified cycle

Each strip is for single use. The indicator measures 20 × 70 mm. The product is supplied in a resealable aluminum pouch. The pack quantity and expiry date are stated on the product packaging. Use only in H_2O_2 gas plasma sterilizers and follow the sterilizer manufacturer's instructions and the facility's validated process. Do not use this indicator in steam, ethylene oxide, or other sterilization processes.

3. Instructions for use

Check that the aluminum pouch is intact and the expiry date has not passed.

Before processing, place one unused indicator inside each pack, peel pouch, or tray to be monitored. Position it at the location specified by the facility's validated packaging and monitoring procedure.

Prepare and close each pack, pouch, or tray according to the facility's approved packaging procedure.

Process the load in an H_2O_2 gas plasma sterilizer according to the sterilizer manufacturer's instructions and the facility's validated process. Use only a sterilization cycle compatible with the items and packaging being processed.

After completion of the cycle, retrieve the packs according to facility procedures. Examine the indicator under adequate lighting.

Record or retain the used strip as required by the facility's documentation procedure. The strip can be kept as a permanent record.

4. Interpretation of results

PASS: The indicator shows the expected, visible color change from orange to yellow after processing.

FAIL: The expected orange-to-yellow change is absent, unclear, or inconsistent with the product acceptance criteria. 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, 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 strips at ambient temperature (15–30 °C) in the original resealable aluminum 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. 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 H_2O_2 gas plasma sterilization and within the expiry date printed on the packaging.

A passing indicator result confirms exposure to the monitored process variables only. It 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.
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