INSTRUCTIONS FOR USE
KRLT-104 Steam Hollow Load PCD

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Product code	KRLT-104	**Brand**	EEP
Product	Steam Type 2 PCD Chemical Indicator	**Device status**	Non-sterile
Indicator strip	6 × 75 mm, single-use	**Pack size**	250 strips
PCD body	Reusable, sold separately	**Maximum use**	1,000 cycles
Shelf life	48 months from manufacture	**Process**	Pre-vacuum steam
Validated exposure	134 °C / 3.5 min	**Alternative exposure**	121 °C / 18 min

1. Intended purpose

KRLT-104 is a Type 2 steam chemical indicator strip for use with the compatible reusable EEP hollow-load process challenge device (PCD). It provides a routine challenge to assess air removal and steam penetration through the PCD lumen under the specified pre-vacuum steam cycle conditions. Use one PCD for every cycle in which lumened instruments are processed. Place it alongside the instruments at the most challenging location for steam penetration in the sterilizer/load. KRLT-104 supplements, and does not replace, physical cycle monitoring, biological indicators where required, sterilizer qualification, or the facility's documented release procedures. A chemical indicator response alone does not establish sterility.

2. Product configuration and cycles

The consumable indicator strip is single-use and supplied in a pack of 250 strips. The compatible reusable PCD body is sold separately and has a maximum service life of 1,000 cycles. Do not use the strip without the compatible PCD or substitute strips from another manufacturer.

Use only in compatible pre-vacuum steam sterilizers at one of these exposure conditions: 134 °C for 3.5 minutes, or 121 °C for 18 minutes. Do not use with gravity cycles or with other sterilization modalities. Follow sterilizer and facility instructions for loading and cycle operation.

3. Instructions for use

- Check product code, lot number, expiry date and pouch integrity. Do not use an expired, damaged, wet or contaminated strip.
- Inspect the reusable PCD body before each use. Check the tube and all openings for blockage, damage, leakage or retained moisture. Do not use a blocked or damaged device.
- Open the compatible PCD indicator holder. Remove one strip from its zip-lock pouch and refold it at the marked fold line, with the reactive yellow indicator areas facing outward.
- Insert the folded strip into the designated holder and close the PCD securely by hand. Do not alter the strip, tube or PCD assembly.
- Place one assembled PCD alongside the instruments at the most challenging location for steam penetration whenever lumened instruments are included in the cycle.
- Run the sterilizer using one of the specified KRLT-104 exposure conditions and the facility's validated cycle.
- At cycle completion, remove the PCD using appropriate heat protection. Allow it to cool before opening. Remove and read the strip.
- Record the result, product code, strip lot, sterilizer/cycle identification, date and operator according to facility procedures. The used adhesive strip may be attached to the sterilization record.

- After use, allow the reusable PCD body and tube to cool and dry. Inspect the tube and openings for blockage before the next use. Retire the PCD after 1,000 cycles, or sooner if damaged, leaking, obstructed or otherwise unfit for use.

4. Interpretation

PASS: all four reactive areas change uniformly and completely from yellow to dark gray, black or dark brown. The final shade may vary depending on the water used. All four areas must show the same completed response.

FAIL: any yellow remains in any of the four reactive areas, or the result is incomplete, uneven, unreadable or otherwise inconsistent with the pass criterion. Do not regard a failed or invalid result as acceptable for load release.

5. Action after a failed result

- Check that the strip was folded, positioned and exposed correctly.
- Inspect the PCD, especially the tube lumen and openings, for blockage. Clear or replace the PCD only according to the manufacturer's maintenance procedure. Do not use it while obstructed.
- Follow facility procedures to investigate the cycle and sterilizer. Hold, quarantine, reprocess or otherwise manage the load according to the facility's validated procedures and applicable requirements.
- Document the result, investigation and corrective action. Repeat monitoring as required before returning the sterilizer or process to routine use.

6. Warnings and limitations

- For professional use by trained CSSD/reprocessing personnel.
- The PCD challenges the specified test pathway. Its result does not prove that every instrument or lumen in the load is sterile.
- Do not use this product as a Bowie-Dick test or as a substitute for required biological or physical monitoring.
- Use each indicator strip once only. Reuse the PCD body only up to 1,000 cycles and only while it remains intact, dry and unobstructed.
- Use only the stated cycle conditions and compatible pre-vacuum steam sterilizers.

7. Storage, shelf life and disposal

Store unused strips at ambient temperature in the original zip-lock pouch. Keep the pouch closed when not in use. Protect strips from light, oxidizing agents and disinfectants. The shelf life is 48 months from the date of manufacture. Do not use after the expiry date printed on the packaging. Dispose of used strips and damaged components according to facility procedures and applicable local requirements.

8. Manufacturer and contact

Legal manufacturer: Krinmed Khavarmianeh Inc.
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in this IFU are those provided by Krinmed.