STRUCTIONS FOR USE

KRBD-200 Bowie-Dick Test Pack

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Product code	KRBD-200	Brand	EEP
Product	Type 2 Bowie-Dick test pack	**Dimensions**	130 × 130 mm
Pack contents	1 single-use test per box	**Use frequency**	Daily, before first load
Sterilizer type	Pre-vacuum steam sterilizer	**Test cycle**	134 °C / 3.5 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 box
Device status	Non-sterile	**Classification**	Class B per product list

1. Intended purpose

KRBD-200 is a single-use Type 2 Bowie-Dick test pack for daily performance monitoring of pre-vacuum steam sterilizers. The test evaluates air removal and steam penetration under the specified test conditions. It is not a sterilization load and does not by itself demonstrate that a load or medical device is sterile.

2. Product configuration and test cycle

Each box contains one 130 × 130 mm test pack for one test. Do not reuse a processed test pack. Conduct the test in an empty pre-vacuum sterilizer chamber each day before processing the first load. Run the specified cycle at 134 °C for 3.5 minutes. Follow the sterilizer manufacturer's instructions and the facility's approved procedure for any required warm-up or conditioning and for cycle selection.

3. Instructions for use

Check that the box is intact, the test pack is dry and undamaged, and the expiry date has not passed.

Ensure the sterilizer chamber is empty. Perform any warm-up or conditioning required by the sterilizer manufacturer.

Place one test pack flat in the chamber at the Bowie-Dick test position specified by the sterilizer manufacturer and the facility procedure. If the facility procedure follows the common Bowie-Dick arrangement, position it on the lower rack near the drain. KRBD-200 has no specified orientation; do not infer a "THIS SIDE UP" direction.

Run the 134 °C, 3.5-minute Bowie-Dick test cycle. Do not process instruments or other loads in the chamber during this test.

At cycle completion, remove the test pack carefully. It may be hot. Allow it to cool sufficiently for safe handling, then open it and examine the indicator under adequate lighting.

Record the test date, sterilizer identification, operator, and result according to facility procedures.

4. Interpretation of results

PASS: The yellow indicator areas have changed completely and uniformly to a dark endpoint. Black, dark gray, or dark brown is acceptable. No yellow may remain.

FAIL: Any yellow remains, or the color change is incomplete, uneven, or unclear. Do not use the sterilizer for routine processing on the basis of a failed test.

5. Action after a failed result

Remove the sterilizer from operational service. Follow the sterilizer manufacturer's troubleshooting and service procedure and applicable national requirements. Arrange inspection and service before returning the sterilizer to operation. Check that the test pack was transported and stored correctly and was within its expiry date. Document the failure and actions taken. Assess any loads processed since the last acceptable test according to facility procedures.

6. Storage and transport

Store unused test packs at ambient temperature (15–30 °C) in the original box. Keep the pouch closed between uses. Protect packs from direct sunlight and other strong light, moisture, detergents, oxidizing agents, and disinfectants. Transport packs in the closed original pouch and protect them from contamination, crushing, and environmental exposure. Do not use damaged, contaminated, wet, or expired test packs.

7. Warnings and limitations

For professional use by trained CSSD and sterilization personnel only.

Use one test pack once only. Do not reuse a processed test pack.

Use only for the daily Bowie-Dick performance test in a pre-vacuum steam sterilizer at 134 °C for 3.5 minutes.

The test pack may be hot after the cycle. Handle it carefully and allow it to cool before opening.

A passing Bowie-Dick test does not independently confirm sterility of a load. Continue all required process monitoring, validation, and release procedures.

Follow the sterilizer manufacturer's instructions, the facility's approved procedure, and applicable national requirements.

8. Disposal

Dispose of the used test pack according to facility procedures and applicable local requirements. Do not return a used test pack to the original pouch.

9. Manufacturer and contact

Legal manufacturer: Krinmed Khavarmianeh Inc.
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