INSTRUCTIONS FOR USE
KRBD-111 Bowie-Dick Helix Test System

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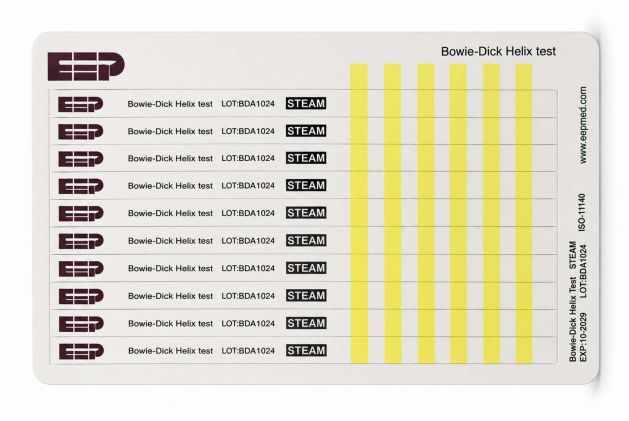



Product code	KRBD-111	Brand	EEP
Indicator	Type 2 steam chemical strip	Strip size	6 × 130 mm
Strip pack	100 single-use strips	Reusable test device	Reusable, supplied separately
Test-device assembly	4 m PTFE tube, stainless-steel capsule	Maximum use	5,000 cycles
Shelf life	48 months from manufacture	Storage	15–30 °C
Exposure cycles	134 °C / 3.5 min	Alternative cycle	121 °C / 18 min
Device status	Non-sterile	Classification	Class B per product list

1. Intended purpose

KRBD-111 is a Bowie-Dick test system comprising a reusable helix test device and single-use steam indicator strips. It is intended for the daily Bowie-Dick functional test of a pre-vacuum steam sterilizer in an empty chamber before the first processing cycle of the day. The test assesses air removal and steam penetration under the specified test conditions. It is a sterilizer performance test, not a sterility test and not routine monitoring of a loaded sterilization cycle.

2. Product configuration and cycle conditions

Each refill pack contains 100 single-use indicator strips. The reusable Bowie-Dick test device, consisting of a 4 m PTFE tube and stainless-steel indicator capsule, is sold separately. Use only the specified KRBD-111 strips with the compatible test device. The test device has a maximum service life of 5,000 test cycles, subject to the inspections and maintenance in this IFU.

Use a pre-vacuum steam sterilizer and one of the following exposure conditions: 134 °C for 3.5 minutes, or 121 °C for 18 minutes. Use the applicable Bowie-Dick test program or a validated equivalent. Do not apply these cycle settings to other sterilization processes.

3. Daily test procedure

- Perform the test once daily before the first production cycle, with the sterilizer chamber empty. Do not place instruments, packs or other load items in the chamber during this Bowie-Dick test.
- Inspect the test device before use. Check the PTFE tube, connections, capsule, closure and seal for visible damage, looseness, blockage, moisture or other abnormal condition. Do not use a damaged, obstructed or leaking device.
- Open the capsule and remove one indicator strip from the pack. Fold the strip at its midpoint. The fold may face inward or outward; either orientation is acceptable for KRBD-111.
- Place the folded strip in the indicator holder/capsule and close the capsule securely by hand. Assemble the Bowie-Dick device as designed. Do not use tools or force the closure.
- Place the assembled test device in the lower section of the empty chamber near the door, in the test position specified by the sterilizer manufacturer or the facility's validated procedure. Position it securely and do not place it inside a pouch, pack or container.
- Run the Bowie-Dick test cycle at 134 °C for 3.5 minutes or 121 °C for 18 minutes.
- At cycle completion, remove the test device carefully using suitable heat protection. Allow it to cool before opening. Remove the strip and read the full reactive area under adequate lighting.
- Record the date, sterilizer identification, selected cycle, strip lot, result and operator. Retain the strip as part of the facility's daily sterilizer record.

4. Result interpretation

PASS: the reactive indicator areas change uniformly and completely from yellow to dark gray, black or dark brown. The final shade may vary with the water used. All reactive areas must show a completed, uniform change. No yellow color may remain.

FAIL: any yellow remains, any reactive area changes incompletely or unevenly, or the strip is unreadable or damaged. A failed result may indicate inadequate air removal or steam penetration, a sterilizer or utility problem, incorrect assembly, or a blocked or leaking test device.

5. Actions after a failed result

- Do not use the sterilizer for routine processing based on a failed Bowie-Dick test. Follow the facility procedure for holding the sterilizer out of service and reporting the failure.
- Check that the correct strip and cycle were used and that the Bowie-Dick test device was assembled and positioned correctly.
- Inspect the test-device tube and openings for obstruction, visible damage or leakage. Do not continue using a device that is blocked, damaged or leaking.
- Have the sterilizer and relevant steam supply conditions assessed by authorized personnel. Repeat the test only as allowed by the facility procedure after the cause is addressed.
- Return the sterilizer to routine use only after the required investigation and a satisfactory test result, in accordance with the facility's procedure and applicable requirements.

6. Test-device inspection and weekly leak check

Before every test, visually inspect the tube, connections, capsule and seal. Confirm that the tube is open and free of blockage, and that no visible damage or abnormality is present.

At least once each week, perform a leak check by applying compressed air to the test device and inspecting it under water for escaping air. Use the facility's controlled maintenance method and do not exceed the pressure specified for the device. If leakage is detected, or if the tube is damaged or obstructed, remove the

device from service and replace or repair it only according to Krinmed's approved maintenance procedure. Record the weekly check and the test-device cycle count.

Do not use the test device beyond 5,000 test cycles. Retire it earlier if inspection or the weekly leak check identifies damage, leakage, blockage, deformation, a loose connection or unreliable closure.

7. Warnings and limitations

- For professional use by trained sterilization personnel.
- This is a daily empty-chamber sterilizer function test. It does not demonstrate that a specific load or every lumen in a load has been sterilized.
- The test does not replace routine physical monitoring, biological monitoring where required, load monitoring, process validation, sterilizer maintenance or the sterilizer manufacturer's instructions.
- Use only KRBD-111 indicator strips with the compatible KRBD-111 Bowie-Dick test device. Do not change tube length, geometry, capsule or strip type.
- The indicator strip is single-use. Do not reuse an exposed strip.

8. Storage, shelf life and disposal

Store unused indicator strips at ambient temperature (15–30 °C) in the original zip-lock pouch. Keep the pouch closed when not in use. Protect the strips from direct sunlight, light, moisture, detergents, 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 parts according to facility procedures and applicable local requirements.

9. Manufacturer and contact

Legal manufacturer: Krinmed Khavarmianeh Inc.
Brand: EEP
Address: Qarchack Industrial Zone, Tehran, Iran
Email: info@krinmed.com
Telephone: +98 21 4126 9999

10. Standards and references

KRBD-111 is identified by Krinmed as a Type 2 Bowie-Dick test system. GKE Bowie-Dick Simulation Test 211-150 instructions and product information were consulted as comparator references for daily empty-chamber testing and general use guidance only. GKE cycle conditions differ from the KRBD-111 conditions stated by Krinmed. This comparison does not establish conformity of KRBD-111 to a standard. Any conformity claim must be supported by Krinmed product-specific test reports and regulatory documentation.

References: ISO 11140-1:2014, Chemical indicators, Part 1: General requirements; ISO 11140-4, indicators for Bowie-Dick-type air-removal tests; GKE Bowie-Dick Simulation Test 211-150 IFU, comparator reference only.