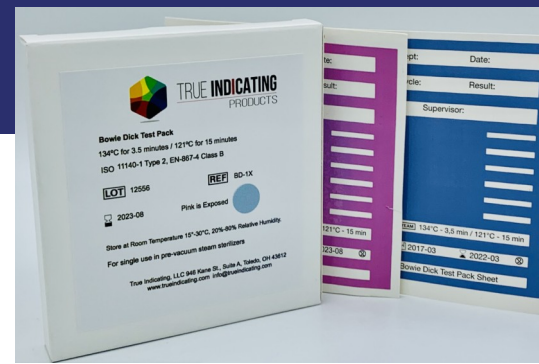




Technical Data Sheet

BOWIE DICK TEST PACKS For Monitoring Air Removal / Steam Penetration ISO 11140-1 TYPE 2, Compliant with ISO 11140-4

True Indicating Code: BD-1X



Product Description

True Indicating Bowie Dick (BD) Test Packs contain no lead or other toxic heavy metals and are made of recyclable materials. The Test Packs contain an internal Indicator sheet which is used to evaluate the efficacy of air removal and steam penetration in pre-vacuum sterilizers. A uniform color change to Pink of the internal Indicator sheet provides evidence that the sterilizer has successfully removed air and can allow steam to penetrate a load placed in the chamber. The Test Packs are for use in pre-vacuum steam sterilizers operating at 121°C and 134°C. The Test Packs simulate a 7kg cotton pack according to ISO 11140-4 Type 2 and EN 867-4 Class B.

Physical Properties

Monitor For	Pre-vacuum Steam Sterilizers
Test Pack Dimensions	L: 123mm x W: 123mm x H: 16mm
Packaging	20 Test Packs / Box
Chemical Indicator	Initial Color: Blue Signal Color: Pink

Intended Use

The Bowie Dick Test Pack detects the presence of residual air in pre-vacuum steam sterilizers operating at 134°C for 3.5 or 121°C for 15 minutes. The internal Indicator sheet will demonstrate a uniform color change from Blue to Pink when proper conditions as identified in ISO 11140-4 for Sub-atmospheric pulsing have been met. If insufficient steam penetration occurs during the exposure cycle, the Indicator sheet will yield an inconsistent color change which is not uniformly Pink.

Indications for Use

Type 2 Indicator

- 121°C, 15 minutes (pre-vacuum)
- 134°C, 3-3.5 minutes (pre-vacuum)

Instructions for Use

- 1) Daily, place the Test Pack on the bottom shelf, over the drain closest to the door, in an otherwise empty chamber.
- 2) Process in a pre-vacuum cycle of 134°C for 3.5 or 121°C for 15 minutes exposure time.
- 3) After processing, carefully remove the Test Pack and allow to cool.
- 4) Confirm that the Indicator dot on the exterior label of the Test Pack has changed color from Blue to Pink and then remove the internal Indicator sheet from the center of the Test Pack.
- 5) The Indicator sheet should be a uniform Pink color. Inconsistent or color change which is not uniform may indicate sterilizer malfunction and should be immediately reported.
- 6) Complete the information on the Indicator sheet and retain as permanent record.

The chemical reaction which causes the color transition is a steam specific reaction and is irreversible.

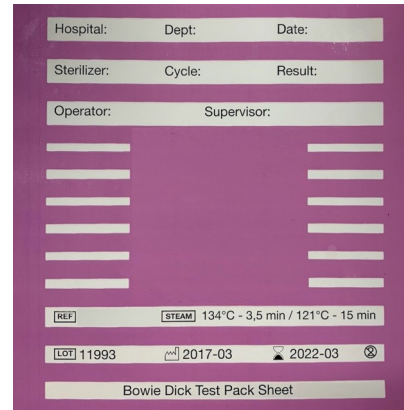
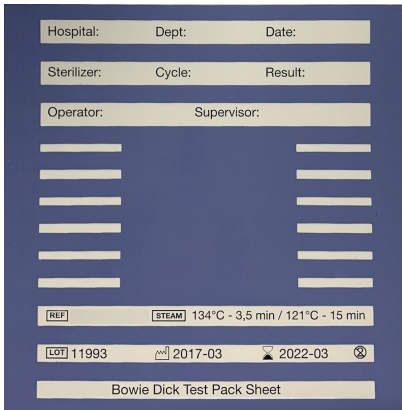


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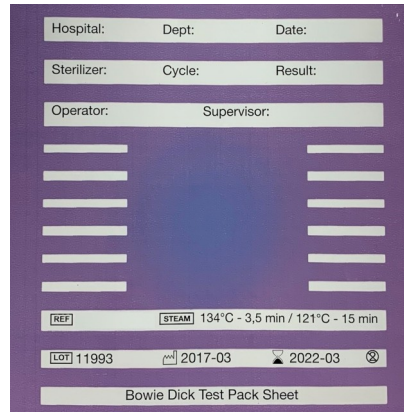
Performance Characteristics

Result Availability	Immediately following exposure to high temperature steam processes
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Unexposed	Exposed to steam 121°C, 15 minutes
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Failure—Residual Air



Colors shown are representations of printed ink initial and signal colors but may vary from actual use.



The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. cycle time, temperature, brand of sterilizer etc.).

Compliance

ISO 11140-1 Sterilization of health care products – Chemical indicators- Part 1: General requirements

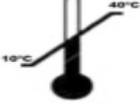





ISO 11140-4 Sterilization of health care products—Chemical indicators—Part 4: Class 2 indicators as an alternative the Bowie and Dick-type test for detection of steam penetration.





Technical Data Sheet

Storage and Shelf Life

	10°C to 40°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep dry
Shelf Life	5 years from the date of manufacture. The date of manufacture is based on the date of manufacture. The remaining shelf life upon receipt will be shorter than 5 years		Do not reuse
	Keep away from sterilants. Do not use after expiration date.		

Disposal

Discard as general waste.

