

INSTRUCTIONS FOR USE – BOWIE-DICK TEST PACK

Product Description:

Our SAFECHECK Bowie-Dick Test Packs consist of a series of vapor penetration barriers with a chemical indicator sheet in the middle to test the performance of the steam sterilizer. The test pack is placed directly into an empty steam sterilizer basket/chamber without the need for any apparatus.

During the sterilization cycle, air must be vacuumed out of the test package and there must be complete steam penetration into the package. The indicator on the chemical indicator sheet in the middle of the test pack shows sufficient vapor penetration if the ink has completely changed from the initial color to the reference color. Special ink formulation detects problems with vapor quality, does not contain lead and other heavy metals. The indicator sheet in the middle of the product can be used to keep a permanent record of 6 months from the sterilization process.

SAFECHECK Bowie-Dick Test Packs comply with the performance criteria of ISO 11140-4 and EN 867-4 Class 2/B. SAFECHECK Bowie-Dick Test Pack provide reliable performance and accurate results.

LOT and expiry date information can be found on the product label.

The shelf life of our product is 3 years.

Instruction:

Preheat the sterilizer by running a full cycle with an empty chamber. It is important to include all racks in the preheat cycle. After completion of the preheat cycle, place the SAFECHECK Bowie&Dick Test Pack above or as close to the chamber drain as practicable without obstructing the drain. Do not place it on the chamber base.

Perform a pre-vacuum exposure cycle at 134°C for 3.5 min minutes or 121°C -15 min (more than 134°C-3.5 min or 121°C -15 minutes invalidates the test). After the test cycle is complete, remove and open the test box. If the air vacuum is sufficient to allow steam to penetrate, the color of the entire indicator ink shape on the indicator test sheet changes from pink to black. (FIGURE 1)



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Figure 1: Bowie-Dick Color Change*

If there is residual air in the chamber and steam penetration is not sufficient, the indicator ink color will remain pink towards the center (see Figure 2). Atypical failures can be caused by steam source quality issues such as non-condensable gas, wet steam, or superheated steam in the steam source. Some possible test page results due to steam quality issues are shown in Figure 2. For detailed usage instructions, see the instructions on the product packaging.



Figure 2a) Insufficient Vacuum



Figure 2b) Air Leakage







Figure 2c) Superheated Steam



Figure 2d) Wet Steam

Indicator Properties:

Product Code	Product Description	Printed Indicator Type	Indicator Initial Color	Indicator Conversion Color
20.110	Bowie-Dick Test Pack (Wrap Type) 200 sheet	Steam	 	 
20.120	Bowie-Dick Test Pack (Wrap Type) 400 sheet	Steam		
20.210	Bowie-Dick Test Pack (Box Type) 200 sheet	Steam		
20.220	Bowie-Dick Test Pack (Box Type) 400 sheet	Steam		
20.250	Bowie-Dick Test Pack (Wrap Type) 200 sheet Adhesive	Steam		
20.260	Bowie-Dick Test Pack (Box Type) 200 sheet Adhesive	Steam		
20.290	Bowie-Dick Test Pack (Box Type) 400 sheet Adhesive	Steam		
20.310	Bowie-Dick Test Package (A4 Test Sheet)	Steam		
20.320	Bowie-Dick Test Pack (Wrap Type) 400 sheet Adhesive	Steam		

*The indicator color specified on the product is not accepted as a reference. Acceptance criteria must be within the color range shown in the Indicator Properties section of the product's IFU.

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Warnings and Precautions:

- The medical device is for single use only. Do not reuse.
- Check the product before using it. Do not use the product that is deformed or has a color change in the indicator color.
- Do not use expired products.
- Do not store the Bowie-Dick Test Pack near steam sterilisers or strongly alkaline or acidic products such as cleaning disinfectants.

Storage, Storing and Disposal Information:

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose of in accordance with the place of use and local regulations.

Symbols and their meanings on the product label and user manual:

Symbols	Meaning	Symbols	Meaning	Symbols	Meaning
	Manufacturer Information		Production Date (Month/Year)		Single Use Only
	Product Lot Information		Expiration date		CE Symbol
	Reference No		Unique Device ID		Medical Device
	Do not expose to sunlight		Keep Dry		Store between 0°C and 40°C
	Max. 70% RH		Metal free		Lead free
	Suitable for steam sterilization				

Packaging and Product Information:

Product Code	Product Description	Inner Box Quantity(pcs)
20.110	Bowie-Dick Test Pack (Wrap Type) 200 sheet	90
20.120	Bowie-Dick Test Pack (Wrap Type) 400 sheet	48
20.210	Bowie-Dick Test Pack (Box Type) 200 sheet	90
20.220	Bowie-Dick Test Pack (Box Type) 400 sheet	48
20.250	Bowie-Dick Test Pack (Wrap Type) 200 sheet Adhesive	90
20.260	Bowie-Dick Test Pack (Box Type) 200 sheet Adhesive	90
20.290	Bowie-Dick Test Pack (Box Type) 400 sheet Adhesive	48
20.310	Bowie-Dick Test Package (A4 Test Sheet)	200
20.320	Bowie-Dick Test Pack (Wrap Type) 400 sheet Adhesive	90

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Packaging and Product Information:

Product Code	Product Description	Package Contents	Inner Box Quantity
60.103	Chemical Indicator Steam Type 6 3,5 min	250 strip	80 packs
60.105	Chemical Indicator Steam Type 6 5 min	250 strip	80 packs
60.107	Chemical Indicator Steam Type 6 7 min	250 strip	80 packs
60.113	Chemical Indicator Steam Type 6 3,5 min Adhesive	250 strip	80 packs
60.115	Chemical Indicator Steam Type 6 5 min Adhesive	250 strip	80 packs
60.117	Chemical Indicator Steam Type 6 7 min Adhesive	250 strip	80 packs
60.203	Chemical Indicator Steam Type 6 3,5 min Dual	500 strip	60 packs
60.205	Chemical Indicator Steam Type 6 5 min Dual	500 strip	60 packs
60.207	Chemical Indicator Steam Type 6 7 min Dual	500 strip	60 packs
60.213	Chemical Indicator Steam Type 6 3,5 min Adhesive Dual	500 strip	60 packs
60.215	Chemical Indicator Steam Type 6 5 min Adhesive Dual	500 strip	60 packs
60.217	Chemical Indicator Steam Type 6 7 min Adhesive Dual	500 strip	60 packs

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