

DISPOSABLE BOWIE-DICK TEST PACK (Test pack 15 mm)



Product description

Disposable Bowie - Dick test pack is designed to perform Bowie – Dick test in high vacuum autoclaves. The pack has an internal reactive sheet in its center, surrounded by paper sheets as uniform material filling acting as a standardized barrier for steam. It is wrapped with medical grade paper that resists pressure in the autoclave and has an external indicator to verify if the test pack passed the process.

Presentation

Test pack of 120 x 120 x 15 mm. Internal reactive sheet with space to write process data on its front, medical grade paper packaging, uniform filling, resistant sealing and external indicator. Lot number and expiration date in internal reactive sheet and external packaging.

Classification

Type 2 sterilization indicator process complies with ISO 11140-1:2014 standards.

Shelf-life

36 months from the date of manufacture

Stated values

Stated values follow standard Bowie - Dick cycle of 134 °C - 3.5 minutes. Test pack is also suitable for a 121 °C - 12 minutes cycle.

Quality control

Quality system according to ISO 9001: 2015, ISO 13485:2016 and GMP (Good Manufacturing Practices).

Stability

Stability has been verified from manufacture to expiration date, 36 months after date of manufacture.

Authorization and habilitation

ANMAT: PM 1454-44

Test Characteristics

Pack to detect steam penetration in high vacuum autoclaves by means of the color change of an internal reactive sheet. The yellow indicator starts to change its color when steam spreads from outside to inside the pack, turning to black when steam reaches 134°C within 3.5 minutes. When steam spreads through all the surface of the reactive sheet, color changes uniformly to black. Final color may vary tone according to the characteristics of the autoclave. If during the test steam does not reach the reactive sheet completely and uniformly, then the autoclave failed to offer efficient steam penetration due to operative malfunctioning. Reactive agents of this test are completely lead free.

Directions for use

Bowie - Dick test must be performed as a first cycle on a daily basis. Pre-heat the sterilizer by running one complete cycle with an empty chamber. Upon completion, perform a Bowie-Dick cycle, which generally is a pre-established programmed cycle in most autoclaves. The test pack should be placed at the front and lower areas of the autoclave, near the door and must be the only load of the chamber. Once the cycle ends, open the autoclave, remove the test pack and allow it to cool down. Open the pack, remove the indicator sheet and register data and color change. If color is not uniform or is too light, steam penetration was not achieved. In such case repetition of the test is recommended. If the test fails again, revision of the autoclave by a qualified technician is suggested. Failure of the test may be attributed to different reasons related to steam penetration that prevents an efficient performance of the autoclave. The attached color guide helps to interpret the test but does not exhaust the possibilities of failure detection.

Cautions and warnings

Storage temperature should be between 5 and 50 °C. Moisture should be avoided to prevent inactivation of reactive agents upon exposure. If the indicator accidentally gets wet must be discarded and cannot be used. Avoid contact with, or storage near volatile chemicals, cleaning agents and adhesives to prevent alterations in the indicator. Once used, handle with care to avoid burns and allow the test to cool before opening it. Filling paper must be discarded due to the loss of air in its fibers during sterilization and therefore is not reusable and can be recycled.

Bowie - Dick Test

Bowie - Dick test was developed by John Bowie to verify steam temperature in clothes packs. In the beginning, it was made of a sheet of paper and an indicator tape attached to it, placed in the package developed by Bowie. Shortly after, the test evolved into a reactive sheet of approximately 30 x 21 cm that was placed in determined package. Originally the test was made of pure cotton sheets, the only ones available at that moment. Later on, users began to prepare packs with towels and sheets made of different fabrics. Consequently, the test was no longer standardized and results depended on the pack assembly. Pre-assembled tests (test packs) improved this situation as the barrier is standardized and uniform in all packs. Modern test packs have an internal reactive agent calibrated according to the barrier used, making results consistent and verifiable, which is an advantage over hand-made packs. Additionally, the use of test packs is time saving and simplifies the interpretation of results.

Results Guide

