Industrial Use Biological Indicators

Mesa Biological Indicators

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Most commercially available Biological Indicators are designed for healthcare applications and are not well suited for many manufacturing situations. Manufacturers and validation specialists require unique tools where spore strips and ampoules are not suitable because of size, packaging or carrier material. In addition to our line of Healthcare BIs, Mesa offers a line of Industrial Use BIs to address the unique requirements of the medical device and pharmaceutical industries.

Woven Cotton Threads

Length: 19mm Diameter: 1.5mm

Threads have been used at the interface of a syringe and plunger to show sterilant penetration and efficacy at that point. Other uses include placement in tubing and small vials.

Bio-threads are 100% cotton, 3/4" long-- and are inoculated with *B. atrophaeus.*

The device/lumen into which the thread is inserted affects its resistance characteristics.

Polyester Sutures

Length: 5cm Diameter: 0.15mm

A polyester suture is desirable in situations where more flexibility and a small diameter is necessary. Polyester sutures are easy to handle and can be wrapped around or inside objects to aid in sterilization validation of a variety of situations and products.

Steel Discs

8mm x 12mm x 0.45mm

Steel discs are representative of materials found in an isolator, and are compatible with vapor hydrogen peroxide. We strongly recommend our polished stainless steel to eliminate crevices in the carrier which can lead to tailing.

The oblong disc is inoculated with *G. stearothermophilus*, catalog # 3A-6100ST for use in H_2O_2 vapor. Discs are packaged in a Tyvek/Tyvek® pouch and may be exposed in the pouch or an off-center hole in the disc allows them to be removed from their package and suspended throughout the isolator to ensure proper flow.

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Steel Coupons

7mm x 32.8mm x 0.45mm

Steel Coupons (same size as our standard paper strip) are intended for use in dry heat ovens at depyrogenation temperatures.

Inoculated with 10^6 *B. atrophaeus* spores, they are used to correlate spore death (sterilization) with endotoxin reduction. Mesa does not sell endotoxin or other LAL reagents at this time.

Paper Discs

6mm and 9mm

Paper discs have been used to validate sterilization of contact lenses in steam where placement of a strip was impossible due to its size. They are also suitable for EO, Dry Heat (up to 180°C) and radiation sterilization. Discs are also available in circular glassines.

Borosilicate Discs

7mm

Made from high quality glass micro-fibers, borosilicate discs are especially useful in sterilization processes where paper products are not compatible (vapor hydrogen peroxide). They are also suitable for steam, EO, Dry Heat and radiation sterilization.

Steri-Chart

Steri-Chart is a set of strips with 5 different populations, all made from the same spore batch for use in cycle development. Expose the five test strips to determine what level of sterility is being delivered by a particular cycle (industrial use only).

Available with *G. stearothermophilus* (log 3, 4, 5, 6, & 7 test strips and a log 5 control) or *B. atrophaeus* (log 4, 5, 6, 7, & 8 test strips and a log 6 control). A control strip is included. Ten charts per bundle.

Packaging

Carriers can be packaged individually in glassine paper, a Tyvek® pouch, or in bulk plastic bags (no primary packaging). Carriers (individually wrapped) are sold in quantities of 100. Bulk packaged items are sold in quantities of 1,000. Steel Discs are only packaged individually in Tyvek® pouches.

Sterilization/Carrier compatibility:

Hydrogen peroxide (vapor or plasma) is not compatible with cellulosics (paper, wood pulp products), so Mesa's spore strips and blue glassine packaging cannot be used with this type of sterilization. Tyvek packaging and steel carriers are recommended.

Depyrogenation temperatures (180° to 250°C) char or incinerate paper, so we recommend our steel strip carrier. This product is packaged in a Tyvek® pouch so the user can handle it without contaminating the lab with spores. Mesa does not offer a foil package for our steel strips, but recommends that the user wrap the strip in foil or place it inside a glass container prior to exposure in the depyrogenation tunnel/oven. This will assist aseptic transfer to media after the exposure.

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