



Applications of Industrial Use BIs

by Annette Bojanski, M.D.

I recently attended the American Biological Safety Association (ABSA) conference in Orlando, Florida where I had the opportunity to discuss Industrial Use Biological Indicators (BIs). Unlike "standard" BIs, such as spore strips and self-contained BIs (SCBIs) often used to monitor the efficacy of sterilization processes in healthcare settings, Industrial Use BIs address the unique requirements of the medical device and pharmaceutical industries. Over the course of the three-day ABSA event, I discovered that there are a lot of questions surrounding the use of these products, so I thought this warranted further clarification.

Manufacturers and validation specialists often face the daunting task of validating a sterilization process in which the area they are monitoring presents specific challenges. In response to the FDA, cycle development validations often challenge locations within a load that are very small in size and which will not accommodate a traditional BI such as a spore strip.

Industrial Use BIs have been developed over the years in response to customer requests for BIs with a specific length, width and "carrier" material (substrate upon which the spores are inoculated). BIs which are calibrated and certified for resistance and population are now available with diameters as narrow as 0.15 mm. Specific carriers made of stainless steel, cotton, polyester and fiberglass allow these BIs to be used in a variety of processes, including H₂O₂, ethylene oxide, dry heat and steam.



Woven Cotton Threads

Length: 19 mm; Diameter: 1.5 mm

Bio-threads may be used to monitor a variety of sterilization processes, including steam and ethylene oxide (EO or dry heat) where a larger BI such as a spore strip would not be appropriate due to its size. Threads are typically used to monitor narrow spaces such as the interface between a syringe and plunger or the interior of small vials, lumens and other devices. Threads are usually inoculated with Log 6 *B. atrophaeus* (for EO or dry heat) or Log 6 *G. stearothermophilus* (for steam), but may also be inoculated with other organisms. Threads are packaged in a Tyvek®/Mylar envelope, but are intended to be used outside of the primary packaging.

After sterilization, threads are to be aseptically removed from the load and aseptically transferred to a laminar flow hood to be placed into a sterile tube of growth medium. As with other BIs, the thread should be dropped into the center of the tube of growth medium, avoiding contact with the outside of the culture media tube. Recommended incubation is 7 days at 30 – 35°C for EO/dry heat and 7 days at 55 – 60°C for steam/H₂O₂. Daily checks should be made for Growth/No Growth and results should be documented.



Polyester Sutures

Length: 5 cm; Diameter: 0.15 mm

Polyester sutures are generally inoculated with Log 6 *G. stearothermophilus* (for steam) or Log 6 *B. atrophaeus* (for EO/dry heat). Polyester sutures are also packaged in Tyvek®/Mylar prior to use. Because of their narrow diameter (0.15 mm) and flexibility, polyester sutures may be used to monitor the sterilization of narrow spaces or lumens, such as those found in syringes, balloon catheters, rigid scopes and tubing. Standard polyester sutures are 5 cm in length, but custom lengths may also be manufactured. For example, a custom suture may be manufactured in a 60 cm length, and the carrier (suture) may be inoculated with spores at each 12 cm interval.

As with threads, careful attention should be paid to aseptic technique during transfer of the BI to growth medium. Recommended incubation is 7 days at 30 – 35°C for EO/dry heat and 7 days at 55 – 60°C for steam/H₂O₂. Daily checks should be made for Growth/No Growth and results should be documented.



Steel Wires

Length: 19 mm (25 mm w/ loop); Wire Diameter: 0.64 mm; Loop Diameter: 2.2 mm

Steel wires are usually inoculated with Log 6 *G. stearothermophilus* (for monitoring steam processes) or Log 6 *B. atrophaeus* (for dry heat) and are packaged in a Tyvek/Tyvek® envelope prior to use. Steel wires are rigid in nature and available with or without a closed loop on one end. Steel wire BIs are twisted, creating grooves in which spores tightly adhere. Due to its high degree of penetrability, steam will effectively enter these grooves and kill the spores; however, this becomes more of a challenge when using a sterilant such as ethylene oxide. It is for this reason that steel wire BIs are generally not recommended for use in EO cycles.

Common applications in which a wire BI would be appropriate include the monitoring of tubing, narrow lumens and narrow spaces within medical devices. If the internal diameter of the space being monitored permits the use of a wire BI with a loop (i.e. ID greater than 2.2 mm), the loop may be used to facilitate retrieval of the BI following sterilization. (Typically, a narrow gauge wire is attached to the loop so that the BI may be easily removed from the lumen.) Alternately, when using a straight wire (e.g. in tubing), a magnet may occasionally be used to position the wire during sterilization, and to move the wire to the end of the tubing during retrieval.

After aseptic transfer to growth medium, recommended incubation is 7 days at 55 – 60°C for steam processes and 7 days at 30 – 35°C for dry heat.



Paper Discs

Diameter: 6 mm or 9 mm

Paper disc BIs are available with a diameter of 6 mm or 9 mm and are typically inoculated with Log 5 *G. stearothermophilus* or Log 6 *B. atrophaeus* (packaged in bulk). Because of their size and shape, paper discs inoculated with *G. stearothermophilus* have often been used to monitor the sterilization of contact lenses in steam. Paper discs packaged in circular glassine have also been used in Steam-In-Place (SIP) applications.

Aseptic transfer to growth medium is similar to that stated earlier, and recommended incubation is 7 days at 55 – 60°C for steam processes. Paper discs may also be used in dry heat cycles (up to 180°C) as well as in processes utilizing EO and irradiation. Recommended incubation for *B. atrophaeus* paper discs (used in EO/dry heat) or *B. pumilus* discs (used in gamma irradiation) is 7 days at 30 – 35°C.



Other Industrial Use BIs

Other Industrial Use BIs include the ProLine PCD (specifically designed for the monitoring of tubing), steel discs, steel coupons (also called steel "strips"), borosilicate discs and micro-Strips. Please feel free to contact me at abojanski@mesalabs.com for further information.

Annette joined Mesa Labs in 2007 as a Healthcare Sales Representative and later transitioned to Technical Support. As a Technical Support Specialist, she provided technical presentations and support to clinical and industrial BI users. Annette continues to provide technical guidance in her new role as US Sales Manager of Mesa's BI division.