Apex Discs - Triplicates

Using BIs in Triplicate for VHP Processes

Some sterilization processes, such as saturated steam under pressure with a pre-vacuum air removal, have great penetrative capabilities. The same is not true for ambient pressure gassing processes such as vapor phase hydrogen peroxide (VHP) at ambient pressures. Due to the limited penetrating capability of VHP, any presence of debris amongst the spores can also lead to spores surviving VHP exposures where kill was otherwise expected; a concept referred to as "rogue BIs" in various publications. Section 8.1 of PDA Technical Report No. 51 suggests that re-running the cycle with a different lot of BIs or re-running the cycle with duplicate or triplicate BIs in the same location may be necessary.

The reason to use multiple BIs at each test location is because we need each BI to be a statistical replicate of its neighbor. Instead of monitoring 100 discrete locations throughout the isolator, the validation technician can identify the 30 or 40 most difficult to sterilize locations and use triplicate BIs at each of these challenge locations, thus consuming 90 or 120 BIs per cycle. When only one BI is used at each test location, and that one BI yields a growth-positive result, there is no way to calculate if that result was due to one surviving spore, or hundreds-of-thousands of surviving spores.

Despite one growth-positive BI at a location of triplicate BIs, one can still document that a 6+ spore log reduction was achieved at that particular test location. Do be advised that this calculation is ONLY possible when replicate BIs are used. To find out more about how triplicate BIs are being used in VHP, click the link below to read the Spore News article on the subject.

http://www.mesalabs.com/wp-content/uploads/2012/09/Spore-News-Vol-9-No4.pdf

- Packaged in Tyvek/Tyvek
- Discs measure 0.35" diameter x 0.008" thick
- Tyvek packaged indicators have perforations for hanging and a thumb notch for peeling
- Available with reference #12980 or #7953
- Catalog #HMV-091T