Apex Biological Indicators

Apex Biological Indicator products are designed specifically for the pharmaceutical, food and medical device industries utilizing H_2O_2 vapor sterilization. Whether it be stainless steel discs/ribbons or a spore suspension, Apex BI products offer the ideal solution to monitoring hydrogen peroxide sterilization.

Gaseous Hydrogen Peroxide Systems Products and Services

The stainless steel carrier material is designed for use with today's isolator and filling line applications.

Apex Discs

- Packaged in Tyvek/Tyvek[1]
- 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

Apex Ribbons

- Bare stainless steel ribbons measure (0.25" x 2.75")
- Inoculated at one end
- Convenient size and flexibility

Key features and benefits

- Grade 304 stainless steel carrier is non-absorptive - no H_20_2 residuals
- Thin carrier (0.008" thick) warms and cools rapidly with chamber variations
- Minimum 1.0 x 10^6 spores per carrier

[1] Tyvek is a registered trademark of DuPont Corporation.

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Apex Biological Indicators

Tri-Scale Biological Indicator for Hydrogen Peroxide

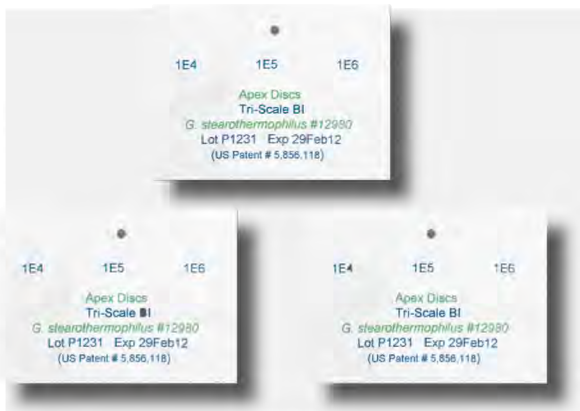
(US Patent # 5,856,118)

Tri-Scale BI (Reorder #LOG-456) features:

- Based on grade 304 stainless steel carriers; no residuals issues
- One convenient Tyvek[1]/Tyvek package; three *G. stearothermophilus* populations
- Three carriers respectively inoculated with >1x10^4, >1x10^5 and >1x10^6 spores and sealed in separate compartments
- Thumb notch for peeling; perforated for hanging

Uses:

- Initial shakedown or validation of new enclosures or filling lines
- Evaluating large or uniquely configured enclosures
- Studying systems with unknown gas distribution dynamics
- Enclosure validations with multiple load configurations
- Routine monitoring of identified worst-case enclosure locations



General Method:

- Place Tri-Scale BIs in selected sites throughout test enclosure
- Conduct an exposure time estimated to be near the 6 log reduction point
- Retrieve Tri-Scale BIs, culture, and observe for outgrowth
- Based on outgrowth patterns, identify worst-case location(s) in enclosure
- Use fractional outgrowth results to estimate a probable 6 log reduction cycle

For example, a location where the 1x10^5 and 1x10^6 carriers grew had adequate sterilant to kill 1x10^4 spores, but not 1x10^5 spores, and will require a longer cycle to ensure sterilization of this location.

Microbial Suspensions

G. stearothermophilus for gaseous hydrogen peroxide
Custom applications and custom preparations

Testing

Complete System Validations
Propagation and Resistance Testing of Environmental Isolates

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