Apex Biological Indicator products are designed specifically for the pharmaceutical, food and medical device industries utilizing \( \text{H}_2\text{O}_2 \) 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 \( \text{H}_2\text{O}_2 \) residuals
- Thin carrier (0.008” thick) warms and cools rapidly with chamber variations
- Minimum 1.0 \( \times 10^6 \) spores per carrier

### 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

\(^1\)Tyvek is a registered trademark of DuPont Corporation.
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 $1 \times 10^5$ and $1 \times 10^6$ carriers grew had adequate sterilant to kill $1 \times 10^4$ spores, but not $1 \times 10^5$ 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