Raven Labs

A division of Mesa Laboratories, Inc.

Sterility Assurance for Industry

Sterility Assurance Products Since 1949

www.ravenlabs.com

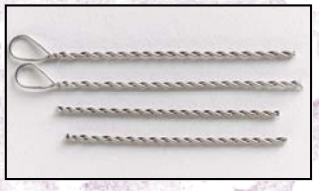
Industrial Use Biological Indicators

Most commercially available Biological Indicators were 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, Raven offers a line of Industrial Use BIs to address the unique requirements of the medical device and pharmaceutical industries.

Length: 19mm
Diameter: 1.5mm

Bio-threads[1,2,3] are woven cotton threads and are available for placement into small openings or lumens. Threads can be used to monitor various sterilization methods.

- 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, 19mm long and can be inoculated with *B. atrophaeus* (reference # 9372) or *G. stearothermophilus* (reference # 7953 or # 12980).



Length: 19mm
(25mm with loop)
Diameter: 0.635mm

Steel wires[1,2,3] are intended for use in steam sterilization.

- Wires are inoculated with *G. stearothermophilus* spores and are designed to be placed into small lumens. Due to their rigid nature, they are easy to retrieve even if there is condensation within the lumen. Wires are also available with a closed loop at one end, so a small wire can be attached to ease in retrieval.

Strips: 7mm X 33mm
0.45mm thick
Discs: 8mm X 12mm
0.45mm thick

Steel strips[1,3] are intended for use in dry heat ovens at depyrogenation temperatures (180°C to 250°C). It is recommended that the user remove the steel carrier from the pouch and wrap the carrier in foil or place it inside a glass container prior to exposure in the depyrogenation tunnel/oven.

- Inoculated with 10^6 *B. atrophaeus* spores, they are used to correlate spore death (sterilization) with endotoxin reduction.

Steel discs[1,3] are compatible with hydrogen peroxide vapor, dry heat and steam sterilization. Raven offers a polished stainless steel surface to eliminate crevices in the carrier which can lead to tailing.

- Inoculated with *G. stearothermophilus* reference # 12980 (catalog # 3A-6100ST) for use in H_2O_2 vapor, *G. stearothermophilus* reference # 7953 (catalog # 3-6100ST) for use in steam or *B. atrophaeus* reference # 9372 (catalog # 1-6100ST).

Complete catalog available upon request. Raven is an FDA registered manufacturer. Raven Labs' Quality System has been registered to ISO Quality Standards since 1997. All Biological Indicators are manufactured and tested in accordance with ISO 11138 and current USP.

Rev. 11/08

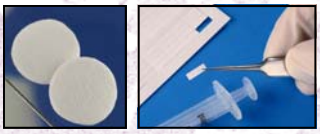
Industrial Use Biological Indicators

Spore Suspensions[1,3] are diluted aliquots from our primary spore crop (batch) used to directly inoculate (challenge) a material or solution with a known concentration of spores.

- Determine if the device's carrier material or pharmaceutical's properties (viscosity, salt content, etc.) have any sporicidal or preservative effect.
- Directly challenge devices or solutions with a known quantity of spores.
- Aids in determining how to sterilize product or how the user should reprocess the device.
- Suspensions are offered in 40% ethanol solution for hydrophobic materials or 100% deionized H_2O.

Paper strips[1,3] can be used in any sterilization method compatible with paper products and are available in our standard 38mm X 6mm (1 ½ X ¼ inches), half length and 2mm X 10mm. Raven has validated a 24-hour incubation period for our *G. stearothermophilus* strips with our culture media for all steam cycles. For more information, please contact us or visit us at www.ravenlabs.com.

Paper discs[1,2,3] 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. Standard sizes are 6 and 9 mm for the cellulose discs and 10mm for the borosilicate discs.



Steri-Chart[1,3] 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 lethality is being delivered by a particular cycle. A control strip is also included. 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). Special or custom charts are available (e.g. steel discs in Tyvek®).

ProLine[1] is a Process Challenge Device (PCD) for use in the validation or monitoring of sterilization cycles of tubing ranging from 3.2mm to 15.8mm (1/8" to 5/8") ID. ProLine contains a filter paper disc inoculated with bacterial spores of *G. stearothermophilus* for steam or *B. atrophaeus* for EO. The spore disc is packaged in a glassine envelope and is located in the center of the ProLine housing. If there is adequate penetration of the sterilant, the spores on the disc will be killed verifying lethality at point of placement. More information available upon request.

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Species

Raven offers many species of non-pathogenic, spore-forming bacteria. Most are used for various types of sterilization, though some have other uses, including the following:

- *G. stearothermophilus* (reference # 7953) for steam , *B. atrophaeus* (reference # 9372) for dry he at and EO and *B. pumilus* (reference # 27142) for gamma irradiation are standard Raven products.

- *B. subtilis* (reference # 6633) – Used to test the growth promotion ability of bacteriological media (specified in USP and other compendia). This organism is not certified for resistance characteristics.

- *B. subtilis* (called "Designate 5230") is used in steam sterilization procedures below 121°C. Some products are sterilized at 106° to 115°C because they are heat labile and would be dam aged at higher temperatures. This species has been used as a challenge to thes e lower temperatures in steam, where *G. stearothermophilus* would be too great a challenge. When using a lesser challenge it is necessary to have an extremely high level of control over the manufacturing process, environment, and bioburden of components. This organism is certified with D and z-value.

- *G. stearothermophilus* (reference # 12980) has been used in steam and other types of sterilization. In particular, it is used to validate Hydrogen Peroxide (H_2O_2) vapor sterilization of barri er isolators and clean areas in m anufacturing suites. This product is typically inoculated onto steel carriers to be com patible with H_2O_2 processes. This organism is certified for D-value in H_2O_2.

- *G. stearothermophilus* (reference # 10149) is used to detect resi dual antibiotics in dairy products. This organism is not certified for resistance characteristics.

- *B. thuringiensis*[4] (reference # 29730) has a protein crystal on the spore coat that is toxic to various insect larvae. Trees are often sprayed with a spore suspension of *B. thuringiensis* to protect them from these larvae. *B. thuringiensis* has also been used as a surrogate to *B. anthracis* and other dangerous organisms in testing decontamination process efficacy.

- *B. cereus*[4] (reference # 11778) and *B. megaterium*[4] (reference # 8245) are often used in steam sterilization at 106° to 115°C. *B. cereus* is also used as a surrogate for *B. anthracis* and other dangerous organisms in testing decontamination process efficacy.

Packaging

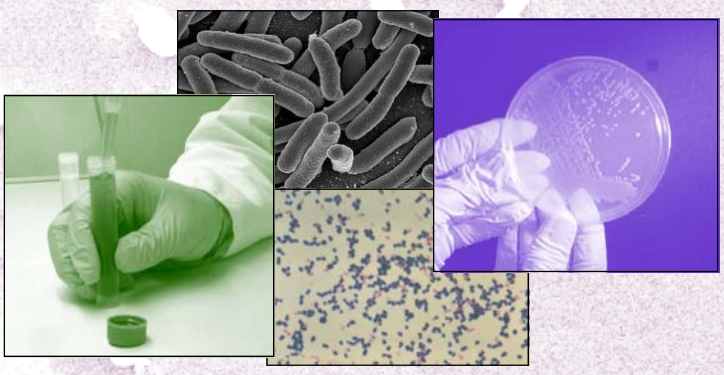
Carriers can be packaged individual ly in glassine paper, a T yvek® pouch, or in bulk plastic bags (no primary packaging). Individually wrapped carriers are sold in quantities of 100. Bulk packaged items are sold in quantities of 1,000. Steel carriers are available individually packaged in Tyvek® pouches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

Sterilization/carrier compatibility:

Hydrogen peroxide (vapor or plasma) is not compatible with cellulosics (paper or wood pulp products). For this reason, spore strips and gl assines cannot be used with H_2O_2. Tyvek® packaging and steel carriers are recommended.

Contract/Testing Services

Raven's state of the art testing laboratory allows the ability to offer several additional and complimentary services. Raven will gladly work with you to develop a testing program tailored specifically to the needs of your company. Raven Labs is licensed by the Drug Enforcement Agency (DEA) to perform testing on controlled substances.



Custom BI Development

- Ampoule Filling for Self-Contained BI
- BI Development for Novel Sterilization Technology
- Inoculation of Client Provided Substrate
- Population and Resistance Characterization

Custom Batch Production

- Environmental Isolate Growth and Characterization Testing
- Contract Batch Production (spore forming non-pathogenic bacteria)

Chemical Indicator Testing

- Label Claim Testing
- Product Development

Commercial BIs

- Certificate of Analysis Verification
- Survival Kill Verification
- BI Culturing
- Population Determination
- Identification/Purity Testing
- D-value and z-value Testing
  - Steam
  - Ethylene Oxide
  - Dry Heat
  - Vaporized Hydrogen Peroxide (VHP)

Pharmaceutical

- Solutions
  - D-value and z-value Testing
  - Bioburden Testing
- Stopper/Septa
  - D-value and z-value Testing
  - Custom Inoculation for Sterilization Cycle Validation Studies

Steam Autoclave Testing

- Temperature Mapping
- Calibration
- Cycle Development

Additional Biological and Chemical Indicators

Footnotes:
1.The device/lumen into which the BI is placed affects its resistance characteristics.
2.Custom lengths and/or sizes available.
3.Various organisms available.
4.Resistance data available as a contract service.

Raven Labs
8607 Park Drive
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FDA Registered

Custom and Standard BIs

ISO 13485:2003 Certified

World Wide Distribution

BIs Meet ISO 11138 and USP

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