



**PRODUCT CHANGE NOTIFICATION**

31 January 2018

**Notification ID:** CN-180104

**Notification Type:** Product Manufacturing, Testing and Labeling Changes

Dear Customer,

We would like to take this opportunity to notify you of changes that will be made to the *Geobacillus stearothermophilus* and *Bacillus atrophaeus* polyester suture biological indicators. As detailed in previous notifications, Mesa Labs is relocating manufacturing operations from its facility at 8607 Park Drive, Omaha, NE 68127 to a newly constructed facility at 625 Zoot Way, Bozeman, MT 59718. This change notification impacts polyester suture catalog numbers:

- 1-6100YT – log 6 *Bacillus atrophaeus* sutures
- 3-6100YT – log 6 *Geobacillus stearothermophilus* sutures

Effective with the first lots to be released from the Mesa manufacturing facility located at 625 Zoot Way, the following changes are being implemented:

**Manufacturing Process**

A new manufacturing process will be implemented for polyester suture biological indicators. These changes are being made to reduce the suture-to-suture population variability. These changes affect:

- Processing of polyester sutures prior to inoculation
- Inoculation method for the sutures

The new process will be validated prior to release of the product line for distribution.

**Product Testing**

Resistance testing will no longer be conducted on polyester sutures biological indicators. They will be certified for heat-shock population only.

This change is being made to support the multiple intended uses of the product. Since use of the product by the customer can result in inconsistencies within primary and secondary packaging, the reported D-value will instead be based on results of testing of the same spore culture lot inoculated on paper spore strips, packaged in glassine envelopes and tested in either steam for *Geobacillus stearothermophilus* or ethylene oxide for *Bacillus atrophaeus*.

As was also true before the change, the resistance data should serve as a reference point for lot-to-lot variation only.



**Product Labeling – Certificate of Analysis and Bag Label**

- The instructions for use have been added to the certificate.
- A part number and revision number have been added to the certificate.
- A new lot number format will be used. A prefix SP will be assigned followed by a 3-digit sequential number. Example: SP-001
- The format of the expiration date format will be aligned with regulatory requirements (YYYY-MM-DD.)
- The address has been changed to reflect the manufacture and distribution of this product from the new facility in Bozeman, MT.
- The reported resistance on the certificate of analysis will be based on previously assessed paper spore strip D-value data instead of on testing of the sutures in glassine. The note regarding resistance testing included on the Certificate of Analysis will be revised.
  - Previous statement: *Determined on cotton threads in glassine envelopes for primary spore crop, Fraction Negative method.*
  - New statement: *Resistance was determined in an AAMI BIER vessel using a paper carrier package in glassine and calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.*

Examples of the revised certificates are attached. As always, if you have any questions, please contact your Mesa Laboratories Representative.

  
 \_\_\_\_\_  
 Robert Bradley, Director of Production 31 Jan 2018  
Date

  
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 Janis E. Smoke, Director of Quality & Regulatory Affairs 31 Jan 2018  
Date



# CERTIFICATE OF ANALYSIS

BIOLOGICAL INDICATOR

*For Industrial Use Only*

# INSTRUCTIONS FOR USE

Reorder No: 1-6100YT

*Bacillus atrophaeus* 9372<sup>(1)</sup>

Biological Indicator recommended for: Ethylene Oxide Gas Sterilization

Culture: Soybean-casein digest broth.

Purity: No evidence of contaminants using standard plate count techniques.

Incubation: 7 days in soybean-casein digest broth at a temperature of 30 – 35°C.

Storage: Cool (60 – 80°F, 15 – 27°C), 30 – 70%RH, away from sterilizing agents, direct sunlight, and all other forms of UV light. Do not refrigerate.

Disposal: Sterilize all cultures before discarding.

Lot No: **SP-000** Manufacture Date: YEAR MONTH DAY

Expiration Date: YEAR MONTH DAY

Nominal Population: 0.0 x 10<sup>6</sup> CFU<sup>(2)</sup>/polyester suture

Carrier size: Approximately 2”

Assayed Resistance:

D-value <sup>(3)</sup>

Ethylene Oxide  
(600 ± 30 mg/l, 60 ± 10%  
RH, 54 ± 1°C) **100% EtO** 0.0 min.

## Poly Sutures:

1. Aseptically place the polyester sutures into the sterilization load. Polyester sutures are designed to be used in areas with small lumen or areas where a spore strip will not fit properly.
2. Run the sterilization cycle as normal.
3. Aseptically remove the polyester sutures from the sterilization load and aseptically transfer the polyester sutures to a sterile tube of growth media (use a laminar flow hood or similar equipment).
4. Incubate for 7 days at 30-35°C for EtO. Daily checks should be made for Growth/No growth and results documented.

NOTE: This is a single-use product. Use of a unit in multiple cycles will invalidate the results and could potentially result in the release of nonsterile product.

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility’s quality standards, USP, and ISO 11138 and all appropriate subsections.

<sup>(1)</sup> Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

<sup>(2)</sup> Colony forming units.

<sup>(3)</sup> Resistance determined in an AAMI BIER vessel using a paper carrier packaged in glassine, and calculated using Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.

Part No.77011  
Rev.1

Certified By:

\_\_\_\_\_  
Quality Assurance Representative

\_\_\_\_\_  
Date



**Bozeman Manufacturing Facility**

625 Zoot Way

Bozeman, MT 59718

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**CERTIFICATE OF ANALYSIS**  
BIOLOGICAL INDICATOR  
*For Industrial Use Only*

Reorder No: 3-6100YT  
*Geobacillus stearothermophilus* 7953<sup>(1)</sup>  
Biological Indicator recommended for: Steam Sterilization  
Culture: Soybean-casein digest broth.  
Purity: No evidence of contaminants using standard plate count techniques.  
Incubation: 7 days in soybean-casein digest broth at a temperature of 55 – 60°C.  
Storage: Cool (60 – 80°F, 15 – 27°C), 30 – 70%RH, away from sterilizing agents, direct sunlight, and all other forms of UV light. Do not refrigerate.  
Disposal: Sterilize all cultures before discarding.  
Lot No: **SP-000** Manufacture Date: YEAR MONTH DAY  
Expiration Date: YEAR MONTH DAY  
Nominal Population: 0.0 x 10<sup>6</sup> CFU <sup>(2)</sup>/polyester suture  
Carrier size: Approximately 2”  
Assayed Resistance:  
Temperature D-value <sup>(3)</sup>  
Steam 121°C 0.0 min.  
Z-value: 0.0°C

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility’s quality standards, USP, and ISO 11138 and all appropriate subsections.

<sup>(1)</sup> Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

<sup>(2)</sup> Colony forming units.

<sup>(3)</sup> Resistance determined in an AAMI BIER vessel using a paper carrier packaged in glassine, and calculated using Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.

Certified By: \_\_\_\_\_

Quality Assurance Representative

\_\_\_\_\_ Date



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**INSTRUCTIONS FOR USE**

**Poly Sutures:**

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2. Run the sterilization cycle as normal.
3. Aseptically remove the polyester sutures from the sterilization load and aseptically transfer the polyester sutures to a sterile tube of growth media (use a laminar flow hood or similar equipment).
4. Incubate for 7 days at 55-60°C for steam. Daily checks should be made for Growth / No growth and results documented.

NOTE: This is a single-use product. Use of a unit in multiple cycles will invalidate the results and could potentially result in the release of nonsterile product.

Part No.77010  
Rev.1

**LIMITATION OF LIABILITY AND INDEMNITY:** In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall Mesa Labs or its suppliers be liable for any consequential or incidental damages including, but not limited to loss of profits or revenues, loss of use of the Products or any associated equipment, loss of the Buyer’s Products, damage to associated equipment, cost of capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer for itself, its successors and assigns, hereby agrees to indemnify Mesa Labs and to hold Mesa Labs harmless from any and all liability for such consequential or incidental damages. The responsibility of Mesa Labs for damages due to injuries to employees of the Buyer or ultimate user of the Product, caused by the Product, shall be limited to repair or replacement of the item, at the option of Mesa Labs. The Buyer agrees to indemnify Mesa Labs and hold Mesa Labs harmless from any further damages, indemnity or contribution. Mesa Labs liability for any claim of any kind, including performance or breach thereof, or from the Products to Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim.