

SUPPLY INTERRUPTION NOTIFICATION

April 10, 2018

Notification ID: CN-180402

Notification Type: Supply Interruption – Suture Biological Indicators

Dear Customer,

This letter is to inform you of a supply interruption from Mesa's 625 Zoot Way Bozeman, MT Manufacturing Facility for the following products:

- 1-6100YT; *Bacillus atrophaeus* log6 2in sutures
- 1-6100YTHW; *Bacillus atrophaeus* log6 2in sutures – Hard Water
- 3-6100YT; *Geobacillus stearothermophilus* log6 2in sutures
- 3-6100YTC2; *Geobacillus stearothermophilus* log6 2cm sutures

This interruption of supply is a result of relocating the manufacture of the suture biological indicators from our Omaha, NE manufacturing facility to our newly constructed Bozeman, MT manufacturing facility. In conjunction with the relocation of each of our BI products we are evaluating the processes for the manufacture of those products. During the evaluation of the suture biological indicators we identified opportunities for improvement. We are currently working to incorporate those improvements into the manufacturing process. Once we are confident we have developed a consistent manufacturing process we will conduct a full validation of the process and subsequently relaunch this product at our Bozeman, MT manufacturing facility. At this time we do not have a projected date as to when the manufacture of these products will resume.

If the status of this situation changes we will update this information.

We appreciate your business and apologize for the inconvenience this condition has created for you.

Please contact us with any questions or concerns at bi-support@mesalabs.com.


Robert Bradley, Director of Production

13 Apr 2018
Date


Janis E. Smoke, Director of Quality & Regulatory Affairs

13 Apr 2018
Date