

April 1, 2019

RE: UPDATE on Bivona® Sterilization Efforts

Dear Bivona® Customer,

Due to the shutdown of the Sterigenics sterilization site in Willowbrook, IL, Smiths Medical is still experiencing a supply disruption on our Bivona® tracheostomy tubes portfolio.

By way of an update, we wanted to let you know that the second sterilization cycle with Bivona® tracheostomy tubes has been completed at the new sterilization site. We are on track to have the preliminary results for these two cycles available within the next two weeks. These results are critical to finalizing the timeline and understanding when we will be able to get sterile Bivona® tracheostomy tubes to you and your patients. Please also note that all standard Bivona® tubes can be reprocessed according to the Instructions for Use that are included with every tube.

Smiths Medical is continuing to build Bivona® tracheostomy tubes per our regular manufacturing schedule. These products will be sent for sterilization upon receipt of satisfactory test results and will be ready as soon as we confirm they meet all safety, quality and compliance requirements.

We value your business and appreciate your understanding during this challenging time. We recognize providing a safe tracheostomy tube to your patient is the most important objective.

If you have any questions, please contact your local Smiths Medical representative, or contact our customer service team at 1-800-258-5361.

Respectfully,



Joan Cummings
Marketing Director
Smiths Medical