



Use of Biological Indicators Manufactured by Third Parties in STERRAD® Systems

Dear Customer,

Thank you for your valued and continued support of Advanced Sterilization Products (ASP) and STERRAD® Sterilization Systems (STERRAD® 100S, STERRAD® NX®, STERRAD® NX® with ALLCLEAR® Technology, and STERRAD® 100NX, STERRAD® 100NX with ALLCLEAR® Technology) (“STERRAD® Systems”) and accessories.

This letter is to inform you that ASP has received several complaints of positive results associated with the use of biological indicators (BIs) manufactured by third parties (i.e. not manufactured by ASP) when used in STERRAD® Sterilization Systems. This represents a significantly higher incidence rate of positive BI complaints reported to ASP as compared to the STERRAD® Biological Indicators (CYCLESURE® 24 or VELOCITY™). **In each of the cases that ASP has investigated, ASP has confirmed that the STERRAD® Sterilization Systems were operating and continue to operate as intended and validated.**

ASP recommends the use of STERRAD® CYCLESURE® 24 or STERRAD® VELOCITY™ Biological Indicators for frequent monitoring of the STERRAD® Sterilization Systems. Complete proprietary sterilization cycle parameter and performance information – only available to the manufacturer of the STERRAD systems – was used to design the STERRAD® CYCLESURE® 24 and STERRAD® VELOCITY™ Biological Indicators to ensure its accuracy in monitoring each of the unique hydrogen peroxide STERRAD® System cycles, optimizing accuracy and performance across all STERRAD® Sterilization Systems.

STERRAD® CYCLESURE® 24 and STERRAD® VELOCITY™ Biological Indicators are the only biological indicators that have been tested and validated by ASP for use in STERRAD® Sterilization Systems.

As a reminder, if a positive result is observed, follow your facility policy and procedures regarding retrieval of unused instruments and notification to physicians, and the instructions within the STERRAD® Sterilization Systems User Guides. If experiencing issues with a BI manufactured by a third party, please also contact the third party manufacturer’s customer service number to report the issue.

If you have any additional questions, please contact your local ASP representative or call customer service.

Again thank you for your continued support of ASP and confidence in STERRAD® Sterilization Systems. We value you as a customer and appreciate the opportunity to assist you in continuing to raise the standard of care at your healthcare facility.

Sincerely,
Chanda Owens
Senior Director, Quality & Compliance

33 Technology Drive, Irvine, CA 92618. Tel: 949.581.5799. Fax: 949.581.5997

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a **Johnson & Johnson** company