



Date: January 30th, 2018

**Subject:
STERRAD VELOCITY™ & non-ASP Biological Indicators used in STERRAD™ Systems**

To whom it may concern

Dear Valued ASP Customer,

Our mission is always to provide infection prevention solutions to healthcare organizations while delivering sterility assurance through products that are safe for devices, healthcare workers, patients, and the environment.

With this letter Advanced Sterilization Products (ASP) would like to provide you with clarification and recommendations regarding the use of non-ASP Biological Indicators into the STERRAD® Sterilization Systems.

The cycle parameters for each of the STERRAD® cycles are different. Because of this, the design of the BI must take into consideration these variations and must work correctly for all cycles. The STERRAD VELOCITY™ BI is precisely designed to provide the appropriate level of challenge to each of the cycles for which it is indicated. The biological indicator must not be fully inactivated before the conditions required to sterilize the most challenging medical devices approved for use in each cycle are achieved (e.g. a false negative). At the same time, the BI must be fully inactivated before the completion of the cycle (to prevent a false positive). The performance targets are different for each indicated STERRAD® cycle, thus the performance of the BI must be tightly constrained to provide the appropriate challenge for all indicated cycles.

ASP is the only entity that has validated the Biological Indicators designed, tested, and manufactured by ASP, to be compatible with and optimized for every cycle on all types of STERRAD® Systems.

ASP has not validated biological indicators manufactured by third parties for use in its STERRAD™ cycles & systems.

In the event of an issue or inconvenience resulting from the use of non-ASP products with STERRAD® sterilizers, the customer will bear any risk and ASP will not be able to provide a solution as always and resolve the complaint.

With the new generation of technologies ASP can offer you a complete Ecosystem experience that helps you remain compliant, safe and efficient with automatic reconciliation of cycle & BI records, automatic record keeping, BI notifications communicated to the STERRAD system, remote access & diagnostics and much more.

Thank you for your continued support and confidence in the STERRAD® technology. We value you as a customer, and appreciate the opportunity to support you with your infection prevention needs.

Sincerely,

Advanced Sterilization Products

ADVANCED STERILIZATION PRODUCTS

Division of Cilag GmbH International

a **Johnson & Johnson** company

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