

Date

**URGENT - MEDICAL DEVICE FIELD SAFETY NOTIFICATION:
STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® 100NX® and STERRAD® NX® System Cassettes
Positive Leak Indicator Stability after Exposure to Hydrogen Peroxide**

Dear [\[insert contact here\]](#),

This communication is to notify you that Advanced Sterilization Products (ASP) recently determined, as part of its routine quality program that the leak indicator on the STERRAD® System cassettes packaging assembly may not function properly after exposure to hydrogen peroxide. STERRAD® System cassette packaging assemblies are designed with a leak indicator on the inner package to provide a visual color indication in the event hydrogen peroxide has leaked from the cassettes.

Description of the Issue

The STERRAD® System cassettes leak indicator turns from yellow to red when exposed to hydrogen peroxide. ASP has determined that the leak indicator may not be stable, which means the color of the leak indicator, after exposure to hydrogen peroxide may not remain red for the duration of the products' shelf-life. ASP has a corrective action in place to address the leak indicator on all STERRAD® System cassettes. In the meantime, ASP is recommending the following actions until that change takes effect:

What Action Is Recommended?

Please note this is not a removal of the product and customers are not being asked to return any product at this time. ASP advises the customer to follow the below precautions when handling new cassettes:

- Please follow hospital guidelines on handling hazardous material to exercise extra precaution. The ASP recommendation on exercising extra precaution when handling new STERRAD System Cassettes is as follows:
 1. **The customer should wear personal protective equipment (e.g. gloves) when handling the cassette. This is a precautionary measure in the event that the customer comes in contact with hydrogen peroxide.**
 2. **In addition to wearing personal protective equipment, the customer should perform a visual inspection of the cassette package to look for signs of liquid leakage prior to opening the package. If a liquid leak is observed, the customer should dispose of the cassette package immediately and contact [\[insert contact here\]](#).**
 3. **If you come into contact with hydrogen peroxide, immediately flush the affected area with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention promptly if symptoms occur after washing. Wash contaminated clothing before reuse.**
- Maintain a copy of this communication with your STERRAD® 50, STERRAD®100S, STERRAD®200, STERRAD® NX® and/or STERRAD® 100NX® System(s) until further notice from ASP regarding this issue.
- This is not a removal of product, and customers are not being asked to return any STERRAD® System cassettes at this time.

Why you are being contacted:

You are receiving this letter because our records indicate that you have received STERRAD® 50, STERRAD®100S, STERRAD®200, STERRAD® NX® and/or STERRAD® 100NX® System(s) cassettes. To report any complaints or suspected problems with your STERRAD® Systems cassettes related to this letter, please contact [\[insert contact here\]](#).

The U.S. Food and Drug Administration (FDA) has been notified and is aware that ASP is voluntarily communicating this information.

We know that you place high value in our products. We appreciate your cooperation in this matter and value you as our customer. ASP is committed to maintaining your confidence in the safety and quality of our products.

Sincerely,

[\[insert contact here\]](#)

ADVANCED STERILIZATION PRODUCTS®

Division of Ethicon, Inc.

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