



URGENT FIELD SAFETY NOTICE

ATTENTION	Central Sterilisation Department
TYPE OF ACTION	Voluntary FIELD SAFETY NOTICE
REF / DATE	ASP05/2014 (FA 158) – November 25, 2014
PRODUCT	STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® 100NX® and STERRAD® NX® System Cassettes Product Codes: 10113, 10114, 10118, 10133, 10144
REASON	<p>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.</p> <p>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.</p>
ACTION	<p>Please note this is not a removal of the product and customers are not being asked to return any product. ASP advises the customer to follow the below precautions when handling new cassettes:</p> <ul style="list-style-type: none">• 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:<ol style="list-style-type: none">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.



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	<ul style="list-style-type: none">This is not a removal of product, and customers are not being asked to return any STERRAD® System cassettes,
TRANSMISSION	<p>Please share this information with any of your staff that work with STERRAD® Cassettes.</p> <ul style="list-style-type: none">Product Codes: 10113, 10114, 10118, 10133, 10144
CONTACT	<p>If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name].</p> <p>We apologize for any inconvenience this will cause you, but rest assured it is our utmost intent to make this process as easy for you as possible.</p>
CONFIRMATION	<p>This action has been notified to the appropriate Regulatory Agencies. Please note that according to MEDDEV/Local Law you have an obligation to co-operate.</p>