



URGENT FIELD SAFETY NOTICE

ATTENTION	Central Sterilisation Department
TYPE OF ACTION	Voluntary FIELD SAFETY NOTICE
REF / DATE	ASP17/2013 (CL-90098-029)/December 16, 2013
PRODUCT	STERRAD 50, STERRAD 100S and STERRAD NX Sterilisation System Product Code: 10050,10101, 10033
REASON	<p>The purpose of this communication is to inform you that Advanced Sterilization Products (ASP) has determined that the STERRAD[®] 50, STERRAD[®] 100S, and STERRAD[®] NX[®] Sterilisation Systems may emit an odour or smell into the surrounding environment that may not be typical to normal operating conditions.</p> <p>ASP has received a limited number of customer complaints by healthcare workers reporting odours/smells potentially emanating from the STERRAD[®] Systems. ASP is investigating this issue to determine the source of the odour/smell and recommends the steps outlined below.</p>
ACTION	<ul style="list-style-type: none">• This is not a product recall, and ASP is not requiring customers to return any product.• If you detect odours and smells as described above, personnel should leave the room as a precaution and discontinue use per the User's Guide of the STERRAD[®] System until the system is serviced. Personnel should avoid working in the room until the odour/smell has cleared. [insert contact here]• Maintain awareness of this communication until ASP has serviced your STERRAD[®] Sterilization system.• Maintain a copy of this communication with your STERRAD[®] 50, STERRAD[®] 100S and STERRAD[®] NX[®] System.
TRANSMISSION	<ul style="list-style-type: none">• Please share this information with any of your staff that work with or around your STERRAD[®] 50, STERRAD[®] 100S and STERRAD[®] NX[®] System.
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	This action has been notified to the appropriate Regulatory Agencies.