




# URGENT FIELD SAFETY NOTICE

<b>ATTENTION</b>	Operating Room Director and Materials Management
<b>TYPE OF ACTION</b>	Voluntary FIELD SAFETY NOTICE
<b>REF / DATE</b>	ASP04/2012/July 16, 2012
<b>PRODUCT</b>	The issue involves the following product code and lot number:  STERRAD 100S Cassette REF 10113  Lot Number: 12A070
<b>DEVICE DETAILS</b>	ASP has discovered that printed information on the cassette results in the sterilizer being unable to properly read the barcode.
<b>REASON</b>	During the automated process used to print information on STERRAD 100S System cassettes an additional thirteenth (13 <sup>th</sup> ) bar, which provided an inadvertent bar, was added to the barcode resulting in an unreadable cassette. Because the STERRAD 100S System is designed to accept only properly coded cassettes, the STERRAD 100S will reject all incorrect cassettes and display an error message, "INCORRECT CASSETTE TYPE".
<b>ACTION</b>	<p>Product Return:</p> <ol style="list-style-type: none"><li>1. Please examine your inventory and return STERRAD 100S cassettes REF 10113 with lot number 12A070.</li></ol>  <p><b>FIGURE 1: Visual difference of the correct vs. incorrect barcode on the STERRAD<sup>®</sup> 100S System Cassette</b></p> <ol style="list-style-type: none"><li>2. Fill out the Business Reply Form and return it back to [Affiliate Name] within 3 business days, <b>even if you do not have affected product</b>. If you have product to be returned, keep a copy of this form for your records.</li><li>3. To return affected product, enclose a copy of the Business Reply Form with the product, and use the pre-paid shipping label to return to:</li><li>4. [Affiliate Name / Affiliate Address]</li></ol> <p><b>Your Sales Representative is available to provide assistance in the completion of this voluntary Field Safety Notice if you should request help.</b></p>
<b>TRANSMISSION</b>	Share this letter with all appropriate staff at your facility.



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<b>CONTACT</b>	<p>[Affiliate Name] will process your product return and issue a credit upon return of the product and the Business Reply Form.</p> <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>
<b>CONFIRMATION</b>	This action has been notified to the appropriate Regulatory Agencies.