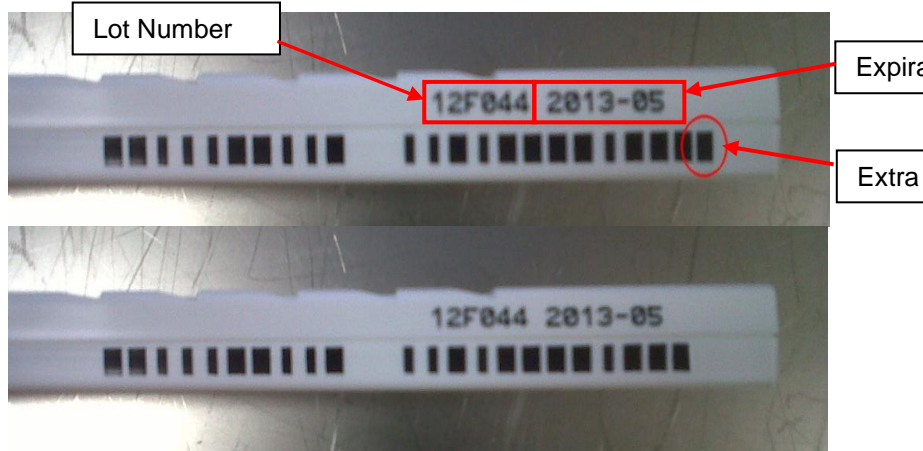




URGENT FIELD SAFETY NOTICE

ATTENTION	Operating Room Director and Materials Management
TYPE OF ACTION	Voluntary FIELD SAFETY NOTICE
REF / DATE	ASP02/2013 / March 18, 2013
PRODUCT	The issue involves the following product code and lot number: STERRAD 100S Cassette REF 10113 Lot Number: 12F044
DEVICE DETAILS	Advanced Sterilization Products (ASP) is recalling (removing) a single lot (#12F044) of STERRAD® 100S System cassettes. ASP has determined that a packaging printing error will result in the STERRAD® 100S System rejecting cassettes that are part of lot # 12F044.
REASON	During the automated process used to print barcodes on STERRAD® 100S System cassettes, an error occurred, adding another bar, resulting in an unusable cassette. The STERRAD® 100S System will reject all cassettes with incorrectly printed barcodes and display the error message, "INCORRECT CASSETTE TYPE." Because this issue does not impact instrument sterilization, please continue to use your STERRAD® Systems according to the Users' Guide.
ACTION	<p>Product Return:</p> <ol style="list-style-type: none">Please examine your inventory and return STERRAD 100S cassettes REF 10113 with lot number 12F044.  <p>FIGURE 1: Visual difference of the incorrect (top image) vs. correct (bottom image) barcode on the STERRAD® 100S System Cassette</p> <ol style="list-style-type: none">Fill out the Business Reply Form and return it back to [Affiliate Name] within 3 business days, even if you do not have affected product. If you have product to be returned, keep a copy of this form for your records.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:[Affiliate Name / Affiliate Address]



URGENT FIELD SAFETY NOTICE

	<p>Your Sales Representative is available to provide assistance in the completion of this voluntary Field Safety Notice if you should request help.</p>
TRANSMISSION	<p>Share this letter with all appropriate staff at your facility.</p>
CONTACT	<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>
CONFIRMATION	<p>This action has been notified to the appropriate Regulatory Agencies.</p>