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URGENT FIELD SAFETY NOTICE

ATTENTION	**Operating Room Director and Materials Management**
TYPE OF ACTION	**URGENT DEVICE RECALL** Ethicon Endo-Surgery (Ethicon) is initiating a voluntary worldwide recall for the ECHELON™ 60mm Black Reload (ECR60T)
REF / DATE	ECR60T-2013-05 / 24-May-2013
PRODUCT	Ethicon Endo-Surgery LLC, ECHELON™ 60mm Black Reload (ECR60T)
DEVICE DETAILS	The recall involves following product: Full Device Name: **ECHELON™ 60 ENDOPATH® STAPLER Endoscopic Linear Cutter Reload Black 4.4 mm, 6 rows** Product Code: **ECR60T**
REASON	The recall will be initiated due to the potential for incomplete staple line formation from reload damage during the firing sequence. This may result in insufficient tissue apposition that could require surgical intervention to help achieve and maintain anastomotic integrity.
ACTION	We need your help in ensuring that **all affected products** are located, accounted for, and returned to [Affiliate Name]. **EFFECTIVE IMMEDIATELY – DO NOT USE PRODUCT CODE ECR60T** **All ECR60T products are affected by this recall, regardless of lot number or expiration date** Please note: This recall does not apply to any other ECHELON™ reloads due to design differences between components located within the interior of the reload. 1) Examine your inventory immediately to determine if you have affected product on hand and **remove** the affected product. 2) 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. 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: [Affiliate Name / Affiliate Address] **Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help**.
TRANS-MISSION	Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred.

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CONTACT	[Affiliate Name] will process your product return and issue a credit/replacement upon return of the product and the Business Reply Form. If you have additional questions about this action, please contact your Sales Representative or call [Affiliate Name]. 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.
CONFIRM-ATION	The Field Safety Action is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and affected EU National Competent Authorities