URGENT: MEDICAL DEVICE RECALL

ENDOPATH® ETS-FLEX Endoscopic Articulating Linear Cutter, 35mm
(Product Code: ATW35, Product Lots: N91L2P and N91N1J)

20th Mar 2017

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

At Ethicon Endo-Surgery, LLC (Ethicon), our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

Ethicon is initiating a global voluntary recall of specific lots of the ENDOPATH® ETS-FLEX Endoscopic Articulating Linear Cutter, 35mm ("ENDOPATH® ETS-FLEX 35mm") (Product Code: ATW35). The event is **isolated to 2 specific lots of the ATW35 device** that were produced using a specific component lot. During production, our quality control processes identified a component quality issue and determined there to be a risk that the pinion gear in the device could fail under extreme use cases. If this condition occurs, staples will be formed past the cut line and the device can be opened and removed from the patient. However, the firing stroke may be interrupted and the knife may not fully return to the home position potentially exposing the healthcare professional to a "sharps injury". Ethicon has received no reports of component failure in the clinical setting nor received any reports of Adverse Events for this issue.

The root cause has been identified as a quality issue during the production of a single component lot resulting in assembly of multiple lots of devices that exhibit the risk described above.

The component supplier has implemented additional quality controls to ensure compliance for all future component lots. With current inventory levels, there is no anticipated backorder.

This voluntary recall has been communicated to the U.S. Food and Drug Administration (FDA).

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE ANY ATW35 DEVICES WITH THE FOLLOWING LOT NUMBERS and return unused product to receive replacements:

Product Code	Description	Unit of Measure	Eaches Per UOM	Impacted Lots
ATW35	ENDOPATH® ETS-FLEX Endoscopic Linear Cutter, 35mm Vascular/ Thin	Box	3	N91L2P N91N1J

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION:

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

Product subject to this medical device recall in your inventory can be identified by product code and lot number (see table above). All unused ENDOPATH® ETS-FLEX 35mm devices from the lots listed above are subject to this recall and are required to be returned. The product code and lot number can be determined by using Attachment 1 - Product Identification Tool.

PLEASE NOTE: This voluntary recall does not include any other ENDOPATH® ETS-FLEX or ECHELON™ products or lots.

Alternative product codes are also available. The following are suggested product substitutes. Substitutes are equivalent or functionally equivalent and in some cases deliver different length staple lines and cut lengths. *Please see the full Instructions For Use for complete product information for each substitute product.*

Substitute Product Codes*	Substitute Product Description	Notes	Alternative Code for:
PVE35A + VASECR35	ETHICON Echelon Flex™ Powered Vascular Stapler	This device does not come preloaded. Loading the device with a VASECR35 reload is required prior to firing.	ATW35
ATS45 with TR45W	ENDOPATH® ETS-FLEX 45 Endoscopic Articulating Linear Cutter ENDOPATH® 45mm reload Vascular/Thin	This device does not come preloaded. Loading the device with a TR45W reload is required prior to firing.	ATW35

*Device operation is different with substitute products. Please refer to the IFU for complete product information.

ACTIONS REQUIRED FROM YOU

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s).

2. Remove the product subject to this recall.

3. If any affected product has been forwarded to another facility, contact that facility to arrange return.

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4. Complete the Customer Acknowledgement Form confirming receipt of this notice within **three (3) business days** and return the Customer Acknowledgement Form to your Ethicon sales representative or fax it to 67200750. Please return the Customer Acknowledgement Form **even if you do not have affected product.**

5. Keep this notice visibly posted for awareness until all affected product has been returned to Ethicon. While processing your returns, please maintain a copy of this notice with the affected product and keep a copy for your records.

6. Customers are required to return all unused ENDOPATH® ETS-FLEX 35mm devices subject to this recall. Product subject to this recall must be returned by May 31, 2017 in order to receive replacement product.

7. To return affected product, photocopy the completed customer acknowledgement form, place it in the box with the affected product, and return the product to your Sales Representative.

If you require any assistance with returning product, please contact your local Sales Representative or ETHICON.

We recognize that this recall of the ENDOPATH® ETS-FLEX 35mm devices may be distruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this recall or to report any customer complaints, or you require assistance with alternative products, please contact your sales representative.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to ETHICON or your National Health Authority.

Thank you for your attention and cooperation.

Yours sincerely,

Marinah Ahmad

Digitally signed by Marinah Ahmad
DN: c=US, o=JNJ, ou=Subscribers, cn=Marinah Ahmad, 0.9.2342.19200300.100.1.1=702169049
Reason: I have reviewed this document
Date: 2017.03.20 09:51:26 +08'00'

Ahmad, Marinah

Regulatory Affairs Associate

cc: Chairman Medical Board

Relevant Head of Departments

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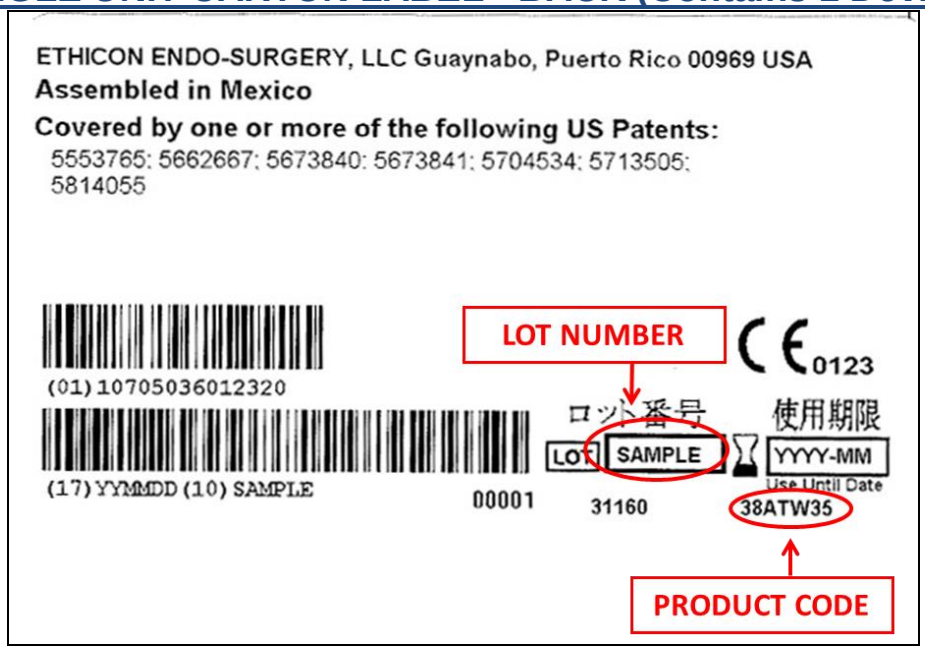
ATTACHMENT 1: Product Identification Tool for ENDOPATH® ETS-FLEX Endoscopic Articulating Linear Cutter, 35mm (Product Code: ATW35)

This tool will help customers identify the affected lots of product using package labels. This information applies to the single unit Tyvek® packaging, single unit carton graphics and label, and the sales unit label for product code ATW35.

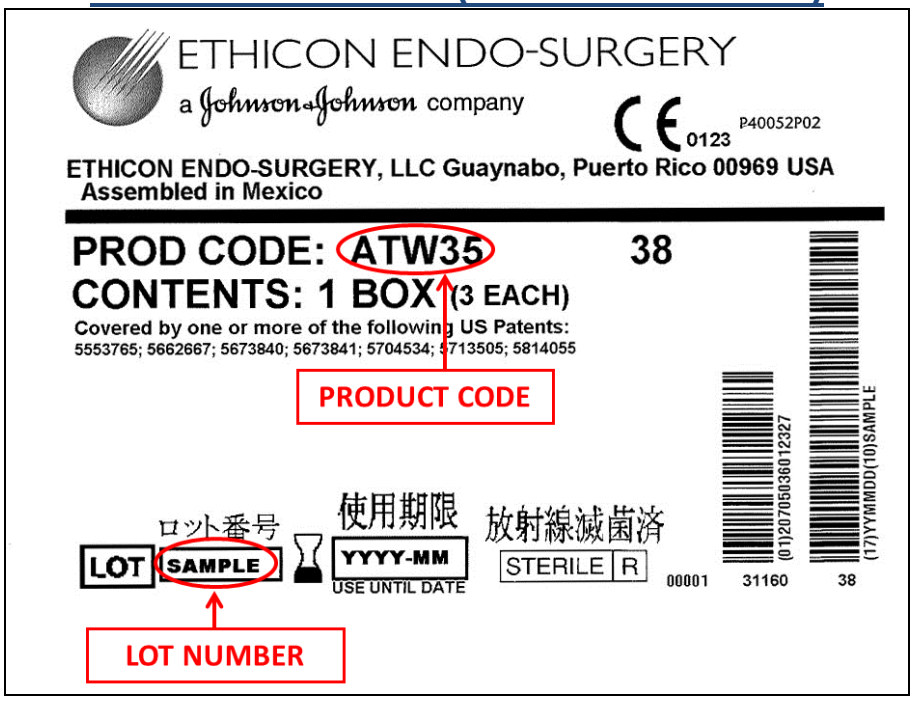
TYVEK® SINGLE UNIT (Contains 1 Device)

SINGLE UNIT CARTON (Contains 1 Device)

SINGLE UNIT CARTON LABEL - BACK (Contains 1 Device)



SALES UNIT LABEL (Contains 3 Devices)



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(Product Code: ATW35, Product Lots: N91L2P and N91N1J)

20th Mar 2017

Please distribute this information to appropriate personnel at your facility.

Your timely response to this customer notification is requested. Please complete this Customer Acknowledgement Form and return to your Ethicon sales representative or fax it to 67200750 within three (3) business days of receipts of the Field Safety Notice, even if you do not have any product to return.

If you have affected product to return, please make a photocopy of your completed Customer Acknowledgement Form and enclose with your return. Thank you for your cooperation.

Product Inventory - Please check (√) one:

☐ We have no **ENDOPATH® ETS-FLEX Endoscopic Articulating Linear Cutter, 35mm Vascular/Thin (ATW35)** subject to this recall.

☐ We have **ENDOPATH® ETS-FLEX Endoscopic Articulating Linear Cutter, 35mm Vascular/Thin (ATW35)** subject to this recall and are returning the following devices:

Device Name	Product Code	Lot Number	Quantity Returning (Number in "Eaches")
ENDOPATH® ETS-FLEX Endoscopic Articulating Linear Cutter, 35mm Vascular/Thin	**ATW35**	**N91L2P**	
		N91N1J	

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____ _____
Customer Name Title

_____ _____
Signature & Date Stamp *(Stamp shall bear facility name)*

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