

URGENT FIELD SAFETY NOTICE

ATTENTION	Operating Room Director and Materials Management	
TYPE OF ACTION	URGENT DEVICE RECALL	
REF / DATE	EPS-2013-04 / 22-April-2013	
PRODUCT	Ethicon Endo-Surgery (Ethicon) Energy has initiated a global voluntary recall for ENDOPATH Probe Plus II Shafts	
DEVICE DETAILS	The recall involves the following product codes:	
	Device Full Name	Product Codes
	EPS01-EPS08 with expiration dates from September 2015 through and including March 2018	
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Hook Electrode – 5 mm	EPS01
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Spatula Electrode – 5 mm	EPS02
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Right Angle Electrode – 5 mm	EPS03
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Curved Dissector Electrode – 5 mm	EPS04
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Hook Electrode – 5 mm	EPS05
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Spatula Electrode – 5 mm	EPS06
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Right Angle Electrode – 5 mm	EPS07
	ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Curved Dissector Electrode – 5 mm	EPS08
	EPS10-EPS13 with expiration dates from April 2013 through and including March 2018	
	ENDOPATH® Electrosurgery Probe Plus II Pool/Sump Suction and Irrigation Shaft – 10 mm	EPS10
	ENDOPATH® Electrosurgery Probe Plus II Suction and Irrigation Shaft – 10 mm	EPS11
	ENDOPATH® Electrosurgery Probe Plus II Stone Retrieval Shaft – 10 mm	EPS12
	ENDOPATH® Electrosurgery Probe Plus II Suction and Irrigation Shaft with Accessory Port – 5 mm	EPS13
Affected products can be identified by expiration date.		
This voluntary recall <u>does not apply</u> to the ENDOPATH Probe Plus II Handles.		
Please use the product identification tool in Attachment A to identify the correct expiration date.		
REASON	The root cause has been identified as an interaction between the rotation knob and the Tyvek® lid which, in remote cases, could result in a sterility breach. The ENDOPATH Probe Plus II Shaft product is sold and labeled as “Sterile”. If a hole were to occur, it results in a potential breach of our sterile barrier such that we can no longer assure the stated sterility levels are met for our product.	

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<p>ACTION</p>	<p>We need your help in ensuring that all affected products are located, accounted for, and returned to [Affiliate Name].</p> <p>EFFECTIVE IMMEDIATELY – DO NOT USE ANY OF THE TWELVE (12) PROBE PLUS II PRODUCT CODES.</p> <ol style="list-style-type: none"> 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] <p>Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help.</p>
<p>TRANS-MISSION</p>	<p>Please share this information with all of the appropriate staff at your facility and any other organization where the product has been transferred.</p>
<p>CONTACT</p>	<p>[Affiliate Name] will process your product return and issue a credit/replacement 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>
<p>CONFIRM-ATION</p>	<p>The Field Safety Action is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and EU National Competent Authorities</p>

Product Identification Tool

ENDOPATH® Electrosurgery Probe Plus II

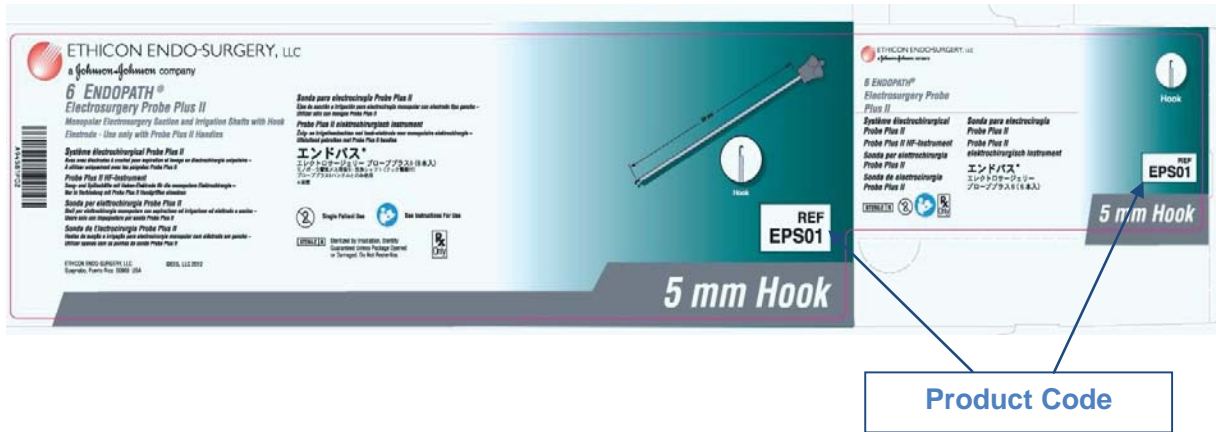
This tool will help customers identify the impacted expiration dates of product using package labels. This document applies to the secondary (single unit carton), Tyvek® primary (lidstock), and tertiary (sales unit) labels of the following product codes:

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ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Hook Electrode – 5 mm	EPS05
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EPS01 is used as an example

SALES UNIT CARTON (Secondary Label)

FRONT and DISPENSER PANELS



SALES UNIT LABEL

(Found on a Panel of Individual Carton)



Expiration Date

**Affected Product:
See table above**

SHIPPER UNIT LABEL

Product Code

Expiration Date
Affected Product:
See table above

Tyvek® Single Unit Package

Expiration Date
Affected Product:
See table above

Product Code

Your timely response to this recall notification is requested. Please fill out and mail or fax this form to [Local Affiliate Address and Fax number] within 3 business days **even if you do not have product to return.** If you have affected product to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

- No, we do not have affected product for return.**
- Yes, we do have affected product for return (complete list below).**

Lot Number	Product Code	Product Description	Units on Hand

Name/Signature/Date

Facility Name

Customer Number