ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

<table>
<tr><td>ATTENTION</td><td>Operating Room Director and Materials Management</td></tr>
<tr><td>TYPE OF ACTION</td><td>URGENT DEVICE RECALL</td></tr>
<tr><td>REF / DATE</td><td>EPS-2013-04 / 22-April-2013</td></tr>
<tr><td>PRODUCT</td><td>Ethicon Endo-Surgery (Ethicon) Energy has initiated a global voluntary recall for ENDOPATH Probe Plus ll Shafts</td></tr>
<tr><td>DEVICE DETAILS</td><td>The recall involves the following product codes:
<table>
<tr><th>Device Full Name</th><th>Product Codes</th></tr>
<tr><td colspan="2">EPS01-EPS08 with expiration dates from September 2015 through and including March 2018</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Hook Electrode – 5 mm</td><td>EPS01</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Spatula Electrode – 5 mm</td><td>EPS02</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Right Angle Electrode – 5 mm</td><td>EPS03</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Curved Dissector Electrode – 5 mm</td><td>EPS04</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Hook Electrode – 5 mm</td><td>EPS05</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Spatula Electrode – 5 mm</td><td>EPS06</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Right Angle Electrode – 5 mm</td><td>EPS07</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Monopolar Electrosurgery Suction and Irrigation Shaft with Curved Dissector Electrode – 5 mm</td><td>EPS08</td></tr>
<tr><td colspan="2">EPS10-EPS13 with expiration dates from April 2013 through and including March 2018</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Pool/Sump Suction and Irrigation Shaft – 10 mm</td><td>EPS10</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Suction and Irrigation Shaft – 10 mm</td><td>EPS11</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Stone Retrieval Shaft – 10 mm</td><td>EPS12</td></tr>
<tr><td>ENDOPATH® Electrosurgery Probe Plus II Suction and Irrigation Shaft with Accessory Port – 5 mm</td><td>EPS13</td></tr>
</table>
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.</td></tr>
<tr><td>REASON</td><td>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.</td></tr>
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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 ANY OF THE TWELVE (12) PROBE PLUS II PRODUCT CODES.** 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.
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 EU National Competent Authorities