Ethicon Endo-Surgery

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>ENSEALG2TS-2012-11 / 27-November-2012</td></tr>
<tr><td>PRODUCT</td><td>Ethicon Endo-Surgery (EES) is initiating a voluntary recall of the ENSEAL® G2 Curved and Straight Tissue Sealer devices due to a potential to self-activate</td></tr>
<tr><td>DEVICE DETAILS</td><td>The recall involves the following product codes:
<table>
<tr><td>NSLG2C14</td><td>ENSEAL 5 mm Diameter Tissue Sealer G2
14 cm Length Curved Jaw</td></tr>
<tr><td>NSLG2C25</td><td>ENSEAL 5 mm Diameter Tissue Sealer G2
25 cm Length Curved Jaw</td></tr>
<tr><td>NSLG2C35</td><td>ENSEAL Laparoscopic 5 mm Diameter Tissue Sealer G2
35 cm Length Curved Jaw</td></tr>
<tr><td>NSLG2C45</td><td>ENSEAL Laparoscopic 5 mm Diameter Tissue Sealer G2
45 cm Length Curved Jaw</td></tr>
<tr><td>NSLG2S14</td><td>ENSEAL 5 mm Diameter Tissue Sealer G2
14 cm Length Straight Jaw</td></tr>
<tr><td>NSLG2S25</td><td>ENSEAL 5 mm Diameter Tissue Sealer G2
25 cm Length Straight Jaw</td></tr>
<tr><td>NSLG2S35</td><td>ENSEAL Laparoscopic 5 mm Diameter Tissue Sealer
G2 35 cm Length Straight Jaw</td></tr>
<tr><td>NSLG2S45</td><td>ENSEAL Laparoscopic 5 mm Diameter Tissue Sealer
G2 45 cm Length Straight Jaw</td></tr>
</table>

Affected products can be identified by expiration date.

NOTE: ALL LOT NUMBERS WITH EXPIRATION DATE FROM OCTOBER 2013 THROUGH SEPTEMBER 2017 ARE IMPACTED.

Please use the product identification tool in Attachment A to identify the correct expiration date.

The recall <u>does not include</u> the ENSEAL® G2 Super Jaw, ENSEAL ® Trio or ENSEAL ® Round Tip products.

See Attachment B f or a detailed list of product codes that can be used for substitutions.</td></tr>
<tr><td>REASON</td><td>There is a potential for self activation while the device is in use, which could result in injury to patients or users (thermal damage). To date, we have not received any reports of patient or user injuries.

The root cause has been determined to be damage to the insulation on the activation wire during manufacturing, which in rare cases may lead to self activation during usage.</td></tr>
<tr><td>ACTION</td><td>We need your help in ensuring that <u>all affected products</u> are located, accounted for, and returned to [Affiliate Name].

EFFECTIVE IMMEDIATELY – DO NOT USE EES ENSEAL® G2 Curved and Straight Tissue Sealers.

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:</td></tr>
</table>

	[Affiliate Name / Affiliate Address] **Your Sales Representative is available to provide assistance in the completion of this voluntary recall if you should request help**.
TRANSMISSION	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.
CONFIRMATION	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