جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
10mm LIGACLIP Endoscopic Rotating Multiple-Clip Appliers Contained in Various Kits

الجهاز المعني بالمنطقة:
- 10mm LIGACLIP Endoscopic Rotating Multiple-Clip Appliers Contained in Various Kits
- Trade Mark: Ethicon Endo Surgery Inc.
- Local Representative:

بناءً على التوصية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في استعمال الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنيّة.

مرفق ربط:
- التوصية الصادرة عن الشركة المصنعة
- بلاغ:
  - دائرة برامج المشاريع
  - المستشفيات الحكومية
  - المحققفات

مدير عام الصحة

Rue de la Musée - Imr. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@mcph.gov.lb
URGENT FIELD SAFETY NOTICE

ATTENTION Operating Room Director and Materials Management

TYPE OF ACTION URGENT DEVICE RECALL

REF / DATE ER320-2013-04 and ER320-2013-04PP / 26-April-2013

PRODUCT Ethicon Endo-Surgery (Ethicon) is initiating a voluntary recall for LIGACLIP® 10 mm M/L Endoscopic Rotating Multiple Clip Appliers (ER320)

DEVICE DETAILS The recall involves the following product codes:

<table>
<thead>
<tr>
<th>Device Full Name</th>
<th>Product Codes</th>
<th>Affected Expiration Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIGACLIP® 10 mm M/L Endoscopic Rotating Multiple Clip Appliers</td>
<td>ER320</td>
<td>2016-11 to 2018-03</td>
</tr>
</tbody>
</table>

The recall involves the following FLEX TRAY™ Procedure Delivery System product codes containing affected ER320 product:

<table>
<thead>
<tr>
<th>EES Flex Tray Product Description</th>
<th>Procedure Pack Product Code</th>
<th>Affected Expiration Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic Cholecystectomy Pack</td>
<td>FNC42XL, KBC17XL, KNC60XL, KNC61XL, TNC20XL, TNC69XL, XCB57S, XCC50S, XCC51S, XCD50S, XCD51S</td>
<td>2016-12 to 2018-02</td>
</tr>
</tbody>
</table>

This recall involves the following Procedure Packs product codes, containing affected ER320 product:

<table>
<thead>
<tr>
<th>Procedure Pack Name</th>
<th>Procedure Pack Product Code</th>
<th>Affected Expiration Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic Cholecystectomy (BASX) Pack</td>
<td>LCHCB2, LCHCB3, LCHCB4, LCHCB6</td>
<td>2016-12 to 2018-02</td>
</tr>
<tr>
<td>Laparoscopic Urology Pack</td>
<td>LUC01</td>
<td>2016-12 to 2018-02</td>
</tr>
<tr>
<td>Laparoscopic Colon Pack</td>
<td>LCOL40, LCOL41, LCOL42</td>
<td>2016-12 to 2018-02</td>
</tr>
<tr>
<td>Laparoscopic Gastric Bypass Pack</td>
<td>LGBP233, LGBP80, LGBP91</td>
<td>2016-12 to 2018-02</td>
</tr>
<tr>
<td>Laparoscopic Nephrectomy Pack</td>
<td>LNP111, LNP14</td>
<td>2016-12 to 2018-02</td>
</tr>
<tr>
<td>Laparoscopic Sleeve Resection Pack</td>
<td>LSR62</td>
<td>2016-12 to 2018-02</td>
</tr>
</tbody>
</table>

This voluntary recall does not apply to the LIGACLIP® 12mm Large Endoscopic Rotating Multiple Clip Applier (product Code ER420).

Please use the Product Identification tool in Attachment A & B for detailed descriptions of the affected products within the specified expiration dates and for images to help identify affected products and procedure packs.
URGENT FIELD SAFETY NOTICE

| REASON | Ethicon Endo-Surgery is initiating a voluntary recall for LIGACLIP® 10mm M/L Endoscopic Rotating Multiple Clip Applier (ER320) due to potential clip formation and feeding issues which may result in improper clip formation and insufficient occlusion of the vessel or other structure.

This voluntary recall involves product code ER320 and/or Procedure Packs and/or FLEX TRAY™ Procedure Delivery Systems containing product code ER320 within the noted expiration dates.

| 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 AFFECTED PRODUCT CODE ER320 AND/OR PROCEDURE PACKS AND/OR FLEX TRAY PROCEDURE DELIVERY SYSTEMS CONTAINING PRODUCT CODE ER320 WITHIN THE EXPIRATION DATES NOTED IN ATTACHMENT A & B.

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.

| 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.