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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٥/٣٨١
رقم الصادر : ١٣/١/٢٠١٩٨
بيروت، في : ١٢ حزيران ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

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

الجهاز المعني بالمتابعة:
- 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 الى وجود خلل في استعمال الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

- **يبلغ:**
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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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:

Device Full Name	Product Codes	Affected Expiration Dates
LIGACLIP® 10 mm M/L Endoscopic Rotating Multiple Clip Appliers	ER320	2016-11 to 2018-03

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

EES Flex Tray Product Description	Procedure Pack Product Code	Affected Expiration Dates
Laparoscopic Cholecystectomy Pack	FNC42XL, KBC17XL, KNC60XL, KNC61XL, TNC20XL, TNC69XL, XCB57S, XCC50S, XCC51S, XCD50S, XCD51S	2016-12 to 2018-02

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

Procedure Pack Name	Procedure Pack Product Code	Affected Expiration Dates
Laparoscopic Cholecystectomy Pack	LCHC13, LCHC15, LCHC16, LCHC17, LCHC21, LCHC23, LCHC24, LCHC25, LCHC26, LCHC27, LCHC28, LCHC29, LCHC30, LCHC32, LCHC36, LCHC38, LCHC39, LCHC42, LCHC43	ALL
Laparoscopic Cholecystectomy (BASX) Pack	LCHCB2, LCHCB3, LCHCB4, LCHCB6	
Laparoscopic Urology Pack	LURO1	
Laparoscopic Colon Pack	LCOL40, LCOL41, LCOL42	
Laparoscopic Gastric Bypass Pack	LGBP233, LGBP80, LGBP91	
Laparoscopic Nephrectomy Pack	LNPH11, LNPH14	
Laparoscopic Sleeve Resection Pack	LSR62	

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.

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URGENT FIELD SAFETY NOTICE

	See Attachment C for a detailed list of product codes that can be used for substitutions.
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.**
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